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Predictive Effects of Length of Treatment and Type of Dialysis on African Americans' Quality of Life

Latoya Benjamin
Walden University

Walden University

College of Health Sciences and Public Policy

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Latoya Benjamin

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Review Committee
Dr. Gudeta Fufaa, Committee Chairperson, Public Health Faculty
Dr. Cynthia Newell, Committee Member, Public Health Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2023

Abstract

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MA, Nova Southeastern University, 2007

BS, Northern Caribbean University, 2001

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Epidemiology

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Abstract

Individuals on dialysis often face challenges with the management of their health, resulting in low health-related quality of life (HRQOL), but the extent of this impact has not been fully examined. The purpose of this quantitative cross-sectional study was, having accounted for relevant demographic variables such as age, gender, family history, employment status, to examine the effects of length of time for treatment and type of dialysis on HRQOL in African American end-stage renal disease (ESRD) patients. This study was guided by the socioecological model. Secondary data from 2016 to 2021 was obtained from the Chronic Renal Insufficiency Cohort (CRIC) database, a prospective cohort study of renal disease which was conducted from 2003 to 2022. This study consisted of 5112 participants. The targeted group was African American dialysis patients age 21-74. The results of the multiple linear regression modeling using data from the CRICS revealed no significant linear relationship between HRQOL and length of time on dialysis, type of dialysis, and demographic variables such as age, gender, and family history. Only employment status showed a statistically significant linear relationship with HRQOL. The implications for positive social change are that the length of time on dialysis and type of dialysis treatment should not be used to predict HRQOL but employment status can be considered an important measure for promoting HRQOL among African American ESRD patients.

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Dedication

First, I would like to thank God for his sustaining power, strength, endurance, and wisdom. I dedicate this dissertation to my cheerleader, my deceased mother Merveta Bailey. A special feeling of gratitude to my husband (Alton) and children (Ashleigh and Ava), who were able to cope and provide support during my extended nights of writing papers and fulfilling assignments. To my brother Kirk and my aunt Grace, who were there to support me along the way. To the remainder of my family members, I thank you for your support.

To my church family, Pastors, and friends who constantly prayed and checked in with me throughout the process. I also want to acknowledge my Professors, Committee Chair Dr. Fufaa, and Second Member Dr. Newell. Thanks for your dedication and advice each step of way.

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Chapter 1: Introduction to the Study

In the 21st century, the prevalence of chronic diseases such as end-stage renal disease (ESRD), the final stage of chronic kidney disease (CKD), is increasing yearly at a high rate (Nagpal et al., 2017). The prevalence of ESRD among individuals age 18 to 44 years is 6% (Garcia-Garcia et al., 2017). In the United States, 124,500 new cases were reported in 2017, with the incidence rate increasing (University of Michigan, 2019). Shahgholian and Yousefi (2015) predicted that by 2020, the number of cases for ESRD would reach 1,200 per million. Individuals who suffer from diabetes or high blood pressure are at greater risk of being affected with ESRD (Centers for Disease Control and Prevention [CDC], 2015, 2017a, 2017b, 2018). ESRD is often life threatening because it does not allow for the removal of waste and water from the blood; therefore, patients require treatment through the administration of dialysis, which is the extraction of waste from the blood to ensure the regular functioning of kidneys (Vadakedath & Kandi, 2017). When left untreated, kidney disease also affects other organs in the body. Moreover, this situation affects the health-related quality of life (HRQOL) of individuals impacted by CKD (Nagpal et al., 2017).

Several researchers have studied the impact of ESRD on individuals’ HRQOL, as well as their social, psychological, and mental functionalities (Nagpal et al., 2017). The number of studies that have systematically assessed the impact of dialysis on HRQOL among racial and ethnic minority populations are limited, however. Therefore, there was a need to quantify the impact of dialysis on the HRQOL of underrepresented populations such as African Americans. The potential positive social change linked to the current study is that through the findings of this study, practitioners and public health policymakers may gain a better understanding of how a person's social ecology combines with causes of ESRD and specific types of treatment to shape patients' HRQOL. This better understanding may contribute to the development of policies or practices to better serve members of the African American population most affected in terms of HRQOL.

In this chapter, I discuss the study's background and identify gaps in the literature. The problem statement, purpose of the study, significance of the study, and research questions are provided in relation to the identified gaps. The theoretical framework that was used to guide this study is also presented. The study assumptions, limitations, definitions, and scope are also discussed.

Background of Study

In the United States, CKD, and its final stage, ESRD, have become an epidemic, and as a result, this disease has significantly impacted the HRQOL of those whom it affects (Chiaranai, 2016). More than 35% of the patients in the United States currently undergoing dialysis care are African American (CDC, 2017b). At the ESRD stage of CKD, patients suffer kidney failure and require dialysis to perform the function of the kidneys. Diabetes has been found to be the major cause of CKD and kidney failure among the African American population (National Kidney Foundation [NKF], 2017). In the United States, approximately 4.9 million African Americans over the age of 20 years have diagnosed or undiagnosed diabetes (Casagrande et al., 2018).

HRQOL, particularly health-related HRQOL, was the key outcome of interest in the current study. The variable of health-related HRQOL was referred to as HRQOL. As it pertains to CKD and dialysis, HRQOL may be divided into the dimensions of effects of kidney disease, burdens of kidney disease, work status, cognitive function, social interaction, sexual function, sleep, social support, dialysis staff support, and patient satisfaction (Hays et al., 1997). This division is supported by a factor analysis and validation (Korevaar et al., 2002). The distribution of HRQOL across these dimensions indicates that HRQOL has mental, physical, and social components. Although HRQOL seems a straightforward variable on the surface, it is a multidimensional measure that incorporates numerous key outcomes.

Researchers have examined many factors related to renal disease and HRQOL. For example, cross-sectional quantitative studies have been conducted to find more information on the relationship between diminishing HRQOL impairments (Bertolin, 2016). Such survey research has been pivotal for the assessment of productivity for family, work, and other social components. Within this literature, several key demographics have emerged as potentially important predictors of health-related HRQOL. One such predictor is race. The experience of dialysis differs along racial lines because the incidence of risk factors for ESRD is significantly higher among some racial groups, particularly Black Americans (Garcia-Garcia et al., 2017; Laster et al., 2018; Norris et al., 2017). Despite this, the perspectives of these population groups remain underrepresented in the literature (Roberti et al., 2018).

Another potentially predictive demographic factor is age. In an interpretative phenomenological analysis study, Sahaf et al. (2017) described the experiences of people over 60 years old who underwent dialysis. A major aspect of the lived experiences of the patients referenced in the result was that of uncertainty, suggesting a psychological toll. Additionally, Salter et al. (2015) conducted a qualitative study on the experiences of 36 African American patients with hemodialysis to identify their views related to kidney transplantation. Their findings demonstrated that older males and females were more positive regarding their experiences related to dialysis than younger ones. Results such as these suggest that age may be a key factor in determining CKD patients' overall outlooks.

Gender may also be a factor that impacts dialysis experiences. For example, assessments conducted on the patients' social functioning indicated that when undergoing dialysis, women have a higher level of anxiety and a lower level of positive attitudes than men (Gerogianni et al., 2014). These psychosocial factors may connect with HRQOL in meaningful ways (Hays et al., 1007). In addition, age is a relevant factor because CKD is more prevalent among women (16%) than men (13%; CDC, 2017a). Considering patients' gender may be relevant to predicting HRQOL outcomes from dialysis.

The type of dialysis could also influence the HRQOL of ESRD patients. Hemodialysis (HD) and peritoneal dialysis (PD) are the types of dialysis available to ESRD patients. Although both PD and HD can be carried out at home, HD requires more specialized equipment and professional personnel (Harris, 2020). Because HD is often done by professionals, it places significantly less responsibility on patients. Conversely, PD provides patients more autonomy and flexibility (Sher & Maldonado, 2019). Both PD and HD have advantages and disadvantages in terms of their influence on a dialysis patient's HRQOL (Sher & Maldonado, 2019). Much research has been done, but additional investigation was needed.

Problem Statement

According to the National Institute of Diabetes and Digestive and Kidney Disease (NIDDKD, 2016), over 661,000 Americans suffer from kidney failure. Out of this number, 468,000 individuals are on dialysis and approximately 193,000 live with an operating kidney as a result of a transplant. Thirty million (15%) of the adults living in the United States suffer from CKD (CDC, 2017b). Moreover, the disease is more prevalent among women (16%) than men (13%; CDC, 2017b). African Americans constitute 35% of all patients receiving dialysis for kidney failure (CDC, 2017a). Overall, about 4.9 million African Americans over the age of 20 years have diagnosed or nondiagnosed diabetes, which is a significant contributor to kidney disease (NKF, 2016). Furthermore, statistics indicated that compared with European Americans, the incidence of kidney failure is 3.7 times higher among African Americans (NIDDKD, 2016). Additionally, Niang et al. (2018) found that patients on dialysis for a longer time period had lower levels of HRQOL. Similarly, Mujais et al. (2009) reported that patients who had been on dialysis for a longer period had a higher burden of disease and lower HRQOL scores.

Time commitment presents a burden for this type of illness, leading to the loss of productivity at work, loss of ability to support family members, and loss to overall society (Walker et al., 2016). Further research is needed to quantify the burdens of CKD with respect to social factors (Roberti et al., 2018). In addition, studies with larger sample sizes are needed to better understand the effects of dialysis for racial minorities (Nagpal et al., 2017; Sciberras & Scerri, 2017). The problem is that individuals on dialysis often face challenges with regard to the management of their health, resulting in low HRQOL (Lim et al., 2016), but the full, quantified extent of this HRQOL toll is not fully understood (Roberti et al., 2018).

Length of time for treatment has a significant impact on dialysis outcomes and the general patient experience. HD is usually done three times a week for 3 to 4 hours a day, depending on how well the kidneys work and how much fluid weight they have gained between treatments (NIDDKD, 2016). HD can be done in a special dialysis center in a hospital or at home. How long individuals receive treatment determines their life expectancy. According to Sahaf et al. (2017), the average life expectancy on dialysis is 5–10 years, but Roberti et al. (2018) established that many patients have lived well on dialysis for 20 or even 30 years. The length of time is also a chief determinant due to the differences in patient outcomes. As observed by Nagpal et al. (2017), some people feel better the first week whereas others notice a difference after a few months.

Purpose of Study

The purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment (how long patients have been receiving treatment) and type of dialysis on patients’ HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. I used data from the Chronic Renal Insufficiency Cohort (CRIC) study of renal disease, which included key outcome data for renal disease patients such as kidney disease-related HRQOL data, which is an 11-dimension construct that is measured using the Kidney Disease Quality of Life (KDQoL)-36 instrument (American College Health Association [ACHA], 2018). The dependent variable in this study was HRQOL, and the independent variables were length of time for treatment and type of dialysis.

Research Questions

RQ1: Is there a significant relationship between demographic variables (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African Americans ESRD patients?

> $H_0$1: There is no significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.
>
> H_a1: There is a statistically significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.

RQ2: Is there a significant relationship between type of dialysis and HRQOL in African American ESRD patients?

> $H_0$2: There is no significant relationship between type of dialysis and HRQOL in African American ESRD patients.
>
> H_a2: There is a statistically significant relationship between type of dialysis and HRQOL in African American ESRD patients.

RQ3: Do the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation moderate the relationships between dialysis and health-related kidney disease and HRQOL in African American ESRD patients?

$H_0$3: Variables of length of time on dialysis, types of dialysis, family history, and occupation do not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

H_a3: Variables of length of time on dialysis, types of dialysis, family history, and occupation moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

Theoretical Framework

I employed the ecological model of Bronfenbrenner (1979) as the theoretical framework. The theory was developed to recognize that individuals affect and are affected by a complex range of social influences and nested environmental interactions (Bronfenbrenner, 1979). The ecological model identifies many facets that influence the health behavior of individuals undergoing health challenges. The ecological model is an approach to health care that is designed to take in the environmental aspects found within an individual's social ecology that may impact or otherwise affect their reaction to the disease in question or ability to deal with it (ACHA, 2018). Adopting the ecological model as a framework enabled me to acquire insights into the impact of dialysis on an individual's overall HRQOL and how ecological demographics factor into that. According to Hays et al. (1997), KDQoL is a complex variable including the dimensions of effects of kidney disease, burdens of kidney disease, work status, cognitive function, social support, dialysis staff support, and patient satisfaction.

Individuals living with CKD face many challenges. According to Lim et al. (2016), the HRQOL of patients who undergo dialysis is impaired, which has also been correlated with clinical outcomes such as mortality and morbidity. As a result of the current study, health care professionals and their families may be better informed about the ecological factors affecting the HRQOL of African American patients who are undergoing dialysis. This may enable these professionals to deliver person-centered care that advances the needs of the patients.

Nature of the Study

The current study was quantitative in nature and included a cross-sectional design. Rather than looking at broader, overarching phenomena, quantitative researchers focus on specific variables and the relationships between them (Balnaves & Caputi, 2001). By asking closed-ended questions, quantitative researchers can gather and analyze data from large sample sizes with relative efficiency (Balnaves & Caputi, 2001). These large sample sizes make quantitative inquiry more empirical than qualitative inquiry, affording significant statistical power and generalizability of the outcomes (Balnaves & Caputi, 2001). The quantitative methodology was appropriate for the current study because this type of research addressed the relationships between key variables, including the predictors of demographic factors and the type of HD that a patient is undergoing. Furthermore, research using larger sample sizes is needed with respect to specific topic (Nagpal et al., 2017; Sciberras & Scerri, 2017), making the quantitative approach appropriate.

A correlational design is a nonexperimental approach is used to assess associations between variables without manipulating or controlling them (Curtis et al., 2016). A correlational design was appropriate for the current study because the purpose was to examine the effects of length of time for treatment and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors (age, gender, occupation, and family history) of HRQOL in African American ESRD patients. Individual-level factors, socioeconomic status, and health behaviors are independent variables, while dependent variables are screening tests; sigmoidoscopy, colonoscopy, or blood stool test. I used data from the CRIC study of renal disease, which included key outcome data for renal disease patients such as kidney disease-related QoL data, which is an 11-dimension construct that is measured using the KDQoL-36 instrument (ACHA, 2018). Data were analyzed using a linear regression model and correlation analysis.

Definition of Terms

Burden of kidney disease: The impact that CKD has on individuals, society, and health care systems (Hill et al., 2016).

Chronic kidney disease (CKD): A condition in which the kidneys are destroyed and incapable of processing blood as they should (Hsu & Powe, 2017).

Continuous Renal Replacement Therapies: A kind of therapy that is used to provide support for acute kidney injuries (Niang et al., 2018).

Diabetic nephropathy: The damage to the kidneys as a result of being diagnosed with diabetes (i.e., patient constantly has high blood-sugar levels; Rett & Hostalek, 2019).

End-stage renal disease (ESRD): Stage 5 (i.e., the last stage) of CKD (Hsu & Powe, 2017).

Health-related quality of life: An individual’s perceived physical and mental health status and the impact that health conditions have on their daily activities, social relationships, and overall well-being (Mapes et al., 2003).

Hemodialysis (HD): A type of dialysis in which the blood of the kidneys that are not functioning normally are purified by a machine (Harris, 2020).

Hypertensive nephropathy: A situation in which constant blood pressure issues (such as high blood pressure) cause the vasculature of the kidneys to get damaged (Himmelfarb & Ikizler, 2018).

Length of time for treatment: The period of time during which a patient has been undergoing dialysis or receiving treatment after kidney failure (Nagpal et al., 2017).

Peritoneal dialysis (PD): A type of dialysis in which waste in the blood is cleaned by the inside lining of a person’s stomach, acting as a natural filter (Harris, 2020).

Assumptions

The assumptions of the study were those inherent in the research design. I assumed that all participants were truthful in their responses in the CRICS data. I also assumed that the use of a quantitative method would yield meaningful results regarding the research topic. These assumptions were shared with other studies drawing on CRICS data and with a large body of literature that included quantitative methodology to address CKD, ESRD, and HRQOL issues (Harris, 2020; Hsu & Powe, 2017; Niang et al., 2018).

