SYMPTOMS, POWER, AND SELF-CARE IN INDIVIDUALS

WITH CHRONIC VENOUS LEG ULCERS

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SYMPTOMS, POWER, AND SELF-CARE IN INDIVIDUALS

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Dissertation

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ABSTRACT

Chronic Venous Leg Ulcers (CVLU) have been overlooked as a chronic condition in the U.S. CVLU is characterized by cycles of healing and ulcer recurrence and debilitating symptoms. Ulcer management is typically directed by health care providers and organizational guidelines with the person often a passive recipient of care. Encouraging self-care in this population may alleviate the burden. Orem's Self-Care Deficit Nursing Theory was used to guide an examination of the relationship between symptoms, power, and CVLU self-care in a population of individuals with CVLU. Measurement tools include the symptom subscale of the Venous Insufficiency Epidemiological and Economic Study-Quality of Life and Symptom Severity (VEINES-QOL/Sym) providing information about types and frequency of symptoms, the Appraisal of Self-Care Agency Scale-Revised (ASAS-R) to measure power, and the CVLU Self-Care survey to measure the level of self-care performed. Data for a final sample of 83 adults was used in the the analysis. Findings indicated that symptoms were not associated with power or self-care. Power was not a mediator between symptoms and CVLU self-care with analysis with and without the inclusion of the covariates income, education, number of comorbidities, and chronicity of the leg ulcer. There was a significant moderate to strong positive correlation between the total power score and total CVLU self-care score. A high frequency of symptoms was found in this population but there was no relationship between symptoms and individual's assessment of capability for self-care or performance of self-care.

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Self-care activities related to reducing leg edema were low. Identifying individuals with

low levels of power or low levels of self-care will facilitate programs and nursing

interventions to improve self-care in this population.

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CHAPTER I

INTRODUCTION

There is little research to guide the understanding of self-care and associated

factors in the population of individuals with chronic venous leg ulcers (CVLU). The

purpose of this study was to examine the relationships between symptoms, power, and

CVLU self-care. Chapter I discusses the background and significance, theoretical

background, and conceptual framework for the study.

Background and Significance

Chronic venous leg ulcers (CVLU) occur in the lower extremities as a result of

venous insufficiency, or incompetence in the function of the venous system. Normally,

the pumping action of calf muscles and the bicuspid-like valves in the veins of the legs

assist in forward flow of blood and prevent retrograde flow of blood back to the heart

(Etufugh & Phillips, 2007). Venous insufficiency causes the antegrade ejection of blood

toward the foot which leads to increased venous pressure in the lower extremity. The

resultant congestion causes a weakening of the structure of the vein and the valves.

Eventually, serous fluid leaks out of the vein walls and into the tissues of the leg. The

consequence is leg discomfort and edema (Wercheck, 2010).

The increased pressure from venous insufficiency is transmitted to fragile

capillaries in the lower leg. This contributes to a leakage of plasma and red blood cells

into surrounding tissue. As the red blood cells break down, a pigment called hemosiderin

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is deposited into the tissues of the leg. Hemosiderin staining is responsible for the bronzy appearance of the skin of the lower leg (Grey, Enoch, & Harding, 2006). Continued increased venous insufficiency can lead to the release of toxic substances that impede the exchange of fluid and nutrients, cell death, and ulcerative lesions. This chronic process leads to chronic tissue changes and unpleasant symptoms such as pain, swelling, itching, and ulceration that occur and are the hallmark of CVLU (Carr, 2008). Ulceration develops in 20% of individuals with chronic venous insufficiency (Eberhardt & Raffetto, 2005). Ulcers are associated with wound drainage that at times may have an offensive odor, especially if the ulcer drains profusely and saturates compression wraps or stockings. In some cases, tissue surrounding the ulceration may become infected and require that the individual enter the hospital for care (Korn et al., 2002).

Individuals with CVLU suffer cyclical bouts of ulcer healing and ulcer recurrence, with some leg ulcers taking more than 12 months to heal, and some not healing at all (Heinen et al., 2007; Hjerppe, Saarinen, Venermo, Huhtala, & Vaalasti, 2010). The results are reduced quality of life and health, and impaired mobility. Individuals with leg ulcers often lose time from work, further increasing the indirect costs of CVLU (Briggs & Flemming, 2007; Heinen et al., 2007; Van Hecke, Verhaeghe, Grypdonck, Beele, & Defloor, 2011).

Additionally, U.S. healthcare costs for venous disease are high, with reports describing figures between $1- 3.5 billion (Bolton, 2008; Jones, 2009). Wound dressings, compression wraps, and compression stockings comprise a portion of care costs. Nurses, physicians, and physical and occupational therapists often have a role in leg ulcer care

with the costs of clinical staff comprising a large percentage of the care costs (Butcher & White, 2013; Whitlock, Morcom, Spurling, Janamian, & Ryan, 2014).

Considering that the personal and societal costs of the chronic disease of CVLU are high, encouraging self-care in this population may alleviate the burden. However, despite the chronic nature of chronic venous insufficiency and CVLU, and the commonality of self-care programs for individuals with other chronic diseases such as rheumatoid arthritis and heart failure (Riegel & Vaughan Dickson, 2008), individuals with CVLU are not typically encouraged to participate in self-care (Husband, 2001; Yarwood-Ross & Haigh, 2012). Instead, care for individuals with CVLU continues to be driven by the traditional biomedical model, directed and implemented by the health care provider (Yarwood-Ross & Haigh, 2012). In fact, at times, individuals may be dissuaded from participating in care for their wounds (Briggs & Flemming, 2007; Husband, 2001). If individuals with CVLU were offered the opportunity to learn about and participate in self-care, they may feel more capable to take responsibility for their care. Very few studies examine self-care in individuals with CVLU. An evaluation about the types and regularity of activities individuals with CVLU participate in may be helpful when assisting them to improve CVLU self-care.

Self-care for individuals with CVLU includes increasing an individual's knowledge of the disease of chronic venous insufficiency, inspecting a wound for infection, dressing the wound, wearing compression stockings of compression wraps, and the performance of activities such as ambulation, leg elevation, or ankle/leg exercises (Brown, 2012; Finlayson et al., 2011; Shannon, Hawk, Navaroli, & Serena, 2013; Van Hecke et al., 2011). These types of activities can improve wellbeing, quality of life, and

reduce complications such as cellulitis. Considering that consistent self-care is necessary in individuals with CVLU, it is important to gain a better understanding of what types of factors may influence self-care.

One factor reported in the CVLU literature that influences individuals with CVLU to engage in self-care are symptoms. Pain, itching, leg edema, and ulceration may decrease an individual's ability to engage in self-care (Briggs & Flemming, 2007; Hareendran et al., 2005; Van Hecke, Grypdonck, & DeFloor, 2009; Walshe, 1995). For instance, the symptoms pain and edema can hinder an individual's ability to walk (Persoon et al., 2004; Roaldsen, 2009). Pain and ulceration can also hamper an individual's wearing of compression wraps or compression stockings (Van Heck et al., 2009). Itching is associated with increased pain and decreased physical activity such as walking (Paul, Pieper, & Templin, 2011).

Studies with populations with a chronic disease other than CVLU have found relationships between symptoms and self-care. A study of cancer patients found that an increased number of symptoms were associated with less self-care (Chou, Holzemer, Portillo, & Slaughter, 2004). Anderson (2001) also found a relationship between health symptoms and self-care in homeless adults, many who had chronic diseases such as substance abuse and mental illness (Anderson, 2001).

An individual's level of self-care can also be influenced by the level of capability to care for the ulcer. This capability can be described as power. Power enables an individual to engage in self-care that is related to the promotion of health or care or management of a disease state (Denyes, 1988; Evers, Isenberg, Jirovec, & Kasno, 1990; Gast et al., 1989; Orem, 2001; Sousa, Zauszniewski, Musil, Lea, & Davis, 2005). Power

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is necessary to institute and maintain self-care (Gast et al., 1989; Sousa et al., 2010). In an individual with the symptom of leg edema for example, having the power to make adjustments or set priorities for health-related self-care may in turn enable an increase in the self-care action of ambulation.

The presence of comorbidities may influence the relationship between symptoms, power, and self-care. There are few studies that examine how comorbid conditions affect individuals with chronic diseases including CVLU, but it is known that as the population ages, the number of chronic conditions also increases (Bayliss, Steiner, Fernald, Crane, & Main, 2003). Increasing numbers of comorbid conditions can serve as barriers to self-care, as an additional medical condition may involve tasks such as medication management (Lansbury, 2000). Patients with congestive heart failure (CHF) report that managing many competing medical conditions impedes their ability for CHF self-care (Riegel & Carlson, 2002). The presence of comorbidities are reported in a few studies that use populations of individuals with CVLU, however, these reports did not examine how comorbidities may or may not influence self-care.

In addition, sociodemographic factors such as education and socioeconomic status can impact an individual's level of self-care (Heinen et al., 2007; Moffatt, Franks, Doherty, Smithdale, & Martin, 2006; Shannon et al., 2013; Van Hecke et al., 2011). Research with chronic diseases other than CVLU, such as Type II diabetes or obesity, has shown that higher levels of attained education and higher levels of income positively influence self-care (Burdette, 2012). Another factor that may influence CVLU self-care is the chronicity, or age, of the leg ulcer. In this study, chronicity of the ulcer is called

"ulcerage" in the analysis of data. Chronicity of the ulcer is explained further later in this chapter.

Theoretical Framework

The theoretical framework for the study is Orem's Self-Care Deficit Nursing Theory (Orem, 2001). The Self-Care Deficit Nursing Theory (SCDNT) as a general nursing theory provides a framework from which to explore the relationships between study concepts symptoms, power, and CVLU self-care. The SCDNT, in a linear model, proposes that certain factors (labeled basic conditioning factors [BCF]), such as symptoms can influence an individual's ability (self-care agency) to engage in self-care. Orem defined self-care as an action an individual performs to maintain life, health, or well-being. Self-care agency is an individual's ability to perform self-care (Orem, 2001). However, other models can be considered, as self-care agency may play an intermediary role between certain BCF's and self-care (Orem, 2001).

It is important to note that the terms self-care and self-management are often used interchangeably. Both terms have a wide range of definitions in the literature. An extensively cited article by Richard and Shea (2001) discussed the similarities and differences between the terms.

The purpose of self-care is to achieve, maintain, or promote good health (Richard & Shea, 2001). Self-care involves abilities and actions under direct control of the individual. Self-care is influenced by many characteristics internal and external to the individual including culture, knowledge, skills, and values (Richard & Shea, 2001). The concept of self-care underpins many nursing studies aimed at supporting an individual's abilities and actions.

Self-management involves individual abilities, but also those of the family, community, and health care providers to manage the consequences of chronic diseases (Wilkinson & Whitehead, 2009). Self-management may be viewed as a process or an outcome. When an individual self-manages, they cope with ramifications of the disease, such as symptoms, while considering the influence of the disease on physical and psychosocial wellbeing (Richard & Shea, 2001). Orem's SCNDT and the concept of self-care was chosen for this study because of its familiarity to nurses and ease of applying the concepts of the theory to develop nursing interventions.

Orem saw individuals as "agents by and for oneself" and self-care as taking action for self (Orem, 2001, p. 43). Orem also described influences of self-care from the individual or the environment, the development of the power of self-care agency, and the relationship between self-care requirement and self-care demand. These concepts along with the concept of nursing agency, which is not explored in this study, formed the Self-Care Deficit Theory of Nursing. Orem classified her theory as a "general theory" but also described it as having a "broad conceptual structure," and consisting of three related theories including the Theory of Self-Care, Theory of Self-Care Deficit, and the Theory of Nursing System (Orem, 2001).

In this study, the BCF of interest is health state. According to Orem (2001), self-care agency can be positively or negatively influenced by the BCF of the individual. Self-care may be influenced by an altered health state that occurs due to a chronic illness. Self-care agency is developed over time and with experience. In individuals with a chronic illness such as CVLU, the level of self-care agency related to the health state may influence an individual's ability to perform self-care.

Self-care agency is a multidimensional concept comprised of three types of capabilities including foundational, operational, and enabling (Orem, 2001). The enabling capabilities, or power, relate specifically to the individual's capability to engage in health-related self-care. Power is needed for health-related self-care, and is needed specifically for CVLU self-care actions.

Considering the above propositions, it can be theorized that self-care performed by individuals with CVLU is influenced by symptoms experienced by individuals with CVLU. In addition, self-care performed by individuals with CVLU (CVLU self-care) is influenced by their level of enabling capability or power for health-related self-care. The determination of an individual's level of power may be important in the development of interventions tailored to meet the needs of individuals with CVLU. This study examined one portion of Orem's theory. The concepts derived from Orem's self-care framework (basic conditioning factors, self-care agency, and self-care) have been delineated more specifically to generate a middle range theory that can facilitate research in the area of self-care of individuals with CVLU. The concepts in the middle range theory for this study are symptoms, power, and CVLU self-care. The conceptual model for this study is depicted in Figure 1.1.
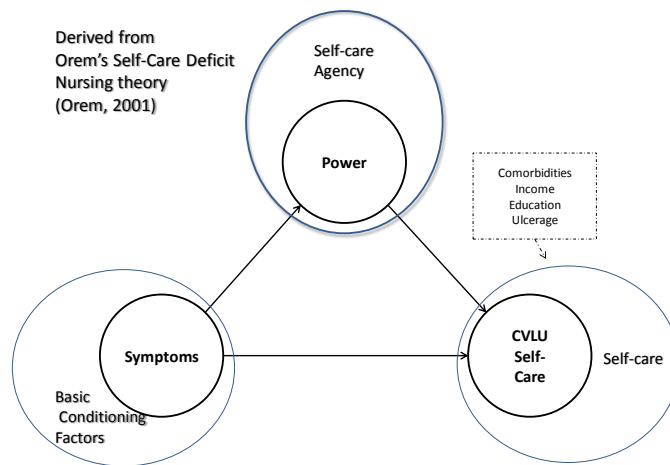
Figure 1.1. Conceptual model.

Development of Concepts

  Basic conditioning factors: Health state. Orem describes basic conditioning

factors as personal or environmental factors that affect the individual's ability to engage

in self-care or affect the kind and amount of self-care needed (Orem, 2001). There are 10

personal or environmentally-related conditioning factors that affect the individual's

ability to perform self-care. Orem describes the 10 factors as age, gender, developmental

state, health state, sociocultural orientation, health care system factors, and patterns of

daily living, environmental factors, and resources available. Orem recognizes these

factors as amenable to change if necessary so that as new factors are realized, they may

be added (Orem, 2001).

  In this study, symptoms experienced by individuals with CVLU, including pain,

were examined as the one of the basic conditioning factors Orem labeled health state.

Orem defined health state as the state or features of the person at a particular time.

Health state is also "combinations of components that serve [individuals] well as an index

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of their health state" (Orem, 2001, p. 186). The components or indicators need to be considered by patients to help them judge what kind of condition they are in (Orem, 2001). An individual's perception of health state influences the development of self-care agency and performing self-care (Orem, 2001). Symptoms are discussed as integral to the individual's health state in the CVLU literature (Briggs & Flemming, 2007; Renner, Seikowski, & Simon, 2014). In addition, several studies use symptoms as the basic conditioning factor health state (Anderson, 2001; Hurst, Montgomery, Davis, Killion, & Baker, 2005; Ovayolu, Ovayolu, & Karadag, 2012).

The influences of four covariates were examined in this study. The most common chronic diseases (World Health Organization, 2014) diabetes, heart disease, chronic breathing problems, kidney disease, and stroke were examined as a group. Three additional covariates ~~level of~~ income, ~~level of~~ education, and chronicity of the leg ulcer were also examined.

Symptoms. Symptoms of chronic venous stasis are described to some extent in all individuals with CVLU (Brown, 2008; Heinen, Persoon, van Kerkhol, Otero, & van Acterberg, 2006). In the CVLU literature, the influence of symptoms experienced by individuals with CVLU on physical and psychological capabilities is mentioned frequently. Pain is a common symptom experienced in individuals with CVLU (Krasner, 1998; Persoon et al., 2004). Pain often causes a lack of energy and can serve as a barrier to making significant changes in activity level (Krasner, 1998). Briggs and Flemming (2007) described how symptoms experienced by individuals with CVLU affect capabilities such as formulating and carrying out measures to change bandages when they are saturated with drainage. A qualitative study by Douglas (2001) suggested that

individuals with CVLU restrict activities such as ambulation due to symptoms which suggests that patients do not make necessary adjustments for self-care as health-related circumstances change. Although not described quantitatively in the literature, it could be hypothesized that more symptoms experienced by individuals with CVLU may be associated with lower levels of self-care.

As stated earlier, the most common symptom reported by individuals with CVLU is pain. However, odor and itching, leg heaviness, tinging, throbbing, and swelling may also be present. The frequency of symptoms is used as an index of the severity of the disease of chronic venous insufficiency (Lamping, Schroter, Kurz, Kahn, & Abenhaim, 2003). Frequency of occurrence is often used by individuals when reporting symptoms. The definition of symptoms is the individual's reported status of symptoms experienced by individuals with CVLU in terms of number and frequency of symptoms.

Education. Demographic variables such as level of income and education can influence power or self-care (Hurst et al., 2005; Sousa et al., 2005). Since power and self-care are learned, it would follow that persons with increased income and education would have more resources to develop power and self-care. Income is self-reported household income for the past year. Education is the highest grade completed.

Comorbidities. Comorbidities serve as barriers to self-care (Bayliss et al., 2003; Burdette, 2012; Kerr et al., 2007). The comorbidities measured in this study are diabetes, heart attack, COPD, ESRD, and stroke. These conditions are the most prominent chronic diseases (WHO, 2014). In this study comorbidities were explored as a covariate.

