1-1-2011

Improving Blood Pressure Control In Esrd Through A Supportive Educative Nursing Intervention

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IMPROVING BLOOD PRESSURE CONTROL IN ESRD THROUGH A SUPPORTIVE EDUCATIVE NURSING INTERVENTION

by

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DISSERTATION

Submitted to the Graduate School

of Wayne State University,

Detroit, Michigan

in partial fulfillment of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

2011

MAJOR: NURSING

Advisor Date

DEDICATION

To my husband Robert Klein, and my children Jacob and Julia whose selfless support and encouragement made this dissertation possible. Without you this journey would not have been possible.

ACKNOWLEDGMENTS

I would like to acknowledge Dr. Nancy Artinian, my mentor and chairperson for my committee. Her guidance, encouragement and support helped develop my research and academic skills. The sharing of her knowledge in hypertension management and her expertise in the research process enabled me to develop strong research skills in my own area of research – hypertension in End Stage Renal Disease.

I would also like to thank my committee for their guidance throughout the dissertation process. Specifically, I would like to thank Dr. Rosalind Peters for helping me develop my theoretical framework to guide this study, Dr. Hossein Yarandi for his expertise and guidance with statistical methods and Dr. Abbey for her expertise in health behavior. I would also like to thank Dr. Jean Davis for her support and encouragement.

I would also like to acknowledge the American Nephrology Nurses' association in addition to the Graduate School and the College of Nursing at Wayne State University for helping finance this research project. A special thanks goes to all the staff and patients at the hemodialysis units and patients who helped make this research project possible. I would also like to thank my employer Dr. Olaf Kroneman for his constant support and flexibility with work throughout the dissertation process – it was greatly appreciated. Lastly, I would like to thank my parents, Draga and Ivan Kauric who always reinforced the value of education.

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CHAPTER 1

Introduction

Background of the Study

According to the latest statistics, 11% of the US adult population (23 million people) have chronic kidney disease and of those, approximately 555,000 are undergoing hemodialysis (U. S. Renal Data System (USRDS, 2010). Based on the most recent statistics, the total cost of the End Stage Renal Disease (ESRD) program in the US is approximately $35 billion (USRDS, 2009). Due to the predicted increase in prevalence of diabetes and hypertension, these numbers are only expected to rise in the future (USRDS, 2010). Despite the financial commitment to the treatment of ESRD, hemodialysis patients experience significant mortality and morbidity.

In the United States, cardiovascular disease accounts for almost 50% of deaths in patients with renal disease (USRDS, 2010). Hypertension in chronic hemodialysis (HD) patients contributes significantly to their morbidity and mortality. Hypertension is very prevalent among patients undergoing chronic HD. Statistics indicate the prevalence of hypertension in HD patients is approximately 75% to 100% (Agarwal et al., 2006; Horl & Horl, (2002); Morse, Dang, Thakur, Zhang & Reisin, 2003; Mettal et al. 1999; USRDS, 2010). Uncontrolled hypertension may result in left ventricular hypertrophy, coronary artery disease, congestive heart failure and cerebrovascular complications (Cheigh, Milite, Sullivan, Rubin & Stenzel, 1992; Rocco, Yan, Heyka, Benz & Cheung, 2001).

The National Kidney Foundation Task Force on cardiovascular disease in chronic kidney disease (CKD) has targeted hypertension as one of the major risk factors in the management of CVD (National Kidney Foundation, 2005). Targeting a reduction in deaths due to cardiovascular causes will lead to a significant reduction in the overall mortality of this population. Controlling hypertension in dialysis patients will help healthcare providers continue to help meet Healthy Peoples' 2010 goal for chronic kidney disease (CKD), i.e., decreasing complications, disability and death in CKD.

Statement of the Problem

The reasons underlying inadequate control of hypertension in this population are poorly understood. To date, hypertension has been managed predominately by pharmacologic means. Agarwal and colleagues (2003) did not find uncontrolled hypertension in the chronic HD population to be related to under recognition of hypertension or the lack of use of antihypertensive medication. Possible reasons for uncontrolled hypertension in this population include poor self-care behaviors such as excessive salt and fluid intake resulting in excessive weight gain, the practice of routinely holding BP meds prior to HD, nonadherence to BP medication regimens, and missing HD treatments or cutting HD treatments short (Agarwall, 1999; Horl & Horl, 2002; Rahman et al. 1999). Agarwal (2003) recommended that optimizing the use of medications and paying closer attention to nonpharmacologic interventions, such as adjustment of dry weight and a low-sodium diet may improve blood pressure control.

Although fluid and salt restriction and following prescribed medication and HD regimens are viewed as mainstays of HD hypertensive self-care, achievement of levels of self-care behaviors that are consistent with best practice guidelines are far from optimal. Studies have indicated that many patients receiving HD do not successfully follow diet, fluid intake and medication regimens. Adherence rates have been reported to range between 30 to 60% (Denhaerynck, Manhaeve, Dobbels, Garzoni, Nolte & Geest, 2007; Christensen, Moran, Wiebe, & Ehlers, 2002; Bame Petersen & Wray, 1993; Welch & Thomas Hawkins, 2005). Since the association between adherence to HD self-care behaviors and patient well-being is strong, interventions to improve adherence are needed.

Maintenance of controlled blood pressure (BP) in this population has been largely attributed to optimal volume control as well as salt restriction (Horl & Horl, 2002). According to Charra (2007), sodium and extracellular volume control is the most important strategy for achieving BP normalization and reducing cardiovascular mortality. Normotensive patients have significantly less total body water than hypertensive HD patients, demonstrating the importance of intravascular volume in the pathogenesis of hypertension in patients with ESRD (Charra, 2007).

According to the National Kidney Foundation K/DOQI guidelines (2005), the volume state of a HD patient is affected by sodium intake, water intake, urine output and removal of excess fluid by ultrafiltration during dialysis. To maintain fluid balance and replace insensible water losses in the HD patient, a daily fluid intake of 1000 to 1500 ml is recommended (Mahan & Escott-Stump, 2000). In the HD patient, fluid intake is monitored using interdialytic weight gain (IDWG), which refers to the weight gain that occurs as a result of fluid retention between HD treatments. With an every other day dialysis schedule, recommended IDWG is 2.5 kg (Tischer & Wilcox, 1993). According to Rigby, Scribner and Ahmad (2000), IDWG appears to be closely related to sodium intake, which stimulates the thirst center forcing patients to drink fluids, thus leading to expansion of extracellular fluid and fluid gains. Specific suggestions for managing excessive fluid accumulation include education, regular counseling, reinforcement of low sodium intake (2 -3 grams/day of sodium), and fluid restriction (< 1000 to 1500 ml/day) (NKF/DOQI guidelines, 2005).

According to NKF/DOQI guidelines for Blood Pressure in Dialysis Patients (2005), management of hypertension in HD patients requires attention to both management of fluid status and adjustment of antihypertensive medication. Literature indicates that 25% to 50% of HD patients are nonadherent to BP medication regimens which is associated with poor control of BP in HD patients (Curtin, Svarstad & Keller, 1999; Rahman et al., 1999; Rahman, Fu, Sehgal & Smith, 2000; Rahman & Griffin, 2004).

Nonadherence to HD regimens can also negatively affect IDWG and in turn BP in the HD population. HD patients dialyze three times weekly. If they should happen to miss a HD treatment or cut a HD treatment short, they will have excess fluid overload which would have normally been removed through the HD process. Skipping treatments has been associated with higher IDWG and higher mortality in a number of studies (Obialo et al., 2008; Unruh, Evans, Fink, Powe, & Meyer, 2005).

Although many studies have been found to identify factors that influence patient adherence, few studies have actually focused on the design, implementation and testing of interventions to improve adherence to HD self-care behaviors. Current BP management strategies usually consist of healthcare providers prescribing medications and reinforcing fluid restrictions, with the expectation that patients will follow these instructions. Research suggests that this approach is ineffective in improving BP control in this population (Montgomery, Harding & Fahey, 2001; Sharp, Wild, & Gumley, 2005).

The literature indicates that management of high BP in HD patients requires a patient-oriented intervention, characterized by active participation, taking personal responsibility and changing lifestyle. Self-care management in relation to chronic disease has been defined as a cluster of daily behaviors that individuals perform in order to manage a chronic illness such as hypertension (Glasgow & Anderson, 1999). The concept of self-care management in chronic disease does not solely address adherence with prescribed medical orders but rather is broader and encompasses the need to manage the chronic illness in the context of an individual's life. Daily self-care management of BP in HD requires the ability to manage a complex treatment regimen and participate in daily self-care behaviors related to dietary and fluid restrictions and adhere to medication and HD regimens (Grey, Knafl & McCorkle, 2006). Self-care behaviors also include the monitoring and tracking of treatment progress related to BP control.

Teaching self-care skills associated with control of BP is not enough to bring about behavior change, the individual will need to integrate these skills into everyday life. When performing these behaviors with success in various situations, the individual will improve their sense of self-efficacy or confidence in their ability to perform their self-care behaviors. Perceived self-efficacy is a proven correlate of self-management behavior in ESRD and other chronic diseases (Curtin et al., 2008). There is evidence that increased self-efficacy is associated with improved participation in self-care behaviors related to BP control and improved outcomes in the HD population (Tsay, 2003) and chronic kidney disease population (Curtin et al., 2008). It is proposed that the supportive educative intervention that will be tested in this study will improve knowledge, skill and self-efficacy in performing self-care behaviors related to BP control which in turn will improve BP outcomes in patients undergoing HD.

Purpose of the Study

The major purpose of this quantitative study is to determine if a supportive educative nursing intervention will improve BP control in a chronic HD population. It is postulated that the intervention will improve self-care capabilities (BP knowledge, self-efficacy and self-regulation behaviors) which will lead to improved adherence to: a) hypertensive self-care behaviors (i.e., fluid and salt intake, adherence to a prescribed medication regimen as well as maintenance of HD visits) and ultimately improve BP control (see Figure 1). This study will also examine the relationship between basic conditioning factors (age, gender, race, education, income, comorbidities, and social support), BP self-care capabilities and BP self-care behaviors.

Theoretical Framework

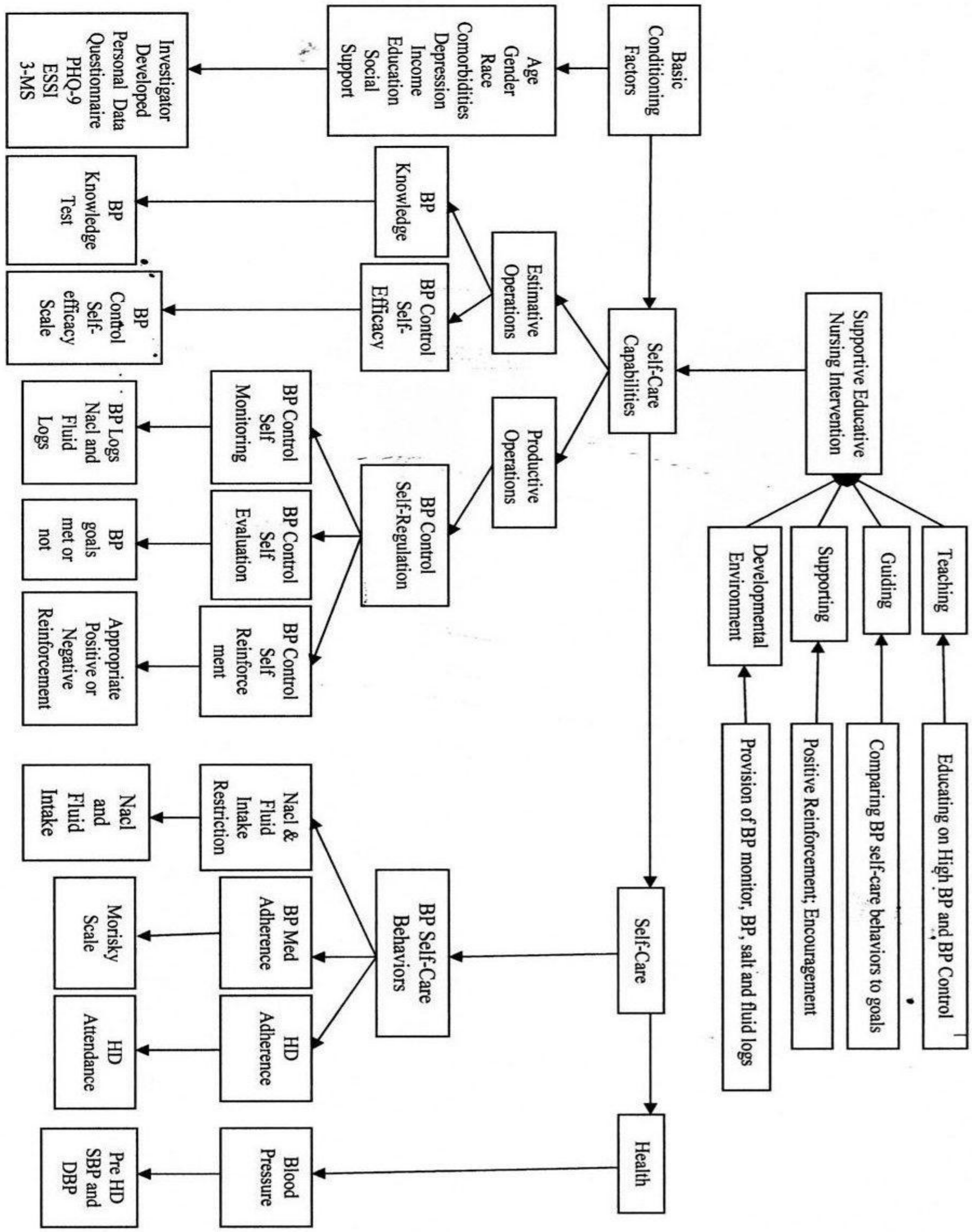
Orem's Self-Care Deficit Nursing Theory (SCDNT) (2001) and the Self-Regulation Theory (Kanfer & Gaelick, 1986) were used to develop the midrange Theory of Improving BP Control in Hypertensive HD patients (Figure 1). The combination of these two theories is useful in understanding and predicting individual behavior related to BP control and identifying methods in which behavior may be modified.

A review of extant theory and conceptual models in nursing found that Orem's Self-Care Deficit Nursing Theory (SCDNT) (2001) provided an excellent general framework to examine self-care in relationship to BP control in the HD patient. Orem's SCDNT (2001) does not focus on one phenomena related to self-care but looks at the complexity of variables such as environmental and personal factors which affect self-care. The major core concepts of SCDNT that will be substructed in the development of this middle range theory are: basic-conditioning factors (BCFs), self-care agency or capabilities (SCA), self-care behaviors (SC), nursing system and health.

Basic Conditioning Factors

Both the ability to engage in self-care and self-care agency are influenced by internal and external factors to the individual known as basic conditioning factors (BCFs) (Orem, 2001). According to Orem (2001), "BCFs refer to those personal conditions or environmental circumstances that may affect the operability or adequacy of peoples capabilities to care for

Figure 1: Conceptual Model: Theory of Improving BP Control in Hypertensive HD Patients



themselves" (Orem, 2001. p. 514). BCFs are specific to the individual and vary with each individual and situation. According to Orem (2001), BCFs can affect a persons' therapeutic self-care demand and their self-care capabilities. These factors can also influence the effect of the proposed intervention on self-care capabilities and self-care behaviors. Orem (2001) identifies 10 BCFs: "age, gender, developmental state, health state, pattern of living, health care system factors, family system factors, sociocultural factors, availability of resources and external environmental factors such as physical or biologic factors of the person's environment" (Orem, 2001, p. 167). A review of the literature found the following BCFs could potentially impact self-care capabilities.

BCFs: Empirical Studies

Age and Gender

The most important demographic factors found to be related to nonadherence to HD self-care behaviors of fluid and dietary restrictions were young age (Bame, Petersen & Wray, 1993; Kimmel et al., 1995; Leggat et al., 1998) and male gender (Aricii et al., 1998; Bame et al., 1993; Cummings, Becker, Kirscht & Levin, 1982; Everett, Brantly, Sletten, Jones & McNight, 1995). Gonsalves-Ebrahim and others (1987) proposed that the greater noncompliance in younger patients was related to the stress of HD and of trying to be independent.

Race

Throughout the literature race has been inconsistently shown as a predictor to adherence to self-care behaviors in HD (Leggat et al., 1998; Bame et al., 1993). Race has been linked to low income in various populations (ie., African Americans) which may affect one's self-care abilities and self-care behaviors secondary to access to limited resources. Many of the studies which investigated the relationship between race and self-care behaviors in HD had small sample sizes and used different criteria to measure adherence which may have resulted in inconsistent findings (Bame et al., 1983). Further exploration of the relationship between race and self-care behaviors will be conducted in the proposed study.

Low Income

Research indicates that low income was associated with nonadherence to self-care behaviors in the HD population (Bame et al., 1993; O'Brien, 1990). Possible explanations could be that people of low income tend to eat foods that are canned and processed with high salt intakes, which may affect their self-care behaviors related to BP control (Artinian, Magnan, Sloan & Lange, 2002). Another explanation may be that adherence to self-care behaviors may not be a priority for someone who is just trying to survive. Sensky, Leger and Gilmour (1996) found complex interactions between employment, income and adherence and did not find a relationship between income and adherence to HD self-care behaviors.

Educational Level

Higher education levels may result in improved problem solving ability and may influence participation in self-care management interventions. Positive relationships between education and self-care behaviors in HD were found in a number of studies (Bame et al., 1993; Cummings et al., 1984; Kugler, Vlaminck, Haverick & Maes, 2005; Morduchowitz et al., 1993; O'Brien 1990). However, other studies did not find any association between highest educational level achieved and dietary, IDWG and adherence to HD self-care regimens (Leggat et al., 1998).

Social support

Social support is an individuals' perceived and physical and emotional support provided by family, friends, co-workers and others. Social support has been found to be associated with adherence to the HD regimens in a number of studies (Boyer, Friend & Chlouverakis, 1990;

Christensen et al., 1992; Cummings et al., 1982; O'Brien, 1990; Sensky et al., 1996). However, social support was not related to HD adherence behaviors in other studies (Kugler et al., 2005). Kugler and others (2005) found that social support could not be examined in isolation of other variables in relationship to adherence to self-care behaviors in the HD population.

Comorbid Conditions

In terms of comorbid conditions, diabetes appeared to be associated with decreased adherence to fluid restrictions in a number of studies (Brady, Tucker, Alfino, Tarrant & Finlayson, 1997; Leggatt et al.,1998; Wiebe & Christensen, 1997). A possible explanation for this is that diabetics may have higher episodes of hyperglycemia which may trigger the thirst mechanism and increase fluid consumption. Further exploration of this finding will be conducted in this study.

Depression

Depression is a disorder of mood, characterized by sadness and loss of interest in usually satisfying activities, a negative view of the self and hopelessness, passivity, indecisiveness, suicidal intentions, loss of appetite, weight loss, sleep disturbances and other physical symptoms (DSM-IV, 2000). Some or all of these symptoms may be present in people suffering from depression. Depression is very prevalent in the HD population. It is estimated that 50% of dialysis patients suffer from depression (Johnson & Dwyer, 2008; Kimmel, 2002). A number of studies have found a relationship between depression in patients and poor adherence to HD self-care behaviors (Kaplan De Nour & Czaczkes. 1976; Kaveh & Kimmel, 2001). Sensky, Leger and Gilmour (1996) did not find a relationship between depression and fluid adherence in a sample of HD patients.

In conclusion, the only variables that have consistently been found to be associated with adherence behaviors in the HD patient are young age and male gender. Diabetes as a comorbid condition and depression have also been linked to poor adherence behaviors. Further exploration of the relationship between these four variables and self-care behaviors will be conducted in the proposed study. Results related to race, education, income, social support were largely inconclusive and will be further explored in this study.

Self-Care Agency

Self-care agency (SCA) is viewed as the specialized capabilities in terms of knowledge and skills an individual needs in order to participate or engage in self-care (Orem, 2001). The structure of the concept was formalized as a three part hierarchical structure of self-care operational capabilities for performing estimative, transitional and productive self-care operations, a set of power components that enable individuals to perform self-care operation and five sets of foundational capabilities and dispositions (Orem, 2001).

The broad structure of the concept of self-care agency is understood as developed self-care capabilities of individuals to engage in "self-care operations" in order for individuals to know and meet their self-care requirements for self-care (Orem, 2001, p. 258). The three self-care operations include: a) estimative self-care operations' or the knowledge needed to regulate health and well-being, b) transitional self-care operations or the ability to judge and decide what to do from the information obtained and c) productive self-care operations or the ability to actually perform self-care actions (Orem, 2001). SCA is activated in response to a demand or a need to care for self which is referred to as the therapeutic self-care demand (TSCD). The TSCD activates the power of SCA and also specifies the actions of self-care (Orem, 2001). A "self-care deficit" occurs when a persons' self-care capabilities are inadequate to meet their therapeutic self-care demands (Orem, 2001, p. 282).

Self Care

According to Orem (2001), self-care is the "practice of activities that individuals initiate and perform on their behalf in maintaining life, health and well being" (p. 43). Self-care is described as a goal oriented activity that is learned. Self-care actions are directed toward meeting three different types of "self-care requisites": a) universal self care requisites (associated maintenance of the integrity of human structure and function), b) developmental self-care requisites (associated with developmental processes and conditions that occur during various stages of the life cycles) and c) health deviation self-care requisites (i.e., human structural and functional deviations and their effects) (Orem, 2001, p. 48). Orem (2001) refers to TSCD as all the self-care activities that should be performed to meet the three types of self-care requisites. In this study, the proposed intervention was expected to help individuals meet universal and health deviation requisites.

Universal self-care requisites are integral to the daily living of individuals and include 1) maintenance of sufficient intake of air, water and food, 2) provision of care associated with elimination, 3) maintenance of a balance between activity and rest and between solitude and social interaction 4) avoidance of hazards of life functioning and well-being and promotion of normalcy (Orem, 2001). Ability to achieve universal self-care requisites can be affected by chronic disease and pathology such as hypertension or ESRD. When there is disease or pathology, universal self-care requisites must be met in order to maintain structure and function (Orem, 2001).

Health-Deviation Self-Care Requisites exist when people are "ill or injured or have specific forms of pathology including defects and disabilities, and who are under medical diagnosis and treatment" (Orem, 2001, p. 233). Health deviation self-care requisites include: 1) seeking and securing appropriate medical assistance, 2) being aware of and attending to effects and results of pathologic conditions and states, 3) effectively carrying out prescribed diagnostic, therapeutic and rehabilitative measures specific to the illness, 4) being aware of and regulating uncomfortable effects of medical care measures; 5) accepting one's state of health and the need for specific health care and 6) learning to live with the effects of the illness and necessary care in a way that promotes continued personal development (Orem, 2001).

Nursing

Nursing is needed when a self-care deficit exists. According to Orem (2001), the purpose of nursing is to know and meet patients' existent or emerging therapeutic self-care demands (TSCD) and to regulate the exercise or development of patients' powers of self-care agency. Nursing care may be needed when an individuals' SCA is not adequate to meet one's TSCD because of their health status (Orem, 2001). New demands may emerge with disease that require more complex actions related to self-care management. For example, patients may need new knowledge and skills to meet their needs related to a newly diagnosed disease process such as diabetes or hypertension.

Nursing Systems

Three nursing systems help people meet their health care deficits (Orem, 2001). They are 1) wholly compensatory nursing systems that are needed when individuals are unable to care for themselves, 2) partly compensatory nursing systems are needed whereby individuals can perform some but not all self-care actions and 3) supportive-educative systems where individuals can perform all self-care actions while engaged in self-care agency development (Orem, 2001). The proposed intervention in this study will use a supportive-educative nursing system. Examples of supportive educative nursing techniques to develop self-care agency in an individual may include offering support, guidance, and teaching. In the supportive-educative systems, the patient's requirements for help are confined to decision making, behavior control and acquiring knowledge and skills (Orem, 2001).

Health and Well-being

Orem (2001) differentiates health and well-being into two different but related human states. According to Orem (2001), health is a state of integrity of developed human structures and mental functioning and an outcome or goal of a self-care system. Well-being is seen as a state of how the individual perceives their condition of existence (Orem, 2001).

Although Orem's SCDNT (2001) describes the cognitive and perceptual skills that are needed to perform self-care, it does not fully explicate how those skills affect behavior. A review of the psychological literature found that Kanfer and Gaelick's (1986) Theory of Self-Regulation provided a useful framework to further expand on Orem's concept of productive operations. The Theory of Self-Regulation further identifies underlying processes by which an individual organizes his or her behavior (Kanfer & Gaelick, 1986).

Self-Regulation Theory

Self-Regulation theory proposes that successfully carrying out a target behavior is a function of three core self-regulatory stages or processes that an individual must engage in: self-monitoring, self-evaluation and self-reinforcement. This theory assumes that human beings are motivated to change their behavior and are capable of both self-direction and self-action, however, such direction and action necessitates skill development (Kanfer & Gaelick, 1986).

Kanfer (1986) suggested that individuals achieve self-regulation by using a feedback loop consisting of continuous monitoring, evaluating, and reinforcing of their own behavior. This loop occurs naturally in everyone. However, the loop can be maladaptive if (a) only negative factors are noticed and positive factors are ignored during the monitoring phase, (b) standards are unrealistic during the evaluation phase, or (c) responsibility is accepted for negative behaviors but not for positive behaviors during the reinforcement phase. Self-regulation strategies help individuals to be aware of these phases and to make the appropriate changes in monitoring, evaluation, and reinforcement.

The self-regulation theory is based on premises of the social learning theory which suggests that everyday behavior consists of chains of behavioral responses which are automatic and cued by preceding responses. This is referred to an “automatic mode of cognitive processing” (Kanfer & Gaelick, 1986, p. 287). These automatic processes do not require attention, can be carried out when completing other activities, and tend to be difficult to change because they are well established. However, in other situations these response behaviors may not have been learned or are no longer effective to deal with the problem at hand. Self-regulation processes are needed when new behavior chains need to be learned, or when habitual responses are ineffective.

A new type of cognitive functioning which is called controlled processing marks the onset of self-regulation. According to Kanfer and Gaelick (1986) controlled processing results in focused attention and continuous decision making amongst alternative responses. Many maladaptive behaviors are associated with well learned repertoires that are automatically executed. The nurse or helper’s task in this situation is to help the individual “deautomatize” troublesome behavior patterns in order to allow self-regulation to take place and in turn "reautomatize" newly learned and more adaptive behavior chains (Kanfer & Gaelick, p. 288).

Self-Monitoring

There are two major functions of self-monitoring: self diagnosis and self-motivation. (Kanfer & Gaelick, 1991). Monitoring allows one to bring their current behavior patterns to conscious awareness. This allows individuals to have more ability to think about their needs, acquire new skills or behaviors and plan their self-care (Wilde & Garvin, 2004). For example, monitoring of consistently high BPs at home may reinforce to an individual that they do indeed have high BP and may help motivate them to take action to improve their BP. As individuals continue to self-monitor, the achievement of an adequate BP can be used as a behavioral reinforcement by the nurse and client.

In order for self-regulation to facilitate behavior change, monitoring should be completed as temporally proximal to the behavior being observed as possible. Additionally, the self-observations should be done on a regular basis and completed with good fidelity and overall quality (Bandura, 1991). Individuals recording their behavior should focus on their successes rather than dwell on failures. The following section validates the use of monitoring in behavior change.

Empirical Studies: Self Monitoring

Several investigators have found self BP monitoring improved BP control (Broege, James & Pickering, 2001; Cuspidi et al., 2004; Halme, Vesalainen, Kaaja, & Kantola, 2005; Obara et al., 2008). Two meta-analysis found similar results. Fahey, Schroeder and Ebrahim (2006) found self BP monitoring to be associated with a significant reduction in diastolic blood pressure. Cappuccio and others (2004) also found that BP control and the proportion of individuals achieving BP targets was increased when self BP monitoring was used as opposed to standard BP monitoring. Only one study was found that tested BP monitoring in a small HD sample. Klein and Artinian (2007) found that home BP monitoring significantly improved systolic BP in a sample 37 HD patients.

Several investigators found that self-monitoring of fluid in combination with other behavioral, educational and cognitive behavioral interventions improved interdialytic weight gains in HD patients (Christensen et al., 2002; Cummings, Becker, Kirscht & Levin, 1981; Nozaki, Oka & Chaboyer, 2005; Sagawa et al., 2001; Sharp et al., 2005; Tanner, Craig, Bartolucci, Alton, & Grieger, 1998; Tsay, 2003; Tucker, 1989). Nozaki et al., (2005) also found that monitoring of salt and fluid in addition to a cognitive behavior intervention was effective in decreasing salt and fluid intake in the HD patient. Thus, we can conclude that self BP, salt and fluid intake monitoring appears to be an effective intervention to help control BP in the HD patient and will be used as one of the major components of the proposed self care management intervention.

Self-Evaluation

Observing one's pattern of behavior is the first step towards behavior change, however, monitoring alone provides little basis for self-directed reactions (Kanfer & Gaelick, 1986). The second stage of self-regulation is referred to as the self-evaluation stage and consists of a comparison between the information obtained from self-monitoring and the individuals performance criteria for that given behavior. This second sub-process of self-regulation is frequently viewed as a goal setting function. Self-evaluation that is based on inaccurate or insufficient self-monitoring or on vague or unrealistic standard criteria interferes with effective self-regulatory behavior because the information attained does not result in the most effective guide for corrective action (Kanfer and Gaelick, 1986). The following studies validate the use of goal setting and evaluation in behavior change.

Empirical Studies: Goal Setting

According to Locke and Latham (2002), individuals who set explicit goals are more likely to focus their efforts on goal directed activities verses goal divergent distractions. Locke and Latham (2002) also found that individuals who set specific, challenging and time limited goals and then monitor their progress were increasingly successful in achieving their goals. Many studies found the positive effect of goal setting in lowering blood pressures (Olivarius, Beck-Nielsen, Andereasen, Horder & Pedersen, 2001; Rachmani, Slavacheski, Berla, Frommer-Shapira & Ravid, 2005).

Goal setting in addition to other behavioral interventions was found to significantly reduce fluid gains in HD patients in a number of studies (Christensen, Moran, Wiebe, Ehler & Lawton, 2002; Cummings et al., 1981; Hegel, Ayllon, Thiel & Oulton, 1992; Sagawa, Oka, Chaboyer, Satoh & Yamaguchi, 2001; Sharp et al., 2005). Goal setting was also found to be effective in addition to behavioral counseling in significantly lowering sodium intake and BP in a sample of moderately overweight men and women with high normal systolic and diastolic BPs (TOHP, 1997). Thus, goal-setting in addition to other behavioral change interventions has been shown to be effective in improving self-care behaviors related to BP control in a number of studies. Goal-setting for BP, fluid intake, salt intake, BP medication adherence and HD regimen adherence is one of the major behavioral interventions used in the current study.

Self-Evaluation-Reinforcement and Feedback

The third stage of the self-regulation process is called self-reinforcement and refers to the individual's reactions to the information obtained from the self-evaluation process. It is also the process by which behaviors are reinforced after successfully accomplishing desired goals. According to Kanfer and Gaelick (1986), the reactions are primarily emotional and cognitive reactions of satisfaction or dissatisfaction with the preceding stages, as opposed to self-administered external reinforcements. The major function of this stage is motivational. Behavior that does not meet the predetermined standard criteria of the individual may cause feelings of dissatisfaction and may result in the individual attempting new behaviors that are more consistent with the preestablished criteria (Kanfer & Gaelick, 1986). On the other hand, if the discrepancies between behavior and goals are viewed as very large, the individual may respond with intense self-punishment or escape behavior rather than behavior designed to correct the discrepancy (Kanfer & Gaelick, 1986). The major purpose of this stage of self-regulation is to determine if an individual is positively reinforcing oneself when goals are met and problem-solving appropriately when goals are not met. The following section validates the use of feedback and reinforcement in behavior change

Empirical Studies- Evaluation and Feedback

Numerous studies have demonstrated the positive effect of reinforcement in behavior change programs related to fluid restriction in the HD population (Christensen, Wiebe, Edwards, Michels, & Lawton, 1996; Sagawa et al., 2001; Sharp, Wild & Gumley; 2005; Tucker; 1989). A component of reinforcement and feedback interventions is based on cognitive behavior therapy. Cognitive theories of behavior change (CBT) have been used to develop interventions to help improve adherence to HD regimens. These theories are based on the premise that people's emotional problems or difficulties in coping are due to a system of dysfunctional beliefs about themselves and their environment (Beck, 1976). Nonadherence to self-care behaviors in BP control may be a result of negative beliefs and attitudes about HD and result in increased cognitive distortion.

The purpose of CBT is to help patients identify dysfunctional cognitions, test them against reality and if necessary alter them in order to improve emotional well-being and coping behavior (Sharp et al., 2005). This approach may be effective in those patients who have experienced multiple failures with fluid restrictions and BP control, resulting in little confidence in their ability to cope or manage their BP. Helping patients to identify negative thoughts or beliefs about their BP self-care behaviors and reframing their thinking may improve their coping skills and self-efficacy in participating in the self-care behaviors related to BP control.

Cognitive behavioral techniques in combination with monitoring and goal setting were found to improve interdialytic weight gain (IDWG) in a number of studies (Nozaki et al., 2005; Sagawa et al., 2001; Sharp et al., 2005; Tsay, 2003; Tucker, 1989). Hegel, Ayllon, Thiel & Oulton (1992) found that the combination of reinforcement and cognitive interventions significantly lowered the degree of 24 hour IDWG in a small sample of eight HD patients compared to reinforcement alone.

In conclusion, there is modest evidence that indicates that interventions which incorporate a combination of self-regulation components including self BP, fluid and salt monitoring, in combination with goal setting, and evaluation (reinforcement/feedback) may be useful in helping control BP in the chronic HD population (Christensenen et al., 2002; Hegel et al., 1992; Nozaki et al., 2005; Sagawa et al., 2001; Sharp et al., 2005; Tsay, 2003; Tucker, 1989).

Self Efficacy

Orem (2001) does not explicitly define self-efficacy, but it can be interpreted as an estimative self-care operations or a “knowledge of self” (Orem, 2001, p.259). Since self-efficacy was not explicitly discussed in Orem's SCDNT, self-efficacy will be further explored using the Self-Regulation Theory (Kanfer & Gaelick, 1986). Kanfer and Gaelick (1986) defined self-efficacy as an individual's confidence in their ability to execute a behavior change program. Self-efficacy is a subcomponent of a broader construct known as perceived control. The three subcomponents of self-efficacy include a) perceived choice over target behavior selection and program development (decisional control), b) perceived control over program execution (self-efficacy) and c) perceived control over program outcomes. According to Kanfer and Gaelick (1986), self-efficacy is frequently low at the beginning of a behavior change program which can negatively affect the initiation and maintenance of new behavior change programs.

Bandura (1997) identifies enhancing client confidence as a major goal in an early behavior change program. Bandura (1997) identified four sources of information that influence self-efficacy beliefs: past performance accomplishments, watching the behaviors of others, exposure to verbal persuasion efforts and emotional arousal related to task performance. According to Kanfer and Gaelick (1986), past performance has the greatest impact on self-efficacy. Thus, tasks related to behavior change need to be tailored to ensure that the task demand does not exceed the client's abilities. In addition, adequate preparation for behavior change can also strengthen self-efficacy (Kanfer and Gaelick, 1986).

According to Kanfer and Gaelick (1986), individuals often hold negative beliefs about their inability to execute behavior changes. Individuals may focus on their inability to execute certain behaviors and forget successful experiences. The health care professional can help the individual refocus on successful experiences which may improve self-efficacy beliefs (Kanfer & Gaelick, 1986). Kanfer and Gaelick (1986) indicated that a change in self-efficacy beliefs required a change in cognitive representations which frequently occurs after behavior change accomplishments (Kanfer & Gaelick, 1986).

According to the Self-Regulation Theory (Kanfer & Gaelick, 1991), an individual's behavior is mediated by their self-efficacy expectations or confidence in being able to engage in self-care behaviors needed to attain BP control. Improved self-efficacy has been found to lead to better self-management outcomes in a number of studies (Curtin et al., 2008; Clark & Dodge, 1999; Marks, Allegrante & Lorig, 2005). It is postulated that active participation by the hypertensive HD patient in the proposed intervention will increase their confidence in their ability to manage BP self-care in relation to fluid and salt restriction and medication regimens.

Concepts and Definitions

The Theory of Improving BP Control in Hypertensive HD patients (Figure 1) is a mid-range theory that was substructed from Orem's SCDNT and Kanfer and Gaelick's (1986) Self-Regulation Theory. According to McQuiston and Campbell (1996), theoretical substruction is a method that enables one to assess congruence between theoretical and operational components of research and is an important technique for conducting theory testing research. Substruction is seen as a hierarchical schematic diagram that progresses from abstract to concrete concepts and relates key concepts, propositions and operationalizations (McQuiston and Campbell, 1996).

The specific concepts from Orem's SCDNT that were used to create this middle range theory include: basic conditioning factors (BCFs), self-care capabilities, self-care, nursing system and health. The specific concepts that will be substructed from Kanfer and Gaelick's (1986) Self Regulation Theory include self-monitoring, self-evaluation and self-reinforcement.

Basic conditioning factors

Both the ability to engage in self-care and self-care agency are influenced by internal and external factors to the individual known as basic conditioning factors (BCF) (Orem, 2001). BCFs are specific to the individual and vary with each individual and situation. Potentially important demographic and contextual variables need to be explored in order to determine their relationship to the successful implementation of various interventions. For the purpose of this study, BCFs will be conceptualized as those demographic and social variables that may affect BP self-care. These variables include: age, gender, race, education, income, comorbidities, social support and depression.

Therapeutic Self-Care Demand

Orem (2001) describes Therapeutic Self-Care Demand (TSCD) as all the self-care actions that are needed to meet the universal, developmental and health-deviation self-care requisites of an individual. For the purpose of this study, TSCD of hypertensive HD patients will be conceptualized as the universal and health-deviation self-care requisites that need to be performed by the individual in order to attain BP control. These self-care actions include: a) daily salt intake < 2 grams/day), b) fluid intake < 1500 ml/day, c) < 2.5 kg weight gain in between HD treatments, d) attend each HD session and e) take all BP medications as prescribed.