Limitations

Several limitations affected the outcome of the study. First, there was the possibility of not achieving the required number of participants. This limitation was addressed by using snowball sampling as a back method to recruit additional participants if the minimum sample size was not achieved using random sampling. Second, access to some participants may have been challenging to me due to wider geographical distribution. This challenge was mitigated using an online platform to distribute the survey questionnaires.

In addition, the study was limited by self-reported data. Because I relied on self-reported data, results may not be fully accurate regarding the underlying issues (see Lauritsen, 2017). Data may have incorporated some of the participants' biases. HRQOL is a subjective topic; therefore, the limitations imposed by the use of self-reported data were lower than they would otherwise have been. Additionally, although the demographic factors chosen were key, it is possible that they excluded other factors that would have significantly impacted the model. Including a fully comprehensive set of demographics, however, was beyond the scope of the study.

Scope and Delimitations

There were two delimitations of the study. First, this study was specific to African American dialysis patients age 21 to 74 years. I selected this age range because it delimited the population to adults within the range of typical adulthood, a period over which default HRQOL should remain somewhat similar, and because it aligned with the data set in the CRIC study. Findings may not be generalizable to populations outside of the stipulated age bracket. Second, because convenience sampling was necessary as opposed to random sampling, it is possible that the results were not fully reflective of the population. The data for the study were from a large-scale cohort study, the CRICS study, which improved the chances of the data being an accurate reflection of the population (see Yarkoni, 2022).

Significance of the Study

The results of this study quantified the social emotional burdens of ESRD and dialysis in a way that may help inform future health policy. The targeted population constituted African American dialysis patients age 21 to 74 years. Such an analysis may provide insights into the experiences of dialysis patients, leading to greater awareness regarding its burden on the overall HRQOL. The benefits that emerge from promoting awareness regarding the burden faced by dialysis patients may support the mobilization and management of families and others who have been impacted so as to improve HRQOL outcomes. The implications of the research findings to positive social change at the individual level are that the length of dialysis treatment should not be used to predict the HRQOL of African American ESRD patients. Recommendations based on this study include further delving into the role of employment/occupation status in the HRQOL of African American ESRD patients, examining the role of treatment in the HRQOL of African American ESRD patients, and exploring other potential moderating variables.

The practical benefits of the study lie include their potential to mitigate the negative HRQOL impacts of ESRD. ESRD is the final stage of CKD and can result in emotional, economic, physical, and social burdens for the sufferers (Agarwal, 2016). In both developed and underdeveloped countries, the leading causes of ESRD are diabetic nephropathy and hypertensive nephropathy. The treatment for this disease requires dialysis or a transplant because of the damage the disease causes to the kidneys.

Researchers have concluded that ESRD is the most precise endpoint decision for patients with CKD (Agarwal, 2016). Therefore, understanding the HRQOL burdens of ESRD and how they can be managed is critical to helping patients with CKD and ESRD.

Summary

The purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment (i.e., how long patients have been receiving treatment) and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. The purpose was fulfilled by answering three quantitative research questions. The findings of this study may provide insights into the burdens experienced by patients on dialysis. Moreover, suggestions are provided for future research and recommendations to aid families and caregivers in improving dialysis patients’ HRQOL. In Chapter 2, I review the literature that was relevant to chronic dialysis patients and the impact of dialysis on their HRQOL.

Chapter 2: Literature Review

The problem was that individuals on dialysis often face challenges with regard to the management of their health, and as a result their HRQOL suffers. The quantified extent of this toll, however, was not fully understood. To address that problem, I examined the effects of length of time for treatment and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. In this chapter, I review the literature upon which the study was based.

The field of nephrology has undergone considerable advancements in terms of research. CKD may affect a person’s HRQOL. Pain, decreased mobility, disruption of activities, and mental health issues in CKD patients negatively affect their HRQOL (Higuita-Gutiérrez et al., 2019; Pauly et al., 2020; Vides & Martins, 2017). HD treatment for CKD can be challenging because it requires strict diet and medication adherence (Higuita-Gutiérrez et al., 2019). Dialysis can also cause fatigue, which limits patients’ daily activities (Higuita-Gutiérrez et al., 2019).

ESRD is as a stark demonstration of racial and ethnic disparities in health. African American people are more susceptible to requiring renal replacement therapy than their White counterparts (Laster et al., 2018). Despite their higher risk of developing ESRD, African Americans have been underrepresented in kidney transplantation (Wang et al., 2019), as well as pre-ESRD nephrology care and education that may have prevented the escalation of their condition (Harding et al., 2017; Nee et al., 2017). These racial disparities may play important roles in African American ESRD patients’ HRQOL. In the current study, the effects of different types of HD on patient HRQOL outcomes and demographic predictors of HRQOL in African American ESRD patients were examined. The chapter includes a discussion of the literature regarding HRQOL, the ecological model, diabetes, CKD, ESRD, the African American population in the United States, and acute and chronic dialysis.

Literature Search Strategy

To guide the present study, existing literature regarding ESRD, dialysis, diabetes, the ecological model, and other related topics were examined. Research strategies involved the use of the Walden Library and Google Scholar. The following databases and journal from the Walden University Library were used: MEDLINE, CINAHL, PsycINFO, ProQuest Central Essentials, Academic Search Complete, and PubMED. Moreover, the following organizations were searched online to access statistical data: CDC, American Diabetes Association (ADA), World Health Organization, ACHA, and NIDDKD.

The following keywords were used: *diabetes*, *dialysis*, *type of diabetes*, *Type 1 diabetes*, *Type 2 diabetes*, *diabetic nephropathy*, *quality of life*, *African American*, *chronic kidney disease*, *acute kidney disease*, *end-stage renal dialysis*, *acute and chronic diabetes*, and *ecological model*. Most articles and books (86.7%) were published between 2017 and 2020, with some important literature (13.3%) from 2016 and earlier. Many of the studies were about African American people, although no study was found that quantitatively investigated the HRQOL of African American dialysis patients. Reviewed studies were primarily peer reviewed and published in English.

Theoretical Framework

The current study was guided by the ecological model developed by Bronfenbrenner (1979). Because the ecological model takes into consideration social factors that influence health care, including intrapersonal, interpersonal, institutional, community, and public policies, the ecological model was appropriate for this study. The constructs of the model include intrapersonal, interpersonal, organizational, community, physical environmental, and policy. The ecological model remains relevant because social inequalities continue to create challenges in health care (Hays et al., 1997). Therefore, the ecological model was appropriate for examining the HRQOL of African American ESRD patients.

The theory recognizes that there are multiple aspects of a developing child’s life that interact with and affect the child. Bronfenbrenner (1979) developed the theory by looking beyond individual development and taking into account wider influencing factors and the context (or ecology) of development. Bronfenbrenner proposed the ecological systems theory based on these dynamic interactions that the environments have on the developing child. Bronfenbrenner suggested that the environment of the child is a nested arrangement of structures, each contained within the next in order of how much of an impact they have on a child. Bronfenbrenner (1992) named these structures the microsystem, mesosystem, exosystem, macrosystem, and chronosystem, arguing that because the five systems are interrelated, the influence of one system on a child’s development depends on its relationship with the others.

The microsystem is the first level of Bronfenbrenner’s (1979) theory, and comprises the things that have direct contact with the child in their immediate environment, such as parents, siblings, teachers, and school peers. As indicated by Darling (2007), relationships in a microsystem are bidirectional, meaning the child can be influenced by other people in their environment and is also capable of changing the beliefs and actions of other people as well. On the other hand, the mesosystem encompasses the interactions between the child’s microsystems, such as the interactions between the child’s parents and teachers or between school peers and siblings (Paat, 2013). According to Bronfenbrenner (1992), the mesosystem is where a person’s individual microsystems do not function independently but are interconnected and assert influence upon one another. The exosystem incorporates other formal and informal social structures, which do not themselves contain the child but indirectly influence them as they affect one of the microsystems (Bronfenbrenner, 1992; Ryan, 2001). The exosystem constitutes the neighborhood, parents’ workplaces, parents’ friends, and the mass media. The macrosystem is a component of Bronfenbrenner’s ecological systems theory that focuses on how cultural elements affect a child’s development, such as socioeconomic status, wealth, poverty, and ethnicity (Bronfenbrenner, 1992; Ryan, 2001). Finally, the chronosystem consists of all of the environmental changes that occur over the person’s lifetime that influence development, including major life transitions and historical events (Bronfenbrenner, 1992).

The theory has been used in similar studies. For instance, Ma et al. (2017) engaged in a study using the ecological model in which they explored public mental health and practice in relation to health outcomes. The researchers focused on examining how different concepts of Bronfenbrenner’s theory have been used in (public) mental health research, and analyzed the value of these different uses for guiding public mental health policy and practice. Findings revealed that using Bronfenbrenner’s ecological system concepts by clearly considering interactions between and within these systems can result in recommendations that are most useful for guiding public mental health policy and practice. In a similar study, Taylor and Haintz (2018) used the theory to study the social-ecological stressors that youths experience during the first year following an HIV diagnosis. Their findings revealed the need for youth-focused services that assist with multiple layers of stressors during the first year following an HIV diagnosis.

Literature Review Related to Key Variables and/or Concepts

Patient Age and Health Care Outcomes

Health care outcomes for patients with kidney issues are influenced by the patient’s age. Giguère et al. (2020) explored health care outcomes with a focus on patients with chronic diseases. The researchers used a systematic review approach and searched MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), HealthStar, CINAHL, ERIC, CAB Abstracts, Global Health, and EPOC Register. For analyses, the researchers grouped the included studies according to study design, type of outcome, and type of comparison. For controlled trials, the researchers reported the median effect size for each outcome within each study, the median effect size across outcomes for each study, and the median of these effect sizes across studies. Findings revealed that although practitioners had attempted to improve kidney dialysis outcomes, the age factor limited the extent of their interventions. These findings are consistent with the results obtained by Buur et al. (2021) who explored whether conservative kidney management offers a quantity or HRQOL benefit compared to dialysis for some patients with kidney problems. The researchers focused on the elements of patient age, mortality, and HRQOL. Findings revealed that when it came to patients older than 60 years, kidney dialysis procedures seldom produced the anticipated quality of health care outcomes.

These findings have also been corroborated by other researchers. For instance, Rose et al. (2017) investigated survival among patients who underwent long exposure to kidney dialysis. The researchers hypothesized that although existing evidence indicated that kidney transplantation is associated with better survival compared to dialysis, age was a critical factor. The study involved 5,365 patients in the Scientific Registry of Transplant Recipients. The researchers focused on this population to determine the adjusted relative risk of death in recipients of a deceased donor kidney transplant after 10 years of dialysis treatment with a focus on the age factor. Findings revealed that the risk of death for patients above the age of 65 was higher when compared to other patient populations, even after kidney dialysis. These findings are consistent with the results obtained by Verberne et al. (2018), who investigated conservative care versus dialysis for advanced kidney patients. The researchers paid attention to the age component hypothesizing that patient age was a key determinant when it came to health care outcomes. Findings indicated that for patients age 60–80 years there were no differences between patients managed conservatively and dialysis patients on physical and mental health summary scores.

Length of Time in Kidney Dialysis Outcomes

Length of treatment time has been associated with notable dialysis outcomes. Levey et al. (2020) explored the aspects of dialysis timing, dialysis initiation, and frequency of hemodialysis sessions. The researchers focused on patients with advanced CKD receiving HD and included randomized or controlled clinical trials in patients undergoing long-term HD if they reported outcomes of interest. Findings revealed that more than 3 times per week HD and extended-length HD during a short follow-up did not improve clinical outcomes compared to conventional HD and resulted in a greater number of vascular access procedures, which constituted very low-quality evidence. These findings are consistent with the results obtained by Webster et al. (2017) who investigated the influences of HD durations on patient outcomes. The researchers found that HD using high-flux membranes did not reduce all-cause mortality but reduced cardiovascular mortality compared to HD using low-flux membranes over a duration of 4 weeks. Consistent with findings from these two studies, Jean et al. (2017) explored factors influencing successful kidney dialysis and discovered that earlier dialysis therapy initiation and more frequent and longer HD did not improve clinical outcomes compared to conventional HD.

Duration of kidney problem treatment has been associated with mortality rates. Hwang et al. (2019) investigated the impacts of kidney duration dialysis on patient outcomes with particular focus on patient outcomes and HD duration treatment. The researchers noted that a decrease in the average duration of HD treatment time is a continuing phenomenon. Therefore, they investigated the relationship of 3-year mortality to duration of dialysis associating mortality with duration of dialysis treatments. Findings revealed that patients receiving an average dialysis treatment duration of less than 3.5 hours had relative mortality risks of 1.17 to 2.18 compared with those with treatments longer than 3.5 hours. These findings are consistent with the results obtained by Prezelin-Reydit et al. (2019) who explored the impact of kidney dialysis procedures on patient outcomes. The researchers hypothesized that reverse causation, which is the possibility that more seriously ill patients received dialysis for a shorter time, was unlikely. Findings indicated that duration of the dialysis procedure is an important element in determining patient mortality as one of the factors determining the adequacy of dialysis.

Gender Factor in Kidney Dialysis Outcomes

Gender has been associated with differing outcomes for patients who undergo kidney dialysis. Alscher et al. (2017) investigated gender-related differences with regard to kidney dialysis. This researcher had realized from literature that gender-specific differences between patients on renal replacement therapy had been rarely investigated. The researcher focused on PD patients and used Cox regression to examine associations between technique failure and gender. Findings revealed that technical survival rates were significantly better in women compared to men over 3 decades and death due to cardiovascular events, and PD-associated peritonitis decreased significantly over the 3 decades in both sexes. These findings are consistent with the results obtained by Brar and Markell (2019), who explored the impact of gender and gender disparities in patients with kidney disease. Initial findings indicated a higher prevalence of CKD in women, but there were fewer women on renal replacement therapy than men. Additional findings indicated that men may progress to ESRD more rapidly even after kidney dialysis compared to women.

Length of Time for Treatment

Treatment length of time and frequency of dialysis vary across the world. T. Lee et al. (2021) noted that due to the economic burden and health insurance, uninsured patients in Mexico receive dialysis only if they pay out of pocket. As a result, many die without receiving dialysis because they cannot afford weekly treatments. Additionally, India reported that there are significant barriers to treatment that impact HRQOL. Observation studies have indicated the association between longer times of treatment and the survival rates of HD patients. The blood flow of patients with longer treatment times were lower and provided stability for these patients (Thurlow et al., 2021).

Overview of Diabetes as a Cause for Renal Disease and Dialysis

One of the key predictors of ESRD is diabetes. Diabetes is a serious public disease all over the world. Diabetes materializes when the pancreas refuses to produce insulin or blocks the entry of glucose for energy (Moini, 2019). In the United States, diabetes is the seventh leading cause of death, and over 30.3 million adults currently have undiagnosed diabetes (CDC, 2017a). Moreover, over 84.1 million adults in the United States (1 in every 3 people) suffer from prediabetes, with 90% of them being unaware of this. What is alarming is that even at the prediabetic stage, individuals are already at risk for CKD (Rett & Hostalek, 2019).

Prediabetes occurs when the sugar amount in the body is greater than normal but has not intensified enough to be diagnosed as Type 2 diabetes. Because no universal definition and standards exist for prediabetes, prevalence rates are not well-defined. Current trends and projections, however, have shown increasing rates of prediabetes worldwide (Rett & Hostalek, 2019). The increased risk for CKD even at prediabetes reveals how the two conditions are strongly interconnected.

There are three major different types of diabetes mellitus: Type 1, Type 2, and gestational diabetes (GD). Type 1 diabetes occurs when the body is accidentally damaged because of the destruction of the pancreatic cells that produce insulin. This type of diabetes is less common than Type 2 diabetes (CDC, 2018). Type 2 diabetes is more widespread than any form of diabetes, taking on 90% of all diabetes mellitus cases (Zhou et al., 2018). It occurs when the body is unable to use insulin effectively. This resistance leads to a lack of maintenance in the blood flow levels (ADA, 2019a, 2019b). Gestational diabetes occurs in pregnant women who have never been diagnosed with diabetes but experience elevated blood-glucose levels during pregnancy. The prevalence rate for GD in the United States has been steadily increasing, with reports from 2010 revealing a rate of 9.2% (DeSisto et al., 2014). On the basis of birth certificates alone, the 2010 prevalence rate was only 4.6%, which then increased to 8.2% in the year 2016 (Zhou et al., 2018). Although the present study only investigated Type 2 diabetes, the most common type, it is important to note the increasing rates of all types of diabetes.