Chronicity of the ulcer. Several studies using a population of individuals with CVLU examine the relationship between the duration or chronicity of the ulcer and outcomes other than self-care, such as healing or adherence to treatment (Finlayson et al., 2011; Moffatt, Franks, Doherty, Smithdale, & Martin, 2006; Van Hecke et al., 2009). It is assumed that having a leg ulcer of longer duration will influence the number and frequency of symptoms, since chronic venous insufficiency causes serious changes in the integrity of the leg tissue over time. In addition, over the time the period the individual has had the leg ulcer, increased opportunities to develop power and self-care would be present.

Self-care agency. Orem (2001) described self-care agency as "the complex acquired capability to meet one's continuing requirements for care of self that regulates life processes, maintains or promotes integrity of human structure and functioning and human development, and promotes well-being" (Orem, 2001, p. 254). Orem added that self-care agency includes "human powers and capabilities" (Orem, 2001 p. 254) associated with the actions individuals take to accomplish goals for caring for self, or self-care (Orem, 2001). Self-care agency is learned and developed and can vary over an individual's lifetime, with health state, education, life experiences, cultural influences, and other resources (Orem, 2001). There are three types of capabilities necessary for self-care agency. They include foundational, operational, and enabling. Foundational capabilities are physical capabilities that are necessary for self-care such as sensation, memory, and orientation. Operational capabilities are decision-making capabilities related to day-to-day self-care (Orem, 2001). Orem labeled the enabling capabilities "power components." In this study, power components are referred to as power, as the

former term is not intuitive to a discussion about self-care. Only power is a focus in this study and is discussed further below.

Power. Orem proposed that enabling capabilities or power is necessary for self-care and must be present for an individual to have the capacity to engage in health promoting self-care (Orem, 2001). Orem described power as one of the constituents of self-care agency in the self-care deficit nursing theory (SCDNT) (Orem, 1991; 2001). Power for self-care varies according to an individual's health or other conditions in the environment (Orem, 2001). Power includes capabilities related to valuing health, the ability to reason and make decisions related to health related self-care, and having the motivation to learn about, maintain attention to, and utilize of available energy for self-care in general (Orem, 2001).

Authors have attempted to further clarify Orem's concept of power. For example, Gast et al. (1989) identified that power includes having knowledge of the self-care actions for a health condition, the ability to reason, solve problems, and have the energy for health-related self-care. In a later exploration of the measurement of self-care agency and power, Carter agreed with Gast's interpretation (Carter, 1998).

Sousa et al. (2010) recognized the importance of the further refinement and operationalization of the concept of power as it relate to engaging in health-related self-care. The authors revised the Appraisal of Self-Care Agency Scale (ASAS, Evers & Isenberg, 1987) as this tool specifically measures power (Sousa et al., 2010). Power for health-related self-care is of interest in this study, as it is necessary and separate from the other capabilities such as the functional capabilities needed for any type of deliberate action (Orem, 2001). Power for self-care has not been specifically addressed in the

CVLU population, but could be inferred from some studies. For example, Herber et al. (2008) recognized the importance of supporting leg ulcer patients to care for themselves and developed a program to enhance self-care agency (Herber, Schnepp, & Rieger, 2008). Swedish nurse researchers Ebbeskog and Ekman conducted a quantitative study examining patient perceptions of living with a leg ulcer and found that individuals with non-healing leg ulcers often express feelings of a lack of power (Ebbeskog & Ekman, 2001). These feelings cast negative feelings about engaging in everyday life activities, which may carry over to CVLU self-care. Similarly, in another qualitative study, a lack of capability or "powerlessness" to take ownership of caring for the leg ulcer was described (Chase, Melloni, & Savage, 1997).

An examination of power is somewhat more prominent in the literature describing self-care in the general population (Anderson, 2001; Burdette, 2012; Frey & Denyes, 1989; Hurst et al., 2005; Lukkarien & Hentinen, 1997). For instance, Anderson (2001) stressed the importance between power and self-care a population of homeless individuals. Her study examined power and self-care in homeless individuals and found a significant correlation. Power is also described to a limited extent in literature describing self-care in individuals with chronic diseases such as Type II diabetes (Sousa et al., 2009). Power in this study is an individual's self-report of capability for CVLU related self-care, or CVLU self-care actions. Power was examined as a mediator between symptoms and CVLU self-care.

Self-care. The definition of self-care follows that of Orem (Orem, 2001). Orem described self-care as "the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health, and well-being" (Orem, 2001, p. 43). Self-

care is also the deliberate and goal-oriented actions of individuals who have or are developing the powers and capabilities to use appropriate measures to manage functioning on their own behalf within both stable and unstable environments (Orem, 2001). Deliberate actions are intentional acts that an individual performs to modify a condition that did not exist previously (Orem, 2001). Actions require judgment and decision-making capabilities (Orem, 2001). Actions may focus on seeking or participating in medical care (Orem, 2001). Care does not have to be carried out by the individual but can also be care directed by the individual on his or her own behalf (Orem, 2001).

The intention of self-care is to meet self-care needs, with the purpose of maintaining life, health, and well-being. Subsequently, self-care actions are based upon self-care needs. Situations may be present or may occur that influence the type of actions needed for self-care (Orem, 2001). The situations may be internal or external to the individual, or may be a condition of changes in health or due to an illness (Orem, 2001).

CVLU self-care. According to Orem, there are two types of self-care, universal self-care and health-deviation self-care. Health-deviation self-care is care actions needed related to a health condition or illness (Orem, 2001). In individuals with CVLU, the chronic disease chronic venous insufficiency is a health deviation. Self-care needed by individuals with CVLU related to chronic venous insufficiency is called CVLU self-care in this study. CVLU self-care is what individuals with leg ulcers should perform on their own behalf to manage CVI. Self-care includes recognizing symptoms, applying bandages, leg elevation, or ambulation (Brown, 2010; Moffatt et al., 2006; Van Hecke et al., 2009). CVLU self-care is care individuals with CVLU perform on their own behalf to

manage chronic venous insufficiency. A table summarizing the study definitions can be

found in Table 1.1.

Table 1.1

Theoretical and Operational Definitions of Concepts

Concept	Theoretical Definition	Operational Definition
Independent Variables		
Basic Conditioning Factors		
Symptoms	The frequency of symptoms is used as an index of the severity of the disease of chronic venous insufficiency (Lamping et al., 2003)	Self- reported status of symptoms experienced by individuals with CVLU in terms of number and frequency using the VEINES/Sym.
Self-care agency		
Power	The capability to engage in health-related self-care (Orem, 2001).	Self-report of capability for health-related self-care.
Covariates		
Basic Conditioning Factors		
Comorbidities	Coexisting chronic diseases of the most prominent chronic diseases (World Health Organization, 2014).	Self-report of chronic diseases.
Income	An individual's access to resources.	Self-reported household income. Self-report of the highest grade completed.
Education	An individual's access to resources.	
Chronicity of the ulcer	The time period the leg ulcer has been present	Self-report of how many months the leg ulcer has been present (Ulcerage)
Dependent Variable		
Self-care		
CVLU Self-Care	Care individuals with CVLU should perform on their own behalf to manage chronic venous insufficiency Finlayson, Edwards, & Courtney, 2011; Van Hecke et al., 2011).	Self-report of self-care performed.

The conceptual, theoretical, empirical framework adapted from Orem's Self-Care

Deficit Nursing Theory can be found in Figure 1.2.
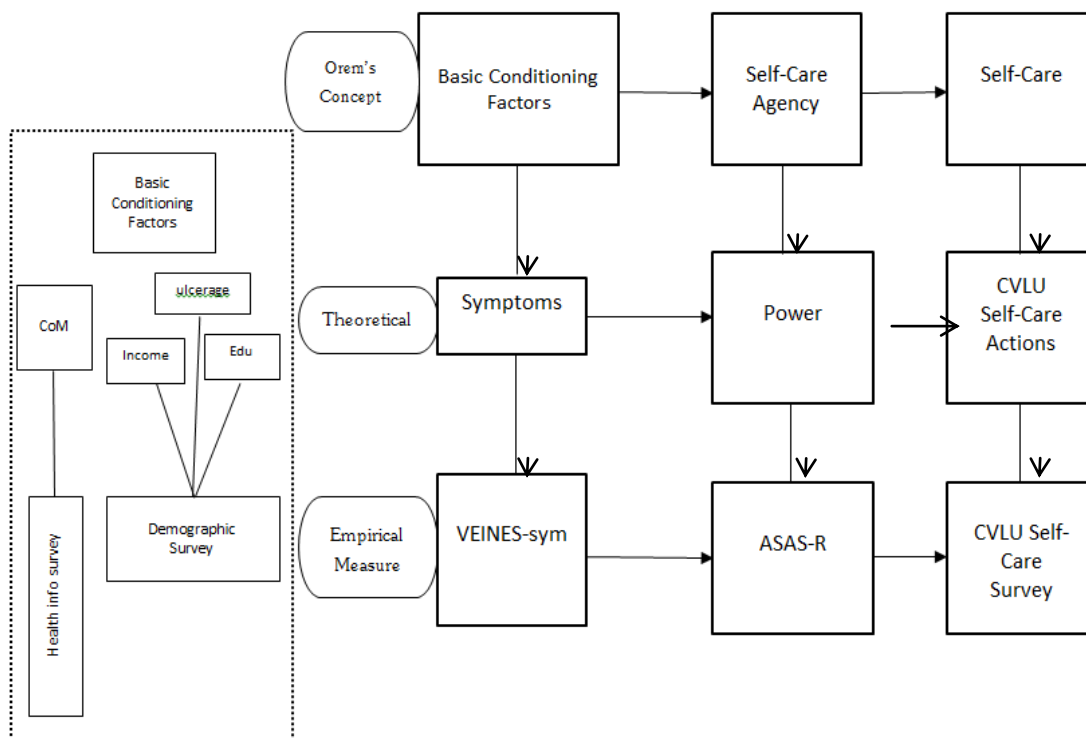
Figure 1.2. Conceptual, theoretical, empirical framework.

Study Purpose

The purpose of this study was to a) address a gap in the knowledge about self-care in individuals with CVLU, b) address a gap in the knowledge about the power needed to engage in self-care in the population of individuals with CVLU, c) examine the relationships between symptoms, power, and CVLU self-care, and d) determine if Orem's Self-Care Deficit Nursing Theory is useful in supporting the relationships between study concepts. The knowledge gained from this study will serve as a starting point in the development of further studies and programs designed to enhance CVLU self-care. The research questions for this study were:

1. What is the relationship between symptoms, power, and CVLU self-care?

2. Does power mediate the effects of symptoms on CVLU self-care?

3. What is the mediating effect of power on CVLU self-care when controlling for comorbidities, income, education, and chronicity of the leg ulcer?

Summary

Engaging in self-care for the promotion of better health is not a new idea but has become an important initiative lately. Because of the increased prevalence of chronic disease and an awareness of the resources needed to manage them, there has been a push toward a shift in the role of patients from that of a passive recipient to a role that includes patients taking a more active role in the assumption of responsibility for their own health (McNichol, 2014; Sarasohn-Kahn, 2013). In 1998 the American Academy of Nursing (AAN) identified quality outcomes including the achievement of appropriate self-care made the assessment and evaluation of patients more important (Angela & Shea, 2011). Furthermore, it is well accepted that engaging in self-care leads to better health outcomes (Vaughan Dickson et al., 2014). General self-care activities such as exercising, eating a balanced diet, monitoring blood pressure, or monitoring blood glucose are important components that contribute to self-care.

There is a vast body of qualitative literature where individuals with CVLU talk about the influence of symptoms experienced by individuals with CVLU, especially the influence that pain can have on an individual. Pain can affect sleep and mobility (Heinen et al., 2007). Other symptoms such as excessive odor and drainage may negatively influence personal hygiene (Walshe, 1995). Briggs and Flemming explored the possibility that symptoms experienced by individuals with CVLU are extremely overwhelming in people's lives, having physical, social, and psychological effects (Briggs & Flemming, 2007).

Unfortunately, there is only a rare study that uses a theoretical perspective and quantitative methods to gain a better understanding of factors that are related to self-care in individuals with CVLU. Patients with CVLU perform self-care activities such as elevating legs, performing ankle exercises or ambulating, and wearing compression wraps or compression stockings. Many of these studies that examine these activities look at CVLU self-care in terms of adherence, or an outcome of healing, which is not the aim of this study.

An individual's ability to perform self-care is also influenced by the enabling capabilities needed to carry out the self-care. The CVLU literature provides accounts of patient's recognition of personal needs and what is required to attain these needs (Ebbeskog & Ekman, 2001). Power has not been studied in the population of CVLU patients, but may be a relevant point to consider.

There are studies in the chronic care literature that describe links between aspects of health status, perception of abilities to carry out care, and self-care. Studies of patients with chronic diseases such as diabetes, obesity, rheumatoid arthritis, and HIV have found significant relationships between symptoms and self-care agency, and also between self-care agency and self-care.

In summary, there is a gap in the CVLU literature that explains factors associated with self-care. A small body of research with individuals with chronic conditions examines relationships between Orem's SCNDT concepts including basic conditioning factors, self-care agency, and self-care. This study will increase knowledge of how self-care in individuals with CVLU is influenced by symptoms and power. In addition, this study hopes to illuminate the significance of CVLU as a chronic disease that may be

managed to some degree with self-care. On a policy level this is important, as self-care

has been shown to reduce costs associated with readmissions to the hospital, improved

outcomes, and improvement in patient satisfaction (James, 2013).

CHAPTER II

REVIEW OF THE LITERATURE

Orem's Self-Care Framework in the Literature

Self-care is integral in the promotion of positive outcomes in chronic diseases

such as coronary heart disease, end stage renal disease, and HIV (Horsburgh, 1999; Hurst

et al., 2005; Lukkarinen & Hentinen, 1997). In the chronic disease chronic venous

insufficiency, self-care has not been widely studied. A better understanding of factors

influencing CVLU self-care is necessary to the development of nursing interventions to

enhance self-care.

Self-care is the main concept in Orem's work. Orem asserted that individuals are

constantly producing their own systems of self-care to meet their needs to live day-to-day

for health, and for well-being (Orem, 2001). Such systems include health care behaviors

that are necessary to maintain overall health. Self-care can be learned or performed by

other on the individual's behalf. In this study, self-care is care individuals with CVLU

should perform on their own behalf to manage chronic venous insufficiency.

Another concept, self-care agency (Orem, 2001), explains how each individual,

influenced by age, health, environmental, and available resources (Orem, 2001), has

developed or can develop a set of capabilities for health-related self-care. There are three

types of capabilities, including foundational, operational, and enabling. Enabling

capabilities or power is selected by the individual with CVLU to perform an action for a

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health situation such as symptoms experienced by individuals with CVLU that did not

previously exist. Power also refers to occurrences that enable the performance of

behaviors needed for health-related self-care. Power for health-related self-care includes

motivation to perform the behaviors and decision-making about the behaviors (Orem,

2001). Power in this study is the capability to engage in health-related self-care.

The last concept in this study, which Orem labeled basic conditioning factors, are

factors particular to individuals that influence or condition self-care agency or self-care

(Orem, 2001). There are 10 basic conditioning factors necessary for an individual to

perform self-care. Orem's 10 basic conditioning factors are discussed in more detail in

Chapter I. The basic conditioning factor of interest in this study is health state, which has

been further refined into the variable symptoms. An individual's health state is associated

with specific health disorders from which the individual suffers (Orem, 2001, p. 379). In

addition, Orem stated that one's health state is influenced by factors including

demographics and one's biological environment (Orem, 2001) such as the concurrent

disease states of the individual. The health state in individuals with CVLU is associated

with symptoms that occur as a result of chronic venous stasis. In general, symptoms may

be influenced by factors such as socioeconomic status and other aspects of health, though

this relationship may be spurious (Apouey, 2013). In this study, the basic conditioning

factor of interest is symptoms experienced by individuals with CVLU.

The relationship between self-care agency and self-care is stated in a proposition

by Orem as "persons who take action to provide their own self-care or care for

dependents have specialized capabilities for action" (Orem, 2001, p. 147). The

relationship between self-care agency and self-care is further supported by the definition

of self-care agency as the capabilities or powers necessary for persons caring for themselves (Orem, 2001). Therefore, self-care is the action of persons who have or are developing the powers to implement actions to regulate their own functioning.

The above propositions and definitions define the relationship between the concepts self-care agency and self-care. A relationship between power and CVLU self-care can be hypothesized because self-care agency is antecedent to self-care. In addition, power is a function of self-care agency within Orem's theory (Orem, 2001).

Research Relevant to the Concepts in This Study

The relationship between the power and CVLU self-care and details about the self-care carried out by individuals with CVLU were the main focus of this inquiry. The importance of symptoms experienced by individuals with CVLU to power and CVLU self-care were also examined. Thus, literature relevant to the relationships between basic conditioning factors/symptoms and power, basic conditioning factor/symptoms and self-care, and self-care agency/power and self-care are reviewed in this section. In addition, studies where self-care agency/power is a mediator between symptoms and self-care are reviewed. Since research using Orem's framework and a population of individuals with CVLU are sparse, studies that use Orem's framework with other populations are included.

Relationship Between Basic Conditioning Factors/Symptoms and Self-Care Agency/Power

Orem (2001) proposed that basic conditioning factors such as health state impact the development and exercise of self-care agency (Orem, 2001). Self-care agency can be lost or gained as factors such as a new symptom emerge (Orem, 2001). Many studies

have reported relationships between various basic conditioning factors including health state, family system, and other sociocultural factors and self-care agency (Anderson, 2001; Armer et al., 2008; Frey & Deynes, 1989; Hurst et al., 2005; Sousa et al., 2005).

