EXPERIENCE OF MANAGING ESRD DIETARY MODIFICATIONS

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A STUDY OF HEMODIALYSIS PATIENT EXPERIENCE OF DIETARY

MODIFICATION MANAGEMENT

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Aims: The purpose of this mixed-methods study is to explore the impact of participant characteristics on dietary patterns, adherence, perceived problems, and self-efficacy; identify characteristics of hemodialysis patients most likely to experience difficulty adhering to restrictions; and to explore perceived dietary related barriers experienced in this patient population.

Methods: A secondary analysis using data of 122 participants from an ongoing randomized clinical trial examining the effects of a technology supported behavioral intervention on dietary sodium intake in hemodialysis patients was performed. Semi-structured interviews were conducted on a subset of 30 participants to complete the qualitative analysis.

Results: Younger participants were more likely to report problems managing the hemodialysis diet and low self-efficacy for restricting sodium intake. Consistent with these findings, younger participants had a higher median sodium intake and average daily weight gain. Females reported more problems managing the diet. Race and perceived income adequacy did not appear to influence outcome measures. Barriers included time and convenience, cost, and content of nutritional counseling. Participants were satisfied with efforts made by dialysis center staff to disseminate information.

Conclusions: Our findings suggest that there may not be a need to customize interventions in regard to race or income adequacy. There may, however, be a need to customize counseling and interventions for younger adults and females. Further investigation is needed to understand the independent effects of age and gender on variations in hemodialysis dietary recommendations and problems and self-efficacy. Additionally, while participants were satisfied with nutritional counseling efforts, interventions which improve food choices and decision making in real time would be helpful.

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PREFACE

This study was supported through NIH funding via the following grants: NIH-R01-NR010135, NIH-K24-NR012226, and 1F31NR013410. The principal investigator would like to acknowledge the individual contributions of her dissertation chair, co-chair, and committee; Lin Hough, MPH, Ann Steenkiste, MS; Susan Stark, RD, MS, Beth Hall, RD; Jennifer Thurheimer, MSN, RN; and Tienna Luster. She would also like to thank her family and friends for their patience and support. The contents of this dissertation document do not represent the views of the Department of Veterans Affairs or the United States Government.

1.0 INTRODUCTION

End stage renal disease (ESRD), a global health concern, is increasing in incidence. The number of patients enrolled in this Medicare-funded program, which, provides life-sustaining hemodialysis for ESRD patients has exponentially increased from approximately 10,000 in 1973 to over 570,000 in 2009 (USRDS, 2011) and was estimated to further increase to more than 650,000 patients by 2010 (USRDS, 2011; Graudal & Galloe, 2000; Bostrom et al., 2010). The most common causes of ESRD are hypertension and diabetes (Blagg, 2007). Although Caucasians comprise the majority of ESRD patients, African Americans and individuals of lower socioeconomic status (SES) are disproportionately represented. Statistics indicate ESRD prevalence is 3.6 times greater for African Americans compared to Caucasians (Vassaloti, Li, McCullogh, & Barkis, 2010; Ulasi, Arodiew, & Ijoma, 2006). Additionally, low SES has been demonstrated to be a predictor of greater morbidity and mortality in ESRD (Ulasi, et al., 2006; Young, Mauger, Jiang, Port, & Wolfe, 1994; Fried, 2010; Crews, Charles, Evans, Zonderman, & Powe, 2010).

Cardiovascular related events are the major cause of morbidity and mortality in patients with ESRD (Kopyt, 2007; Xue, Ma, Louis, & Collins, 2001; Zhang & Rothenbacher, 2008; Lunsford, et al., 2006; Silberberg, Barre, Prichard, & Sniderman, 1989). Of cardiovascular conditions, left ventricular hypertrophy (LVH) is the most ominous. The development of LVH is hastened by the multiple comorbid conditions associated with ESRD, particularly hypertension

(Xue, Ma, Louis, & Collins, 2001). Additionally, because hemodialysis patients produce little or no urine, uremic waste increases in the bloodstream, triggering thirst and excessive fluid intake. Hemodialysis is highly effective in removing excessive fluid. However, large fluctuations in interdialytic weight gain (IDWG) cause extracellular volume expansion and increase blood pressure, which in turn, place increased strain on the heart, and further predispose the patient to LVH. Hypertension and extracellular volume expansion are responsive to fluid restriction and, therefore, hemodialysis patients are typically urged to consume as little as 0.5 liters of fluid per day (Denhaerynck, et al., 2007). From a practical perspective, it is unrealistic to expect hemodialysis patients to reduce fluid intake if they do not also minimize sodium intake. High sodium intake exacerbates thirst and makes it difficult for hemodialysis patients to restrict fluid intake. High dietary sodium also contributes to hypertension, and blunts the effectiveness of some antihypertensive agents (Nicholson, Resnick, & Laragh, 1987). From a study enrolling ESRD patients, Sevick and colleagues demonstrated that dietary sodium restriction alone resulted in a clinically significant reduction of IDWG (Sevick, et al., 2008).

Dietary sodium intake reflects personal preferences and learned behaviors that develop over a person's lifetime. It is commonly believed that these preferences and behaviors are shaped by education, income, family, religious, racial, and ethnic norms, local availability of food, and the perceived nutrition-health link (Asp, 1999; Wyndels, et al., 2011; Furst, Connors, Bisgoni, Sobal, & Falk, 1996; Holmberg, Coveney, Henderson, & Meyer, 2010; Lin, Wu, & Anderson, 2012.). It is therefore logical that the same preferences and behaviors would continue to influence choices of patients both before and after development of ESRD. A secondary analysis of data (MNC) from an ongoing randomized trial (R01 NR010135), indicated that adequacy of income was more important than race, sex, or marital status in predicting dietary problems

experienced by hemodialysis patients (**See Preliminary Work, Chapter 4.0**). An extensive review of the literature failed to identify any studies that explored the specific barriers faced by minorities and low SES patients attempting to follow the hemodialysis dietary regimen and, in particular, dietary sodium restriction.

1.1 PURPOSE

T**he purpose of this mixed-methods study** was to explore the impact of sociodemographic and economic characteristics on dietary patterns of ESRD patients attempting to meet dietary goals for hemodialysis.

1.2 SPECIFIC AIMS

The specific aims were to:

1. Fully explore the problems and barriers perceived by a diverse hemodialysis patient population in their attempts to follow the hemodialysis diet, with specific attention to African American and low SES patients;

2. Describe dietary patterns (in particular sodium intake) and patterns of IDWG among hemodialysis patients; and

3. Explore associations between diet, IDWG, problems experienced, barriers and perceived self-efficacy and sociodemographic and economic characteristics.

1.2.1 Significance

Adequate self-management of dietary sodium and fluid restriction are paramount for health maintenance in ESRD. It is, however, challenging to follow expected guidelines. These ongoing challenges may be a factor influencing findings of prior studies, which report that only 34% of patients survive 5 years after initiation of hemodialysis therapy (USRDS, 2011). Medicare is the primary payer for ESRD care, devoting 5.9% of its entire budget ($26.8 Billion) in 2008 to this health issue (Menon & Sarnak, 2005; Graudal & Galloe, 2000). Poor outcomes and escalating costs make identification of interventions to improve outcomes a priority.

2.0 LITERATURE REVIEW

2.1 END STAGE RENAL DISEASE

In 2009, the adjusted rate of incidence for ESRD was 355 per million persons, with a prevalence of 1,738 per million persons. Medicare is the principal payer for ESRD and hemodialysis management. The number of patients enrolled in this Medicare-funded program has increased from approximately 10,000 beneficiaries in 1973 to over 570,000 in 2009. By 2010, projections indicated the number of ESRD patients would increase to over 650,000 and total Medicare ESRD program costs to $28 billion dollars (USRDS, 2011). Despite the magnitude of resources committed to the treatment of ESRD and substantial improvements in the quality of dialysis therapy, patients continue to experience significant mortality and morbidity (Crews, Charles, Evans, Zonderman, & Powe, 2010). Notably, survival for hemodialysis patients at one, two and five years is 81%, 65%, and 34% respectively (USRDS, 2011).

Prior studies consistently demonstrate significant racial/ethnic and socioeconomic disparities in regard to the incidence, prevalence, and outcomes of patients with ESRD (Magrab & Papadopoulou, 1977). Statistics indicate ESRD prevalence is 3.6 times greater for African Americans compared to Caucasians (Vassalot, Li, McCullough, & Bakris, 2012; Ulasi, Arodiwe,

& Ijoma, 2006; Martins, Tarren, & Norris, 2002). ESRD also begins earlier; the median age at diagnosis for African Americans is 59.2 years of age compared to 66.8 years of age for Caucasians. Minorities demonstrate poorer survival than Caucasians and are less likely to receive renal transplantation (Crews, Charles, Evans, Zonderman, & Powe, 2010; Sehgal, 2003). Economic factors are also an issue. Several studies have identified low SES as a predictor of greater morbidity and mortality in ESRD (Ward, 2007; Young, Mauger, Jiang, Port, & Wolfe, 1994). Young et al. (1994) demonstrated an inverse relationship between lower SES and ESRD risk, regardless of race.

Cardiovascular disease is the most common cause of death in ESRD (Xue, Ma, Loius, & Collins, 2001). Left ventricular hypertrophy, a harbinger of cardiovascular morbidity and mortality in ESRD patients, is caused primarily by hypertension and large gains in fluid volume between hemodialysis treatments. Consequently, hemodialysis patients are urged to minimize IDWG by controlling dietary sodium intake and limiting fluid intake to as little as 0.5 liters per day (Denhaerynck, et al., 2007). Recent small studies suggest that salt restriction and strict fluid restriction can reduce IDWG (Fisher, et al., 2006; Christensen, Moran, Wiebe, Ehler, & Lawton, 2002) and in turn, reduce left ventricular hypertrophy (Rahman, et al., 1999) and death (Ozkahya, et al., 2002). In addition to the cardiovascular effects of excess dietary sodium intake, patients with substantial IDWG (>1.0 kg) require increased ultrafiltration (fluid removal) during hemodialysis, which has been shown to cause intradialytic hypotension and post-dialysis symptoms (Rahman, et al., 1999). Thus, improved control of sodium intake is likely to have a positive impact on the health, survival, and quality of life of a substantial number of hemodialysis patients.

2.2 DIALYSIS MODALITIES

For those with ESRD, renal replacement therapy is required to sustain life. Therapy can be either intermittent, (performed multiple times per week, for a duration of less than 24 hours) or continuous (performed 24 hours per day without interruption) (Mehta et. al, 2001). Patients may elect to perform peritoneal or hemodialysis in their home or an outpatient treatment site. For the purpose of this study, individuals undergoing outpatient intermittent hemodialysis therapy were recruited for participation because they are more likely to experience fluid and sodium related weight gains between therapy sessions and therefore at greatest risk for adverse cardiovascular and other health related outcomes.

2.3 HEALTH CARE DISPARITIES

Health care disparities are often associated with provision or access to care. In the United States, neither provision nor access to care is a concern in regard to ESRD. In 1972, Medicare coverage was extended by federal law to all individuals with ESRD (Blagg, 2007; US Congress, 1971). Hemodialysis is most commonly provided in for-profit centers (Brookes, et al., 2006). During patient visits, solutes and fluids are removed via a surgically created fistula or hemodialysis catheter, which is connected to the hemodialysis machine. Each center provides care for multiple patients at a time, with treatment scheduled three times a week for 3-5 hour periods, depending on the amount of fluid to be removed (Klag, et al., 1997). These centers provide an excellent setting for individualized teaching.

2.4 DIETARY SODIUM

Two agencies, the U. S. Department of Agriculture and the U.S. Department of Health & Human Services, recommend a daily dietary sodium intake of less than 2300 mg per day (USDA, 1998). In addition, *The Dietary Guidelines for Americans 2005*, (and again in 2010) (MMWR, 2010) recommend further restriction of dietary sodium intake to 1500 mg per day for persons with hypertension and/or kidney disease, middle-aged and older adults, and African Americans. Together, these groups account for approximately 70% of the American adult population (MMWR, 2010).

Despite these and earlier recommendations aimed at promoting a lower sodium intake, most Americans consume far more dietary sodium than is both necessary and healthy. In fact, over the last 20 years, dietary sodium consumption in the general United States population has plateaued at approximately 3300mg per day (NHANES 1971-2000, and others). The CDC analyzed NHANES 2005-2006 data to determine the proportion of adults whose dietary sodium consumption was within recommended limits. They determined that only 5.5% of adult Americans with a recommended intake of ≤1500 mg per day and only 18.8% of adult Americans with a recommended intake of ≤ 2300 mg per day met these expectations (MMWR, 2010). Therefore, only 9.6% of all survey participants met their applicable 2005/2010 recommended dietary sodium limits.