African Americans also disproportionately suffer from diabetes. According to the ADA (2013), 13.2% African Americans aged 20 years and above have diabetes.

Moreover, it has been reported that compared with non-Hispanic Whites, African Americans are more likely to have diabetes (ADA, 2013). In a study conducted by NIH (2018) in Birmingham (Alabama), Chicago (Illinois), Minneapolis (Minnesota), and Oakland (California), it was found that the weight and fat around the abdomen was the major factor behind the higher rates in diabetes among African Americans compared with White Americans (NIH, 2018). Given the above figures and findings, African Americans may need specific culturally relevant interventions to adjust their lifestyles as a disadvantaged population.

The repercussions of diabetes are wide ranging. First, the disease puts immense economic burden on a country's health care system (Bommer et al., 2018). Reported absolute cost for the year 2015 was at $1.32 trillion worldwide. This cost was projected to increase almost twofold in the year 2030 (Bommer et al., 2018). In the United States alone, health care costs related to diabetes was estimated at $302 billion in 2017, with the additional burden of loss of labor due to diabetes at $102 billion (Dall et al., 2019). These financial burdens were purported to be approximately $1,240 per person (Dall et al., 2019).

For another, it negatively affects one's HRQOL. Health care costs of individuals with diabetes increase substantially with the added burden of CKD (Blonde et al., 2019). Dialysis maintenance with or without a diabetes diagnosis may encounter both hyperglycoma and hypoglycemia through multifactorial mechanisms related to kidney dysfunction, the uremic environment, and dialysis (Rhee et al., 2014). Because of that, diabetes becomes the leading cause of ESRD in both developed and undeveloped countries (Williams, 2019). Individuals with diabetes are indeed faced with several disadvantages, including higher rates of CKD, which negatively impacts their HRQOL.

Existing literature also illustrates that diabetes is a major factor for the high rates of dialysis throughout the world. This happens because when diabetes has already caused ESRD, it requires dialysis (Williams, 2019). African Americans continue to register high rates of dialysis due to lifestyle and economic deportment, as well as limited knowledge and accessibility to alternative options such as kidney transplantation (Cabacungan et al., 2020). This condition presents a unique context that may influence their HRQOL. The present cohort study on African American dialysis patients is of significant value as it may provide empirical evidence on patients' perspectives regarding how their dialysis treatments impact their HRQOL. Their experience of dialysis may be unique because of possible social factors, requiring further investigation. The following section discusses existing literature on different types of dialysis and the possible influence of social factors such as race on patients' experiences with dialysis.

Dialysis

Kidney diseases disrupt the flow of activities for patients, their families, and their caregivers. Without treatment, death is normally the result; however, life can be sustained through the continuation of dialysis (NIDDK, 2018). Patients suffering from ESRD can select either of the following options of treatment: hemodialysis (HD), peritoneal dialysis (PD), and transplantation (Harris, 2020). These treatment options compensate for weakened kidney function. Dialysis supports two of the functions that a damaged kidney cannot perform by helping in the extraction of waste material manufactured by the body on a regular basis. Moreover, dialysis also supports the extraction of salt and water from the body. Alternatively, kidney transplantation is the more effective—but more expensive—option for ESRD patients (Harris, 2020). The existing treatment options for ESRD present opportunities for patients to undergo treatments other than the usual hemodialysis; however, not all options are available to or easily accessible for all patients.

Because of the high cost of HD, low-income countries have difficulty in obtaining access to care for ESRD. Harris (2020) reported that annual costs of HD alone in the United States estimated at $42 billion. Although PD is relatively cheaper than HD, most countries prioritize HD over PD because of patient or physician preference, familiarity, late referrals, or other reasons (Niang et al., 2018). In some low-income countries, PD may be more expensive due to the need to import the necessary fluids and supplies for the treatment (Niang et al., 2018). The financial burdens related to ESRD treatments may impact patients' HRQOL as they struggle to find and access the most cost-effective treatment for them. This warrants further investigation on how each type of dialysis affects HRQOL in a disadvantaged population.

Existing treatment options vary in terms of processes. Although both PD and HD can be carried out at home, HD requires more specialized equipment and professional personnel (Harris, 2020). As HD is often done by professionals, it places significantly less responsibility on patients. Conversely, PD provides patients more autonomy and flexibility (Sher & Maldonado, 2019). Both PD and HD have their own advantages and disadvantages in terms of their influence on a dialysis patient’s HRQOL (Sher & Maldonado, 2019).

Kidney transplantation has the major advantage of prolonging life after the procedure in comparison to both HD and PD (Axelrod et al., 2018). It was also purported to lead to better HRQOL, as patients were mostly able to return to their routines and activities before the onset of their disease (Rocha et al., 2020). As a major surgical procedure, however, kidney transplantation may result in significant distress and frustrations for the patient (Rocha et al., 2020). Considering these advantages and disadvantages, patients who are presented with these options must carefully examine and consider the procedures before agreeing to their treatment plan.

The process of PD presents more flexibility for patients to continue with their daily routines than HD. Peritoneal dialysis necessitates the insertion of a catheter in the peritoneal section, while HD encompasses the positioning of vascular entry (Harris, 2020). The peritoneum is the layer that forms as a border around the cavity that plays vital roles in selective fluid and cell transport, trans-cellular migration, and other protective functions (Isaza-Restrepo et al., 2018). When the peritoneal cavity is saturated with the dialyzing fluid and the purified blood is released through the peritoneal layer, a purified fluid known as dialysate is expelled into the abdomen through a catheter (Stromberg, 2020). This fluid renewal is conducted over a few hours (NIDDKD, 2018a, 2018b, 2018c, 2018d, 20183). The process of PD may be more appealing to individuals with busy schedules, such as those who need to continue employment.

Peritoneal dialysis can further be differentiated into more specific processes. There are three types of peritoneal dialysis: continuous ambulatory peritoneal dialysis (CAPD), continuous cycle peritoneal dialysis (CCPD), and intermittent peritoneal dialysis (IPD; NIDDKD, 2018c; Stromberg, 2020). CAPD is a continuous process and does not require a machine; as a result, it is the most commonly used option. Moreover, CAPD is self-operated, with a duration of 4–6 hours per treatment. The CCPD and CAPD procedures are similar, with the exception that in the case of CCPD, there is a machine that is connected to the catheter, which automatically fills and drains the dialysate of the abdomen throughout the course of the night. CCPD is performed for a duration of 10–12 hours each day. As for IPD, a duration of 36–44 hours per week is required for treatment. IPD is performed within a hospital setting with the use of a machine (NIDDKD, 2018b). Although not statistically significant, a meta-analysis by Zazzeroni et al. (2017) indicated that PD is related to slightly better HRQOL than HD. Peritoneal dialysis warrants further investigation as an alternative to HD that may possibly allow for better HRQOL.

The older and more established treatment for CKD is HD. The HD treatment is received in the arms, which is then transmitted through a machine with a dialyzer (NIDDKD, 2018b). The treatment is conducted through a specific filter that is used to purify the blood using a machine for a duration of 2–4 hours, 5–7 times per week. Recently, nocturnal HD, which involves 6–10 hours of HD, has gained attention as a more intensive procedure leading to better health outcomes for ESRD patients (Koh, 2019). Hemodialysis treatment can be conducted at a facility and or at home (NIDDKD, 2018d). Home HD has been purported to increase patient HRQOL, especially with developments on patient-friendly equipment (Trinh & Chan, 2017). As the HD procedure continues to develop, it remains to be a viable treatment for ESRD.

A major reason for patients' difficulty in choosing the right treatment option is because they lack the education from health care providers. Lipford et al. (2018) indicated that African American patients are also disadvantaged in terms of patient education and health literacy, recommending a need for a liaison that could properly explain treatment details to African American patients in a way they could understand. Providing initial education regarding treatment options can reduce the patients' anxiety, thereby maximizing the intervention's ability to decrease the progression of the disease (St. Clair Russell & Boulware, 2018). Many patients with CKD reportedly felt uninformed regarding their conditions and treatment options, which could cause regret if the treatment did not align with the patients' wishes and preferred lifestyle (Saeed et al., 2019).

In reference to dialysis ESRD patients, many medical challenges may arise as side effects of the treatment, including cardiovascular disease, atherosclerosis, vascular access, and decreased HRQOL (NIH Consensus Statement, 1993). Discussing HRQOL with their physicians appeared to be an important step for patients before choosing a treatment option (Saeed et al., 2019). Patient knowledge regarding these challenges may be vital in determining their subsequent HRQOL during treatment, as they may be more prepared. As explained above, the existing treatment options for ESRD are diverse, and more research is necessary to understand how these different types of dialysis could influence African American ESRD patients' HRQOL.

Racial disparities exist regarding treatments for ESRD. African Americans continued to be disadvantaged in terms pre-ESRD care as compared to Whites (31% vs. 38%), and they were also less probable to have visited any nephrologist in the last 12 months prior to the commencement of dialysis (24% vs. 30%) in the year 2015 (Norris et al., 2017). The statistical adjustment concluded that with the inclusion of insurance coverage and region of care, African Americans were 34% less likely than Whites to have nephology care than no care at all (Norris et al., 2017). Most African Americans' choice of modality is hemodialysis; this is due to various possible factors such as socioeconomic status and health insurance barriers (Norris et al., 2017; Shen et al., 2020), which might not actually be cost-effective, given the related machinery and supplies required. As racial disparities continue to appear in ESRD treatment statistics, a specific focus on African American patients is necessary to see how the different modalities of dialysis influence their HRQOL.

Patient experience has been the focus of studies in recent years. During the past decade, more focus has been given to patient experience as a valuable health care aspect (Dad et al., 2020). Instruments have been developed to measure patients' experience of care to assess health care quality (Rhee et al., 2017). Studies have also been conducted to explore patient experiences with dialysis. It was found that the psychosocial needs of patients are more effectively met in a dialysis treatment using a patient-centered model (Nagpal et al., 2017). In another study, Seshasai et al. (2019) focused specifically on home hemodialysis (HHD) and found that independence, support, technical aspects, home environment, and attitude and expectations were vital factors that determined the experiences of patients. While patients identified several challenges related to HHD, they all preferred it over in-center hemodialysis. The patient-centeredness of HHD appeared to make it more comfortable and convenient for patients, leading to more positive experiences with hemodialysis (Seshasai et al., 2019). The findings of both studies supported the value of patient-centeredness as a factor for positive patient experience in hemodialysis. It implies that the type of dialysis treatment may impact HRQOL through patient experiences.

Demographics and ESRD

Race, gender, and family history have been found to be risk factors of CKD. For example, an African American person above the age of 65 years with low birth weight and a family history of hypertension, diabetes mellitus, and kidney disease is a good candidate for the exposure to kidney disease and, subsequently, dialysis treatment (Kazancioğlu, 2013). In addition, kidney disease is more prevalent among African Americans than other populations, with a higher probability of requiring hemodialysis as a permanent treatment for ESRD (Garcia-Garcia et al., 2017; Laster et al., 2018; Norris et al., 2017). In general, the risk factors related to kidney disease are the highest among African Americans, American Indians, and Hispanics compared to Caucasians (Nee et al., 2017). More than 35% of the patients who receive the dialysis treatment for kidney failure are African American, even though they only constitute 13.2% of the U.S. population (National Kidney Foundation [NKF], 2016). Therefore, African Americans are three times likelier than their non-Hispanic or White counterparts to be constrained for RRT (Laster et al., 2018). This disadvantaged population warrants further attention in terms of how they experience ESRD treatment and how it affects their HRQOL.

Socioeconomic Status and Employment

Renal disease may also be related to poverty. While existing literature regarding the relationship between poverty and kidney outcomes is inconsistent, poverty is generally related to reduced access to health care, poorer health literacy, and increased stress, which could impact health outcomes (Norton & Eggers, 2020). Norton and Eggers concluded that poverty interacts with other factors including biological, clinical, and social factors, increasing the risk for kidney diseases for the affected populations. In a study conducted by Lipworth et al. (2012), the San Francisco Community Heath Network represented by the urban poor population, provided the data on adults with non-dialysis-dependent CKD. Out of this group, 73% represented individuals who had an annual income of less than $15,000. After comparing and modifying the socioeconomic values and risks, Blacks were reported to have a higher risk of advancing to ESRD than Whites (Lipworth et al., 2012). Interestingly, the findings of a meta-analysis by Vart et al. (2017) showed that Whites with low socio-economic status had significantly higher risk of CKD than African Americans with low socio-economic status. This finding was surprising, considering that African Americans had a higher risk for CKD when socio-economic factors were controlled (Vart et al., 2017). The role of poverty in relation to race may be more complex in terms of how it affects CKD development, hence the need for further investigation on how demographic factors influence ESRD treatment and HRQOL.

African American Population and Dialysis

Diabetes and hypertension are the primary risk factors for the development of ESRD (Lee et al., 2019). These factors, coupled with obesity and overweight, can trigger comorbid disorders (Lee et al., 2019). Compared with Whites, African Americans are more prone to obesity or overweight (76.3% vs. 68.5%), diabetes (18% vs. 9.6%), and hypertension (43.3% vs 29.1%), subsequently increasing their risk for diabetes and hypertension, and in turn, ESRD (Laster et al., 2018). These disparities warrant further investigation of the HRQOL of African Americans in relation to ESRD.

Ironically, the cases of death risk in dialysis patients are lower for older Black patients compared with White patients (Nee et al., 2017). Age disparities have been indicated by researchers showing how Black adults aged 50 years and older had the lowest death rates, while younger Black adults aged 18 to 30 years had higher death rates than Whites. It was then argued that the racial disparity in death rates could be attributed to socio-economic or cultural factors, such as increased risks of homicide or suicide, more than biological ones (Nee et al., 2017). The paradoxically higher survival rates of older Black dialysis patients call for further investigation on how their treatments as well as demographic factors influence their HRQOL.

Aside from dialysis treatments, African American ESRD patients may also be affected by racial factors in transplant decisions. Race-related issues regarding kidney transplantation have historically placed African Americans at a disadvantageous position (Crenesse-Cozien et al., 2019). Scholars have noted that the timing of the referral to nephrologists and the replacements for individuals on the waiting list can be attributed to the biases of physicians regarding the survival for ethnic patients undergoing transplant surgery. For this reason, the NKF (2016) instituted a strategy to increase the knowledge regarding early referral to nephrologists, which should lead to prior referral for transplantation, as late referrals diminish the probability of preventative kidney transplant, leading to dialysis. Health care providers, however, continue to show bias, as some may attribute health care outcomes to stereotypes such as African Americans' "laziness" (Lipford et al., 2018, p. 9). These biases caused African Americans to prefer the in-center hemodialysis (ICHD) treatment.

A host of components control the ESRD-related consequences for the African American population undergoing dialysis. A major contributor is the ethnic/racial dissimilarities in the infection, in addition to their nutritional status (Nicholas et al., 2013). The biological disadvantages of African Americans must not be ignored, as these also contribute to the development of kidney disease (Norris et al., 2017). The numerous factors related to the health outcomes of African Americans necessitate the development of holistic intervention strategies to lower the prevalence of CKD and ESRD in this population. Therefore, awareness of the possible preventive options needs to be increased among the African American population.

Summary

In this review of literature, I identified the recurring themes related to CKD. Information was also gathered as to the preferred CKD treatment of different populations based on factors such as culture, economic status, affordability, and predialysis education. The literature consistently showed racial disparities in health care for CKD and ESRD patients, revealing how racial minorities may have different experiences of treatment than their Caucasian counterparts. Previous findings revealed the gap in current knowledge regarding the influence of social factors on ESRD patients and dialysis and the need for further quantitative inquiry (Nagpal et al., 2017; Roberti et al., 2018; Sciberras & Scerri, 2017).