Self-Care Capabilities

Self-care capabilities are viewed as the specialized knowledge and skills an individual needs in order to participate or engage in self-care (Orem, 2001). The two major self-care capabilities concepts that will be substructed for this study are estimative and productive operations.

Estimative Operations

According to Orem (2001), estimative operations refers to the knowledge that is needed for individuals to produce adequate self-care. For the purpose of this study, estimative knowledge was substructed into BP knowledge. BP knowledge was conceptualized as knowledge related to hypertension, associated risks of high BP and self-care behaviors needed to to achieve BP control.

Productive Operations

Orem (2001) refers to productive operations as courses of action that need to be performed in order to meet the demands of self-care. According to Orem (2001), productive self-care operations is the process used by individuals to produce, monitor and evaluate self-care following a decision to engage in self-care. For the purpose of this study, productive operations was substructed into the self-regulation subcomponents of self-monitoring, self-evaluation and self-reinforcement.

Self-Regulation

According to Kanfer and Gaelick (1986), self-regulation refers to a systematic process of human thought and behavior that involves setting personal goals and steering oneself toward the achievement of those goals. For the purpose of this study, BP self-regulation was conceptualized as the continuous monitoring, evaluating and reinforcing of an individuals' behaviors related to BP control.

Self-Monitoring

According to Kanfer and Gaelick (1986), self-monitoring involves deliberately and carefully attending to one's behavior against a set of performance criteria or standards by which an individual judges his or her own behavior. In this study, BP control self-monitoring was referred to as monitoring and recording of BP, salt and fluid intake and associated behaviors.

Self Evaluation

According to Kanfer and Gaelick (1986), self-evaluation is the second stage of self-regulation and involves the comparison between information obtained from self-monitoring and the performance criteria or standards for a particular behavior. For the purpose of this study, BP control self-evaluation was conceptualized as the cognitive evaluations or discrimination process associated with comparing BP self-care behaviors with predetermined BP goals or criteria in order to determine if goals were met or not met. The performance criteria that the behaviors were compared to were the goals identified by the NKF guidelines (2005) for BP control in HD which included: a) pre HD BP < 140/90 mmHg, b) fluid intake < 1500 ml/day, c) salt intake (< 2 grams/day or < 1 tsp of salt per day) d) < 2.5 kg weight gain in between HD treatment, e) attending each HD session and f) taking all medications as prescribed.

Self Reinforcement

According to Kanfer and Gaelick (1986), self-reinforcement is the process by which a behavior is reinforced after successfully accomplishing a desired goal. For the purpose of this study, BP control self-reinforcement was conceptualized as the positive or negative reinforcement given in response to BP goals met or not met.

Self-Efficacy

Kanfer and Gaelick (1986) defined self-efficacy as the confidence one has in their ability to execute a behavior change program. BP Control Self Efficacy was conceptualized as the confidence one has in their ability to carry out self-care behaviors related to BP control.

Self Care

According to Orem (2001), self-care refers to the actions an individual takes to meet their Self-Care Requisites. In this study, BP self-care behaviors was referred to as the actual performance of self-care activities aimed at achieving improved BP control which include: , fluid intake < 1500 ml/day, salt intake < 2 grams/day, IDWG < 2.5 kg between HD treatments and adherence to HD regimens and BP medication regimens.

Nursing System

According to Orem (2001), nursing systems refers to the actions that nurses perform in coordination with the action of patients in order to know and meet the components of the individuals therapeutic self-care demands and to protect and regulate the exercise or development of the patients self-care capabilities. The nursing system used in this study was the supportive educative system. Orem (2001) indicates that a supportive educative system is needed when a patient's requirements for helping are confined to decision making, behavior control and acquiring knowledge and skills. There can be many variations of this system. Helping techniques in this system include combinations of teaching, support, guidance, provision of a developmental environment and teaching. The supportive educative system was substructed into the following concepts: teaching, guiding, supporting and providing a developmental environment.

Supportive-Educative System

Teaching

According to Orem (2001) the nurses' role in teaching is to help a person through instruction develop knowledge or particular skills. For the purpose of this study, teaching was conceptualized as providing basic knowledge on hypertension in ESRD, associated risks of uncontrolled hypertension and providing instructions on methods that will help control BP (i.e., fluid and salt restriction and adherence to HD regimens and BP medications).

Guiding

The nurse's role in guiding or directing is to provide factual or technologic information relevant to the regulation of self-care agency or the meeting of self-care requisites (Orem, 2001). Guiding is considered a method of assisting an individual when an individual has to make a choice or pursue a course of action. Guidance requires that an individual and the helper be in communication with one another. In this study, guiding was conceptualized as the nurses' role in reviewing BP, salt and fluid logs and comparing them with the participant to predetermined goals in order to determine if goals were attained on a weekly basis.

Supporting

According to Orem (2001), supporting an individual means to sustain in an effort and prevent the person from failing or from avoiding an unpleasant situation or decision. The nurse is able to offer physical and emotional support and encourage another person to initiate or persevere in the performance of a task, to think about the situation or to make a decision. The role of the nurse in supporting is offering an understanding presence, listening or using other methods of helping if necessary (Orem, 2001). For the purpose of this study, supporting was conceptualized as offering verbal positive reinforcement for goals associated with BP control attained and offering further exploration and problem solving for goals related to BP control not attained.

Developmental Environment

The role of the nurse in providing a developmental environment involves providing environmental conditions that motivate an individual to establish appropriate goals and adjust behavior to achieve goals (Orem, 2001). In this study, providing a developmental environment was conceptualized as providing: educational pamphlets on salt and fluid intake, a home BP monitor, BP logs, salt and fluid logs in order for the participant to monitor their BP, compare home BPs to predetermined goals and to help guide behavior in order to achieve desired BP goals.

Health

Orem (2001) defines health as a state of integrity of developed human structures and mental functioning. According to Orem (2001), health is an outcome or goal of a self-care system. In this midrange theory, health was measured as a decrease in systolic and diastolic BPs with an ultimate goal of a predialysis BP of <140/90 mm Hg (NKF-K/DOQI Clinical Practice Guidelines, 2005)

Assumptions

Synthesis of the research literature related to self-care and concepts from SCDNT, hypertension, hemodialysis and self-regulation was performed in order to develop assumptions for the middle range theory 'Improving BP Control in HD patients'. The explicit theoretical assumptions are:

1. Blood pressure control in hemodialysis patients is a complex multifactorial process.
2. Hypertensive hemodialysis patients are purposeful unitary beings who influence and are influenced by their environment.
3. A supportive educative intervention can improve self-care ability and help meet self-care requisites.
4. BCFs influence self-care ability.
5. Increased self-care capabilities improve ability to perform self-care actions.
6. Improved self-care actions will improve BP control.

Relational Propositions

The relational propositions connecting the middle range concepts are as follows and outlined in Figure 1:

1. A supportive education intervention will improve BP knowledge, self-efficacy and self-regulation operations (self monitoring, self-evaluation and self-reinforcement).
2. There will be a positive significant relationship between self-care capabilities and self-care behaviors.
3. There will be positive significant relationship between BP self-care behaviors and BP.
4. Basic conditioning factors influence self-care capabilities and self-care behaviors related to BP control.

Specific Aims and Hypotheses

The specific aims and hypotheses of this study are as follows:

Specific Aim 1: Determine if a supportive-educative intervention focusing on self care capabilities will improve BP control in chronic HD patients.

Hypothesis 1A: Chronic HD patients randomized to a 90 day supportive-educative intervention will have a decrease in systolic BP at 12 and 16 weeks compared to the usual care group.

Hypothesis II B: Chronic HD patients randomized to a 90 day supportive-educative intervention will have a decrease in diastolic BP at 12 and 16 weeks compared to the usual care group.

Research Question 1: Is there a relationship between BCFs (i.e. age, gender, race, education, income, comorbidities and social support) and BP self-care capabilities.

Research Question 2: Is there a relationship between BCFs (i.e. age, gender, race, education, income, comorbidities and social support) and BP self-care behaviors (salt and fluid intake, medication adherence and HD adherence)?

Specific Aim 2: To determine if a supportive educative intervention improves BP self-care capabilities (i.e. BP knowledge, self-efficacy and self-regulation).

Hypothesis IIA: Chronic HD patient randomized to a 90 day supportive-educative intervention will have increased BP knowledge scores compared to baseline scores and will have greater BP knowledge than the usual care group at 12 weeks.

Hypothesis IIB: Chronic HD patients randomized to a supportive-educative intervention will have increased BP control self-efficacy scores compared to their baseline self-efficacy scores and greater BP control self-efficacy scores then the usual care group at 12 weeks. .

Hypothesis IIC: There will be a relationship between BP control self-efficacy and self-regulation behaviors with increases in both noted at 12 weeks.

Specific Aim 3: To determine the relationship between self-care capabilities (i.e., BP knowledge, self-efficacy and self-regulation) and BP control self-care behaviors.

Hypothesis IIIA: There will be a relationship between BP control knowledge and BP control self-care behaviors.

Hypothesis IIIB: There will be a direct positive relationship between BP control self-efficacy and BP self-care behaviors.

Hypothesis IIIC: There is relationship between self-regulation behaviors (i.e., self-monitoring, self-evaluation, self-reinforcement) and BP control self-care behaviors.

Specific Aim IV: Determine if increased adherence to BP control self-care behaviors results in improved BP control.

Hypothesis IVA: There will a relationship between BP control self-care behaviors (fluid gains, salt intake, medication adherence and HD attendance) and BP.

Hypothesis 1VB: Self-care capabilities (BP knowledge, BP control self-efficacy, self-regulation) and BP self-care behaviors mediates the effect of a supportive-educative intervention on BP control.

Significance of Study

The incidence of hypertension in ESRD is extremely prevalent and poorly treated. The individual and societal costs of hypertension in HD are immense. The future health of this population and the associated health care costs depends on the effective management of high BP. However, in spite of National Kidney Foundation (2005) standards and medical care, current methods to help control BP in the HD population are largely ineffective.

Research is needed to indicate interventions that improve adherence to BP self-care behaviors and ultimately BP control. To date, no studies have tested whether a supportive-educative intervention incorporating self-regulation components could improve BP control in the HD population. The contribution this study could make to society is to improve BP control in the chronic HD population. This intervention could potentially lead to decreased cardiac morbidity and mortality in this population if learned self care behaviors are maintained over time. This in turn, may decrease the tremendous costs associated with cardiovascular care in HD patients.

Significance of the Study for Nursing

According to the American Nurses' Association position statement on the definition of nursing, "Nursing is the protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response, and advocacy in the care of individuals, families, communities, and population" (Nursing's Social Policy Statement, 2004). This study proposed that a supportive-educative nursing intervention will promote and optimize self-care abilities related to BP control and ultimately health of HD patients.

This study also validates an intervention guided by nurses in improving patient outcomes in the HD population. This study contributed to the discipline of nursing by generating knowledge related to : 1) the effect of a supportive educative nursing intervention incorporating self-regulation components on adherence to BP self-care behaviors in the HD patient, 2) the relationship between basic conditioning factors, BP self-care capabilities and BP self-care behaviors in hypertensive HD patients. Until now, few well conducted studies tested interventions that could be administered by nursing to improve BP self-care capabilities and BP self-care behaviors in the HD population. Knowledge regarding the conceptual elements and relationships of Orem's SCDNT and Self-Regulation Theory may provide direction for future nursing practice.

Summary

A study which proposed how a supportive-educative intervention may improve BP control in the HD population has been presented. Investigations that explore interventions that may improve adherence to self-care behaviors related to BP control are needed. Further examination of factors that may affect participation in BP self-care abilities and self-care behaviors are needed to help guide nurses in their care of hypertensive ESRD patients.

LITERATURE REVIEW

Chapter 2

The areas of research literature reviewed for this study include: a) review of studies testing self-monitoring to improve health outcomes, b) review of studies testing self-monitoring to improve BP, c) review of studies testing interventions to limit fluid and salt intake and d) review of studies that examine basic conditioning factors (demographic factors) which may affect self-care behaviors and e) review of studies measuring self-efficacy and its relationship to self-care behaviors.

Self-Monitoring

An intervention that is consistently found in the literature as a method to improve self-care management in chronic disease is self-monitoring. Self-monitoring has been used successfully in a variety of chronically ill populations including hypertension, diabetes mellitus, obesity and asthma. Using a sample of 250 patients with type 2 diabetes (mean age = 60 years, *SD* $\pm$ 7 years) from multicenter outpatient settings in Germany and Austria, Schwedes, Siebolds and Mertes (2002) conducted a 6 month prospective randomized controlled trial (RCT) to investigate the effect of self-monitoring of blood glucose (SMBG) on glycemic control and well-being. Subjects were randomized to either using a blood glucose monitoring device and keeping a blood glucose/eating diary plus standardized counseling or to nonstandardized counseling on diet and lifestyle. Investigators found a significant improvement in glycemic control in the treatment group who used meal related SMBG in combination with the other interventions as compared to the control group. Participants self monitored glucose an average of 25 times a week, which was twice as often as requested. Eighty-seven percent of the SMBG group still monitored their blood glucose levels at the end of the follow-up period reinforcing the acceptance of using the self-monitoring device.

Ignacio-Garcia and Gonzalex-Santos (1995) conducted a six month RCT to determine if 35 adult patients with asthma who used home monitoring of peak expiratory flow rate (PEFR) in association with an education program and a medication self-management plan had less morbidity than 35 control patients who used asthma symptoms, spirometric data obtained in the physician office, and followed a physician's treatment plan. The mean age of the sample was 42 years with equal representation of males and females and social class, compared to the control group. Patients who self-monitored their PEFR showed significant improvement in the following morbidity parameters: days lost from work, acute asthma attacks, days on antibiotic therapy, physician consultations and emergency room admission for asthma compared to the control group who did not monitor PEFR. A reduction in use of inhaled B-agonists, oral theophylline and oral steroids was observed in the experimental group compared to the control group.

Linde, Jeffrey, French, Pronk and Boyle (2005) examined cross-sectional and longitudinal associations between self-weighing frequency and weight in two distinct groups: 1226 adults enrolled in a weight gain prevention trial and 1800 adults enrolled in a weight loss trial. Investigators found that regular self-weighing of at least weekly frequency was associated with lower BMI and greater weight losses over a 12 and 24 month follow-up time period. Less frequent weighing was associated with weight gain in both groups. In both groups, self-weighing was associated with other healthy behaviors such as eating less fat, getting more exercise and not smoking. Although, the samples differed significantly in weight and baseline demographic characteristics, the distribution of baseline weighing frequencies did not differ by study.

In a sample of forty obese sedentary participants, Carels and others (2005) conducted a study to determine the relationships among self-monitoring of exercise, outcome expectancies difficulties with eating and exercise, physical activity, cardiorespiratory fitness and weight loss during a six month behavioral weight loss program (BWLP). The mean age of the sample was 43.4 years (*SD* = 9.4), eighty-three percent were women, 75.5% worked full time, 77.4% had an annual income greater than $30,000 per year, and 41.5% had at least a baccalaureate degree. Participants self-monitored by completing daily exercise diaries describing exercise type and duration, as well as recording food intake over four days at pre and post treatment. Outcome expectancies and difficulties with eating and exercise were measured weekly throughout the intervention using a 13-item questionnaire designed to assess outcome expectancies and difficulties in achieving eating and physical activity goals.

Age, income and education were not significantly associated with outcome expectancies, difficulties with eating, difficulties with exercise, self-monitoring, caloric intake or physical activity and cardiorespiratory fitness variables. Participants who completed the self-monitoring program had significantly greater education and baseline leisure time physical activity than individuals who did not complete self-monitoring. Greater self-monitoring of exercise was significantly associated with fewer difficulties with exercise, higher levels of weekly exercise and greater weight loss. Consistent self-monitors of exercise lost twice as much weight (23 vs. 12 lb), exercised nearly twice as long each week and reported fewer difficulties with exercise than inconsistent self-monitors. Limitations of the study included small sample size, mostly Caucasian representation and a 24% attrition rate. This study demonstrated that helping participants maintain self-monitoring habits and positive outcome expectancies may help reduce weight loss fluctuations during treatment and improve behavioral weight loss treatment outcomes (Carels et al., 2005).

Gleeson-Kreig (2006) conducted a six week RCT intervention study of 58 individuals with type II diabetes with a mean age of 53 years. Participants were randomly assigned to an intervention group which kept daily activity records verses a control group which kept no records. The sample was 100% Caucasian, had a median income of $50,000 and an average of 15 years of education. No relationship was found between any of the demographic variables and physical activity. Physical activity significantly increased from the beginning of the study to the end of the study in both groups. Possible explanations for this finding may be that the participants who had agreed to participate may have been interested in physical activity from the start of the study or that the additional contact between the researchers and individual in the intervention group may have resulted in the finding.

Thus, we can conclude that self-monitoring can play an important role in improving health care outcomes in a variety of disease states. Further examination of the intensity and duration of monitoring to improve health care outcomes should be explored.

Self Blood Pressure Monitoring

Self-BP monitoring has proven to be effective in improving BP control in a number of populations. In a meta-analysis examining 18 RCTs to determine the effect of self BP monitoring on blood pressure, self BP monitoring was associated with a significant reduction in mean systolic BP -2.5 mmHg (CI -3.7 to – 1.3 mmHg) (Glynn, Murphy, Smith, Schroeder & Fahey, 2010). In terms of mean diastolic BP, self BP monitoring was associated with a decrease in diastolic BP of -1.8 mmHg (CI -2.4 to – 1.2 mmHg). The population used for this meta-analysis was composed of adult patients (aged 18 years or above) with essential hypertension (treated or not currently treated with blood pressure lowering drugs) in a primary care, outpatient or community setting (Glynn et al., 2010). The study included 1988 participants, the lengths of the studies ranged from six weeks to two years. The methodological quality of the studies was poor to moderate and few of the studies indicated the randomization process. Many of the studies used more than one intervention so it was difficult to determine the effect of home BP monitoring by itself. The majority of the studies used twice daily monitoring of BP, although a few studies used three times weekly BP monitoring.

A second meta-analysis of 18 RCTs by Cappuccio, Kerry, Forbes, and Donald (2004) examined the effect of home BP monitoring on BP levels and the proportion of people with essential hypertension achieving BP goals. The number of participants included 2714 people, the lengths of studies ranged from 2 to 36 months, and the settings included hospital out-patient clinics, communities, general practices and mixed settings. The overall effect of the HBPM intervention on systolic BP was - 4.2 (95% CI, 1.5 to 6.9) mm Hg. The overall effect of the intervention on diastolic BP was - 2.4 (95% CI, 1.2 – 3.5) mmHg. The proportion of individuals achieving BP targets was increased when home BP monitoring was used as compared to standard BP monitoring (RR = .90, CI, .80 to 1.00).

Limitations of the above meta-analyses included having several trials that contained complex interventions in addition to home BP monitoring that may have affected results (Fahey, Schroeder & Ebrahaim, 2006; Cappucio et al., 2004). These contextual variables or mediators could have potentially affected the effect size. Other limitations included studies were conducted in a variety of settings, using different methods, BP criteria and different comparative groups. The majority of the studies did not examine the effect of adherence to medications and control of blood pressure in home BP monitoring. Lastly, many of the RCTs did not report the outcome of

BP achieved or BP control. In terms of methodological quality, many of the studies were poor, particularly with regard to randomization (Fahey, Schroeder & Ebrahaim, 2006). Sample sizes in many of the trials were too small to detect clinically relevant differences.

A six month prospective RCT tested the effectiveness of two levels of a hypertension disease management program in improving BP control in a sample of 5932 adult African American participants (Brennan et al., 2010). From an initial sample of 5932 potential participants, only 638 completed the study. The intervention group received educational materials, lifestyle and diet counseling and a home BP monitor and the control group received a home BP monitor alone. The outcome variables measured was the proportion of subjects in each group with BP < 120/80. Mean systolic BPs decreased for both groups, however the intervention group's systolic BP (123.6 mmHg) was significantly lower than the control group's systolic BP (126.7 mmHg)(p = .03). Mean diastolic BPs also decreased in the intervention group from 84.6 mmHg (*SD* = 12.3) to 80.6 mmHg (10.5) and from 83.6 mmHg (*SD* =12.3) to 80.1 mmHg (*SD* = 10.4) in the control group. There was no significant difference between groups in diastolic BP (p = .99). The intervention group was 50% more likely to achieve BP control (<120/80 mmHg) (p = .05) than the control group and were 46% more likely to monitor their BP at least weekly than the control group (p = .02). Limitations of the study included low recruitment and program completion rates.

Obara and others (2008) conducted a cross-sectional study on 2,363 essential hypertensive patients in primary care settings in Japan to determine the effects of taking home BP measurements on BP control. Home BP monitoring was associated with significantly improved control of morning home BPs (Odds Ratio 1.46, 95% CI 1.33-1.57) and evening home BPs (Odds Ratio 1.35, 95% CI 1.21-1.47) and office BPs (Odds Ratio 1.23, 95% CI 1.06-1.37).

Patients who were monitoring their BP at home were found to: be significantly older, more likely to be male, have a family history of hypertension, and to receive a greater number of antihypertensive drugs.

Halme, Vesalainen, Kaaja and Kantola (2005) conducted a RCT of 269 hypertensive patients in primary care centers in different parts of Finland. The average age of the participants was 57 years with a larger proportion of females (67.5%). Home BP was measured in the self-monitoring group twice daily for 1 week periods at 0, 2, 4, and 6 months and in the control group at 0 and 6 months. Further office measurements were made at the beginning and end of the study in both groups. Patients kept a diary of their BP readings and returned it to the physician at the end of each measurement week. The physicians then decided if they needed to intensify the treatment if the BP target was not met.

Systolic, diastolic and pulse pressures decreased significantly in both the self-monitoring and control groups. The BP readings followed a decreasing trend across the entire study period. Home measurements for systolic and pulse pressures decreased significantly more in the self-monitoring group than in the control group; diastolic pressures were not different between groups. A nonsignificant trend towards lower BP was found in the self-monitoring group compared to the control group. A significant greater number of patients reached their BP target in the self-monitoring group (p =.041) at the end of the study compared to the beginning of the study. Fourteen percent of the patients (65% from the self-monitoring group) withdrew from the study, indicating intensive home BP monitoring was too difficult for many of the participants to complete. More females completed the study compared to males.

Cuspidi and others (2004) conducted a study to evaluate the prevalence of home BP monitoring as well as assess the rate of BP control in a large group of treated hypertensive patients referred to an outpatient hypertension clinic. The sample consisted of 1350 hypertensive patients who attended the hypertension clinic over a period of twelve months. Home BP monitoring was associated with a significantly greater rate of satisfactory BP control. Clinic BP control was defined as systolic and diastolic BPs that were lower than 140/90 mmHg. Satisfactory BP control in the home BP monitoring group was considered < 135/85 mmHg.

The sample was equally represented by both men and women. The average mean age was 59 $\pm$ 12 years. Sixty seven percent of the sample indicated that they used home BP monitoring regularly. Males were found to perform home BP monitoring more frequently, were younger, and had a higher educational level. The group that self-monitored had significantly lower systolic clinic BPs than the group that did not monitor (140 $\pm$ 16.5 vs 142.3 $\pm$ 15.7 mmHg, $p < .05$). Statistically significant correlations were also found between home BP monitoring and systolic and diastolic BPs ($r = .06$, $p < .0001$ and ($r = .51$, $p < .00$) respectively. Limitations of the study were that the results were not generalizable to the normal hypertensive population because the sample consisted mostly of patients who were referred or self-referred to a specialist centre, which could have influenced the rate and motivation in using home BP monitoring. The study also didn't examine the accuracy of BP measurement or the type of device used at home for reliability.

Broege, James and Pickering (2001) conducted a three month RCT study consisting of 40 hypertensive patients with an average age of 73 $\pm$ 6 years to determine whether home BP monitoring could be used to manage hypertension in the elderly. The participants were randomized to one of two treatment groups: 1) the home group (n = 20) who had their BP managed and medication changed according to home BP measurements; and 2) the clinic group (n = 20) who had medications adjusted based on BP readings taken by a clinic nurse.

Approximately half of the patients in both groups were on antihypertensive medications. Patients were trained to measure and record their BP three times in the morning and three times in the evening at approximately the same time every other day. Every two weeks the participants were telephoned by the project nurse for their home BP readings and treatment decisions were made based on these readings.

Participants in the home BP monitoring group were seen in the clinic monthly, but clinic BP readings were not used to make medication decisions. Patients in the clinic group were seen in the clinic every two weeks, had their BP taken by a trained nurse, and treatment decisions made based on these readings. The BP goal of treatment for both the home and clinic groups was BP < 150/90 mmHg, with the least amount of medications. Treated hypertensives with good BP control had the number or dosage of antihypertensive medication reduced during the study period.

Overall, the study found home BP monitoring to be effective in BP management. At baseline, the home group had significantly higher ($p < .05$) systolic BPs than the clinic group, but decreased to near the level of the clinic group (not statistically significant) at the end of three months. Values in the clinic group did not change. Additionally, previously untreated patients had a significant ($p < .05$) reduction in ambulatory awake and nurse measured BPs, while those who started the study on medications showed a significant increase in blood pressures. A possible explanation for this could be due to the higher acceptable limit of pressure control (150/90 mmHg) compared to other studies. The study also demonstrated how significant the white coat phenomena could be, the home pressures remained within normal limits while the clinic readings were consistently higher. Average home BPs of the home group were consistently lower than nurse measured clinic pressures over the 3 month periods indicating persistent white coat phenomena. Similar changes in total quality of life and decrease of antihypertensives was equally achieved in both groups at the end of three months. These findings demonstrate that home BP monitoring can be effective aid in BP management.

Only one study was found that tested home BP monitoring in a small sample of HD patients (Klein & Artinian, 2007). The major purpose of the RCT was to determine if home BP monitoring could improve BP control in a sample of 34 outpatient HD patients. The intervention group received a HEM 780 automatic BP monitor and was instructed to monitor and record their BP two times daily in a BP log. The intervention group was educated on hypertension, associated risks and BP self-care behaviors that could improve BP control. The PI followed the participants weekly for 12 weeks to review BP logs and BP goals, offer positive reinforcement for goals met and problem solve if goals were not achieved. The control group received usual care which included BP assessment during HD treatment as well as having a health care provider deliver information and education about BP.

The average age of the sample was 49 years $\pm$ 11 years. Ninety seven percent of the sample were African American and sixty eight percent of the sample were female. The entire sample had at least a tenth grade education or more and earned an annual income of $10,000 per year or less. The findings indicated that home BP monitoring significantly lowered systolic BP (p = .018) in the home BP monitor group compared to the usual care group. No significant differences were found between groups in diastolic BP or fluid gains. Limitations of the study included poor generalizability secondary to the large representation of African Americans and females in this sample. Future studies with larger samples and representation by a larger variety of ethnic groups needs to be conducted in order to increase generalizability of findings.

From the above findings, we can conclude that home BP monitoring can be an important intervention to improve BP control in a variety of populations and has shown promise in the HD population. Additional studies need to be conducted in the HD population in order to determine effectiveness and increase generalizability. Further analysis of the dosage and duration of the intervention needs to be conducted to increase efficacy and decrease the possibility of individuals feeling overburdened with the intervention.

Fluid Restriction Intervention Studies

Although few studies testing interventions to improve BP control in HD patients were found, numerous studies were found that examined possible interventions to improve restriction of fluid intake in HD patients. Reports of behavioral, educational and cognitive interventions were found throughout the literature. The most common type of interventions to enhance fluid restrictions in the HD population were based on behavioral models (Sharp, Wild & Gumley, 2005).

Examples of behavioral interventions to enhance adherence to self-care behaviors include reinforcing desirable behavior patterns through token economy strategies, behavioral contracting and self-monitoring. Interventions were often supplemented with either verbal or written educational components. More recent strategies have incorporated cognitive therapy and social support in their interventions. Many of the interventions reviewed used a multidimensional approach and incorporated several interventions in treatment.

Educational Interventions to Reduce Fluid Intake

Findings related to education as a means to achieving reduction in fluid intake were inconsistent, but the majority of findings appeared to indicate that education alone is not effective in changing adherence to self-care behaviors in HD patients. Two studies testing educational only interventions were not found to be effective in decreasing interdialytic weight gain (IDWG). One education program was based on the stages of change (Molaison & Yadrick , 2003). The purpose of the RCT was to evaluate the effects of a 12 week education intervention verses control on fluid gain in a sample of 216 HD patients. Readiness to change, knowledge of appropriate weight gain and mean weight gains were obtained from five intervention (n = 216) HD units and five control (n = 100) HD units.

The intervention was developed around two stages: preaction (precontemplation and contemplation) and action (preparation, action and maintenance). The 'preaction' material was delivered during the first six weeks of the intervention and the "action material" was delivered during the second six weeks. The first six weeks focused on consciousness raising and involved increasing knowledge of the sources of fluid in the diet and understanding the meaning of interdialytic weight gain (IDWG). The benefits of changing fluid intake habits and the importance of minimizing weight gain were also emphasized. The intervention used three methods to communicate stage specific information to patients during the two intervention phases: bulletin board displays, patient education handouts and patient feedback. Bulletin boards were hung in the HD waiting room reinforcing fluid restriction. Dieticians met with the participants in a 20 minute group education session to assure that all patients were exposed to the same educational material. During the intervention, patients received three handouts which were reviewed individually by the dietician with the patient as part of their monthly lab report and nutrition education. Additionally, the dietician gave specific feedback to each participant who exceeded the average 2.5 kg weight gain limit.

During the second six week period, information concentrated on the skills needed to implement and maintain appropriate IDWG. Participants were taught the appropriate method of measuring and consuming 1000 ml of fluid per day. The intervention also taught skills in counterconditioning and stimulus control in an attempt to help participants progress to the maintenance stage and prevent relapse to an earlier stage. Patients were given strategies to avoid excessive fluid intake and ways to substitute other items for liquid. Motivational messages and skills building were also used.

The intervention and control units did not differ significantly on demographic data. The average age of the patients was 53.8 $\pm$ 15 years. The majority of the sample was African American (82%). Interestingly, patient gender was found to be a significant predictor of IDWG in the intervention group. Females were found to have lower average weight gains between HD treatments than males. Age was also found to be a significant predictor of IDWG in the intervention group with older patients gaining less fluid than younger patients. Length of time on HD was a predictor of stage in the control group. Participants on HD for shorter time periods were less likely to be ready to make change in fluid intake habits. The authors recommend incorporating behavior change theory at the initiation of HD to help motivate those new to HD to necessary dietary changes. Knowledge scores increased significantly in the intervention group (p = .00), but fluid gains increased from baseline to 12 weeks in the intervention group, while not changing in the control group. Thus, we can conclude that education alone was not an effective behavioral intervention to change behavior related to fluid control.

Casey, Johnson and McCelland (2002) conducted a one group pilot study to assess if providing verbal and written advice about fluid balance to a sample of 21 HD patients in a Northern England city would decrease IDWG. The 18 week intervention was divided into three six week blocks and consisted of a stepped program incorporating verbal and written education on fluid recommendations. Average mean IDWGs were calculated for each six week block. The first 6 week block involved data collection and occurred prior to the implementation of the intervention. The second block of six weeks involved the dietician and ward staff meeting with the patients during HD in order to provide information reinforcing fluid adherence. The third six week block followed the introduction of a health promotion leaflet designed to provide patients with practical information on fluid balance, measuring fluid intake and hints for controlling fluid intake. At baseline and during the final six weeks of the study, all patients were advised on a no added salt diet of 80 to 100 mmol of sodium per day. No added salt was reinforced verbally and within the handout with an emphasis upon the role of sodium intake in control of thirst. During the final six weeks of the study, each patient was seen weekly by the dietician and IDWGs were recorded.

The mean age of the participant was 54.1 years. The mean weight gains between HD sessions was 2.6 kg for Block 1, 2.3 kg for Block 2 and 2.4 kg for Block 3. Forty-eight percent of the sample showed an overall improvement in their mean weight gain between block one (2.6 kg) and block three (2.4 kg), however the improvement was not statistically significant (p = .504). Limitations of the study included small sample size and no control group to compare results. Although patients were advised to limit salt intake during the study, dietary sodium intake was not formally assessed. This study validates the use of IDWG and salt monitoring and reinforcement as an intervention to decrease IDWG in the HD population.

Findings from the previous two studies are similar to those found in a systematic review conducted by Fahey, Schroeder and Ebrahaim (2006) who found that education alone, directed at patients was unlikely to influence control of BP as a single intervention. Thus, we can conclude that knowledge is a necessary but insufficient condition for behavior change and it appears that more proactive strategies such as self-monitoring, goal setting and reinforcement must be included. A possible reason to explain this finding is that with education alone, patients may take a more passive role in terms of responsibility in care and need to be more actively engaged in their self-care.

Barnett and others (2008) conducted a exploratory study to examine the effectiveness of a patient education program and reinforcement on fluid compliance. The intervention was effective in significantly decreasing patients' mean IDWG. The sample consisted of 26 noncompliant HD patients with a IDWG of 2.5 kg or greater in a HD centre in Malaysis. The two month exploratory study was conducted using a quasi-experimental, one-group design with measurements of IDWG, mean predialysis BP and rate of fluid adherence taken after the educational intervention. The intervention consisted of a one to one initial 20 to 30 minute educational session. The major content areas of the educational program included: reasons why HD is needed, importance of fluid control, fluid intake and tips on control, salt and sodium intake, controlling weight gain and complications of excess fluid (Barnett, Yoong, Pinikahana & Si-Yen, 2008). The initial educational session was followed by weekly 10 minute reinforcement sessions over a two month period where encouragement and positive reinforcement were given to patients to adhere to fluid restrictions.

The median age of the sample was 52 years ± 11.6 years, the majority of the sample had a secondary education or greater (84%). The mean IDWG decreased significantly following the education intervention from 2.64 kg to 2.21 kg ($p < 0.05$) and adherence to fluid restrictions increased from 47% to 71% following the intervention. Maximum predialysis systolic BPs decreased from 220 mmHg to 161 mmHg. Limitations of the study included small sample size and lack of a control group. A likely explanation for these significant findings was the addition of weekly reinforcement to education which may have resulted in synergistic effects as compared to education alone.

Cognitive-Behavioral Interventions

Early on, investigators used some form of behavioral modification in their interventions to promote adherence to fluid restrictions in HD patients. Capelli (1990) and others found that a monetary incentive program did not improve adherence to fluid restrictions in a sample of 60 HD patients. In another small observational four week study of 10 HD patients, Hart (1979) found that positive reinforcement alone resulted in an immediate one-week reduction in IDWG, however IDWG began rising by the second week.

Behavioral contracting in combination with other interventions did not significantly reduce IDWG in two studies (Cummings, Becker, Kirscht & Levin, 1981; Tanner, et al., 1998). In another study examining behavior contracting only, no significant changes in IDWG were found (Sagawa et al., 2001).

Cummings and others (1980) investigated the effect of three intervention strategies designed to improve adherence to fluid restrictions in a HD sample. The sample consisted of 116 HD patients from two outpatient HD clinics in Michigan (mean age of 54.8 years) who were randomized to either a control group or one of following three groups: a) behavioral contracting (setting goals and timelines for fluid adherence, maintaining records of progress and rewards for meeting goals (lottery tickets); b) same procedure as above with a relative or friend participating in the contract agreement, and c) weekly telephone contacts made by a nurse to provide verbal support and discuss benefits and consequences of nonadherence to fluid restrictions. The study used a pretest, posttest control group design; patients were interviewed before the intervention period began (T1), after a 6 week intervention period (T2), and also at 3 months after completion of the intervention period (T3).

Results showed that all three groups had substantial reductions in fluid gains between dialysis treatments and after the six week intervention phase. In order of largest to least average IDWG at T2, the control had an average mean weight gain of 2.64 kg ± .17, the weekly telephone contact group had an average mean weight gain of 2.51 kg ± .16, the behavioral contract group had an average mean weight gain of 2.38 kg ± .17, and the behavioral contract with a family member or friend group had the least weight gain of 2. 26 kg ± 2.0. However, only the patients in the group "behavioral contract with a family member or friend" had significantly lower mean IDWGs compared to patients in the control group ($p < .05$). Those in the weekly telephone group were the least adherent to fluid restrictions compared to the other treatment groups.

The program effects tapered off to preintervention levels once the intervention was completed. This may indicate that the intervention was not long enough to maintain behavior change. Other explanations for this finding may be that the effectiveness of the intervention was related to factors external to the individual such as conformity to authority, identification with the nurse or response to a tangible reward (Cummings et al., 1980). When these factors were no longer available during the post intervention period, the effects of the intervention tapered off. Future research must look at ways behavior change occurs over time and how it can be maintained. Limitations of the study included a poor description of the randomization process.

Tanner and others (1998) conducted a six month RCT in 40 HD patients with a history of noncompliance to determine the effectiveness of a self-monitoring tool on perceptions of self-efficacy, health beliefs and adherence. Noncompliance was defined as an average IDWG greater than 3 kg for six to 12 HD sessions and monthly serum phosphorus levels > 5.9 mg/dl. Investigator developed Self-Efficacy, Health Beliefs and Knowledge surveys were administered during the first and sixth months to both the treatment and control groups. The Self-Efficacy survey measured perception of self-efficacy for self-monitoring and the Health Beliefs survey measured beliefs and attitudes toward health before and after receiving the intervention.

Progress reports and contracts were reviewed monthly with subjects in the treatment group by the investigator. Progress reports documented subject's monthly phosphorus and IDWG levels and were used to educate subjects on acceptable values for serum phosphorus and IDWG. Smiley face stickers were provided for each criteria met and additional reward stickers or candy were provided when both criteria were met for the month. Frown stickers were used for unacceptable values. Monthly written contracts were used to assist in developing one to two monthly goals to improve phosphorus levels and fluid control. Goals were reviewed with the monthly progress reports. The subject and investigator would then identify reasons for nonadherence and areas for improvement. Each month a new contract with new goals was developed.