The population of adult Americans with ESRD has perhaps the most benefit to achieve from adhering to dietary sodium restrictions. In this patient population, a reduction in dietary

sodium can maximize efficacy of adjunctive therapies, reduce symptoms resulting from excess fluid gain and the risk of left ventricular hypertrophy, a common cause of death in ESRD (Xue, Ma, Loius, & Collins, 2001). Therefore, the National Kidney Foundation has recommended that this patient population restrict their dietary sodium intake to 2400 mg per day (NKF K/DOQI, 2000).

2.5 DIETARY BEHAVIOR

Dietary behavior change is widely known to be difficult to achieve and sustain (Kursat, Ozgur, & Alici, 2003). Reducing dietary sodium may be particularly difficult for hemodialysis patients who must also adhere to other dietary considerations (calories, proteins, potassium, phosphorus), multiple medications, and a time consuming hemodialysis treatment regimen, i.e., 3-5 hours a session or longer (depending on IDWG), three times a week (Klag, Whelton, Randall, Neaton, Brancati, & Stamler, 1997). Seventeen behavioral intervention trials addressing fluid volume in the hemodialysis patient population were found in the literature, including one at the proposed data collection site. All but two targeted fluid intake, without addressing dietary sodium restriction (Rahman, et al., 1999; Oxkahya, et al., 2002; Saran, et al., 2003; Kursat et al., 2003; Burke, et al., 2005; Tucker, 1989; Tanner, et al., 1998; Sagawa, Oka, & Chaboyer, 2003; Fisher, et al., 2006; Christensen, Moran, Wiebe, Ehler, & Lawton, 2002; Casey, Johnson, & McClelland, 2002; Cummings, Becker, Kirtscht, & Levin, 1981; Hart, 1979; Keane, Prue, & Collins, 1981). As pointed out by Ahmad (2004), educating hemodialysis patients about fluid control without addressing sodium is usually futile, since the urge to drink caused by salt intake is too strong to

resist. Consequently, interventions to control fluid intake that do not address dietary sodium are not likely to result in lasting change or desired outcomes.

Interventions to reduce dietary sodium intake will likely be more effective if they help patients negotiate the unique barriers they encounter in making real-time dietary decisions. For example, patients who rely on local food banks may need to consume more canned foods, which often contain more sodium than their fresh or frozen counterparts. Those who rely on public transportation may find it necessary to eat at fast food establishments along their bus route and, so, may benefit from assistance locating lower sodium items on the menu. Others might benefit most from information about kidney-friendly adaptations of ethnic foods. Descriptive information on the barriers encountered by hemodialysis patients in trying to follow their dietary regimen would be useful for developing such targeted intervention materials. Despite an extensive literature search, no studies were identified that explored the specific barriers experienced by African American and low SES patients in adhering to the hemodialysis diet.

2.6 NEED FOR INNOVATIVE APPROACHES

Prior studies and the experience of the clinicians suggest that a large proportion of ESRD patients do not fully understand the hemodialysis dietary regimen or are not completely aware of the long-term consequences of not adhering to the dietary regimen. Well-informed patients, along with providers with the resources to adequately counsel patients, can directly translate into improved cardiovascular outcomes for this patient population. Better stated, dietary counseling targeted to the specific barriers experienced by African American and low SES patients can

result in longer, healthier, and better quality lives for them. The main obstacle for hemodialysis patients and providers to overcome in dietary management is lack of understanding of the unique problems experienced by these patients. There is a lack of literature to provide guidance as to how to appropriately advise and counsel patients on the appropriate dietary intake, taking into account what is available in their individual worlds. Whether the culprit is financial, societal, or personal; the barriers to dietary adherence far outweigh the patients' understanding of the benefits.

Current clinical practice guidelines call for nutritional counseling of ESRD patients every 6 months.[1] Such an approach can hardly be expected to address the barriers hemodialysis patients experience in making real-time dietary decisions. The principal investigator's long-term goal is to use study findings to design an interactive web based intervention for engaging ESRD patients in reducing sodium intake that could interface with routine hemodialysis care. ESRD patients spend 3-5 hours undergoing treatment three times a week in a setting that includes television access and often Internet access. Ultimately, the principal investigator hopes to implement a program of research begun with this dissertation study that results in a technology supported intervention that builds upon the parent study. One approach might be a web-supported intervention in which hemodialysis patients monitor their dietary intake in real-time, using a smart phone, personal computer, and/or iPad. The interventionist could remotely access electronic dietary records from the web. Based on the barriers previously reported by the patient and dietary behaviors gleaned from the electronic record, the interventionist could access previously developed counseling materials (or develop new counseling materials as needed). These materials will be used to individualize the intervention approach to meet the unique needs

of African American and low SES ESRD and other patients. Such an intervention could potentially be delivered via a computerized expert system, with automated counseling messages generated directly from the electronic food record. Given recent American Heart Association recommendation that all African Americans and individuals at risk of heart disease limit dietary sodium to 1,500 mg/day, such an intervention has the potential for broad dissemination. The principal investigator's research trajectory has the potential for significant public health implications. This dissertation study is particularly timely as a priori customized dietary intervention efforts are virtually nonexistent for African American and low SES patients living with ESRD.

3.0 THEORETICAL FRAMEWORK

This study was founded in a conceptual model developed to explain behavior change and designed to assist intervention development targeted at promoting healthy behavior and preventing or altering unhealthy behaviors. Variables within this model depict the influence of patient characteristics, psycho/behavioral/economic factors, and knowledge from dietary counseling on ESRD patient outcomes (National Academy of Sciences, 2002)(Figure 1).

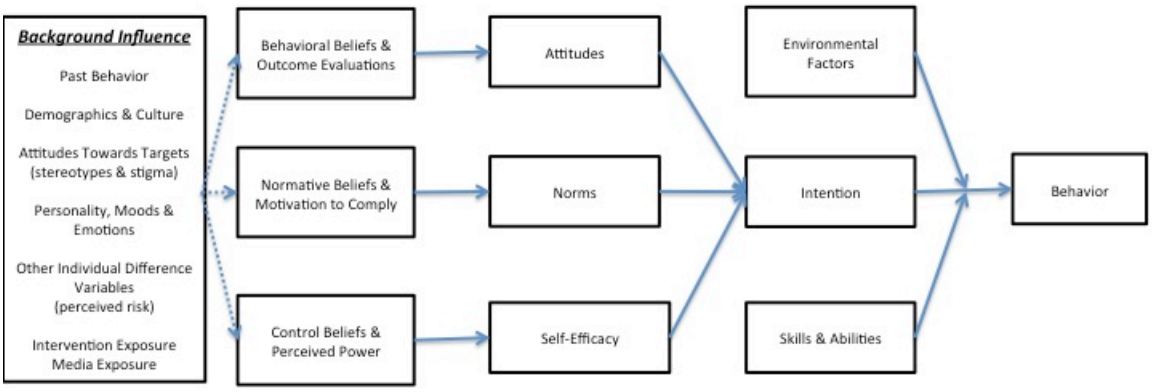

Figure 1. Behavior change conceptual model

As depicted in the model, background influences (e.g., duration of ESRD, comorbidities, residual renal function, race, culture, SES), have a direct impact on behavioral beliefs, outcome evaluations, motivation to comply, and perceived power. These in turn influence an individuals' attitude toward the desired behavior and confidence that they can successfully perform the desired behavior (e.g., restrict dietary sodium consumption). Intention is born of attitude, norms and confidence (self-efficacy), though intention can be moderated by environmental factors (e.g., resources, transportation, access to appropriate foods) and skills and abilities (e.g., low sodium food preparation and reading and interpreting food labels). Performing a desired behavior is the outcome. Dietary counseling may not be targeted to established dietary patterns and or barriers to

adherence experienced by these patients. By more clearly identifying the challenges encountered by African American and low SES patients when attempting to meet dietary goals, this study will identify ways to reduce barriers and thereby improve dietary patterns and, potentially, reduce risk for adverse patient outcomes.

4.0 PRELIMINARY WORK

The principal investigator conducted a secondary analysis using data from an ongoing NIH funded study (R01 NR010135), "*Intervention to Reduce Dietary Sodium in Hemodialysis"* (aka BalanceWise) to examine problems experienced when following the hemodialysis diet. Data from 83 subjects were examined using a 34-item investigator-developed instrument, which characterized problems experienced in following the hemodialysis diet on a 5-point scale in regard to perceptions regarding the extent to which they encountered a variety of barriers to dietary adherence. Barriers were categorized in 5 subscales. i.e., physical health (e.g., comorbid conditions, and symptoms experienced), resource adequacy (e.g., adequate income, access to transportation and grocery stores), social network (e.g., family, friends), motivation, and technical aspects (e.g., ability to interpret food labels).

Thirty-four 34 (41%) participants were African American and 34 (41%) were women. Thirty-six (43%) were married, and 26 (31%) participants described their annual household income as inadequate for meeting their basic needs. The two most common causes of ESRD were diabetes (n=36, 42.4%), and hypertension (n=17, 20.0%).

Dietary problems associated with the social network were more important for Caucasians than minorities (p=0.014). Physical health problems were marginally more important for females than males (p=0.067). Technical problems related to diet were marginally more important for those married or living as married than single (p=0.064). Adequacy of income appeared to be

more important than race, sex, or marital status in predicting hemodialysis dietary problems. Table 1 shows the extent to which adequacy of income influenced problems reflected in the five subscales.

Table 1. Adequacy of income upon problems experienced.

Income adequate to meet needs? Subscale:	No (N=26) Mean(SD)	Yes (N=54) Mean(SD)	Don't Know (N=3) Mean(SD)	p
Physical health	2.3 (1.3)	1.8 (0.9)	3.1 (0.8)	0.0052
Resource adequacy	2.0 (0.8)	1.5 (0.6)	2.2 (0.6)	0.001
Social network	1.9 (0.9)	1.7 (.09)	2.3 (0.8)	0.172
Motivation	2.5 (1.0)	2.9 (0.8)	2.9 (0.1)	0.019
Technical aspects	2.5 (1.1)	1.8 (0.7)	2.2 (0.5)	0.025

Findings suggested the need for additional research to characterize problems contributing to difficulty following the dietary regimen.

5.0 RESEARCH DESIGN AND METHODS

5.1 DESIGN

A mixed methods design was used to achieve the aims of this study. A simultaneous qualitative and quantitative design was utilized for the purposes of complementarity and inclusivity**.** The goal of this approach was to explore complex phenomenon to achieve a thorough and robust understanding of said phenomenon (Happ, Dabbs, Tate, Hricik, & Erlen, 2006; Greene, Caracelli, & Graham, 1989). This approach was appropriate for this situation as a single research method was considered to be insufficient and a combination of methods was therefore necessary to fully understand the phenomenon (Greene, Caracelli, & Graham, 1989).

Aims of the qualitative inquiry were to explore the problems and barriers perceived by a diverse hemodialysis patient population in their attempts to follow the hemodialysis diet (in particular sodium intake) and patterns of IDWG among hemodialysis patients with specific attention to African American and low SES patients. The quantitative inquiry was utilized to expand this analysis using data from an ongoing R01 (NR010135) (hereafter termed the parent study). The purpose of parent study was to evaluate, in a randomized clinical trial, the efficacy of a behavioral intervention to reduce dietary sodium in hemodialysis patients. The 16-week intervention paired technology supported dietary self-monitoring with behavioral counseling based in Social Cognitive Theory. Many subjects were African American and low SES.

However, study aims of the parent study did not include examination of African American and low SES patients as a subgroup and anecdotes offered by the research team suggested the intervention could be strengthened by future modifications to address economic and racial barriers to dietary adherence and migration to web-based self-monitoring. The availability of parent study data provided a unique opportunity to more fully inform the qualitative inquiry through comparison of interview responses and objective measures obtained as part of the parent study.

5.2 SETTING

Participants were subjects in the BalanceWise study recruited from 13 hemodialysis centers in the Greater Pittsburgh Metropolitan Area, which is located in ESRD Network 4.

5.3 SAMPLE

Inclusion criteria for the parent study were: 1) ≥ 18 years, 2) literate, 3) community dwelling, and 4) undergoing maintenance hemodialysis therapy for at least 3 months. Exclusion criteria were: 1) inability to read or write, non-English speaking, 2) intent to move out of the area or change in hemodialysis centers within 6 months, 3) terminal illness or life expectancy of less than 12 months, and 4) planned receipt of living donor transplant in the study period.

To avoid potential contamination of the intervention, baseline data were analyzed for the present study. A total of 124 subjects enrolled in the parent study by October 2011 constituted

the quantitative sample. Two respondents did not complete baseline data and were not included. The remaining subjects (n=122) had a mean age of 60 years (SD=13.8). Respondents were primarily male and Caucasian; accounting for 60.7%, and 52.5% of the sample respectively. Fifty-three (53%) percent of respondents were married or living as married. Thirty-one percent reported their income as inadequate to meet their basic needs of living. The mean duration of hemodialysis treatment for ESRD was 51 months (SD=56).