The ecological model that guided the current study was found to be highly relevant in the 21st century as racial disparities continue to exist in health care (Wesner et al., 2020). Studies on diabetes as well as CKD showed how each system within the model was relevant to health behaviors and health outcomes, especially to racial minority groups (Goff et al., 2019; Nonterah & Gardiner, 2019; Norton & Eggers, 2020; Whipple et al., 2019). Demographic factors represent the social and cultural aspects within the ecological model—and, as such, require deeper understanding in terms of their relation to ESRD treatment.

The increase in the prevalence of ESRD has made it a grave public health concern globally. As highlighted in the research, one of the major factors contributing to ESRD and, consequently, the need for dialysis is diabetes (González-Pérez et al., 2019; Shen et al., 2017). African Americans are particularly disadvantaged in the development of diabetes, showing a need for better diabetes education in this population (ADA, 2013; Cabacungan et al., 2020). Race-related barriers were also identified in dialysis treatment (Norris et al., 2017). Patients with CKD or ESRD reportedly felt uninformed regarding their disease and treatments, thereby negatively affecting their HRQOL upon treatment (Saeed et al., 2019). The interplay of these factors, including dialysis treatment and demographic factors, are thus worth investigating to provide more solid empirical evidence that would aid in the understanding of African American patients’ experience of ESRD treatment, and how to best help them. In the next chapter, I describe the methodology that was used in this study, primarily focusing on the data collection methods and data analysis procedures.

Chapter 3: Research Method

The prevalence of ESRD has been highlighted as a grave public health concern. The purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment (how long patients have been receiving treatment) and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. In this chapter, I present the research design and rationale of the study, along with the population, instrumentation, and variables. Additionally, the research methodology procedures are highlighted, including the data collection process and the sampling methods. The description of the data analysis includes the software programs that were used. Moreover, methods for achieving validity and reliability in the study are examined. Finally, the ethical considerations are provided. The chapter ends with a summary of the methodology.

Research Design and Rationale

The current study was quantitative in nature. Quantitative research is relational and empirical in nature (Balnaves & Caputi, 2001). Quantitative research focuses on specific variables and the relationships between them (Balnaves & Caputi, 2001). Because of this focus on variables, this type of research is theory driven and closed ended in nature (Balnaves & Caputi, 2001). Using closed-ended questions, quantitative researchers can gather and analyze data from large sample sizes with relative efficiency (Balnaves & Caputi, 2001). These large sample sizes make quantitative inquiry more deeply empirical compared to qualitative inquiry, affording significant statistical power and generality to the outcomes (Balnaves & Caputi, 2001). The price of this greater empiricism is that quantitative research cannot be exploratory and must rely on existing theory to determine the hypothetical relationships to be tested (Balnaves & Caputi, 2001). Quantitative methodology was appropriate for the current study because I aimed to address the relationships between key variables, including the predictors of demographic factors and the type of HD a patient is undergoing. Furthermore, the study rested on strong theoretical foundations, and research using larger sample sizes was needed with respect to this topic (see Nagpal et al., 2017; Sciberras & Scerri, 2017).

In contrast, qualitative inquiry is exploratory and descriptive (Merriam & Tisdell, 2015). Qualitative researchers do not focus on variables or their relationships, but rather on the subjective, human experience of the phenomenon (Merriam & Tisdell, 2015). Qualitative inquiry is appropriate for exploring new theoretical content through open-ended questioning that addresses the full range of responses in a population (Merriam & Tisdell, 2015). The tradeoff for this approach, however, is that copious qualitative data cannot be effectively collected from large sample sizes and is too heterogeneous to be analyzed statistically. Hence, qualitative research was a poor fit for the current study. The focus of this study was not directed at a phenomenon or broader subjective experiences, but rather at how key variables relate. Moreover, existing qualitative research on similar topics had been substantial (Nagpal et al., 2017; Roberti et al., 2018; Sciberras & Scerri, 2017); therefore, there was no need for a new qualitative exploration.

Quantitative research can be experimental, quasi-experimental, or nonexperimental. Of the three types, experimental research is the strongest. Experimental studies can show causation in terms of variables’ interrelationships (Balnaves & Caputi, 2001). This power, however, comes at the expense of experimental research requiring stringent conditions to be carried out, including the control of variables, manipulation of variables, and randomization of the participants into groups (Balnaves & Caputi, 2001). None of these conditions were feasible for the current study, which addressed immutable factors such as demographics. Quasi-experimental research produces stronger results, but still requires control and manipulation (Balnaves & Caputi, 2001). Only nonexperimental research was feasible for the current study. Nonexperimental research can only show correlational relationships, but it can be conducted using real-world data (Johnson, 2001). Furthermore, the results of nonexperimental research reflect functional relationships that can be observed in reality.

The research design for the current study was the cross-sectional design. An appropriate choice of research design is necessary to achieve credible outcomes by eliminating potential bias, facilitating accurate assessment of research variables, and accounting for potential marginal errors (Zangirolami-Raimundo et al., 2018). There are different types of quantitative designs selected to suit different types of studies based on the nature of data sources and participants; these designs include descriptive, quasi-experimental, and cross-sectional research designs. A cross-sectional design was adopted in the current study over quasi-experimental and descriptive analysis to guide me in conducting this research. A quantitative cross-sectional survey design was considered appropriate in collecting required data to answer research questions and test the research hypotheses.

Methodology

Population

In the current study, secondary data were obtained from the CRIC study. Data from 2016 to 2021 were obtained from the database. The CRIC was conducted from 2003 to 2022 and consisted of 5,112 participants recruited from seven trial centers in the United States. A sample size of 3,200 was found suitable for the current study.

Sampling and Sampling Procedure

The population in the current study included African American dialysis patients age 21 to 74 years. This age range was selected because it delimited the population to adults within the range of typical adulthood, a period over which default HRQOL should remain somewhat similar, and because it aligned with the data set in the CRIC study. To obtain the study sample, I used purposive sampling to recruit participants who met inclusion criteria (see Ragab & Arisha, 2018). The purposive sampling method was relevant in selecting participants with information that was required to answer the research questions. The inclusion criteria ensured that only those who had the right data and information were enlisted in the sample (see Nguyen et al., 2021).

Power analysis was used to arrive at the sample size of 3,200. A priori power analysis determined this study’s sample size of 3,200 through the use of G* Power Version 3.1.9.2. The sample size computation was based on factors such as type of statistical analysis, Cohen’s effect size, level of significance, and the statistical power or the probability of rejecting a false null hypothesis. For this study, the statistical analysis that was conducted was a *z* test of logistic regression considering a standard normal distribution to determine the relationship between the encompassed variables. A priori power analysis was conducted with the following factors: (a) statistical test of logistic regression, (b) one-tailed test, (c), odds ratio of 1.50, (d) medium effect size of 0.20 for a logistic regression analysis, (e) level of significance of 0.05, and (f) statistical power of 0.80, which is normally used in quantitative studies. The effect size is the measure of the strength of the relationship between independent and dependent variables (Cohen, 1988). Effect size is normally categorized into small, medium, and large. The medium effect size is commonly used for quantitative studies because it strikes balance between being too strict and too lenient in estimating the degree of relationship between the variables. For the purpose of the current study, a medium effect size was employed to ensure that the analysis was not too strict or too lenient in identifying significant relationships. The significance level involves the confidence that the statistical result is true. For the current study, a 5% significance level was employed. The power of the analysis was set at 80% because this is the standard considered in most research studies. The a priori power analysis computation yielded a sample size of 3,200.

As age increases, base HRQOL tends to decrease regardless of dialysis (Winkelmayer et al., 2011). By focusing on relatively younger patients undergoing hemodialysis, I examined the population that requires improvements in their HRQOL. To be included in the study, the participants needed to be undergoing dialysis treatment for at least 1 year and meet the established demographic and age criteria.

In the original study, the participants were recruited using an age-stratified approach to ensure that all age groups 21–74 years were adequately represented. The scope of this study excluded participants with polycystic kidney disease or those who were on active immunosuppression for glomerulonephritis. Overall, renal insufficiency was defined in terms of a 25 ml/min per 1.73 m2 decline in glomerular filtration rate from baseline or the necessity of renal replacement therapy. About half of the sample had diabetes mellitus. Not all participants in the CRICS were at the ESRD stage and on dialysis. Because the current study was concerned with ESRD and not kidney disease more generally, only participants with ESRD were included. Data from participants with less severe CKD were excluded.

To ensure statistical validity, a minimum number of samples is necessary. G*Power v3.1.0 was used to determine the minimum number of samples for the study. A priori power analysis involves a number of factors to consider, such as the power of analysis, significance level, effect size, and type of analysis. For the purpose of the current study, 80% power, a medium effect size of 0.15, and a significance level of .05 were considered. This study included five predictor variables and a multiple linear regression analysis (see Faul et al., 2007). Based on the G*Power calculation, a minimum sample of 92 participants was necessary to ensure 80% statistical power. All participants in the CRIC study were required to have disease; therefore, it was possible that the subsample of participants who were African Americans with ESRD would exceed 92. The subsampling approach was to review the data set and include all members of the CRIC study data set who reported their race as African American and whose renal disease has reached the end stage.

Procedures for Recruitment, Participation, and Data Collection

Obtaining data for the study involved retrieving data from the CRIC study, a prospective cohort study of renal disease run from 2003 to the present. The CRIC is a multisite study in which participants were recruited from a number of sites across the United States. The study was conducted in multiple waves, allowing the researchers to track the participants' progress and renal disease progression over time. The researchers enrolled those with any stage of kidney disease, not only ESRD, but many patients progressed to ESRD and required dialysis over the course of the study. In this study, data from the most recent wave were drawn.

The first step of the current study was to request formal access to the data from the CRIC study. After preliminary data authorization was obtained, the study proposal was submitted for institutional review board (IRB) review through the university. At this stage, any changes necessary to secure IRB approval were made. After IRB approval was achieved, official data use authorization was requested from the CRIC data repository (see Appendix A).

Once IRB authorization was obtained and permission to use the data was granted, the CRIC study data were accessed through the Scientific and Data Coordinating Center at Penn, which manages the CRIC data. The data were transformed from the format provided in into a format that could be loaded in Statistical Package for the Social Sciences (SPSS) statistical analysis software. The CRIC data set contains many more measures than were relevant to the current study. The specific portions of the data that were retrieved for use in this study are listed in the following section.

Instrumentation and Operationalization of Constructs

All data analyzed in the current study were drawn from the CRIC data set. Measures corresponded to the data measures found in the original CRIC study, but only a relevant subset of CRIC data were retrieved. Table 1 includes coding categories for variables.

Table 1

Categorical Variable Coding

Variable	Coding
Gender	0 = male
	1 = female’
Family history	0 = no
	1 = yes
Employment status	0 = unemployed
	1 = employed

Demographics

Demographic data were retrieved in alignment with the study’s theoretical framework, including the factors of age, gender, length of time for treatment, family history, and occupation. These demographics were each represented as a single item with a binary, categorical, or continuous response. In alignment with RQ1, the following demographic variables were included.

Age

Age referred to the participant’s age at time of data collection, measured using the field AGE as a continuous variable.

Gender

The participants' gender was measured using the field GENDER as a categorical variable.

Family History

Each participant's family history of ESRD was collected. A binary variable was taken as true if any of MED55_1, MED55_2, MED55_3, or MED55_4 were true.

Length of Time for Treatment

This variable described the length of time for which the participant had received treatment for dialysis. This variable was calculated as a continuous variable from the item MED12, which reflected when the participant sought dialysis treatment.

Dialysis

Additionally, the type of dialysis that a participant used was retrieved from the CRIC data set. These data were recorded as a categorical variable with categories of no dialysis, satellite hemodialysis, standard dialysis, or other.

Quality of Life

The key dependent variable, participants' health-related quality of life, was assessed using an existing, validated instrument, the Kidney Disease Quality of Life Questionnaire (KDQoL; Hays et al., 1994; see Appendix C). In particular, to assess the effect of ESRD, the Specific Burden of Kidney Disease Subscale was utilized. This was operationalized as the KDQoL_BURDEN variable in the CRICS study, comprising four items: KDQ12 a: My kidney disease interferes too much with my life, (b) Too much of my time is spent dealing with my kidney disease, (c) I feel frustrated dealing with my kidney disease, and (d): I feel like a burden on my family. The overall KDQoL instrument measures health-related quality of life in renal disease patients using 36 items and has been validated and determined to have acceptable reliability scores (Korevaar et al., 2002). The specific subscale has also been validated for individual usage as is used in this study, given that the KDQoL does not have an overall index value (Hays et al., 1997). The KDQoL_BURDEN scores are on a scale of 0–100 translated from a 5-point Likert scale.

Data Analysis Plan

I carried out all data analyses out using SPSS statistical analysis software (IBM SPSS 29). The descriptive analysis was used to characterize the sample and the variables. It included the calculation of means, medians, ranges, and other statistical properties. Some of the data were graphed against demographics to indicate their distribution within the sample. To recall, the research questions to be answered were as follows:

RQ1: Is there a significant relationship between demographic variables (i.e., age, gender, length of time for treatment, family history, and occupation) and HRQOL in African Americans ESRD patients

RQ2: Is there a significant relationship between type of dialysis and HRQOL in African American ESRD patients?

RQ3: Do the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation, moderate the relationships between dialysis and kidney disease and HRQOL in African American ESRD patients?

To answer RQ1 and RQ2, an initial multiple linear regression model was developed. First, the assumptions of multiple regression were tested. These include the normality of the dependent variables and the homoscedasticity of the data (Nathans et al., 2012). If the assumptions could not be validated, appropriate transforms would have been attempted and, failing those, nonparametric regression would have been used instead. Then, a regression model with the demographic variables of age, gender, length of time for treatment, family history, and occupation as predictors and health-related quality of life was developed. Provided that the overall multiple R^2 of the regression model is significantly different from 0 and at least one predictor has a statistically significant coefficient of regression, the null hypothesis for RQ1 and RQ2 could have been rejected.

Then, RQ3 was tested, which entailed adding the factors of demographics and type of dialysis to the model developed in RQ1. As before, I verified the assumptions and took appropriate steps if they were not met. I determined whether the overall R^2 of the new model was significantly different from 0 and significantly greater than the multiple R^2 achieved with just the demographics. If the multiple R^2 increased, then the null hypothesis RQ3 would have been rejected the coefficient of regression for type of dialysis is significantly different from 0. In estimation of the sample size, as per the population and sample size section, the minimum necessary sample was expected to be 3,000, well exceeded by the 5,112 participants in the dataset.

Threats to Validity

In the present study, the data were drawn from the CRICS. The CRICS was conducted using existing, validated instrumentation regarding the key measures, such as quality of life. In addition, the CRICS included a large, nationally representative sample. Therefore, the current study inherited this validity through use of secondary data.

I assured internal validity in this study by the careful alignment of the study. The research problem and corresponding research gap directly led to the study purpose, and the purpose informs the research questions. The research questions, in turn, are used to determine the instrumentation. Insofar as the validity of the instrumentation, all of the instruments outlined above for use in the current study were either intrinsic measurements or existing, validated instruments whose psychometric properties have been analyzed and independently verified (Korevaar et al., 2002). In particular, the CRICS measured quality of life using the KDQoL-36, an existing and validated measure of kidney disease-related quality of life. To ensure appropriate use of these data, the original 11 dimensions of the KDQoL were retained and no attempt was made to combine them into an overall index value. Hence, internal validity and reliability with respect to the research instruments are strong.

External validity refers to how well the results generalize to other populations (Balnaves & Caputi, 2001). The primary measure upon which the external validity of the current study rested was the power analysis. Through power analysis, I was able to ensure that the sample size exceeds the minimum necessary for the results to have a meaningful statistical power relative to the larger population. The CRICS data used in this study offered extensive external validity. The CRICS is a multisite study conducted at a large scale, with a resultantly high sample size. Although this sample still may have incurred self-selection bias, the size and breadth of the sample used offers a much greater likelihood of representativeness than a sample collected by a single researcher directly would allow for. Hence, the use of secondary data greatly enhanced the current study's external validity.