Ninety-eight percent of the sample was African American, sixty three percent were male with an average age of 49 years. There was a significant increase in knowledge in the treatment group (p = .002) compared to the control group at post-intervention. However, knowledge did not result in increased adherence to dietary and fluid restrictions. No significant differences were found in phosphorous levels and IDWG between the two groups post intervention (Tanner et al., 1998). No significant differences were found in self-efficacy and health belief scores between the treatment group and control group. These findings have been supported by other studies which have not found a correlation between increasing patient's knowledge level and evidence of improved adherence to self-care behaviors (Cummings et al., 1981; Wilson, 1991). This finding was used in the development of the current study intervention which used education in addition to other cognitive and behavioral interventions to improve behavior change.

Interestingly, patients had nonsignificant trends towards improvement in IDWG and or phosphorous over time, but rarely did anyone excel in both areas. According to Tanner et al., (1998), a possible explanation is that patients may comply with some aspects of treatment while not adhering to others. This study focused on changing two behaviors: limiting fluid intake and foods high in phosphorous. Attempting to change two behaviors at one time may have been too difficult. Tanner and others (1998) recommended that future studies using self-monitoring should focus on the alteration of only one behavior at a time.

Limitations of the study included small sample size and multiple providers implementing the intervention. In addition, the intervention did not involve self-monitoring; the HD unit staff monitored IDWG and phosphorous levels, with little active involvement on the part of the patient. The findings from this study helped develop the current proposed intervention whereby only behaviors related to self-care of BP will be targeted and the subject will be actively involved in self-monitoring.

Influence of Multidimensional Interventions on Adherence to Fluid Restriction

The following studies incorporated a combination of interventions thus making it difficult to evaluate the independent contribution of any one intervention. However, significant reductions in IDWG were found in all studies combining self-monitoring with other intervention strategies (Christensen et al., 2002; Sagawa et al., 2001; Tsay, 2003; Tucker, 1989).

Christensenen, Moran, Wiebe, Ehler and Lawton (2002) examined the efficacy of a group administered behavioral intervention to increase adherence to fluid intake restrictions in a sample of 40 HD patients. The intervention was administered to groups of four to six participants meeting for seven one hour long weekly sessions. The participants were guided by a psychologist to develop behavioral goals related to fluid restriction, generate plans to reach goals, and establish criteria to monitor responses. The intervention protocol was highly structured and based on Kanfer's self-regulatory framework of self-monitoring, self-evaluation and self reinforcement of a target behavior (Kanfer & Gaelick, 1986).

The mean age of the sample was 55 $\pm$ 13.7 years, and 90% of the sample was Caucasian. The sample was highly educated, with an average of 12.6 $\pm$ 2.4 years of education. No significant differences in IDWG were found between treatment and control groups immediately post intervention, however a significant reduction in IDWG was found between the two groups two months after the intervention. The intervention group displayed a pattern of decreased IDWG (improved adherence) over time whereas control patients displayed a pattern of increased IDWG (poorer adherence) over time ($p < .05$). Significance of the study findings were limited secondary to small sample size. However, the findings highlight the importance of goal setting to the process of behavior change. Generalizability was limited secondary to 90% of the sample being Caucasian, which is an underrepresentation of the ethnic diversity of the broader HD population.

Sagawa, Oka, Chaboyer, Satoh and Yamaguchi (2001) conducted a 12 week experimental study in a small sample of 10 HD patients (47.8 years, *SD* = 11.4 years) from Japan to evaluate the effectiveness of a cognitive behavior therapy (CBT) intervention in controlling daily weight gain in HD patients. The interventions included self-monitoring, self-contracting and reinforcement.

Data collection was divided into three phases: a four week baseline phase, a six week intervention phase and a four week follow-up phase. Average IDWGs were calculated during the baseline phase. During the six week intervention phase, average IDWGs were calculated and the participants were asked to record their food and water intake using a five day diary. At the beginning of the sixth week of the intervention, participants reviewed their dietary habits and discussed factors associated with weight gains with the investigators. During this period, three CBT techniques were introduced: reinforcement, self-contracting or goal setting and self-monitoring. The participants were also informed to record their thoughts and behaviors related to their personal objectives during each day of the intervention.

Objectives were assessed as being met or not met at each HD session during the intervention phase. The four week follow-up phase was a repeat of the baseline phase except a diary was not kept. The effect of the intervention was found to be significant $F(2, 18) = 10.21$, $p < 0.01$. Significant differences in IDWG were found between baseline and the intervention phase ($p < 0.01$) and between baseline and the four week follow-up phases ($p < 0.05$). Limitations of the sample included small sample size, no control group, and the CBT intervention was not adequately described. These findings validated the use of a CBT intervention encompassing goal setting, self-monitoring and reinforcement in improving IDWG in a small HD sample.

Tucker (1989) conducted a six week RCT that investigated the effect of a nurse delivered behavioral-cognitive intervention on IDWG in a sample of 103 HD patients with a mean age of 53 years. The sample was randomly assigned to three treatment groups: (a): self-monitoring of fluid intake with praise from nephrology nurses for bringing in fluid records and money incentives for reducing IDWG, (b) Treatment (a) plus behavioral control technique, and (c) treatment (b) plus family support. A significant decrease in IDWG was found in all three groups at post intervention. The inclusion of family support with other interventions did not add to further reductions in IDWG. These findings highlighted the effectiveness of self-monitoring and reinforcement as behavior change interventions and were used in the proposed study.

Tsay (2003) conducted a RCT of 62 chronic HD patients (ages 20 to 64 years) to examine the effectiveness of self-efficacy training on fluid intake adherence. The study took place in Northern Taiwan over a six month period. The experimental group received 12 sessions of structured self-efficacy training and the control group received routine care. The intervention included an educational component, self-monitoring of dietary and fluid intakes, performance mastery, experience sharing and stress management. Participants recorded daily food and fluid intake which were reviewed during each HD treatment. The experimental group was found to have decreased IDWG and decreased fluid intake for up to six months following the intervention as compared to the control group. Limitations of the study included lack of generalizability as the study was conducted in Taiwan. These findings also demonstrate the importance of self-monitoring as a behavior change intervention.

Nozaki, Oka and Chaboyer (2005) conducted a quasi-experimental study to compare the effects of a standard patient education program (SPE) with a cognitive behavioral therapy (CBT) intervention on sodium intake and fluid gains in a sample of 22 Japanese HD patients. The SPE group was provided with a self-management pamphlet that described the function of the kidney, fluid and salt management and an educational pamphlet on water and salt content of foods. The CBT intervention consisted of a self-monitoring component, a shaping method and assertion training and response prevention. The self-monitoring component consisted of having patients monitor and record behaviors related to salt and fluid intake and record associated attitudes emotions and thoughts. The expectation was that monitoring would aid individuals' subjective evaluations and modify habitual behaviors related to salt and fluid consumption. The shaping method divided the target achievement process into several steps and identified behaviors in each step to finally achieve the target behaviors. This intervention was expected to increase self-efficacy through the accumulation of successful experiences in achieving objectives that arose from their actions. In assertion training, patients performed role playing by assuming the role of a difficult person in their life that may encourage them to abuse fluids or salt and discussed appropriate responses to avoid being influenced into negative behaviors. In response prevention, patients were encouraged to discuss ways they could control impulsive behavior induced by a stress reactions by doing something other than ingesting fluid and salt.

The intervention period consisted of a four-week baseline period to calculate mean IDWG. During this time period, participants recorded eating habits and drinking behaviors for five days and daily salt intake was measured during the fourth week. The duration of the intervention was six weeks. Mean IDWG was calculated during the six weeks and mean daily salt intake was measured during the second, fourth and sixth weeks of the study. A 12 week follow-up phase was conducted to measure average IDWG and salt intake in order to determine if changed behavior continued after the completion of the intervention.

The mean age of the sample was 52.9 years $\pm$ 9.5 years. In the CBT group, significant differences were found in weight gains between the baseline and intervention phase (p = .04) and 12 week follow-up phase (p = 0.10). In the SPE group, significant differences were found between baseline and the intervention phase (p = 0.045). Interdialytic weight gain decreased in both groups, however the effect lasted longer in the CBT group (12 weeks) compared to the SPE group (8 weeks). These findings indicate that both interventions were effective; however the

CBT intervention appeared to have a longer effect. In addition, daily salt intake decreased from baseline to intervention completion and persisted for 12 weeks. Limitations of the study included small sample size. The significant findings from this study validated the use of many of the components of the intervention for the proposed study: monitoring and recording fluid, salt intake and behaviors associated with salt and fluid intake and using a shaping method with established goals and response prevention.

Sharp and others (2005) conducted a RCT trial of a group-based cognitive behavioral intervention aimed at improving fluid restriction adherence in a sample of 56 HD patients. Groups of participants were randomly assigned to an immediate treatment group (ITG) or deferred treatment group (DTG). The intervention in the ITG included baseline pre randomization assessment, a four week treatment phase and follow up assessment at ten weeks after treatment. The DTG received standard care for four weeks before starting treatment. The deferred group permitted experimental control in the form of both an extended baseline and replication of the intervention effect.

The intervention consisted of four weekly one hour sessions using educational, cognitive and behavioral strategies to enhance effective self-management of fluid consumption. Educational components included conveying information related to the importance of fluid restriction. Behavioral techniques included self-regulations techniques (self-monitoring, goal setting, and reinforcement) of adequate fluid intake. Dietary sodium intake was not formally assessed.

Cognitive components included encouraging patients to identify associations between their thoughts, emotions and behaviors. Patients were requested to complete thought records between sessions in order to identify and gain insight into maladaptive cognitive thinking influencing nonadherence to fluid intake. A muscular relaxation tape was given to patients for daily practice to aid in stress reduction. The importance of social support networks and how to gain optimal support from significant others was discussed. Suggestions were also given on how to interact appropriately with others regarding the management of fluid consumption.

The average age of the sample was 54.3 $\pm$ 12.7 years, and males composed 68% of the sample. No significant differences in mean IDWG were found during the initial four week intervention phase between groups ($F = 0.03$, $p > .05$). However, there were significant within group differences in IDWG between baseline and post intervention follow-up at 10 weeks ($p < .001$) which reflected improved adherence over time. A possible explanation for the nonsignificant differences in IDWG between the two groups at four weeks was that the initial four week treatment phase was not long enough to apply the knowledge and consolidate the skills learned through the treatment phase (Sharp et al., 2005).

According to Sharp and others (2005), the reasons for the decrease in IDWG after treatment cessation was due to the development and refinement of effective cognitive and behavioral management strategies. Christensen and others (2004) found similar results whereby no significant differences in IDWG were found between treatment and control groups immediately after treatment, but significant differences were found at 8 weeks follow-up. Implications from this study affected the development of the current intervention by implementing the intervention over a longer time period (12 weeks) and adding the component of salt monitoring in addition to fluid monitoring.

In summary, it appears a combination of interventions including: education, goal setting, self-monitoring, reinforcement and cognitive components are most effective in decreasing IDWG in the HD populations. Limitations of the studies included small sample sizes, short intervention durations and lack of description of interventions administered. These findings helped to develop the current proposed intervention which includes: education related to volume overload and associated risks, goal setting related to BP, salt and fluid restriction, monitoring of fluid and salt intake over a three month period and a cognitive component which involves having patients record and discuss feelings and attitudes related to monitoring and BP self-care behaviors. Positive reinforcement was given by the investigator when goals were met and feedback and problem solving were offered when goals were not met.

IDWG was used as the major outcome variable in all reviewed studies. One limitation of the studies reviewed was that there was much variability in the measurement of IDWG across studies. The development of uniform criteria for problematic IDWG would be useful in testing differences between patient groups and treatment outcomes. More recent studies have used a 2.5 kg cutoff value (Sharp, Wild & Gumley, 2005) and will be used as the cutoff goal for the current study.

Salt Restriction

Upon examining the literature, few studies were found that tested interventions to improve adherence to salt restriction in the HD population. Rupp, Stone and Gunning (1978) conducted a RCT of 20 male HD patients (mean age of 50 years). In an attempt to simplify dietary recommendations, the participants in the treatment group (n = 10) were instructed on a simplified diet consisting only of sodium restriction. The control group (n = 10) was instructed on the traditional sodium and fluid restriction diet. Lab values and dietary results were reviewed twice weekly for eight weeks. A significant ($p = < .05$) decrease in weight gain and mean arterial BP (-3.94 mm Hg) was found in the intervention group. There were no significant changes in mean weight gain, sitting and standing blood pressures or serum sodium concentrations in the control group. This study suggests that patients who were instructed on salt restriction alone compared to the traditional combined fluid and salt restriction instruction had improved fluid gains and mean arterial blood pressures. The authors postulated that dietary simplification in terms of sodium restriction could improve fluid adherence. The authors also speculated that controlling thirst through salt restriction could provide adequate fluid control in the HD patients. Due to small sample size, these findings are not sufficient to solely develop an intervention targeting restriction of salt intake. The literature to date indicates the need for both fluid and salt restriction to improve BP control in the HD population.

Krautzig and others (1998) conducted a one group small prospective study of eight German hypertensive HD patients who were assigned to a regimen of gradual lowering of dialysate sodium concentration in combination with dietary salt restriction. The participants were instructed to consume a moderately salt restricted diet of no more than six grams per day, to avoid adding salt to their meals and to avoid canned and salty tasting food. In addition, dialysate sodium concentration was lowered from 140 to 135 mmol/l at a rate of 1 mmol/l every three to four weeks. Predialysis systolic pressures decreased from 147 $\pm$ 9.3 to 136 $\pm$ 17 mmHg and predialysis diastolic blood pressures dropped from 88 $\pm$ 5.5 to 80 $\pm$ 9.6 mmHg. Mean arterial blood pressure fell significantly from 108 $\pm$ 4.4 to 98 $\pm$ 10.9, p = .02) and antihypertensive medications were stopped completely in four of the eight participants. The study did support the need for salt restriction in the HD patient in order to control BP. Limitations of the study included small sample size, no control group, and difficulty determining the effect of each intervention.

Since only a few research studies were found that examined the effect of reducing salt intake in the HD population, literature was reviewed to examine interventions to decrease salt intake in other hypertensive populations. In a meta-analysis to assess the effect of modest salt reduction in a sample of 802 hypertensive individuals with a mean age of 50 years, MacGregor (2004) found a reduction in urinary sodium of 4.6 g per day of salt resulted in a mean reduction in systolic BP of -5.06 mmHg (95% CI: -5.81 to -4.31) and -2.70 mmHg (95% CI: -3.16 to 2.24) for diastolic BP. A significant relationship was found between the reduction in urinary sodium and the reduction in blood pressure. A dietary salt reduction of 100 mmol/day (6 g/day) predicted a decrease in systolic BP of 7.2 mmHg (95% CI: 5.6 to 8.8) and a decrease in diastolic BP of 3.8 mmHg (85% CI:2.8 to 4.7). Twenty RCTs were included in the meta-analysis. Study durations varied from four weeks to one year. None of the trials used concomitant interventions in either group. Participants were 18 years or older with elevated BP irrespective of gender and ethnicity. Pregnant women were excluded. This meta-analysis clearly validated the use of dietary sodium reduction as a method to decrease high BP. For the current study, participants were instructed on a 2 – 3 gm/day salt restricted diet. Weekly salt intake checklists were monitored to determine salt intake. Urinary sodium was not measured.

Swift and colleagues (2005) conducted a randomized double-blind and cross over placebo controlled study to determine the effects of reducing salt intake on blood pressure in a sample of 40 African Americans. The average age of the sample was 50 ± 10 years. During the initial four weeks of the study, participants were asked to continue their usual diet. Participants were then given written and verbal advice by nurses on how to reduce salt intake and a goal of achieving a salt intake of less than five grams per day. Reducing salt intake from ten to five grams per day was significantly associated with a decrease in BP ($p < 0.01$). Blood pressures decreased from 159/101 ± 13/8 mmHg to 151/98 ± 13/8 mmHg.

The Trials of Hypertension Prevention (TOHP) (1997) was a randomized two by two factorial clinical trial of 2382 moderately overweight men and women with high normal systolic and diastolic BPs who were not taking antihypertensive medications. The participants were randomly assigned to one of four treatment groups: weight loss alone, sodium reduction alone, weight loss plus sodium reduction (combined) or no active intervention (usual care). Participants were followed for 36 to 48 months and net changes in systolic and diastolic BPs were measured as outcome measures. The goal of the sodium reduction group was to achieve a sodium intake of 70 mmol per day or less. Participants met monthly on an individual basis with a counselor. The program began with an intensive intervention phase during which the groups of 11 to 34 participants were counseled weekly for ten weeks on sodium reduction. The primary goal of the intervention phase was to provide participants with core knowledge and behavioral skills necessary to make and maintain reductions in sodium intake. Progress was monitored by measurement of overnight sodium excretion and diet diaries.

The intensive intervention phase was followed by a transitional phase consisting of four monthly sessions for the sodium reduction groups. This phase was designed to prevent relapse and to ease transition from weekly to less frequent contact. The goal of the final extended phase intervention was to maintain participant's behavior changes. The final phase included once or twice monthly contacts with all active participants and attempts to reengage inactive participants. In addition, a series of three to six refresher sessions was offered on intervention related topics to promote contact and adherence with the intervention.

Overall the mean age of the participants was 44 years, 66% were men and 18% were Black. About half of the participants were college graduates. After 6 months, the estimated net reduction in the sodium reduction group was 50 mmol per day ($p < .001$) compared to the usual care group. BP reduction was statistically lower (2.9/1.6 mmHg) for the sodium reduction group compared to the usual care group at six months ($p < .001$). The BP reductions were less at 18 months (2/1 mmHg) compared to six months, but still remained statistically significant ($p < .003$). At 36 months, BP changes continued to be reduced in all groups, but changes in systolic BP only remained significant in the sodium reduction group ($p < .03$). Although there was a decreased effect on BP and salt intake at 36 months, systolic BP was still significantly reduced at 36 months.

He, Markandu and MacGregor (2005) reanalyzed data from four previous moderate salt reduction trials. Hypertensive individuals were studied in randomized double blind crossover studies: one month of usual salt intake (from 10 to 12 g per day) compared with one month of reduced salt intake (5 to 6 g per day) (MacGregor et al., 1982; MacGregor, Markandu, Sagnella, Singer & Cappuccio, 1989; Cappuccio, Markandu, Carney, Sagnella, He, MacGregor, 2003). The sample consisted of 112 participants, 27% of whom had isolated systolic hypertension, and 79% had combined systolic and diastolic hypertension. The average age of the participants was 59 $\pm$ 11 years and 54% of the sample was Caucasian. Individuals with secondary causes of hypertension were excluded from the study. All participants were given written and verbal advice by nurses on how to reduce their salt intake to three or five grams of salt per day. After two to four weeks on the low salt diet, patients entered an eight week randomized double blind crossover study of slow sodium tablets versus placebo tablets while still remaining on the low salt diet. This regimen provided patients with a salt intake of either ten to twelve grams per day compared to five to six grams per day. In the isolated systolic hypertension group, BP was reduced from 166 $\pm$ 19/86 $\pm$ 7 mmHg to 156 $\pm$ 20/85 $\pm$ 7 mmHg (systolic p = .00; diastolic p = 0.459) with a reduction in urinary sodium from 175 $\pm$ 51 to 87 $\pm$ 38 mmol per 24 hour period. In the combined hypertension group, BP was reduced from 161 ± 16/100 ± 9 to 154 ±17/96 ± 9 mmHg ($p < 0.001$), and urinary sodium was reduced from 176 ± 65 to 98 ± 51 mmol per 24 hr period. These findings demonstrate that written and verbal advice by nurses on salt reduction was effective in lowering BP in a sample of hypertensive patients. Similar instructions were given within the proposed study, with a further salt intake goal reduction of two to three grams per 24 hours and the addition of a salt check list monitoring intervention.

Some of the trials involving salt restriction and hypertension tested bundled interventions. The Dietary Approaches to Stop Hypertension (DASH) – Sodium Trial investigators combined reduced dietary sodium with the DASH diet (which is rich in fruits, vegetables and low fat dairy products) (Sacks, Svetkey, Vollmer, Appel, Bray, Harsh, et al., 2001). A total of 412 participants with a mean age of 48 ± 10 years and an average BP exceeding 120/80 mmHg were randomly assigned to eat a control diet typical of salt intake in the United States or the DASH diet. The participants did not have any comorbid cardiac disease and were not on any antihypertensive medications. Participants were provided all their meals and were randomized to meals with high (3450 mg/d), intermediate (2300 mg/d), and low levels of sodium (1150 mg/d) for 30 days in random order. During the initial two week period, all eligible participants ate the high sodium control diet and were then randomly assigned to follow one of the other two diets. The participants ate their assigned diet at each of the three sodium levels for 30 consecutive days in random order in a crossover design.

The reduction of sodium intake significantly lowered BP in both the control diet group and the DASH diet. There was a greater reduction in BP with progressively lower levels of sodium. The low-sodium DASH diet produced the greatest reductions in systolic and diastolic BP compared to the DASH diet alone or reduction in sodium alone. The DASH diet resulted in a significantly lower systolic BP at every sodium level and in a significantly lower diastolic BP at the high and intermediate sodium levels as compared to the control diet. Reducing sodium intake from the high to the low level in both the control diet and DASH diet reduced systolic BP in participants with and without hypertension. The effects were greater in those with hypertension compared to those without hypertension and in African Americans compared to other races (p = .007). The combination of the two dietary interventions lowered systolic BP more in participants with hypertension than in those without hypertension (p = .004) and more in women than in men (p = .02). The largest reductions in systolic BP occurred in black hypertensive patients (-12.6 mmHg). Lowering sodium intake from 2300 to 1150 mg per day was twice as effective in decreasing systolic BP compared to lowering sodium intake from 3450 to 2300 mg per day.

Weaknesses of the study included study duration and that subjects were not preparing their own meals. The duration of the study was only 30 days, and interventions to change behavior typically take longer to have an effect. Although the DASH diet appears to be more effective in lowering BP than the control diet, the diet is not recommended in the HD population due its' high potassium content which can result in hyperkalemia.

These findings clearly indicate the benefit of dietary sodium reduction in lowering BP in a variety of populations. The majority of the studies did not clearly outline how the salt reduction interventions were delivered. Most of the studies only indicated that the participants were instructed on sodium restriction through verbal or written instruction. None of the studies examined the effect of self monitoring of salt intake on BP. Based on the evidence, the intervention developed for this study incorporated both verbal and written education on salt restriction in combination with self-monitoring, goal setting and reinforcement. It was postulated that this intervention would improve salt restriction and in turn, decrease thirst and fluid gains in the HD patient.

From the literature review, it appears that self-monitoring of fluid and salt intake shows promise as a BP control intervention strategy and should be further explored. Interventions that incorporated education and self-regulation components (self-monitoring, goal setting and reinforcement) appeared to have the most impact on fluid adherence. Given the poor quality of current evidence, a methodologically rigorous trial needs to be conducted to determine the true effectiveness of an intervention incorporating education and BP self-regulation in improving BP control in the HD population.

Influence of Basic Conditioning Factors (BCFs) on Self-Care Behaviors

A review of the literature was conducted to determine the relationship between BCFs and self-care behaviors related to BP control in the HD patient. Evidence suggests that the most important demographic correlates of nonadherence to fluid and dietary restrictions in the HD population are young age (Bame et al., 1993; Kimmel et al., 1995; Leggat et al., 1998) and male gender (Arici et al., 1999; Bame et al., 1993; Cummings et al., 1984; Everett et al., 1993).

Age

A significant inverse relationship has been reported between age and IDWG (Christensen et al., 1996; Kugler et al., 2005; Leggat et al., 1998; Moran et al., 1997; Vlaminck et al., 2001; Wiebe & Christensen, 1997). In a large study of 1230 HD patients, with a mean age of 59 years (range 18 – 90 years), older patients were more adherent to self-care behaviors involving fluid restrictions (Bame, Petersen & Wray, 1993). According to Bame and others (1993), the likelihood of adherence increased 1.4 times for every 10 year increase in age. A multicenter study of 916 German and Belgium HD patients with a median age of 67 years (range 19 – 91 years) found that younger male patients were consistently at highest risk for non adherence to fluid restrictions (Kugler, Vlaminck, Haverick & Maes, 2005).

Leggat et al., (1998) conducted a large study with 6,251 HD patients to determine predictors and outcomes of noncompliance. The strongest predictor for noncompliance with fluid restriction was young age. The 20 to 39 years age group was considerably more likely to be noncompliant to fluid restrictions (AOR = 1.27 to 2.08) compared to 40 to 59 year age groups. The 60 and older age group was much less likely to be noncompliant to fluid restrictions (AOR = .50 to .69). Gonsalves-Ebrahim and others (1987) proposed that noncompliance in the younger age groups may be related to the stress associated with HD and trying to be independent and the multiple competing obligations of work, family and dialysis. These findings will be further explored in the current study.

Gender

Findings related to gender and adherence to HD regimens were inconsistent. In a number of studies, males were more nonadherent to HD regimens (Bame et al., 1993; Kimmel et al., 1995; Kugler, Vlaminck, Haverick & Maes, 2005). Bame, Petersen and Wray (1993) found that males were approximately two-thirds less likely to be adherent to fluid restrictions than females in a sample of 1230 HD patients. Being female was found to be correlated to dietary self-care behaviors (Zrinyi et al., 2003; Cummings, 1981). In a large study of 6251 HD patients, Leggat et al., (1998) did not find differences in levels of IDWG between men and women. Since the relationship between gender and adherence to self-care behaviors in HD appears to be inconsistent, further exploration will be conducted in the proposed study.

Social Support

Studies that examined the relationship between social support and adherence to HD medical regimens were inconsistent. In a longitudinal study of 126 HD patients in a US urban setting, perception of support from family and caregivers was correlated with improved adherence to self-care behaviors (O'Brien, 1990). Other studies confirmed that social support appeared to have a positive effect on adherence to self-care regimens (Mai et al., 1999; Oka & Chaboyer, 1999). In a sample of 916 HD patients in Germany and Belgium, Kugler, Vlaminck, Haverich and Maes (2005) found a significant correlation between social support and the frequency of fluid nonadherence (p = .005) but not dietary nonadherence.

Moran, Christensen, and Lawton (1997) examined the effect of a personality trait of conscientiousness and social support in predicting fluid intake and medication adherence in a sample of 56 HD patients. Perceived social support was measured using a Social Provisions Scale (SPS) that measured the degree to which family, friends and coworkers were supplying support for the HD patient. Interestingly, high support among patients with low conscientiousness was associated with poorer fluid intake adherence, while support had little effect on fluid intake adherence among high conscientiousness patients. These findings indicate social support may work differently among patients with different personality traits and can not be examined in isolation of other variables. Thus, findings related to social support and adherence to self-care behaviors in HD appears to be inconsistent and will be further explored in the proposed study.

Income

In a sample of 1230 HD patients, Bame, Petersen and Wray (1993) reported individuals with low income were more likely to be nonadherent to self-care behaviors related to fluid restrictions and medication regimens. O'Brien (1990) conducted a study to identify the variables associated with positive or negative adherence behaviors. The study was conducted in a sample of 64 HD patients over a period of nine years. HD patients of lower socioeconomic status were frequently found to be nonadherent to fluid and dietary restrictions. O'Brien (1990) suggested that among the poor, medical care and treatment are not high priorities. Simply having enough food to survive may be a greater priority than maintaining a low-sodium diet. The proposed study will further explore the relationship between income and adherence to BP self-care behaviors.

Education

Findings related to education and adherence behaviors in the HD population were inconsistent. Some studies found that HD patients with higher education levels demonstrated better adherence to HD regimens (Cummings, et al., 1984; Morduchowitz et al., 1993; O'Brien, 1990). Education was shown to have little correlation with adherence to HD regimens in other studies (Leggat et al., 1998; Kugler, Vlaminck, Haverick & Maes, 2005; Bame, Petersen & Wray, 1993). Since the findings related to education and adherence to BP self-care behaviors were inconsistent, further exploration will be conducted in the proposed study.

Race

The findings related to race and adherence to self-care behaviors were inconsistent. In a large study of 6,251 HD patients conducted to determine predictors of nonadherence, race was not associated with differences in IDWG between African Americans and Caucasians (Leggat et al., 1998). In a study conducted to investigate the prevalence and associated demographic characteristics of noncompliance with fluid restrictions, Bame, Petersen and Wray(1993) found that African Americans were 1.4 times more likely to be adherent to fluid restriction than whites in a sample of 1230 HD patients. The relationship between race and BP self-care capabilities and BP self-care behaviors will be further explored in this study. .

Comorbid Conditions

In a sample of 70 HD patients, Wiebe and Christensen (1997) conducted a secondary analysis to determine whether demographic variables were related to IDWG adherence measures. Diabetic status explained significant portions of variance in IDWG, indicating that those with diabetes were less adherent to fluid restriction. Similarly, a number of other studies found the comorbid condition of diabetes was associated with increased IDWG (Brady, Tucker, Alfino, Tarrant & Finlayson, 1997; Leggat et al., 1998). A possible explanation for this finding is that diabetes is related to increased levels of hyperglycemia which could result in increased thirst and fluid gains. The relationship between diabetes and interdialytic fluid gains will be further explored in this study.

Depression

It is estimated that 50% of dialysis patients suffer from depression (Johnson & Dwyer, 2008; Kimmel, 2002). Depression has been found to be associated with decreased adherence to HD self-care behaviors of fluid restrictions, nutrition and medication adherence. According to Kaveh and Kimmel (2001), patients on HD may manifest suicidal behavior in a different manner from non-medically ill populations, either by shortening or skipping HD treatments or by a lack of compliance with dietary and fluid restrictions. In a sample of 135 Israel patients, depressed patients had significantly poorer compliance and manifested behaviors such as low frustration tolerance, hostility and denial (Kaplan De Nour & Czaczkes,1976). Increased levels of depressive affect were associated with nonadherence to HD regimens in a number of studies (Kimmel, 2001; Kaveh & Kimmel, 2001; Kimmel, Peterson, Weihs, Simmens et al., 1995).

None of these studies examined the relationship between depression and adherence to salt or fluid restriction and will be explored further in the current study.

Sensky, Leger and Gilmour (1996) investigated the relationship between psychosocial factors, dietary adherence (measured by serum K) and fluid restriction (IDWG) in a small sample of HD patients in Switzerland (Sensky et al., 1996). Depressed patients were not found to have greater IDWGs than patients who were not depressed. Sensky and colleagues (1996) concluded that simple models can not be used to explain adherence and indicated that adherence is likely influenced by multiple factors including age, gender, locus of control, social adjustment and past psychiatric history.

The major purpose of the study conducted by Friend, Hatchett, Schneider and Wadhwa (1997) was to determine if depression was related to changes in fluid adherence over time. Depression was not found to be significantly related to nonadherence to fluid restrictions in a sample of 50 HD patients with an average age of 56 years (SD $\pm$ 15.2). Everett and colleagues (1995) conducted a study of 42 HD patients to determine if psychological variables of stress and depression were related to patient's failure to adhere to fluid restrictions as measured by increased IDWG. The duration of the study was 34 months. Perception of stress was related to increased IDWG, and interestingly increased depression was found to associated with lower levels of IDWG. Possible explanations for this finding may be that depressed individuals may eat and drink less.

Thus, we can conclude that findings related to depressive symptoms and adherence with fluid restrictions have been inconsistent and need further exploration. No studies were found that examined the relationship between depression and adherence to salt intake. Although studies have indicated that depression is related to participation in self care behaviors in a number of chronic illnesses, the findings related to the relationship of depression and participation in self-care behaviors in the hypertensive HD are inconsistent and will be further explored in the current study.

In summary, we can conclude that research concerning demographic factors and their relationship to BP self-care behaviors in the HD population are inconclusive. Young age and male gender have been found to be related to decreased participation in self-care behaviors related to fluid and dietary restrictions and will be further explored in this study. Findings related to the relationship between race, social support, educational level, income, depression, comorbid diseases and participation in HD self-care behaviors were inconclusive and were further explored in this study.

Self-Efficacy

Self-Efficacy is a construct that is increasingly found throughout the self-care management literature. Self-efficacy has been conceptualized as the degree of confidence an individual has in their ability to perform their BP control self-care abilities in order to achieve BP control. Two studies were found that investigated the relationship between self-efficacy and self-care behaviors in the HD population.

Curtin and others (2008) conducted a cross-sectional survey in a sample of 174 chronic kidney disease patients, (mean age 51 $\pm$ 13.67 years) to determine the association between patients' perceived self-efficacy and participation in self-care behaviors. In this study, self-care behaviors included: healthy eating and exercise, self monitoring of BP, glucose, laboratory values, symptoms and maintaining doctor appointments. After controlling for demographic variables of age, education, diabetic status, hypertension, serum creatinine, physical functioning and mental health, self-efficacy was found to be positively associated with self-care behaviors related to CKD (r =.27, p = .00) and medication adherence (r = .20, p = .01). Self-efficacy was also found to be a more consistent correlate of self-management than demographic or health characteristics (Curtin et al., 2008).

Limitations of the study included inability to draw causality findings from the conclusions due to the cross-sectional study design. Other limitations included small sample size and differing sample composition from the general HD population which limited generalizability. These limitations influenced the development of the proposed intervention which used a randomized control design, with a large sample size in order to increase generalizability of findings.

Tsay (2003) conducted a RCT of 62 chronic HD patients to examine the effectiveness of a self-efficacy training program on fluid intake adherence. The program consisted of 12 one hour sessions conducted three times weekly by a trained nephrology nurse specialist while the patient was on HD. The program topics included renal failure and HD, medications, complications, nutrition, fluid restriction, control of thirst and urge to drink and stress management. Participants were also asked to record their food and liquid intake daily and the records were reviewed by the nurse during each treatment. Participants were encouraged to set attainable goals such as decreasing a cup of fluid a day. Praise and recognition were given for goals achieved. When goals were not met, factors associated with weight gain were assessed and discussed. Individual counseling sessions were also offered stressing physical and emotional adjustment to chronic illness. Interdialytic weight gain (IDWG) was the only outcome measure taken. A significant difference in IDWG was found between the two groups (p = .006) which supported the hypothesis that self-efficacy training improved fluid intake adherence in the treatment group.

The authors made the implication that the significant findings supported the theory that patients who receive self-efficacy training are more confident in their ability to engage in self care behaviors and adhere to fluid intake restrictions. Limitations of the study included short duration and lack of generalizability of findings because the study was conducted in Taiwan. In addition, the construct of self-efficacy was not formally assessed as an outcome but only implied through IDWG. Although self-efficacy may have improved after the intervention, one can not conclude that decreased IDWG was a result of improved self-efficacy. Future studies need to measure the construct of self-efficacy in participating in self-care behaviors related to fluid control. The intervention itself may have improved IDWG without any affect on self-efficacy. These findings influenced the development of the BP control self-efficacy scale for the current study, in order to measure BP self-efficacy and determine if it is related to the BP self-care behaviors.

Since only a few studies were found that examined the effect of self-efficacy on self-care behaviors in the HD population, the literature search was expanded to include self-efficacy and self-care behaviors in the general cardiovascular population. Clark and Dodge (1999) explored self-efficacy as a predictor of disease management behaviors in 570 women with a mean age of 71.8 years who had a diagnosis of cardiac disease. Data was collected at baseline, four months and 12 months using the following measures: 1) a self-efficacy questionnaire related to confidence in medication use, modifying diet, getting adequate exercise and stress management, 2) outcome expectations related to the above behaviors, 3) use of monitoring techniques and 4) self-care behaviors related to cardiac disease management.

The self-efficacy construct was shown to be a statistically significant ($p < .05$) post baseline predictor of several disease management behaviors at both 4 and 12 months, including taking prescribed medication, getting adequate exercise, managing stress and following a recommended diet. The authors concluded that self-efficacy may be a good starting point in the implementation of interventions related to disease management. According to Clark and Dodge (1999), emphasis on building confidence specific to a given behavior through a self-care management intervention or clinician patient communication may increase the possibility of the subsequent behavior occurring. Limitations of the study included lack of description of the self-management education intervention administered and lack of identification of the psychometric properties of tools administered. Although generalizability of the study was limited due to the population used, findings still demonstrate that improving self-efficacy in disease management may be a good starting point in implementing behavioral change. Further studies with different populations need to be conducted in order to validate this finding. It was the intention of the proposed study to determine if improving self-efficacy would improve BP self-care behaviors and outcomes related to BP control in the ESRD population.

Anderson, Winett and Wojcik (2007) conducted an exploratory study of 2454 adult church members in south western Virginia with an average age of 54 years to determine the extent that social support, self-efficacy, outcome expectations and self-regulation influence nutrition behavior. Participants with greater self-efficacy in their ability to make healthy food choices consumed lower levels of fat ($p < .001$), higher levels of fiber ($p < .001$) and fruits and vegetables ($p < .001$) than those who had low levels of self-efficacy related to nutrition. Although self-efficacy made an important contribution to nutrition behavior, it was not the major determinant of healthier nutrition. Interestingly enactment of self-regulatory behaviors was the best predictor of nutrition and exerted greater total effects on fat, fiber and fruit and vegetable purchases and intake ($\beta = .61$, $p < .001$) related to healthy nutrition variables. Nutrition was also affected by negative outcome expectations and participants who had negative expectations about physical outcomes (i.e., taste), social outcomes (i.e., spending too much time and energy on nutritional goals) and negative emotions to changing nutrition habits had poorer nutrition habits. Limitations of the study included the use of nonexperimental and correlational data resulting in an inability to prove causality. These findings influenced the development of the current research design which used a RCT.

Thus we can conclude that self-efficacy may mediate the relationship between interventions and outcomes and needs to be further explored. Studies have measured self-efficacy in a variety of ways and more consistent measurement of the construct needs to be done in future studies. Also future studies need to use RCTs or experimental designs in order to confirm causality and increase generalizability.

CHAPTER 3

Methods

This chapter describes the research design and methods that were used to conduct the study. The following paragraphs will describe the design, setting, sample, intervention procedures, instruments, data collection, and data analysis procedures.