Qualitative interviews were performed on a subsample of 30 subjects recruited from the parent study. A diverse sample of subjects was *purposively sampled* to insure variability on age, gender, race, health status, and psycho/behavioral/economic factors.

5.4 RECRUITMENT

Individuals were prescreened for potential eligibility. The prescreening approach used varied by dialysis chain due to differences in what was viewed as acceptable involvement by the dialysis center staff. In some centers, potential participants were prescreened by hemodialysis center staff and, if eligible, asked about their willingness to discuss the study with research staff and sign a HIPAA release. In other centers, potential participants were given a study brochure, and if interested, referred themselves to a study team member present in the dialysis unit's waiting room. The study team member screened the potential participant and, if eligible, a HIPPAA release was obtained. Potential participants referred by self or hemodialysis center staff underwent an additional screening to verify they met eligibility criteria and signed informed

consent was obtained. Recruitment ended, for the Qualitative portion of the study, when the analysis reached a saturation point (no new themes or qualifying patterns), which included 30 interviews.

5.5 MEASURES

For the quantitative component of the study, study data were those included in the parent study and consisted of the following:

5.5.1 Dietary Sodium Intake

Dietary sodium intake was assessed via three dietary recalls obtained with unscheduled face to face meetings in the dialysis unit or with telephone calls placed during a 2-week period prior to randomization. To account for day-to-day variation in dietary intake (i.e., loss of appetite on hemodialysis days and changes in eating patterns during the weekend hiatus from hemodialysis), three dietary recalls were collected including 1 dialysis weekday, 1 non-dialysis weekday, and 1 non-dialysis weekend day. The recall was entered into the Nutrient Data System for Research [NDS-R]. NDS-R is a comprehensive, nutrient calculation software maintained by the Nutrition Coordinating Center at the University of Minnesota. The database contains over 18,000 foods, 8000 brand name products and a number of ethnic foods. The research team then abstracted dietary sodium intake for each recall from the NDS-R record. The three dietary sodium intake totals were averaged across the 3 days for the analysis. The three dietary sodium intake totals were averaged across the three days for the analysis. To account for variation in dietary intake by

body size, dietary sodium intake was normalized to caloric intake (i.e. mgs sodium/1000 kcals consumed).

5.5.2 Average Daily Weight Gain (ADWG)

Weights were obtained prior to and at the conclusion of each hemodialysis treatment. Pre- and post-dialysis weights were abstracted from the daily dialysis flow sheet for four hemodialysis treatments immediately prior to randomization. Three interdialytic weight gains were calculated from these data. The post dialysis weight from the last treatment was subtracted from the more recent dialysis weight, and divided by the number of days elapsed since the last treatment to yield average interdialytic weight gain ($ADWG_{).}$ The average of these 3 ADWGs were used in our analysis.

5.5.3 Self-Efficacy for Restricting Dietary Salt in Hemodialysis (Appendix C)

The Self-Efficacy for Restricting Dietary Salt in Hemodialysis (hereafter referred to as the Self-Efficacy Survey) was an investigator-developed visual numeric scale (VNS) (0="not confident at all" to 100="very confident") that consisted of 15 items designed to capture confidence regarding one's ability to follow the general hemodialysis diet; and in particular limit foods that were high in sodium (i.e. "How confident are you that in the next month, you will be able to control the amount of salt that you eat"), limit their fluid intake (i.e. "How confident are you that in the next month you will be able to limit the amount of fluids you drink"), keep their IDWG under control (i.e. "How confident are you that in the next month, you will be able to limit the amount of weight you gain from fluid between hemodialysis sessions"), and resist food

temptations (i.e. “How confident are you that in the next month, you will be able to limit the number of times each week you eat at fast food restaurants”). Psychometric analysis revealed a three factor structure that was utilized to derive confidence subscale scores in the realms of “sources of sodium”, “daily schedule” and “circumstantial.” Subscales scores were derived by averaging responses given to items within each subscale. Total scores were derived by averaging responses to the three subscale scores. Cronbach’s alpha for the present study was .815. The Self-Efficacy Survey was developed for use in the parent study.

5.5.4 Problems with the Hemodialysis Diet Questionnaire (Appendix D)

The Problems with the Hemodialysis Diet Questionnaire (hereafter referred to as the Problems Survey) was an investigator-developed tool that contained 34-items and 5 subscales describing the various problems HD patients encounter in trying to follow the diet. The subscales include items geared to isolate dietary problems related to the participant’s physical condition (i.e. “Because I feel ‘washed out’ after dialysis, it is hard to eat healthy on dialysis days”), resource adequacy (i.e. “Appropriate foods are not available in my home”), social network (i.e. “People in my life do not support my efforts to eat a healthy diet”), behavioral factors (i.e. “It is difficult to motivate myself to eat the right foods”), and technical difficulties (i.e. “I have trouble keeping track of the amount of the different nutrients that I eat from meal to meal”). Participants responded to each item using a 5-point visual numeric scale (VNS) on which 1=“not a problem at all for me” to 5=“a very important problem for me”. The subscale scores were derived by averaging responses given to items within each subscale. Total scores were derived by averaging subscale scores. Cronbach’s alpha for the present study was .961. The Problems Survey was developed for use in the parent study.

5.5.5 Sociodemographic, Economic and Health Characteristics

Sociodemographic and medical condition variables were abstracted from the medical record or collected from the participant during a baseline interview; these data included age, gender, race, ethnicity, marital status, self-reported income adequacy, and duration and etiology of ESRD.

6.0 QUANTITATIVE ANALYSIS

6.1 DESCRIPTIVE STATISTICS

Data analysis was conducted using SPSS (version 20, International Business Machines, Corp. Armank, NY). A descriptive analysis of all quantitative data from the BalanceWise study was performed to assess data accuracy and describe sample characteristics. Descriptive statistics were computed based on primary grouping variables (age, race, SES, marital status).

6.2 DATA SCREENING

Data were evaluated for missingness; data imputation occurred dependent upon necessity and type of missingness. Deletion of cases and or items occurred based on amount and pattern. Screening for univariate and multivariate outliers was conducted via graphical and statistical means. Assessment of appropriate assumptions, including: normality, linearity, independence, multicollinearity, and homoscedasticity were also conducted. Normality assessment included examination of histograms, normal probability plots, and skewness and kurtosis of individual variable response distributions. Linearity and independence of continuous variable responses were assessed via bivariate scatterplots. Multicollinearity was assessed using regression,

tolerance and VIF scores. Homoscedasticity was examined using scatterplots. For bivariate data expected cell counts were scrutinized to assess feasibility of data of chi-square data analysis.

6.3 DATA ANALYSIS

Chi-square tests of independence and univariate logistic regression analyses were used to explore associations and predictive value amongst sociodemographic and economic characteristics and Self-Efficacy and Problems Survey scores. Due to positively skewed response distributions, item responses were dichotomized to the lowest score and all others for the Problem Survey ("a very important problem for me" versus "else"), and the highest score versus all others for the Self-Efficacy Survey ("very confident" versus "else").

Logistic regression modeling was used to assess the independent effects of the Problems Survey and Self-Efficacy Survey subscale scores on IDWG and dietary sodium intake. The saturated model for both outcome variables included the main effects for those sociodemographic and economic characteristics found to be associated with lower self-efficacy scores and higher perceived problem scores.

7.0 QUALITATIVE METHODS

Semi-structured narrative data were collected via telephone and audiotaped. The principal investigator (MNC) who was trained by the qualitative expert on the research team (SZ) performed all interviews. The telephone interview duration was approximately 20 minutes (mean 13.7 ± 6.7 minutes, range 8 to 34 minutes). Audiotapes were converted into verbatim transcription by the principal investigator. Data analysis and management were supported by the use of the qualitative software program, Atlas.ti (v.7, Berlin, Germany).

The interview was guided by a 17-item tool that included open-ended questions designed to elicit information about the problems/barriers patients experience in following the hemodialysis diet and the extent to which the dietary counseling subjects received was perceived to be adequate to help them manage the dietary regimen (Appendix C). The interview also explored subject understanding of dietary counseling instructions and compatibility of health care provider education with barriers encountered in real-life dietary decision-making. The 17-item tool was developed from review of barriers identified in the literature over several iterations and revised by members of the research team (MAS, LAH, SZ). In addition, dietitians on the parent study were asked to assess face validity and consistency and revisions were made as suggested. Finally, the tool was pilot tested on a former hemodialysis patient; and revised further based on the patient responses.

Qualitative analysis of transcribed interviews was performed to identify predictors of dietary maintenance success or difficulty and to explore the need for customized dietary interventions. The codebook construction process began after one third of the interviews were collected. Three members of the research team (MAS, LAH, SZ) were asked to review and revise initial codes as appropriate. This approach exploited the expertise of the research team, reduced analytic bias, and promoted consistency in data analysis. All interviews were de-identified prior to analysis and coded by the Principal Investigator with review by an expert in qualitative analysis (SZ) and the use of the Atlas data analysis software package. Emerging themes were discussed with the study team and were incorporated into the codebook as needed. The final codebook was applied to all interviews in the sample. A co-coder was trained by the qualitative expert (SZ) and analyzed 50% of the interviews independently of the main coder. The two coders then discussed all codes and used a discussion process to adjudicate any differences in coding. The inter-coder reliability was determined using the coding files prior to this adjudication process. All final adjudicated codes were then added into a master codebook that use used for the final analysis.

The principal aim of coding and constant comparative analysis was to identify negative and qualifying evidence via constructing simple matrices to display the potential relationship between interview responses and demographic and questionnaire data. Through this process, patterns and interpretations not initially recognized from single method analysis alone were identified. Qualitative and quantitative data were combined (when appropriate) to amplify findings and identify within group and between group differences.

8.0 SUMMARY OF FINDINGS

Cost and time limitations were identified by HD patients as important barriers to dietary adherence. Participants were satisfied with the dietary counseling they received as part of routine care, but had difficulty implementing dietary recommendations and desired greater customization. Additionally, our study has demonstrated that a need may exist to manage HD patients in an individualized fashion, though not as originally expected. The independent effect of age and gender in ESRD requires further investigation, but offers preliminary guidance for structuring individualized dietary counseling based on age and gender. Further inquiries are needed to fully understand experiences of younger aged and female ESRD sufferers to better support dietary decision-making and inform tailored dietary interventions for this patient population.

9.0 STUDY RESULTS

Findings of this study will be presented in the format of three manuscripts submitted to the *Topics in Clinical Nutrition, Journal of Renal Nutrition,* and the *Journal of the Academy of Nutrition and Dietetics.* A future manuscript will include analysis of the mixed methods portion of the study.

Appendix A

IRB APPROVAL LETTER

University of Pittsburgh ***Institutional Review Board***

Memorandum

To: Maya Clark
From: Christopher Ryan, Ph.D., Vice Chair
Date: 8/23/2011
IRB#: PRO11050304

The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section

45 CFR 46.102(f) No human subject.

Please note the following information:

- If any modifications are made to this project, use the " **Send Comments to IRB Staff**" process from the project workspace to request a review to ensure it continues to meet the exempt category.

- Upon completion of your project, be sure to finalize the project by submitting a "**Study Completed**" report from the project workspace.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Appendix B

PERMISSION TO REPRINT LETTER

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July 9, 2012 **Reference #: 07091201**

Maya N. Clark, ACNP-BC
5627 Jackson Street
Pittsburgh, Pa 15206

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Appendix C

SELF-EFFICACY RESTRICTING DIETARY SALT IN HEMODIALYSIS SCALE

Table 2. Self-Efficacy Restricting Dietary Salt in Hemodialysis Scale

Item #	**How confident are you that in the next month that you will be able to…**
1	…follow the dialysis diet in general?
2	…control the amount of salt that you eat?
3	…limit the amount of fluids that you drink?
4	…avoid the amount of canned food that you eat?
5	…avoid adding table salt to your food?
6	…limit the amount of processed meat (such as bacon and luncheon meat) that you eat?
7	…read food labels so that you know how much salt is in your food?
8	…limit the amount of weight that you gain from fluid between dialysis treatments?
9	…limit salty snacks?
10	…limit the number of times each week you eat at fast food restaurants?
	How confident are you that in the next month, you can limit your salt intake when you are….
11	…are feeling blue or depressed?
12	…experiencing a day when your appetite is poor?
	How confident are you that in the next month, you can limit your salt intake on….
13	…dialysis treatment days?
14	…weekdays when you have no dialysis treatments?
15	…weekend days when you have no dialysis treatments?