Ethical Procedures

During this study, ethical codes were followed (Arifin, 2018). Obtaining permission is an essential component of any ethical research. I requested and used data from CRICS after written permission to do so had been granted by the office controlling the data at Pennsylvania State University. In addition, I sought IRB approval for the study before attempting to gain access to the secondary data. The final ethical concern for this study was the process of recruiting the participants. In order to avoid HIPAA violation, the potential participants were not approached me personally (U.S. Department of Health and Human Services, 2019). Instead, the data were drawn from a secondary dataset of existing data in which the participants have already agreed to participate. The original CRICs data collection also involved significant effort to ensure ethical compliance. All participation in the study was voluntary, with participants having the option to withdraw.

Although the study's longitudinal nature was such that anonymity was not possible, all data were collected confidentially. In addition, the data were fully anonymized before being offered for use in studies such as this one. The CRICS also requires a more elaborate approval process for some of its more sensitive data, ensuring that only legitimate users can gain access to the data. Once retrieved, the data were stored using a computerized software that was only accessible by myself. A secondary backup was stored in a safe data structure both at my home and offsite.

Summary

In summary, the purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment (i.e., how long they have been receiving treatment) and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. In Chapter 3, I presented and justified the research methods for the study. The research method was quantitative, while the research design was a nonexperimental cohort study. The population included African American dialysis patients who participated in the CRICs, who were between 21 and 74 years of age, and who have been on dialysis treatment for over 1 year. The data were retrieved from the existing CRICs dataset. Data analysis involved multiple linear regression. I adhered to ethical research practices at every stage of the research.

Chapter 4: Results

The purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment on dialysis (i.e., how long patients have been receiving treatment) and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. I used data from the CRIC study of renal disease, which included key outcome data for renal disease patients such as kidney disease-related QoL data, which is an 11-dimension construct that is measured using the KDQoL-36 instrument (ACHA, 2018). Burden of kidney disease was used to measure kidney disease-related HRQOL. Studies have found that higher levels of kidney disease burden are associated with lower health-related HRQOL and greater impairment in daily activities. For example, a study conducted by Almutary et al. (2013) showed that burden of kidney disease was a significant predictor of HRQOL in patients undergoing HD. The dependent variable in the current study was burden of kidney disease, and the independent variables were the demographic variables, length of time for treatment on dialysis, and type of dialysis.

RQ1: Is there a significant relationship between demographic variables (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African Americans ESRD patients?

> $H_0 1$: There is no significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.

H_a1: There is a statistically significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.

RQ2: Is there a significant relationship between type of dialysis and HRQOL in African American ESRD patients?

H_02: There is no significant relationship between type of dialysis and HRQOL in African American ESRD patients.

H_a2: There is a statistically significant relationship between type of dialysis and HRQOL in African American ESRD patients.

RQ3: Do the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation moderate the relationships between dialysis and health-related kidney disease and HRQOL in African American ESRD patients?

H_03: Variables of length of time on dialysis, types of dialysis, family history, and occupation do not moderate the relationships between type of dialysis HRQOL in African American ESRD patients.

H_a3: Variables of length of time on dialysis, types of dialysis, family history, and occupation moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

In the current chapter, the data collection procedure is detailed. After that, the results from the data analyses are provided. The results from the descriptive statistics are reported to characterize the sample and the variables. The results from the multiple linear regression analyses conducted to answer the research questions as well as discussions of tests of assumptions for these analyses are provided. All analyses were performed using IMB SPSS Statistics 26.

Data Collection

In the current study, secondary data from the CRIC study, a prospective cohort study of renal disease run from 2003 to the 2022, were used. I analyzed the data from 2016 to 2021. CRIC is a multisite study in which participants were recruited from a number of sites across the United States. The study was conducted in multiple waves, allowing the researchers to track the participants’ progress and renal disease progression over time. The CRIC enrolled those with any stage of kidney disease, not only ESRD, but many patients progressed to ESRD and required dialysis over the course of the study. In the current study, data from the most recent wave were drawn.

The first step of the data collection was to request formal access to the data from the CRIC to use in the current study. After preliminary data authorization was obtained, I submitted the study proposal for IRB review through the university. After IRB approval was achieved, official data use authorization was requested from the CRIC data repository (see Appendix A).

The CRIC dataset contained many more measures than were relevant to the current study. The portions of the data set corresponding to the following variables of interest were retrieved: age, gender, length of time for treatment, family history, dialysis, HRQOL, and occupation. Only data from 2016 to 2021 were obtained from the database. The population under study was African American dialysis patients age 21 to 74 years. Only participants who had undergone dialysis treatment for at least 1 year were included.

The scope of this study excluded participants with polycystic kidney disease or those who were on active immunosuppression for glomerulonephritis. Not all participants in the CRIC were at the ESRD stage and on dialysis. Because I was concerned with ESRD and not kidney disease in general, only participants with ESRD were included. Data from participants with less severe CKD were excluded.

Results

All data analyses were conducted using SPSS statistical analysis software Version 26. Descriptive statistical analyses were conducted to characterize the sample and the variables. Linear regression analysis was used to examine the hypothesized associations. Before fitting the linear regression model, I checked the model assumptions. These included the normality of the dependent variables and the homoscedasticity of the data (see Nathans et al., 2012). The assumption of normality was evaluated by visually inspecting the normal P-P plots of the residuals from each regression model. In addition, the homoscedasticity assumption was assessed by evaluating the scatter plot of the standardized residuals compared to standardized predicted values from each regression model.

Descriptive Statistics

After excluding missing values, non-Blacks, and those who did not have a diagnosis of ESRD, I reduced the size of the sample from 5,625 to 510. Table 2 reports the results from the frequency analyses for the categorical variables of the study. Among the patients, 52.5% were male, whereas 47.5% were female. Furthermore, 25.5% had a family history of ESRD. Regarding occupation status, 33.5% were employed and 66.5%

were not employed. Lastly, modality of first ESRD for 83.7% was HD, for 12.9% was PD, and for 3.3% was transplant.

Table 2

Frequency Analysis for Categorical Variables (N = 510)

Variable	Category	Frequency	Percentage
Gender	Male	268	52.5%
	Female	242	47.5%
Family history	No	380	74.5%
	Yes	130	25.5%
Employment status	Unemployed	339	66.5%
	Employed	171	33.5%
Modality of first ESRD	Hemodialysis	427	83.7%
	Peritoneal dialysis	66	12.9%
	Transplant	17	3.3%

Table 3 reports the descriptive statistics for the continuous variables. The values for length of time on dialysis ranged from 0 to 6 and had a mean of 3.81 (*SD* = 1.69). Furthermore, HRQOL had a mean of 57.69 (*SD* = 31.83), and the age of the patients had a mean of 61.140 (*SD* = 9.97). The skewness and kurtosis values for all these variables were less than ±1, indicating that the distributions of these variables were not highly skewed or too peaked.

Table 3

Descriptive Statistics for Continuous Variables (N = 510)

Variable	Min	Max	Mean	*SD*	Skewness	Kurtosis
Length of time on dialysis	0.000	6.000	3.810	1.694	-0.438	-0.547
HRQOL	0.000	100.000	57.6961	31.831	-0.160	-1.200
Age	27.000	74.000	61.140	9.966	-0.953	0.448

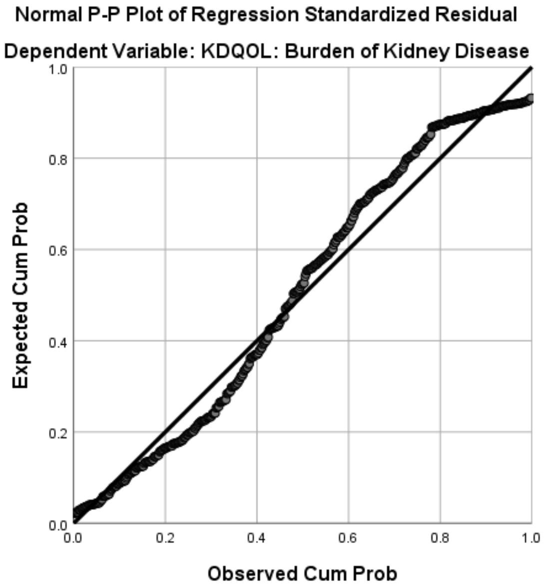
This sample size of *N* = 510 exceeded the minimum required sample size of 92 as determined by a priori power analysis. There was no issue concerning the number of patients included in the analysis. The following research questions and hypotheses were evaluated based on this sample.

Research Question 1

The first research question asked whether there was a significant relationship between demographic variables and HRQOL in African American ESRD patients. The null hypothesis corresponding to this question was there is no significant relationship between demographic predictors (age, gender, family history, and occupation) and HRQOL in African American ESRD patients. A multiple regression analysis was conducted to answer this question. In this analysis, the dependent variable was HRQOL, and the independent variables were the demographic variables of age, gender, and occupation status. Before calculating the results from this analysis, I conducted tests of assumptions underlying this parametric procedure. First, the normality assumption of residuals was assessed. As depicted in Figure 1, an evaluation of the normal P-P plot of the standardized residuals indicated that the observations did not fall substantially far away from the normality line. From this plot, no substantial deviation from the normality assumption of the residuals was identified.

Figure 1

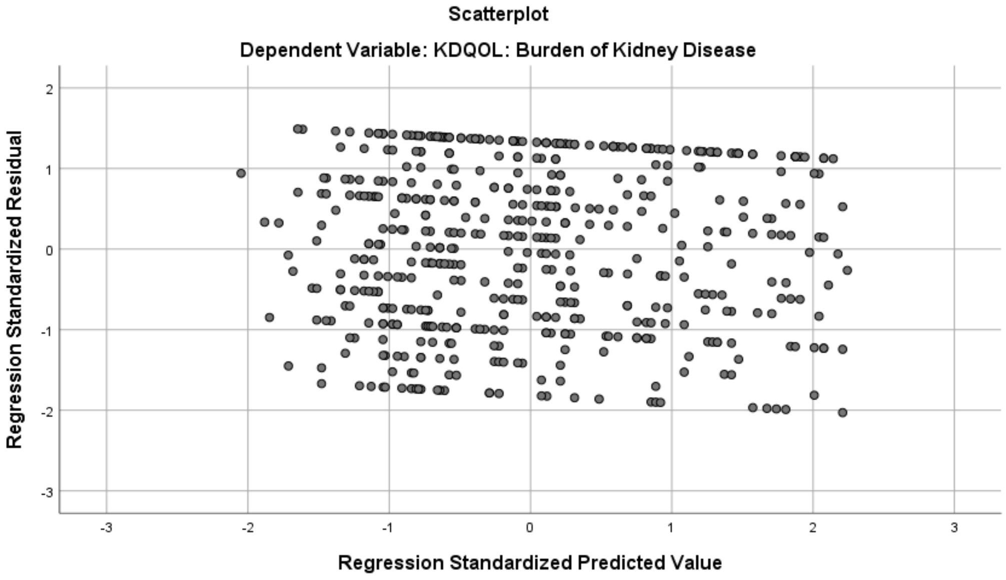
Assessment of the Normality Assumption for the Regression of HRQOL on the Demographic Variables



In addition, I assessed the homoscedasticity of the residuals assumption using the scatter plot of the standardized residuals against the standardized predicted values from the regression model (see Figure 2). This plot exhibited a slight downward pattern in the observations; however, this pattern did not seem to be substantial to indicate deviation from the homoscedasticity assumption.

Figure 2

Assessment of the Homoscedasticity Assumption for the Regression of HRQOL on the Demographic Variables



The third assumption to check was a lack of multicollinearity. This assumption was evaluated using variance inflation factor (VIF) values for each predictor variable included in the model. As shown in Table 4, all VIF values for the predictor variables were well below 10, indicating there was no multicollinearity problem among these variables.

Table 4

Assessment of Multicollinearity Among Age, Gender, Family History, and Employment Status

Variable	Tolerance	VIF
Age	.923	1.084
Gender	.996	1.004
Family history	.998	1.002
Employment status	.918	1.089

No substantial departures from the assumptions underlying the regression model were identified. Therefore, this model was performed to assess the relationship between the demographic variables and HRQOL. The results showed that this model did not provide a significant fit to the data, $F(5,505) = 1.208$, $p = .307$, $R^2 = .009$. Table 5 reports the parameter estimates for this regression model. The only significant predictor of HRQOL was employment status. Given that the overall R^2 of the regression model was not significantly different from 0, the null hypothesis that there is no significant relationship between demographic predictors (age, gender, family history, and occupation) and HRQOL in African American ESRD patients was not rejected.

Table 5

Parameter Estimates for the Regression of HRQOL on the Demographic Variables

Variable	Unstandardized coefficients		Standardized coefficients	*t*	*p* value
	B	Std. Error	Beta		
Age	.104	.147	.033	.705	.481
Gender	2.645	2.827	.042	.936	.350
Family history	-1.242	3.235	-.017	-.384	.701
Employment status	6.190	3.113	.092	1.988	.047

I performed a Pearson correlation analysis to examine whether age and HRQOL were significantly correlated. The results from this test showed that the correlation between the two variables was nonsignificant ($r(508) = .006$, $p = .885$). Furthermore, multiple independent samples *t*-tests were also conducted to assess whether there were significant differences in HRQOL by each of the dichotomous demographic variables of gender, family history, and occupation status. I identified no significant differences by these demographic variables ($p > .05$). These results showed that the difference in the mean HRQOL between those who had a family history of ESRD ($M = 56.635$, $SD = 32.075$) and those who did not ($M = 58.059$, $SD = 31.782$) was nonsignificant ($t(508) = 0.440$, $p = .660$). Moreover, the difference between males ($M = 56.623$, $SD = 31.372$) and females ($M = 58.884$, $SD = 32.356$) was nonsignificant ($t(508) = .424$, $p = .399$). Lastly, no significant difference was identified between those who were employed ($M = 61.330$, $SD = 32.540$) and those who were not ($M = 55.863$, $SD = 31.356$, $t(508) = -1.836$, $p = .067$).

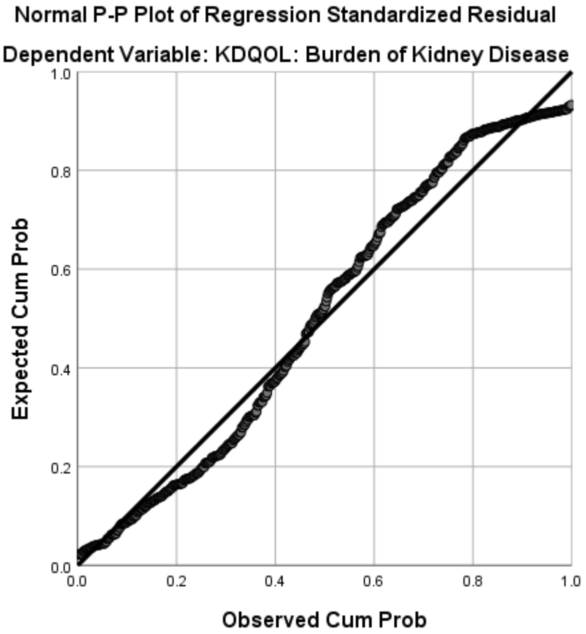
Research Question 2

The second research question asked whether there was a significant relationship between the length of time on dialysis and HRQOL in African American ESRD patients. The null hypothesis developed based on this question was that there is no significant relationship between type of dialysis and HRQOL in African American ESRD patients. I conducted a multiple regression analysis to address this question. In this analysis, the dependent variable was health-related HRQOL, the independent variable was length of time for treatment, and the control variables were the demographic variables of age, gender, and occupation status. Before reporting the results from this analysis, a discussion of tests of assumptions underlying this parametric procedure are detailed.

The first assumption to evaluate was the normality of the residuals from this regression model. This assumption was assessed using the normal P-P plot of the residuals (see Figure 4). An inspection of this plot revealed that the data point typically did not fall greatly far away from the normality line in the P-P plot. Thus, this plot did not indicate a substantial deviation from the normality assumption of the residuals.