Design

A randomized controlled design was used to determine if a supportive educative nursing intervention improved BP control in a chronic HD population. Data were collected at baseline, 12 weeks and 16 weeks. The hemodialysis units were randomized to intervention or control by flipping a coin.

Sample Size

In order to determine an adequate sample size, a power analysis was conducted using a computer program called G Power. It was determined that a sample size of 59 participants per group was needed in order to detect a medium effect size with an alpha error probability of .05 for a multiple regression analysis with seven predictor variables. Since 80 to 90% of HD patients are hypertensive and 50% were likely to participate, it was anticipated that four HD units would be sufficient to attain the sample. However, the PI ran into difficulty trying to recruit sufficient participants from the four HD units and had to recruit from two additional HD units.

Setting

Data were collected from 6 HD units. Four units were located in the metropolitan Detroit area and were affiliated with major health care systems. The largest unit had approximately 182 patients with a racial composition of 65% African American and 35% Caucasian and other. The second largest unit had approximately 124 patients with a racial composition of 90% African

American and 10% Caucasian and other. The third HD unit had approximately 90 patients with racial composition of 90% African American and 10% Caucasian and other. The fourth unit had 83 patients with a racial composition of 60% African American and 40% Caucasian and other. The two other units used for recruitment and enrollment were located in the inner city of Detroit. The largest control unit had 126 patients and the smaller unit had only 64 patients. Both of the control groups were made up of 96% African American and 4% Caucasian and other. A total of six HD units with a total number of 836 potential participants were used to draw 118 participants from. Four of the six HD units were located in the metro Detroit area and two of the control units were located in the inner city Detroit region.

Recruitment and Sample

A convenience sample was drawn from six outpatient HD units in Michigan. After approval from IRB and the HD units, the HD staff and physician in charge were in-serviced by the PI on the study. The medical director and nurse manager were provided the participant eligibility criteria. Patients were considered eligible for the study if they were (a) > 18 years, (b) had a four week average pre HD BP > 150 mm Hg or diastolic BP > 90 mm Hg and (c) read and spoke English. Exclusion criteria included: (a) on HD less than 6 months; (b) scheduled for renal transplantation; (c) illicit drug use history; (d) history of mental illness or; (e) lack of orientation to person, time or place; (f) major health problem such as terminal cancer or HIV; and (g) missing greater than two HD treatments over a four week period. If determined eligible, the medical director and/or nurse manager of each HD unit initially contacted patients. If patients indicated interest in the study they were referred to the PI.

Sampling Procedure – Random Assignment

After the medical director or nurse manager identified participants who were interested and eligible to participate in the study, the PI explained the study to the potential participant in detail and provided the opportunity to ask and answer questions in a private room in the HD unit. If the potential participant was interested in participating in the study, they were asked to sign a written consent.

Once the consent was signed, the investigator reviewed charts and flow sheets to verify eligibility for enrolment in the study. The Modified Mini Mental State Exam (3MS) (Appendix A) was administered to participants to assess cognitive function and the PHQ-9 test (Appendix B) was administered to determine if they had major depression. Participants who scored less than 80 on the 3MS and or > 15 on the PHQ-9 were ineligible to participate in the study.

Protection of Human Subjects

Approval from the Human Investigation Committee at Wayne State University and the hemodialysis units was received prior to the initiation of the study (Appendix C). No procedure, situation and/or materials in this study were hazardous to subjects. No risks were anticipated for the participants other than anxiety about self-monitoring BP or other intervention activities. It was reinforced to the participant that they could withdraw from the study at any time. The Principal Investigator (PI) was present during the delivery of the intervention to all treatment group participants. No participants experienced stress or anxiety that required any treatment or referral to psychological services.

Intervention Procedures

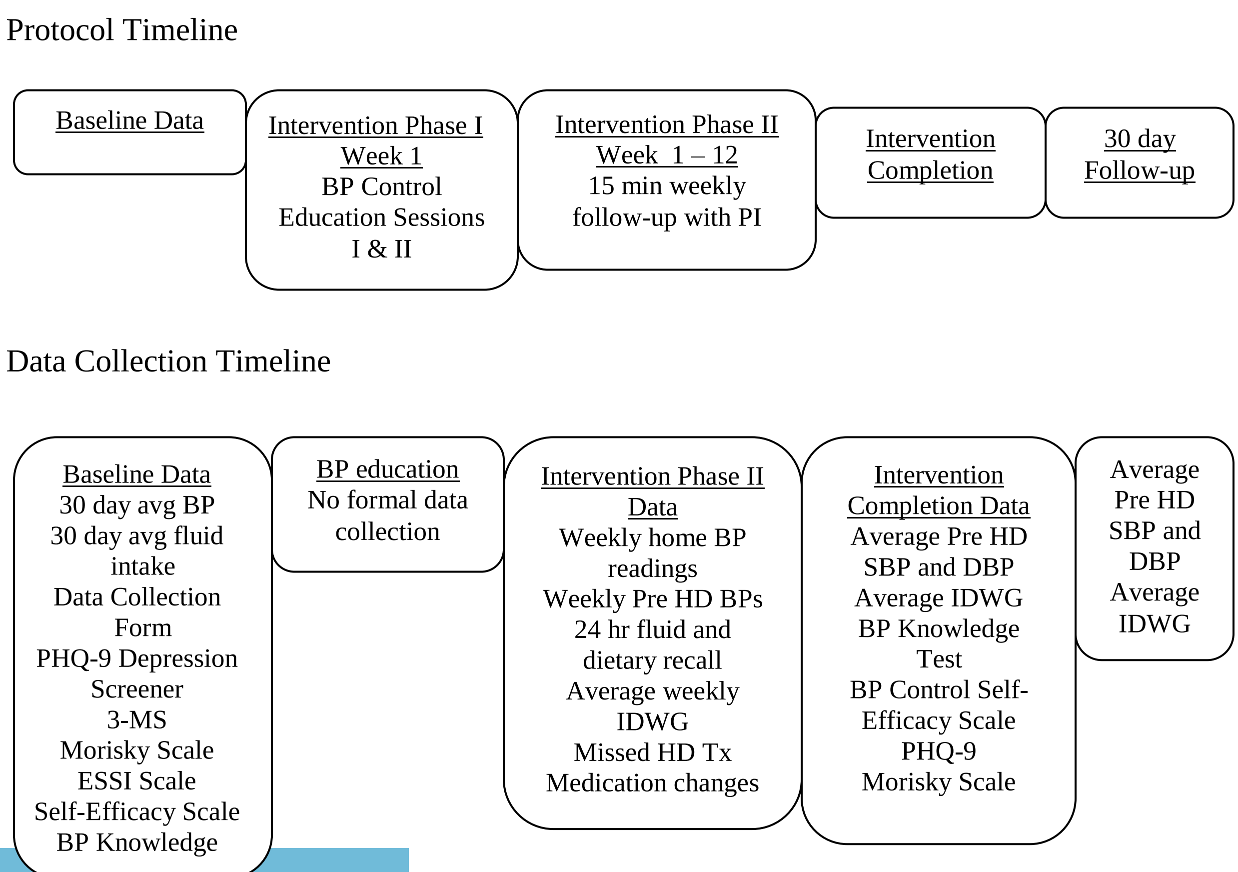
The supportive educative intervention targeted improving BP self-care abilities in hypertensive HD patients. Subcomponents of the intervention included: teaching, guiding, supporting and offering a developmental environment. The intervention procedures were divided into two phases: Intervention Phase I and Intervention Phase II. Figure 2 outlines the protocol and collection timelines for the study.

Intervention Phase I

Education Sessions

The PI delivered all components of the intervention. In phase one, the experimental participants received two educational sessions related to BP control in ESRD. Appendix D outlines in detail the content that was covered during the educational sessions. The content for the educational sessions was developed by the PI and based on the NKF-KDOQI (2005) clinical guidelines for hypertension in ESRD. The educational sessions were expected to improve the BP knowledge related to BP control in the HD patient. The duration of the first educational

Figure 2. Protocol and data collection timelines



session was approximately 20 -30 minutes. The main objectives of the first educational session were to: explain the underlying pathophysiology of hypertension in ESRD, to identify risks associated with having hypertension in ESRD, to describe the self-care interventions/goals that could improve BP control and to describe the role of self-regulation in changing behavior related to BP control. Predetermined goals based on NKF-KDOQI (2005) clinical guidelines for hypertension in ESRD were established by the PI and reviewed with the participant prior to the initiation of the study. The goals were: a) Pre HD BP <140/90 mmHg and post HD BP < 130/80 mmHg, b) salt intake (< 2 grams/day or 1 tsp/day), c) fluid intake (<1500 ml/day) or less than 2.5 kg weight gain in between HD treatment, d) 100% adherence to HD regimen and e) 100% adherence to medication regimen. The importance of self-regulation was also discussed in behavior change.

Education session II (Appendix D) involved providing a developmental environment to help motivate individuals to establish appropriate goals and adjust behaviors to achieve specified goals (Orem, 2001). A home BP monitor, BP and fluid logs, salt intake checklists, and educational pamphlets on sodium and fluid restriction were provided for the participant to facilitate them in monitoring their behaviors related to BP control and facilitate achieving specified goals. The major objectives for the second educational session included: demonstrating correct participant use of home BP monitors, correct recording of home BPs, 24 hour fluid recalls, and salt intake checklists. The educational session lasted approximately 20 to 30 minutes.

Participants in the experimental group were instructed on the correct use of the Omron HEM-780 memory-equipped home BP monitor. BP readings were taken according to the BP protocol established by the American Heart Association (Pickering et al., 2005). The principal investigator demonstrated correct use of the home BP monitor, then participants were asked to demonstrate use in order to confirm accuracy of technique. Participants were asked to take two BP measurements (one minute apart) between 6 am to 10 am and between 6 pm to 10 pm while in a sitting position and were informed not to smoke, drink caffeine or exercise one half hour prior to measuring their blood pressure (The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7 Report, 2003).

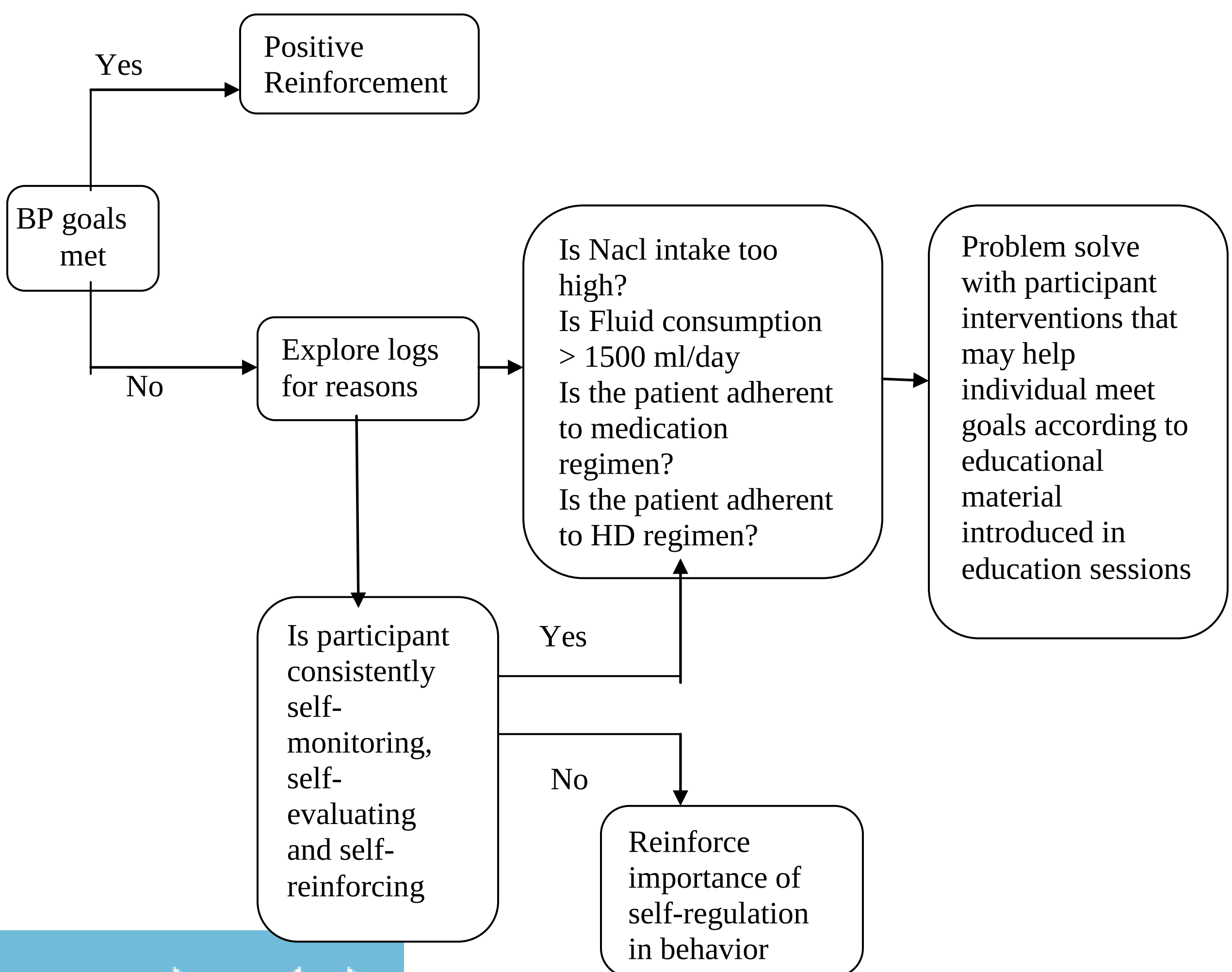
Participants were asked to record all BPs in a written log (Appendix E). BPs were monitored for 12 weeks. The participants were asked to record any comments pertaining to why their BP was elevated (i.e., stressful day, forgot to take their BP medications). The investigator also monitored and recorded pre HD BPs taken in the HD unit in order to determine if there was a correlation between HD unit BPs and home BPs.

The intervention group was also asked to measure and record 24 hour fluid intakes in 24 Hour Fluid Intake Recall logs (Appendix F) twice weekly over a 12 week period. In addition, participants were asked to record behaviors related to fluid intake and associated attitudes, emotions and thoughts. Examples of recorded information included such behaviors as eating out at a restaurant, or attending a party where they may have drank more than usual. In addition, participants were instructed on how to complete a 24 hr salt checklist (Appendix G). The checklist was to be completed twice weekly over the 12 week period. The participants were also given two brochures on sodium (Appendix H) and fluid restriction (Appendix I). Participants were asked to monitor and record whether goals related to BP, fluid and salt intake were met or not met on a weekly basis and to document whether positive self-reinforcement was given for goals met and what was done when goals were not met. The participants were asked to bring these logs to the HD unit on a weekly basis to review with the PI.

Intervention Phase II

Following the educational sessions in intervention phase I, the PI visited experimental patients weekly for 10 to 15 minutes to guide and support patients toward meeting self-care goals. Weekly visits to provide support and guidance were the basis of intervention phase II. The major role of the PI in guidance was to review BP, salt and fluid logs in order to determine if predetermined goals had been met. The PI also offered support (i.e., emotional support and encouragement) in order to help the participant persevere in the performance of BP control self-care behaviors. The PI offered verbal positive reinforcement for goals met and further exploration and problem solving when goals were not met (Figure 3).

Figure 3: Weekly Visit Protocol



The education offered in intervention phase I sessions was reinforced during weekly follow-up visits in order to offer alternative problem solving for unsuccessful attempts at meeting goals. Examples of possible discussions with the participant included offering advice related to oral substitutions of gum or sour candy when an individual was over consuming fluids. If an individual tended to drink more in certain social situations, the individual was counseled in avoiding those situations or exploring possible behaviors that may limit fluid consumption (i.e., filling drinks with ice cubes). If participants were not taking their BP medications as prescribed, exploration of reasons for nonadherence to BP medication regimens and possible solutions to increase adherence were discussed. If individuals were consuming excessive amounts of salt, dietary reviews were conducted to ensure that participants understood the quantity of salt in various food products and to avoid those that were highest in salt such as processed, canned and junk food. The link between salt and fluid intake was consistently reinforced.

During phase II sessions, exploration of thoughts, emotions and behaviors was also conducted. This allowed participants to gain insight into possible cognitive distortions that may have negatively affected self-regulation and ultimately impacted BP control self-care behaviors. For example, if an individual had negative beliefs about their ability to adhere to BP self-care goals, the participant was encouraged to refocus on self-regulation and episodes where the individual had effectively reached their goals.

Control Group

The control group received standard care. Standard care involved BP monitoring and medication adjustments by health care providers in the HD unit on a weekly basis as needed. BP medications were monitored and adjusted in both groups by the attending physician/nurse practitioner as needed. For the control group, three weekly pre-HD BPs were recorded from the dialysis flow sheets and documented in a data flow sheet. Dialysis flow sheets were also reviewed on a weekly basis for sixteen weeks to determine and record fluid gains in between HD treatments in both groups. At the conclusion of the study, control group participants did receive a home BP monitor. All data were collected by the PI in the HD units that the participants attended. Data collection was completed over 13 months from June 2009 until July 2010.

Treatment Fidelity

Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions (Bellg et al., 2004). There are five major areas that need to be addressed when considering treatment fidelity in behavior change intervention studies: study design, training providers, delivery of treatment, receipt of treatment and enactment of treatment skills (Bellg et al., 2004). Examples of how treatment fidelity was ensured in this study are explained below.

Design

A major factor in intervention fidelity of study design is ensuring that the same treatment doses are given to all participants. To avoid cross contamination across groups, hemodialysis units were randomized to treatment or control. This prevented the control group from getting any of the intervention dose.

Training Providers

The PI was the only individual who administered the intervention. This prevented any inconsistencies in intervention administration.

Delivery of Treatment

The intervention was implemented as planned and outlined in intervention phase I and II. The initial educational session was conducted in the same manner for all participants as outlined in Appendix D. However, weekly counseling sessions varied depending on the guidance and support that was needed for each individual. For example, some participants required repeated education or reinforcement related to fluid restrictions, others only needed guidance related to medication adherence and others only required reminders to self-regulate consistently. The information that was offered during these weekly sessions did not differ from the original information introduced in the educational session outlined in Appendix D. Because of the low return rates on the salt intake and fluid logs, the participants were only asked to complete one log on a weekly basis compared to the original two. Logs that documented length of time and intervention administered were kept by the PI to ensure consistency of intervention given to participants. In terms of missed weekly follow-up interventions, only 5 participants missed 1 weekly intervention and one participant missed two.

Receipt of Treatment

Receipt of treatment involves processes that monitor and improve the ability of patients to understand and perform treatment related behavior skills and cognitive strategies during treatment delivery (Bellg et al., 2004). Receipt of treatment was ensured in this study through a number of mechanisms. The information offered during the initial educational sessions was continuously reinforced by the PI during the intervention phase.

Proper use of the home BP monitor with return demonstration was conducted at the initial education session. If the participants had any difficulty with the BP machine or logs, they were asked to bring their devices or paperwork to the HD unit during weekly follow-up visits where further demonstration or feedback was given to ensure understanding. Weekly follow-up by the PI also ensured that the educational material introduced in the initial education sessions related to BP control and self-care behaviors was repeated regularly during the 12 week intervention. By reviewing weekly BP, salt and fluid intake logs, the PI was able to determine if the individual understood the information given to them and intervene with problem solving if necessary.

Enactment of Treatment Skills

According to Bellg et al., (2004), 'enactment of treatment' ensures that participants use the cognitive and behavioral skills provided during the intervention in real life settings (Bellg et al., 2004). The participants did this by monitoring and recording their BP salt and fluid intake in their homes. They were also asked to record reasons in their logs why they were unable to control their BP, salt and fluid intake based on real life experiences. These logs were reviewed with the PI and the participant on a weekly basis in order to problem solve and determine methods to improve adherence to BP self-care behaviors.

Measures

The following study variables were measured quantitatively: BP Control in HD Knowledge, BP Control Self-Efficacy, BP Control Self-Regulation, BP Control Self-Care behaviors, and blood pressure. Demographic data were obtained from the baseline review of the chart and investigator interview of the participant. An investigator-developed general demographic information questionnaire (Appendix J) was developed to measure BCFs. The following BCFs or variables were measured: age, gender, race, comorbidities, depression, income, education and social support.

Global Cognitive Function

Since cognitive impairment is very prevalent in HD patients and can negatively affect participation in the intervention, cognitive function was assessed (Murray, 2008). In order to determine if participants met inclusion criteria related to cognitive ability, the Modified Mini-mental State (3MS) exam was used to determine global cognitive function (Appendix A). This

10 minute investigator delivered exam measures global cognitive function with aspects that assess orientation, attention, immediate and short-term recall and language. The maximum score on the 3MS is 100 and is considered to be more sensitive for mild cognitive impairment. A score of less that 80 was reported to have a sensitivity of 91% and specificity of 97% for detecting possible dementia in the general population (Teng & Chui, 1987). Patients with a score of less than 80 did not meet inclusion criteria to be included in the study. The 3MS is more sensitive to detecting cognitive impairment than the traditional Mini Mental State examination (Teng & Chui, 1987). The tool has been increasingly used to assess cognitive function in individuals diagnosed at various stages of chronic kidney disease (Kurella et al., 2004). In a metanalysis conducted to test the reliability and validity of various screening tools for dementia and cognitive impairment, the 3MS was found to have a sensitivity of 83 – 94% and specificity of 85% - 90% (Cullen, O'Neill, Evans, Coen & Lawlor, 2007).

Depression

Since depression has been found to be associated with decreased adherence to self-care behaviors related to dialysis, fluid restrictions, nutrition and medication, the variable was further explored in this study. Depression was measured using the nine item Patient Health Questionnaire (PHQ-9) (Appendix B) (Depression Management Toolkit, 2004). The PHQ-9 is a brief depression screening instrument that takes approximately five minutes or less to complete. According to the Flesch-Kincaid readability index, the PHQ-9 has a grade five reading level. The PHQ-9 assesses symptoms and functional impairment to make a tentative depression diagnosis and derives a severity score to help select and monitor treatment.

The questionnaire asks patients to identify how often they are bothered by symptoms of depressed mood and anhedonia over the past 2 weeks and each item is scored as 0 (not at all) to 1 (for several days), to 2 (more than half of the days) to 3 (nearly all of the days). The items are added together to determine a total score for depression severity. According to the PHQ-9, a score of 10 would be considered minor depression, 11 to 14 would be considered mild depression, and a score of greater than 15 would be considered major depression. Individuals with PHQ-9 scores of 15 or higher indicate a high probability of depression and should be referred to a mental health professional. For the purpose of this study, a cut off score of less than 15 was used for inclusion in the study.

According to First, Spitzer, Gibbon and Williams (2001), a cut of score of 10 yields sensitivity and specificity scores of 92% for depressive disorders. These scores are similar to those of the Beck Depression Inventory, which has a sensitivity of 92% and a specificity of 80% using a cutoff score of 15 (Graven, Rodin & Littlefield, 1988). The PHQ-9 was validated in a HD population (Watnick, Wang, Demandura & Ganzini, 2005). Watnick and others (2005) conducted a cross-sectional study of 62 HD patients to validate and compare two depression assessment tools: the 21 question Beck Inventory (BDI) and the 9 question PHQ-9. Optimal cutoff values for screening depression were found to be 10 or greater for a depressive diagnosis in the PHQ-9 and 16 or greater for the BDI. Positive predictive values at this score were 59% for the BDI and 71% for the PHQ-9 and negative predictive values were 98% for both tools. Sensitivities and specificities for the BDI were 91% and 86% respectively, compared to sensitivities of 98% and specificities of 92% for the PHQ-9. Watnick and others (2005) concluded that although the BDI and PHQ-9 demonstrated equal degrees of validity, the PHQ-9 was a good alternative because of its accuracy and ease of administration.

Social Support

Social support has been found to affect participation in self-care behaviors in the HD population. Social support in this sample was measured using the ENRICHD Social Support Instrument (ESSI) (Appendix K). The ESSI is a self-administered seven item questionnaire which primarily measures functional social support and in particular emotional support and has primarily been used in cardiac patients (Mitchell et al., 2003). The tool consists of six questions where participants self-report on the availability of someone to: listen to them, give good advice about a problem, show love and affection, help with daily chores, help with a difficult decision and provide consistent contact as a trusted confidant. The questionnaire requires five minutes to complete. Five response categories are used for each of the items ranging from 1 (none of the time) to 5 (all of the time). Item seven measures whether or not participants are living with a spouse or partner and scores 4 for "yes" and 2 for "no". Possible scores can range from 8 to 34 with higher scores indicating greater social support. Mitchell and others (2003) found support for construct validity and internal consistency of the tool in a sample of 196 post MI participants from large clinical centers across the United States that compared the performance of the ESSI instrument with other validated social support surveys. Mitchell and others (2003) found the seven item ESSI tool to have an internal consistency level of .86.

Blood Pressure Control in HD Knowledge

The BP Control in HD knowledge Scale (Appendix L) measured the participant's comprehension of behaviors necessary for BP control in HD. The scale was given to all participants in the intervention and control groups at baseline and 12 weeks. Since a review of the literature did not reveal any instruments that measured the knowledge necessary to control BP in HD, the BP Control in HD Knowledge Scale was developed. This investigator developed tool used format similar to that of R. Peters' (personal communication, September 24, 2007) original Blood Pressure Knowledge Scale in combination with NKF guidelines (2005) for BP control in HD which identified specific self-care behaviors that are needed to control BP in hemodialysis.

The major factors that have been implicated in the pathogenesis of hypertension in HD include sodium and volume excess, and nonadherence to BP medication regimens and HD regimens. The seven item instrument takes approximately five minutes to complete and participants were asked to rate each item on a scale of 0 to 7 where 0 indicates strongly disagree and 7 indicates strongly agree. Total scores were calculated as average scores on each item, with average scores near seven indicating high levels of BP control knowledge. Reliability of the original BP Control Knowledge Scale was .90 and evidence for content and construct validity were also found (R. Peters, personal communication, October 7, 2007). According to the Flesch-Kincaid readability index, the reading level of this scale was at a 6.5 grade level.

Self Efficacy

Self-efficacy was measured using the BP Control in HD Self Efficacy Scale (Appendix M). It was administered at baseline and completion of study. This scale was originally designed to measure self-efficacy in the management of Type II Diabetes Mellitus, but was adjusted by the investigator to measure self-efficacy in hypertension management in the HD patient (Bijl, Peoelgeest-Eeltink & Shortridge-Baggett, 1999). This questionnaire was chosen based on the similarity of self-management content that is used for patients with type II diabetes and hypertensive patients. The scale measures the level of confidence people have in participating in self-care behaviors related to BP control such as: taking their medication as prescribed, choosing foods low in salt, maintaining daily fluid restrictions and attending weekly HD sessions as prescribed. The 11-item questionnaire takes approximately five minutes to complete and is scored on a 5-point Likert scale ranging from 1 (strongly disagree) to 2 (disagree) to 3 (neither agree or disagree) to 4 (agree) to 5 (strongly agree). The internal consistency of the original scale was α = 0.81 (Bijl et al., 1999). The scale was also revised and tested in a sample of 236 patients with recently established vascular disease and found to have internal consistencies of 0.78 (Berna, Graaf, Bijl, Goessens & Visseren, 2006). According to the Flesch-Kincaid readability index, the BP self-efficacy scale had a reading grade level of grade 3.2 years.

BP Control Self Regulation

BP Control Self-Monitoring

BP control self-monitoring was measured as adherence to recommended guidelines for monitoring in the study: BP monitoring (twice daily X 90 days = 180), salt and fluid intake monitoring (twice weekly X 12 weeks = 24). This number was calculated as actual episodes of monitoring over recommended monitoring for the study. Thus, if an individual monitored their BP daily as compared to twice daily their adherence rate to BP monitoring was calculated as 90/180 or 50%. This data was used to determine if there were any relationships between level of monitoring and participation in self-care behaviors.

BP Control Self-Evaluation/Self Reinforcement

BP control self-evaluation was measured as number of weekly goals met (BP, salt and fluid) over 12 weeks. Thus, if a participant met their BP goals 9 out of 12 weeks, there adherence rate to meeting their goals was 75%. Fluid and salt intake self-evaluation were measured in the same way. Reinforcement was calculated as the number of times the participant was appropriately reinforced for goals related to BP, salt and fluid intake met over 12 weeks. The adherence rate for reinforcement was calculated in the same manner as adherence rates to goal setting.

BP Self-Care Behaviors

The BP self-care behaviors measured were fluid intake, salt intake, BP medication adherence and HD adherence.

Fluid Intake

Participant 24 hour fluid intake recall logs (Appendix F) were collected by the PI on a weekly basis in order to determine 24 hr fluid intakes. The logs were analyzed by the PI to determine total milliliters consumed over 24 hours. In addition, dialysis flow sheets were reviewed by the investigator for both treatment and control groups to determine average fluid gains in between HD treatments. Patients were weighed in the HD unit before HD treatments and after their HD treatments. Fluid gains or interdialytic weight gain (IDWG) were calculated by subtracting their weight after their last HD treatment from their weight before their next HD treatment. Three IDWGs were averaged in order to determine average weekly IDWG. Average IDWGs were compared to fluid logs to determine if there were consistencies between patient logs and actual fluid gains.

Salt Intake

Salt Intake was measured using a revised sodium intake check-list (Millar & Beard, 1988) (Appendix G). The most heavily salted foods in the typical Western diet are listed in the check-list. The check-list consists of 16 items which were to be answered in relation to the previous three days' salt intake with a frequency rating of zero to eight or more (Millar & Beard, 1988). The check-list takes approximately five minutes to complete. According to the Flesch-Kincaid readability index, the salt check list has a grade 6.2 reading level. The final checklist score is the sum of all the scores which can range from 0 indicating no salt intake to 128 indicating a very high salt intake. Baseline salt intake was compared to 12 week salt intake to determine if there was a significant change in salt intake.

According to Millar and Beard (1988), the most accurate way to measure salt intake is to analyze duplicate food samples, however this method was too labor intensive to conduct in this study. Another method would be to measure sodium chloride in urine. This method is limited because it only estimates 24 hr salt intake and does not explain what foods the patient actually consumed that were high in salt. The cost of attaining urine samples would also prohibit its use in this study. This checklist was chosen for the current study because it was designed to reduce the problems that have been encountered with previous questionnaires (Millar & Beard, 1988). It offers a comprehensive list of foods that are high in salt content. It assesses salt intake twice weekly which offers a more realistic assessment of salt intake as compared to many questionnaires that monitor salt intake once weekly. In addition, the check-list employs recognition memory as compared to recall memory which has been found to be superior in experimental studies (Millar & Beard, 1988).

The tool was tested in two samples: 1) 190 college students (Miller & Beard, 1988) and 2) 40 volunteers who were entering a Canberra Blood Pressure Trial (Beard, Cooke, Gray & Ellem, 1984) whose main goal was to return to a diet of natural, unsalted foods. Reliability was confirmed with a Cronbach α coefficient of .75 which indicates acceptable internal reliability. The checklist scores were also correlated to 24 hr urine sodium excretion and 24 hr urine potassium to sodium ratios and found to have a better correlation with 24 hr sodium excretion (r = .701, $p <. 001$) versus 24 hr potassium sodium ratio ($R = .51$, $p < .001$) indicating discriminant validity.

Medication adherence

Since adherence to medication regimens is very important for BP control in the HD population, adherence to the medication regimen was measured using the Morisky Scale (Appendix N). The Morisky Scale was used to measure adherence to antihypertensive treatment regimens at baseline and 12 weeks. The Morisky Scale (Morisky, 1986) has four items with dichotomous (yes/no) response options. The sum of yes responses provides a total score of nonadherence. Patients who scored "no" on all questions were classified as highly adherent and those who answered "yes" to at least one question were classified as having medium or low adherence. This scale, originally designed to evaluate medication adherence in hypertensive patients, has been validated and found to be reliable in a variety of medication adherence studies (Krapek et al., 2004; Sung et al., 1998; Patel & Taylor, 2002). According to the Flesch-Kincaid readability index, the reading level of this scale was at a grade two level

HD Adherence

To determine adherence to HD regimens, HD records were reviewed to calculate number of HD treatments missed over 12 weeks. Missing HD treatments results in fluid overload and increased BP in the HD patient. This data was correlated to outcome data and participation in self-care BP behaviors to determine if there were any relationships.

Health Outcome

Blood Pressure

Average BP was measured in the intervention and control groups at baseline, 12 weeks and 16 weeks. In both the experimental and control groups, average BP was operationalized by averaging three weekly prehemodialysis BPs from the HD flow sheets. In the treatment group, HD BPs were compared to BP logs and readings stored in the Omron BP machines to confirm accuracy.

Data Collection Procedures

Data collection occurred in five phases: informed consent, screening procedures, baseline data collection, intervention phase I, intervention phase II, intervention completion (12 weeks) and 16 week follow-up (*Figure.* 2)

Informed Consent

Once the medical director/nurse manager identified those patients who initially met inclusion criteria and were interested in participating in the study, the participants were approached by the PI to determine if they were interested in participating in the study. If the participants were interested, the study was explained in detail to potential participants and any questions were answered. If the subject agreed to participate, written informed consent was obtained (Appendix O).

Baseline Data

Baseline data collection included: a) An investigator developed personal data questionnaire (Appendix J), b) Modified Mini Mental State Exam (3MS) (Appendix A), and c) PHQ-9 (Appendix B). Subjects who scored less that 80 on the 3MS exam or greater than 15 on the PHQ-9 did not meet criteria for inclusion in the study. For those who met the inclusion criteria, the Morisky Scale (Appendix N), ENRICHD Social Support Instrument (ESSI) (Appendix K), BP Control in HD Knowledge Scale (Appendix L), and BP Control in HD Self-Efficacy Scale (Appendix M) were administered. All surveys were administered in the HD unit by the PI. The process took approximately 30 minutes.

Intervention Phase I

During week 1 of the study, the education sessions were conducted and no data were collected.

Intervention Phase II

Daily BP logs and weekly 24 hr fluid and salt intake checklists were collected by the PI and recorded in a data collection form. Pre HD BPs and interdialytic fluid gains were collected in the control group over a 12 week period. After 12 weeks the Self-Efficacy Tool, BP Control in HD Knowledge Scale, PHQ-9 and Morisky scale were administered by the PI to the intervention and control groups. The PI continued to collect average weekly BPs and fluid gains for four more weeks after the completion of the intervention to bring the completion of the study to 16 weeks.

Equipment Management

The following methods were used to ensure reliability. Each home BP monitor was checked against a mercury sphygmomanometer for accuracy within 3 mmHg before distribution. The home BP monitors were also checked for reliability by comparing machine readings to clinic BP readings prior to initiation of the study and on a monthly basis. HD staff and management were educated and monitored on accurate recording of weights and BPs in the HD units. Blood pressures were taken in the HD unit by an automatic BP monitor which is attached to the dialysis machine. The staff were instructed to take the participant's pre-HD BP after five minutes of rest in a sitting position using appropriate cuff size. The dialysis weight scale was calibrated on a weekly basis by the HD staff in order to ensure accuracy.

Data Management

All data were checked twice to ensure that there was no missing data and that scores from the instruments fell within the instrument scoring range. Demographic data and data from questionnaires were coded and entered into SPSS 17.0 data entry by the PI. Only the principal investigator had access to the data.

Missing Data

All data were checked twice by the investigator to ensure there were no missing or incorrect data. In the case of missing data from scales, case mean substitution was used to replace the missing data which involves replacing the missing value with the mean of the remainder of items for that case. In the case where all items were missing on a scale, group mean substitution was used to replace the missing data. This involved replacing the missing value for a composite score on a scale with the mean sample for that scale.

Testing for Parametric Assumptions

All data were screened and analyzed prior to data analysis in order to assure that the data met parametric assumptions about outliers, normality, linearity, homoscedasticity and collinearity.

Outliers

Data were examined for univariate and multivariate outliers. Univariate outliers were identified through the use of histograms and standardized scores or z-scores using a cut-off point of $z = \pm 3.29$ to identify outliers (Cohen, Cohen, West & Aiken, 2003). Raw scores from each instrument were converted to standardized scores or z-scores. Any raw score that represented a z-score of more than an absolute value of 3.29 (p = .001) was evaluated for a recording or input error.

Normality

All variables were examined for normal distribution with the assessment of skewness (symmetry of the sample distribution), kurtosis (peakedness of the sample distribution). Continuous variables were examined using statistics and histograms. Absolute skewness, kurtosis values and Fisher coefficients were used to determine deviation from the assumption of normality for each continuous variable. Any variable which suggested non-normality was transformed in order to normalize distribution for parametric use and increase statistical power (Cohen et al., 2003).

Linearity

The assumption of linearity assumes there is a linear relationship between two variables so that that the population means on the dependent variable at each level of the predictor variable are assumed to be a straight line (Cohen et al., 2003). Evaluation of bivariate and regression plots were used to assess compliance with the assumption of linearity. Transformations were conducted if the assumptions of linearity were not met.

Homoscedasticity

The assumption of homoscedasticity refers to the property that the standard deviations of errors of prediction are approximately equal for all predicted criterion scores (Cohen et al., 2003). Homoscedasticity was evaluated by examining standardized residual plots against predicted criterions.

Data Analysis Plan

Statistical analysis was conducted using SPSS version 17.0. Descriptive statistics were used to analyze all study variables. Demographic information was compared between the experimental and control group in order to determine the effectiveness of randomization. When significant differences in groups were found, covariate adjustment was conducted to minimize the effect of the differences.

Hypothesis testing was conducted to test the first two hypotheses in order to determine if there were significant differences in systolic and diastolic BPs between the two groups at 12 weeks and 16 weeks. Repeated measures ANCOVAs were conducted in order to determine if there were significant differences between the two groups in BPs over 16 weeks. Paired T-tests were also conducted to determine if there were significant within group differences in BPs over time.

In order to answer research questions one and two, Pearson correlations were conducted to determine if there were any relationships between BCFs (age, gender, race, education, income, comorbidities, depression and social support), BP control self-care capabilities (BP control knowledge, BP control self-efficacy and BP self-regulation behaviors) and BP self-care behaviors (fluid and salt intake, medication adherence and missed HD treatments).