For instance, in a 2006 study of 120 Turkish individuals with hypertension, factors related to self-care agency were examined (Akyol, Cetinkaya, Bakan, Yarah, & Akkus, 2006). Education and other basic conditioning factors were measured using a demographic tool developed by the authors. Self-care agency was measured using the Exercise of Self-Care Agency Scale (ESCA, Kearney & Fleischer, 1979). The 43-item ESCA was developed by Kearney and Fleischer in 1979. The scale measured four dimensions of self-care agency including active versus passive responses to situations, motivation, knowledge, and self-worth. Items were scored on a 5-point scale ranging from 0 (very uncharacteristic of me) to 4 (very characteristic of me). Scores range from 0 to 172 with higher scores showing greater perceived self-care agency. Most participants in the study did not have any advanced education and the level of self-care agency was determined as "moderate." Specific results of the analysis are not reported, but according to the authors, a significant relationship exists between education and self-care agency (Akyol et al., 2006).

Education was not found to correlate with self-care agency in the 2005 study of 62 HIV-positive African American women (Hurst et al., 2005). The authors examined the relationship between the basic conditioning factors including education and health state and self-care agency. Education was measured using a demographic tool developed by the authors. Health state was measured using a question that asked participants about their physical, emotional, and mental health related to their HIV diagnosis. Self-care

agency was measured using the Denyes Self-Care Agency Instrument (DSCAI-90,

Denyes, 1980). The DSCAI-90 is a 34-item questionnaire that measures 7 of the 10

power components of self-care agency. Six factors including ego strength, valuing of

health, health knowledge, energy, feelings, and attention to health are addressed.

Responses range from 0 (not at all) to 100 (totally, all). Most of the participants, or 61%,

reported finishing high school. The mean self-care agency score was 84.64 (SD = 10.34).

In the Hurst et al. study, specific results from correlation analyses are not reported, but

the author states there was no correlation found between education and self-care agency,

but a significant high correlation between the basic conditioning factor health state and

self-care agency (Hurst et al., 2005).

Another study found significant correlation with both education and health state

and self-care agency. Burdette (2112) examined the relationship between several

different basic conditioning factors and self-care agency and self-care in 224 middle-aged

women living in rural areas in the north-central states in the United States. Education was

addressed via a demographic instrument developed by the author. Self-care agency was

measured using the DSCAI-90. Most of the participants in the study had at least a

bachelor's degree and reported their health as very good. The mean score for self-care

agency was 75.713 (SD = 10.06) on a scale of 0-100. The author found a small,

significant, positive correlation between education and self-care agency (r = .213, p =

.001) and a moderate, significant, positive correlation between health state and self-care

agency (r = .46, p < .001).

A 2007 study of 43 Turkish individuals with rheumatoid arthritis examined the

relationship between pain as a symptom and self-care agency (Tokem, Akyol, & Argon,

2007). Pain was measured using a visual analogue scale standardized to 15 cm in length with the range of 0 for "no pain" and 10 for "very severe pain." Distances were measured in centimeters using a metric ruler, with the number of centimeters being converted to a score. Self-care agency was measured using the Self-as-Carer Inventory (SCI) (Geden & Taylor, 1991). The range of possible scores for this instrument is 40-240. In this study, the mean score for pain was 1.48 (SD = 0.74). The mean score for self-care agency in this study was 80.95 (SD = 27.80). The authors reported 69.8% of the participants as having either "good" or "average" self-care agency. A very small, negative significant correlation was found between pain and self-care agency (r = -.04, p < .05).

Different results were found in a similar 2011 study of 467 Turkish individuals with rheumatoid arthritis. In this more recent, larger study, the relationship between pain as a symptom and self-care agency was again examined (Ovayolu et al., 2012). Pain was measured using a visual-analog scale. Self-care agency was measured using the SCI (Geden & Taylor, 1991). In this study, the authors reported a mean pain score of 1.7 (SD = 0.6), which is similar to that of the 2007 study. In addition, for most of the participants, the level of self-care agency was 13.7% and 86.3% for "moderate" and "poor," respectively. These results are vastly different compared to the 2007 study by Tokem et al. There was a small, significant, positive correlation between pain and self-care agency (r = 0.28, p < 0.001) in this study.

Studies that examine symptoms and power exist in the literature. Anderson (2001) used a sample of 150 homeless adults and investigated the relationship between several influencing factors including health symptoms and power. Health symptoms determined to be relevant to the homeless community were measured using the Symptoms Scale of

the Omega Screening Questionnaire where scores can range from 0-18. Power

(Anderson, 2001) was measured using the DSCAI-90. In this study, the mean score for

symptoms was 4.99 ($SD = 4.18$). The mean score for power was 71.65 ($SD = 13.4$). In

addition, health symptoms were found to be significantly, moderately, and negatively

correlated with power ($r = -.35, p < .001$).

In contrast to the above studies, a 2001 study examined factors including

symptoms self-care agency and quality of life among those with inflammatory bowel

disease (Smolen & Topp, 2001). Symptoms were measured using a valid and reliable

tool, the Inflammatory Bowel Disease Questionnaire. This tool was divided into four

sections including two that measured disease specific symptoms and systemic symptoms.

Self-care agency was measured using the ASAA. The authors did not find a significant

relationship between the two symptom subscales and self-care agency.

Relationship Between Basic Conditioning Factors and Self-Care

Orem (2001) proposed that basic conditioning factors affect an individual's ability

to engage in self-care. Several studies have examined the relationship between basic

conditioning factors and self-care. For instance, in the above 1999 study by Lee, the

investigator examined the associations between multiple basic conditioning factors

including education and income and self-care. Basic conditioning factors were measured

using an investigator-authored tool (Lee, 1999). Self-care was measured using the

Denyes Self Care Practices Instrument-90 (Denyes, 1980). The Denyes Self Care

Practices Instrument-90 (DSCPI-90) is a general measure of self-care and has been found

to be suitable for healthy individuals as well as those with chronic conditions (Andrews,

Richard, & Aroian, 2009; Burdette, 2012). The 18-item self-report questionnaire was

based upon Orem's definition and theory of self-care (Deynes, 1988). Each question uses a visual scale that has participants rate how consistently various self-care practices are completed. The score ranges are from 0-100. Study results found a mean power score of 42.8 ($SD = 14.4$) and self-care score of 41.1($SD = 13.4$). Significant correlations were found between both education and income and the DSCPI-90 scores ($r = 0.30$, $p < .001$; $r = 0.22$, $p < 0.05$ respectively). Contrary results were found in Hurst et al. (2005). Results of the analyses were not available, though the authors stated no significant correlations between the basic conditioning factors education and income and self-care (Hurst et al., 2005).

Another study found varying results between a number of basic conditioning factors and self-care. Burdette conducted a predictive correlational study using a population of obese rural midlife women using Orem's framework (Burdette, 2012). Basic conditioning factors including education, chronic illness, and health state were measured using an investigator-authored tool that was informed by Orem's SCDNT (Burdette, 2012). Self-care was measured using the DSCPI-90. A positive, significant correlation was found between education and self-care scores, and a negative, significant correlation was found between chronic disease and self-care scores. In regard to the relationship between health state or symptoms and self-care, the Burdette study also examined the relationship between health state and self-care. A strongly significant, strong relationship was found between health state and self-care ($r = 538$, $p = .000$).

Relationship Between Self-Care Agency/Power and Self-Care

Orem (1995) proposed that individuals who feel they have the power to engage in self-care are more likely to engage in self-care. There is scarce if any literature that

examines the relationship between self-care agency/ power components of self-care

agency and self-care activities of individuals with CVLU. However, other studies

examine similar concepts in other populations.

Horsburgh (1999) studied the relationship between self-care agency and self-care

in 109 well-adults and 141 individuals with end stage renal disease in Ontario, Canada.

Self-care agency was measured using the Appraisal of Self-Care Agency (ASAA, Evers

& Isenberg, 1987). The ASAA is a 24-item scale with possible score ranges from 24-120.

Self-care was measured using the Self-Care Inventory (SCI, Gazda, 1986). Notable is that

the SCI has been used in other studies as a measure of self-care agency. The mean score

for self-care agency for the individuals with ESRD was 86.5 (SD = 15.7). The mean score

for self-care was 36.0 (SD = 8.0). The range of possible scores for the SCI is 40-240. A

moderate, strong correlation (r = .43, p < .001) was found between self-care agency and

self-care.

Self-care agency and diabetes self-care were examined in a 2005 study by Sousa

et al. A secondary analysis of 141 adults with Type I or Type II diabetes attending an

outpatient facility completed a survey. Self-care agency was measured using the ASAA

(Evers & Isenberg, 1987). Diabetes self-care actions were measured using Hurley's

Insulin Management Diabetes Self-Care Scale. Self-care agency showed a strong,

significant correlation with diabetes self-care (r = .75, p < .01.).

A 1999 study of women living in Pakistan (Lee, 1999) tested the hypothesis that

power and enabling capabilities will have a direct and positive relationship with self-care.

The participants in the study were women living in Pakistan. Pakistani women are

generally in poor health, poorly educated, and of low socioeconomic status. The sample

for the study was 162 women aged 18-60. Power was measured using the DSCAI-90.

Self-care was measured using the Deynes Self-Care Practices Instrument (DSCPI-90,

Deynes, 1990). Since the range of possible scores for each scale is 0-100, this population

scored relatively low in both areas. A strong, significant correlation was found between

power and self-care ($r = 0.81$, $p = .001$). In addition, power explained 65% of the

variance in self-care and was significant predictor of self-care ($R^2 = .65$, $\beta = .76$, $t = 15.0$.

$p < .0001$).

Similar results were found in the 2001 Anderson study that looked at relationships

between several different influencing factors, the power components of self-care agency,

and self-care in a population of homeless individuals. The homeless population in this

study scored somewhat higher than the Pakistani women on both power and self-care.

Power was measured using the DSCAI-90. Self-care was measured with the DSCPI-90.

The mean score for power was 71.65 ($SD = 13.4$). The mean score for self-care was 60.86

($SD = 15.01$). In addition, the author reports that power was the sole predictor of self-care

(Anderson, 2001).

Self-Care in Individuals With CVLU

Self-care for chronic disease involves an individual's engagement in activities

related to long-term management of symptoms or limitations due to the effects of the

disease (Jaarsma, Riegel, & Stronberg, 2012). Self-care actions for chronic disease

involve engagement in activities related to diet, exercise, or the alleviation or control or

symptoms (Sousa et al., 2005). Only one study, described in the next paragraph, was

found that examined the self-care within Orem's framework and used a population of

individuals with CVLU.

A 2007 study conducted by Seppanen examined self-care activities of individuals with leg ulcers in Finland (Seppanen, 2007). The study's aim was descriptive and to determine the extent of self-care activities. In the study, 88 individuals with leg ulcers in various settings including hospitals, primary care centers, and nursing homes were interviewed by nurses using a German questionnaire, the Wittener Aktivitätenkatalog der Selbstpflege bei venös bedingten offenen Beinen or WAS-VOB survey (Panfil, Mayer, & Evers, 2004). The WAS-VOB is a 59-item survey that examines eight different types of self-care activities that patients in Finland would be expected to perform. Categories include compression, wearing of compression bandages, wearing compression hose, mobility, and temperature, overloading of the venous systems, prevention of skin damage, and wound healing. The survey uses a 4-point Likert scale with the anchors definitely yes and positively no. Pain was also assessed using a numeric scale of 0-10. Of the 88 participants, 47 reported pain. Almost two-thirds or 63% of the participants reported leg edema.

The study also found that the most commonly performed self-care activities of individuals with leg ulcers were related to the prevention of edema and using compression therapy. A majority of participants, 72%, reported wearing their compression every day. Of other activities, 28% reported elevating their leg when possible, and 50% reported they walk often. However, only 23% reported walking at least one-half hour every day. More than half reported avoiding standing often, and 35% reported avoiding sitting for long periods of time.

Relationship Between Basic Conditioning Factors, Self-Care Agency, and Self-Care

According to Orem (2001) self-care can be impacted by factors internal or external to the individual (basic conditioning factors), and also by an individual's capabilities for self-care (self-care agency). Some studies found that self-care agency acts as a mediator between various basic conditioning factors and self-care. For instance, Wang and Laffery (2001) used path analysis to develop a predictive model of well-being and self-care using Orem's self-care theory (Wang & Laffery, 2001) and found self-care agency to be a mediator of health state on self-care. A sample of 284 Taiwanese rural-dwelling women over the age of 60 was randomly selected to participate in the study. An investigator developed survey measured demographic variables. Self-care agency was measured using the ESCA (Kearney & Fleischer, 1979). The Health Promotion Lifestyle Profile (HPLP) was used to measure self-care behavior. The HPLP is a 48-item scale that measures six dimensions of self-care. There was a strong positive correlation found between self-care agency and self-care ($r = .80$, $p < .01$). Structural equation modeling revealed that age, social class, and perceived health directly predicted self-care agency which also directly predicted self-care and indirectly predicted well-being through self-care.

Another study found self-care agency to act as a mediator between the basic conditioning factor severity of illness and self-care. Gatlin (2014) examined the associations between the basic conditioning factor severity of illness as a health state, executive function as a functional capability of self-care agency, and self-care in a population of 67 older adults with Type II diabetes. Executive function demonstrated full mediation between severity of illness and self-care (Gatlin, 2014).

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The associations between basic conditioning factor social support, self-care confidence, and self-care were examined in a 2008 study of 134 patients with heart failure (Riegel &Vaughan Dickson, 2008). Self-care confidence, a concept similar to self-care agency, was found to act as a mediator between social support and self-care.

Summary

All in all, a moderate body of literature is available that examines the associations using Orem's self-care framework between Orem's concepts of basic conditioning factors, self-care agency, and self-care in populations with chronic diseases. Several studies using Orem's self-care theory use older adults or individuals with other chronic diseases such as Type 2 Diabetes or rheumatoid arthritis. Individuals with CVLU are often older adults dealing with chronic venous insufficiency. Most quantitative studies suggest a linear relationship between the variables. However, since a) no studies can be found using a population of individuals with CVLU that examine the concepts in this study, and b) a small body of literature exists that supports the proposition that power can have a mediating effect between basic conditioning factors and self-care, power was be examined as a mediator between symptoms and CLU self-care. From the literature it can be surmised that an individual having many symptoms of chronic venous stasis may need increased power to engage in CVLU self-care. Power may be a relevant point to consider in the development of programs to enhance self-care in those with CVLU.

Across studies, there is no consistency in the tools used to measure the concepts, which can diminish validity. A major aim of this study was to examine the self-care that individuals with CVLU are engaged in. This study used a disease-specific tool authored

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by the investigator to measure self-care, as there is not an appropriate tool available at this time.

There is a large gap in the CVLU literature that uses a conceptual framework or theory to guide a course of research. The use of frameworks or theory to guide research clarifies and provides structure from which to investigate a phenomenon of interest (Fawcett, 2005). It is difficult to compare or generalize knowledge generated from studies that are not guided by a conceptual framework or theory.

Furthermore, ample evidence exists that supports the link between self-care and improved health in individuals with other chronic diseases such as rheumatoid arthritis. Rheumatoid arthritis has some similarities with CVLU. Both diseases occur in about 1-2% of the population, are characterized by disabling symptoms including pain, and are associated with mobility issues. Programs exist that enhance self-care and self-care agency to assist individuals with rheumatoid arthritis to live healthier lives. Self-care agency maybe enhanced through nurse-led programs (Herber et al., 2008).

In summary, despite a gap in the CVLU literature about factors that are related to or predict self-care, research with other populations examining relationships between Orem's concepts basic conditioning factors, self-care agency, and self-care exist. Increasing our knowledge of what types of factors contribute to or serve as barriers to self-care in the CVLU population can assist in the development of attainable goals and plans of care and can add quality and value to health care in individuals with CVLU.

CHAPTER III

METHODOLOGY

This study was designed to examine the relationships between three concepts proposed in Orem's Self-Care Deficit Theory (Orem, 2001) in patients with lower extremity ulcers due to chronic venous insufficiency (CVI). Power for health-related self-care was examined as a mediator between symptoms and CVLU self-care while controlling for the co-variates comorbidities, income, education, and the chronicity of the leg ulcer. This chapter describes the study design, sample, setting and sample, instruments, procedures, and data analysis. The protection of human subjects is also discussed.

The research questions for the study are:

1. What is the relationship between symptoms, power, and CVLU self-care?

2. Does power mediate the effects of symptoms on CVLU self-care?

3. What is the mediating effect of power on CVLU self-care when controlling for comorbidities, income, education, and chronicity of the leg ulcer?

Study Design, Setting, and Sample

A cross-sectional survey design was used to analyze data collected at two outpatient wound clinics in Northeastern Ohio between July 2015 and January 2016.

The primary site is located in an urban area within a community hospital, and averages approximately 130-150 visits per month. The secondary site is located in a suburb of Cleveland and averages about 100 visits per month. The nature of the wound etiologies at both sites included venous, diabetic, trauma, and pressure. For patient visits each month, approximately 25% are for those with a wound due to venous insufficiency. At any given time, there are approximately 30-50 active patients seeking care for a wound due to venous insufficiency. Fifteen to 20% of the active patients reside in a residential care facility so would not fit inclusion criteria. Most patients are scheduled to come weekly; however, the cancellation rate is 10-50%.

Inclusion criteria were that the potential participant is over 18 years of age, is able to read and write in the English language, has the diagnosis or chronic venous leg ulcer for least one month, and is currently seeking care in the outpatient wound care center. Exclusion criteria were a diagnosis of a leg ulcer caused by arterial disease, pregnancy, the inability to ambulate without assistance, and is currently residing in a skilled nursing facility. Since wounds with an etiology of arterial insufficiency often exhibit different signs and symptoms, they may require different types of treatment modalities including surgery. In addition, wounds of arterial etiology have different prognoses compared to persons with venous insufficiency (Bonham, 2003).

Data Collection Technique

Data collection techniques were nearly identical at both recruitment sites. Participants were informed of the research via an Informational Flyer (Appendix A) that was displayed in the reception areas of each wound care clinic. A written script, "Recruitment Script" (Appendix D) was used for recruitment and to guide data collection

procedures. This information included the exact verbiage that was delivered to each participant regarding the study purpose, methods, participant requirements, and the importance of answering every question. It also included a series of steps that was taken in the data collection process for each participant to ensure that each participant was treated uniformly and to enhance study reliability.