Figure 3

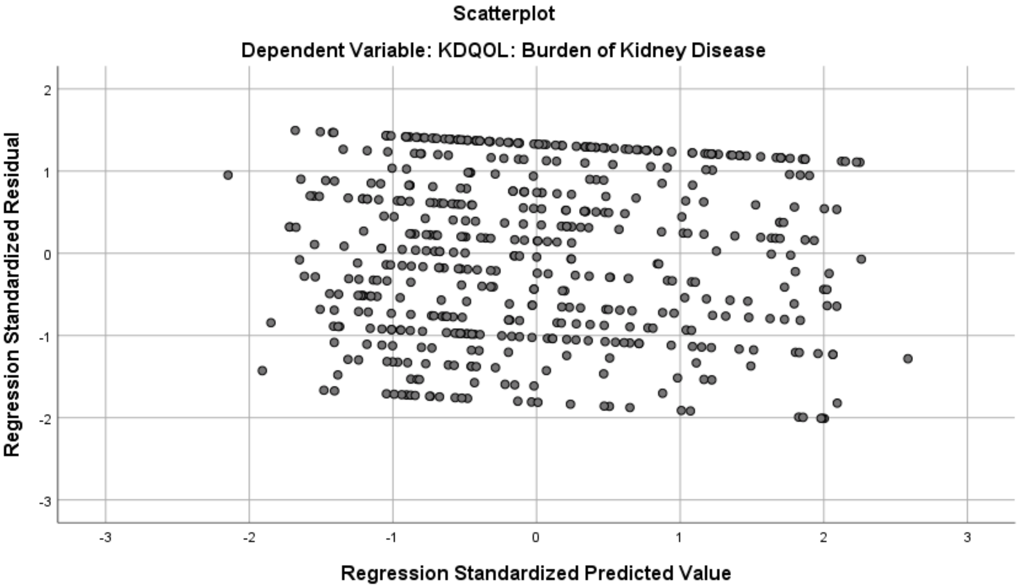
Assessment of the Normality Assumption for the Regression of HRQOL on Length of Time on Dialysis and the Demographic Variables



The second assumption to assess was the homoscedasticity of the residuals. I evaluated this assumption by assessing the scatter plot of the standardized residuals against the standardized predicted values from the regression model (see Figure 5). From this plot, I determined that there was a slight downward pattern in the data points; however, this pattern did not seem to indicate deviation from the homoscedasticity assumption.

Figure 4

Assessment of the Homoscedasticity Assumption for the Regression of HRQOL on Length of Time on Dialysis and the Demographic Variables



Lastly, I evaluated the absence of multicollinearity assumption using VIF values for each predictor variable included in the model. As reported in Table 6, all VIF values for the predictor variables were well below 10. Hence, this assumption was considered valid.

Table 6

Assessment of Multicollinearity Among Length of Time on Dialysis and the Demographic Variables

Variable	Tolerance	*VIF*
Age	.922	1.085
Gender	.995	1.005
Length of time on dialysis	.977	1.024
Family history	.993	1.007
Employment status	.901	1.110

As detailed above, no substantial departures from the assumptions underlying the regression model were identified. Hence, I performed this model to assess Research Question 2. The results showed that this model did not provide a significant fit to the data ($F(5,504) = .991$, $p = .423$, $R^2 = .010$). Furthermore, the results revealed that while controlling for other demographic variables included in the model, length of time on dialysis was not a significant predictor of HRQOL ($B = -0.305$, $t(504) = -0.362$, $p = .718$). Thus, these results did not provide support to reject the null hypothesis that there is no significant relationship between type of dialysis and HRQOL in African American ESRD patients.

Research Question 3

The third research question was formulated to determine whether the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation, moderated the relationships between dialysis and kidney disease HRQOL in African American ESRD patients. The null hypothesis developed based on this question was that the variables of length of time on dialysis, types of dialysis, family history, and occupation, do not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

A moderation analysis was performed to address this question. This procedure involved two steps: First, a regression analysis was performed to assess the relationship between type of dialysis and HRQOL. After that, a second regression analysis was conducted by including the interaction terms between each of the demographic variables and the dummy variables for the hemodialysis and peritoneal dialysis groups. The results from these regression analyses, as well as assessments of the assumptions, are provided in the following subsections.

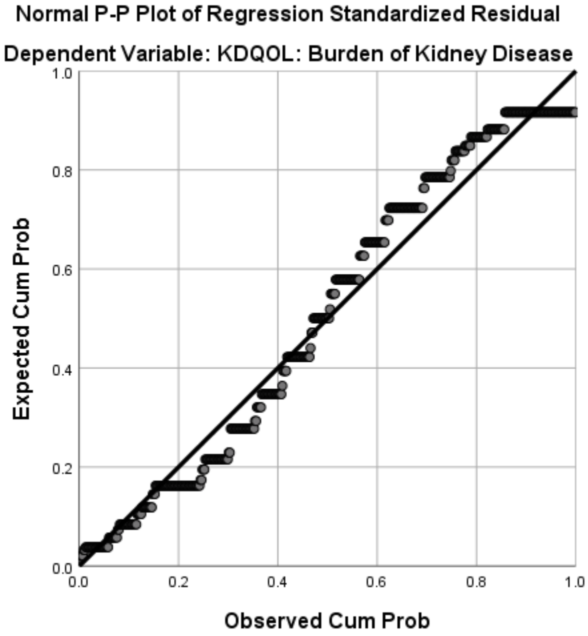
First Regression Model

In the first regression, model the dependent variable was HRQOL, and the predictor variables were the dummy variables for the hemodialysis and peritoneal dialysis groups. Before reporting the results from this analysis, a discussion of tests of assumptions underlying this parametric procedure are detailed.

The first assumption of this regression model to evaluate was the normality of the residuals. An assessment of the P-P plot of the standardized residuals from this regression model shows that the data points generally fell close to the normality line (see Figure 6). Thus, this plot provided support that there was no substantial deviation from the normality assumption.

Figure 5

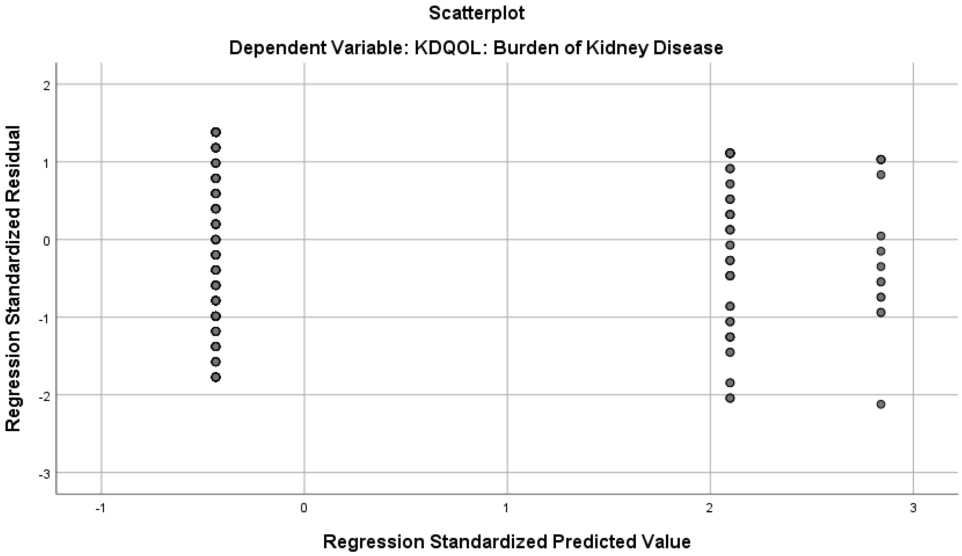
Assessment of the Normality Assumption for the Regression of HRQOL on Type of Dialysis



The second assumption of this regression model to check was the homoscedasticity of the residuals. As seen in Figure 7, the dispersion of the residuals did not seem to greatly differ across the predicted values. I concluded from this plot that there was no substantial deviation from the homoscedasticity of the residuals assumption.

Figure 6

Assessment of the Homoscedasticity Assumption for the Regression of HRQOL on Type of Dialysis



In addition, I assessed the lack of multicollinearity assumption using VIF values for the predictor variable included in the model. As displayed in Table 7, all VIF values for the predictor variables were below 10, suggesting that there were no deviations from this assumption.

Table 7

Assessment of Multicollinearity Among the Dummy Variables Representing the Hemodialysis and Peritoneal Dialysis Groups

Variable	Tolerance	VIF
ESRD1	.235	4.251
ESRD2	.235	4.251

As discussed above, there were no substantial departures from the assumptions underlying the regression model. Therefore, I performed this model to assess the relationship between type of dialysis and HRQOL. The results showed that this model did not provide a significant fit to the data ($F(2,507) = 2.881$, $p = .057$, $R^2 = .011$). An assessment of the parameter estimates for this model shows that none of the predictor variables contributed significantly to the model (see Table 8).

Table 8

Parameter Estimates for the Regression of HRQOL on Type of Dialysis

Variable	Unstandardized coefficients		Standardized coefficients	*t*	*p* value
	B	Std. Error	Beta		
ESRD1	-11.059	7.843	-.128	-1.410	.159
ESRD2	-2.507	8.626	-.026	-.291	.771

Note. ESRD1and ESRD2 are dummy variables representing the hemodialysis and peritoneal dialysis groups, respectively.

Second Regression Model

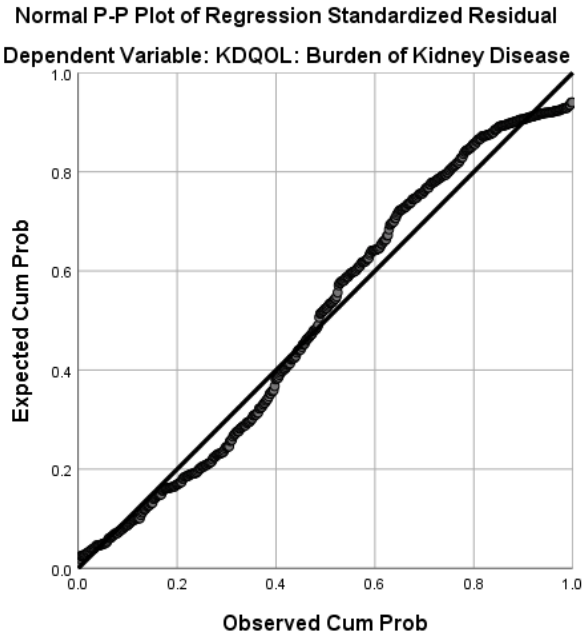
In the second regression model, the dependent variable was HRQOL and the predictor variables were the demographic variables, the dummy variables for the hemodialysis and peritoneal dialysis groups, and the interactions between these variables. Before reporting the results from this analysis, a discussion of tests of assumptions underlying this parametric procedure are detailed.

The first assumption to assess was the normality of the residuals from this regression model. As can be seen from the normal P-P plot of the residuals depicted in Figure 8, the data points do not seem to fall greatly far away from the normality line.

Thus, this plot did not indicate a substantial deviation from the normality assumption of the residuals.

Figure 7

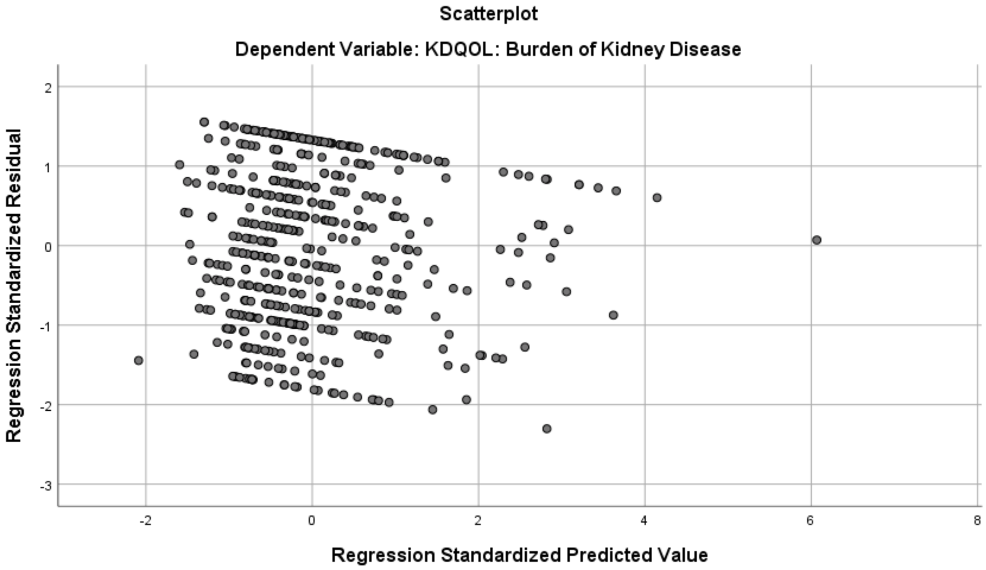
Assessment of the Normality Assumption for the Regression of HRQOL on Type of Dialysis and Demographic Variables and the Interactions Between These Variables



The second assumption to evaluate was the homoscedasticity of residuals from the regression model. I assessed this assumption through a visual examination of the scatter plot of the standardized residuals against standardized predicted values from the regression equation (see Figure 9). This plot shows that there was a slight downward pattern in the observation. This pattern, however, did not seem to be substantial to indicate great deviation from the homoscedasticity assumption.

Figure 8

Assessment of the Homoscedasticity Assumption for the Regression of HRQOL on Type of Dialysis and Demographic Variables and the Interactions Between These Variables



Furthermore, I assessed the absence of multicollinearity assumption using VIF values for each predictor variable included in the model. As shown in Table 9, all VIF values for the predictor variables were below 10, providing support that this assumption was met.

Table 9

Assessment of Multicollinearity Among the Dummy Variables Representing Type of Dialysis, Length of Time on Dialysis, and the Demographic Variables

Variable	Tolerance	VIF
ESRD1	.226	4.433
ESRD2	.232	4.308
Age	.894	1.119
Family history	.989	1.011
Length of time on dialysis	.965	1.036
Gender	.994	1.006
Employment status	.881	1.135

As discussed above, no substantial departures from the assumptions underlying the regression model were detected. Therefore, this regression equation was conducted to assess the relationship between the predictor variables of demographic variables, type of dialysis, and the interactions between these variables and the outcome variable of HRQOL.

The results was revealed that this model did not provide a significant fit to the data ($F(17,492) = .915$, $p = .556$, $R^2 = .031$). Furthermore, after an assessment of the parameter estimates for this regression model, I found that none of the interaction terms between the demographic variables and the dummy variables for the hemodialysis and peritoneal dialysis groups were statistically significant. It is possible to conclude from these results that the demographic variables did not moderate the relationship between type of dialysis and HRQOL. Hence, these results did not provide evidence to reject the null hypothesis that the variables of length of time on dialysis, types of dialysis, family history, and occupation do not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

Table 10

Parameter Estimates for the Regression of HRQOL on Type of Dialysis and Demographic Variables and the Interactions Between These Variables

Variable	Unstandardized coefficients		Standardized coefficients	*t*	*p* value
	B	Std. Error	Beta		
ESRD1	2.150	93.868	.025	.023	.982
ESRD2	14.756	97.808	.156	.151	.880
Age	.830	1.289	.260	.644	.520
Family history	15.849	24.514	.217	.647	.518
Length of time on dialysis	-3.693	6.625	-.197	-.557	.577
Gender	-3.945	15.579	-.062	-.253	.800
Employed	8.240	32.675	.122	.252	.801
ESRD1*Age	-.657	1.300	-.506	-.505	.614
ESRD1*Family history	-15.336	24.767	-.199	-.619	.536
ESRD1* Length of time on dialysis	2.921	6.686	.192	.437	.662
ESRD1*Gender	6.645	15.883	.149	.418	.676
ESRD1*Employed	-1.835	32.864	-.025	-.056	.956
ESRD2*Age	-.901	1.346	-.557	-.670	.503
ESRD2*Family history	-29.411	26.157	-.166	-1.124	.261
ESRD2*Time	6.256	7.130	.292	.878	.381
ESRD2*Gender	7.810	17.540	.127	.445	.656
ESRD2*Employed	-5.967	33.673	-.049	-.177	.859

Note. ESRD1and ESRD2 are dummy variables representing the hemodialysis and peritoneal dialysis groups, respectively.