To test hypothesis IIA and IIB, independent t-tests were used to determine if there were significant differences between the intervention and control groups in BP control knowledge and BP control self-efficacy scores. Repeated T-tests were conducted to determine if there were significant within group differences in BP Knowledge scores and BP control self-efficacy scores between baseline and 12 weeks. To test Hypothesis IIC, correlational analyses were conducted to determine if there were any relationships between BP control self-efficacy and BP self-regulation behaviors.

Correlational analyses were conducted to test the relationships between BP control knowledge and BP control self-care behaviors (Hypothesis IIIA), BP control self-efficacy and BP self-care behaviors (IIIB), self-regulation behaviors and BP control self-care behaviors

(Hypothesis IIIC). Correlational analyses were also conducted to determine if there were relationships between BP control self-care behaviors and BP (Hypothesis IVA).

To test Hypothesis IVB, a mediation analysis was conducted to determine if the relationship between the intervention and BP was mediated by BP self-care capabilities (BP knowledge, BP control self-efficacy, self-regulation) and BP self-care behaviors (fluid and salt intake, medication and HD adherence). In addition, multiple regression was conducted to determine the amount of variance in systolic and diastolic BP accounted for by BP self-care capabilities and BP self-care behaviors.

CHAPTER 4

Results

The major purpose of this quantitative study was to determine if a supportive educative nursing intervention would improve BP control in a chronic HD population. It was predicted that the intervention would improve self-care capabilities (BP knowledge, self-efficacy and self-regulation behaviors), which in turn would lead to improved adherence to: a) hypertensive self-care behaviors (i.e., fluid and salt intake, adherence to a prescribed medication regimen as well as maintenance of HD visits) and ultimately improved BP control. This study also examined the relationship between basic conditioning factors (age, gender, race, education, income, comorbidities, and social support), BP self-care capabilities and BP self-care behaviors.

The major purpose of this chapter is to describe the sample and the quantitative results of this study. The chapter is divided into two sections. The first section will describe the sample and study variables using descriptive statistics and the second section will outline the findings of the inferential statistics used to test the hypotheses.

Description of the Sample

One hundred and thirty participants were initially recruited to the study. Twelve participants did not complete the study for the following reasons: death (n = 3), attended another hemodialysis (HD) unit (n = 3), were hospitalized for an extended period of time (n = 2), or felt that the intervention was too labor intensive (n = 4). Participants were recruited from six outpatient HD units located in the metropolitan Detroit area. The demographic characteristics of the sample are described in Table 1.

An equal number of participants participated in the control group (n = 59) and the intervention group (n = 59). The average age of the sample was 59.69 years (SD = 15.98) with

Table 1

Frequency Distributions – Demographic Characteristics of the Sample (N = 118)

Variable	Intervention Group (n = 59) M (*SD*)/Frequency (%)	Control Group (n = 59) M(*SD*)/Frequency (%)	T test/Chi Square	*p*
Age	63.4 (16.4)	56 (14.8)	- 2.6	.01
Gender				
Male	28 (47)	32 (54)	.54	.46
Female	31 (53)	27 (46)		
Race				
AA	42 (71)	59 (100)	19.8	.00
Caucasian	14 (23.7)	0 (0)		
Middleastern	3 (5)	0 (0)		
Income				
< $5,000	1 (1.6)	11 (18.6)	20.8	.00
$5,000-$9,999	20 (33.8)	26 (44)		
$10,000-$19,999	14 (23.7)	15 (25.4)		
$20,000-$29,000	12 (20.3)	6 (10)		
$30,000-$49,999	7 (11.8)	0 (0)		
>$50,000	5 (8.5)	1(1.6)		
Educational Level				
≤ Grade 8	2 (3.4)	4 (6.8)	10.7	.64
Some High School	11 (18.6)	15 (25.4)		
HS Graduate	15 (25.4)	15 (25.4)		
Some College	20 (33.8)	21 (35.6)		
College Grad	11 (18.6)	4 (6.7)		
Employment				
Not employed	47 (80)	52 (88.1)	4.5	.10
Part-time	11 (18.6)	4 (6.8)		
Fulltime	1 (1.7)	3 (5.0)		
Married or Living With a Partner				
Yes	27 (45.8)	17 (28.8)	3.6	.06
No	32 (54.2)	42 (71.1)		

an age range of 19 to 91 years. There was a significant age difference t (116) = -2.6, p = .010) between the groups. The control group was significantly younger with an average age of 55.9 years (SD = 14.77) compared to 63 years (SD = 16.3 years) for the treatment group. The sample (N =118) consisted of 60 (51%) men and 58 (49%) women. Gender was not significantly different between the two groups $\chi^2(1, N = 118) = .54, p = .461$). The sample race composition consisted of 101 (86%) African Americans, 14 Caucasians (12%) and 3 Middle Eastern (2.5%) participants. A chi-square test showed there was a significant difference in groups n racial composition $\chi^2(2, N = 118) = 19.81$, p = .000. The control group was entirely represented by African Americans (n = 59, 100%). The treatment group was made of African Americans (n = 42, 71%), Caucasians (n = 14, 24%) and Middle Eastern (n = 3, 2.5%).

For the entire sample, the average years of education was 12.43 years (SD = 2.3) with a range of three to twenty years. Overall, the sample was not well educated. Six participants (5%) had a grade 8 or less level of education. Sixty two (52.5%) of the sample had completed some level of high school and fifty six (47%) had completed some level of college. The control and treatment groups were not statistically different in terms of educational level t(116) = -1.8, p = .072. The treatment group had an average mean educational level of 12.81 years (SD = 2.5 years) and the control groups had an average mean educational level of 12.1 years (SD = 2.1 years).

In terms of income, 58 (49.2%) of the sample had a total yearly household income of less then $10,000 which is considered below poverty level. Approximately 54 (45%) of the sample had a total household income between $10,000 to $50,000 and 6 (5%) had a total household yearly income of greater than $50, 000. The two groups differed significantly in income (χ^2 (2, N = 118) = 20.8, p = .00) with the control group having a significantly lower yearly income than the treatment group. Thirty seven (62%) of the participants in the control group had an annual household income of less than $10,000 dollars compared to 21 (36 %) participants in the treatment group (n = 21). Twenty one participants (36%) of the control group earned a yearly household income between $10,000 to $30,000 compared to 26 (44 %) participants in the treatment group. Only one participant (2%) in the control group earned an annual household income above $30,000 compared to the treatment group where twelve (20%) participants earned a yearly income of greater $30,000.

The majority of the sample were unemployed (n = 99, 83.9%). Approximately 15 (13%) of the sample were employed in a part-time status and only 4 (3.4%) were employed in a full-time status. The two groups were not significantly different in terms of employment status (χ^2 (2, N = 118) = 4.5, p = .104). In terms of being married or living with a partner, 74 (63%) participants in the sample indicated they were not married and 44 (37%) were married or living with a partner. The two groups were not significantly different in terms of marital status (χ^2(1,N = 118) = 3.62, p = .57).

Description of Health Status of Sample

Comorbid Conditions

Table 2 identifies the frequencies of comorbid conditions. In terms of comorbidities, approximately 50% of the sample had diabetes. Thirty eight (32%) of the sample had Type I dependent diabetes and 21 (17.8 %) had Type II dependent diabetes. Forty (34%) had atherosclerotic heart disease and 28 (24%) had congestive heart disease. Congestive heart failure was the only comorbid condition for which the incidence was significantly different between the two groups (t(109) = -2.19, p = .031). Nineteen (32%) of the participants in the treatment group had congestive heart failure compared to 9 (15%) participants in the control group.

Table 2

Comorbid Conditions of the Sample at Baseline (N = 118)

Variable	Intervention Group Frequency (%) (n = 59)	Control Group Frequency (%) (n = 59)	Chi Square χ^2	*p*
Type I Diabetes	23(39)	15(25.4),	2.5	.12
Type II Diabetes	9(15.3)	12(20.3)	.52	.47
Coronary Artery Disease	24(40.6)	16(27.1)	2.4	.12
Congestive Heart Failure	19(32.2)	9(15.3)	4.7	.03

BP Medications

The majority of the participants were taking blood pressure medications (*n* = 114, 96.6%). Only four participants (3.4%) were not taking any blood pressure medications. Table 3 identifies the frequencies of medications classes taken. In order of frequency, beta blockers were the most frequently used BP medication (*n* = 94, 79.7%), followed by calcium channel blockers (*n* = 65, 55.1%). Ace inhibitors were used by 57 (49.2%) participants of the sample and (*n* = 48, 41%) of the sample were taking alpha blockers. Twenty five (21%) participants of the sample were taking angiotensin receptor blockers. Diuretics were only used by (n = 13, 11%) of the sample. There were no significant differences between the groups in BP medication use except for diuretics (F(1.116) = 7.3, p = .008). Eleven participants (19%) in the treatment group were taking a diuretic compared to (*n* = 2, 3%) of the control group.

Table 3

Frequency Distributions – Blood Pressure Medications (N = 118)

Variable	Treatment Group Frequency (%) (*n* = 59)	Control Group Frequency (%) (*n* = 59)	Chi Square χ^2	*p*
Diuretics	11(18.6)	2(3.4)	7.0	.01
Beta-Blockers	49(83.1)	45(76.3)	.84	.36
Ace Inhibitors	25 (42.3)	33 (55.9)	2.2	.14
Angiotension Receptor Blockers	16 (27)	9 (15.3)	2.5	.12
Calcium Channel Blockers	35 (59.3)	30(51)	.85	.36
Alpha Blockers	27 (46)	21 (35.6)	1.3	.26

Table 4 identifies the numbers of BP medications taken. Sixty four participants (54%) in the sample were taking three or more blood pressure medications. Total medications taken by the sample ranged from zero to six. There was no significant difference in number of BP medications taken between the two groups $F(1, 116) = -1.8$, $p = .064$). The treatment group was taking an average of 2.4 ($SD = .99$) blood pressure medications and the control group was taking an average of 2.8 ($SD = 1.25$) blood pressure medications.

BP Medication Changes

Independent t-tests were conducted to determine if there were significant differences in BP medication changes between the two groups at the end of 12 weeks. A significant difference was found between the two groups at the end of 12 weeks (t (115) = - 2.1, $p = .04$). The treatment group had more changes in BP medications ($M = .73$, $SD = .45$) than the control group ($M = .54$, $SD = .50$).

Table 4

Frequency Distributions of Number of BP Medications

Number of BP Medications	Treatment Group Frequency (%) (*n* = 59)	Control Group Frequency (%) (*n* = 59)	Overall ind *t*-test	*p*
1	8 (13.6)	12 (20.3)	-1.8	.06
2	16 (27.1)	16 (27.1)		
3	20 (34)	25 (42.3)		
4	8 (13.6)	4 (6.8)		
5	5 (8.5)	1 (1.7)		
5	1 (1.7)	0 (0)		

Description of Baseline Blood Pressure and Fluid Gain

The intervention and control groups were not statistically different in terms of baseline systolic blood pressure (BP) $t(106) = .513$, $p = .609$. The average systolic BP was 163 mmHg ($SD = 10.3$) for the treatment group and 164 mmHg ($SD = 14.2$) for the control group. Baseline diastolic blood pressures (BPs) were significantly different between the two groups $t(116) = 2.7$, $p = .008$ with the treatment group having an average baseline diastolic BP of 84.9 mmHg and the control group having an average baseline diastolic BP of 89.5 mmHg. Average baseline fluid gains were not significantly different between the two groups $t(116) = .228$, $p = .820$). The treatment group had an average baseline fluid gain of 2.44 kg ($SD = 1.19$) and the control group had an average baseline fluid gain of 2.48 kg ($SD = .86$).

Summary

The participants in this sample were predominately African American, not well educated with an average age of 60 years. Almost half of the sample earned a total household yearly income below poverty level and the majority of the sample were unemployed. The sample was made up equally of males and females. The control group was entirely African American, significantly younger, and had less yearly income than the treatment group. In terms of comorbidities, 50% of the sample had diabetes, 33% of the sample had preexisting atherosclerotic heart disease and 25% of the sample had congestive heart failure (CHF). The only significant comorbid condition between the two groups was CHF which was more prevalent in the treatment group. The majority of the sample was taking BP medications with half of the sample taking three or more BP medications to help control their BP. The two groups were not statistically different in systolic BPs or fluid gains at baseline, but were statistically different in diastolic BP with the control group having a statistically significant greater diastolic BP.

Description of Major Study Variables

The following section will describe the findings of the major study variables at baseline and 12 weeks. Descriptive statistics were used to summarize the variables (Table 5).

Social Support

The average mean social support score for the sample was 29.32 (*SD* = 4.75) with a range of scores from 9 to 38. There was a significant difference between the two groups in social support scores $t(116) = -2.08$, $p = .04$. The mean score of the control group was 28.42 (*SD* = 4.38), slightly lower than the mean score of the treatment group (*M* = 30.22, *SD* = 5.0) which indicated that the treatment group had a significantly higher level of social support compared to the control group.

Depression

Table 5 identifies the summary statistics for depression scores for both the treatment and control groups. The total mean baseline depression score for the sample was 10.97 (*SD* = 1.60)

Table 5

Study Variables Summary Statistics (N =118)

Variable	Baseline Mean (*SD*)	Between Group *t*-test, (*p*)	12 Week Follow-up Mean (*SD*)	12 Week Within Group t-test, (*p*)	12 Week Between Group *t*-test, (*p*)
Social Support					
Treatment (*n* = 59)	30.2 (5.0)	-2.1, (.04)			
Control (*n* = 59)	28.4 (4.3)				
Depression					
Treatment (*n* = 59)	11 (1.7)	-.12, (.91)	11 (1.5)	.17, (.87)	-1.6, (.11)
Control (*n* = 59)	11 (1.5)		10.5 (1.2)	3.2, (.00)	
BP Knowledge					
Treatment (*n* = 59)	42.5 (4.7)	2.4, (.02)	43 (6.5)	-.74, (.47)	1.4, (.16)
Control (*n* = 59)	44.5 (4.1)		44.5 (4.1)	.32, (.75)	
BP Self-Efficacy					
Treatment (*n* = 59)	49 (4.2)	- 1.8, (.07)	49.4 (4.0)	-1.0, (.32)	-.86, (.07)
Control (*n* = 59)	47.5 (4.4)		48.7 (4.8)	-3.1, (.00)	

with scores ranging from 4 to 14. At 12 weeks, the total mean depression score was slightly lower at 10.75 (*SD* = 1.37), with scores ranging from 9 to 14. According to the depression assessment tool used for this study (PHQ-9), the sample score indicated a minor level of depression. At baseline, the average depression score was 10.95 (*SD* = 1.5) in the control group and 10.98 (*SD* = 1.7) in the treatment group. After 12 weeks, the depression scores decreased significantly in the control group (*M* = 10.54, *SD* = 1.23) (*t*(58) = 3.2, *p* = .00) and remained the same in the treatment group (*M* = 10.95, *SD* = 1.5) (*t*(58) = .165, *p* = .87). The two groups were not significantly different in depression scores at baseline (*t*(116)= -.115, *p* = .91) or at 12 weeks (*t*(116) = -1.62, *p* = .11).

BP Self-Care Capabilities

BP Knowledge

Patients had fairly good levels of knowledge about blood pressure control behaviors at baseline and there were no significant improvement in scores at 12 weeks. BP knowledge scores for the sample ranged from a minimum of 17 to a maximum of 49 with higher scores indicating more BP knowledge. The mean BP Control in HD Knowledge score for the sample was 43.5 (*SD* = 4.5) at baseline and 43.9 (*SD* = 4.7) at 12 weeks. At baseline, the treatment group (*M* = 42.5, *SD* = 4.7) had a statistically significant lower BP knowledge score than the control group (*M* = 44.5 *SD* = 4.1) (*t* = 2.4, *p* = .02). This indicates that the treatment group scored 87% correct on the BP knowledge test compared to the control group who scored 91% correct at baseline. At 12 weeks, the treatment group's score increased slightly to 43.4 (*SD* = 5.5) (88% correct) with no change in the control groups' score 44.4 (*SD* = 3.8) (91% correct). BP knowledge scores were not significantly different between the two groups at 12 weeks (*t* = 1.2, *p* = .25).

To assess whether the seven items that were summed to create the BP knowledge score formed a reliable scale, Cronbach's alpha was computed. The alpha for the BP knowledge scale was .62 which indicates a questionable level of internal consistency. A Pearson's correlation (r(118) = .80, p = .00) was computed to assess test-retest reliability of the BP knowledge test scores at baseline and 12 weeks, which indicated a good test-retest reliability.

BP Control Self- Efficacy

At baseline, the mean BP self-efficacy score in the entire sample was 48.23 (SD = 4.36). The scores ranged from a minimum of 36 to a maximum of 55 with higher scores indicating more self confidence in participating in BP self-care behaviors. At 12 weeks, the overall BP self-efficacy score increased slightly to 49.1 (SD = 4.4) with mean scores ranging from 35 to 55. At baseline, the treatment group had a higher BP self-efficacy score (M = 49, SD = 4.2) than the control group (M = 47.5, SD = 4.4). However, the difference in BP self-efficacy scores between the two groups was not significant (t = -1.8, p = .07). At 12 weeks, the treatment group's BP self-efficacy score remained virtually unchanged (M = 49.4, SD = 4). Interestingly, the control group's BP self-efficacy score increased from 47.5 (SD = 4.4) to 48.7 (SD = 4.8) at 12 weeks. There were no significant differences in BP self-efficacy scores between the two groups at 12 weeks (t = -.86, p = .39).

To assess the internal consistency of the BP Self-efficacy Scale, Cronbach's alpha was computed. The alpha was .74 which indicated that the items from the scale had a reasonably good internal consistency. The only item that had very low item-total correlation was item 11: "I can attend my weekly HD treatments". The cronbach's alpha would only increase to .75 if the item was removed. These results are similar to results found in previous studies. The internal consistency of the original scale was α = 0.81 (Bijl et al., 1999). The scale was also revised and tested in a sample of 236 patients with recently established vascular disease and found to have internal consistencies of 0.78 (Berna et al., 2006). A Pearson's correlation ($r(118) = .73$, $p = .00$) was computed to assess test-retest reliability of the BP Self-Efficacy scale at baseline and 12 weeks and indicated good test-retest reliability.

Blood Pressure Control Self Regulation

Self-Monitoring

Adherence rates to self monitoring behaviors were determined by dividing the number of self-monitoring logs (BP, salt and fluid) completed by the participant by the total number of self-monitoring logs requested of the participants. The total number of logs requested of the treatment participants was: BP monitoring (twice daily X 90 days = 180), salt and fluid intake monitoring (twice weekly X 12 weeks = 24). Table 6 identifies the number of logs collected and adherence rates to recommended logs.

Adherence rates for BP logs ranged from 0% to 100% with an average mean of 42% adherence rate. Approximately 20.3% (n = 11) of the treatment group did not complete any of the BP logs. Nearly 26% (n = 15) of the treatment group completed 100% of their logs. Participants in the treatment group were even less adherent to recording salt and fluid logs. The average mean adherence rate for salt logs was 11% and 12% for fluid logs. Many of the participants complained that there were too many forms to fill out on a weekly basis, so the participants were only asked to fill out one salt and fluid log on a weekly basis compared to the two logs originally requested. The range of adherence to recording salt logs was zero to six logs. The range of adherence to recording fluid logs was zero to 12 logs. Only one participant had 100% adherence to recording 12 fluid logs. No participant completed all 12 of the recommended salt checklists. Approximately 44% (n = 26) of the treatment group did not record any salt logs or fluid logs.

Table 6

Self Monitoring Behaviors - Adherence to Logs (n = 59)

Logs	Average Logs Recorded Mean (range)	Logs Recommended	Adherence Rate (%)
BP	76 (0 – 180)	180	42
Salt	1.3 (0 – 6)	12	11
Fluid	1.4 (0 – 12)	12	12

Self Evaluation Behaviors

BP, fluid and salt logs were reviewed by the PI with the participant on a weekly basis to determine if predetermined goals had been met (Table 7). If goals related to BP, salt and fluid intake were met, positive verbal reinforcement was given. Since the majority of the participants did not indicate on their logs whether or not goals had been met, evaluation of goals met was done mutually with the PI during weekly follow-up visits. Participants met their BP goals an average of 4.3 weeks out of the 12 weeks (36%), with some participants meeting their goals every week and others never meeting their BP goals during any of the 12 weeks. Participants were more successful in meeting their fluid goals compared to their BP goals during the intervention period. Participants met their goal for fluid adherence an average of 7 out of 12 weeks (61%). The sample was most successful with meeting their salt goals. Participants met their goals 93% of the time with decreases in salt intake with most successive logs.

Table 7

Self-Evaluation/Reinforcement Behaviors (*n* = 59)

Goal	Weekly Goals Met (M, *SD*)	Range (Min – Max)	Adherence Rate (%) Mean/12 weeks
Blood Pressure	4.3 (3.2)	12 0 - 12	36
Fluid	7.3 (4.4)	12 0 – 12	61
Salt	6 (.8)	1 5 - 6	94

Self Reinforcement Behaviors

As indicated earlier, with goal setting, the majority of the participants did not complete the second page of their BP, salt and fluid logs indicating whether or not they had reinforced themselves for goals met. This was done mutually by the PI and participant during weekly follow-up visits. If goals were met, the participant received positive verbal reinforcement by the PI. The rates of reinforcement were the same as weekly goals met as indicated in Table 7.

BP Self-Care Behaviors

Table 8 identifies the descriptive statistics for BP Self-Care Behaviors (fluid gains, salt intake, BP medication adherence and missed hemodialysis treatments).

Average Fluid Gains

Total average fluid gains, i.e., gain in fluids retained between HD treatments, for the sample (*N* = 118) was 2.5 kg (*SD* = 1.0) at baseline, 2.5 kg (*SD* = 1.1) at 12 weeks and 2.4 kg (*SD* = 1.1) at 16 weeks. Fluid gains for the sample ranged from a minimum of .10 kg to 6.7 kg. Average fluid gains were not significantly different between the control (*M* = 2.48, *SD* = .86) and treatment groups (*M* = 2.44, *SD* = 1.2) at baseline $t(116) = .228$, $p = .820$.

Table 8

BP Self-Care Behaviors (N = 118)

Variable	Baseline M(*SD*)	Ind *t*-test *t*(*p*)	12 Week M(*SD*)	Ind *t*-test *t*(p)	Paired *t*-test *t*(*p*)	16 Week M(*SD*)	Ind *t*-test *t*(*p*)	Paired *t*-test *t*(*p*)
Average Fluid Gain								
Treatment	2.4(1.2)	.23(.82)	2.4(1.1)	.37(.72)	0.01(.96)	2.4(1.2)	.14(.89)	.13(.90)
Control	2.5(.86)		2.5(.97)		-.38(.70)	2.5(1.0)		.23(.82)
Average Salt Intake								
Treatment	18.5(10.9)		13.5(5.0)					
Med Adherence								
Treatment	.83(1.0)	.28(.78)	.78(.98)	1.0(.30)	.44(.67)			
Control	.88(.93)		.98(1.1)		-.76(.45)			
Missed HD Treatments								
Treatment			.75(.99)	2.4(.02)				
Control			1.4(1.7)					

After 12 weeks, average fluid gains were not significantly different between the treatment (*M* = 2.44, *SD* = 1.12) and control groups (*M* = 2.51, *SD* = .97) (*t*(116) = .372, *p* = .71). At 16 weeks, fluid gains were not significantly different between the control (*M* = 2.46, *SD* = 1.01) and treatment groups (*M* = 2.42, *SD* = (1.1), *t*(115) =.208, *p* = .84. There were no significant differences within each group for fluid gains from baseline to 12 or 16 weeks (Table 8).

Salt Intake

Average salt intake was measured using a sodium intake check-list. Total salt checklist scores can range from 0 to 128 with a score of 128 indicating a very high salt intake. The control group did not participate in recording salt intake. Average salt intake for the treatment group was 14.8 (*SD* = 8.7) indicating a low salt intake with a range of 4 to 53 (Table 8). The average salt intake decreased from a mean of 18.5 (*SD* = 10.9) at baseline to 13.5 (*SD* = 5.0) at 12 weeks. Repeated measures ANOVA was conducted and found no significant pattern of change in salt intake over 12 weeks (*F*(5) = 2.6, *p* = 1.6).

Blood Pressure Medication Adherence

For the entire sample, medication adherence scores ranged from zero (100% adherence) to four (maximum non-adherence) with an average mean score of .86 (*SD* = .97) at baseline and .88 (*SD* = 1.1) at 12 weeks. According to the Morisky scale, those who answer “yes” to at least one question are classified as having medium or low adherence. This indicates that overall, the sample had a medium level of medication adherence. At baseline, the control and treatment groups were not significantly different in total BP medication adherence scores *t*(116) =.28, *p* = .78, with the control group having an average mean score of .88 (*SD* = .93) and the treatment group having a slightly lower average mean score of .83 (*SD* = 1.0).

After 12 weeks, there were no significant differences between groups in medication adherence scores (116) = 1.05, *p* = .297. The control group had a higher average score (M = .98, *SD* = 1.1) than the treatment group (*M* = .78, *SD* = .98) indicating less adherence to BP medication regimens in the control group. There were no significant changes in medication adherence scores from baseline to 12 weeks within the treatment (*t*(58) = .44, *p* = .66) or control groups (*t*(58) = - .76, *p* = .45). A Pearson's correlation was computed to assess test-retest reliability of the Morisky medication adherence scores, *r*(118) = .56, *p* = .00 which indicates a moderate level of correlation. To assess whether the Morisky scale formed a reliable scale, Cronbach's alpha was computed. The alpha for the four items was .62 which indicates a moderately reliable scale. Two of the items scored low on the item total correlation. Item three: "When you feel better do you sometimes stop taking your medicine" scored .27. Item four: "Sometimes if you feel worse when you take the medicine do you stop taking it?" scored .30. However removing either item would only minimally increase the alpha to .63 and .62

HD Attendance

The overall average missed HD treatments was 1 (*SD* =1.4) with a range of zero to six missed HD treatments (Table 8). The two groups were significantly different in missed HD treatments at 12 weeks *t(*94) = 2.39, *p* = .019. The control group missed more HD treatments at 12 weeks (*M* = 1.4, *SD* = 1.7) than the treatment group (*M* = .75, *SD* = .99).

Blood Pressure

Table 9 identifies the average BPs in the control and treatment groups at baseline, 12 weeks and 16 weeks. The average systolic BP did not significantly differ between the two groups at baseline *t*(106) = .51, *p* = .61. At baseline, the average systolic BP of the control group was 164 mmHg (*SD* = 14.2) and 163 mmHg (*SD* = 10.3) in the treatment group. However, there was a significant difference between the two groups in DBP $t(116) = 2.7$, $p = .008$ at baseline. The baseline diastolic BP was higher in the control group (M = 89.9 mmHg, SD =10.7) than the diastolic BP in the treatment group (M = 84.9 mmHg, SD = 9.0).

Table 9

Mean Blood Pressures at Baseline, 12 weeks and 16 Weeks by Treatment Group (N=118)

Variable	Baseline Mean (SD)	Between Group *t*-test *t*(p)	12 Week Mean (SD)	Between Group *t*-test *t*(p)	Within Group *t*-test *t*(p)	16 Week Mean (SD)	Between Group *t*–test *t*(p)	Within Group *t*-test 12–16wk *t*(p)	Overall Within Group t-test *t*(p)
SBP									
Treatment (*n* = 59)	163 (10.3)	.51 (.61)	155 (10.5)	3.0 (.00)	7.0 (.00)	153.5 (12.2)	2.5 (.01)	1.5. (.15)	6.4 (.00)
Control (*n* = 59)	164 (14.2)		161.9 (13.5)		1.8, (.08)	160 (14.8)		1.5 (.15)	2.4 (.02)
DBP									
Treatment (*n* = 59)	84.9 (9.0)	2.7 (.01)	82.2 (9.5)	.48 (.00)	4.1 (.00)	81 (9.5)	3.3 (.00)	2.4 (.02)	4.8 (.00)
Control (*n* = 59)	89.9 (10.7)		88.4 (10.3)		2.0, (.05)	86.8 (9.9)		2.1 (.04)	3.2 (.00)

Covariates

The variables found to be significantly different between the treatment and control group at baseline were: age, income, comorbidity CHF, use of diuretics, social support, BP knowledge and diastolic BP. Social support was the only significant variable found to be related to systolic BP and was controlled for when conducting repeated measures ANCOVA. Baseline diastolic BP and social support were the only significant variables found to be correlated with average diastolic BP and were controlled for when conducted repeated measures ANCOVA.

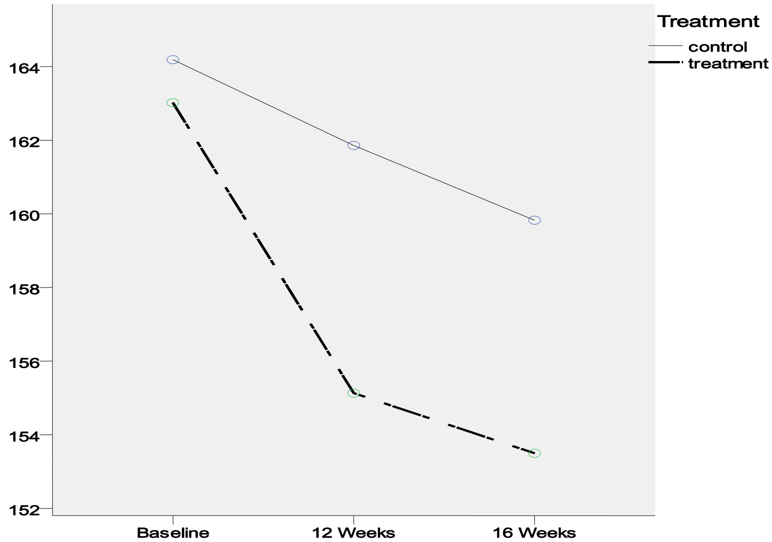
Hypotheses

Hypothesis 1 A: Chronic HD patients randomized to a 90 day supportive educative intervention will have a decrease in SBP at 12 and 16 weeks compared to the usual care group.

This hypothesis was supported by the data (Table 9). Overall, there was a significant difference in systolic BP between treatment and control groups at 12 weeks (t = 3.02, p = .003) and 16 weeks (t = 2.53, p = .013), with the treatment group having significantly lower systolic BPs (Table 9, Figure 4). At 12 weeks, the treatment groups' average systolic BP was 155 mmHg (*SD* = 10.5) compared to 161.9 mmHg (*SD* = 13.5) in the control group. At 16 weeks, the treatment groups' average systolic BP remained significantly lower at 153.5 mmHg (*SD* = 12.2) compared to 160 mmHg in the control group (*SD* = 14.8) (Figure 4).

Paired t-tests were conducted to determine if there was a significant decrease in systolic BPs from baseline to 12 and 16 weeks within both groups. There was a significant decrease in systolic BP in the treatment group from baseline to 12 weeks ($t(58)$ = 7.0, p = .00). The treatment group's systolic BP decreased from 163 mmHg (*SD* = 10.3) to 155 mmHg (*SD* = 10.5) at 12 weeks. Although the systolic BP continued to decrease in the treatment group to 153.5 mmHg from 12 weeks to 16 weeks, the decrease in systolic BP was not significant (t (58) = 1.5, p = .15). Overall, there was a significant decrease in systolic BP from baseline to 16 weeks (t (58) = 6.4, p = .000); the SBP decreased from 163 mmHg to 153.5 mmHg. The control group's systolic BP decreased nonsignificantly from 164 mmHg (*SD* = 14.2) at baseline to 161.9 mmHg (*SD* = 13.52) at 12 weeks ($t(58)$ = 1.8, p = .08). There was also a nonsignificant decrease in systolic BP in the control group from 161.9 mmHg at 12 weeks to 160 mmHg (*SD* = 14.8) at 16 weeks ($t(58)$ = 1.5, p = .15) (Table 9). However, there was a significant overall decrease in systolic BP in the control group from baseline to 16 weeks ($t(58)$ = 2.4, p = .02); the systolic BP

Figure 4 Systolic Blood Pressure at Baseline, 12 Weeks and 16 Weeks

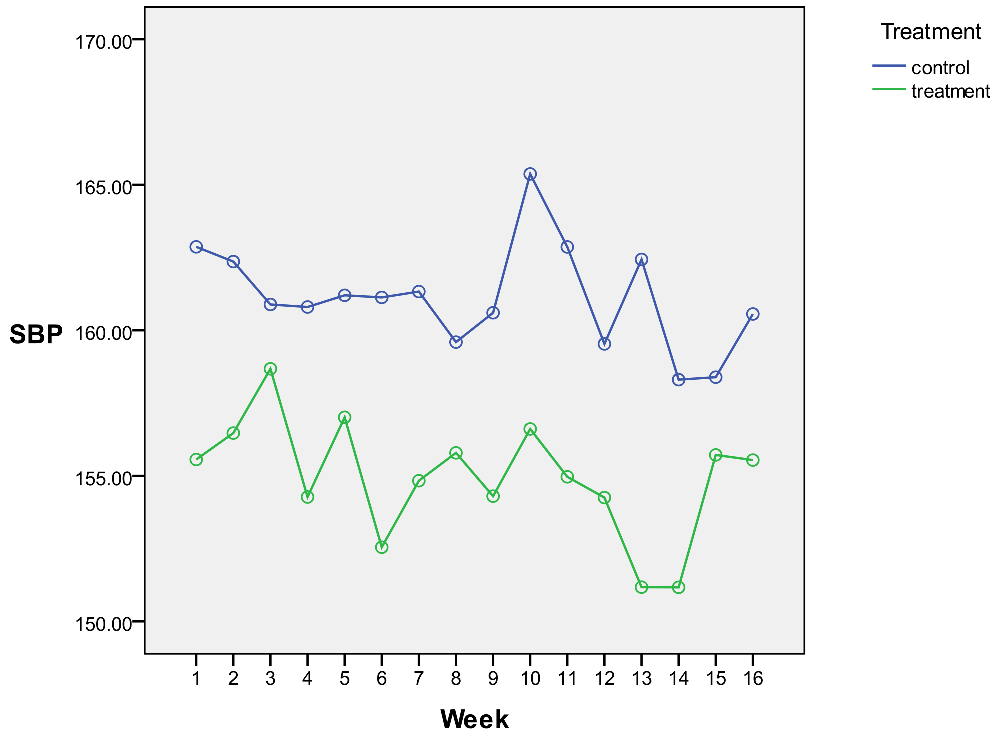


decreased from 164 mmHg (*SD* = 14.2) to 160 mmHg (*SD* = 15).

Multivariate repeated measures analysis of covariance was used to determine the change in BP within subjects, between groups, and within-subject-by-between-group interaction over 16 weeks (Figure 5). The covariates used in the analysis were age, income, co-morbidity CHF, diuretic use, social support and baseline BP knowledge. Among the covariates used, only social support was significantly related to SBP ($F(15) = 2.1$, $p = .02$). Thus, the analysis was repeated to include only social support as the significant covariate.

Since Mauchly's test indicated that the assumption of sphericity had been violated, χ^2 (119) = 186, $p = .000$, the degrees of freedom were corrected for using Huynh-Feldt estimates of sphericity ($\varepsilon = .93$). Using multivariate testing, a significant overall main effect change was found in systolic BP ($F = 2.3$, $p = .001$) over the 16 weeks. However, the pattern of change in systolic BP was not significant between the groups ($F = 1.2$, $p = .32$).

Figure 5 Pattern of Weekly SBP over 16 Weeks

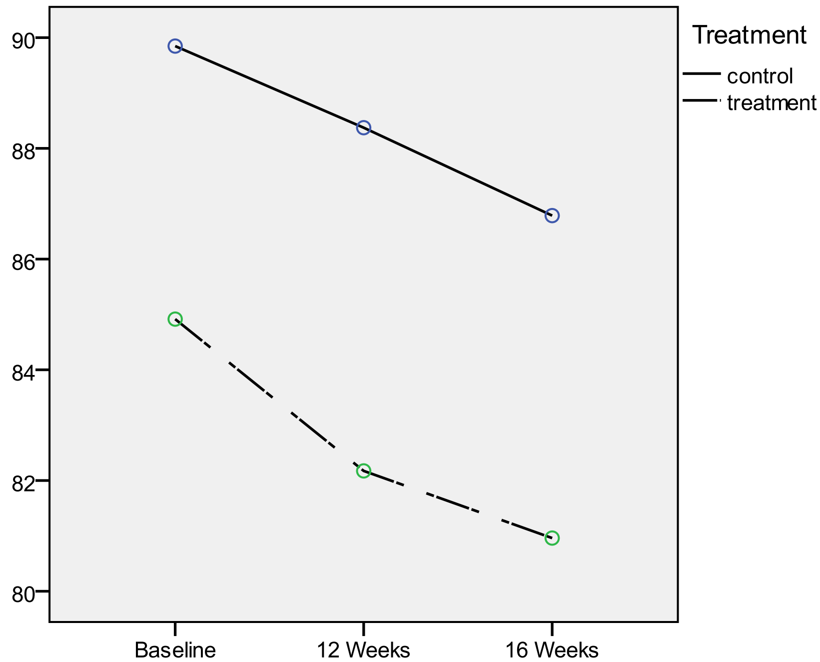


Covariates appearing in the model are evaluated at the following values: TotSS = 29.32

Hypothesis IB: Chronic HD patients randomized to a 90 day supportive educative intervention will have greater decrease in DBP at 12 weeks and 16 weeks compared to the usual care group.

The major aim of this hypothesis was to determine if there was a significant difference in diastolic BP between the two groups at 12 and 16 weeks. This hypothesis was supported by the data (Table 9, Figure 6). Diastolic BPs were significantly different between the treatment and control group at baseline (t = 2.71, p = .008). There were significant differences in diastolic BPs between the two groups at 12 weeks (t = .48, p = .001) and 16 weeks (t = 3.3, p = .001) (Table 9). At 12 weeks, the treatment group's diastolic BP was significantly lower at 82.2 mmHg compared to 88.4 mmHg in the control group and at 16 weeks the treatment group's diastolic BP was significantly lower at 81 mmHg (*SD* = 9.5) compared to 86.8 (*SD* = 9.9) in the control group (Figure 6).