Appendix D

PROBLEMS WITH THE HEMODIALYSIS DIET QUESTIONNAIRE

Table 3. Problems with the Hemodialysis Diet Questionnaire

Item #	
	Below is a list of problems that sometimes make it hard for people to follow the hemodialysis diet or any healthy diet. Please think about your diet over the past 2 months. For each problem below, circle the number from 1 to 5 that best reflects how much of a problem this was for you. One (1) means it was not a problem at all, and five(5) means it was a very important problem for you.
1	Appropriate foods are not available in my home.
2	People in my life do not support my efforts to eat a healthy diet.
3	I have trouble estimating portion sizes.
4	I have trouble keeping track of the amount of the nutrients that I eat from meal to meal (such as sodium, potassium, phosphorus).
5	It is difficult to motivate myself to eat the right foods.
6	I use food as a reward or treat for myself.
7	It is difficult to find time to plan healthy meals for myself.
	Think about how closely you have followed the dialysis diet over the past 2 months. For each problem below, circle the number from 1 to 5 that best reflects how much a problem this was for you.
8	I don't see any benefits from my efforts to follow a healthy diet.
9	It is difficult to shop in the grocery store for one person.
10	I don't know which foods I should and should not be eating.
11	I have difficulty controlling my eating when I am with friends or family.
12	When I am very hungry I have trouble controlling what I eat.
13	The dialysis diet seems too complicated.
14	I feel deprived when I have to restrict what I eat.
15	I find it difficult to select the right foods when shopping.
16	Sometimes I crave salty foods.
17	It is hard to eat a healthy diet because the nearest grocery store is too far away.
18	Eating a healthy diet costs more than I can afford.
19	It is hard to eat a healthy diet because my grocery store has a very limited selection of food.
20	I do not have time to cook healthy foods.
21	Resisting salty foods where I work is difficult for me (Check here [ ] if this does not apply to you.
22	When I am busy or feeling overwhelmed, I find it difficult to control what I eat.
23	I do not cook, so I do not have control over what is served or how it is prepared.
24	The hemodialysis diet is bland and tasteless.
25	Sometimes I just do not have an appetite.
26	Sometimes I am too tired to cook.
27	I do not have time to cook.
28	Sometimes I eat the wrong foods when I feel stressed.

	Over the past two months…
29	Because I have to spend so much time at the dialysis center, it is hard to eat a healthy diet on dialysis days.
30	Because I feel “washed out” after dialysis, it is hard to eat healthy on dialysis days.
31	The hemodialysis diet requires a great deal of work in preparation.
32	The hemodialysis diet requires extra time for shopping.
33	It is next to impossible to follow a hemodialysis diet when eating away from home, such as in restaurants or cafeterias.
34	It is hard to start new dietary habits because my health changes so often.

Appendix E

QUALITATIVE SEMI-STRUCTURED INTERVIEW SCRIPT

We would like to ask you some questions about your diet and your experience of being on hemodialysis. Feel free to express anything you'd like. If you would prefer not to answer any questions, also feel free not to. We also would to audio record this discussion so that we can remember what you said. Do we have your permission to start the interview and record it? Many thanks and we'll being with the interview now.

1. **First, how many months or years have you been on dialysis?**
   Prompt:
   a. [only if needed] Your medical record says you have been on dialysis for [XXXX]. Does this sound right? So you would have been how old when you started dialysis?
2. **Now we want you to think about how your appetite has changed over time. What was your appetite like in the 3 months before you started dialysis and the 3 months right after you started dialysis?**
   Prompt:
   a. [only if needed] Can you remember how you were feeling right before you started dialysis? How much enjoyment did you get from eating right before started dialysis treatments?
   b. [only if needed] Can you remember how you were feeling the early months of dialysis? How much enjoyment did you get from eating in the early months after starting dialysis treatments
3. **Have you noticed any recent change in your appetite?**
   Prompt:
   a. [only if needed] Do you enjoy eating? Would you say the enjoyment you get from eating is getting worse over time, better over time? Or would you say that the enjoyment you get from the food has not changed recently?
4. **I would like you to think about how your appetite and diet change during the average week. How do your appetite and diet differ on dialysis and nondialysis days?**
   Prompt:
   a. [only if needed] Is your appetite better or worse on dialysis days? Do you eat differently on dialysis days? If so, how?
5. **What foods do you think a person on dialysis should eat, and what should they avoid?**
   Prompt:
   a. [only if needed] Think about the things you have heard or read about the dialysis diet. What should a person on dialysis eat?
   b. [only if needed] Think about the things you have heard or read about the dialysis diet. What foods should a person on dialysis avoid?
6. **Do you think you are currently eating a diet that is healthy for you?**
   Prompt:

a. [only if needed] Think about what we just talked about regarding the foods a dialysis patient should eat and avoid. Do you eat the foods you should and avoid those you should not?

7. **What are the things that get in the way of eating a healthy diet?**
   Prompt:
   a. [only if needed] Here we're trying to understand circumstances that cause you to eat poorly.
8. **What things are helpful to you in your effort to eat a healthy diet?**
   Prompt:
   a. [only if needed] Here we're trying to understand those circumstances that you find helpful for promoting good eating habits.
9. **Do you have any goals for how you would like to change your diet over the next year?**
   Prompt:
   a. [only if needed] What, if anything, would you like to change about your current eating **habits?**
10. **How confident are you that you can follow the hemodialysis diet?**
    Prompt:
    a. [only if needed] If you want to follow the hemodialysis diet, how much do you believe you are able to succeed?

We would like to know a little about where you usually get your food. We are interested in grocery stores, churches, food banks, food pantries, farmer's markets, soup kitchens, restaurants and cafeterias.

11. **Which of these are sources of food for you?**
    a. Tell me about [supplier]. Can you tell me about the quality of food?
    b. Does [supplier] have the kinds of foods that dialysis patients should eat?
12. **How many meals a week do you eat out? What types of places do you go?**
13. **Name three(3) restaurants where you eat most frequently?**
14. **What sort of transportation do you use to get your food?**
    a. Here we are want to know if you can get to and from the grocery store and how you do that.
15. **How does money influence whether or not you are able to follow the hemodialysis diet?**
16. **Can you describe your kitchen area? How do you store your food?**
    a. We would like to know what your kitchen looks like to better understand the types of foods you can prepare and we would also like to know what you do with your leftover meals.
17. **So I have asked you about the availability and quality of food, transportation, your financial resources, and kitchen facilities. Are there other things that you lack that get in the way of following the hemodialysis diet?**
18. **In your personal experience, when health care professionals give you advice about your diet, do they take your personal circumstances into consideration?**
19. **Is there anything that health care professionals could do better in the way they give dietary advice?**

Appendix F

PSYCHOMETRIC VALIDATION OF "THE SELF-EFFICACY RESTRICTING DIETARY SALT IN HEMODIALYS SCALE"

Title Page

Manuscript Title: Psychometric Validation of the "Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale"

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Abstract

Background: Identifying perceptions of self-efficacy can be an important step in assisting hemodialysis patients to achieve optimal self-management of dietary sodium and fluid restriction.

Aim: Test the psychometric properties of the 15-item "Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale" (hereafter referred to as the Self Efficacy Survey).

Methods: Baseline data from 124 study participants enrolled in an ongoing randomized control trial were analyzed.

Results: The overall Cronbach's alpha was 0.93. A three-factor structure was extracted explaining 67.8% of the variance.

Conclusions: Our results indicate the Self Efficacy Survey has overall adequate internal consistency. Confidence in adhering to dietary sodium restriction is a function of participant perceptions about their ability to: (1) limit common sources of sodium, (2) follow the diet on different days of the week, and (3) follow the diet given individual circumstances. The Self Efficacy Survey appears to be a valid instrument for assessing self-efficacy in restricting dietary sodium. Further work is required to confirm the psychometric properties of the Self Efficacy Survey.

Key Words: behavioral research, patient adherence, data collection, instrumentation

Introduction

For those with end-stage renal disease (ESRD), renal replacement therapy is required to sustain life. Therapy can be either intermittent, (performed multiple times per week, for a duration of less than 24 hours) or continuous (performed 24 hours per day without interruption). Patients may elect to perform peritoneal or hemodialysis in their home or an outpatient treatment site. The vast majority of patients undergo intermittent, outpatient hemodialysis therapy[1]. The primary function of hemodialysis session is to replace kidney function, by removing waste and unwanted electrolyte and elemental concentrations (i.e. sodium, potassium, and phosphorus). Intermittent hemodialysis, however, is not a perfect science; and compounds the extensive cardiovascular related risks to this patient population. In particular, left ventricular hypertrophy (LVH) presents the most significant risk of morbidity and mortality to ESRD patients[2-7].

The progression of LVH is hastened by the multiple comorbid conditions associated with ESRD, particularly hypertension and large variations in interdialytic weight gains (IDWG)[8]. Both conditions are responsive to restriction of free fluid, which hemodialysis patients are counseled to restrict to as little as 0.5 liters per day[9]. It may be unrealistic, however, to expect hemodialysis patients to reduce fluid intake if they do not also restrict dietary sodium intake. High dietary sodium intake, elevates serum sodium content and exacerbates thirst, making it difficult for hemodialysis patients to restrict fluid intake[10-11]. Additionally, due to the inability of hemodialysis patients to excrete uremic waste from the bloodstream, thirst can become overwhelming and result in excessive fluid intake and, consequently, large interdialytic weight gain (IDWG). Restriction of fluid and sodium is likely to be difficult for these patients when one considers the complexity of hemodialysis regimen including: multiple medications, dialysis treatments, and other dietary considerations including maintaining adequate calorie and protein

intake, while minimizing phosphorus and potassium. Due to the complicated nature of the hemodialysis regimen in its entirety, it would not be surprising if HD patients lack confidence in their ability to adhere its vast demands.

An extensive body of evidence supports the use of perceived self-efficacy to predict subsequent performance across various behavioral domains including smoking cessation, adherence to exercise programs, and weight control programs.[12-19]. The basic premise underlying self-efficacy theory is that the expectations of personal mastery and success (efficacy expectation) influence the likelihood of an individual engaging in a particular behavior. Thus, behavior is influenced by personal characteristics, beliefs about the consequences of a particular behavior and the confidence individuals have in their ability to achieve that behavior[20].

Several behavioral intervention studies addressing fluid volume in hemodialysis patients were found in the literature[21-34]. All studies, save two[28, 34], focused on fluid intake, without addressing dietary sodium. However, educating hemodialysis patients about fluid control without focusing on sodium is futile[27], as the thirst instigated by high serum sodium cannot be ignored. None of these studies featured self-efficacy based interventions or measurements of dietary self-efficacy.

This observation led to the BalanceWise study (NIH-R01-NR010135), a randomized controlled trial to evaluate the efficacy of a Social Cognitive Theory-based intervention to reduce dietary sodium intake in hemodialysis patients. The BalanceWise investigators developed the Self Efficacy Survey. The purpose of this secondary analysis was to describe the psychometric properties of the Self Efficacy Survey.

Methods

Design

The 16-week intervention paired Social Cognitive Theory-based behavioral counseling with technology-based dietary self-monitoring. The primary aims of the study were to (1) assess the impact of the intervention on average daily interdialytic weight gain, and (2) examine the impact of the intervention on dietary sodium intake. Secondarily, the study explored the impact of the intervention on blood pressure, interdialytic and post-dialytic symptoms, health-related quality of life, and the mediating effect of dietary self-efficacy.

Sample

BalanceWise participants were recruited from 13 dialysis centers in the Pittsburgh area, stratified by dialysis center, and randomized within center strata using permuted blocks. Participants were 18 years of age or older, with no upper age limit, and had received maintenance hemodialysis for at least 3 months. Individuals were excluded if they: (1) could not read, write, or speak English, (2) planned to move out of the area or change dialysis centers within the next 4 months, (3) had a terminal illness and life expectancy of less than 12 months per clinical evaluation of dialysis center staff, (4) could not read the screen of the hand-held computer used in the intervention or use the device's stylus to make selections from the computer screen, (5) were institutionalized (e.g., in a nursing home or personal care facility or incarcerated) that limited control over their dietary intake, or (6) resided with another participant of the study. Data collected at baseline were used for this analysis. This study received approval from the Institutional Review Board of the University of Pittsburgh and all subjects provided signed informed consent.

Measures

For this study, we evaluated the internal consistency, construct validity, and convergent validity of the measure of dietary self-efficacy (Self Efficacy Survey). The Self Efficacy Survey was adapted from "the Cholesterol Diet Self-efficacy Scale" scale[12]. Using an 11-point Visual Numeric Scale (VNS) with responses ranging from 0 = "not confident at all" to 100 = "very confident" in 10-point increments, participants indicated how confident they were that they could adhere to the sodium restriction component of the hemodialysis diet. The items address self-efficacy to: adhere to the diet, in general; limit sodium, fluid, and excess interdialytic weight gains; limit common sources of excess sodium (e.g. canned food, processed meats, salty snacks); follow common strategies to minimize sodium intake (e.g. avoid adding table salt, read food labels, avoid fast food restaurants); adhere given their emotional state (e.g. feeling blue); adhere when appetite was poor; and adhere by day of the week (e.g. dialysis versus non-dialysis treatment day, weekday versus weekend day). The instrument provided written instructions, with examples demonstrating sample responses. For this study, we evaluated the internal consistency, construct validity, and convergent validity of the Self Efficacy Survey.