Summary

Through this quantitative study, I aimed to examine the effects and different types of hemodialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. In conducting this study, I made use of the secondary data from the CRIC study. Data from a total of 510 patients were collected from the CRIC study for the data analysis. Three research questions and their corresponding null and alternative hypotheses guided this study. Multiple linear regression analysis was conducted to evaluate the research hypotheses. Based on these results, none of the null hypotheses for the three research questions were rejected. The results from the regression of HRQOL on the demographic variables indicated that this model did not provide a significant fit to the data. Furthermore, I also found that type of dialysis did not significantly predict HRQOL. In addition, the results from the regression of HRQOL on the demographic variables, type of dialysis, and the interaction between these variables revealed that this model was not statistically significant, and none of the predictor variables included in the model were statistically significantly associated with the outcome variable.

Chapter 5: Discussion, Conclusions, and Recommendations

The purpose of the current quantitative cross-sectional study was to examine the effects of length of time for treatment (how long patients have been receiving treatment) and type of dialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. I used data from the CRIC study of renal disease, which collects and reports key outcome data for renal disease patients such as kidney disease-related HRQOL data. The following research questions and their corresponding null and alternative hypotheses guided this study:

RQ1: Is there a significant relationship between demographic variables (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African Americans ESRD patients?

> $H_0$1: There is no significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.
>
> H_a1: There is a statistically significant relationship between demographic predictors (age, gender, length of time for treatment, family history, and occupation) and HRQOL in African American ESRD patients.

RQ2: Is there a significant relationship between type of dialysis and HRQOL in African American ESRD patients?

> $H_0$2: There is no significant relationship between type of dialysis and HRQOL in African American ESRD patients.

H_a2: There is a statistically significant relationship between type of dialysis and HRQOL in African American ESRD patients.

RQ3: Do the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation moderate the relationships between dialysis and health-related kidney disease and HRQOL in African American ESRD patients?

H_03: Variables of length of time on dialysis, types of dialysis, family history, and occupation do not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

H_a3: Variables of length of time on dialysis, types of dialysis, family history, and occupation moderate the relationships between type of dialysis and HRQOL in African American ESRD patients.

This study was conducted to generate new insights that could be helpful in the mobilization and management of families and others who have been impacted by ESRD to improve HRQOL outcomes. Multiple linear regression analysis was conducted to evaluate the research hypotheses. Based on these results, none of the null hypotheses for the three research questions were rejected. The results from the regression of HRQOL on the demographic variables indicated that this model did not provide a significant fit to the data. Further analysis revealed that employment status was the only demographic variable in the model that predicted HRQOL in African American ESRD patients. The findings also indicated that type of dialysis (i.e., length of time) did not significantly predict HRQOL. In addition, the results from the regression of HRQOL on the demographic variables, type of dialysis, and the interaction between these variables revealed that this model was not statistically significant, and none of the predictor variables included in the model significantly contributed to the variations in the outcome variable. In this chapter, I provide an in-depth discussion of the results. The discussion includes the following sections: (a) interpretation of the findings, (b) limitations of the study, (c) recommendations, and (d) implications. The chapter ends with a conclusion that summarizes key insights about the research findings.

Interpretation of the Findings

In this section, the findings are interpreted by comparing the results to the current literature, indicating whether the findings confirm, disconfirm, or extend knowledge in the discipline. The findings are also interpreted by the theoretical framework, which was the ecological model. This discussion is presented based on the three research findings.

Finding 1

The first finding of the study was that demographic predictors such as age, gender, length of time for treatment, and family history, and HRQOL in African American ESRD patients are not statistically related to each other. This was suggestive of demographic factors not having any relationship to a particular HRQOL among African American ESRD patients. Any HRQOL outcome that African American ESRD patients experience cannot be attributed or linked to these demographic factors. Overall, the model was not a good predictor of HRQOL among African American ESRD patients.

The lack of general significance of demographic factors such as age and gender in this study is not consistent with previous research. For instance, women have been found to have a higher level of anxiety and a lower level of positive attitudes compared to men

(Gerogianni et al., 2014). CKD has also been found to be more prevalent among women (16%) compared to men (13%; CDC, 2017a). In terms of age, one study showed that older people may experience more challenges dealing with treatment for renal diseases (Sahaf et al., 2017). These differences suggest possible connection with HRQOL (Hays et al., 1007). None of these studies coincide with the current findings, which could be explained by the possibility that among African Americans these demographic factors may not be predictive.

Further analysis of the individual variables in the model revealed that employment status was the only demographic variable that predicted HRQOL in African American ESRD patients. The literature on the role of employment or occupation in the HRQOL of people suggested that being unemployed can negatively affect HRQOL (BayinDonar & Top., 2020; Norton & Eggers, 2020). Poverty has been associated with poor health outcomes because of poor access to health care resources and poor health-related literacy (Norton & Eggers, 2020). Therefore, this particular finding supports the literature regarding the role of employment status in HRQOL of individuals.

When interpreted within the context of the ecological model of Hays et al. (1997), the current findings suggest that the social ecology of African American ESRD patients is complex and nuanced. Other than employment status, most demographic factors may not be a sufficient environmental consideration that affects the HRQOL of African American ESRD patients. This is generally consistent with previous findings identifying employment as a predive social ecological factor that affects the health outcomes of patients (Chen et al., 2018). Employment status can be combined with other social ecology factors that were not identified in this study to create a more robust model in predicting HRQOL among African American ESRD patients.

Finding 2

The second finding indicated there is no significant relationship between length of time for treatment and HRQOL in African American ESRD patients. This means that exposure to a particular type of dialysis does not relate to a particular HRQOL among African American ESRD patients. Any HRQOL outcome that African American ESRD patients experience cannot be attributed to a particular type of dialysis.

The literature on the importance of treatment among ESRD patients suggested that African Americans may prefer one treatment from another based on what is comfortable and less challenging to adhere to (Crenesse-Cozien et al., 2019; Nicholas et al., 2013). More specifically, length of time in treatment for dialysis has been generally associated with poorer health outcomes (de Brito et al., 2019). This inconsistency with recent research could be explained by the specificity of the current sample, which focused only on African American ESRD patients. Queeley and Campbell (2018), however, found that the different treatment modalities for ESRD are not different from each other in terms of preference. This appears to be more consistent with the current findings in which length of time of treatment was found not to be statistically significant related to the HRQOL of African American ESRD patients. The current finding suggests that the length of treatment may not play an integral role in HRQOL of African Americans ESRD patients.

When interpreted within the context of the ecological model (see Hays et al., 1997), the current findings suggest that length of treatment is not a predictor of the HRQOL of African American ESRD patients. Social ecology recognizes the complexity of systems in influencing chronic illness (Nagel et al., 2022). Given this complexity, length of treatment alone could not account for the differences in the HRQOL of African American ESRD patients.

Finding 3

The third finding was that length of time on dialysis, types of dialysis, family history, and occupation did not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients. This finding was expected given that neither of the first two hypotheses were supported by the data. This means that no interaction effect exists between length of time on dialysis, types of dialysis, family history, and occupation, and between type of dialysis and HRQOL in African American ESRD patients.

The literature on the different moderators between the relationship of dialysis and HRQOL has been confined to nondemographic factors such as social support, resilience, or intrinsic religiosity (Cho & Lee, 2019; Reyes et al., 2021; Zaman et al., 2022). Current findings suggest that demographic factors do not moderate the relationship between dialysis treatment and the HRQOL of African American ESRD patients.

When interpreted within the context of the Hays et al. (1997) ecological model, this finding suggests that length of time on dialysis, types of dialysis, family history, and occupation are factors within African American ESRD patients’ environment that do not play a role in explaining health care outcomes. The ecological model can be used to frame how an individual's social ecology can affect their reaction to a disease (ACHA, 2018). This assumption appears not to be supported in the current study based on the findings.

Limitations of the Study

Based on the findings that were reported and the choices made regarding the design of the study, several limitations were identified. These limitations have implications to the validity and reliability of the study. First, the framework that was selected for the study can be considered a general model about the effects of environmental factors on the functioning of individuals. Even though social ecology recognizes the complexity of systems in influencing chronic illness, the model provides limited information about the elements of these complex systems (Nagel et al., 2022). More specifically, the model has not identified the variables that can affect the health of individuals. As a result, the model may not have been an effective basis for justifying and supporting the hypotheses of the study, which could explain why almost none of the hypotheses were supported by the data. Second, the study was based on self-reported data. Because the study relied on self-reported data, the information may not have been fully accurate and may have incorporated some elements of the participants' biases. However, HRQOL is an inherently subjective topic. Therefore, this limitation was not expected to significantly interfere with the quality of the data.

Third, the number of demographic variables in the predictor model was not exhaustive. Although the demographic factors chosen were key and were based on the literature, it is possible that other demographic factors that would significantly impact the model were excluded. Including a comprehensive set of demographics, however, would not have been appropriate given the scope of the study. Finally, a potential limitation of this study was that causal conclusions could not be made about the effect of employment status on the HRQOL of African American ESRD patients. The data that were collected and the design that was adopted did not allow for a cause-and-effect relationship to be determined. Instead, the study only provided evidence about the predictive relationship of employment status on the HRQOL of African American ESRD patients.

Recommendations

Based on the strengths and limitations of the current study as well as the literature that was reviewed on HRQOL and African American ESRD patients, I developed several recommendations for future research. These recommendations may further expand the literature on the HRQOL of African American ESRD patients. My first recommendation is to further delve into the role of employment/occupation status in the HRQOL of African American ESRD patients. More specifically, employment can be expanded beyond status to examine different types of employment such as blue-collar and white-collar jobs. This recommendation was informed by the finding that only employment status was found to significantly predict the HRQOL of African American ESRD patients. Further research could extend this finding to provide a deeper understanding of the role of employment in the HRQOL of African American ESRD patients.

Second, more research is needed to examine the role of treatment in the HRQOL of African American ESRD patients. This recommendation was informed by the research finding indicating the length of treatment time has no statistically significant relationship with the HRQOL of African American ESRD patients. Specific areas of research regarding treatment that could be further examined include accessibility, insurance status, and perceived effectiveness. Pursuing these lines of research could be beneficial in terms of discovering other aspects of treatment and their potential relationship with the HRQOL of African American ESRD patients.

Third, moderating variables that affect the relationship between employment status and the HRQOL of African American ESRD patients need to be further examined. This recommendation was informed by the research finding indicating that length of time on dialysis, types of dialysis, family history, and occupation do not moderate the relationships between type of dialysis and HRQOL in African American ESRD patients. Pursuing this line of research could be beneficial in terms of having a better understanding of the possible interaction effects that employment status may have that could affect the HRQOL of African American ESRD patients.

Implications

The implication of the research findings to positive social change at the individual level is that the length of dialysis treatment should not be used to predict the HRQOL of African American ESRD patients. When considering whether HRQOL could be affected by demographic variables and length of treatment, patients’ employment status appears to be the most relevant and significant. At the family level, the positive social change that could be facilitated by this study is the focus on empowering African American ESRD patients by helping them with their employment. At the societal/policy level, more efforts are needed to ensure that employment will not interfere with the HRQOL of African American ESRD patients.

The methodological implication of the study is that more efforts are needed in order to determine plausible variables that can predict HRQOL among African American ESRD patients. The current variables that were part of the model included age, gender, length of time for treatment, family history, and employment status. Given that employment status was the only demographic variable that was statistically significant, more relevant variables need to be examined and assembled to create a stronger predictor model. A qualitative research study about the employment status of African American ESRD patients could also provide a more detailed description of its influence on their HRQOL.

The theoretical implication of this research is that the Hays et al. (1997) ecological model may be too general to capture the experiences of African American ESRD patients, particularly in terms of their HRQOL. Only employment status was able to show significant association with the HRQOL of African American ESRD patients. Employment has been previously found to be one of the challenges that ESRD patients experience during their treatment (Hallab & Wish, 2018).

Among African American ESRD patients, maintaining employment can be challenging especially among older adults (Robinson et al., 2019). Employment can also be particularly challenging among African Americans who are just beginning their renal disease treatment (Erickson et al., 2018). Given that this demographic variable appears to be specifically significant to the HRQOL of African American ESRD patients, the role of employment in the social ecological environment of African American ESRD patients needs further emphasis.

Based on the research findings of this study, I have created several recommendations for practice. First, medical practitioners should not make decisions regarding the HRQOL of African American ESRD patients based on their gender, age, or length of treatment. It is important, however, to note previous findings that age and gender could play a role in the overall health outcomes of people, including ESRD patients (Gerogianni et al., 2014; Sahaf et al., 2017). Second, given that only employment status was found to significantly predict the HRQOL of African American ESRD patients, health care professionals should be particularly mindful of those who are unemployed and may be needing more assistance in order to improve their overall HRQOL.

Conclusion

In this study, I examined the effects and different types of hemodialysis on patient HRQOL outcomes above and beyond demographic predictors of HRQOL in African American ESRD patients. The results of the study indicated that demographic factors such as age, gender, length of time for treatment, and family history have no significant relationship with the HRQOL of African American ESRD patients. Only employment status was found to be significantly associated with the HRQOL of African American ESRD patients. None of the demographic variables moderated the relationship between length of treatment and the HRQOL of African American ESRD patients.

The ecological model of Hays et al. (1997) appears to be not a good fit in conceptualizing the HRQOL among African American ESRD patients, which could explain why almost none of the hypotheses were supported by the data. Among the demographic variables that were part of the model, only employment status was found to be significantly associated with the HRQOL of African American ESRD patients. Therefore, the ecology model could still be useful when framing the role of employment in the health outcomes of individuals.

Even though many of the hypotheses of the study were not supported by the data, the findings that were generated from this study could still provide beneficial insights to both practitioners and scholars. Health care practitioners may use the findings to inform their decisions when considering the HRQOL of African American ESRD patients. Future researchers should further expand the literature on the HRQOL of African American ESRD patients by further examining the role of employment and the possible moderators or mediators that can affect this relationship.

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Appendix A: CRIC Data Repository

DocuSign Envelope ID: D0FAF815-2FA5-4BAD-A0C9-D6C9E96D6BD9

NIDDK Central Repository

Data Use Agreement

Contact: NIDDK-CRsupport@niddk.nih.gov

Requestor: Gudeta Fufaa

E-mail Address: gudeta.fufaa@mail.waldenu.edu

Requesting Institution: WALDEN UNIVERSITY

Requested Data: CRIC

If Requestor is funded by NIH for this Research Project, the grant number is:

If Research Project is associated with X01 access mechanism, the number is: ___________

Introduction

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) has supported collection of data from participants in numerous studies. The data are held by the NIDDK Central Repository (hereinafter referred to as the "Repository"). In order to maximize the benefits of these resources collected with public funds and maximize their research value, it is important that these resources be made available, with appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Transfer of resources to and from the Repository is governed by the NIH and NIDDK data sharing policies.

The Repository does not receive personally identifiable information or codes linking such information to Data.

In the event that investigators from more than one institution will be collaborating on a project using the Data transferred under this Certification, an investigator from each institution is required to complete a separate Data Use Agreement (DUA).

It is the intent of the NIDDK that Requestors of Repository held resources recognize the limitations imposed by the original informed consent agreements of contributing studies.

NIDDK has established policies and processes to make these Repository held resources available through appropriate terms and conditions to qualified requestors. The Repository requires the Requestor to read, understand, and sign this DUA and their institution to acknowledge and agree to abide by the terms and conditions of this DUA as a condition of access. A Requester who is granted access to Data must adhere to the specifications of this DUA as executed in its final form. Failure to do so shall result in denial of further access by the Requestor's Institution to resources available through the Repository.

Terms of Access

1. **Definitions:**

   Contributing Study Investigators: Research investigators who provided the phenotypic data and specimens to the NIDDK Central Database Repository.

   Materials: Include but are not limited to data, specimens, products, analytes, metadata, documentation, code, analytic tools, algorithms, workflows, results, summaries, or analyses provided by the NIDDK or generated by the Research Project.

   Requestor: Research investigator(s) who submitted a request for access to Repository held resources, have been approved by the appropriate NIH oversight committee, and have a fully-executed agreement for the requested resources.