At the start of each data collection session, the wound clinic staff provided a list of patients with the diagnosis of leg ulcer due to chronic venous stasis to help the PI identify potential participants. The Wound Healing Center staff also assisted the PI in identifying the potential participants in the waiting area. Using the scripted information, the PI asked each potential participant if they would be interested in participating in the study mentioned in the posted flyer. If the potential participant stated they were interested, they were directed to a quiet area in the wound clinic. Questions regarding the research were encouraged. If the potential participant agreed to continue, they were presented with the packet of study materials, a pen, and a clipboard. The study materials consisted of the Study Questionnaire (Appendix B) and the Patient Information Sheet (Appendix C). Completed surveys were placed back into the envelope and then into a secure area within the Wound Center.

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Power Analysis and Sample Size

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A power analysis was conducted using G* Power 3.1.7 (Faul, Erdfelder, Lang, & Buchner, 2007) with a significance level of 0.05, medium effect size, power of 0.80, and six predictors. Using these parameters, a sample size of 98 was needed**.** To account for 10% missing data, a final sample size of 107 was proposed. At the conclusion of this study, data from 89 participants from two outpatient wound care centers were collected.

Six surveys were excluded from the final data analysis. The reasons included not meeting the inclusion criteria (non-ambulatory, n = 3) and incomplete data from 50% or more survey questions (n = 3). Therefore a final sample of 83 participants was used for data analysis.

Several barriers to recruitment were identified after 89 participants completed the survey. At month five of data collection, every active patient fitting inclusion criteria had been recruited at both sites. In addition, due to the upcoming holiday season, the rate of new patients with chronic venous leg ulcers was predicted to be lower than usual for the next several weeks. Another barrier to recruitment was that one of the vascular surgeons would no longer accept uncomplicated venous patients, further reducing the rate of potential participants. For these reasons, data collection was terminated. However, a post-hoc power analysis revealed that the study was under-powered. A poc-hoc power analysis for each research question was conducted using G* Power 3.1.7 (Faul et al., 2007). For research question 1 using a sample size of 83, Pearson's correlation, effect size of .25, alpha .05, two-tailed, the post hoc power was calculated as .64. For research questions 2 and 3, post-hoc power was calculated using a sample size of 83, F-test, data including the calculated effect size from correlation coefficient, number of predictors, and alpha. For research question 2, the post-hoc power calculation was .55. For research question 3, the post-hoc power calculation was .40.

Protection of Human Subjects

Approval to conduct the study was obtained from the Dissertation Committee and the IRB. A waiver of documentation of informed consent was granted by the IRB. Filling out the survey involves minimal risk to the participant, the rights and welfare of the

participants would not be adversely affected by the waiver. In lieu of an informed consent

document, the investigator provided each participant with a written statement regarding

the research, the Patient Research Information (Appendix C). Confidentiality was

preserved as there were no requests for personal identifiers on the survey. Scripted

directions included the statement "do not write the name or any other personal

information about the participant on this survey." There was minimal risk to participants

in completing the survey questionnaire. Completion of the survey questionnaire was

voluntary and did not involve coercion or persuasion by the PI or wound care center

employees to participate. There was no compensation offered for participation.

Instruments

The variables chosen for this study were based upon a review of studies using

Orem's SCDNT and populations with CVLU and other chronic diseases. Variables in this

study include symptoms, power, CVLU self-care, income, education, comorbidities, and

chronicity of the leg ulcer. Three instruments were used to measure the variables. A

subscale of the Venous Insufficiency Epidemiological and Economic Study-Quality of

Life and Symptom Severity or the VEINES-QOL/Sym (Lamping et al., 2003) was used

to measure the variable symptoms. Power was measured using the Appraisal of Self-Care

Agency Scale-Revised (ASAS-R, Sousa et al., 2010). CVLU self-care was measured

using the CVLU Self-Care Survey. General demographic and health information

including age, gender, marital status, ethnicity, education, income, and health information

including number of comorbidities, use of assistive devices, height, weight, smoking

status, and chronicity of the leg ulcer was also collected. Table 3.1 summarizes the

instruments used in this study.

Table 3.1

Instruments Used in This Study

Variables	Instruments	Items	Possible total score range
Symptoms	VEINES-QOL/Sym, (Lamping et al., 2003)	10-item scale 9 items 5 point Likert (1-5) 1 item 6 point Likert (1-6)	Raw score of 10-51. Higher scores indicate lower level of symptom severity
Income	Investigator developed demographic and health information tool	Multiple choice question	Less than $20,000- More than 70,000
Education	Investigator developed demographic and health information tool	Open-ended question	Higher number indicates more education
Comorbidities	Investigator developed demographic and health information tool	Multiple choice question, total sum	0-5. Higher value indicates more concurrent diseases
Chronicity of the Ulcer (Ulcerage)	Investigator developed demographic and health information tool	Open-ended question	Higher number indicates The ulcer has been present for more time
Power	ASAS-R (Sousa et al., 2010)	15-item, 5 point Likert scale (1-5)	15-75. Higher scores indicate higher power for health-related self-care
CVLU Self-Care	Investigator developed tool	9-item, 5 point Likert (1-5)	9-45. Higher scores indicate higher level of CVLU self-care

Symptoms

A subscale of the Venous Insufficiency Epidemiological and Economic Study-Quality of Life and Symptom Severity or the VEINES-QOL/Sym, (Lamping et al., 2003) was used to examine symptoms that are the result of chronic venous insufficiency and experienced by participants with leg ulcers. There are very few, if any other, validated tools to measure symptoms in individuals with CVLU. The VEINES-QOL/Sym has been used in several other studies in Europe (Enden, Garratt, Klow, & Sandset, 2009; Mean, Limacher, Kahn, & Aujesky, 2014; Van der Velden, Biemans, Nijsten, & Sommer, 2009) and Canada (Kahn et al., 2006).

The VEINES/Sym is a 10-item subscale. Nine items in the VEINES/Sym are related to the frequency of symptoms a person with CVLU may experience including heavy legs, sore legs, swelling, burning sensation, itching, numbness, night cramps, restless legs, or throbbing legs. A 10th item assesses pain intensity. A 5-point Likert-type scale is used to assess the frequency of each of nine symptom over the past 4 weeks where 1-every day, 2-several times a week, 3-about once a week, 4-less than once a week, and 5-never. A 10th item about pain asks about pain intensity over the past 4 weeks on a 6-point scale where 1-no pain and 6-severe pain. The question about pain is reverse scored.

To account for the differences in response format, the VEINES QOL/Sym is accompanied by a statistical package for the social sciences (SPSS) scoring program (Lamping & Schroeder, 2007) that transforms raw scores into z-scores (mean of 0 and standard deviation of 1), which are then transformed into T-Scores (mean of 50, standard deviation of 10). The SPSS scoring program, which was requested from the authors of the tool via email, is in the form of an SPSS syntax file. Higher values on the VEINES/Sym indicate a better outcome as explained by a lower level of symptom severity and a lower level of self-reported pain (Kahn et al., 2006). In other words, an individual whose scores are higher would be responding more frequently to choice 5 (never have the symptom), and lower to the pain scale question which is reverse-scored.

Lamping et al. (2003) reported that internal consistency is good for both the VEINES-QOL ($\alpha = 0.89$) and the VEINES/Sym ($\alpha = 0.86$) as indicated by a high Cronbach's alpha. The inter-item correlations range from 0.21 to 0.79 for the VEINES-QOL, and from 0.22 to 0.82 for the VEINES/Sym. Test-retest reliability has values of

0.89 for the VEINES-QOL and 0.86 for the VEINES/Sym. According to Lamping et al. (2003), content validity was evaluated during the development of the survey using pre-testing with patients, expert opinion, and a review of the literature. The Cronbach's alpha for this study was .891.

Power

The ASAS-R (Sousa et al., 2010) was chosen to measure power in this study because a) power is capabilities or enabling traits that are necessary to performing self-care, b) Orem's work (Orem, 2001)stresses the importance of power for self-care, c) the ASAS-R has been used in health research to measure power with persons with chronic disease (Damasio & Koller, 2013), and d) future studies could use the ASAS-R to quickly assess power for self-care in order to develop programs tailored to each individual's needs. According to the authors, the ASAS-R specifically measures an individual's level of power. Studies have shown that power reflects an individual's ability to engage in self-care (Anderson, 2001; Damasio & Koller, 2014; Gast et al., 1989; Sousa et al., 2005).

There are other survey instruments that measure self-care agency; however, only the ASAS-R measures power. Recent research that used the ASAS-R is a study of 97 women receiving chemotherapy in China (Zhang, Kwekkeboom, & Petrini, 2014), and in patients receiving insulin in Brazil (Stacciarini, & Pace, 2013).

The original 24-item version of the tool, the Appraisal for Self-Care Agency Scale (ASAS) (Evers & Isenberg, 1987) was developed in the 1980s by a panel of experts in Orem's work (Sousa et al., 2005). The tool was further examined by Sousa et al. to improve efficiency and internal consistency for future use with a population of

individuals with a chronic disease, type II diabetes. The resultant ASAS-R is a 15-item revised version of the original tool used in this study.

The ASAS-R consists of 15 self-reporting items that assess power for health-related self-care. Participants are asked to select their degree of agreement for each statement using a Likert scale of 1 to 5. Four of the 15 questions require reverse coding. The range of possible scores is 15 to 75 where a higher score indicates a greater level of power for health-related self-care. Questions asking about having power for health-related self-care include "As circumstances change, I make the needed adjustments to stay healthy" and "I look for better ways to take care of myself." The alpha for the tool in this study was .809.

CVLU Self-Care

The CVLU self-care survey, developed by the principal investigator (PI), measures self-care actions taken by individuals with leg ulcers due to chronic venous insufficiency. Content validity was established using a review of the literature and review by three clinical experts in venous ulcer care. The experts were experienced (15 years or more) Advanced Practice Nurses (APNs) specializing in treating individuals with CVLU and other wounds.

Cognitive interviewing techniques were also used to review survey questions. Cognitive interviewing is a type of instrument pre-testing that looks at a respondent's thinking process as they hear or read questions in a survey. Cognitive interviewing examines how respondents interpret the meaning of questions and the possible responses, how it is decided how they will answer, and what their answers mean. A modified version of the verbal probing technique of cognitive interviewing as suggested by Willis

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(1999) was attempted. In this study, 10 active wound clinic patients agreed to participate in the process. Initially, the intended process of cognitive interviewing included using a probing question or questions. For instance, for the survey question that asks about frequency of performing leg exercises, the probing question asked was "what does the term leg exercises mean to you?" or "what types of things do you think of when you think about leg exercises?" A majority of the patients were not able to provide meaningful responses to the probing questions and instead suggested ways the questions could be presented with more clarity. Subsequently, the survey questions were assessed for clarity of meaning. The PI reviewed the data from each question and made modifications according to the feedback given. Four of the original nine questions were retained in their original form, and the remaining five were modified to provide more clarity.

The CVLU self-care survey originally consisted of nine self-reporting items that assess self-care in individuals with CVLU. In the CVLU self-care survey, participants are asked to select their degree of agreement for each of the nine statements using a Likert scale of 1 to 5. The range of possible scores is 9-45. To obtain a total score, a summation of the nine-item scores is calculated. Higher scores indicate greater levels of CVLU self-care. Statements about CVLU self-care include "I avoid sitting for long periods of time" and "I recognize signs and symptoms of infection." The CVLU self-care survey uses a response format similar to that of the ASAS-R. The Cronbach's alpha for the nine-item CVLU self-care survey was .55.

Cronbach's alpha is a measure of the internal consistency, examining if several items on a scale measure the same general construct. Cronbach's alpha is expressed as a

value of 0 to 1 and is linked to the inter-relatedness of items within a scale (Tavakol &

Dennick, 2011). A Cronbach's alpha of less than .60 is considered unacceptable

(DeVellis, 2003; Nunnally & Bernstein, 1994).

Since the Cronbach's alpha for the nine-item CVLU self-care survey scale was

only .55, an item analysis was performed. First, the inter-item correlations were examined

(Table 3.2). Nunnally and Bernstein (1994) suggested that items with negative inter-item

correlations are problematic, often having interpretation problems. Several items had

negative and low inter-item correlations.

Table 3.2

Inter-Item Correlations Between Items in the Nine-Item CVLU Self-Care Survey

	Elevate legs	Go to doctor	Recognize signs	Not afraid to look	Wear compression	Do leg exercises	Avoid standing	Walk often	Avoid sitting
Elevate legs	1.00								
Go to doctor	.32	1.00							
Recognize signs	.24	.31	1.00						
Not afraid to look	.03	.16	.36	1.00					
Wear compression	.25	.29	.07	.14	1.00				
Do leg exercises	.46	.21	.20	.01	.27	1.00			
Avoid standing	.24	.22	-.05	.01	.16	.26	1.00		
Walk often	-.01	.04	-.15	-.16	.10	.10	-.35	1.00	
Avoid sitting	.34	.20	.11	-.07	.15	.12	-.13	.25	1.00

Table 3.3 shows the results for the item analysis of the nine-item scale. The

average inter-item correlation was .13, which is low. Field (2005) suggests examining the

corrected item total correlations for each item. Items with low corrected item total

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Table 3.3

Item Analysis for Nine-Item CVLU Self-Care Survey

Statistics for Scale	N	Mean	SD	Mean Inter-item correlation
	9	33.12	4.68	.13
Scale item		Corrected item total correlation		Alpha when item deleted
Elevate legs		.52		.44
Go to doctor		.44		.47
Recognize signs and symptoms		.25		.53
Not afraid to look at wound		.10		.57
Wear compression		.37		.50
Do leg exercises		.45		.46
Avoid standing for long periods		.079		.58
Walk often		-.04		.62
Avoid sitting for long periods		.26		.53
		Alpha		Cronbach's alpha based upon standardized items
Reliability coefficient for 6 items		.56		.57

correlations (less than about .3) do not correlate well with the scale overall and may need

to be deleted (Field, 2005). The item "walk often" showed the lowest corrected item total

correlation (-.04) and was deleted first. The item analysis was repeated. The Cronbach's

alpha for eight items was improved (.62), with three items showing low corrected item

total correlations. For the remaining eight items, the corrected item total correlation for

"not afraid to look at wound" was the lowest (.14), so was deleted, with Cronbach's alpha

for seven items again improved (.63). However, two items ("avoid sitting for long

periods" and "avoid standing for long periods") showed low corrected item total

correlations. "Avoid sitting" and "avoid standing" had nearly identical corrected item

total correlations (.20). The avoidance of sitting and standing are important to prevent

edema in individuals with CVLU, but these items may have been problematic as they

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have similar interpretations. Therefore, six items were again reanalyzed separately using

"avoid sitting" and "avoid standing." Cronbach's alpha retaining six items with "avoid

standing" was .63, but improved to .64 retaining "avoid sitting."

The remaining six items had corrected item total correlations around .3, and the

alpha when deleted column showed no improvement by deleting further items. The six-

item scale was retained as the remaining corrected item total correlations were around

0.3, which suggests no factorability (Field, 2009). In addition, the average mean inter-

item correlation improved to .23. The new six-item scale showed a Cronbach's alpha of

.64, which is a marginally acceptable value for reliability. Table 3.4 shows the item

analysis for the six-item CVLU self-care score. For the six-item scale, the Kaiser-Meyer-

Olkin measure of sampling adequacy for the revised scale was marginal at .69, and the

Bartlett's test of sphericity was significant ($X^2(15) = 59.01, p < .0001$). Two of the

corrected item total correlations had values lower than 0.3, which can suggest problems

with factorability (Field, 2009).

Table 3.4

Item Analysis for Six-Item CVLU Self-Care Survey

Statistics for Scale	N	Mean	SD	Mean inter-item correlation
	6	21.96	3.92	.231

Scale item	Corrected item total correlation	Alpha when item deleted
Elevate legs	.56	.53
Go to doctor	.40	.59
Recognize signs and symptoms	.29	.63
Wear compression	.31	.62
Do leg exercises	.41	.59
Avoid standing for long periods	.29	.63
	Alpha	Cronbach's alpha based upon standardized items
Reliability coefficient for 6 items	.64	.64

Next, a factor analysis was conducted to determine what, if any, underlying structure exists for the six items. The scree plot for the revised scale is shown in Figure 3.1. The scree plot shows that one factor with an eigenvalue greater than one falls above the point of inflection of the curve.
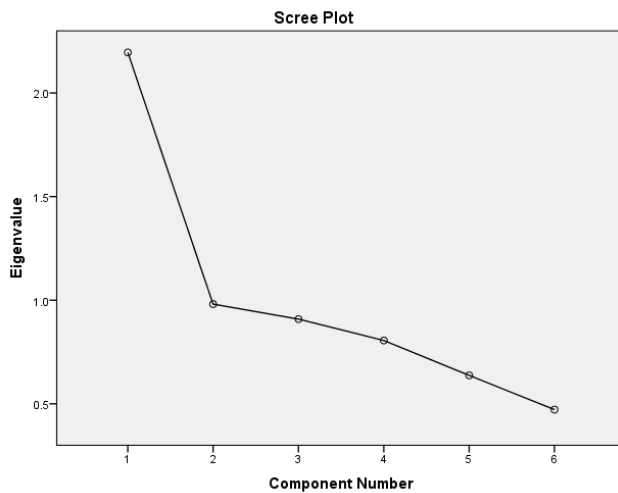
Figure 3.1. Scree plot for factor analysis of the six-item CVLU self-care scale.

Principal component analysis with Varimax rotation was conducted on the revised six-item scale. A one factor solution explained 36.59% of the total variance in the scale. The communalities were above .2, suggesting that there was some common variance shared between the items. The component matrix showed factor loadings on the component were $\geq .50$, which suggest strong associations with the single underlying factor (Table 3.5). From a theoretical standpoint, the items retained on the six-item CVLU self-care score represent the construct of CVLU self-care. The CVLU literature describes the six items as actions important for those with CVLU to perform.