Figure 6 Diastolic Blood Pressures at Baseline, 12 Weeks and 16 Weeks

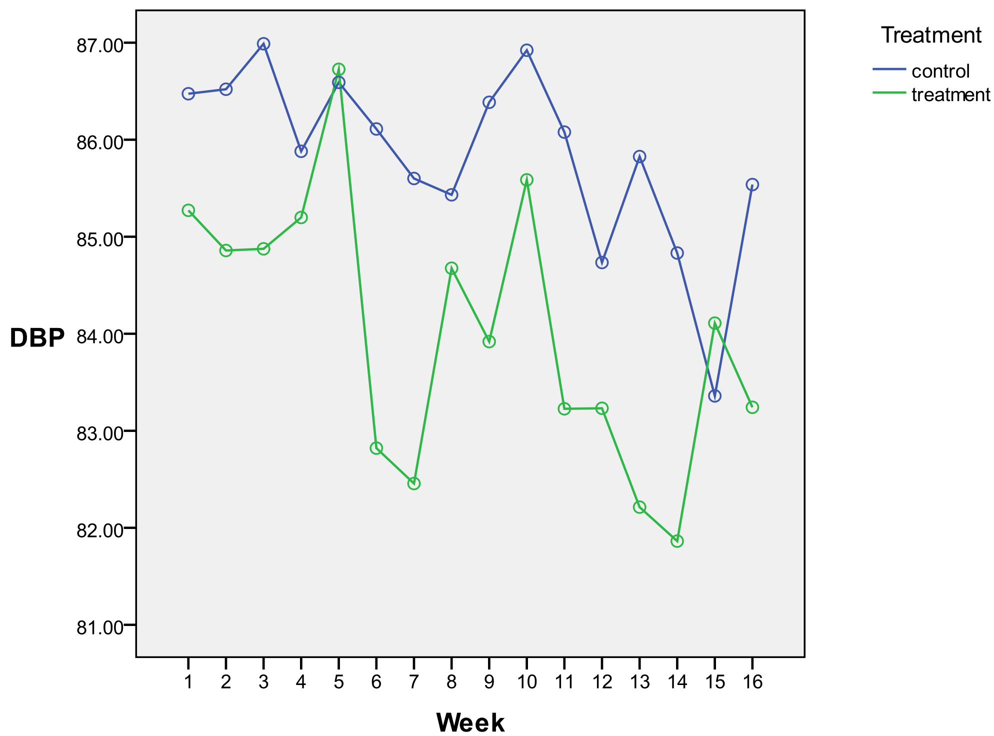


Paired *t*-tests were also conducted to determine if there was a significant decrease in diastolic BPs from baseline to 12 and 16 weeks in the treatment and control groups. There was a significant decrease in diastolic BP in the treatment group from baseline to 12 weeks where the average diastolic BP decreased from 84.8 to 82.2 mmHg ($t(58) = 4.1$, $p = .000$). The diastolic BP in the treatment group continued to decrease significantly from 82.2 mmHg at 12 weeks to 81 mmHg at 16 weeks ($t = 2.4$, $p = .02$). Overall, there was a significant decrease in diastolic BP in the treatment group from baseline to 16 weeks ($t = 4.8$, $p = .00$).

The average diastolic BP in the control group decreased nonsignificantly from 90 mmHg at baseline to 88.4 mmHg at 12 weeks ($t(58) = 2.0$, $p =.054$). The diastolic BP continued to decrease significantly from 88.4 mmHg at 12 weeks to 86.8 mmHg at 16 weeks ($t\ (58) = 2.1$, $p =$

.04). Overall, there was a significant decrease in diastolic BP in the control group; the diastolic BP decreased from 90 mmHg at baseline to 86.8 mmHg at 16 weeks (t = 3.2, p = .00).

Figure 7 Pattern of Weekly Diastolic BP over 16 Weeks



Covariates appearing in the model are evaluated at the following values: PreDBP = 87.38, TotSS = 29.32

Multivariate repeated measures analysis of covariance was used to determine the change in diastolic BP within subjects, between groups, and within-subject-by-between-group interaction over 16 weeks (Figure 7). The covariates used in the analysis were age, income, co-morbidity CHF, diuretic use, social support and baseline BP knowledge. Among the covariates used, only baseline diastolic BP (F = 2.39, p = .01) and social support (F = 1.9, p = .03).were significantly related to DBP. Thus, the analysis was repeated to include only baseline diastolic BP and social support as significant covariates.

Since Mauchly's test indicated that the assumption of sphericity had been violated ($\chi^2(119) = 199$, $p = .00$), the degrees of freedom were corrected using Huynh-Feldt estimates of sphericity ($\varepsilon = .92$). Using multivariate testing, a significant overall main effect change was found in diastolic BP ($F = 2.04$, $p = .02$) over the 16 weeks. However the pattern of change in diastolic BP was not significant between the groups ($F = 1.1$, $p = .38$).

Research Question 1: Is there a relationship between BCFs (i.e. age, gender, race, education, income, comorbidities and social support) and BP self-care capabilities (i.e., knowledge level, self-efficacy, adherence to self-monitoring, self-evaluation and self-reinforcement).

Pearson correlations were run to determine if there were any significant relationships found between BCFs and BP self-care capabilities (BP knowledge, BP control self-efficacy) and BP self regulation behaviors (monitoring, self evaluation, self-reinforcement) (Table 10 and 11). Table 10 identifies the significant relationships between BCFs, BP knowledge and BP self-efficacy and Table 11 identifies significant relationships between BCFs and self regulation behaviors (monitoring, self-evaluation and self-reinforcement).

Correlations Between BCFs and Self-Care Capabilities

Age was found to be significantly correlated with baseline ($r = .29$, $p = .00$) and 12 week BP self-efficacy scores ($r = .37$, $p = .00$) in the entire sample. These findings indicate that increased age may be related to increased confidence in BP self-care. Social support was also found to be related to 12 week BP self-efficacy scores in the entire sample ($r = .19$, $p = .04$).

None of the BCFs were found to be related to BP knowledge except for baseline depression scores ($r = -.19$, $p = .04$), indicating that increased levels of depression may be related to decreased BP knowledge. Twelve week depression scores were also found to be inversely significantly related to 12 week BP knowledge scores ($r = -.33$, $p = .00$).

Table 10

Correlations Between BCFs and BP Self-Care Capabilities (BP Knowledge, BP Self-Efficacy)(N = 118)

BCFs	Baseline BP Knowledge	12 Week BP Knowledge	Baseline BP Self-Efficacy	12 Week BP Self-Efficacy
Age	.15	.13	.29**	.37**
Gender	.03	.05	.04	.10
Race	-.13	-.09	.07	.07
Education	-.02	.00	-.03	-.05
Income	-.04	-.04	.06	.09
Total CM	-.02	-.05	-.07	-.03
Social Support	-.06	-.14	.09	.19*
Baseline Depression	-.12	-.19 *	-.12	-.16

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

Pearson correlations were conducted to determine relationships between BCFs and self-regulation behaviors (Table 11). Income was found to be related to increased BP self-monitoring (*r* =.29, *p* < .05). No other relationships were found between the BCFs and BP, fluid or salt self-monitoring. Significant relationships were found between age and fluid goals met and reinforced (*r* = .41, *p* < .00) indicating that the elderly met more goals related to fluid gains. Gender was also found to be related to fluid goals met reinforced (*r* = .43, *p* < .001) indicating that females met more weekly fluid goals compared to males. Education was found to be inversely related to fluid goals met (*r* = -.28, *p* < .05), indicating that participants with higher education met less of their weekly fluid goals.

Table 11

Correlations between BCFs and Self-regulation Behaviors (N= 118)

BCFs	BP SM	Fluid SM	Salt SM	BP Goal setting	Fluid Goal setting	Salt Goal setting	BP Goal Reinforce ment	Fluid Goal Reinforce ment	Salt Goal Reinforce ment
Age	.09	-.12	-.12	.17	.41**	-.29	.17	.41**	-.29
Gender	.04	-.03	.02	.08	.43**	-.16	.08	.43**	-.16
Race	.08	-.02	-.02	-.13	-.22	-.19	-.13	-.22	-.19
Education	.12	.07	.08	.21	-.28*	-.07	.21	-.28	-.07
Income	.29 *	-.02	.07	-.03	.00	.09	-.03	.00	.09
Total CM	-.07	.12	.09	.16	-.10	-.05	.16	-.10	-.05
Social Support	.16	.15	.14	-.04	-.05	.17	-.04	-.05	.17
Baseline Depression	.04	.03	.08	.06	.26*	.04	.06	.26*	.04

Note * p < .05, ** p < .001

Research Question 2: Is there a relationship between BCFs (i.e. age, gender, race, education, income, comorbidities and social support) and BP self-care behaviors (salt and fluid intake, medication adherence and HD adherence)?

Pearson correlations were conducted to determine if there were significant relationships between BCFs and BP self-care behaviors (salt and fluid intake, medication adherence and HD adherence) (Table 12). Age was found to be inversely related to fluid gains (*r* = -.37, *p* = .00) indicating that elderly individuals consume less fluid. Age was also found to be significantly correlated with baseline medication adherence (*r* = -.186, *p* = .04) and 12 week medication adherence scores (*r* = - .29, *p* = .002) indicating that the elderly were more adherent to medication regimens. Age was also found to be inversely related to missed HD treatments (*r* = -.37, *p* = .00) and diastolic blood pressures (*r* = -.60, *p* = .00).

Table 12

Correlations between BCFs and BP Self Care Behaviors (N=118)

BCFS	Salt Intake	Fluid Intake	Medication Adherence	Missed HD Treatment
Age	-.20	-.37**	-.29**	-.39**
Education	.37*	.15	-.03	-.05
Income	.41*	.03	.04	-.04
Total CM	-.10	-.01	.23*	.03
Social Support	-.05	-.03	.05	-.22*
Baseline Depression	.23	-.24	.24**	.05

Note * p < .05, ** p < .001

Gender was found to be inversely related to fluid gains (*r* = -.28, *p* = .00) indicating females gained less fluid. Females gained an average of 2.2 kg in fluid between HD treatments and males gained an average of 2.8 kg. Gender was also found to be inversely related to diastolic BP in the overall sample (*r* = -.23, *p* = .01) indicating that being female may be related to lower diastolic BP. Race was found to be related to missed HD treatments (r = .22, p = .02) indicating that African Americans missed more HD treatments (M = 1.2) than Caucasians (M = .29).

Education was found to be positively correlated with salt intake (r = .37, p = .04) in the treatment group indicating a relationship between higher education and higher salt intake. Income was also found to be related to increased fluid gains (r = .28, p = .03) and diastolic BPs (r = .36, p = .01). Total comorbidities (CM) was related to baseline medication adherence in the overall sample (r = .23, p = .01) indicating that increased CM resulted in decreased medication adherence. However, no significant relationship was found between total CM and 12 week medication adherence scores. Total CM was also found to be inversely related to diastolic BP in the entire sample (r = -.22, p = .02) indicating that increased CM may be related to decreased diastolic BP.

Social support was found to be significantly related to missed HD treatments in the overall sample (r = -.22, p = .02). A significant inverse relationship was found between social support and diastolic BP (r = - .37, p =.00) indicating that increased social support was related to decreased diastolic BP. Baseline depression scores were found to be inversely correlated to fluid gains (r = -.24, p = .01) and medication adherence scores (r = .24, p = .01). These findings indicate a relationship between increased depression, decreased fluid intake and decreased medication adherence.

Correlations were also found between medication adherence (r =.22, p = .02) and missed HD treatments indicating that non adherence in one area of BP self-care was related to nonadherence in other areas of BP self-care. Total missed HD treatments was found to be related to increased fluid gains (r = .26, p = .00).

Summary

Age was found to be related to a number of self-care capabilities and BP self-care behaviors including increased BP self-efficacy, medication adherence, decreased fluid gains, decreased missed HD treatments and decreased diastolic BPs. Gender was found to be related to fluid gains and decreased diastolic BP, with females having less fluid gains and lower diastolic BPs than males. Race was found to be related to missed HD treatments with African Americans missing more HD treatments than Caucasians. Social support was found to be related to both increased BP self-efficacy and less missed HD treatments.

Hypothesis II A: Chronic HD patients randomized to a 90 day supportive-educative intervention will have increased BP knowledge scores compared to baseline scores and will have greater BP knowledge than the usual care group at 12 weeks.

A significant difference was found between the two groups in BP knowledge at baseline $t(116) = 2.4$, $p = .019$). At baseline, the control group scored slightly higher ($M = 44.5$, $SD = 4.0$) on the BP knowledge test than the treatment group ($M = 42.5$, $SD = 4.7$). After 12 weeks, there were no significant differences in BP knowledge scores between the two groups ($t(116) = 1.42$, $p = .16$). The average BP knowledge score in the control group was 44.4 ($SD = 3.8$) while the treatment group scored an average mean score of 43 ($SD = 6.5$).

Paired samples t-tests were run to determine if there were significant differences in BP knowledge scores within groups from baseline to 12 weeks. No significant change in BP knowledge scores were found within the control group $t(58) = .32$, $p = .75$ or treatment group $t(58) = -.74$, $p = .47$ from baseline to 12 weeks. These results indicate that the intervention did not have much influence on changing BP knowledge scores in the treatment group.

Hypothesis IIB: Chronic HD patients randomized to a 90 day supportive-educative intervention will have increased BP control self efficacy compared to their baseline self-efficacy scores and greater BP control self-efficacy scores than usual care group at 12 weeks.

Independent *t*- tests were conducted to determine if there were significant differences between the groups in BP self-efficacy scores (Table 5). There were no significant differences in BP self-efficacy scores between groups at baseline ($t(116) = -1.8$, $p = .07$) or at 12 weeks ($t(116) = -.86$, $p = .39$). At baseline, the control group scored an average mean score of 47.5 (*SD* = 4.42) and the treatment group scored an average mean score of 48.9 (*SD* = 4.2). After 12 weeks, the control group's average BP self-efficacy score increased to 48.7 (*SD* = 4.8) and the treatment group's self-efficacy score increased to 49.4 (*SD* = 4.0).

Paired samples t-test were conducted to determine if there were significant changes in self-efficacy scores within each group over 12 weeks. A significant difference in BP self-efficacy scores was found in the control group $t(58) = -3.1$, $p = .00$ from baseline to 12 weeks. No significant differences in BP self-efficacy scores were found in the treatment group from baseline to 12 weeks ($t(58) = - 1.0$, $p = .32$).

Hypothesis IIC: There will be a relationship between BP control self-efficacy and self-regulation behaviors with increases in both noted at 12 weeks.

This hypothesis was tested by conducting correlations between post BP self-efficacy scores and self-regulation behaviors (adherence rates to BP, salt and fluid logs, goal setting and reinforcement). No significant relationships were found between BP monitoring and BP self-efficacy (r =.12, p = .39), fluid monitoring and BP self-efficacy ($r = .05$, $p = .72$) or salt monitoring and BP self-efficacy ($r = .03$, $p = .81$). Pearson correlations were also conducted between self-evaluation (goals met and reinforcement) and BP self-efficacy. No significant relationships were found between BP goals met and BP self-efficacy ($r = .18$, $p = .18$). A significant relationship was found between fluid goals met and BP self-efficacy (*r* = .27, *p* = .04). No significant relationship was found between salt intake goals met and BP self-efficacy (*r* = .14, *p* = .45).

Reinforcement for BP goals met was not found to be related to BP self-efficacy (*r* = .18, *p* = .18). Reinforcement for fluid goals met was found to be related to BP self-efficacy scores (*r* = .27, *p* = .04). Reinforcement for salt intake goals met was not found to be related to BP self-efficacy (*r* = .14, *p* = .45). In conclusion, it appears that the only significant BP self-regulation behaviors related to BP self-efficacy were fluid goals met and reinforced.

Hypothesis III A: There is a relationship between BP control knowledge and BP control self-care behaviors.

Pearson correlations were conducted between BP control knowledge scores and BP self-care behaviors (salt intake, fluid gains, medication adherence, missed HD treatment) to determine if there were any relationships. BP control knowledge scores were found to be significantly related to average fluid gains at 12 weeks (*r* = -.184, *p* = .05) and average fluid gains at 16 weeks (*r* = -.25, *p* = .01) indicating that increased BP control knowledge scores were related to decreased average fluid gains in the entire sample.

BP control knowledge scores at 12 weeks was also found to be related to medication adherence (*r* = -.22, *p* = .02) indicating that more BP control knowledge was related to improved adherence to medication regimens (*r* = -.15, *p* = .27*)*. No relationships were found between BP control knowledge, salt intake and HD adherence.

Hypothesis IIIB: There will be a relationship between BP control self-efficacy and BP self-care behaviors.

Pearson correlations were conducted to determine if there were any relationships between BP control self-efficacy scores and BP self-care behaviors (i.e., sodium/salt and fluid intake, medication adherence and HD adherence). BP self-efficacy scores were found to be moderately related to 12 week average fluid gains (*r* = -.32, *p* = .000) and 16 week average fluid gains (*r* = -.33, *p* = .001), indicating that higher BP self-efficacy scores resulted in decreased fluid gains. Total BP self-efficacy scores were also found to be inversely related to missed HD treatments (*r* = -.36, *p* = .00), indicating that more BP self-confidence was related to decreased missed HD treatments. Twelve week BP self-efficacy scores were also related to medication adherence scores (*r*(116) = -*.33, p* = .00) indicating a moderate relationship between BP self-efficacy and medication adherence.

Hypothesis IIIC: There is a direct positive relationship between self-regulation behaviors and BP control self-care behaviors.

Pearson correlations were conducted to determine if there were any relationships between self-regulation behaviors (self-monitoring, self-evaluation and self-reinforcement) and BP control self-care behaviors (fluid gains, salt intake, medication adherence and HD attendance) (Table 13). BP monitoring was found to be related to missed HD treatments (*r* = -.31, *p* < .05), indicating that participants who monitored their BP more had less missed HD treatments. The total number of fluid goals met and reinforced was found to be significantly inversely related to fluid gains (*r* = -.84, *p* < .00) indicating the more a participant met and had their weekly fluid goals reinforced, the less fluid they gained. No significant relationships were found between self-regulation behaviors, salt intake or medication adherence (Table 13).

Table 13

Correlations between Self Regulation Behaviors and BP Self-Care Behaviors (N = 118)

SR behaviors	Fluid gain	Salt intake	Missed HD Tx	Med adherence
Monitoring				
BP	.06	-.07	-.31*	-.19
Fluid	-.01	.12	-.13	-.01
Salt	-.07	.03	-.16	.17
Self Evaluation				
BP goals	-.02	-.07	-.09	-.04
Fluid goals	-.84**	-.18	-.17	-.20
Salt goals	.07	-.04	-.07	.33
Reinforcement				
BP goals met	-.02	-.07	-.09	-.04
Fluid goals met	-.84**	-.18	-.17	-.20
Salt goals met	.07	-.04	-.07	.33

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

Hypothesis IVA: There will be a relationship between BP control self-care behaviors (fluid gains, salt intake, medication adherence and HD attendance) and BP.

Pearson correlations were conducted (Table 14) and significant relationships were found between medication adherence and average systolic BP ($r(116) = .203$, $p = .03$) and average diastolic BP ($r(116) = .258$, $p = .005$). Missed HD treatments were was also found to be related to average systolic BP ($r(116) = .315$, $p = .001$, and average diastolic BP ($r(116) = .45$, $p =. 00$). Average fluid gains were found to be significantly related to average diastolic BP $r(116) = .20$, $p = .027$). Average salt intake was not found to be significantly correlated to 12 week systolic BP ($r = .19$, $p = .30$) or 12 week diastolic BP ($r = .14$, $p =.51$).

Table 14

Correlations between BP and BP self Care Behaviors (N = 118)

Blood Pressure	Fluid Gain	Salt Intake	Medication Adherence	HD Adherence
Systolic	.09	-.19	.20*	.32**
Diastolic	.20*	.14	.26**	.45**

Note * p < .05, ** p < .001

Hypothesis 1VB: Self-care capabilities (BP knowledge, BP control self-efficacy, self-regulation) and BP self-care behaviors mediates the effect of a supportive-educative intervention on BP control.

A mediation analysis could not be conducted since there were no significant relationships between the independent variable (intervention) and the mediator (BP self-care capabilities) (Baron and Kenny, 2009). Multiple regression was conducted to determine the best linear combination of BP knowledge, BP control self-efficacy, BP self-regulation, average fluid gains, average salt intake, medication adherence, medication changes and missed HD treatments in predicting systolic BP and diastolic BP. Step-type regression (forwards, backwards and stepwise) was conducted to determine the optimal model. The combination of the following three variables significantly contributed to the prediction of systolic BP: total BP goals met (β = - .45, p = .01), missed HD treatments (β = 2.6, p =.01) and medication change (β = .32, p = .04) explaining 44% of the variance in systolic BP. According to Cohen (1988), this is a large effect.

Multiple regression was also conducted to determine the best linear combination of variables: BP knowledge, BP control self-efficacy, BP self-regulation, average fluid gains, average salt intake, medication adherence, medication changes and missed HD treatments in predicting diastolic BP. Step-type regression (forwards, backwards and stepwise) was conducted to determine the optimal model. Two of the variables: missed HD treatments, (β = .39, p = .00), total BP goals achieved (β = - .38, p = .00) predicted 30% of the variance in diastolic BP.

Additional Analyses

Multiple regression was conducted to determine the significance of the variables age, gender, race, education, income, social support and comorbidities in predicting BP self-care capability scores. This combination of variables did significantly predict baseline BP knowledge, F(8, 109) = 2.9, p =.01. However, the only variables that contributed significantly to BP knowledge scores was depression (β = - .34, t = - 3.8, p = .000) and total social support (β= -.21, t = -2.4, p = .02) accounting for 12 % of the variance in BP knowledge scores.

Multiple regression was also conducted to determine the best linear combination between the above mentioned variables and BP self-efficacy scores. The combination of variables did significantly predict 12 week BP self-efficacy scores (F(8, 108) = 2.6, p = .010). The model explained 18% of the variance in BP self-efficacy scores. The only variable which contributed significantly to the prediction was age (β = .36, t = 3.6, p = .000). No significant relationships were found when multiple regression was conducted to determine the best linear combination for age, gender, race, education, income, social support, comorbidites and BP log self-monitoring behaviors F(6, 52) = 1.11, p = .37, salt monitoring behaviors F (6, 52)= .677, p = .67 and fluid monitoring behavior F(6, 52) =.73, p = .63. None of the BCF variables were significantly related to BP self-monitoring behaviors.

Multiple regression was also conducted to determine the best linear combination of age, gender, race, education, income, social support, comorbidities and BP self-care behaviors (salt and fluid intake, BP medication adherence, HD attendance). The combination of variables did not significantly predict salt intake (F = (6, 24), p = .114). However, age (β = -.36, t = - 4.0, p =

.000) and gender (β = -.233, *t* = -2.7, *p* = .01) significantly predicted adherence to fluid intake (*F(*6, 111) = 4.85, *p* = .000). The combination of variables predicted 17 % of the variance in fluid gains.

Multiple regression was also run to determine whether there was a relationship between the BCF variables and medication adherence. This combination of variables significantly predicted 18.5% of the variance in medication adherence scores (*F*(9, 108) = 2.7, *p* = .007). The only variables that were significant in predicting medication adherence were age (β = .29, *t* = -3.1, *p* = .003) and comorbidities (β = .18, *t* = 2, *p* = .048). Multiple regression was also run to determine if there was a significant relationship between the BCF variables and missed HD treatments. This combination significantly predicted adherence to HD treatments *F*(6, 111) = 4.56, *p* = .00 with the model explaining 16% of the variance in HD adherence. The only variable that significantly predicted HD adherence was age (β = -.39, *t* = -4.3, *p* = .00) indicating that age was inversely related to HD adherence.

CHAPTER 5

Discussion

The major purpose of this randomized controlled trial was to determine if a supportive educative nursing intervention would improve BP control in a chronic HD population. It was predicted that the intervention would improve self-care capabilities (BP knowledge, BP self-efficacy and self-regulation behaviors) which would lead to improved adherence to: a) hypertensive self-care behaviors (i.e., fluid and salt intake, adherence to a prescribed medication regimen as well as maintenance of HD visits) and ultimately improved BP control. This study also examined the relationship between basic conditioning factors (age, gender, race, education, income, comorbidities, and social support), BP self-care capabilities and BP self-care behaviors. This chapter will discuss the findings of the study according to each hypothesis and further discuss study limitations, implications for theory and clinical practice and directions for future research.

Sample Characteristics

This study's sample contained 118 hypertensive chronic HD patients who were predominately African American, not well educated with an average age of 60 years. The sample was made up equally of males and females. The treatment and control groups were statistically different at baseline on the following variables: age, race, income, CHF comorbidity, diastolic BP and BP knowledge. The randomization process should have eliminated this non-equivalency of groups at baseline. However, since randomization of patients may have resulted in diffusion of the intervention to the control group, and the fact that patients frequently changed their assigned HD days, randomization was carried out by HD units. This resulted in two inner city HD units being randomly assigned to the control group and four smaller suburban units being assigned to the treatment group.

Age

The average age of the entire sample (60 years) is similar to the average age of the general HD population, i.e., 64.4 years (USRDS, 2009). However, there was a statistical difference between the two groups in age with the average age of the control group being 56 years compared to 63 years in the treatment group. A possible reason for this finding may be that the median age for African Americans on HD is 59.1 years and 66.8 years for Whites (USRDS, 2009), indicating that whites on HD tend to be older. Since the control group was entirely African American, this could explain the age difference between the two groups. Also Detroit statistics indicate that the average age of individuals living in Detroit is 31 years (Detroit Census Data Center, 2010), which would explain why the control group was significantly younger.

Race

Overall the racial characteristics differ from national statistics, and the two study groups were statistically different in racial make-up. The entire sample consisted of 86% African Americans and 14% Caucasian or others. Racial composition of the US general HD population is 42% African American. However, the majority of participants (and 100% of the control group) in this study were recruited from Detroit, which is 85% African American (Michigan Census Data Center (2010) and 15% Caucasian or other.

Income

Compared to the average income of US citizens nationally, this sample had a lower average yearly income. The treatment and control groups were also significantly different in average yearly income (p = .00). A likely explanation for this finding was the control units were composed of predominately younger African American sample of lower income participants than the treatment groups. Almost half of the sample earned a total household yearly income below poverty level. The most likely explanation for this is that 84% of the sample was unemployed. Medicare and Medicaid requirements for insurance coverage helps to explain this finding. In order to be entitled to Medicare /Medicaid insurance and have their HD care covered, HD patients can only be employed on a part-time status or less. Trying to find part-time work and juggle the weekly HD regimen is too difficult for most HD patients to manage. Thus, the majority of HD patients do not work resulting in a low yearly income.

Description of Health Status of Sample

Comorbidities were similar across study groups, with one exception. There was a higher incidence in CHF in the treatment group compared to the control group (t = -2.2, p = .03). According to the USRD (2010), age is an important independent predictor for risk of developing cardiovascular disease including atherosclerotic heart disease and CHF. The greater prevalence of older patients in the treatment group who have an increased incidence of CHF may explain this finding.

BP medications

Study groups were similar relative to their prescribed medications. The majority of the sample (54%) was taking three or more BP medications. The only medication that differed between the two groups was diuretics (p = .01) with 18.6% of the treatment group taking diuretics compared to 3.4% of the control group. A possible explanation for this is the greater incidence of patients with CHF in the treatment group. Another significant difference between the treatment and control group was the change in BP medications over 12 weeks. The treatment group had a significantly greater change in BP medications after 12 weeks compared to the control group (t = -2.1, p = .04). This finding suggests the intervention may have made a difference between the two groups. Weekly BP monitoring may have resulted in increased changes in BP medications by the health provider, which in turn contributed to the difference in systolic and diastolic BPs between the treatment and control groups at 12 weeks.

Blood Pressure and Fluid Gains

Baseline diastolic BPs were statistically different between the two groups (t = 2.7, p = .01). Compared to the treatment group, the control group was significantly younger. These younger participants consumed more fluids which resulted in higher average diastolic BPs in the control group (r = -.37, p = .00).

Major Baseline Study Variables

Social support

At baseline, the treatment group reported a significantly higher level of social support than the control group. Enrollment of control group participants from inner city HD units with a lower socioeconomic status may explain the lower levels of social support in the control group. Additionally, the incidence of being married or living with a partner was significantly higher in the treatment group compared to the control group (p =. 04), which may also explain the differences in social support.

Depression

The control and treatment group did not differ in levels of depression at baseline. Approximately 43% of the sample scored a mild to moderate level of depression on the PHQ-9 scale at baseline. These findings are consistent with those found in the literature which indicate that 50% of dialysis patients suffer from depression (Johnson & Dwyer, 2008; Kimmel, 2002).

BP Knowledge

Both the control and treatment groups had fairly good levels of BP knowledge at baseline. Interestingly, the control group had a significantly greater level of BP knowledge at baseline compared to the treatment group. A possible explanation for this finding is that the BP educational programs may have been better in the units assigned to the control groups. Another explanation could be that the BP knowledge scale may not have been a reliable tool to measure BP knowledge in this sample. Further evaluation and testing of the investigator developed BP knowledge scale will be conducted in the future.

BP Self-Efficacy

At baseline, BP self-efficacy was similar and relatively good in the entire sample. There were no significant differences in BP self-efficacy scores between the two groups at baseline or 12 weeks. A surprising finding was the increase in BP self-efficacy scores in the control group over 12 weeks (p = .03). A possible explanation for this finding was that the control group may have been experiencing 'compensatory rivalry' which occurs when the control group feels disappointed or disadvantaged for not receiving the intervention. The study was explained to all of the participants before enrollment, so the control group understood that the treatment group was receiving a different intervention. This may have resulted in a competitive attitude towards the treatment group, whereby the control participants scored themselves more favorably on the BP self-efficacy scale.

BP Self Regulation

Participation in BP control self-regulation behaviors (i.e., BP, fluid and salt monitoring, BP self evaluation and reinforcement) varied greatly amongst participants in the treatment groups. Adherence rates for BP monitoring ranged from 0 to 100% with an overall adherence rate of 42%. Rates for monitoring of salt (11%) and fluid intake (12%) were much lower. A possible explanation for this was that the intervention may have been too labor intensive for the participants to complete. Many of the participants indicated they were overwhelmed with all of the forms they had to complete and were often to busy to complete them. Requesting the participants to fill out many weekly forms on top of a heavy dialysis schedule may have been too much to ask of the participants. These findings were similar to those found by Tanner (1998) who found that attempting to change two behaviors (phosphorous and fluid intake) in the HD patient was too difficult. Recommendations for future studies would be to monitor one behavior (i.e., salt, fluid, BP) at a time in order to decrease the intensity of the intervention.

BP Self-Care Behaviors

Fluid Gains

There were no significant differences in average fluid gains between the two groups at baseline, 12 and 16 weeks. The average fluid gain for the control group was 2.48 kg at baseline, 2.51 kg at 12 weeks and 2.46 kg at 16 weeks. In the treatment group, the average fluid gain remained virtually unchanged over the 16 weeks. Average fluid gains were 2.44 kg at baseline and 12 weeks and 2.42 kg at 16 weeks. There were no significant differences within or between the groups over 12 weeks. A possible explanation for these findings was that it was difficult to further decrease IDWG because the fluid gains were already relatively low at the start of the study.

Salt Intake

Adherence rates to recording salt logs were quite low at 11%. Many of the participants indicated that there were too many logs to fill out on a weekly basis. For those who did complete the checklists, average salt intake for the group was found to be very low. Possible explanations for these findings may be inaccurate self-reporting or 'social desirability bias' which refers to the tendency of respondents to reply in a manner that will be viewed favorably by others. Since the response rates for the salt check-lists were so low, it was difficult to make any solid conclusions about the relationship between salt intake and other variables. Recommendations for future studies would be to conduct studies on a smaller scale and focus strictly on self-regulation of salt intake. It would also be recommended to monitor sodium content of urine samples to ensure accuracy of self-reports.

Medication Adherence

At baseline and 12 weeks follow-up medication adherence rates in the intervention and control groups were not statistically different. Both groups had a medium level of medication adherence. This is not surprising considering the high level of comorbidities and medications these participants have to take on a daily basis. At 12 weeks, there was a nonsignificant trend towards improvement in medication adherence in the treatment group compared to the control group. A possible explanation for the nonsignificant trend was time. Perhaps with a longer intervention period i.e., (6 months), the result would have been significant.

Medication Change

There was a significant difference in BP medication changes between the two groups with the treatment group having significantly more changes. Participants in the treatment group were encouraged to show their BP logs to their health care providers when their BPs were running high which could help explain the finding. Thus, BP monitoring may have led to more aggressive BP medication management which ultimately improved BP in the treatment group.

HD Attendance

At 12-weeks follow-up the control group had missed significantly more HD treatments than the treatment group. This finding suggests that the intervention had the intended effect. However, the control group was younger, African American and of lower socioeconomic status, all variables that may also influence HD attendance.

Hypothesis 1 A: Chronic HD patients randomized to a 90 day supportive educative intervention will have a decrease in SBP at 12 and 16 weeks compared to the usual care group.

Findings supported this hypothesis. Overall, there was a significant difference in systolic BP between treatment and control groups at 12 weeks (t = 3.0, p = .00) and 16 weeks (t = 2.5, p = .01), with the treatment group having a significantly lower systolic BP. There was a significant decrease in systolic BP within the treatment group from baseline to 16 weeks (t = 6.4, p = .00); the systolic BP decreased from 163 mmHg to 153.5 mmHg. There was also a significant overall decrease in systolic BP in the control group from baseline to 16 weeks where the systolic BP decreased from 164 mmHg to 160 mmHg (t = 2.4, p = .02).

The findings of this study are consistent with those found in other studies. A number of studies found that interventions incorporating a combination of home BP monitoring, contracting, goal setting and reinforcement improved systolic BP control in patients in a variety of outpatient settings (Broege et al., 2001 ; Cappuccio et al., 2004; Cuspidi et al 2004; Fahey et al., 2006; Halme et al., 2005; Klein & Artinian, 2007).

A possible explanation for the significant decrease in systolic BP in the control group was the Hawthorne effect. The Hawthorne effect refers to a form of reactivity whereby participants in a study improve or change their behavior being measured because they are being observed (Kerlinger and Lee, 2000). In the current study, participants in the control group may have been performing more BP self-care behaviors because they were expecting that their BP was being monitored by the PI.

Hypothesis IB: Chronic HD patients randomized to a 90 day supportive educative intervention will have greater decrease in DBP at 12 weeks and 16 weeks compared to the usual care group.

This hypothesis was supported by the findings. The treatment group's diastolic BP was significantly lower (*M* = 82.2 mmHg) compared to the control group (*M* = 88.4 mm Hg) at 12 weeks follow-up. The treatment group's diastolic BP was also significantly lower at 16 weeks. Overall, there was a significant within group decrease in diastolic BP in the treatment group from baseline to 16 weeks ($t = 4.8$, $p = .00$). There was also a significant decrease in diastolic BP in the control group; the diastolic BP decreased 3.2 mmHg from baseline to 16 weeks ($t = 3.2$, $p = .00$). Once again, the Hawthorne effect may explain the significant decrease in diastolic BP in the control group. Another explanation may be that at 12 weeks, the control group received their complementary BP monitor for participation in the study and may have begun to more closely monitor and control their BP. These findings are supported in the literature. Numerous studies have found that home BP monitoring in addition to other self-regulation behaviors improved diastolic BP control (Broege et al., (2001); Cappucio et al., 2004; Cuspidi et al., 2004; Fahey et al., 2006; Halme et al., 2005; Obara, 2008).

Research Question 1: Is there a relationship between BCFs (i.e., age, gender, race, education, income, comorbidities and social support) and BP self-care capabilities (i.e., knowledge level, self-efficacy, adherence to self-monitoring, self-evaluation and self-reinforcement).

Increased levels of depression were found to be inversely related to BP knowledge at baseline and at 12 weeks follow-up indicating that the experimental intervention in this study may not improve knowledge in participants who may have increased levels of depression.

Age was found to be related to BP self-efficacy; older participants reported greater self-efficacy. Older participants may have been on HD for longer time periods contributing to more self-confidence in their ability to control their BP compared to younger patients who may have been on HD for shorter time periods.

Social support was found to be related to BP self-efficacy; participants with more social support had greater self-efficacy. A possible explanation for this finding may be that the more someone feels supported, the more confident they may feel in their ability to manage their HD regimen.

In terms of self-regulation behaviors (i.e. BP, salt and fluid monitoring, self-evaluation and reinforcement), age was found to be related to total fluid goals met which was related to decreased fluid gains. Gender was also found to be related to total fluid goals met with females meeting more of their fluid goals.

Research Question 2: Is there a relationship between BCFs (i.e. age, gender, race, education, income, comorbidities and social support) and BP self-care behaviors (salt and fluid intake, medication adherence and HD adherence)?

Age was found to be inversely related to fluid gains; these findings are supported in the literature (Bame et al., 1993; Christensen et al., 1996; Kugler., 2005; Leggat et al., 1999; Moran et al., 1997; Vlaminck et al., 2001; Wiebe & Christensen, 1997). Peters and Templin (2008) also found a relationship between younger age and decreased BP self-care behaviors. In a large study conducted by Leggat et al., (1998), the strongest predictor of noncompliance with fluid restriction was younger age. As indicated earlier, one of the possible explanations for this is that the older adults may have been on HD for a longer period of time compared to younger participants, thus adapted to the self-care behaviors needed in HD. Another explanation is the younger participant may consume more fluid secondary to increased alcohol intake. Further exploration of this possibility should be conducted in future studies. Gonsalves-Ebrahim and others (1987) proposed that younger age groups may be noncompliant to fluid gains due to the stress associated with HD, and at the same time trying to be independent and manage multiple family and work obligations.