Analysis

Statistical analysis was performed utilizing SPSS version 20.0. The internal consistency of the items was calculated using the Cronbach's alpha coefficient. Additionally, internal consistency of the factor structure and subscales were evaluated. The factor structure was determined using Principal Components Analysis (PCA) extraction with an oblique rotation for initial factor extraction. A multifaceted approach was used in the initial factor extraction including examination of Cattell's scree plot, percent of variance explained and meaningfulness of factors (eigenvalues and communalities) to determine the number of factors within the structure. Convergent validity was examined by computing inter-item correlations.

Results

Sample

Data from the first 124 participants recruited to the study were considered for this report. Two of the participants withdrew from the study prior to completion of baseline measures and the final sample therefore consisted of 122 participants. Respondents were primarily older, male Caucasian, and married or living as married; they received maintenance hemodialysis for more than 4 years (Table 1). Notably, over a third of participants reported their income to be inadequate for meeting their basic living requirements.

Exploratory Factor Analysis

A three-factor structure was extracted from the obliquely rotated principal components analysis. The scree plot (Figure 1) demonstrates a natural bend at either 2 or 3 factors within the structure. Total variance explained and eigenvalues verified the structure to be three factors. Total variance explained by factor I was 52.9%, 8.2% by factor II, and 6.7% by factor III. Eigenvalues were 7.9, 1.2, and 1.0, respectively (table 2).

Factor I focused on 'sources of dietary sodium' and consisted of 5 items. Factor loadings ranged from 0.52 to 0.82 and accounted for the largest amount of variance (52.9%). The items that loaded on this factor focused on ability to control sodium intake derived from various dietary sources that were high in sodium content. Three items that represented confidence in particular strategies for reducing sodium intake (including ability to "avoid table salt," "limit fast food," and "read food labels so that [they knew] how much salt [was] is in [their] food") cross-loaded on factor II or factor III. Forcing these items onto factor I, resulted in a minimal increase of Cronbach's alpha from 0.87 to 0.88.

Factor II named ‘daily schedule’ was comprised of the 3 items addressing confidence in ability to restrict dietary sodium given the day of the week (i.e. dialysis weekdays, non-dialysis weekdays, and non-dialysis weekend days). Factor loadings ranged from 0.89 to 0.95. Cronbach’s alpha for factor II was 0.94.

Factor III, ‘contextual factors’ focused on situations in which individual circumstances might impact decisions about dietary sodium intake. These included confidence in limiting food intake when “experiencing poor appetite”. Item #11 (How confident are you that you can limit your food intake when feeling blue?”) cross-loaded on factor II. Forcing the item onto factor III, which the content most closely resembles, increased Cronbach’s alpha to 0.79 (previously 0.69). The factor loadings ranged from 0.51 to 0.79 (Table 3 displays reliability, table 4 displays Factor loadings).

Discussion

The primary aim of this report was to evaluate the psychometric properties of the investigator developed instrument, Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale (Self Efficacy Survey), for which no prior psychometric testing had been conducted. Based on the results of this analysis, the Self Efficacy Survey is a valid instrument for assessing self-efficacy in restricting dietary sodium in the hemodialysis patient population. Additionally, the high Cronbach’s alpha coefficients for the individual Self Efficacy Survey subscales and the instrument as a whole, suggest good internal consistency.

Interventionists often turn to Social Cognitive Theory (SCT) to explicate the process of lifestyle modification. Specifically, several SCT driven interventions to reduce dietary sodium intake in hypertension have rendered successful results[12-17, 26, 29-32, 34-36]. The tenets of SCT (self-

efficacy expectancies) are thought to have a direct impact upon behavior and an indirect effect due to their influence upon intentions. In short, optimistic self-beliefs predict actual behavioral performance, and individuals will typically perform behaviors they perceive to be within their control[20]. Therefore, the use of SCT appears an appropriate approach to evaluate behaviors of end stage renal disease patients who require hemodialysis. Because, no instruments employing this concept were found, we constructed the Self Efficacy Survey based on items contained in the literature.

There is evidence to support that all items within the instrument were measuring the same construct. Cross-loading of items, specifically items 7 and 8, suggest the potential to remove these items with the goal of shortening the instrument and reducing patient burden. Further investigation into the content of these items and their contribution to the overall usefulness of the instrument is therefore warranted.

Limitations

Due to concerns regarding respondent burden, retesting of subjects was not judged to be feasible, therefore test-retest reliability could not be determined. Future iterations of the study may want to examine instrument stability. Discriminant validity also could not be performed, as we were unable to identify an instrument with a similar purpose within this patient population. This instrument however, offers a unique opportunity to assess self-efficacy of adhering to a sodium-restricted diet in a research or clinical setting.

Conclusion

The Self Efficacy Survey has adequate internal consistency and construct and convergent validity. Future research to evaluate the psychometric properties of the instrument is required.

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Table 4. Sociodemographic Characteristics of BalanceWise Study Participants (N=122)

Variable	n	%
Sex		
Male	74	60
Female	48	40
Ethnicity		
White/Caucasian	64	52
Black/African American	58	47
Married or Living Married	64	52
Income inadequate to Meet Needs	38	31
	Mean	SD
Mean Age (Years)	61	56
Duration of ESRD treated with dialysis (Months)	51	56

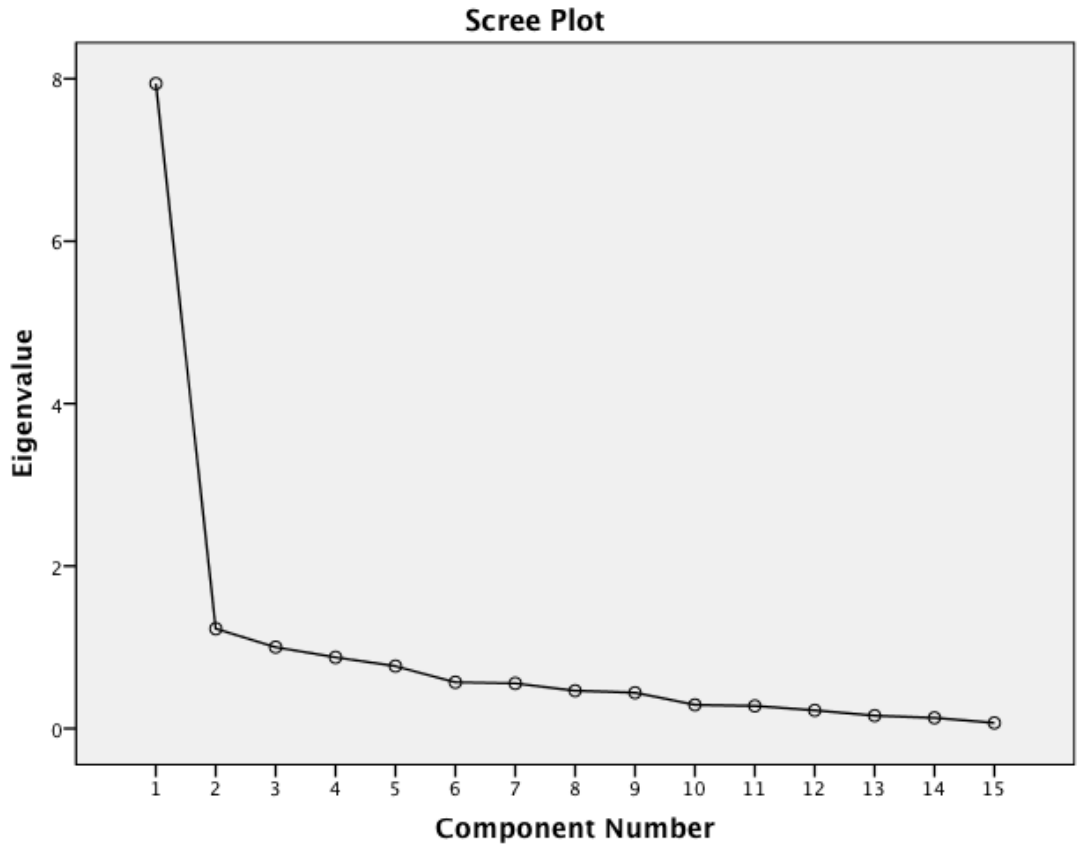

Figure 2. Scree Plot of Factors Extracted from the "Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale" (N=122)

Table 5. Total Variance Explained by the Three Extracted Factors from the "Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale"

Factor	*Initial Eigenvalues*			*Extracted Sums of Squares Loadings*		
	Total	*% Variance*	*Cumulative %*	*Total*	*% Variance*	*Cumulative %*
I	7.941	52.938	52.938	7.941	52.938	52.938
II	1.228	8.189	61.127	1.228	8.189	61.127
III	1.002	6.677	67.804	1.002	6.677	67.804

Table 6. Reliability: Internal Consistency of the "Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale" and Three Extracted Factors

	Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
Overall Instrument	0.934	0.936	15
Factor I: Sources of Dietary Sodium	0.872	0.876	7
Factor II: Daily Schedule	0.945	0.945	3
Factor III: Situational	0.791	0.797	3

Table 7. Self-Efficacy for Restricting Dietary Salt in Hemodialysis Scale

Factor	Item #	How confident are you that in the next month that you will be able to…
	1	…follow the dialysis diet in general?
I	2	…control the amount of salt that you eat?
III	3	…limit the amount of fluids that you drink?
I	4	…avoid the amount of canned food that you eat?
I	5	…avoid adding table salt to your food?
I	6	…limit the amount of processed meat (such as bacon and luncheon meat) that you eat?
I	7	…read food labels so that you know how much salt is in your food?
	8	…limit the amount of weight that you gain from fluid between dialysis treatments?
I	9	…limit salty snacks?
I	10	…limit the number of times each week you eat at fast food restaurants?
		How confident are you that in the next month, you can limit your salt intake when you are….
III	11	…are feeling blue or depressed?
III	12	…experiencing a day when your appetite is poor?
		How confident are you that in the next month, you can limit your salt intake on….
II	13	…dialysis treatment days?
II	14	…weekdays when you have no dialysis treatments?
II	15	…weekend days when you have no dialysis treatments?

Appendix G

ADHERENCE TO HEMODIALYSIS DIETARY RECOMMENDATIONS: INFLUENCE OF PATIENT CHARACTERISTICS, SELF-EFFICACY AND PERCEIVED BARRIERS

Title Page

Manuscript Title: Adherence to Hemodialysis Dietary Recommendations: Influence of Patient Characteristics, Self-Efficacy and Perceived Barriers

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Abstract Word Count: 214

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Short Title: Influence of Patient Characteristics

Abstract

Objective: To identify characteristics of hemodialysis patients most likely to experience difficulty adhering to restrictions associated with the hemodialysis dietary regimen.

Design: Secondary analysis using data from an ongoing randomized clinical trial examining the effects of a technology based behavioral intervention on dietary sodium intake in hemodialysis patients.

Setting: 13 dialysis centers in southwestern Pennsylvania.

Subjects: 122 participants (61% women, 48% African American) aged 61 ± 14 years receiving maintenance, intermittent hemodialysis for end stage renal disease.

Main outcome measure: Normalized dietary sodium intake, average daily weight gain, perceived problems and self-efficacy for restricting dietary sodium.

Results: Younger participants were more likely to report problems managing the hemodialysis diet and low self-efficacy for restricting sodium intake. Consistent with these findings, younger participants had a higher median sodium intake and average daily weight gain. Females reported more problems managing the diet. Race and perceived income adequacy did not appear to influence outcome measures.

Conclusion: Our findings suggest that there may not be a need to customize interventions regarding race or income adequacy. However, there may be a need to customize counseling and interventions for younger adults and females. Further investigation is needed to understand the independent effects of age and gender on adherence to the hemodialysis dietary recommendations and perceived self-efficacy.

Support and Financial Disclosure Declaration
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Introduction

Currently, over 570,000 patients in the United States have end stage renal disease (ESRD), and the prevalence is increasing[1]. Despite the fact that Caucasians comprise the majority of ESRD patients, African Americans and individuals of lower socioeconomic status (SES) are disproportionately represented. Statistics indicate ESRD prevalence is 3.6 times greater for African Americans compared to Caucasians[2, 3]. Additionally, low SES has been demonstrated to be a predictor of greater morbidity and mortality in ESRD[3-5]. The vast majority of patients with ESRD are treated with intermittent in-center hemodialysis, in which patients dialyze every two to three days to remove kidney wastes and fluid volume. Because fluid elimination is intermittent, rather than continuous as is the case with normal kidney function, dialysis patients treated with this regimen are at high risk for fluid volume overload between treatments.