Table 3.5

Component Matrix Showing a One-Factor Solution for the Six-Item CVLU Self-Care Survey

	1
Elevate legs	.77
Go to doctor if notice infection	.63
Recognize signs and sx of infection	.50
Wear compression	.51
Do leg exercises	.66
Avoid sitting for long periods	.50

Data Screening

An evaluation of missing values from the final sample of 83 participants was performed in SPSS version 23. A depiction of the pattern of missing values can be found in Figure 3.2. The variable income has the highest percentage of missing values.
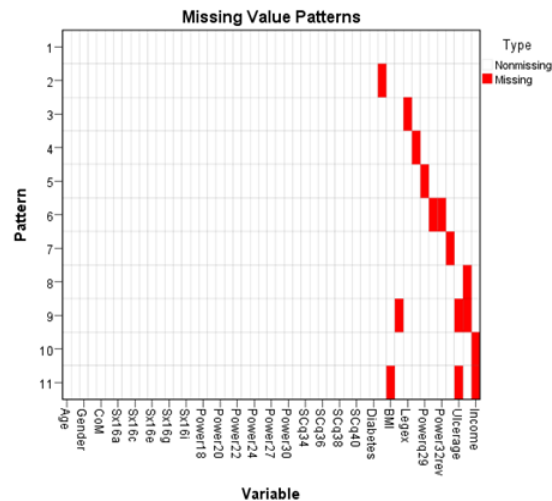
Figure 3.2. Pattern of missing values.

Little's Missing Completely at Random (MCAR) test was used to investigate the pattern of missing data. Little's MCAR tests the hypothesis that data are missing in a random or non-random fashion. Results of the analysis indicated that the means of missing and non-missing groups were not statistically different from each other (Chi-

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Square = 461.24, df = 465, p = .54). Thus the missing data were considered as MCAR. Since the percentage of missing data was very low, more sophisticated methods of imputation were not necessary (Polit, 2010). For this study, missing value was replaced using the recommendations from Mertler and Vanatta (2010). Mean substitution was used when a variable has less degree of variability (standard deviation less than 2) and median substitution was used when a variable with a standard deviation of greater than 2 (Mertler & Vanatta, 2010).

Assumptions Testing for Multiple Regression

The assumptions of multiple regression of the other variables were tested for outliers, multicollinearity, normality, linearity, and homoscedasticity. To check for outliers, the multivariate and univariate ungrouped data statistics were examined. To check for multivariate outliers, the variables in the multiple regression were examined using the procedure suggested by Mertler and Vanatta (2010). Mahalanobis Distance test is a statistical measure of the extent to which cases are multivariate outliers based on a chi-square distribution assessed using $p < .001$. If the maximum Mahalanobis Distance is larger than the critical chi-square value for the number of predictors in the model at a critical alpha value of $p < .001$, the cases are identified as outliers. Results of the Mahalanobis Distance test showed only the chronicity of leg ulcer variable (coded as "ulcerage variable" in SPSS) had an outlier (case # 73 has had leg ulcer for 588 months). To replace this outlier, Mertler and Vanatta (2010) suggested using the datum closest to the outlier. Thus, the value of 180 months was used to replace this outlier. After removing the outlier, the Mahalanobis Distance test showed no extreme value that was greater than the critical value of chi-square ($p = .001$, df = 7, $X^2 = 24.32$). To check for

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multicollinearity assumption, tolerance values were examined. Tolerance value greater than 0.1 indicates that no multicollinearity exists between the independent variables (Mertler & Vanatta, 2010). In this study, tolerance ranged from .77 to .96.

To check for normality, a normal q-q plot was generated. Figure 3.3 shows data points are close to the line indicating a normal distribution of the data.
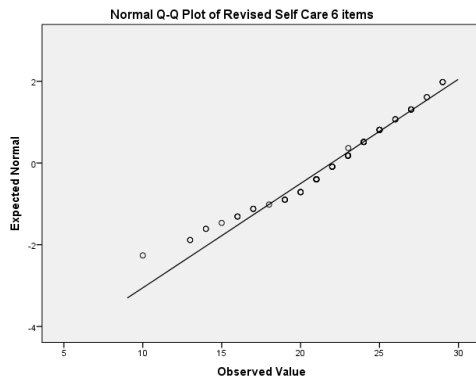
Figure 3.3. Normal q-q plot.

To test for homoscedasticity, a scatterplot predicting the homoscedasticity of self-care when predicted by symptoms and power was generated. The data points in the scatterplot resemble an elliptical shape, indicating homoscedasticity (Figure 3.4).
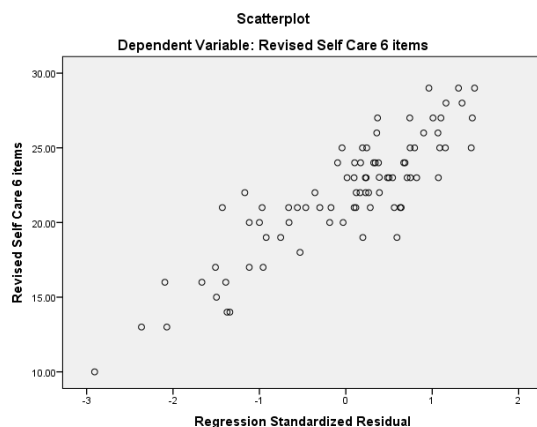
Figure 3.4. Normal scatter plot.

Additional statistical testing was performed to assessment the study variables for normality. Since the mean and the median of the covariate ulcerage were far apart (M = 22.13, median = 8.00 months), it was suspected that this variable had a non-normal distribution. Tests of normality were performed.
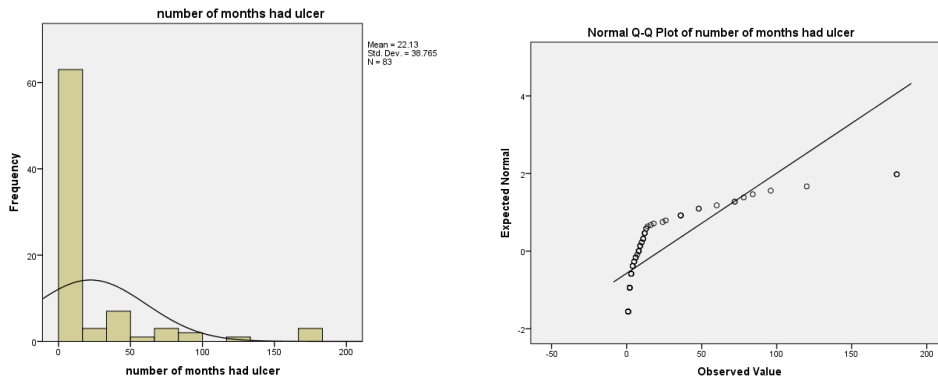
Figure 3.5. Histogram and q-q plot for the untransformed ulcerage variable.

In Figure 3.5, the histogram on the left shows that the untransformed ulcerage variable has a tail with the long end pointing toward the right, and the q-q plot on the right shows scores above the line, which suggests deviation from normality. Descriptive statistics show the untransformed ulcerage variable to have a substantial positive skew of 2.91 (skew/standard error of skew), which is considerably different than the acceptable range of +/- 1.96. In addition, the Kolmogorov-Smirnov and Shapiro-Wilk tests were both significant at the $p < .001$ value; further suggesting the untransformed variable did not show a normal distribution. Tabachnick and Fidell (2007) recommend using a log10 transformation for variables with a substantial positive skew. After log10 transformation, the histogram and q-q plot for the ulcerage variable depicts a more normalized visual representation (Figure 3.6). The skewness statistic for the transformed ulcerage variable

is .44, which is within the normal range. It was determined that the transformed variable wound be used in the data analysis.
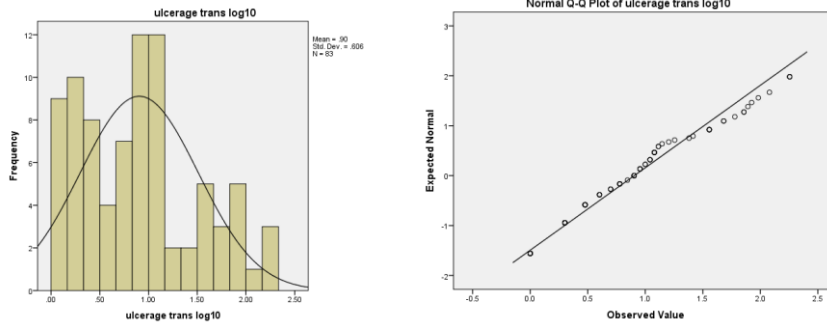
Figure 3.6. Histogram and q-q plot for the transformed ulcerage variable.

The other variables were also examined for normality. For the revised six-item self-care variable, the histogram showed a fairly normal curve and the q-q plot showed scores fairly close to the line (Figure 3.7). The revised six-item self-care variable was not substantially skewed (skewness = -.64). However, the Kolmogorov-Smirnov and Shapiro-Wilk tests were both significant ($p < .05$), suggesting a non-normal distribution. To determine whether or not to transform the six item self-care variable was more difficult but would be explored. Tabachnick and Fidell (2007) recommended using a reflect square root transformation for variables with a small negative skew.
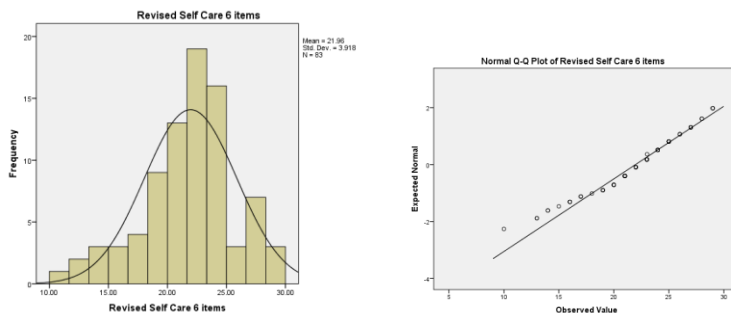
Figure 3.7. Histogram and q-q plot for the untransformed self-care variable.

After transformation, visual inspection of the six-item self-care variable showed a more

normalized histogram and scores close to the line on the q-q plot (Figure 3.8.) The skew

for the transformed self-care variable was -.20, which was improved. In addition, the

Kolmogorov-Smirnov and Shapiro-Wilk tests were now non-significant at $p < .05$,

suggesting normality.
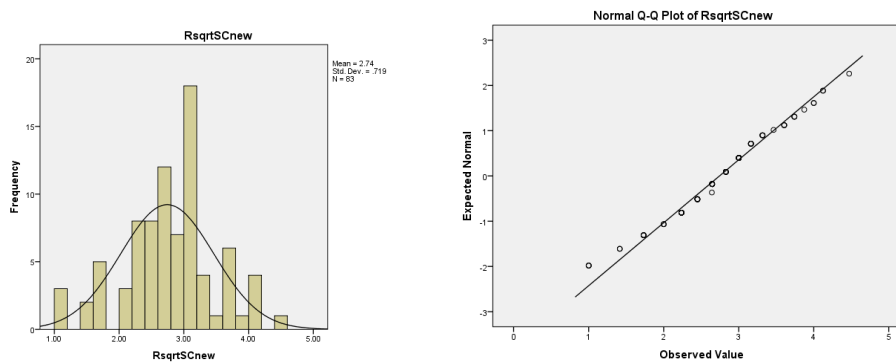
Figure 3.8. Histogram and q-q plot for the transformed self-care variable.

To investigate if using the transformed six-item self-care variable would influence

the interpretation of study results, statistical analyses using the transformed six-item self-

care variable were performed. Using an independent t-test, the mean total self-care scores

of those having an ulcer less than eight months, and greater to or equal to eight months

were examined using the untransformed and transformed six-item self-care variable in

separate analyses. Eight months was chosen as the point of comparison, as it was the

median value for the ulcerage variable. Table 3.6 shows a comparison of t-test results

using the transformed and untransformed self-care variable. Both analyses show a

statistically significant difference in mean total self-care scores between the lower and

higher ulcerage; however, the direction of the scores using the transformed self-care

variable was counter-intuitive and required further evaluation. The results of the t-test

analysis using the transformed self-care variable showed higher mean total self-care scores for those with a leg ulcer for less time. Theoretically, an individual with a chronic condition for a longer period of time would have a higher, not lower level of self-care. Therefore, interpretation of the t-test results using the transformed self-care variable seemed problematic. The results of the t-test analysis using the untransformed self-care data are more interpretable. There is a statistically significant difference in mean total self-care scores between the groups, with the self-care scores for those with a longer ulcerage being higher than those with the shorter ulcerage (t(81) = -2.097, $p < 0.5$).

Table 3.6

Comparison of T-Test Results Using the Transformed and Untransformed Self-Care Variables

Variable	Ulcerage In months	M	SD	t	df	p	CI	
							Lower limit	Upper Limit
Transformed Self-care	< 8	2.91	.69	2.180	81	.032	.03	.65
	>8	2.58	.72					
Untransformed Six-item self-care	<8	21.0	4.03	2.16	81	.034	3.50	-.14
	>8	22.82	3.65					

Based upon these findings and cautionary advice in the literature regarding interpretation of findings when using transformed variables, it was concluded that the transformed self-care variable would not be used in the analyses for this study. It was also concluded that the two other variables would not be transformed. Transforming negatively skewed data can lead to problems in interpretation of the data (Tabachnick & Fidell, 2007), which was illustrated in the example above. Table 3.7 presents a summary of the results of the statistical tests of normality for the variables discussed in this section.

Table 3.7

Normality Statistics for Transformed and Untransformed Study Variables

Variable	Skewness	Mean	SD	Median	95% CI		K-S	S-W
					Lower limit	Upper limit	*p*	*p*
Revised self-care 6-item	-.64	21.96	3.92	22.0	21.11	22.82	.001	.01
Revised self-care 6-item (Transformed)	-.20	2.74	.72	2.83	2.59	2.90	.06	.18
Ulcerage	2.91	22.13	38.77	8.0	13.67	30.60	.00	.00
Ulcerage (Transformed)	.44	.91	.61	.90	.77	1.04	.04	.01
Symptoms	-.56	50.0	10	51	48.58	51.42	.05	.01
Power	-.60	58.16	3.92	59.0	56.51	58.81	.01	.01

CHAPTER IV

RESULTS

This chapter is organized to first present a brief description of the study and the research questions, followed by description of the participant characteristics and study variables, then data analysis and results for each research question.

Brief Description of the Study and Research Questions

This cross-sectional survey design study aimed to examine power for health-related self-care as a mediator between symptoms and CVLU self-care in a population of individuals with CVLU. The original power analyses recommend a sample size of 107. At the conclusion of this study, 89 participants from two outpatient wound care centers participated and data were collected from these participants. However, six individuals were excluded from the final data analysis. The reasons include not meeting the inclusion criteria (non-ambulatory, n = 3) and incomplete data from 50% or more survey questions (n = 3). Thus, the data analyses were conducted on a sample of 83 participants.

The instruments used in the study were the VEINES-QOL/Sym (Lamping et al., 2003), ASAS-R (Sousa et al., 2010), and investigator developed tool, the CVLU self-care survey. SPSS version 23 was used to analyze data.

The research questions for the study were:

1. What is the relationship between symptoms, power, and CVLU self-care?

2. Does power mediate the effects of symptoms on CVLU self-care?

3. What is the mediating effect of power on CVLU self-care when controlling for comorbidities, income, education, and chronicity of the leg ulcer?

Description of Participants

Detailed demographic information of the 83 participants is listed in Tables 4.1 and 4.2. Fifty percent of the participants were older than 66 years of age ($M = 67$, SD = 15.41). More white, male participants were included in this study. Years of education showed a wide range of among the participants (3-19 years) with most having at least a high school degree. More than 50% of the participants reported annual household incomes less than $30,000. The median number of comorbidities was one ($M = 1.04$, *SD* = 1.15). The most commonly reported comorbidity was diabetes (N = 36). The median length of time a participant reported having a leg ulcer was eight months ($M = 22.13$, *SD* = 38.82), with the length of time having a wide range (1-180 months).

Table 4.1

Characteristics of Participants, Continuous Variables (N = 83)

Characteristic	Range	Mean +/- SD	Median
Age (years)	24-94	67 ± 15.40	66
Years of Education	3-19	13.4 ± 2.57	12
Number of Comorbidities	0-4	1.04 ± 1.15	1
Chronicity of the Leg ulcer (months) Untransformed	1-180	22.13 ± 38.82	8

Table 4.2

Characteristics of Participants, Categorical Variables (N = 83)

Characteristic	N	%
Gender		
Male	48	57.9
Female	35	42.2
Race	66	79.5
White	10	12.0
African American	6	7
Others		
Marital Status	16	19.3
Single	38	45.8
Married	8	9.6
Divorced	21	25.3
Widowed		
Household Income per year		
< 20,0000	26	31.3
20,000-29,000	18	21.7
30,000-39,000	9	10.8
40,000-49,000	7	8.4
50,000-59,000	3	3.6
60,000-69,000	4	4.8
>70,000	7	8.4

Data Analyses and Study Results

The next sections present information related to data analysis and results for each research question. Descriptive statistics for each variable are presented first, followed by the data analyses for each research question. The last section presents additional data analyses pertinent to the study results.

Descriptive Statistics for Symptoms

Information about item statistics and frequency of symptoms other than pain can be found in Table 4.3.The items in the VEINES/Sym symptom survey consist of nine items that are related to the frequency of symptoms a person with CVLU may experience and a 10th item that assesses pain intensity. The participants in the study reported a wide range of types and frequency of symptoms. Using the algorithm for the 10-item

symptom score (Lamping & Schroter, 2007), T-scores were calculated. The mean score

for symptoms was 50 (SD = 10). The range of mean total scores was 26-66. The items

show similar patterns of variability. No items show a substantial skew. Leg swelling was

the symptom most commonly reported as being experienced on an everyday basis (51%).