During weekly follow-up visits with the participants in this study, a common theme verbalized by the older HD participant was that they may have gained more fluid when they first started HD, but had learned to decrease fluid gains "because they just didn't feel good" (e.g., encountered excessive leg cramps during HD or their BP dropped excessively during HD because too much fluid was removed at one time). These statements indicate that patients may have experienced negative reinforcement during HD for excessive fluid gains which may have decreased their fluid intake. Age was also found to be significantly related to other BP self-care behaviors including decreased missed HD treatments and increased medication adherence.

Females were found to consume less fluid than males. These findings are consistent with those found in the literature (Arici et al., 1999; Bame et al., 1993; Cummings et al., 1984; Everett et al, 1993; Molaison & Yadrick, 2003). Race was found to be related to missed HD treatments. The only variable found to be related to education was salt intake (r = .37, p = .04). A possible explanation for this finding was that higher levels of education were related to being employed in this study (r = .19, p = .04). Individuals who are working and needing to attend HD may have time conflicts, thus eat more fast food which is higher in salt. No other relationships were found between education and BP self-care behaviors.

Social support was found to be inversely related to missed HD treatments and diastolic BP in this sample. These findings are consistent with those reported in the literature. O'Brien (1990) found that social support was related to improved adherence to self-care behaviors in a sample of 126 HD patients in a US urban outpatient HD setting. Other studies also found that social support had a positive effect on adherence to self-care regimens (Mai et al., 1999; Oka & Chaboyer, 1999)

Baseline depression levels were correlated to average fluid gain (r = -.24, p = .01) indicating that increased levels of depression were associated with decreased fluid gains. This finding was supported in the literature. Sensky and others (1996) found that depression was not associated with increased fluid gains in a small sample of HD patients. Everett and others (1995) found that increased depression was associated with lower levels of fluid gains in a small sample of 42 HD patients. A possible explanation for this finding is that depressed individuals may drink less fluid. Post intervention depression levels were also correlated with 12 week medication adherence (r = .20, p = .03), indicating increased depression was related to less adherence to medication regimens.

Type I diabetics and Type II diabetics had slightly greater IDWG than nondiabetics, however the differences were nonsignificant. These findings are consistent with the findings found in the literature. Brady and others (1997) and Leggat and others (1998) found that the comorbid condition of diabetes was associated with increased IDWG. A possible explanation for this finding is that hyperglycemia may trigger the thirst response in diabetics which increases fluid consumption.

Hypothesis II A: Chronic HD patients randomized to a 90 day supportive-educative intervention will have increased BP knowledge scores compared to baseline scores and will have greater BP knowledge than the usual care group at 12 weeks.

The intervention did not significantly increase BP knowledge in the treatment group at 12 weeks. As indicated in the results, participants in both the treatment (M = 42.5) and control group (M = 44.5) had fairly good levels of BP knowledge at baseline. Although the treatment group's BP knowledge score increased slightly at 12 weeks, the increase was non significant. A possible explanation for this finding was that the participants in the sample already had a good level of BP knowledge at baseline secondary to education that the HD may have provided. Another possibility to explain this finding is the low reliability of the BP control knowledge scale that was used to measure knowledge of behaviors necessary to control BP. Further work on the BP control knowledge scale will be conducted by the PI in the future.

Hypothesis IIB: Chronic HD patients randomized to a supportive-educative intervention will have increased BP control self efficacy compared to their baseline self-efficacy and greater self-efficacy than usual care group at 12 weeks.

BP self-efficacy scores did not increase in the treatment group from baseline to 12 weeks (p = .32) indicating that the intervention did not improve BP self-efficacy in the treatment group. As indicated in the results section, the control group did have a significant increase in BP self-efficacy over 12 weeks despite not receiving the intervention. A possible explanation for this finding was that the control group was experiencing 'compensatory rivalry' which occurs when the control group feels disappointed or disadvantaged for not receiving the intervention. The study was explained to all of the participants before enrollment, so the control group understood that the treatment group was receiving a different intervention. This may have resulted in a competitive attitude towards the treatment group, whereby the control participants scored themselves more favorably on the BP self-efficacy scale.

Hypothesis IIC: There will be a relationship between self-efficacy and self-regulation with increases in both noted at 12 weeks.

No significant relationships were found between BP, salt and fluid monitoring and BP-self-efficacy. A possible explanation for this finding may be that monitoring as a behavior by itself may not be enough to improve BP self-efficacy. A significant relationship was found between fluid goal achievement/reinforcement and BP self-efficacy (r = .27, p = .04) indicating that goal-setting/reinforcement may be an effective intervention in improving BP self-efficacy.

Tsay (2003) found similar results in a RCT of 62 chronic HD patients who received a self-efficacy training program on fluid intake adherence. The intervention consisted of fluid restriction education, fluid monitoring, goal setting and reinforcement. There was a significant decrease in IDWG (p = .006). Tsay (2003) implied that the decrease in IDWG was related to an increase in BP self-efficacy. These findings need to be examined with caution, since the construct of self-efficacy was never formally measured in the study. In this study, no relationships were found between BP goal achievement/reinforcement, salt intake goal achievement/reinforcement and BP self-efficacy.

Hypothesis III A: There is a relationship between BP control knowledge and BP control self-care behaviors.

BP knowledge scores were found to be significantly related to average fluid gain at 12 weeks (r = -.18, p = .05) indicating that increased BP knowledge scores were related to decreased average fluid gains in the entire sample. BP knowledge scores at 12 weeks were also found to be related to medication adherence (r = -.22, p = .02) indicating that increased BP knowledge was related to improved adherence to medication regimens (r = -.15, p = .27). These findings are similar to those found by Peters and Templin (2008) who found a moderately strong significant relationship between BP knowledge and BP self-care behaviors (r = .31, p < .01) in a sample of 306 community dwelling African Americans. Other studies have confirmed these findings as well (Cummings et al., 1981; Wilson, 1991). No relationships were found between BP knowledge, salt intake and HD adherence.

Hypothesis IIIB: There is a direct positive relationship between BP control self-efficacy and BP self-care behaviors.

BP self-efficacy scores were found to be moderately related to 12 week average fluid gains (r = - .32, p = .00) indicating that higher BP self-efficacy scores resulted in decreased fluid gains. Consistent findings were found in the literature. Tsay (2003) found that a self-efficacy training program significantly improved fluid intake adherence in a sample of 62 chronic HD patients compared to a control group (p = .01). Total BP self-efficacy scores were also found to be inversely related to missed HD treatments (r = -.36, p = .00), indicating that more BP self-confidence was related to decreased missed HD treatments.

In the current study, 12-week BP self-efficacy scores were related to medication adherence scores (r(116) = -.33, p = .00) indicating a moderate relationship between BP self-efficacy and medication adherence. Improving self-efficacy in a disease management program was also found to be related to medication adherence in a study of 570 women with cardiac disease conducted by Clark and Dodge (1999).

Hypothesis IIIC: There is a direct positive relationship between self-regulation behaviors and BP control self-care behaviors.

The only monitoring behavior found to be related to BP self-care behaviors was missed HD treatments (r = -.31, p < .05), indicating that participants who monitored their BP more, missed less HD treatments. One could conclude from this finding that the intervention decreased missed HD treatments in the treatment group. Another possible explanation may be that those who monitored their BP more were more adherent to there BP self-care behaviors and missed fewer HD treatments from the start of the study.

No relationships were found between BP monitoring, salt and fluid monitoring and the other BP self-care behaviors. These findings are inconsistent with those found in the literature which indicate that self-monitoring of various behaviors improved health care outcomes in a variety of disease states including diabetes, asthma, and weight and exercise management (Carels et al., 2005; Gleeson-Kreig, 2006; Ignacio-Garcia and Gonzalez-Santos , 1995; Linde et al., 2005; Siebolds & Mertes, 2002). Low response rates on fluid and salt logs may partially explain these findings. The low response rates may have resulted in lack of power in detecting an effect. Additionally, self-monitoring by itself may not improve BP self-care behaviors, rather the combination of self-monitoring with other interventions (i.e., goal setting, reinforcement) improves BP self-care behaviors.

In terms of goal setting and reinforcement, total BP goals met and reinforced were related to average systolic BP (r = -.67, p = .00) and average diastolic BP (r = -.42, p = .00) indicating the more a participant met and had their BP goals reinforced, the better their systolic BP and diastolic BP. Total number of fluid goals met and reinforced was also found to be significantly related to fluid gains (r = -.84, p < .00) indicating the more a participant met and had their weekly fluid goals reinforced, the less fluid they gained. Other studies have validated the positive effect of goal setting in lowering blood pressures (Olivarius, Beck-Nielsen, Andereasen, Horder & Pedersen, 2001; Rachmani, Slavacheski, Berla, Frommer-Shapira & Ravid, 2005). Numerous studies have also demonstrated the positive effect of reinforcement in behavior change programs related to fluid restriction in the HD population (Christensen, Wiebe, Edwards, Michels, & Lawton, 1996; Sagawa et al., 2001; Sharp, Wild & Gumley; 2005; Tucker; 1989). No significant relationships were found between salt intake goal setting/reinforcement and salt intake, fluid intake or medication adherence.

A possible explanation for the nonsignificant findings related to salt intake goal setting/reinforcement and salt intake was the low response rates on salt logs. This low response rate could have resulted in lack of power in detecting an effect. The intensity of the intervention and having to monitor and evaluate numerous behaviors related to BP self-care at one time was difficult for many participants to do. Future recommendations would be to focus on one BP self-care behavior at a time (i.e., salt intake, fluid intake or medication adherence) in order to decrease the intensity of the intervention. This would likely increase response rates for monitoring specific behaviors i.e., salt and fluid logs which would result in increased data to make more conclusive results.

Hypothesis IVA: There will be a relationship between BP control self-care behaviors (fluid gains, salt intake, medication adherence and HD attendance) and BP.

Significant relationships were found between medication adherence and average systolic BP ($r(116) = .203$, $p = .03$) and average diastolic BP ($r(116) = .258$, $p = .005$) indicating the less adherence to medication regimens the higher the systolic BP and diastolic BP. Although nonsignificant, there was a trend towards improved medication adherence in the treatment group compared to the control group.

Missed HD treatments were found to be related to average systolic BP $r(116) = .315$, $p = .001$, and average diastolic BP $r(116) = .45$, $p =. 000$). Average fluid gains were also found to be significantly related to average diastolic BP $r(116) = .20$, $p = .027$). Missed HD treatments were related to average fluid gains ($r = .26$, $p = .00$). A likely explanation for this finding is that missed HD treatments will lead to increased fluid gains because accumulated fluids will not be removed and ultimately lead to higher BPs. There was a significant difference in missed HD treatments in the treatment group. Possible explanations could be that the intervention decreased missed HD treatments or could also be explained by the demographic make-up of the control group, which was younger and African American.

Hypothesis 1VB: Self-care capabilities (BP knowledge, BP control self-efficacy, self-regulation) and BP self-care behaviors mediates the effect of a supportive-educative intervention on BP control.

In this study, self-care capabilities did not mediate the effects of the supportive educative nursing intervention on BP control. The intervention did not statistically improve BP knowledge and BP self-efficacy. A possible explanation could be that the sample already had a relatively high level of BP knowledge. Another possible explanation could be the questionable reliability of the BP knowledge tool used in this study and whether it reliably measured BP knowledge in this population. Relationships were found between BP knowledge and BP self care behaviors (i.e., fluid gains and medication adherence) indicating greater BP knowledge resulted in decreased fluid gains and improved medication adherence.

Relationships were also found between BP self-efficacy scores and BP self-care behaviors indicating greater BP self-efficacy resulted in decreased fluid gains, less missed HD treatments and improved medication adherence. Increased BP monitoring and less missed HD treatments was the only significant relationship found between BP self-regulation behaviors and BP self-care behaviors. However, a number of the self-regulation behaviors were found to be directly related to BP. Total BP goals met and reinforced was significantly related to decreased average systolic BP and average diastolic BP. Total number of fluid goals met and reinforced was also found to be significantly related to decreased fluid gains.

The reasons why BP self-care behaviors did not mediate the relationship between self-regulation and BP outcomes is complex. A possible explanation is that the fluid gains were already quite low in the sample at baseline and the intervention did not significantly change fluid gains in the sample. In terms of salt intake, response rates for salt logs were low thus making statistical analysis questionable. There was a nonsignificant improvement in medication adherence in the treatment group, perhaps a longer intervention period would have resulted in a significant improvement in medication adherence scores. There was a significant change in BP medications in the treatment group which could help explain the decrease in BPs. The intervention may have resulted in fewer missed HD treatments in the intervention group, but could also be likely explained by the demographic make-up of the control group, which was younger and African American. It appears that the intervention was too labor intensive for many of the participants to complete. It required focusing on a number of variables (fluid, BP and salt intake). This may have resulted in the low response rates of fluid and salt logs. Future studies should target changing only one BP behavior at a time in order to improve response rates of various BP self-care behaviors which would improve interpretation of data.

Conclusions

Overall, three of the four specific aims were met. The study did lend support for: Specific Aim I: A supportive educative intervention focusing on self-care capabilities will improve BP control in a chronic HD patients, Specific Aim 3: Self-care capabilities are predictive of BP control self-care behaviors and Specific Aim 4: Self-care behaviors are predictive of BP control. The only specific aim which was not supported was Specific Aim 2: A supportive educative nursing intervention will improve BP self-care capabilities.

We can conclude from this study that the intervention did significantly lower systolic and diastolic BP in the treatment group compared to the control group. The exact method of how and why the intervention worked is difficult to decipher. The intervention did not improve BP self-care capabilities (BP knowledge or BP self-efficacy) in the treatment group. Possible explanations for this was the low reliability of the BP knowledge scale, the intensity of the intervention or the high level of BP knowledge the two groups already had at baseline. The only self-regulation behaviors found to be related to BP self-efficacy were fluid goals met and reinforced. In terms of goals met and reinforced, total BP goals met and reinforced were related to average systolic BP and average diastolic BP indicating the more BP goals met and reinforced the lower the systolic and diastolic BPs. The intervention had no significant effect on fluid gains; however this could be explained by the low average interdialytic weight gain of the participants at baseline. Despite a decreased trend in salt intake for the intervention group over 12 weeks, there was no significant effect. This finding could partially be explained by low response rates for salt monitoring. Although there was a trend for improved medication adherence in the treatment group, there was no statistical difference between groups in medication adherence scores at 12 weeks. The only BP self-care behavior that was statistically different between the two groups was missed HD treatments. The treatment group missed statistically less HD treatments than the control group and had more BP medication changes over the 12 weeks. Thus, we can conclude that the intervention decreased systolic and diastolic BPs through its effect on meeting and reinforcing BP goals, decreasing missed HD treatments and increasing BP medication changes over 12 weeks.

This study found many relationships between basic conditioning factors (BCFs), BP self-care capabilities and BP self-care behaviors. In terms of BCFs and BP self-care capabilities, significant relationships were between age and BP self-care efficacy, age and fluid goals met and reinforced and gender and fluid goals met and reinforced. In terms of BCFs and BP self-care behaviors, age was significantly inversely correlated to fluid gains, missed HD treatments and medication adherence both at baseline and 12 weeks indicating that older patients are more adherent to BP self-care behaviors.

Limitations of the Study

One of the limitations of the study was the randomization process. Because of fear of diffusion of the intervention across units, the randomization process was carried out by HD units. Since both control groups were drawn from inner city hemodialysis units and the treatment groups came from suburban settings, the two groups were significantly different on a number of variables. Recommendations for future studies would be to take into account geographical area before randomizing groups in order to prevent differences in group compositions or conduct stratified random sampling to ensure that the samples are representative of the US HD population.

Another limitation of the study was that the intervention may have been too labor intensive for the participants to complete. Many of the participants indicated that there were too many forms to fill out. Thus, many of the logs related to fluid and salt monitoring were not completed. Future studies may focus on changing one BP self-care behavior at a time (ie., BP, salt or fluid) in order to make the intervention more manageable for the participant.

The reliability of the BP knowledge scale was also questionable. Two of the items had very low item total correlations and need to be reexamined for wording problems and conceptual fit. Another limitation was using the Morisky Scale to assess adherence to medication administration. The investigator fully understands that electronic monitoring is the gold standard for assessing medication adherence, but was unable to attain this monitoring regimen due to financial constraints in implementing the study. Although the Morisky scale was not ideal, its' use still provided valuable information in terms of medication adherence for the purpose of this study.

Variables that may play an important role in hypertension in hemodialysis were not monitored or screened for in this study. These variables include: parathyroid hormone levels, administration of erythropoietin and sodium dialysate sodium concentrations. According to Goldsmith, Covic, Venning and Ackrill (1996), an elevated parathyroid hormone level can result in intracellular calcium excess and elevated BP. Hemodialysis patients receive manufactured erythropoietin (a synthetic hormone) to treat anemia associated with ESRD. According to Raine and Roger (1991), erythropoietin can elevate BP in one third of all hemodialysis patients. The mechanism for its relationship is unknown. Participants should also have been monitored for dialysate sodium concentration throughout the study. Higher dialysate sodium concentrations have been linked to higher BPs in hemodialysis patients (Krautzig, Janssen & Koch, 1998). These variables should be monitored and controlled for in future studies.

Another limitation was duration of study. Evidence indicates that for behavior change to take place, most interventions should be administered for 6 to 9 months. Future studies should administer the intervention for at least six to 12 months in order to determine if BP improvements maintain over time.

Another limitation in this study was having the principal investigator administer both the intervention and collect data. This may have resulted in the 'Social Desirability Bias' where participants will answer surveys in a favorable manner according to how they feel the PI would want them to respond. A method to have prevented this bias would have been to have another experimenter who is unaware of the anticipated results collect data. This was not feasible in the current study due to cost constraints.

Implications for Theory

The findings from this study lend some support for the 'Theory of Improving BP Control in Hypertensive HD patients', a model which was deduced from Orem's Self-Care Deficit Nursing Theory (SCDNT) (2001) and the Self-Regulation Theory (Kanfer & Gaelick, 1986). Although all the theoretical linkages in the model were not supported, a number of them were. Specific Aim1 supports the theory that when given a supportive educative intervention, patient outcomes improve. Basic Conditioning factors were predictive of Self-Care Capabilities. Depression was found to be significantly related to BP knowledge. Age and social support were found to be significantly related to BP self-efficacy. Income was found to be significantly related to self monitoring. Age, gender and education were all found to be related to fluid goals met and reinforced.

Basic conditioning factors were also predictive of BP self-care behaviors. Depression was significantly related to decreased fluid gains and decreased medication adherence. Total comorbidities was related to decreased medication adherence. Social support was related to decreased missed HD treatments. Age was significantly related to decreased fluid gain, increased medication adherence and decreased missed HD treatments. Gender was related to fluid intake with females consuming less fluids. Race was found to be related to missed HD treatments with African Americans missing more HD treatments.

Self-care capabilities were predictive of self-care behaviors (Specific Aim III). Increased BP knowledge was related to decreased average fluid gain and improved medication adherence. Increased BP self-efficacy was related to decreased average fluid gains and decreased missed HD treatments. There was some support for self-regulation behaviors and BP control self-care behaviors. Increased BP monitoring was found to be related to less missed HD treatments. Fluid goals met and reinforced were related to decreased fluid gains. Total BP goals met and reinforced were related to decreased average systolic and diastolic BPs. Total number of fluid goals met and reinforced was also significantly related to decreased fluid gains

BP self-care behaviors were predictive of BP control (Specific Aim IV). Medication adherence was found to be significantly related to systolic and diastolic BP. Total number of missed HD treatments was significantly related to systolic and diastolic BP. Increased average fluid gains was significantly related to average diastolic BP. The intervention group had significantly less missed HD treatments and more BP medication changes than the control group which may help explain how the intervention worked. However, the theoretical mechanisms proposed to lead to lower BP were not all supported. The intervention did not improve BP knowledge or BP self-efficacy in the treatment group (Specific Aim II). Self-care capabilities did not mediate the effect of the intervention on BP. Possible explanations for this are that the two groups may have already had high levels of BP control knowledge from the initiation of the study or that the reliability of the BP Knowledge Scale was questionable.

The concept of self-efficacy was incorporated as an estimative operation and found to have many significant theoretical linkages with basic conditioning factors and BP self-care behaviors. These finding offers support for the integration of the concept of self-efficacy within Orem's SCDNT to further explicate the construct of self-care agency. The self-regulation concept was integrated as a productive operation. Findings from the study supported the linkage between increased BP monitoring and decreased missed HD treatments, total fluid goals met/reinforced and fluid gains and total BP goals met/reinforced and BP. These theoretical linkages should be explored in future studies.

For the self-regulation theory, it was difficult to empirically measure/quantify self-evaluation and self-reinforcement. The goals in this study were initially set by the PI according to NKF BP guidelines. Thus, the participant was not involved in initial goal setting. The term 'goals met' was substructed from the concept of self-evaluation and 'number of goals reinforced' was substructed from self-reinforcement. There was also a correlation between goals met and reinforced so it was difficult to disentangle whether it was the number of BP goals met or reinforced that was most influential in the long term goal achievement. As indicated earlier, it was the intent of the PI to have the participant self-evaluate and self-reinforce. However, few participants completed their logs indicating whether or not goals had met and were reinforced. Thus, in the majority of cases the PI acknowledged whether goals were met and reinforced rather than the participant. Thus, the participant did not actually 'self-regulate' BP behavior, but rather the participant and PI were regulating the behavior together. Evidence suggests that individuals need goals to guide behavior change, whether that be provider or individually developed. Further development of the constructs of self-evaluation and self-reinforcement needs to be conducted in order to determine how these constructs are best measured. Further research also needs to be conducted to determine which components of regulation of behavior (monitoring, evaluation of goals or reinforcement of goals) has the most impact on behavior.

Implications for Practice

The incidence of hypertension in hemodialysis is very prevalent and poorly treated**.** The results of this study have several implications for nursing practice. The findings in this study indicate that a supportive educative nursing intervention which monitored weekly achievement of goals and reinforced achievement of goals improved BP outcomes. Nurses can implement interventions such as those outlined in this study. Since, HD nurses are the health care providers who have the most interaction with HD patients and are most familiar with HD patients' behaviors related to BP control, they are in the best position to implement interventions such as these. They can teach, guide and support hypertensive HD patients in monitoring home BPs, reviewing BP goals on a weekly basis and positively reinforcing patients when BP goals are met. They can also offer further guidance and problem solving for possible reasons goals were not met (i.e., excessive fluid gains, missed medications). Since medication adherence was found to be strongly linked to BP outcomes, nurses should also be encouraged to promote medication adherence with their HD patients.

This study also validates the need to target younger African American HD patients. Since this group was the least adherent to BP self-care behaviors (i.e., fluid gains, medication adherence and missed HD treatments), HD nurses need to focus on intervening with younger African American patients in order to help improve their BP control. These patients need to be targeted early in order to decrease the morbidity and mortality associated with cardiovascular disease in ESRD. They may need more tailored interventions which are not so labor intensive. Asking them to monitor their BP a few times a week, reviewing and reinforcing goals in the HD unit may decrease the intensity of the intervention and improve BP. Mistrust in providers is commonly found in the African American population. A supportive interpersonal relationship between the nurse and patient may decrease mistrust and improve the acceptance of interventions by the patient. Since this group tends to consume more fluids, goal setting and reinforcement with respect to fluids should also be reinforced by the HD nurse. Hemodialysis units should develop programs that incorporate weekly BP, salt and fluid monitoring, goal setting, and reinforcement in patients who have poorly controlled BP.

Since the incidence of depression (43%) was found to be moderately high in this sample, efforts to consistently assess for depression in this population need to be reinforced. Patients who are found to have moderate depression need to be referred for further evaluation and treatment before attempting to initiate any behavior change intervention.

Since literature has consistently indicated that education alone does not produce behavior change, health professionals should not rely on educational materials alone to change behaviors in this population. Nurses can use other interventions in addition to education such as monitoring, goal-setting and reinforcement to help meet change BP self-care behaviors. .

Implications for Future Research

The findings present several implications for future research. Since the intervention implemented in this study appeared to be too labor intensive for most individuals to complete, future studies should test interventions which focus on changing one BP self-care behavior at a time (i.e., BP, fluid or salt). It would also be advisable to test interventions tailored according to HD patients' needs (i.e., age, SES). In conducting this study, there were many patients who were hypertensive, but did not have high fluid intakes. Instead of having every hypertensive HD patient monitor every behavior related to BP control, it may be more beneficial to target only those behaviors they are having difficulty with (i.e., medication adherence, salt intake).

Further recommendations would be to test the intervention over longer time intervals (i.e., 6 to 12 months) in order to determine if the reduction in BP achieved at 3 months follow-up can be maintained over time. Longer post intervention follow-up is also recommended to determine how long the desired behaviors continue after the intervention has been completed. This will provide valuable information as to when patients may need short follow-up reminders or boosters in order to continue their BP self-care behaviors.

Since the underlying mechanisms responsible for the intervention's BP reducing effects was not fully explained in this study, further studies should be conducted. Since two of the intervention components (salt intake and medication adherence) had a nonsignificant trend towards improvement, future studies should focus on improving these intervention components (i.e., focusing on one behavior at a time). Since the sample in this study was not representative of the general HD population, future studies should use stratified random sampling in order to achieve a more representative sample.

Further testing of the BP Control Knowledge scale needs to be conducted. The internal consistency of the tool was .62 and two of the items had very low inter-item correlations. Further item analysis and testing of the tool will be conducted.

Final Summary

The major purpose of this randomized controlled trial was to determine if a supportive educative nursing intervention would improve BP control in a chronic HD population. To my knowledge this is the first study that used a supportive educative nursing intervention incorporating BP, salt and fluid monitoring, goal setting and reinforcement to improve BP control in a chronic HD population. This study has advanced nursing science though the development of a midrange Theory of Improving BP Control in Hypertensive HD patients which helped guide the development of the intervention used in the current study. The theory was useful in understanding and predicting individual behavior related to BP control in HD and identifying methods in which behavior may be changed. Orem's SCDNT was extended by integrating self-regulation concepts as production operations and incorporating the concept of self-efficacy as an estimative operation. The findings from this study support a number of these theoretical linkages (ie. BCFs predict self-efficacy; self-efficacy predicts behaviors) and BP monitoring predicts BP self-care behaviors. Further studies need to be conducted to validate these findings.

The intervention did significantly decrease both systolic and diastolic BP in the treatment group. It appears that the intervention improved systolic and diastolic BPs through BP goal achievement and reinforcement, improved HD adherence and increased medication changes within the treatment group. Further studies should be conducted to validate these findings.

APPENDIX A

Appendix: The Modified Mini-Mental State (3MS)

Subject ______________________yr__________ /mo______/ d_____ Examiner ____________

Normal or Dx __________ Age /yrs__________ Edu /yrs__________ M_____ F _____

3MS __________ /100

MMS __________/30

3MS	MMS		3MS	MMS		
		DATE AND PLACE OF BIRTH	— 10		**FOUR-LEGGED ANIMALS** (30 seconds) 1 point ea.	
— 5		Date: year ______ month_____ day _____	— 6		**SIMILARITIES**	
		Place: town __________			Arm-Leg	
		state_______________			Body part; limb; etc	2
— 3	— 3	**REGISTRATION**			Less correct answer	0 1
		(No. of presentations: ______)			Laughing-Crying	
		SHIRT, BROWN, HONESTY			Feeling; emotion	2
		(or: SOCKS, BLACK, MODESTY)			Other correct answer	0 1
		(or: SOCKS, BLUE, CHARITY)			Eating-Sleeping	
					Essential for life	2
					Other correct answer	0 1
—	—	**MENTAL**	—	—	**REPETITION**	

7	5	**REVERSAL**	
		5 to 1	
		Accurate	2
		1 or 2 errors/misses	0 1
		DLROW	0 1 2 3 4 5
— 9	— 3	**FIRST RECALL**	
		Spontaneous recall	3
		After "Something to wear"	2
		"SHOES, SHIRT, SOCKS"	0 1
		Spontaneous recall	3
		After "A color"	2
		"BLUE, BLACK, BROWN"	0 1
		Spontaneous recall	3
		After "A good personal quality"	2
		"HONESTY, CHARITY, MODESTY"	0 1
— 15	— 5	**TEMPORAL ORIENTATION**	

5	1			
		"I WOULD LIKE TO GO HOME/OUT"		2
		1 or 2 missed/wrong words	0	1
		"NO IFS___ANDS___OR BUTS___"		
— 3	— 1	**READ AND OBEY "CLOSE YOUR EYES"**		
		Obeys without prompting		3
		Obeys after prompting		2
		Reads aloud only (spontaneously or by request)	0	1
— 5	— 1	**WRITING** (1 minute)		
		(I) WOULD LIKE TO GO HOME/OUT		
		(MMS: Spontaneous sentence: 0 1)		
— 10	— 1	**COPYING TWO PENTAGONS** (1 minute)		
			Each Pentagon	
		5 approximately equal sides	4	4
		5 unequal (>2:1) sides	3	3

	Year		
	Accurate	8	
	Missed by 1 year	4	
	Missed by 2-5 years	0 2	
	Season		
	Accurate or within 1 month	0 1	
	Month		
	Accurate or within 5 days	2	
	Missed by 1 month	0 1	
	Day of month		
	Accurate	3	
	Missed by 1 or 2 days	2	
	Missed by 3-5 days	0 1	
	Day of week		
	Accurate	0 1	
— — 5 5	**SPATIAL ORIENTATION**		
	State	0 2	
	County	0 1	

	Other enclosed figure	2 2
	2 or more lines	0 1 0 1
		Intersection
	4 corners	2
	Not 4-corner enclosure	0 1
— — 3 3	**THREE-STAGE COMMAND**	
	___ TAKE THIS PAPER WITH YOUR LEFT/RIGHT HAND	
	___ FOLD IT IN HALF, AND	
	___ HAND IT BACK TO ME	
— 9	**SECOND RECALL**	
	(Something to wear)	0 1 2 3
	(Color)	0 1 2 3
	(Good personal quality)	0 1 2 3

(Teng EL, Chui HC. A Modified Mini-Mental State (3MS) Examination. Journal of Clinical Psychiatry 1987;48:314-318. Copyright Physicians Postgraduate Press. Reprinted with permission.)

		City (town)	0 1	
		Hospital/office building/home?	0 1	
__ 5	__ 2	**NAMING** (MMS: Pencil ___ Watch ___) Forehead ___ Chin ____ Shoulder ____ Elbow _____ Knuckle _____		

APPENDIX B

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: ______________________________ **DATE:** ____________________

Over the *last 2 weeks,* how often have you been bothered by any of the following problems? *(use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
add columns:		+	+	
TOTAL:				

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

- **Not difficult at all** ______
- **Somewhat difficult** ______
- **Very difficult** ______
- **Extremely difficult** ______

PHQ-9 is adapted from PRIME MD TODAY, developed by Drs Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr Spitzer at rls8@columbia.edu. Use of the PHQ-9 may only be made in accordance with the Terms of Use available at *http://www.pfizer.com*.

APPENDIX C

WAYNE STATE UNIVERSITY

HUMAN INVESTIGATION COMMITTEE
101 East Alexandrine Building
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
http://hic.wayne.edu

Association for the Accreditation of Human Research Protection Programs, Inc. Full AAHRPP Accreditation

NOTICE OF EXPEDITED CONTINUATION APPROVAL

To: Zorica Kauric-Klein
Adult Health/Administration
301 Cohn Rm

From: Ellen Barton, Ph.D. E. Barton / LS
Chairperson, Behavioral Institutional Review Board (B3)

Date: May 12, 2010

RE: HIC #: 049009B3E

Protocol Title: Improving Blood Pressure Control in End-Stage Renal Disease through a Supportive-Educative Nursing Intervention

Funding Source: Sponsor: AMERICAN NEPHROLOGY NURSES ASSOCIATION

Protocol #: 0904007039

Expiration Date: May 11, 2011

Risk Level / Category: Research not involving greater than minimal risk

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Continuation for the above-referenced protocol and items listed below (if applicable) were APPROVED following Expedited Review by the Chairperson/designee of the Wayne State University Institutional Review Board (B3) for the period of **05/12/2010 through 05/11/2011**. This approval does not replace any departmental or other approvals that may be required.

- Consent Form

- Federal regulations require that all research be reviewed at least annually. You *may* receive a *"Continuation Renewal Reminder"* approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval ***before*** the expiration date. Data collected during a period of lapsed approval is unapproved research and can ***never*** be reported or published as research data.
- All changes or amendments to the above-referenced protocol require review and approval by the HIC **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the HIC Policy (http://www.hic.wayne.edu/hicpol.html).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the HIC office must be contacted immediately.
2. Forms should be downloaded from the HIC website at ***each*** use.

*Based on the Expedited Review List, revised November 1998

APPENDIX D

Educational Session I: Improving BP Control in HD

Objectives	Content
The participant will discuss and identify the underlying cause of hypertension in ESRD.	The PI will explain and discuss the role of the following factors in hypertension. • Excess salt intake • Excess fluid intake • Nonadherence to BP medications • Nonadherence to HD regimens
The participant will discuss and identify the risks associated with uncontrolled BP.	The PI will explain and discuss the relationship between high BP and increase risk for CV death. • Coronary artery disease (CAD) • Left Ventricular Hypertrophy (LVH) • Cerebral Vascular Accident (CVA)
The participant will identify BP self-care behaviors/goals which will improve BP control in HD.	The PI will explain and discuss the following BP self-care behaviors and goals: • Decreased salt intake < 2 gm/day or < 1 tsp/day • Fluid intake < 1500 ml • < 2.5 kg IDWG in between HD treatments • Adherence to BP medication regimens and HD regimens.
The participant will understand and discuss the importance of self-regulation in changing BP self-care behaviors.	The PI will identify the role of: • Monitoring in enhancing awareness and perceived control over BP self-care behaviors. • Goal-setting in allowing the participant to focus on BP related behaviors and avoid distractions. • Reinforcement for goals met increasing the likelihood of repeating BP self-care behavior in the future.

Education Session 2

Objectives	Content
The participant will demonstrate Correct use of the HEM 780 automatic home BP monitor.	The PI will demonstrate correct use of the HEM 780 automatic home BP monitor. The participant will return demonstrate correct use of home BP monitor.
The participant will demonstrate correct recording of BP in the BP log.	The PI will distribute and explain correct recording of BP in the BP log. The participant will demonstrate correct recording of BP in the BP log.
The participant will understand and demonstrate how to record 24 hour Fluid Intake.	The PI will distribute and explain correct recording for 24 hour Fluid Intake Recall. The participant will record their fluid intake for the last 24 hours.
The participant will understand how to measure fluid intake accurately and discuss methods to decrease fluid intake.	The PI will review the Fluid Restriction Pamphlet. The PI will discuss other methods to avoid thirst: • Avoid the sun • Gums that combat thirst: Gator gum and Quench
The participant will discuss methods to decrease salt consumption.	The PI will explain and discuss methods to decrease salt consumption. • Avoid fast food restaurants. • Avoid adding salt to food when cooking. • Add spices and herbs rather than salt to enhance the flavor of food. • When planning meals and snacks: Use fresh and plain vegetables which are low in sodium. • When selecting canned food – choose only those prepared with reduced or no sodium.
The participant will discuss foods high in salt content.	The PI will discuss food to avoid that are high in salt content. • Barbecues, cured, salty meat or fish • Salty Bread products • Canned Foods • Others

APPENDIX E

Home BP Log Name:____________________
Target BP:__________________

Record your BP every morning and afternoon at the same time. Make comments in the comment box about possible reasons for BP results.

Date	Time (a.m.)	Blood Pressure	Comments	Time (p.m.)	Blood Pressure	Comments
Sample 12/05	8:30	148/90	Forgot to take meds	6:30	156/88	Stressful day

Please circle:

Were BP goals met pre HD BP < 140/90 and post HD BP <130/80? Yes No

If yes, did you positively reinforce yourself for BP goals met? Yes No
(ie. Positive Affirmations or engaging in pleasurable activities)

If goals were not met, list possible reasons and what you plan to do over the next week to help meet your goals.

APPENDIX F

24 Hour Fluid Intake Recall

Name:____________________

Record what you drank and the over the last 24 hrs from 6am yesterday to 6 am today. Include associated thoughts, emotions and behaviors (ie. I drank more because I went to a party, or was really thirsty).

Breakfast	Amount	Thoughts, Emotions, Behaviors

Snack

Lunch

Snack

Dinner

Snack

Please circle:

How close were you to meeting your goals?

1	2	3	4	5
Not at all		Half of the time		All of the time

If yes, did you positively reinforce yourself for goals met? (ie. Positive comments or engaging in pleasurable activities)

1	2	3	4	5
Not at all		Half of the time		All of the time

If goals were not met, list possible reasons and what you plan to do over the next week to help meet your goals.

APPENDIX G

Salt Intake Check-List Name:______________________

Please circle the number of times that you have eaten the following foods in the past three days, not counting today. It is important that you fill in the questionnaire as accurately as possible, indicating every time you have eaten any of the foods mentioned. We counted the occasions, not the amounts (for example three slices of bread score 1, if eaten on one occasion).

1. Food with salt added in cooking.

   0 1 2 3 4 5 6 7 8

2. Food with salt added at the table.

   0 1 2 3 4 5 6 7 8

3. Cured meats such as ham, bacon, sausages or luncheon meat.

   0 1 2 3 4 5 6 7 8

4. Corned/canned meats, meat pastes.

   0 1 2 3 4 5 6 7 8

5. Smoked or canned fish, fish pastes (salted).

   0 1 2 3 4 5 6 7 8

6. Processed cheese, cheese spreads.

   0 1 2 3 4 5 6 7 8

7. Olives, salted nuts, crackers, pretzels potato chips.

   0 1 2 3 4 5 6 7 8

8. Canned vegetables, canned soups (other than unsalted)

0 1 2 3 4 5 6 7 8

9. Packet soups, beef/chicken cubes

0 1 2 3 4 5 6 7 8

10. Salad dressings, sauces, condiments (other than unsalted)

0 1 2 3 4 5 6 7 8

11. Pot pies and TV dinners.

0 1 2 3 4 5 6 7 8

12. Ordinary (salted) butter or margarine

0 1 2 3 4 5 6 7 8

13. Ordinary (salted) breads.

0 1 2 3 4 5 6 7 8

14. Ordinary (salted) breakfast cereals.

0 1 2 3 4 5 6 7 8

15. Cakes, pastries, biscuits (other than low-sodium/salt)

0 1 2 3 4 5 6 7 8

16. Any salt-containing food that is not mentioned above.

0 1 2 3 4 5 6 7 8

Please circle:

Have you decreased your salt intake over the last week?