Studies have shown that large fluctuations in interdialytic weight gain (IDWG) result in extracellular volume expansion and elevated blood pressure, placing increased strain on the heart or cardiovascular system[6]. IDWG is the product of water accumulation in the body from dietary and fluid intake, and metabolism. Thirst also plays a significant role in IDWG fueled by the osmotic stimulus related to excess dietary sodium intake and even dialysate sodium. Consequently hemodialysis patients are advised to restrict free fluid intake and minimize dietary sodium intake[7,8]. The literature overwhelmingly demonstrates that while these lifestyle modifications are essential to the well-being and survival of hemodialysis patients, adherence is poor [9-15].

Research in non-ESRD populations has shown diet to be highly variable, and to be a function of cultural, psychological, geographical and lifestyle factors; food trends; and daily

routines [16, 17]. Diet-related decisions are influenced by multiple factors, including taste, financial constraints, individual preferences, social status, education level, societal norms, health, relationships, trust in food sources, and convenience [16-20]. Dietary preferences and behaviors are highly individual. Consequently, when trying to change behavior, it is unlikely that a single intervention approach can be identified that is generalizable to all ESRD patients. Some tailoring may be required to address individual dietary preferences. Unfortunately, current literature offers limited guidance for clinicians who wish to develop targeted dietary counseling plans.

Prior to developing targeted interventions, it is necessary to identify characteristics of those most likely to experience difficulty adhering to hemodialysis dietary restrictions. In this report we describe hemodialysis patients' dietary sodium intake and weight gain between treatments, confidence in their ability to adhere to the dietary restrictions, and reported barriers to dietary adherence. Additionally, we explore variations in adherence to dietary sodium restrictions, average weight gain, perceived problems, and self-confidence with the sociodemographic and economic characteristics of study participants.

Methods

Design

A secondary data analysis was performed using data obtained from an ongoing randomized clinical trial (R01 NR010135) to evaluate a behavioral intervention designed to reduce dietary sodium intake in hemodialysis patients. Our analysis used baseline data obtained prior to randomization. This study was approved by the Institutional Review Board of the University of Pittsburgh. Signed informed consent was obtained from participants prior to baseline data collection.

Sample

Participants were recruited from 13 dialysis centers in southwestern Pennsylvania. Individuals were eligible if they were 18 years of age or older, and had received maintenance hemodialysis for at least 3 months. They were excluded if they: (1) could not read, write, or speak English, (2) planned to move out of the area or change dialysis centers within the next 4 months, (3) had a terminal illness and life expectancy of less than 12 months per clinical evaluation of dialysis center staff, or (4) resided with another participant of the study. Because the parent study required use of a hand-held computer, individuals were excluded if they: (5) could not see the screen of the hand-held computer or use the device's stylus to make dietary selections from the computer screen, or (6) were institutionalized (e.g., in a nursing home, personal care facility, or incarcerated) which limited control over their dietary intake. Baseline data from all participants (n=122) recruited between September 2009 to October 2011 were analyzed for the present report.

Measures

Baseline sociodemographic and health data were abstracted from the medical record or collected via survey and included age, gender, race, marital status, and etiology and duration of ESRD. Income adequacy was evaluated with a single item asking participants (yes or no) if their financial resources were adequate for meeting their basic living needs.

Dietary sodium intake was assessed via three unannounced dietary recall interviews conducted by telephone; calls were placed during a two-week window prior to randomization. To account for day-to-day variation in dietary intake (e.g., differences in appetite on dialysis and non-dialysis days and changes in eating patterns during the weekend hiatus from dialysis), three recalls were obtained including one dialysis weekday, one non-dialysis weekday, and one non-

dialysis weekend day. The recalls were structured using the Nutrition Data System Research (NDS-R)[21], a comprehensive nutrient calculation software program maintained by the Nutrition Coordinating Center at the University of Minnesota. The database contains over 18,000 foods, 8000 brand name products and a number of ethnic foods. The research team abstracted dietary sodium intake for each recall from the NDSR record, and averaged them across the three days for the analysis. To account for variation in dietary intake by the amount of food consumed, dietary sodium intake was normalized to caloric intake (e.g. mgs sodium/1000 kcals consumed). Pre- and post-dialysis weights were abstracted from the medical record for four HD treatments preceding randomization. Three average daily weight gains (ADWGs) were calculated from these data, by subtracting the post-dialysis weight for the prior HD treatment from the more recent pre-dialysis weight and dividing by the number of days since last treatment (which ranged from 2-3 days). The mean of these three ADWGs were used in our analysis.

Pre- and post-dialysis weights were abstracted from the medical record for four hemodialysis treatments preceding randomization. Three average daily weight gains (ADWGs) were calculated from these data, by subtracting the post-dialysis weight for the prior hemodialysis treatment from the more recent pre-dialysis weight and dividing by the number of days since last treatment (which ranged from 2-3 days). The mean of these three ADWGs was used in our analysis.

The Problems with the Hemodialysis Diet Survey (hereafter referred to as the "Problems Survey") was an investigator-developed tool that was adapted from "the Barriers to Healthy Eating Scale[22]," and contained 34-items and 5 subscales describing the various problems hemodialysis patients encounter in trying to follow the diet. The subscales evaluated dietary problems related to the participant's physical condition (e.g.. "Because I feel 'washed out' after

dialysis, it is hard to eat healthy on dialysis days"), resource adequacy (e.g. "Appropriate foods are not available in my home"), social network (e.g. "People in my life do not support my efforts to eat a healthy diet"), behavioral factors (e.g. "It is difficult to motivate myself to eat the right foods"), and technical difficulties (e.g. "I have trouble keeping track of the amount of the different nutrients that I eat from meal to meal"). Participants responded to each item using a 5-point visual numeric scale (VNS) on which 1="not a problem at all for me" to 5="a very important problem for me".

The Self-Efficacy in Restricting Dietary Salt in Hemodialysis Scale (hereafter referred to as the "Self-Efficacy Survey") was an investigator-developed instrument adapted from the "Cholesterol-Lowering Diet Self-Efficacy Scale[23-24]. The 15-item visual numeric scale (VNS) (0="not confident at all" to 100="very confident") consists of items designed to capture confidence regarding one's ability to follow the general hemodialysis diet and, in particular, limit foods high in sodium (e.g. "How confident are you that in the next month, you will be able to control the amount of salt that you eat"), limit fluid intake (e.g. "How confident are you that in the next month you will be able to limit the amount of fluids you drink"), keep their IDWG under control (e.g. "How confident are you that in the next month, you will be able to limit the amount of weight you gain from fluid between dialysis sessions"), and resist food temptations (e.g. "How confident are you that in the next month, you will be able to limit the number of times each week you eat at fast food restaurants").

Data Analysis

Data were analyzed using IBM SPSS (version 20, International Business Machines, Corp. Armank, NY). A descriptive analysis of all baseline variables of interest from the parent study

was performed to assess data accuracy; evaluate distributions; and describe participant characteristics, sodium intake, ADWG, dietary problems, and self-efficacy.

Univariate logistic regression analysis was used to explore associations between participant characteristics, normalized dietary sodium, ADWG, and scores on the Problems and Self-Efficacy Surveys. To examine associations between participant characteristics and dietary sodium intake, we dichotomized mean normalized sodium intake, using the median value as the cut point. To examine associations between participant characteristics and fluid gain between hemodialysis treatments, we dichotomized ADWG in regard to whether mean ADWG was less than 1.0 kg (a commonly used ceiling recommended to patients in the participating dialysis units).

Preliminary data analyses revealed positively skewed response distributions on the Problems and Self-Efficacy surveys. Consequently, item responses were dichotomized for both surveys. A response of a “very important problem for me” on the Problems survey or “not confident at all” on the Self-Efficacy survey were assigned a value of “1” and all other responses assigned a value of “0”. The cut point of a score of “1 (not a problem at all for me)” was used for the Problems Survey versus all others, and a mean of 80% for the Self-Efficacy Survey. To identify those individuals at greatest risk for non-adherence; multivariate logistic regression was used with a forward entry method on those independent variables found to be associated with increased normalized dietary sodium intake, increased ADWG, more perceived problems and decreased self-efficacy in terms of dietary sodium restriction. The effects of interaction terms created from participant characteristics were also explored.

Results

Participants were primarily older, white, unemployed, married males having a high school education or less (Table 1). Nearly one-third reported their income to be inadequate for meeting their basic living requirements. On average, participants had been receiving treatment for ESRD for over 4 years. Mean daily dietary sodium intake for the entire sample was 2,346 mg (SD=904). The mean normalized dietary sodium intake average was 1.7 mg per 1000 kcals consumed. The mean ADWG was 1.23 kilograms (SD=0.54). Fifty-seven percent (57%) of participants reported they were "very confident" in their ability to restrict their dietary sodium intake. Forty-one percent (41%) of participants reported problems navigating the dietary regimen.

Younger aged participants were more likely to have a normalized dietary sodium intake greater than the median (Table 2). Younger adults (< 65 years of age) were also found to be more likely, than their older aged counterparts, to have ADWG greater than 1.0 kg (Table 3). Male participants were also found to be more likely, than their female counterparts, to have fluid gains greater than 1.0 kg, though this was result was only marginally significant.

Younger aged participants and females were more likely to report problems in managing the hemodialysis diet (Table 4). Also, younger aged participants were more likely to report low self-efficacy for restricting dietary sodium intake (Table 5).

The multivariate logistic regression analyses were conducted by entering the participant characteristics found to be associated with increased normalized dietary sodium intake, increased ADWG, more perceived problems, and lower self-efficacy into the model. Only a single characteristic (age; p=0.18) was associated with increased normalized dietary sodium intake and self-efficacy. Because results from multivariate regression analysis did not provide information

over and above that of univariate regression analyses they are not reported here. Similarly, interactions effects between participant characteristics were not significant.

Discussion

The major findings of this study were as follows: 1) Younger adults were more likely to exhibit difficulty restricting dietary sodium intake, have larger ADWGs, and report problems when navigating the hemodialysis diet. Younger adults also expressed lower self-efficacy in their ability to restrict dietary sodium. 2) Males were more likely to have higher ADWGs, but females were more likely to report experiencing problems adhering to the hemodialysis diet. 3) Race and income adequacy were not associated with normalized dietary sodium intake, ADWG, perceived problems or self-efficacy. Similar to the USRDS 2011[1] statistics, participants in our study were primarily white and older aged, suggesting sample results would likely be generalizable to the ESRD patient population.

Little is known about the influence of age in patients with ESRD being treated with hemodialysis [25], particularly in terms of adherence to dietary modification and perceived problems. Studies have demonstrated associations between older age and greater adherence to exercise regimens and medication taking in comparison to younger adults [26-29], however, no studies were identified within the ESRD body of literature addressing the relationship of age with adherence to the hemodialysis dietary regimen. To further understand these results, we returned to the data to explore whether associations existed between age, and duration of ESRD and reported self-efficacy. The Self-Efficacy Survey subscale responses demonstrated that older aged participants were less likely to report low self-efficacy on all three subscales[30], e.g., in regard to common sources of sodium ($p=.024$), on different days of the week ($p=.010$), and regardless of personal circumstances ($p=.035$). We also observed a direct relationship between

duration of ESRD and age (p=0.007). Thus, it may be that older patients had more experience working through the challenges of following the diet and greater opportunity to adjust to the demands of the regimen, resulting in better self-efficacy. It is also likely that younger adults are more active outside the home, with larger social networks and therefore experience a greater number of barriers and temptations. Additionally, other researchers have shown that older adults tend to consume less food than younger adults, which could contribute to the observed lower weight gains between hemodialysis treatments [31-32]. Findings of this study suggest the need to explore factors influencing choices of younger individuals prior to developing interventions and that particular attention to younger adults during dietary counseling may be warranted.

In our sample, females were likely to report more problems with the hemodialysis diet than their male counterparts. To further explain this finding we returned to the data to see if subscale scores of the Problems Survey reflected gender-related differences, and found that female participants were significantly more likely to report dietary problems related to their physical condition. These findings could be related to the role of women in domestic situations; women tend to bear a greater responsibility in terms of food purchasing and preparation[33] and, therefore, may experience more problems related to dietary choices. The fatigue and physical health problems commonly associated with dialysis could be more problematic for those responsible for purchasing and preparing food. Future studies should attempt to clarify factors influencing these perceptions with the goal of better addressing specific needs of female ESRD patients.

Neither race nor income adequacy were found to be associated with any of the outcome variables examined in this report. Although studies have demonstrated that dietary behaviors are closely related to social status and culture [16-20], our study was unable to replicate these results.

Prior studies report that ethnic minorities and individuals of lower SES tend to consume more dietary sodium; however, our study did not support this conclusion. It may be that loss of appetite, which is common in hemodialysis patients, is more important than either race or SES in influencing dietary sodium intake. We did not see a large variability in normalized dietary sodium intake. Over 50% percent (57%) of study participants reported consuming 2400mg or less of dietary sodium per day as recommended by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines [34]. Accordingly, our findings do not support the need for tailored interventions specific to race and SES, although the literature suggests otherwise [35-37].