Restless legs was the symptom least reported as being experienced on a daily basis, with

more than half (57%) of the participants reporting that they never experience this

symptom. The mean pain level reported was 2.72 (SD = 1.77).

Table 4.3

Statistics and Frequency of Symptoms for Symptoms Survey (N = 83)

Total score symptom survey	Mean	SD	Minimum score	Maximum Score			
	50	10	26	66			

	Item Statistics				Frequency of Symptoms		
Symptom scale item	Mean	SD	Median	Skewness	Every Day	<Once-several times per week	Never
					%	%	%
Heaviness	3.61	1.64	5.00	-0.62	19	30	51
Aching	3.02	1.65	3.00	0.06	27	39	34
Swelling	2.34	1.58	1.00	0.64	51	33	16
Night cramps	4.02	1.26	5.00	-1.17	7	42	51
Heat or burning	3.84	1.57	5.00	-0.93	16	30	54
Restless legs	3.75	1.58	5.00	-0.74	14	29	57
Throbbing	3.52	1.63	4.00	-0.49	19	34	47
Itching	2.94	1.63	3.00	0.07	30	42	28
Tingling	3.20	1.73	3.00	-0.18	29	30	41
Pain*	2.72	1.78	2.00	0.52			

*non-reversed score for pain

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Data for the non-reverse, self-reported pain levels ranged from 1 (no pain) to 6 (severe pain). Many of the participants reported no pain (41%). Approximately 10% of the participants (n = 8) reported severe pain (Table 4.4). One participant reported having all nine symptoms and severe pain, and four participants reported never having any of the nine symptoms and no pain.

Table 4.4

Self-reported Pain Levels (N = 83)

Pain level (range 1-6)	N	%
1 (No pain)	34	41.0
2	9	10.8
3	11	13.3
4	12	14.5
5	9	10.8
6 (Severe pain)*	8	9.6

 *non-reversed score for pain

Descriptive Statistics for Power

Item statistics and frequencies of responses for the ASAS-R are reported in Table 4.5. The mean score for power was 58.16 (*SD* = 7.55) with the range of scores being 29-72. No items show a substantial skew. The most commonly reported response was "agree," which corresponds to a value of four on the 1 to 5 Likert scale. The items are normally distributed. There are no items that show a substantial skew. More than half, (67%) of the participants agreed or totally agreed with 11 of the 15 items. Less than 41% agreed or totally agreed with the four negatively worded items "I lack energy to care for myself," "I seldom make time to care for myself," "I seldom have time for myself," and "I am not always able to care for myself."

Table 4.5

Statistics and Frequency of Responses for Power Survey (N = 83)

Total score power survey	Mean	SD	Minimum score	Maximum score			
	58.16	7.55	29	72			
Item Statistics				Frequency of Responses			
Power survey item	Mean	SD	Median	Skewness	Agree/ Totally Agree %	Neither Agree or Disagree %	Disagree/ Totally Disagree %
Make adjustments if things change	4.18	0.80	4.00	-1.08	83	13	4
Make adjustments if mobility changes	4.22	0.75	4.00	-1.45	90	5	5
Set new priorities for health	4.10	0.78	4.00	-0.65	81	14	5
Lack energy*	2.86	1.27	3.00	0.02	41	22	37
Look for better ways to care for self	3.93	1.06	4.00	-1.19	76	12	12
Make time to care for self	4.05	0.87	4.00	-1.24	81	13	6
Look up info about new medication	4.24	0.85	4.00	-0.98	82	12	6
Have changed old habits to improve health	4.10	0.92	4.00	-1.36	83	8	9
Take measures to insure safety of self/family	4.26	0.62	4.00	-0.24	88	10	2
Eval effectiveness of healthy habits	3.88	0.95	4.00	-0.96	67	27	6
Seldom take time care/self*	3.64	1.09	4.00	-0.51	16	25	59
Able to get info when health threatened	4.18	0.83	4.00	-1.15	87	6	7
Seek help when unable to care for self	3.80	1.06	4.00	-1.10	71	17	12
Seldom time for self*	3.52	1.15	4.00	-0.51	16	31	53
Not always able care/self*	3.27	1.26	3.00	-0.04	33	27	40

Note.*reverse scored items

Descriptive Statistics for CVLU Self-Care

A summary of the item statistics and frequency of responses for the six-item self-care score can be found in Table 4.6. The mean total score for the six-item CVLU self-care survey is 21.96 (SD = 3.92). The range of scores is 10 to 29. The items show a similar pattern of variability and are normally distributed. One item "wear compression" has a moderate skew of -1.9, which is most likely do to most participants reporting they agree or totally agree with the item. A majority of the participants reported they agreed or totally agreed with four of six self-care activities. Approximately one-third (35%) of the participants agreed or totally agreed with the remaining two items. Performing leg exercises and avoiding sitting for long periods are beneficial to reducing edema. Since there was also a higher rate of neutral opinion for these two statements, it is possible that participants were not as familiar with the activities.

Table 4.6

Statistics and Frequency of Responses for Six-Item CVLU Self-Care Survey (N = 83)

Total score six-item Revised CVLU Scale	Mean	SD	Minimum Score	Maximum Score			
	21.96	3.92	10	29			
Item Statistics				Frequency of Responses			
CVLU Self-care Survey item	Mean	SD	Median	Skewness	Totally agree/ Agree (%)	Neither agree or Disagree (%)	Totally disagree/ Disagree (%)
Elevate legs	3.49	1.11	4.00	-.70	59	23	18
Go to doctor	4.07	.99	4.00	-.1.20	80	10	10
Recognize signs and symptoms	4.17	.93	4.00	-1.54	84	11	5
Wear compression	4.33	1.01	5.00	-1.90	88	4	8
Avoid sitting for long periods	3.02	1.19	3.00	-.05	35	28	37
Do leg exercises	2.88	1.26	3.00	-.07	35	32	33

Statistical Analysis of Research Question 1: What Is the Relationship Between

Symptoms, Power, and CVLU Self-Care

To answer this research question, Pearson correlations were used. For the major study variables, a significant, positive, moderate correlation was found between the total power score and total CVLU self-care score($r = .41$, $p < .001$). There was no significant correlation found between total symptom score and total power score. Relative to the covariates in the study, there was a significant, positive, and small to moderate correlation between the CVLU self-care total score and chronicity of the ulcer ($r = .25$, $p < .05$). In addition, a significant, positive, moderate correlation was found between income and education ($r = .45$, $p < .001$). The results of the correlations between study variables can be found in Table 4.7.

Table 4.7

Correlations Between Study Variables (N = 83)

	1	2	3	4	5	6	7
1.Symptom Score Standardized Total	1.0						
2. Power Score Total	-.05	1.0					
3.CVLU Self-Care Score Total	-.05	.41**	1.0				
4.Income	.02	.11	.03	1.0			
5.Education	.04	.13	.14	.45**	1.		
6.Number of Comorbidities	-.16	.01	-.11	.03	.15	1.0	
7.Chronicity of the Leg Ulcer (transformed)	.07	.09	.25*	-.03	.11	-.12	1.0

Note. **$p < 0.001$, * $p<.05$

Statistical Analysis of Research Question 2: Does Power Mediate the Effects Of

Symptoms on CVLU Self-Care?

Multiple regression was carried out to answer this research question. To test for the mediating effects of power between symptoms and CVLU self-care, the four steps as

suggested by David Kenny (2016) were used. Table 4.8 shows the results from each step. In the overall model, power explains 17% of the variability in self-care and is a unique contributor to the model ($R^2\Delta = .17$, $\beta = .41$, $t(81) = 4.00$, $p < .001$). The results of the Sobel Test were non-significant (-.438, SE = .02, $p = .662$). In addition, there are no total, direct, or indirect effects. All in all, power does not mediate the relationship between symptoms and CVLU self-care. Table 4.8 presents detailed information for each step.

Table 4.8

Regression of Testing Mediator Effect of Power Without Covariates (N = 83)

Variable	R^2	R^2_{adj}	ΔR^2	t	β
Step 1	.01	-.01	.01	-.44	
Symptoms					-0.05
Step 2	.01	-.01	.01	-.44	
Symptoms					-0.04
Step 3	.17	.16	.17	4.04	
Power					0.41**
Step 4	.17	.15	.17	4.00	
Symptoms					-0.03
Power					0.41**

**p=<.001, *p<.05

Statistical Analysis of Research Question 3: What Is the Mediating Effect of Power on CVLU Self-Care When Controlling for Income, Education, and Chronicity of the Leg Ulcer?

To test for the mediating effects of symptoms on CVLU self-care while controlling for covariates, the same multiple regression equations suggested by Kenny (2016) were used. In addition, hierarchical regression approach was used in each step. In this research question, four covariates (number of comorbidities, income, education, and chronicity of the leg ulcer) were added to the first step of a hierarchical regression, and independent variable(s) were added in step 2. In the overall model, while controlling for the four covariates, power explains 15% of the variability in self-care and is a unique

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contributor to the model ($R^2\Delta = .15$, $\beta = .38$, $t(76) = 3.73$, $p < .001$). In addition, there are

no total, direct, or indirect effects. The Sobel test is not significant (0.66, SE = .02, $p =$

.51). Table 4.8 presents detailed information for each step.

Table 4.9

Regression of Testing Mediator Effect of Power With Covariates (N = 83)

Variable	R^2	R^2_{adj}	ΔR^2	t	β
Step 1	.094	.035	.007	-.769	
Education					0.14
Income					-0.01
Comorbidities					-0.12
Ulcerage					0.23*
Symptoms					-0.09
Step 2	.03	-.03	.01	-.667	
Education					0.10
Income					0.08
Comorbidities					-0.01
Ulcerage					0.08
Symptoms					-0.08
Step 3	.23	.18	.14	3.80	
Education					0.11
Income					-0.06
Comorbidities					-0.11
Ulcerage					0.20
Power					0.39**
Step 4	.23	.17	.15	3.73	
Education					0.10
Income					0.04
Comorbidities					0.12
Ulcerage					0.20
Power					0.38**
Symptoms					-0.05

**$p<.001$, *$p<.05$

Post-hoc Analyses

This section describes analyses that were not included in the study questions, but

that were related to study results. Questions were built into the demographic/health

portion of the questionnaire to validate that individuals were reporting self-care actions

consistently. Three self-care survey questions were paired with similar questions that

would quantify the self-care action. The survey item regarding elevating legs did not

correlate with number of minutes doing leg exercises per day. The number of minutes

walked per day (*M* = 149, *SD* = 178.73) showed a significant, positive correlation with "I

walk often" (*r* = .49, *p* < .01); however, this item was removed from the CVLU self-care

scale due to poor correlation with other CVLU survey items. Number of minutes doing

leg exercises (*M* = 2, *SD* = 5.90) showed a significant, positive correlation with "I do leg

exercises often" (*r* = .26, *p* < 05). Correlation and statistics for CVLU survey validation

items can be found in Table 4.10.

Table 4.10

Correlation and Statistics for CVLU Survey Validation Items (N = 83)

CVLU survey item	Validation item	M	SD	Median	*r*
Elevate legs	Number of minutes elevating legs	166	105.0	178.14	.13
Walk often	Number of minutes walked per day	149	90.0	178.73	.49**
Leg exercises	Number of minutes do leg exercises per day	2	5.90	0	.26*

**p < 0.01, * p<.05

Summary

The results from the analysis of data collected from a convenience sample of 83

individuals with CVLU were presented in this chapter. A majority of the participants

were over 65 years of age, Caucasian, male, a low income, a high school education, had

one comorbidity, and a leg ulcer eight months or more. Mean total score for the

symptoms survey was 50 (SD = 10). Participants reported a wide range of symptoms

including heavy legs, aching legs, leg swelling, night cramps, heat or burning sensation,

restless legs, throbbing, itching, or tingling sensation. Leg edema was self-reported as the

most commonly reported symptom experienced every day (51%) , and restless leg, heat

or burning, heaviness, and night cramps were the least self-reported symptom, with more

than half never experiencing these symptoms. A majority of the participants reported

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some pain, but 41% reported no pain. The mean total score for the power survey was 58.16 (SD = 3.91). Most participants reported having power for making decisions about health and balancing energy for personal and health issues. On the other hand, most participants disagreed that they lacked energy for self-care.

The original nine-item CVLU self-care scale authored by the PI was found to have a very low level of reliability. Subsequently, psychometric testing of the tool including an item analysis and principal component analysis was performed. As a result of the testing, six of the nine items were retained. The mean score for the revised six-item scale was 21.96 (SD = 3.92). Of the six activities in the revised CVLU self-care survey, the most commonly reported CVLU self-care activities were wearing compression (88%), recognizing signs and symptoms of infection (84%), and going to the doctor if a wound infection was noted (81%). Participants were unsure of or disagreed with the remaining three activities including performing leg exercises, avoiding sitting for long periods, and elevating legs. Findings demonstrate that in persons with CVLU, power is not a mediator between symptoms and self-care with or without controlling for covariates. Symptoms do not have a direct effect on power. Power does have a direct effect on self-care.

CHAPTER V

DISCUSSION

This chapter comprises a brief reiteration of the study, discusses the study's findings, compares the current study findings with previously published studies, identifies limitations and nursing implications as well as offers recommendations for future research.

Reiteration of the Study

This study was guided by Orem's self-care deficit nursing theory in order to understand what types of factors influence self-care in a population of individuals with CVLU. The results of this study both challenge and support propositions in Orem's theory. In this study, Pearson correlations examine the relationships between the variables symptoms, power, and CVLU self-care. Multiple regression was used to test for the mediating effects of power on CVLU self-care with and without the covariates (comorbidities, income, education, and chronicity of the leg ulcer).

Discussion of the Findings

Before discussing the study results related to research questions, the demographic characteristics of the study are addressed. In this study, there was a higher percentage of males than females, and most of the participants were over the age of 65, and a majority were Caucasian (79.5%). Approximately one-third reported at least one comorbidity, with diabetes the most commonly reported comorbidity (N = 36). These results are

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consistent with most of the studies reviewed in this report. The most commonly reported interval for household income level was $30,000, which is lower than the U.S. average of $38,000 for those 65 years and older in the year 2014 (U.S. Census Bureau, 2015).

Discussion of Research Question 1: What Is the Relationship Between Symptoms, Power, and CVLU Self-Care?

Findings from this study indicate that there is no correlation between symptoms and power or symptoms and CVLU self-care. A strongly significant moderate to strong correlation does exist between power and CVLU self-care. Direct comparison of the study's results to the literature is not plausible because few studies examine these relationships in individuals with CVLU. Consequently, comparison with studies that use other populations are examined in the following paragraphs.

A few studies reviewed used populations of individuals other than those with CVLU and found correlations between the three variables used in this study. In two studies, symptoms played a role in having sufficient power for self-care. In Anderson's 2001 study with the homeless, who suffer from a host of mental and physical symptoms and chronic disease (Anderson, 2001), health symptoms were significantly correlated to power ($r = -.35$, $p < .001$) and to self-care ($r = .69$, $p < .001$). The DSCPI was used to measure power and the DSCAI-90 was used to measure self-care. In another study from the same year, Wang and Laffery (2001) found correlations between health state and self-care agency ($r = .27$, $p < .001$), health state and self-care ($r = .18$, $p < .01$), and self-care agency and self-care ($r = .80$, $p < .01$) in a population of elderly women in Taiwan. The authors of the Wang and Laffery study explained that many older women in Taiwan suffer from poor health and chronic illness (Wang & Laffery, 2001). Health state was

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measured using an investigator-authored tool that asked three questions related to perceived health. Self-care agency was measured using the ESCA (Kearney & Fleischer, 1979). The Health Promotion Lifestyle Profile (HPLP) was used to measure self-care behavior.

Several additional studies found relationships between two of the three variables used in this study. For instance, with regard to a relationship between symptoms and self-care agency, Tokem et al. (2007) found a small negative correlation between the symptom pain and self-care agency ($r = -.05$, $p < .05$) in Turkish individuals with rheumatoid arthritis. Pain was measured using a visual analogue scale, and self-care agency was measured using the SCI (Geden & Taylor, 1991). Another similar study done in Turkey using the same tools to measure pain and self-care agency a few years later (Ovayolu et al., 2012) found a significant, small, positive correlation between pain and self-care agency ($r = .28$, $p < .001$). Burdette (2112) examined the relationship between health state and self-care agency and found a moderate, significant, positive correlation between health state and self-care agency ($r = .46$, $p < .001$). Health state was measured using an investigator-authored tool that was informed by Orem's SCDNT (Burdette, 2012). Self-care was measured using the DSCPI-90.

Several studies found relationships between self-care agency/power and self-care in various populations. Horsburgh (1999) studied individuals with end-stage renal disease and found a strong, moderate correlation between self-care agency and self-care ($r = 43$, $p < .001$). Self-care agency was measured using the Appraisal of Self-Care Agency (ASAA, Evers & Isenberg, 1987). Self-care was measured using the Self-Care Inventory (SCI, Gazda, 1986). Notable is that the SCI has been used in studies as a generic measure

of self-care or self-care agency. In another study, a strong correlation was found between self-care agency and self-care ($r = .75$, $p < .01$) in Sousa et al. (2005) in a population of individuals with Type II diabetes. Self-care agency was measured using the ASAA (Evers & Isenberg, 1987). Diabetes self-care actions were measured using a disease-specific tool, Hurley's Insulin Management Diabetes Self-Care Scale.

Discussion of Research Questions 2 and 3: Does Power Mediate the Effects of Symptoms on CVLU Self-Care With and Without the Effect of the Covariates Income, Education, and Chronicity of the Leg Ulcer?