1	2	3	4	5
Not at all		Some of the time		All of the time

If yes, did you positively reinforce yourself for goals met? (ie. Positive comments or engaging in pleasurable activities)

1	2	3	4	5
Not at all		Some of the time		All of the time

If goals were not met, list possible reasons and what you plan to do over the next week to help meet your goals.

APPENDIX H

SODIUM

Sodium is a mineral that is found in salt (sodium chloride) and also in many foods. Sodium makes you thirsty and salt is almost half sodium. Not using salt is a good way of cutting down on sodium.

AVOID THESE HIGH SODIUM FOODS

BARBECUED, CURED, SALTY MEAT OR FISH

Bacon (beef or pork)
Ham and Corned Beef
Hot Dogs
Luncheon Meats
(bologna,salami, pickle loaf etc)
Frankfurters
Sausage
(beef, pork – Vienna, Polish or breakfast)
Canned Meats

Anchovies
Caviar
Herring
Lox
Sardines
Dried Chipped Beef
Salt Pork
Ham Hocks

SALTY BREAD PRODUCTS

Snack Foods (potato chips, corn chips, etc.)
Salted Crackers
Salted Popcorn
Pretzels

Boxed Dinner Helpers
Bread Stuffing Mixes
Instant Pudding Mixes

CANNED MAIN DISHES AND OTHER CANNED FOODS

Canned Chili
Corned Beef Hash
Soups (canned or dehydrated)
Bouillon (canned or cubes)
Pork and Beans

Tomato and Vegetable Juices
Pickled Vegetables (beets, okra, etc.)
Sauerkraut
Pickles and Olives

OTHERS

Cheese Spreads
Processed Cheese (e.g. Velveeta)
Pot Pies, TV Dinners
Buttermilk
Meat Tenderizers and Seasoning Salt
Salted Nuts and Snacks

Sauces Containing Salt
(catsup, chili sauce, soy sauce, steak sauce, BBW sauce, gravy, etc.)
Celery Salt and Accent

APPENDIX I

Helpful Hints For Fluid Control

Too much fluid is harmful to your heart and lungs. It may also make your dialysis time longer and uncomfortable (for example, muscle cramping). Two cups of fluid retained will equal one pound of weight gain. If you are diabetic, high blood sugar will increase your desire for excess liquids. Controlling your liquid intake and your weight gains between dialysis treatments is best for you.

1. Drink to satisfy thirst only. If you avoid high sodium (salty) foods, you will be less thirsty.

2. Ice cold liquids and ice may satisfy your thirst better than a warm hot beverage.

3. Try a lemon slice to moisten "dry" mouth.

4. Rinse your mouth with water or chilled mouthwash, but do not swallow it.

5. Take your medications with mealtime liquids.

6. Use very small cups and glasses for beverages. A full small cup looks more appealing than a half filled large cup.

7. Measure the ice allowed for the day and store in a special container in your freezer.

8. Try putting a small amount of lemon juice in the ice cubes; you will use fewer.

9. Suck on sugar free sour candies or chew gum to moisten your mouth and to help satisfy your thirst.

10. Be sure to eat as your diet plan recommends and you will have less desire for excess fluids.

11. Weigh yourself in the morning and evening and adjust your fluid intake so you do not gain more than one kilogram per day.

Fluid Restrictions

1 cup = 240 cc = 8 ounces (240cc)
¾ cup = 180 cc = 6 ounces (180 cc)
½ cup = 120 cc = 4 ounces (120cc)
¼ cup = 60 cc = 2 ounces (60cc)

Directions:

1. **Measure in standard measuring cups.**

2. **Medications must be taken with allowed fluids.**

3. **Drain liquids from fruits and vegetables.**

4. **The following count as fluid:**

   - **Any beverage such as coffee, tea, milk, juice, soda pop, water**
   - **Jello**
   - **Ice**
   - **Sherbert, ice cream popsicles**
   - **Liquid used for taking medications**

5. Many fruits and vegetables contain a lot of water and are therefore high in fluid content. If a fluid problem exists it may be necessary to avoid these foods or add them to your total fluid intake.

APPENDIX J

Data Collection Form

Patient ID #: **Baseline Weight:______ Baseline Height_________**

Demographic Information:

Age: _____ Gender: ☐ M ☐ F

Race: ___African American ___ Caucasian ___ Hispanic ___Asian ___Mideast/Arabian

___Native American Indian___Other___

Highest Education Level Completed:

Grade School: 1 2 3 4 5 6 7 8

High School: 9 10 11 12

College: 13 14 15 16

Graduate School: 17 18 19 20 21 22

Total household income for one year?

Less than $5000 ____

$5000 to $9999 ____

$10,000 to $19,999 ____

$20,000 to $29,999 ____

$30,000 to $49,999 ____

Greater than $50,000 ____

Are you employed?

No____ Yes ____ Part-time _____ Full-Time_____

Comorbid Conditions: Circle

DM IDDM NIDDM

CAD

CHF

Arthritis

COPD/Emphysema

Current Medications:

Drug	Dosage	Frequency

APPENDIX K

ENRICHD Social Support Instrument

Item 1 Is there someone available to whom you can count on to listen to you when you need to talk?

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

Item 2 Is there someone available to you to give you good advice about a problem?

Item 3 Is there someone available to you who shows you love and affection?

Item 4 Is there someone available to help with daily chores?

Item 5 Can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)?

Item 6 Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide in?

Item 7 Are you currently married or living with a partner?

Yes	No
□	□

APPENDIX L

BP Control in HD Knowledge Scale

1. I have high Blood pressure.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

2. Uncontrolled BP can lead to serious complications.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

3. Eating a low salt diet will help keep my blood pressure under control.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

4. Maintaining my fluid gains to 2 – 3 kg in between hemodialysis treatments will keep blood pressure under control.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

5. I drink more than six 8oz glasses of fluid a day.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

7. Taking my blood pressure medications as prescribed will help keep my blood pressure under control.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

8. Following my prescribed hemodialysis regimen will help keep my blood pressure under control.
   Strongly Disagree:__1__:__2__ :__3__:__4__:__5__:__6__:__7__Strongly Agree

APPENDIX M

BP Control in HD Self Efficacy Scale

Self Efficacy Question	Strongly Agree				Strongly Disagree
I can take my medication as prescribed.	5	4	3	2	1
I can restrict my daily salt intake.	5	4	3	2	1
I can limit junk food.	5	4	3	2	1
I can limit canned foods or soup.	5	4	3	2	1
I can limit salt with cooking.	5	4	3	2	1
I can limit salt on dinner table.	5	4	3	2	1
I can limit fast foods.	5	4	3	2	1
I can restrict my daily fluid intake to 6 - 8 8 ounce cups	5	4	3	2	1
I can limit my fluid gains to 2.5 kg in between HD treatments.	5	4	3	2	1
I can control my BP.	5	4	3	2	1
I can attend my weekly HD treatments	5	4	3	2	1

APPENDIX N

Morisky scale: No—0 points, Yes—1 point; total score of 0—high adherence, 1 to 2—medium adherence, 3 to 4—low adherence.

1. Do you ever forget to take your medicine?

   Yes or No

2. Are you careless at times about taking your medicine?

   Yes or No

3. When you feel better do you sometimes stop taking your medicine?

   Yes or No

4. Sometimes if you feel worse when you take the medicine, do you stop taking it?

   Yes or No

APPENDIX O

Improving BP Control in ESRD through a Supportive-Educative Nursing Intervention

Research Informed Consent

Title of Study: Improving Blood Pressure Control in End Stage Renal Disease through a Supportive-Educative Nursing Intervention

Principal Investigator (PI): Zorica Kauric-Klein, MSN, APRN-B, PhD-C
College of Nursing
(248)-425-1274

Funding Source: American Nephrology Nursing Association

Purpose

You are being asked to be in a research study to see if a nursing intervention will improve your blood pressure (BP). You are able to participate in this study because your current BP is not well controlled. This study is being conducted at Wayne State University and other hemodialysis (HD) units throughout the Detroit metropolitan area. The number of study participants to be enrolled in this study is about 140. **Please read this form and ask any questions you may have before agreeing to be in the study.**

Study Procedures

If you agree to take part in this study, your chart will be looked at by the principal investigator (PI) to make sure that you meet the criteria needed to be included in the study. If you meet initial criteria to participate in the study, you will be then be asked to fill out two surveys that should take about 10 minutes to finish. If the surveys indicate you meet the requirements to be in the study, you will then be asked to complete three short 5 minute surveys.

If you are able to enroll in the study, you will be randomized (by flipping a coin) into one of two groups of 70 participants according to the hemodialysis unit that you currently dialyze at. The study will take place over 12 weeks.

Group A: If you are a patient assigned to this group, you will receive the usual care you are currently receiving in the HD unit. Usual care consists of your health care provider monitoring your BP, teaching about BP and changing your BP pills as needed.

Group B: If you are a patient assigned to this group, you will receive usual care in addition to the intervention. The intervention will involve education on BP control in hemodialysis, home BP, salt and fluid intake monitoring and weekly follow-up with the principal investigator (PI).

At the end of 12 weeks, both groups will be given four short surveys to complete that will take about 20 minutes to complete. On a weekly basis, average pre HD BPs and fluid gains will be collected for both groups from your HD flow sheets.

Benefits

As a participant in this research study, there may be no direct benefit for you; however, information from this study may benefit other people now or in the future.

The possible benefits to you for taking part in this research study are improved blood pressure control and an increased understanding of high blood pressure and those factors that affect blood pressure control.

Risks

At this time, there are no known risks to participate in this study. There may be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

You do not have to participate in this study to receive treatment for your high blood pressure. You will receive all usual and medical care that is given to patients with hypertension and on hemodialysis.

Study Costs

- Participation in this study will be of no cost to you.

Compensation

You will not be paid for taking part in this study. However, every participant will receive a free home BP monitor for completion of the study.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study.] You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

Questions

If you have any questions about this study now or in the future, you may contact Zorica Kauric-Klein, MSN, APRN-BC, at the following phone number 1-248-425-1274. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

Improving BP Control in ESRD through a Supportive-Educative Nursing Intervention

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative *	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

*Remove LAR reference if you don't intend to consent participants that have or may have a LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD
MAY 12 '10 MAY 11 '11
HUMAN INVESTIGATION COMMITTEE

Signature of translator	Date
Printed name of translator	Time

REFERENCES

Agarwal, R., Nissenson, A., Batille, D., Coyne, D., Trout, J., & Warnock, D. (2003). Prevalence, treatment and control of chronic hemodialysis patients in the United States. *American Journal of Medicine*, *115*(4), 291-297

Agarwal, R. (1999). Role of home blood pressure monitoring in hemodialysis patients. *American Journal of Kidney Disease, 33*(4), 682-687.

Anderson, E., Winett, R., & Wojcik, J. (2007). Self-regulation, self-efficacy, outcome expectations and social support: social cognitive theory and nutrition behavior. *Annals of Behavioral Medicine*, *34*(3), 304-312.

Arici, M., Altun, V., Usalan, C., Ulusoy, S., Erdem, Y., Yasavul, U., et al., (1999). Compliance in hemodialysis patients. Unanticipated monitoring of biochemical indices. *Blood Purification*, *16, 27*5-280.

Badzek, L., Hines, S., & Moss, A. (1998). Inadequate self-care knowledge among elderly hemodialysis patients: assessing its prevalence and potential causes. *ANNA Journal*, *25*(1), 293-299

Bame, S., Petersen, N., & Wray, N. (1993). Variation in hemodialysis patient compliance according to demographic characteristics. *Social Science Medicine*, *37*(8), 1035-1043.

Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavioral change. *Psychological review, 84,* 191-215.

Bandura, A. (1991). Social cognitive theory of self-regulation. *Organizational behavior and human decision processes, 50,* 248-287.

Bandura, A. (1997). *Self-efficacy: the exercise of control*. New York: Freeman. Barnett, T., Yoong, T., Pinikahana, J., & Si-Yen, T. (2007). Fluid compliance among patients having haemodialysis: can an educational programme make a difference? *Journal of Advanced Nursing 61*(3), 300-306

Brady, B., Tucker, M., Alfino, P., Tarrant, D., & Finlayson, G. (1997). An investigation of factors associated with fluid adherence among hemodialysis patients: a self-efficacy theory based approach. *Annals of Behavioral Medicine, 19*(4), 339-343.

Brennan, T., Spettell, C., Villagra, V., Ofili, E., McMahill-Wairaven, C., Lowy, E., Daniels, P., Quarshie, A., & Mayberry, R. (2010). Disease management to promote blood pressure control among African Americans. *Population Health Management, 13*(2), 65-72.

Broege, P., James, G., & Pickering, T. (2001). Management of hypertension in the elderly using home blood pressures. *Blood pressure monitoring, 6*(3), 139-144.

Burns, N, & Grove, S. (2005). *The practice of nursing research: conduct, critique and utilization* (5th ed.). St. Louis, Missouri: Elsevier Saunders.

Capelli, C., (1990). Behavioral contracting with a monetary incentive program to improve fluid compliance of hemodialysis patients. (Doctoral Dissertation: Hattiesburg, MS: University of Southern Mississippi.

Cappuccio, F., Kerry, S., Forbes, L., & Donald, A. (2004). Blood pressure control by home monitoring: meta-analysis of randomized trials. *British Medical Journal, 329*(7458), 145-159.

Cappuccio, F., Markandu, N., Carney, C., Sagnella, F., & MacGregor, G. (1997). Double blind randomized trial of modest salt restriction in older people. *Lancet, 350*, 850-854.

Carels, R., Darby, L., Rydin, S., Douglass, O., Cacciapaglia, H., & O'Brien, W. (2005). The relationship between self-monitoring, outcome expectancies, difficulties with eating and exercise and physical activity and weight loss treatment outcomes. *Annals of Behavioral Medicine*, *30*(3), 182-190.

Casey, J. Johnson, V., & McClelland, P. (2002). Impact of stepped verbal and written reinforcement of fluid balance advice within an outpatient hemodialysis unit: a pilot study. *Journal of Human Nutrition and Dietetics*, *15*, 43-47.

Charra, B. (2007). Fluid balance, dry weight and blood pressure in dialysis. *Hemodialysis International*, *11*, 21-31.

Cheigh, J., Milite, C., Sullivan, J., Rubin, A., & Stenzel, K. (1992). Hypertension is not adequately controlling hemodialysis patients. *American Journal of Kidney Disease*, *19*(5), 453-459.

Christensen, A., Wiebe, J., Edwards, D., Michels, J., & Lawton, W. (1996). Body consciousness, illness-related impairment and patient adherence in hemodialysis. J*ournal of Consulting and Clinical Psychology*, *64*(1), 147-152.

Christensen, A., Moran, P., Wiebe, J., Ehlers, S., & Lawton, W. (2002). Effect of a behavioral self-regulation intervention on patient adherence in hemodialysis. *Health Psychology* *21*(4), 393-397.

Clark, N., & Dodge, J. (1999). Exploring self-efficacy as a predictor of disease management. *Health Education and Behavior*, *26*(1), 72-89.

Cohen, J., Cohen, P., West, S., & Aiken. (2003). *Applied multiple regression/correlation analysis for the behavioral sciences (third edition)*. Mahwah, New Jersey: Lawrence Erlbaum Associates, Inc.

Cummings, M., Becker, M., Kirscht, J., Levin, N. (1981). Intervention strategies to improve compliance with medical regimens by ambulatory hemodialysis patients. *Journal of Behavioral Medicine, 4,* 111-127.

Curtin, R., Svarstad, B., & Kellar, T. (1999). Haemodialysis patient non-compliance with oral medications. *American Nephrology Nurses' Association, 26*(3), *307-316.*

Curtin, R., Walters, B., Schatell, D., Pennell, P., Wise, M., & Klicko, K. (2008*).* Self-efficacy and self-management behaviors in patients with chronic kidney disease. *Advances in Chronic Kidney Disease, 15(2),* 191-205.

Denhaerynck, K., Manhaeve, D., Dobbels, F., Garzoni, D., Nolte, C., & DeGeest, S. (2007). Prevalence and consequences of nonadherence to hemodialysis regimens. *American Journal of Critical Care*, *16*(3), 222-235

DiMatteo, . R., Lepper, H., & Croghan, T. (2000). Depression is a risk factor for noncompliance with medical treatment. *Archives of Internal Medicine, 160,* 2101 – 2107.

Dowson, C., Town, G., Frampton, C., & Mulder, R. (2004). Psychopathology and illness beliefs influence COPD self-management. *Journal of Psychosomatic Research*, *56*(3), 333-340.

Everett, K., Brantly, P., Sletten, C., Jones, G., & McNight, G. (1995). The relation of stress and depression to interdialytic weight gain in hemodialysis patients. *Behavioral Medicine, 21,* 25-27.

Everett, K., Stetten, C., Carmack, C., Brantley, P., Jones, G., & McKnight, R. (1993). Predicting noncompliance to fluid restrictions in hemodialysis patients. *Dialysis and Transplantation*, *22*(10), 614-620.

Glynn, L., Murphy, A., Smith, S., Schroeder, K., & Fahey, T. (2010). Interventions used to improve control of blood pressure in patients with hypertension (Review). *Cochrane Database of Systematic Reviews, Issue 3,* Art. No.: CD005182.

Fahey, T., Schroeder, K., & Ebrahaim, S. (2006). Interventions used to improve control of blood pressure in patients with hypertension (Review). *Cochrane Database of Systematic Reviews, Issue 4,* Art. No.: CD005182.

Foque, F. (2003). Nutritional requirements in maintenance hemodialysis. *Advances in Renal Replacement Therapy*, *10*(3), 183-19.

Friend, R., Hatchett, L., Wadhwa, N., & Schneider (1997). Serum albumin and depression in end-stage renal disease. *Advance in Peritoneal Dialysis, 13*, 155-157.

Glasziou, P., Irwig, L., & Mant, D. (2005). Monitoring in chronic disease a rational approach. *British Medical Journal, 330*(19), 644-648.

Gleeson-Kreig, (2006). Self-monitoring of physical activity: effects on self-efficacy and behavior in people with type 2 diabetes. *The Diabetes Educator, 32*(1), 69- 82.

Goldsmith, D., Covic., Venning, M., & Ackrill, P. (1996). Blood pressure reduction after parathyroidectomy for secondary hyperparathyroidism: further evidence implicating calcium homeostasis in blood pressure regulation. *American Journal of Kidney Disease, 27,* 819.

Gonzalez, J., Safren, S., Cagliero, E., Wexler, D., Lelahanty, L., Wittenberg, E, Blais, M., Meigs, J., & Grant, R. (2007). Depression, self-care and medication adherence in type 2 diabetes: relationship across the full range of symptom severity. *Diabetes Care, 30*(9)

Halme, L., Vesalainen, R., Kaaja, M., & Kantola, I. (2005). Self-monitoring of blood pressure promotes achievement of blood pressure target in primary health care. *American Journal* *of Hypertension, 18,* 1415-1420.

Hart, E. (1979). Utilization of token economy within a chronic dialysis unit. *Journal of Consulting and Clinical Psychology*, *47*(3), 646-648.

He, F., Markandu, N., Grahm, A., & MacGregor, G. (2005). Modest salt reduction lowers blood pressure in isolated systolic hypertension and combined hypertension. *Hypertenion, 46,* 66-70.

Hegel, M., Ayllon, T., Thiel, G., & Oulton, B. (1992). Improving adherence to fluid restriction in male hemodialysis patients: a comparison of cognitive and behavioral approaches. *Health Psychology*, *11*(5), 324-330.

Horl, M. & Horl, W. (2002). Hemodialysis-associated hypertension: pathophysiology and therapy. *American Journal of Kidney Diseases*, *39(2)*, 227-244.

Ignacio-Garcia J., & Gonzalez-Santos, P. (1995). Asthma self-management education program by home monitoring of peak expiratory flow. *American Journal of Respiratory and Critical Care Medicine*, *151*(2), 353-359.

Johnson, S. & Dwyer, A. (2008). Patient perceived barriers to treatment of depression and anxiety in hemodialysis patients. *Clinical Nephrology*, *69*(3), 201-206.

Kanfer, F. & Gaelick, L. (1986). Self-management methods. In F. Kanfer & A. Goldstein (Eds.), *Helping people change* (3rd ed.). New York: Paergamon Press.

Kaplan De-Nour, A., Czaczkes, W. (1978). The influence of patients personality on adjustment to chronic dialysis. *Journal of Nervous Mental Disorder*, *162*, 323-333.

Kauric-Klein, Z., & Artinian, N. (2007). Improving blood pressure control in hypertensive hemodialysis patients. *The CANNT journal*, *17*(4), 24 -29.

Kaveh, K., & Kimmel, P. (2001). Compliance in hemodialysis patients: Multidimensional measures in search of a gold standard. *American Journal of Kidney Diseases, 37*(2), 244-266.

Kerlinger, F., & Lee, H. (2000). *Foundations of Behavioral Research*. (4th ed). Belmont California: Wadsworth Publishing.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D & Verne, D., et al. (1995). Behavioral compliance with dialysis prescriptions in hemodialysis patients. *Journal of American Nephrology, 5,* 1826-1834.

Kimmel, P. (2002). Depression in patients with chronic renal disease: what we know and what we need to know. *Journal of Psychosomatic Research, 53*, 951-956.

Kitis, Y., & Emiroglu, O. (2005). The effects of home monitoring by public health nurse on on individuals' diabetes control. *Applied Nursing Research, 19*(3), 134-143.

Krapek, K., King, K., Warren, S., George, K., Caputo, D., & Mihelich, K. (2004). Medication adherence and associated hemoglobin A1C in type 2 diabetes. Annals of Pharmacotherapy, *38*(9), 1357-1362.

Krautzig, S., Janssen, U., Koch, K., Granolleras, C., & Shaldon, S. (1999). Dietary salt restriction and reduction of dialysate sodium to control hypertension in maintenance hemodialysis patients, *Nephrology Dialysis Transplantation, 13*, 552-553.

Kroenke, K., Spitzer, R., & Williams, J. (2003). The patient health questionnaire-2: validity of a two item depression screener. *Medical Care, 41*(11), 1284-1292.

Kugler, Vlaminck, Haverich & Maes (2005). Nonadherence with diet and fluid restrictions among adults having hemodialysis. *Journal of Nursing Scholarship, 37*(1), 25-29.

Leggat, J., Orzol, S., Hulbert-Shearon, T. Golper, T., Jones, C., & Held, P. (1998). Noncompliance in hemodialysis predictors and survival analysis. *American Journal of Kidney Disease, 32*(1), 139-145.

Linde, J,. Jeffrey, R., French, S., Pronk, N & Boyle, R. (2005). Self-weighing in weight gain prevention and weight loss trials. *Annals of Behavioral Medicine, 30*(3), 210-216.

Locke, E., & Latham, G. (2002). Building a practically useful theory of goal setting and task motivation. A 35 year odyssey. *American Psychologist, 57*, 705-717.

Mai, F. Busby, K & Bell, R. (1999). Clinical rating of compliance in chronic hemodialysis patients. *Canadian journal of Psychiatry, 44*(5), 478-482.

Mazzuchi, N., Carbonell, E. & Fernandez-Cean, J. (2000). Importance of blood pressure control in hemodialysis patient survival. *Kidney International*, *58,* 2147-2154.

MacGregor, G., Markandu, N., Best, F., Elder, D., Cam, J., Sagnella, G & Squiires, M. (1982). Double- blind randomized crossover trial of moderate sodium restriction in essential hypertension. *Lancet*, *1*, 351-355.

MacGregor, G., Markandu, N, Sagnella, G., Singer, D., Cappuccio, F. (1989). Double-blind study of three sodium intakes and longterm effects of sodium restriction in essential hypertension, *Lancet, 2,* 1244-1247.

McKellar, J, Humphreys, K., & Plette, J. (2006). Depression increases diabetes symptoms by complicating patients self-care adherence. *The Diabetes Educator, 30(3),* 485-486.

McQuiston, C. M. & Cambell, J. C. (1996). Theoretical substruction: A guide for theory testing research. *Nursing Science Quarterly, 10*(3).

Mettal, S., Kowalski, E., Trenkle, J., MacDonough, B., Halinski, D., Devlin, K., Boylan, E., Flaster, E., & Maesaka, J. (1999). Prevalence of hypertension in a hemodialysis population. *Clinical Nephrology, 51*, 77-82.

Molaison, E., & Yadrick, M. (2003). Stages of change and fluid intake in dialysis patients. *Patient Education and Counseling, 49*, 5-12.

Montgomery, J., Harding, J., & Fahey, T. (2001). Shared decision making in hypertension: the impact of patient preferences on treatment choice. *Family Practice, 18*, 309-313.

Moran, P., Christensen, A., & Lawton, W. (1997). Social support and conscientiousness in hemodialysis adherence. *Annals of Behavioral Medicine*, *19*(4), 333-338.

Morisky, D., Green L., Levine DM. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care, 24*(1*)*, 67-74.

Morse, S., Dang, A., Thakur, V., Zhang, R., & Reisin, E. (2003). Hypertension in chronic dialysis patients: pathophysiology, monitoring and treatment. *American Journal of the Medical Sciences, 325*(4), 194-201.

Murray, A. (2008). Cognitive Impairment in the aging dialysis and chronic kidney disease populations: an occult burden. *Advances in Chronic Disease*, *15*(2), *123-132*

Nozaki, C., Oka, M., & Chabooyer, W. (2005). The effects of a cognitive behavioral therapy programme for self-care on hemodialysis patients. *International Journal of Nursing Practice, 11*, 228-236.

Obialo, C., Bashir, K., Goring, S., Robinson, B., Quarshie, A., Al-Mahmou, A., & Alexander-Squires, J. (2008). Dialysis "no-shows" on saturdays: implications of the weekly hemodialysis schedules on nonadherence and outcomes. *Journal of the National Medical Association*, *100*(4), 412-419.

O'Brien, M. (1990). Compliance behavior and long-term maintenance dialysis. *American Journal of Kidney Disease*, *15*, 209-214.

Oka, M., & Chaboyer, W. (1999). Dietary behaviors and sources of support in hemodialysis Patients. *Clinical Nursing Research, 8*(4), 302-317.

Olivarius, N., Beck-Nielsen, H., Andreasen, A., Horder, M., & Pedersen, P. (2001). Randomised controlled trial of structured personal care of type 2 diabetes mellitus, *British Medical Journal*, *323*, 970-975.

Orem, D. (Ed.). (2001). *Nursing: Concepts of Practice* (6th ed.). St. Louis: Mosby Ozkahya, M., Cirit, M., Aydin, S., Akcicek, F., Basci, A., et al., (1998). Regression of left ventricular hypertrophy in haemodialysis patients by ultrafiltration and reduced salt intake without antihypertensive drugs. *Nephrology Dialysis Transplantation*, *13*(6), 1489-1493.

Ozkahya, M., Toz, H., Qzerkan, F., Duman, S., Od, E, Basci, A., et al., (2002). Impact of volume control on left ventricular hypertrophy in dialysis patients. *Journal of Nephrology*, *15*(6), *655-660.*

Patel, R., & Taylor, S. (2002) Factors affecting medication adherence in hypertensive patients. *Annals of Pharmacotherapy*, *36*, 40-45.

Peters, E., & Templin, T. (2008). Measuring blood pressure knowledge and self-care behaviors of African Americans. *Research in Nursing and Health, 31,* 543-552.

Pickering, T., Miller, N., Ogedegbe, G., Krakoff, L., Artinian, N., & Goff, D. (2008). Call to action on use and reimbursement for home blood pressure monitoring: executive summary: a joint scientific statement from the American Heart Association, American Society of Hypertension and Preventive Cardiovascular Nurses Association. *Hypertension*, *52*(1), 1-9.

Rachmani, R., Slavacheski, I., Berla, M., Frommer-Shapira, R., & Ravid, M. (2005) Treatment of high risk patients with diabetes: motivation and teaching intervention: a randomized, prospective 8-year follow-up study. *Journal of American Society of Nephrology, 18,* S22-S26.

Rahman, M., Dixit, A., Donley, V., Gupta, S., Hanslik, T., Lacson, E., Ogundipe, A., Weigel, K., & Smith, M. (1999). Factors associated with inadequate blood pressure control in hypertensive hemodialysis patients. *American Journal of Kidney Diseases, 33*, 498-506.

Rahman, M., Fu. P., Sehgal, A., & Smith, M. (2000). Interdialytic weight gain, compliance with dialysis regimen and age are independent predictors of blood pressure in hemodialysis patients. *American Journal of Kidney Disease*, *35*, 257-265**.**

Rahman, M., & Griffin, V. (2004). Patterns of antihypertensive medication use in hemodialysis patients, *American Journal of Health-System Pharmacy, 61*(14), 1473-1478.

Raine, A., & Rogers, S. (1991). Effects of erythropoietin on blood pressure. *American Journal of Kidney Disease, 18*(4), 76-83.

Rigby, A., Scribner, B., & Ahmad, S. (2000). Sodium not fluid controls interdialytic weight gain. *Nephrology news and issues, 14*(9). 21-22.

Rocco, M., Yan, G., Heyka, R., Benz, R., & Cheung, A. (2001). Risk factors for hypertension in chronic hemodialysis patients: baseline data from the HEMO study. *American Journal of nephrology, 21*(4), 280-288.

Rupp, J., Stone, R., and Gunning, B., (1978). Sodium versus sodium-fluid restriction in hemodialysis: control of weight gains and blood pressures. *The American Journal of Clinical Nutrition, 31*, 1951-1955.

Sacks, F., Svetkey, L., Vollmer, W., Appel, L., Bray, F., Harsh, D., Obarzanek, E., et al., (2001). Effects of blood pressure of reduced dietary sodium and the dietary approaches to stop hypertension (dash) diet. *The New England Journal of Medicine, 344*(1), 3 – 10.

Safdar, N., Baakza, H., Kumar, H. & Naqvi, S. (1995). Non-compliance to diet and fluid restrictions in hemodialysis patients. *Journal of the Pakistanian Medical Association, 45(11),* 293-295.

Sagawa. M., Oka, M., Chaboyer, W., Satoh, W., & Yamaguchi, M. (2001) Cognitive behavioral therapy for fluid control in hemodialysis patients. *Nephrology Nursing Journal, 28*(1), 37-39.

Schneider, M., Friend, R., Whitaker, P., & Wadhwa, N. (1991). Fluid noncompliance and symptomatology in end stage renal disease: Cognitive and emotional variables. *Health Psychology, 10(3),* 209-215.

Schnoll, R., & Zimmerman, B. (2001). Self-regulation training enhances dietary self-efficacy and dietary fiber consumption. *Journal of the American Dietetic Association, 101*(9), 106-1011.

Schwedes, U., Siebolds, M., & Mertes, G. (2002). Meal related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin treated type 2 diabetic patients. *Diabetes Care*, *25*(11), 1928-1932.

Sensky, T., Leger, C., & Gilmour, S. (1996). Psychosocial and cognitive factors associated with adherence to dietary and fluid restriction regimens by people on chronic haemodialysis. *Psychotherapy and Psychosomatics, 61*(1), 36-42.

Sharp, J., Wild, R., & Gumley, A. (2005). A systematic review of psychological interventions of nonadherence to fluid-intake restrictions in people receiving hemodialysis. *American Journal of Kidney Diseases, 45*(1), 15-27.

Sung, J., Nichol, M., Centurini, F., Bailey, K., McCombs, J., & Cody. (1998). Factors affecting patient compliance with antihyperlipidemic medications in an HMO population. *American Journal of Managed Care, 4,* 1421-1430.

Swift, P., Markandu, N., Sagnella, G., He, F., & MacGregor, G. (2005). Modest salt reduction reduces blood pressure and urine protein excretion in black hypertensives: a randomized control trial. *Hypertension, 46,* 308-312.

Tanner, C., Craig, C., Bartolucci, M., Alton, L & Geiger, B. (1998). The effect of a self-monitoring tool on self efficacy, health beliefs and adherence in patients receiving hemodialysis. *Journal of Renal Nutrition, 8,* 203-211.

Trials of Hypertension Prevention Collaborative Research Groups. (1997). Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure: the trials of hypertension prevention, phase II. *Archives of Internal Medicine, 157*(6), 657-667.

Tsay, S. (2003). Self-efficacy training for patients with end-stage renal disease, *Journal of Advanced Nursing, 43*(4), 370-375.

Tucker, C. (1989). The effects of behavioral intervention with patients, nurses and family members on dietary noncompliance in chronic hemodialysis patients, *Transplantation Proceedings, 21*(6), 3985-3988.

Unruh, M., Evans, I, Fink, N., Powe, N., & Meyer, K. (2005). Skipped treatments, markers of nutritional nonadherence, and survival among incident hemodialysis patients. *American Journal of Kidney Disease, 46*(6), *1107-1116.*

U.S. Renal Data System, (2006). *USRDS 2006 Annual Data Report: Atlas of End-Stage Renal Disease in the United States.* Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

U.S. Department of Health and Human Services, (2003). *Healthy People 2010.* Hyattsville, MD: Office of Disease Prevention and Health Promotion.

Vlaminck, H., Maes, B., Jacobs, A., Reyntjens, S., & Evers, G. (2001). The dialysis and fluid non-adherence questionnaire: Validity testing of a self-report instrument for clinical practice. *Journal of Clinical Nursing, 10,* 707-715.

Welch, J., Perkins, S., Evans, J., & Bajpal, S. (2003). Differences in perception by stage of fluid adherence. *Journal of Renal Nutrition, 13*(4), 275-281.

Welch, J., & Thomas-Hawkins, C. (2005). Psychoeducational strategies to promote fluid adherence in adult hemodialysis patients: a review of intervention studies. *International Journal of Nursing Studies, 42*(5), 597-608.

Wiebe, J. S. & Christensen, A. (1997). Health beliefs, personality, and adherence in hemodialysis patients: an interactional perspective. *Annals of Behavioral Medicine, 19*(1), 30-35.

Wilde, M. H., & Garvin, S. (2007). A concept analysis of self-monitoring. *Journal of Advanced Nursing: Theoretical Paper,* 339-346.

Wilson, B. (1991). Matching instructional methods to renal patients' learning abilities: The effect on knowledge and compliance with fluid restriction. *Journal of Renal Nutrition, 1,* 173 -181.

Zrinyl, M., Juhasz, M., Balla, J., Katona, E., Ben., T., Kakuk, G., & Pall, D. (2003). Dietary self-efficacy: determinant of compliance behaviours and biochemical outcomes in hemodialysis patients. *Nephrology, dialysis, transplantation, 18*(9), 1869-1873.

ABSTRACT

IMPROVING BLOOD PRESSURE CONTROL IN ESRD THROUGH A SUPPORTIVE EDUCATIVE NURSING INTERVENTION

by

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May 2011

Advisor: Dr. Nancy T. Artinian

Major: Nursing

Degree: Doctor of Philosophy

Problem: Hypertension in chronic hemodialysis (HD) patients contributes significantly to their morbidity and mortality. Statistics indicate the hypertension rate amongst HD patients ranges from 75 to 100 %. Studies have indicated that adherence rates to self-care behaviors related to salt and fluid intake and medication regimens are very poor in the HD population. Traditional hypertension management strategies have been found to be largely ineffective. There is modest evidence indicating that interventions which incorporate a combination of self-regulation components (self-monitoring, goal-setting and reinforcement) appear to have the most impact on adherence to BP self-care behaviors in the HD patient. **Purpose:** The major purpose of this study is to determine if a supportive educative nursing intervention incorporating self-regulation components will improve BP control in a chronic HD population. **Theoretical Framework**: 'Theory of Improving BP Control in Hypertensive HD patients' deduced from Orem's Self-Care Deficit Nursing Theory and Self Regulation Theory. **Design:** A randomized experimental design. **Sample:** 118 participants recruited from 6 HD units in the Detroit Metro area. **Method:** The intervention consisted of : 1) BP education sessions, 2) 12 week intervention and 3) 30 day post intervention follow-up period. The participants in the treatment group received an Omron

HEM-780 BP monitor and were asked monitor and record home BP twice daily. They were also asked to monitor and record their 24 hr fluid intake and salt intake on a weekly basis. BP, fluid and salt logs were reviewed weekly to determine if goals were met or not met. Reinforcement was given for goals met and problem solving offered when goals were not met. The control group received standard care which involved BP monitoring and medication adjustment by health care providers on a weekly basis in the HD unit as needed. **Findings:** The intervention significantly decreased both systolic and diastolic BP in the treatment group. It appears the intervention improved systolic and diastolic BP through BP goal setting and reinforcement, improved HD adherence and increased medication changes within the treatment group. Further studies should be conducted to validate these findings.

AUTOBIOGRAPHICAL STATEMENT

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EDUCATION

Wayne State University, Detroit , MI	PhD candidate	2003-Present
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Kidney Care Specialists, Berkley, MI	Nephrology Nurse Practitioner	2009-
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St Clair Specialty Physicians, Detroit, MI	Nephrology Nurse Practitioner	2000-2004
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Henry Ford Medical Centre Woodhaven, MI	Internal Medicine NP	1996-1999
St. John's Hospital, Detroit, MI	Advance Practice Nurse	1994-1996
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PUBLICATIONS

Kauric-Klein, Z. & Artinian, N. (2007). Improving blood pressure control in hypertensive hemodialysis patients. *Canadian Association of Nephrology Nurses and Technologists Journal, 17(4),* 24 -29.

CERTIFICATION & LICENSURE

Michigan Board of Nursing	Registered Nurse and Specialty Certification – Adult Nurse Practitioner
ANCC	Adult Nurse Practitioner certification