Limitations and Strengths

Due to a large amount of missing data, self-reported income adequacy was used in place of household income or other commonly used indicators of economic resources. A single, dichotomous item on income adequacy may not have been sensitive to differences in economic resources we sought to detect. Despite this, our study, offers guidance on future dietary counseling-related interventions.

Practical and Research Implications

Our study has demonstrated that a need may exist to tailor behavioral counseling to hemodialysis patients, though not as originally expected. Additional research is needed to fully understand the dietary experiences of younger aged and female hemodialysis patients to better support behavioral counseling interventions for this patient population.

Table 8. BalanceWise Sample Characteristics (N=122)

Variable	n (%)
Race	
Caucasian	64 (52.5)
African American	58 (47.5)
Age	
< 65 years	75 (62.5)
≥ 65 years	45 (37.5)
Gender	
Male	74 (60.7)
Female	48 (39.3)
Marital Status	
Single	58 (47.5)
Married, or Coupled	64 (52.5)
Income Adequacy	
Income Adequate	79 (64.8)
Income Inadequate	38 (31.1)
Education	
High School	73 (59.8)
> High School	49 (40.2)
Employment Status	
Employed	19 (15.6)
Unemployed	103 (84.4)
History of CVD	64 (52.5)
Variable	**Mean (SD)**
Mean age, years	60.7 (14)
Duration of ESRD (months)	51.3 (56)
Average Dietary Sodium intake (mgs/day)	2346 (904)
Average Normalized Dietary Sodium intake (mg/kcals consumed)	1.74 (4.3)
Average Interdialytic Weight Gain (ADWG, avg kg)	1.23 (.54)

Table 9. Univariate Logistic Regression of BalanceWise Participant Characteristics with Normalized Sodium

Variable		B	P-Value	OR	95% CI	
Race						
	Caucasian (Reference Group)					
	African American	-.472	.200	.624	.303	1.28
Age	Younger Aged (Reference Group)					
	Older Aged	-9.31	.018*	.394	.182	.855
Gender						
	Male (Reference Group)					
	Female	-.371	.327	.690	.329	1.45
Marital Status						
	Married, Cohabiting (Reference Group)					
	Single, Not Married	-.608	.100	.545	.064	1.12
Income Adequacy						
	Adequate (Reference Group)					
	Inadequate	-.238	.555	.788	.358	1.74
Time on HD (LG10)	(Continuous)	.005	.176	1.01	.998	1.01

*p<0.05

Table 10. Univariate Logistic Regression of BalanceWise Participant Characteristics with Average Daily Weight Gains

Variable		B	P-Value	OR	95% CI	
Race						
	Caucasian (Reference Group)					
	African American	-.103	.792	.902	.421	1.94
Age	Younger Aged (Reference Group)					
	Older Aged	-.935	.020*	.393	.178	1.03
Gender						
	Male (Reference Group)					
	Female	-.751	.059**	.472	.216	1.030
Marital Status						
	Married, Living as Married (Reference Group)					
	Single, Not Married	.508	.198	1.66	.747	3.60
Income Adequacy						
	Adequate (Reference Group)					
	Inadequate	-.261	.546	.770	.330	1.80
Time on HD (LG10)	(Continuous)	.237	.601	1.27	.522	3.08

*p<0.05, **p<0.10

Table 11. Univariate Logistic Regression of BalanceWise Participant Characteristics with "Problems with Hemodialysis Diet Questionnaire" Scores

Variable		B	P-Value	OR	95% CI	
Race						
	Caucasian (Reference Group)					
	African American	.541	.147	1.71	.826	3.57
Age	Younger Aged (Reference Group)					
	Older Aged	-.789	.050*	0.45	.206	1.00
Gender						
	Male (Reference Group)					
	Female	1.09	.005*	2.98	1.40	6.36
Marital Status						
	Married, Living as Married (Reference Group)					
	Single, Not Married	.126	.734	1.14	.548	2.35
Income Adequacy						
	Adequate (Reference Group)					
	Inadequate	-.546	.177	.580	.262	1.28
Time on HD (LG10)	(Continuous)	.443	.305	1.56	.669	3.63

*p<0.05

Table 12. Univariate Logistic Regression of BalanceWise Participant Characteristics "Self-Efficacy Restricting Dietary Salt in Hemodialysis Scale" Scores

Variable		B	P-Value	OR	95% CI	
Race						
	Caucasian (Reference Group)					
	African American	-.038	.919	.963	.464	1.99
Age						
	Younger Aged (Reference Group)					
	Older Aged	-1.37	.001*	.249	.108	.577
Gender						
	Male (Reference Group)					
	Female	.201	.596	1.22	.582	2.57
Marital Status						
	Married or Living as Married (Reference Group)					
	Single, Not Married	.018	.960	1.02	.491	2.11
Income Adequacy						
	Adequate (Reference Group)					
	Inadequate	-.033	.935	.967	.463	2.15
Time on HD (LG10)	(Continuous)	.652	.132	1.92	.821	4.50

*p<0.05

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Appendix H

PERCEIVED BARRIERS TO ADHERENCE TO HEMODIALYSIS DIETARY RECOMMENDATIONS

Title Page

Manuscript Title: Perceived Barriers to Adherence to Hemodialysis Dietary Recommendations

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Abstract

Adherence to hemodialysis dietary recommendations is important to achieve desired clinical outcomes, however this goal is difficult to achieve. Barriers to dietary recommendations have been described[11, 12, 18, 24, 27], but not from the patients' perspective. The purpose of this qualitative study was to explore hemodialysis patients' perceived barriers to adherence to dietary recommendations. Thirty participants, aged 63.2 ± 13.3 years, 37% female, 53% Caucasian were interviewed. Each interview was audio-taped and transcribed verbatim. Coding was conducted by two coders using an iterative process. Barriers included time and convenience, cost, and content of nutritional counseling. Participants were satisfied with efforts made by dialysis center staff to disseminate information. Suggestions for addressing these barriers include technology-based interventions that allow patients to improve food choices and improve decision-making in real-time.

Introduction

Intermittent, in-center hemodialysis is the most common form of end stage renal disease (ESRD) therapy[1, 2]. During twice or thrice weekly hemodialysis (HD) sessions, fluid and renal solutes are removed that would usually be excreted by functioning kidneys[3]. Patients who undergo intermittent, in-center hemodialysis are at risk for left ventricular hypertrophy, a consequence of extracellular volume expansion, and blood pressure elevation secondary to large fluctuations in interdialytic weight gain[4, 5]. Atherosclerotic cardiovascular disease, a common comorbidity, also contributes to the high mortality of ESRD patients[6, 7]. Myocardial infarction and stroke occurs 5 to 15 times more frequently in ESRD patients than the general population and cardiac events reduce life expectancy of ESRD patients by 50%[8-10].To minimize these risks, patients must take multiple medications and adhere to dietary and fluid restrictions.

The hemodialysis diet is a complex regimen geared toward minimizing excessive accumulation of sodium, potassium and phosphorus, while achieving adequate daily energy (caloric) and protein intake. Non-adherence to this diet is well documented[11, 12], though the factors that contribute to an individual's decision to adopt, maintain, or ignore dietary recommendations are not well understood. Little is known about how hemodialysis patients make real-time dietary decisions or practical use of information and counseling provided during standard care. Descriptive information on the barriers encountered by hemodialysis patients when trying to follow their dietary regimen could be critically important for developing a strategy to accomplish these goals. To our knowledge, however, no such descriptive information exists in a US patient population. Therefore, the purpose of this qualitative methods study is to explore the barriers

Methods

Setting and Sample

Participants were enrolled in an ongoing clinical trial to evaluate a technology-supported behavioral intervention designed to reduce dietary sodium intake in intermittent, in-center, hemodialysis patients. Recruitment occurred in 8 hemodialysis centers in ESRD Network 4 from September 2011 to May 2012. A subsample of 30 adult participants was purposively sampled for variation in age, gender, race, etiology and duration of ESRD. Participants were eligible if they met sampling criteria for the parent study which included: an age of 18 years or older and having received maintenance hemodialysis for at least 3 months. Exclusion criteria included: (1) inability to read, write, or speak English, (2) a plan to move out of the area or change dialysis centers within the next 4 months, (3) a terminal illness and life expectancy of less than 12 months per clinical evaluation of dialysis center staff, or (4) lived with another participant of the study. Because the parent study required use of a hand-held computer, participants were also excluded if they: (5) were unable to see the screen of the hand-held computer or use the device's stylus to make selections on the computer screen, or (6) were institutionalized (e.g., in a nursing home, personal care facility, or were incarcerated), which limited control over their dietary intake.

To prevent bias from participation in the parent study, baseline measurements occurred prior to randomization and counseling per the parent study's protocol. Approval to conduct the study was obtained by the University of Pittsburgh Institutional Review Board. All participants provided signed informed consent.

Data Collection and Analysis

Semi-structured narrative data were collected via telephone and audiotaped. Interview duration was approximately 20 minutes (mean 13.7 ± 6.7 minutes, range 8 to 34 minutes). The interview was guided by a list of 17 open-ended questions designed to elicit information about the problems/barriers patients experienced in attempting to follow the hemodialysis diet and extent to which routine dietary care was perceived to be adequate to help them manage the dietary regimen (Table 1). The interview also explored participants' understanding of dietary counseling instructions and compatibility of routine dietary counseling with barriers encountered in real-life dietary decision-making.

After completion of the interview, audiotapes were converted into verbatim transcription by the principal investigator (MNC). Data analysis and management were supported by the use of the qualitative software program, Atlas.ti (v.7, Berlin, Germany). Qualitative analysis of transcribed interviews was performed using the editing style specified by Crabtree and Miller[13] to identify problems/barriers participants cited when attempting to follow the recommended diet. The script was used to identify the need for customized dietary interventions.

The codebook construction process began after one third of the interviews were collected. Members of the research team were asked to review and revise initial codes as appropriate. This approach exploited the expertise of the research team, reduced analytic bias, and promoted consistency in data analysis. All interviews were de-identified prior to analysis and coded using Atlas data analysis software. The principal investigator and a co-coder (JT), with the guidance and assistance of the qualitative expert (SZ), performed final coding.

Results

Inter-coder Reliability

Nineteen codes from the final codebook were used for inter-coder reliability. To complete assessment of inter-coder reliability, 15 transcripts were selected at random and independently coded by both coders. Agreement and disagreement of coders were documented in a spreadsheet. Agreement on 19 codes was evaluated and an overall Cohen's kappa of 0.86 and percent agreement of 86% were achieved[14].

Sample Characteristics

Participants were primarily older aged (≥ 65 years), Caucasian and male (Table 2). On average, participants had been on hemodialysis for 3.5 years and 60% had a history of cardiovascular disease (CVD). Twelve reported their income as adequate to meet their daily basic needs of living and few were employed.

Thematic Analysis

Study participants described their experience of barriers and facilitators while following the hemodialysis diet based on counseling received as standard care. The themes identified from the narrative data included: barriers and facilitators associated with schedules and convenience, financial constraints, and the quality of counseling provided.

Schedule and Convenience

Participants often said that "time" constraints and inconvenience influenced decisions about following the prescribed diet. They often described their meal plan on dialysis days as "up in the air" due to timing of the treatment schedule and the fact that hemodialysis patients were not permitted to eat during treatments which can last a few hours. One participant, in particular, offered "on dialysis days, I don't have a chance to eat lunch, [which] makes me hungrier when I

get home." Another participant added that he postpones eating until after the hemodialysis treatment and then comes home and "pigs out." Hence, scheduling issues, both before and after treatments, created problems following dietary restrictions:

> "If you don't eat before you get up and get out, and then you're hungry when you get out [of dialysis], and there really isn't a place where you can get some regular food. You might go to McDonald's and all that fast food really isn't good for you."

Because of time consuming nature of the dialysis treatment schedule, convenience played a significant role in dietary decision-making. Specifically, one participant stated he was "always looking for an easy meal." Another participant mentioned that if he became hungry while working, he "[ate] whatever [was] available."

Financial Constraints

The financial struggle associated with the hemodialysis dietary regimen was multifaceted. Finances were a major barrier for one participant who said, "you got to have the money," in order to meet the recommendations of dietary counseling sessions, and "sometimes I have it, and sometimes I don't".

> "We live on SSB [social security benefits], and combined, after we pay utilities and everything, it hurts, we are down to $200 in the bank, and that ain't crap to have. You know what I mean?"

Hemodialysis dietary recommendations were repeatedly described, as "expensive," influencing both the type and amount of foods purchased. Several said that if they had more money, they "could really follow [the hemodialysis diet]." One participant said that his resources were so limited that he could not purchase a "week's supply of food." Another participant described food

purchases and dietary adherence as being in "survival mode" behavior in which "you gotta do what you gotta do."

> "And then [for] people [on] low sodium [diet], like for us, you could get a big thing of seasoning salt for about $7.00 and Mrs. Dash will cost you $9.00 and it's a little shaker. If you get two or three different types it could be mighty expensive, like $30, for something you can get for $7.00."