Findings from this study suggest that there is no relationship between symptoms and power. In addition, no relationship exists between symptoms and CVLU self-care. Power does not affect CVLU self-care. These relationships hold true with or without controlling for the covariates income, education, number of comorbidities, and chronicity of the leg ulcer (ulcerage) and demonstrate that power is not a mediator between symptoms and self-care. Again, direct comparison of these results to the literature is not plausible because few, if any studies examine these relationships in individuals with CVLU. Comparison will be made to studies using populations other than those with CVLU.

In the Gatlin study using older adults with Type II diabetes (Gatlin, 2014), the role of executive function, a concept similar to self-care agency or power was examined as a mediator between the basic conditioning factor "severity of illness" and self-care. Executive function is described as one of the foundational capabilities of self-care agency (Gatlin, 2014). Foundational capabilities include capabilities regarding sensation, attention, memory, perception, and orientation (Orem, 2001). The foundational

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capabilities are necessary to the capabilities of self-care agency such as reasoning, judgement, and decision-making that requires a higher level of cognitive function (Gatlin, 2014). The author reported executive function demonstrated full mediation between severity of illness and self-care.

The Wang and Laffery study (2001) found self-care agency to be a mediator of health state on self-care. Self-care agency was measured using the ESCA (Kearney & Fleischer, 1979). The Health Promotion Lifestyle Profile (HPLP) was used to measure self-care behavior. In a recent study by Gharaibeh et al. (2016), self-care agency was found to mediate the relationship between depression and diabetes self-care management. Depression was measured using the CES-D. Self-care agency was measured using the ASAS-R (Sousa, 2010), and diabetes self-care management was measured using the Diabetes Self-Management Scale (Sousa et al., 2009). Only a few studies exist that support the proposition that self-care agency acts as a mediator between factors that are conceptually similar to health state.

Additional Findings

Findings related to descriptive statistics of the variable power. The mean score for power was 58.16 (SD = 3.91) with the range of scores 29-72. A majority of the participants (67%) in this study expressed some degree of agreement to every item in the ASAS-R demonstrating an adequate level of power for health-related self-care. No studies could be found that examined power or self-care agency levels in individuals with CVLU; self-care agency/power have been measured in other populations with chronic diseases using the original 24-item version of the Appraisal of Self-care Agency Scale (ASAS) (Evers & Isenberg, 1987). The range of possible scores for the ASAS is 24 to

120. Smolen and Topp (2001) found an adequate level of self-care agency in individuals with inflammatory bowel disease. The authors reported the mean score for self-care agency as 91.32 (SD=11.96), with the lowest score being 53 and highest 116. Smolen and Topp reported that the high levels of self-care agency were unexpected. Sousa et al. (2005) also found results similar to the above researchers in individuals with Type II diabetes. In the Sousa et al. study, self-care agency was measured using the ASAS (Evers & Isenberg, 1987). The mean score for self-care agency, similar to the results of Smolen and Topp, were 92.42 (SD = 10.96).

Findings related to the descriptive statistics for the variable self-care. The results of the six-item CVLU self-care survey showed that three of the most commonly self-reported self-care behaviors in CVLU patients were related to wound management. A majority of participants agreed or totally agreed with wearing compression (89%), recognizing symptoms of infection (84%), and going to the doctor if recognizing signs and symptoms of infection (81%). However, fewer of the participants in this study reported agreeing or totally agreeing to carrying out behaviors related to improving circulation and enhancing venous return to their legs including elevating legs (59%), avoiding sitting for long periods (35%), and doing leg exercises (35%). A direct comparison of these results cannot be made to other studies; however, one study will be examined. A Finnish study (Seppanen, 2007) examined levels of self-care in individuals with CVLU within the context of Orem's SCDNT. The next paragraphs describe the similarities and differences in the results between the two studies.

Approximately half of the study participants in both studies reported agreeing or totally agreeing to elevating their legs (59% in this study, 57% in the Finnish study). A

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smaller percentage in both studies reported agreeing or totally agreeing to performing leg exercises (35% in this study and 37% in the Finnish study). With regard to leg exercises, the participants in this study are not specifically educated by wound clinic staff on how to perform leg exercises, which may account for the low percentage. Regarding wearing compression, more participants in this study (89%) compared to of the Finnish participants (72%) reported agreeing or totally agreeing to wearing compression wraps or compression stockings. However, regarding the avoidance of sitting for long periods, fewer participants in this study (35%) compared to the Finnish study (60%) agreed or totally agreed to avoiding sitting for long periods of time. More individuals in this study (84%) reported agreeing or totally agreeing to knowing how to recognize signs and symptoms of wound infection than in the Finnish study (69%).

Comparing the two studies once again regarding the chronicity of the ulcer, both this study and the Finnish study reported extreme variability in the length the participants have had their leg wounds. In this study, the range to time was one month to nearly 15 years. The Finnish study did not report descriptive statistics related to the chronicity of the leg ulcer but did mention that the longest duration as more than 60 years.

General Discussion

In this study, some of the results, including that the variable symptoms were not related to power or to CVLU self-care were not expected. In fact, symptoms were not related to any of the major study variables. There are several possible explanations to explain the absence of a relationship between symptoms and power, and symptoms and self-care. In the reviewed studies, pain was examined alone as a symptom, whereas in this study, a group of symptoms measured the concept symptoms. Pain as one symptom

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is likely conceptually different than a collection of symptoms that include pain. In this study, pain was one of 10 symptoms included in the symptoms scale.

It is possible that the symptoms or other factors associated with the presence of the participants' leg ulcers were not severe enough to affect capability or hinder their self-care activities. Many of the participants in this study have had a leg ulcer for many months or even many years. The symptoms may have become a part of everyday life, not affecting their power for health-related self-care, or their ability to perform CVLU self-care actions. This is in contrast to the Chou et al. (2004) analysis of the negative relationship between HIV symptoms and self-care, and the Anderson (2001) study where health symptoms were negatively correlated with self-care.

Another possible reason that the variable symptoms were not correlated to power or self-care may be that the VEINES QOL/Sym did not capture the entire repertoire of symptoms experienced by individuals with CVLU related to having a chronic wound. Individuals with wounds due to venous status can have copious foul smelling drainage from the wound. Infections may be frequent. The wounds may heal and recur over the individual's lifetime (Briggs & Flemming, 2007; Heinen et al., 2006; Walshe, 1995). Although this tool has been validated several times (Kahn et al., 2006; Lamping et al., 2003; Mean, et al., 2014), it was created to be used with individuals with chronic venous stasis, not necessarily with individuals where the disease progressed to having a wound or wounds. In fact, the original development and psychometric testing of the VEINES-QOL/Sym (Lamping et al., 2003) included a population of 1,516 patients from four European counties and Canada but fewer than 5% of participants had an active ulcer as indicated by Clinical Etiology Anatomy Pathophysiology (CEAP) score of 6.

Orem proposed that self-care agency is antecedent to self-care. In addition, power is a function of self-care agency (Orem, 2001). Individuals who have the power to engage in self-care are more likely to perform the self-care needed to maintain health (Orem, 1995). This study finding provides further support for the above propositions and supports the finding in this study that in individuals with CVLU, those that possess a higher level of power perform more CVLU-related self-care behavior.

Some study results were better than was expected. The participants in this study reported having adequate power to perform a majority of the self-care behaviors included in the CVLU self-care survey. It was expected that due to the participants having a chronic disease, they would report their power for health-related self-care to be lower.

One reason power levels are reported as adequate by individuals with CVLU may be that the ASAS-R may not capture certain details associated with the disease process that may affect their perception of power. For instance, the power survey asks participants about how capable they feel in gathering health information, achieving a balance between available energy and the energy need to care for self, setting priorities related to current state of health. The participants in this study had an average of one comorbidity in addition to CVLU, so may have felt a higher level of capability in dealing with a disease state. Most of the participants (88%) agreed or totally agreed to wearing compression wraps or compression stockings. It should be noted that although wearing compression is the single most important component associated with improvement of wound healing and prevention of the recurrence of leg ulcers (Finlayson et al., 2011; Jones, 2009; Moffatt et al., 2006), participants in this study rarely apply the compression independently. It is standard procedure at each wound clinic appointment the staff nurses

remove the compression wraps, cleanse and assess the wound, wash the periwound skin, and then reapply the compression wrap to each affected leg. Anecdotally, at times patients remove compression wraps after their appointments due to reasons such as feeling too tight, being too painful, or interfering with walking. The item in the CVLU self-care survey that asked if they agreed or totally agreed to wearing compression should be revised. The revised question should ask participants if they apply the compression independently and if they ever remove the wraps between appointments. The additional information gained by the revision may be helpful in more accurately capturing the participants' self-care actions related to wearing compression.

In summary, the results of this study were not supported by Orem's theory or the other studies in the literature using Orem's theory. Studies using Orem's SCDNT in populations other than those with CVLU found relationships between basic conditioning factors, power, and self-care. In individuals with CVLU, the basic conditioning factor symptoms were not related to power or to CVLU self-care. The concept basic conditioning factors encompass a multitude of factors. In individuals with CVLU, basic conditioning factors other than symptoms should be explored in further research. All in all, in this study, only a portion of Orem's theory was useful in explaining the proposed relationships.

Limitations

This section describes characteristics in the design and methodology of this study that influenced the interpretation of the results. The primary aim in this study was to explore self-care in individuals with CVLU using a disease-specific survey. A limitation that was acknowledged prior to data collection was the lack of availability of a valid and

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reliable tool to measure self-care in a population of individuals with CVLU using Orem's approach. There are several tools available to measure self-care within Orem's self-care framework (Fawcett, 2005). The tools measure self- care in diverse populations such as adolescents with chronic diseases such as diabetes and in adults with chronic diseases such as congestive heart failure, rheumatoid arthritis, and Type II diabetes. Very few tools exist to measure CVLU self-care. In this study, since an examination of the self-care activities performed by individuals with CVLU was the primary aim, a disease-specific tool was desired. Only one tool using Orem's self-care framework to measure self-care in a population of individuals with CVLU was found, the WAS-VOB (Panfil et al., 2004).

The WAS-VOB is a 59-item survey that examines eight different types of self-care activities that patients in Finland would be expected to perform. Categories include compression, wearing of compression bandages, wearing compression hose, mobility, and temperature, overloading of the venous systems, prevention of skin damage, and wound healing. Using this tool may have been problematic for several reasons including that the CVLU self-care practices differ between the U.S. and Finland. The WAS-VOB survey was developed in Europe where self-care practices including behaviors such as using a sauna for bathing are not common in the U.S. Another difference in practice is related to application of compression bandages. Individuals in Finland are encouraged to apply their own compression bandages (Seppanen, 2007). This is not a common practice in the U.S., where patients are instructed to leave the wraps intact until the next clinic visit.

In addition, the length of the WAS-VOB was a consideration. In this study, the number of original survey items totaled 49, which includes the nine items in the CVLU

self-care scale. The addition of several additional survey questions would likely produce respondent burden. In this study, some participants required more than 30 minutes to answer all 49 items. Considering the participants needed to spend extra time at the wound clinic to fill out the survey, a lengthier survey may have not been well received. For these reasons, a tool developed by the investigator was used to measure CVLU self-care.

The use of the new tool significantly influenced many of the results of this study. For example, the CVLU self-care survey lacked of internal consistency. The CVLU self-care survey was developed using a review of the CVLU literature, examination of the survey by three clinical experts in wound and venous ulcer care, and cognitive interviewing. However, the reliability of the original nine-item CVLU self-care survey was .56, which is unacceptable. A post-hoc item analysis of the original nine-item CVLU self-care survey revealed that some items had very low (<.1) or negative inter-item correlations, low item-total correlations, and low mean inter-item correlations. Three items were deleted, retaining a six-item scale with Cronbach's alpha of .64, which is marginally acceptable and influenced internal consistency reliability.

Pilot-testing the survey using approximately 20 individuals (Fowler, 2009) to complete the survey, then analyzing the results would have identified problems with reliability and validity of the questionnaire. The three items with very low and negative inter-item and total item correlations could have been examined and revised. For example, the item "I walk often" was not detailed enough and could include quantifying the time period necessary to enhance circulation. The item "I am not afraid to look at my leg ulcer when my stockings or compression wraps are removed" lacked enough theoretical support. The item "I avoid standing for long periods of time" may have been

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problematic as it does not account for those who are employed in positions that require standing, and does not quantify a time period that will negatively impact venous circulation.

Another potential limitation related to the reliability of the CVLU self-care survey was the influence of social desirability. Often, there is error in participants' self-report of behaviors due to several factors including cognitive biases (Fowler, 2009). In this study, it was possible that the participants answered questions as to provide socially desirable responses. For example, participants may feel that it is more socially desirable to perform higher levels of CVLU self-care such as walking often or avoiding sitting for long periods. As a result, the participants reported inflated response levels to those questions.

To address the potential influence of social desirability, the response set for the items could be more objective (Fowler, 2009). The current response set asks respondents their degree of agreement with the self-care items. A more objective means, such as "what percentage of the time do you perform the following?" may have yielded less problematic results. Another means to reduce the problem of respondents answering questions with more accuracy (i.e., how they thought the wound clinic nurses thought they should answer) could have been using a mail survey. However, since the number of participants refusing to complete the survey was very low, it is anticipated that achieving the target sample size using a mail survey would have taken considerably longer.

A lack of construct validity in the concept symptoms may have influenced the ability of the study to capture a relationship between symptoms and the other variables, power and CVLU self-care. Health stated is defined by Orem (2001) as the state or features of the person at a particular time. Health state is also "combinations of

components that serve [individuals] well as an index of their health state" (Orem, 2001, p. 186). The components or indicators need to be considered by patients to help them judge what kind of condition they are in (Orem, 2001). An individual's perception of health state influences the development of self-care agency and performing self-care (Orem, 2001).

CVLU symptoms are a collection of indicators of the disease of chronic venous insufficiency, described theoretically in this study as "the frequency of symptoms, used as an index of the severity of the disease of chronic venous insufficiency, as measured by the VEINES/Sym" (Lamping et al., 2003). The VEINES/Sym instrument was developed to measure clinical indicators correlating with the severity of the disease of chronic venous insufficiency. Conceptually, Orem's definition of health state seems similar to this study with one clear difference. The items in the VEINES/Sym do not address how the patient feels about having a collection of symptoms, i.e., help them judge what kind of condition they are in, or how their health may be affected by the symptoms. The CVLU literature describes how symptoms can negatively affect factors such as self-esteem or well-being. CVLU symptoms may influence an individual to decline to participate in social activities or avoid wearing preferred clothing or shoes (Briggs & Flemming, 2007; Krasner, 1998). In this study, it was expected that the level of symptoms experienced by the individual would influence their level of power and level of self-care. Since this relationship was not found, it is likely that the collection of symptoms experienced by the participants in this study did not influence how they viewed health, thus, a re-exploration into the concept of symptoms is important to maximize construct validity.

A final and important limitation in this study was the lack of statistical conclusion validity. One of the threats to statistical conclusion validity is low statistical power (Shadish, Cook, & Campbell, 2002). A post-hoc analysis of power was conducted and found that the study was inadequately powered. Low statistical power increases the probability of Type II error and diminishes the ability of the statistical analyses to detect relationships between the variables (Shadish et al., 2002). Another threat to statistical conclusion validity may have been the outdated methods used to analyze and determine sample sizes for research questions 2 and 3. The Baron and Kenny (1986) basic method to detect mediation has been appraised as failing to look at the results of mediation on a continuum, which may compromise the power of the test of the indirect effect. Preacher and Hayes (2008) described an alternative method using bootstrapping to estimate the indirect effect.

Nursing Implications and Recommendations for Further Research

A majority of the participants in this study reported low levels of self-care behaviors to reduce leg edema. It is critical that individuals with CVLU be instructed on the importance of leg elevation, walking, avoiding sitting with legs in a dependent position for long periods, and performing leg exercises. In addition, it is important for this population to have adequate knowledge about improving life-style habits.

A shift in paradigm must occur in ambulatory care of individuals with CVLU. Improvements in the way care is delivered to include individualized education related to necessary self-care behaviors and healthy life-style habits must be considered a priority. Clinic visits must also include an evaluation of each individual's capabilities for health-related self-care and level of self-care behaviors. Patients who attend the wound clinic do

not consistently receive structured instruction regarding what types of self-care activities support capability for health and healing, but they are most likely devoted to finding knowledge on their own. Many participants reported some degree of agreement to knowledge finding activities. The aspect of having the capability of seeking knowledge for health, setting new priorities for health, and having the ability to look for better ways to improve health was evident in the results of the power survey.

The results of this study found a significant relationship between power for health-related self-care and CVLU self-care. Nurses caring for individuals with CVLU can use this information when talking to patients about what types of deficits in capabilities and self-care behaviors might be present. Nurses may not be familiar with how to educate their patients about strategies to improve capabilities or self-care behaviors. Interventions to increase nursing knowledge of a) assessment of levels of power for health-related self-care and CVLU self-care and b) strategies to improve overall capabilities to carry out self-care behaviors are important to assist individuals with CVLU to deal with their chronic condition and promote optimal functioning in this population.

Further research is needed to advance the development and testing of the CVLU self-care survey to improve the reliability of the tool. Since very few reliable instruments exist to measure CVLU self-care, improvement of the current scale is important. In addition, since the model for this study was found to lack internal validity, it is important to examine the influence of construct validity. Refining the concept symptoms, or constructing the model to include factors such as social support, self-efficacy, or

functional status may help predict what factors are the strongest predictors of CVLU self-care.

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APPENDICES

INFORMATIONAL FLYER

How Do You Care for Your Leg Wound?

People with leg wounds needed to complete a survey

<u>WHO:</u>
Adults 18 years of age and older who have been told they have a venous leg ulcer (leg wound as a result of vein problems) are eligible.

<u>WHY:</u>
This survey is being done to look at:
- How you feel about your ability to care for your leg wound
- What you do to take to care of your leg wound.

<u>BENEFITS AND RISKS:</u>
It is unlikely that there will be any direct or significant risk to you from participating in the study. The primary benefit is to gain new knowledge. If you participate, you may help others in the future.