Dietary decision-making based on finances resulted in choices about where to purchase foods. Participants chose grocery stores with poorer quality because they resulted in lower costs for similar products. One participant reported making a "conscious effort to combine our budget with our needs" and this often took precedence over stores with better food quality. Participants talked about going to grocery stores in search of "sales," and "cheaper" items.

> "It's horrible [laughs], I wouldn't say the quality of food is good, but some of the stuff is pretty good. We go for the prices. We gotta go for what we can afford. We have kids, so we go for what's affordable and try to make our money stretch."

Financial constraints sometimes meant that, to make ends meet, participants had to make difficult choices between competing needs and possibly, go "without something else." One participant who did not drive a car described his transportation needs as "putting holes" in his pocket. Some were forced to make decisions about which aspects of the hemodialysis regimen to adhere to:

> "[…]sometimes I skip my medicine. It's just another day or a couple days and then I'll just go ahead instead of going to get my medicine if I am going somewhere with somebody, I will keep those $2.00 to get something I can stretch for a long time. Like the ground beef I can make something I can eat two or three times."

Others reported having "problems" paying for prescriptions despite applying for financial assistance:

> "[…]when you have to pay bills and have doctor's appointments[…], and have to pay copays […], even though I have Medicare and private insurance, it's expensive. […]and you have to cut somewhere you know?"

Although financial constraints were not a current concern for some participants, they observed it could be in the future. In other words, as long as "everything stay[s] like it is, I won't have any problem." One participant said "it doesn't really influence it now, but when I retire [finances] may become a problem."

Quality of Counseling Provided

Those interviewed for this study were satisfied with the dietary and counseling provided by dietitians as part of routine care. Dietitians were described as "going over and beyond the call of duty," and being able to "answer [their] questions, and if she [didn't] know the answer, she [would] find it." Dietitians sometimes "brought in foods for us to try," and gave "cooking demonstrations" of snack alternatives. As a result of these efforts, patients described themselves as being motivated to "eat healthy," live for the "long-term," and "stay healthy for [their] transplant." Participants also said routine dietary care prepared them to "pick and choose," "know what to look for" when purchasing foods, and understand "what not to eat and what to eat."

> "[…]We have a renal diet that we use to know what not to eat. […]I am not supposed to eat salt. I am not supposed to eat a lot of milk products; I am not supposed to eat organ products. […]Some vegetables I am not supposed to eat because they are grown with potassium in them. […]I am allowed to eat chicken, beef, coleslaw; I am not allowed to

> eat pineapple. I am not allowed to eat ice cream, avocadoes, and okra. I am not allowed to eat chitterlings 'cause its an organ product or kidneys or tripe; none of those I am allowed to eat because of the phosphorus and stuff.'

Despite these efforts, for some individuals the content of dietary counseling sessions resulted in a disconnect between the information related and personal beliefs. Some said that it was their belief that their experience and basic physiology (i.e. response to dietary sodium or increased fluid intake) was "different" from others with similar diagnoses and, therefore, warranted individualized counseling. In short, participants felt as though they were "just" being told "what to eat and what not to eat," and recommended to follow the diet "tried and true" without their personal circumstances falling into the equation or addressing topics of their interest:

> "Everybody is different. Our needs are different, you have to respond to the people who have the [financial] means and the ones that [don't] have the [financial] means. You know what I mean? Yeah, you wouldn't recommend my diet to someone else because they might not be able to afford it, ok [laughs]. You have to be aware of that."

More to the point, one participant felt that real-time customization was necessary:

> "Try to specialize with certain people. I know there are those who are really sickly and need to follow [the hemodialysis diet] to the "t" because they have other systemic problems. But try to tailor it a little more for that person."

Additionally, some participants used knowledge of laboratory values and frequency of dialysis related symptoms to self-regulate dietary decisions. They rationalized this decision by noting their "uniqueness" and acknowledged "cheating," because "if you don't, you will just blow your mind."

> "I understand, they are saying that certain foods are not good for you. You know for your kidneys, but I haven't been observing that too much. I like going by trial and error. I like to go with how I feel."

Finally, requests were made for "meal plans," "breaking it down to a point where you can really plan your diet and know what you're eating and so forth;" and advice that is more consistent and could be practically applied:

> "[…] They tell you 'well you can only have like 30 grams,' what is 30 grams? What does that mean? And if I have 32 grams, what is going to happen? You want to know, if you cheat, how it's going to affect you because then you can decide whether to cheat or not."

Discussion

Three themes emerged from interviews conducted in individuals undergoing maintenance hemodialysis: 1) issues related to time and convenience created barriers to following dietary recommendations, 2) financial constraints made dietary decision-making challenging, and 3) despite patient satisfaction with counseling by dialysis center dieticians, the information was difficult to translate into daily decision-making and not always followed, leading to a disconnect between knowledge from dietary counseling sessions and participant adherence to the dietary recommendations.

Based on the recommendations of the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF KDOQI), intensive nutritional counseling should be given to each patient receiving hemodialysis. This counseling should include a multi-disciplinary, individualized plan devised at the initiation or during early phases of care and updated every 3 to 4 months based on the individual's personal circumstances, or more frequently if there was a change in status, e.g. malnutrition or adverse events[15-17].

Responses of participants indicated that recommended nutritional counseling was achieved in terms of sharing required information but judged insufficient, by some, to meet real-world dietary decision-making needs. Some suggested changes would appear relatively simple to implement, e.g., providing hemodialysis patients with detailed nutritional information (including measurement equivalents), recipes, and meal plans. Technology-supported dietary self-monitoring programs (such as that used in the parent BalanceWise Study) are available that provide such information and may help hemodialysis patients make better dietary decisions. Such programs are increasingly available for use with mobile devices, allowing users to access dietary information in the time and place that dietary decisions are made. Labeling of foods that are "kidney friendly" with an easily recognizable icon may help hemodialysis patients make better-informed purchases.

When facing cost constraints, participants tended to trade long-term health benefits, for short-term benefits[18]. This phenomenon is commonly observed in chronic illness[19]. Unfortunately, low cost is often associated with low quality foods and limited choice[20]. This, coupled with the fact that lower income neighborhoods are more likely to be food deserts (e.g. lack established markets with choice foods and amenable prices[21], increases the likelihood that food choices will be inconsistent with dietary recommendations. Diet-related behavior interventions, therefore, should include the creation and promotion of meal plans that are inexpensive and take into consideration foods available in local food banks or pantries. Additionally, education and acquired knowledge, however, have been shown to be counter balances to economic barriers to desired dietary patterns[23-25].

The frequency of food consumption away from home has been steadily increasing, and may make it more difficult for individuals to make informed choices regarding the nutritional

content of meals[24, 27]. This was a particular concern for those experiencing difficulty managing dietary recommendations due to time of the scheduled dialysis session and impact of hunger if meals are missed or omitted, or for those participants looking for a quick meal. Mothersbaugh et al. were able to demonstrate that dietary education can offset negative effects of perceived time constraints on dietary choices or eating behaviors. Therefore, this area of concern might be improved by developing a meal component to the technology-supported dietary self-monitoring program that offers practical suggestions regarding recipes that could be prepared for dialysis session days, and a navigation component for foods that could be purchased in stores or restaurants near the treatment center, in restaurants frequented by the individual patient.

Due to the complex nature of the hemodialysis diet, an expectation of perfection would be unrealistic. Participants in this study admittedly strayed from dietary recommendations based on the observations of laboratory values and frequency of dialysis related symptoms, and because strict adherence to a "one-size-fits-all" regimen was perceived to be impossible or unacceptable. We were unable to identify anything in the literature offering guidance to clinicians or patients wishing to make tailored food choices. Such tailoring is difficult without readily available nutritional information that can be used by patients to make real-time dietary decisions. Tailored behavioral interventions are now possible with the development of new dietary self-monitoring technologies. Future research is needed regarding the efficacy of technology-supported diet-related interventions for engaging HD patients in diet-related behavior change.

Conclusion

Cost and time limitations were identified by HD patients as important barriers to dietary adherence. Participants were satisfied with the dietary counseling they received as part of

routine care, but had difficulty implementing dietary recommendations and desired greater customization. Additional research is needed on alternative approaches to engaging HD patients in diet-related behavior change.

Table 13. Semi-Structured Interview Script

We would like to ask you some questions about your diet and your experience of being on hemodialysis. Feel free to express anything you'd like. If you would prefer not to answer any questions, also feel free not to. We also would to audio record this discussion so that we can remember what you said. Do we have your permission to start the interview and record it? Many thanks and we'll being with the interview now.

1. **First, how many months or years have you been on dialysis?**
   Prompt:
   a. [only if needed] Your medical record says you have been on dialysis for [XXXX]. Does this sound right? So you would have been how old when you started dialysis?
2. **Now we want you to think about how your appetite has changed over time. What was your appetite like in the 3 months before you started dialysis and the 3 months right after you started dialysis?**
   Prompt:
   a. [only if needed] Can you remember how you were feeling right before you started dialysis? How much enjoyment did you get from eating right before started dialysis treatments?
   b. [only if needed] Can you remember how you were feeling the early months of dialysis? How much enjoyment did you get from eating in the early months after starting dialysis treatments
3. **Have you noticed any recent change in your appetite?**
   Prompt:
   a. [only if needed] Do you enjoy eating? Would you say the enjoyment you get from eating is getting worse over time, better over time? Or would you say that the enjoyment you get from the food has not changed recently?
4. **I would like you to think about how your appetite and diet change during the average week. How do your appetite and diet differ on dialysis and nondialysis days?**
   Prompt:
   a. [only if needed] Is your appetite better or worse on dialysis days? Do you eat differently on dialysis days? If so, how?
5. **What foods do you think a person on dialysis should eat, and what should they avoid?**
   Prompt:
   a. [only if needed] Think about the things you have heard or read about the dialysis diet. What should a person on dialysis eat?
   b. [only if needed] Think about the things you have heard or read about the dialysis diet. What foods should a person on dialysis avoid?
6. **Do you think you are currently eating a diet that is healthy for you?**
   Prompt:
   a. [only if needed] Think about what we just talked about regarding the foods a dialysis patient should eat and avoid. Do you eat the foods you should and avoid those you should not?
7. **What are the things that get in the way of eating a healthy diet?**

Prompt:

a. [only if needed] Here we're trying to understand circumstances that cause you to eat poorly.

8. **What things are helpful to you in your effort to eat a healthy diet?**
   Prompt:
   a. [only if needed] Here we're trying to understand those circumstances that you find helpful for promoting good eating habits.
9. **Do you have any goals for how you would like to change your diet over the next year?**
   Prompt:
   a. [only if needed] What, if anything, would you like to change about your current eating **habits?**
10. **How confident are you that you can follow the hemodialysis diet?**
    Prompt:
    a. [only if needed] If you want to follow the hemodialysis diet, how much do you believe you are able to succeed?

We would like to know a little about where you usually get your food. We are interested in grocery stores, churches, food banks, food pantries, farmer's markets, soup kitchens, restaurants and cafeterias.

11. **Which of these are sources of food for you?**
    a. Tell me about [supplier]. Can you tell me about the quality of food?
    b. Does [supplier] have the kinds of foods that dialysis patients should eat?
12. **How many meals a week do you eat out? What types of places do you go?**
13. **Name three(3) restaurants where you eat most frequently?**
14. **What sort of transportation do you use to get your food?**
    a. Here we are want to know if you can get to and from the grocery store and how you do that.
15. **How does money influence whether or not you are able to follow the hemodialysis diet?**
16. **Can you describe your kitchen area? How do you store your food?**
    a. We would like to know what your kitchen looks like to better understand the types of foods you can prepare and we would also like to know what you do with your leftover meals.
17. **So I have asked you about the availability and quality of food, transportation, your financial resources, and kitchen facilities. Are there other things that you lack that get in the way of following the hemodialysis diet?**
18. **In your personal experience, when health care professionals give you advice about your diet, do they take your personal circumstances into consideration?**
19. **Is there anything that health care professionals could do better in the way they give dietary advice?**

Table 14. Participant Characteristics (N=30)

Variable	n (%)
Race	
Caucasian	16 (53)
African American	14 (47)
Age	
< 65 years	14 (47)
≥ 65 years	16 (53)
Gender	
Male	19 (63)
Female	11 (37)
Marital Status	
Single	20 (67)
Married, or Coupled	10 (33)
Income Adequacy	
Income Adequate	12 (40)
Income Inadequate	15 (50)
Other	3 (10)
Education	
High School	20 (67)
> High School	10 (33)
Employment Status	
Employed	5 (17)
Unemployed	25 (83)
History of CVD	18 (60)
Variable	**Mean (SD)**
Mean age, years	63.2 (13.3)
Duration of ESRD (months)	45.7 (42.7)

CVD = cardiovascular disease

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