<u>WHEN AND WHAT:</u>
The study requires that you complete a written survey following one of your upcoming wound clinic visits. The survey consists of 48 questions and takes about 15 minutes to complete. Choosing to fill out the survey is completely voluntary and how you answer the questions will not affect your care at the Lutheran Hospital Wound Care Center in any way. The survey does not ask for any personal information. Collette LaValey is the only person who will see the surveys.

<u>HOW:</u>
Collette LaValey will ask you if you are interested in participating. Once you are done with your appointment, you will be directed to a quiet area, a survey will be given to you. There will be soft drinks available and pens for you use top fill out the survey. If you have any questions, my contact information can be found below.

Collette LaValey, MSN, CNS, CWOCN
Principal Investigator/Researcher
University of Akron Nursing Doctoral Student
cbl9@zips.uakron.edu
216-633-6028

APPENDIX B

STUDY QUESTIONNAIRE

Survey #_____

Leg Ulcer Survey

Instructions:

Please do not put your name or any other personal information on this survey.

Answer every question by filling in the blank, check the appropriate box, or circling the answer. If you are unsure about how to answer, please give the best answer you can.

General Information:

1. **Age**_____ years old

2. **Marital Status:** Married   Single   Divorced   Widowed

3. **Gender:** Male Female

4. **Ethnicity:** Caucasian   Black (non-Hispanic) Hispanic Asian

   Other_____

5. **Education:** How many years of school have you attended? (For example, if you graduated from high school, years of school attended are 12.)   _____ years

6. **Household Income per year:**
   ☐ Under $20,000
   ☐ $20,000-29,999
   ☐ $30,000-39,999
   ☐ $40,000-49,999
   ☐ $50,000-59,999
   ☐ 60,000-69,000
   ☐ More than $70,000

Health Information:

7. **Do you have any of the following:** (circle each condition your doctors have told you that you have/ have had).

   ☐ Diabetes (high sugar levels in your blood)

   ☐ Had a heart attack in the past

   ☐ Breathing problems -- COPD-chronic obstructive pulmonary disease (lung disease, such as asthma or emphysema)

   ☐ Kidney disease where you need to be on dialysis

   ☐ Stroke

8. **Do you use any of the following to help you get around?**

   Cane   Walker   Wheelchair   None

9. **To the best of your knowledge, what is your height? _____feet _____inches**

10. **To the best of your knowledge, what is your weight? _____pounds**

11. **To the best of your knowledge, how long have you had your leg wound? _____month**

12. **To the best of your knowledge, how many minutes per day do you elevate your legs? _____/minutes per day**

13. **To the best of your knowledge, how many minutes per day do you walk? _____/minutes per day**

14. **Do you smoke?**   Yes   No

15. **To the best of your knowledge, how many times per day do you do leg exercises? _____/times**

Venous Insufficiency Epidemiological and Economic Study/Sym (Lamping et al., 2003).

Below are some questions about your views about your legs. Please answer every question. If you are unsure about an answer, please give the best answer you can.

16. **During the past four weeks how often have you had any of the following leg symptoms:**
For each symptom, place an "x" in the box that best fits how you feel

	Every day	**Several times per week**	**About once per week**	**Less than once per week**	**Never**
Heavy legs					
Aching legs					
Swelling					
Night cramps					
Heat or burning sensation					
Restless legs					
Throbbing					
Itching					
Tingling sensation					

17. If you have pain, how would you rate it right now?

| 1 | 2 | 3 | 4 | 5 | 6 |
| No Pain | | | | | Severe pain |

Appraisal of Self-Care Agency Scale-Revised (Sousa et al., 2010).

For the next set of questions, please circle the best answer for each statement below using the following scale:

1=Totally disagree

2= Disagree

3= Neither Agree or Disagree

4=Agree

5=Totally Agree

18. As circumstances change, I make the needed adjustments to stay healthy

    1   2   3   4   5

19. If my mobility is decreased, I make the needed adjustments.
    1   2   3   4   5

20. When needed, I set new priorities in the measures I take to stay healthy.
    1   2   3   4   5

21. I often lack the energy to care for myself in the way that I know I should
    1   2   3   4   5

22. I look for better ways to take care of myself.
    1   2   3   4   5

23. When needed, I manage to take time to care for myself.
    1   2   3   4   5

24. If I take a new medication, I obtain information about the side effects to better care for myself.
    1   2   3   4   5

1=Totally disagree

2= Disagree

3= Neither Agree or Disagree

4=Agree

5=Totally Agree

25. In the past I have changed some of my old habits in order to improve my health.
        1   2   3   4   5

26. I routinely take measures to insure the safety of myself and my family.
        1   2   3   4   5

27. I regularly evaluate the effectiveness of things that I do to stay healthy.
        1   2   3   4   5

28. In my daily activities, I seldom take time to care for myself.
        1   2   3   4   5

29. I am able to bet the information I need when my health is threatened.
        1   2   3   4   5

30. I seek help when unable to take care of myself.

31. I seldom have time for myself.
        1   2   3   4   5

32. I am not always able to care for myself the way that I would like.
        1   2   3   4   5

33. I elevate my legs at every opportunity possible
        1   2   3   4   5

34. I go to my doctor as soon as I can if I notice signs or symptoms of leg wound infection
        1   2   3   4   5

35. I recognize the signs and symptoms of leg wound infection
        1   2   3   4   5

36. I am not afraid to look at my leg wound when my stockings/wraps are removed
        1   2   3   4   5

37. I wear my compression stockings or compression bandages
        1   2   3   4   5

38. I do leg exercises such as calf pumps and leg raises often

        1   2   3   4   5
39. I avoid standing for long periods of time
        1   2   3   4   5

40. I walk often
        1   2   3   4   5

41. I avoid sitting for long periods of time
        1   2   3   4   5

Thank you very much for completing this survey!

PATIENT RESEARCH INFORMATION

Taking Part in the Care of Your Leg Ulcer Study

This research study is being conducted to find out how we can better help you to take care of yourself. You will be asked to complete a questionnaire about yourself and your care.
Participation is voluntary. You will receive the same quality of care if you decide to participate or not.

This information sheet tells you about the research. Please read this sheet before agreeing to take the survey. If you have any questions, you can contact the researcher, Collette LaValey at (216) 633-6028. You may leave a message at that number and Collette LaValey will return your call. If you have any questions regarding your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

Why am I being asked to take part in the study?
You are being asked to take part in this study because you have a leg wound due to venous stasis (bad veins in your legs).

Why Is This Study Being Done?
The purpose of this study is to look at the symptoms you have because of your leg ulcer and also to determine if there are ways to better assist you to take care of yourself.

What do I have to do to participate?
You will receive a face-to-face invitation from the researcher to participate, a research information sheet, and a survey. A quiet area will be provided for you to complete the survey. Please complete the survey to the best of your ability. There are no right or wrong answers.

How long will it take?
Your participation is limited to the amount of time it takes to fill out the survey, which is about 15 minutes.

Are there any risks?
There are no physical risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer

any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Benefits to Being in the Study:
There are no direct benefits to participating in this survey research. Your responses might help us determine how to help you deal with your leg wound(s) in the future.

Confidentiality:
The survey is strictly confidential. There is a risk of breach of confidentiality if you provide information beyond what the survey asks for. The information we collect in this survey does not identify you.

APPENDIX D

RECRUITMENT SCRIPT

CVLU Self-Care Study
Principal Investigator: Collette LaValey MSN, RN, ACNS-BC

Recruitment Script

When Data Collection will Occur:
Following organizational policy on student data collection, potential participants will be
approached in the lobby of the Lutheran Wound Healing Center every Tuesday and
Friday from 11a-4pm. After each potential subject checks in for their appointment, they
will be asked if they would like to participate in the study. The scripted information listed
below will be used.
Decision to Participate
Read the scripted information (information in quotation marks) about the study to the
potential subject.
Introduction
"My name is Collette LaValey. I am a nurse and a doctoral nursing student
conducting a study that uses a survey for individuals with leg wounds that are due
to chronic venous stasis, or bad veins in the legs. Do you have a leg wound due to
chronic venous stasis?"

If potential participant states "yes," they will be asked:

"Are you interested in hearing more about the study?"

**If participant states "yes," the participant will be lead to a quiet area with a table
and chair. A survey packet will be opened. The principal investigator will hand the
research information sheet to the participant. Additional information will be given:**

"Again, my name is Collette LaValey. I am a doctoral nursing student interested
in examining the symptoms you have due to your leg wound, how you feel about
your level of ability to care for yourself and your leg wound, and then how
regularly you actually take measures to care for yourself and your leg wound. Do
you have a leg wound that your doctors told you are from chronic venous stasis,
or bad veins?"

"The next thing we will do is go over the research information sheet. I will read the document out loud to you. If you have any questions about anything that is said, we can stop to discuss it."

The research information sheet is read to the participant.

If the participant does not have any further questions, directions will be given regarding completing the survey.

"The first questions in the survey ask about your age, gender, socioeconomic, educational status, health status, comorbidities (other diseases you have), and self-care/health promotion measures (things you do or do not do for your health)."

"Other questions ask about symptoms you have that are related to having your leg wound, your feelings about your level of ability to care for yourself and your leg wound, and the actual measures you take to take care of yourself and your leg wound."

"Please answer all of the questions to the best of your ability. It is very important that you answer all of the questions. If you do not want to answer a certain question, that is ok.
"When you are finished filling out the survey, please place it into the envelope. Keep the research information sheet in case you would like to refer to it later. Bring the envelope to me. I will place the envelope in a designated box in the manager's office for safe keeping."

"Would you like to participate in the study?"

APPENDIX E

PERMISSION TO USE VEINES

http://www.ladydavis.ca

Hôpital général juif
Jewish General Hospital   McGill

Institut Lady Davis de recherches médicales | Lady Davis Institute for Medical Research

From: Collette LaValey [mailto:cblavaley@gmail.com]
Sent: July 28, 2013 7:31 PM
To: Susan Kahn, Dr.
Subject: PhD student requests permission to use VEINES QOL SYM

[Quoted text hidden]

Collette LaValey < cblavaley@gmail.com>   Mon, Jul 29, 2013 at 2:43 PM
To: "Susan Kahn, Dr." <susan.kahn@mcgill.ca>

Hi Dr. Kahn,
Thank you very much for your prompt reply. My study is only for academic purposes (my PhD dissertation)
and is not receiving funding from any commercial source.
Collette

Collette LaValey MSN, RN, CWOCN, ACNS-BC
PhD(c), The University of Akron

[Quoted text hidden]

Carole Bohbot < Carole.Bohbot@ladydavis.ca>   Mon, Jul 29, 2013 at 3:07 PM
To: "cblavaley@gmail.com" <cblavaley@gmail.com>
Cc: Carole Bohbot <Carole.Bohbot@ladydavis.ca>

Dear Colette,

Thank you for your interest.

The VEINES QOL/Sym questionnaire and scoring program are attached. For your information, the file "VQOL SPSS
scoring pgm REVISED Nov 07.SPS" is an SPSS (statistical software) file and should not be opened in any other
program than SPSS (this software cannot be sent).

You can use the questionnaire freely (there is no copyright or fee), but please acknowledge the papers that describe
the development and validation of VEINES-QOL (i.e. Lamping et al., J Vasc Surg 2003; Kahn et al., J Clin Epi 2006) in
papers that arise from your studies that use the questionnaire.

Sincerely,

APPENDIX F

PERMISSION TO USE ASAS-R

Collette LaValey <cblavaley@gmail.com>
To: "Jaclene.Zauszniewski@case.edu" <Jaclene.Zauszniewski@case.edu>

Fri, Oct 11, 2013 at 7:41 AM

Dr. Z.,
Thank you very much for your help and timely reply.
Collette
[Quoted text hidden]

—
[Quoted text hidden]

Marge Bott <mbott@kumc.edu>
To: "Jaclene.Zauszniewski@case.edu" <Jaclene.Zauszniewski@case.edu>, Collette LaValey <cblavaley@gmail.com>

Fri, Oct 11, 2013 at 10:58 AM

Dear Collette LaValey,

You have the permission of the University of Kansas School of Nursing to use Dr. Sousa's self-care agency revised scale for your dissertation work.

Attached is a copy of the 15-item revised Appraisal of Self-Care Agency Scale. Please note that 4 items needs to be recoded when you score the scale.

Please do not hesitate to contact me if you have further questions.

Sincerely,

Marge J. Bott, RN, PhD

Associate Professor and Associate Dean, Research

University of Kansas School of Nursing

3901 Rainbow Blvd. MSN 4043

Kansas City, KS 66160

913-588-1692

913-588-4531 (FAX)

APPENDIX G

PERMISSION TO COLLECT DATA AT LUTHERAN HOSPITAL

WOUND HEALING CLINIC

6/4/2015

Dr. Rajesh Sharma, Medical Director, Lutheran Wound Healing Center
1711 West 25th Street, Cleveland, Ohio 44113

RE: Permission to Conduct Research Study

Dear Dr. Sharma and Monica,

I am writing to request permission to conduct a research study at the Wound Healing Center. I am currently enrolled in the University of Akron/Kent State University Joint PhD Nursing Program and have been working on a research proposal for my study entitled Symptoms, Power, and Self-Care in Individuals with Chronic Venous Ulcers. IRB approval was granted by the CCF IRB 5/1/2015 (letter included).

I hope that the Wound Healing Center will allow me to recruit 110 participants with the diagnosis of a venous leg ulcer. I intend to recruit participants in person in the Wound Center lobby using an informational flyer. Prior to filling out the survey, a research information sheet which summarizes the study will be read to each participant. A copy of the research information will be given to each participant.

The survey should take no longer than 20 minutes to complete. Survey data will be imported into a data analysis program and will remain confidential and anonymous. Should the study results be published or presented at a research meeting, only pooled results will be described.

Your approval to conduct this study will be greatly appreciated. I would be happy to answer any questions or concerns that you may have. You may contact me at my email address: lavalce3@ccf.org, or by phone: 216 633 6028.

If you agree, kindly sign below, and return the signed form in the attached self addressed envelope.

Sincerely,

Collette LaValey, MSN, RN, CWOCN, ACNS-BC
Doctoral Student
The University of Akron/Kent State University Joint PhD Nursing Program

Enclosures

cc: Monica Minissale, Program Director, Lutheran Wound Healing Center

Approved by:

MONICA MINISSALE

PROGRAM DIRECTOR   *[signature]*   4.8.2015

Print your name and title here | Signature | Date

RAJESH SHOKEEN   *[signature]*   6/8/15

Print your name and title here | Signature | Date

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APPENDIX H

IRB APPROVAL

Lavaley, Collette

From:	irb@ccf.org
Sent:	Tuesday, June 02, 2015 12:01 AM
To:	Lavaley, Collette
Cc:	IRB Account, IRB
Subject:	15-687; EXEMPT: Symptoms, Power, and Self-Care in Individuals with Chronic Venous Leg Ulcers

June 1, 2015

Collette LaValey, MSN, CNS, doctoral student

RE: IRB# 15-687: EXEMPT: Symptoms, Power, and Self-Care in Individuals with Chronic Venous Leg Ulcers

Dear Ms. LaValey:

Your new study application received on 5/29/2015 was approved under expedited review on 6/1/2015 as Exempt Research for the collection of data in an anonymous manner in which participants will not be identifiable nor linked to a code that could identify them.

Exempt status means that continuing IRB review and approval is not required. Only changes that no longer meet the criteria for exemption listed above will require submission to the IRB.

The PI is responsible to ensure research team members are knowledgeable of the study protocol and appropriately trained.

If you have any questions regarding study changes or modifications, please call the IRB office at 216-444-2924.

Sincerely,

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APPENDIX I

PERMISSION TO USE ALTERNATE SITE

Dear IRB:

Collette LaValey, University of Akron doctoral nursing student has the approval of the South Pointe Wound Healing Center to recruit participants and collect data for her research study.

Sincerely,

Beth Gore RN BSN

Nurse Manager

Cleveland Clinic South Pointe Wound Center

Office: 216.491.7840

Center: 2167111

APPENDIX J

IRB APPROVAL TO USE ALTERNATIVE SITE

From: <irh@ccf.org>
Date: December 2, 2015 at 12:00:27 AM EST
To: <lavalec2@ccf.org>
Cc: <irh@ccf.org>
Subject: 15-687: EXEMPT: Symptoms, Power, and Self-Care in Individuals with Chronic Venous Leg Ulcers

December 1, 2015

Collette LaValey, MSN, CNS, doctoral student

RE: IRB# 15-687: EXEMPT: Symptoms, Power, and Self-Care in Individuals with Chronic Venous Leg Ulcers

Dear Ms. LaValey:

Your submission on 11/23/2015 of the Protocol Ver. 2 dated 11/19/2015 was approved under expedited review on 11/30/2015.

The revision is to add South Pointe as a site.

If you have any questions or concerns, you may contact the IRB Office at 216-444-2924 or email IRB@ccf.org.

The study expiration date of remains unchanged.

Sincerely,

APPENDIX K

THE UNIVERSITY OF AKRON PERMISSION TO START DATA COLLECTION

Huff,Marlene S <mhuff@uakron.edu>
To: "McWhorter,Sharon" <sm48@uakron.edu>
Cc: "Collette LaValey (cblavaley@gmail.com)" <cblavaley@gmail.com>

Wed, Jun 3, 2015 at 1:12 PM

Thank you. Her research is being done at a CCF facility.

Marlene Huff

From: McWhorter,Sharon
Sent: Wednesday, June 03, 2015 9:46 AM
To: Huff,Marlene S
Subject: RE: research approval

Marlene – If she's doing her research at the clinic and they have approved, we really don't need to have the UA IRB review. I believe as long as she has the evidence of IRB approval from them she is ok.

Sharon

Sharon McWhorter, MA, CRA

Director, Pre-award Research Administration

Office of Research Administration

The University of Akron

Akron, OH 44325-2102

Ph: 330-972-8311

Fax: 330-972-4850