   Requesting Institution: An institution, organization, or corporation who is the employer of the Requestor. The Requesting Institution assumes responsibility for the Requestor's compliance with the terms and conditions of this agreement, and is responsible for complying with all applicable federal, state, and local laws and regulations for research participant protections.

   Repository Data (referred to as "Data"): The relevant data from a specific project(s). Access to these resources may be available from repositories other than the Repository (for example, dbGaP).

   Research Project: A summary of the proposed research that includes the project title, the Requestor's name and Requesting Institution's name, the names of any Requestor's collaborators and their institutions, a one to two paragraph Research Use Statement, a description of the research objectives and design, and an analysis plan. (Appendix A)

   Research Use Statement: Statement of proposed research to be conducted which may be made publicly available. The Research Use Statement is submitted by the Requestor as a part of the Research Project request for access to data.

   Study Participant: An individual who participated in the clinical research protocol as either a healthy human or a patient in a specific area of study.

2. **Research Project: Use of Data**

   a) The Requestor and Requesting Institution agree that the Repository Data shall be used only for research purposes by the Requestor in his/her laboratory under suitable conditions, as outlined in Article 5 for the research described with specificity in the Research Project

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Name of Principal Investigator: Gudeta Fufaa		
Title of Research Plan: The Impact of Dialysis on Quality of Life for African Americans: A Cohort Study		
Version 3.0		

attached as Appendix A. The Data shall not be used in any research that is not disclosed and approved as part of the Research Project. The Requestor and Requesting Institution agree to retain control over the Data and further agree not to transfer the Data to any third parties not under the direct supervision of the Requestor.

b) New uses of the Data outside those described in the current Research Project require submission of a new DUA request. Modification to an approved Research Project requires submission to the appropriate NIH oversight committee of amendment to the Research Project. Appointment of another or different Requestor requires completion of an approved new Research Project and requires submission of a request to amend this DUA.

c) The Requestor and Requesting Institution acknowledge that other researchers have access to Repository resources, and that duplication of research is a distinct possibility.

d) The Requestor and Requesting Institution further acknowledge that they are responsible for ensuring that all their uses of the Data are consistent with federal (including 45 CFR Part 46), state, and local laws and any applicable institutional policies and that limitations in the informed consents delineated by the Repository will be complied with.

e) The Requestor and Requesting Institution shall use the Data only in accordance with the individual studies' IRB approved informed consents and Approved Research Plan in Appendix A.

It is anticipated that, at least in some cases, the Data at the Repository will be updated with additional information and will be so identified by an appropriate version number. All statements herein will apply to current and all future versions of the Data, and instructions provided by the Repository.

3. **Human Subject Protections: Compliance with Requirements**

a) The Requestor and Requesting Institution acknowledge that the conditions for use of these Data may require the review and subsequent approval or a determination of "Not Human Subjects Research" by the Requestor's and Requesting Institution's Institutional Review Board (IRB) or other approval body operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. The Requestor and Requesting Institution agree to comply fully with all such conditions as instructed by the Repository.

b) In order to respect the privacy of the Study Participants, the Requestor and Requesting Institution agree not to contact or make any effort to identify individuals, families, communities, tribes or populations which are or may be the source of the Data. Should the Requestor inadvertently receive identifiable information or otherwise identify a participant, Requestor shall promptly notify the Repository and follow the Repository's reasonable written instructions, which may include return or destruction of the identifiable information. (This condition is not applicable to Contributing Study Investigators who provided the data used to generate the Data at and from the Repository, if they have appropriate IRB approval to retain the Study Participant identities or re-contact Study Participants.)

c) The Requestor and Requesting Institution shall not combine or link the resources provided with any other collection or source of information that may contain information specific to individuals, unless specifically indicated and approved in the proposed research (Appendix A).

d) The Requestor and Requesting Institution shall promptly report to the Repository any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.

e) The Requestor and Requesting Institution agree to report to NIDDK in advance of implementation of any proposed modifications in the Research Project and any unanticipated issues involving risk to Study Participants or others, at the following e-mail address: NIDDK-CRsupport@niddk.nih.gov. The Requestor and Requesting Institution agree to this provision in addition to any of Requestor's and Requesting Institution's institutional policies or any federal, state, and local laws and regulations which provide additional protections for human subjects. Such agreement to report to the NIDDK does not supersede Requestor and Requesting Institution's responsibilities to comply with the applicable laws, regulations and policies related to protections for human subjects.

4. **Public Posting of Approved User's Research Use**

The Requestor and Requesting Institution agree that if the attached Research Project is approved, information about the proposed research use may be posted on a public website that describes the Data requested from the Repository. The information may include the Requestor's and Requesting Institution's names, project title, and Research Use Statement. Prior to NIDDK Repository approval of a Research Project, the contents of all requests for access are consider confidential and are not published or shared with any third party.

5. **Data Security/Non-transferability**

The Requestor and Requesting Institution agree to store the Data in a secure manner and environment with adequate security controls, and to maintain appropriate control over the Data. Best practices for computer security and data control are available online at https://www.niddkrepository.org/static/bestpractices.pdf. The Requestor and Requesting Institution agree to establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the Data and to prevent unauthorized access to it. The Requestor and Requesting Institution agree to ensure that the Data is protected by reasonable safeguards against loss, unauthorized access, use, modification, or disclosure, and any misuse, and agree to notify the Repository at the following e-mail address: NIDDK-CRsupport@niddk.nih.gov as soon as a security breach is discovered.

a) Data from the Repository represent a significant investment on the part of NIDDK. The Requestor and Requesting Institution therefore agree to retain control over the Data, and further agree not to transfer or distribute the Data in any form to any third party or entity or individual not under the Requestor's direct supervision. The Data may be shared with Requestor's collaborating investigators listed in the attached Research Project who are also approved users who have a fully-executed DUA for the purposes of this Research Project. The

Requestor and Requesting Institution acknowledge responsibility for ensuring appropriate use of these Data in accordance with the terms of this Agreement.

b) The Requester agrees to retain control over the Data and further agrees not to distribute, sell, or license individual-level data in any form. No copies or derivatives shall be made of the Data except as necessary for the purposes authorized in this DUA. The Requestor and Requesting Institution acknowledge that if any copies of the Data are generated, the terms and conditions of this DUA apply to such copies. The Requestor shall keep an accurate written account of all such copies and derivative files, which will be furnished to the NIDDK upon request. Upon completion of the Research Project or the termination of this DUA, the Requestor shall destroy all files received or return any copies and derivatives to the Repository, if requested.

c) Subject to Article 7, the Data transferred under this DUA will be safely maintained by the Requestor for no longer than five (5) years from the date of receipt. No later than the end of the five (5) year period the Requestor and Requesting Institution shall send the Repository contact person an email at NIDDK-CRsupport@niddk.nih.gov certifying that all data, copies, and derivatives have been returned and deleted.

d) The Requestor agrees that if he/she changes institutions, a new DUA must be executed in which the new Requesting Institution agrees to NIDDK principles, policies, procedures and the terms of access per this DUA in order for the Requestor to continue the Research Project at the new institution.

6. **Intellectual Property**

By requesting access to Data from the Repository, the Requestor and Requesting Institution acknowledge the guidelines outlined below:

a) Achieving maximum public benefit is the ultimate goal of Data distribution through the Repository mechanisms and it should be considered pre-competitive.

b) The Repository does not explicitly prohibit the patenting and licensing of results generated by the Research Project. In view of the current law (Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. (2013), naturally occurring DNA sequences and their use as a biomarker of disease or biological function are not patentable in the United States. Therefore, basic sequence data and certain related information (e.g., genotypes, haplotypes, p-values, allele frequencies), and all conclusions derived directly from them are pre-competitive and should remain freely available, without any licensing requirement in accordance with the NIH sharing policies.

c) New Materials generated from use of NIDDK Central Repository resources must remain freely available and adhere to NIH sharing policies.

7. **Data Access Renewal Period**

Initial access is granted for two (2) years from the date of approval of the DUA. Renewal of access may be granted, if requested of the Repository, by submitting a letter through the original online Repository request. The letter should be signed by the Requestor and an authorized representative of their institution in the same manner as this Data Use Agreement. An example template is located at https://repository.niddk.nih.gov/static/NIDDKCR_Static_Extension_Template.pdf. Questions regarding this process may be directed to NIDDK-CRsupport@niddk.nih.gov

8. **Research Progress Reporting and Dissemination of Research Results**

Prompt publication or any public disclosure of the results of the Research Project is encouraged. The Requestors are strongly encouraged to publish their results in peer-reviewed journals.

a) The Requestor and Requesting Institution agree to submit, one (1) year from the date of the DUA approval or renewal of access being granted, a progress report to the Repository on the Research Project. The progress report should include all annotated data associated with any publications submitted for publication, any unpublished or published analyses and summaries, and all published references conducted with the Data. The aforementioned Materials, documents, and progress report may then be included in the Repository at the discretion of NIDDK.

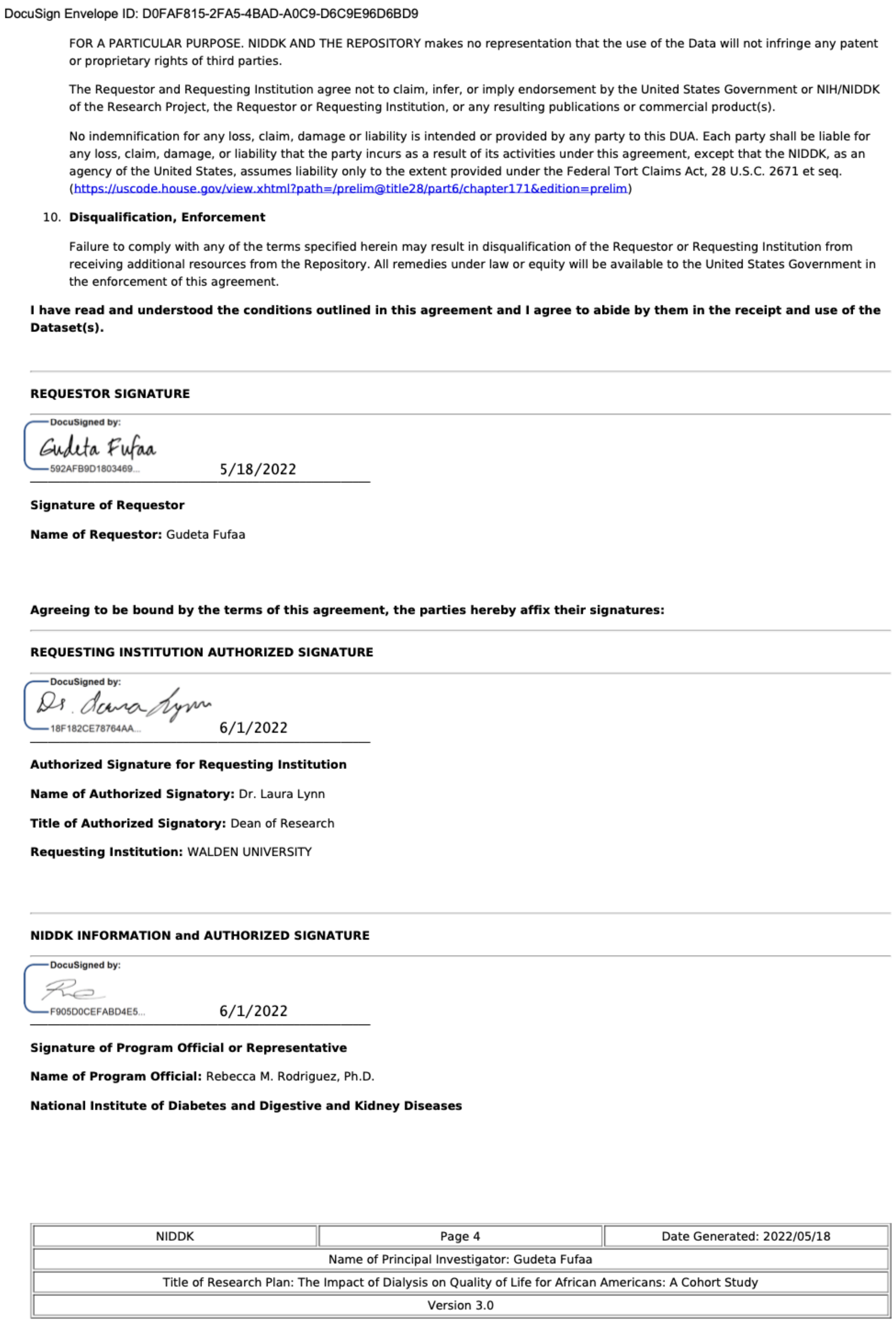
b) Before the Requestor or the Requesting Institution submits any publication, abstract, or other Materials for publication or intends to publicly disclose any information about the Data, they will send a copy of the Materials to the Repository (NIDDK-CRsupport@niddk.nih.gov) at least thirty (30) days in advance of submitting for publication or otherwise publicly disclosing the Materials, in order for the Repository to review it for confidentiality requirements and compliance with research objectives as described in Appendix A.

c) The Requestor and Requesting Institution agree not to publish or otherwise disclose the Data to any person or organization unless the Data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten (10) individuals or fewer than five (5) providers or facilities. The Requestor and Requesting Institution shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred.

d) The Requestor and Requesting Institution agree to acknowledge the contribution of the Contributing Study Investigators and the Repository in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of the Data. A sample statement to be used in acknowledgements can be found at: https://repository.niddk.nih.gov/pages/acknowledgements.

9. **Non-Endorsement, Non-Indemnification**

The Requestor and Requesting Institution acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of the Data in the Repository, the Data are provided as a service to the research community. The Data are supplied to Requestor and Requesting Institution with NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS



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FOR A PARTICULAR PURPOSE. NIDDK AND THE REPOSITORY makes no representation that the use of the Data will not infringe any patent or proprietary rights of third parties.

The Requestor and Requesting Institution agree not to claim, infer, or imply endorsement by the United States Government or NIH/NIDDK of the Research Project, the Requestor or Requesting Institution, or any resulting publications or commercial product(s).

No indemnification for any loss, claim, damage or liability is intended or provided by any party to this DUA. Each party shall be liable for any loss, claim, damage, or liability that the party incurs as a result of its activities under this agreement, except that the NIDDK, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq. (https://uscode.house.gov/view.xhtml?path=/prelim@title28/part6/chapter171&edition=prelim)

10. **Disqualification, Enforcement**

Failure to comply with any of the terms specified herein may result in disqualification of the Requestor or Requesting Institution from receiving additional resources from the Repository. All remedies under law or equity will be available to the United States Government in the enforcement of this agreement.

I have read and understood the conditions outlined in this agreement and I agree to abide by them in the receipt and use of the Dataset(s).

REQUESTOR SIGNATURE

DocuSigned by:
Gudeta Fufaa
592AFB9D1803469... 5/18/2022

Signature of Requestor

Name of Requestor: Gudeta Fufaa

Agreeing to be bound by the terms of this agreement, the parties hereby affix their signatures:

REQUESTING INSTITUTION AUTHORIZED SIGNATURE

DocuSigned by:
Dr. Laura Lynn
18F182CE78764AA... 6/1/2022

Authorized Signature for Requesting Institution

Name of Authorized Signatory: Dr. Laura Lynn

Title of Authorized Signatory: Dean of Research

Requesting Institution: WALDEN UNIVERSITY

NIDDK INFORMATION and AUTHORIZED SIGNATURE

DocuSigned by:
F905D0CEFABD4E5... 6/1/2022

Signature of Program Official or Representative

Name of Program Official: Rebecca M. Rodriguez, Ph.D.

National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK	Page 4	Date Generated: 2022/05/18
Name of Principal Investigator: Gudeta Fufaa		
Title of Research Plan: The Impact of Dialysis on Quality of Life for African Americans: A Cohort Study		
Version 3.0		

DocuSigned by:
Agnes Eley
EDCBCCBBD9D4470... 6/1/2022

NIDDK Authorized Signature or Representative

Name of Authorized Official: Agnes Eley on behalf of Charles Niebylski Ph.D., J.D.

Title of Authorized Official: Director, Technology Advancement Office

Address: 31 Center Drive, Bethesda, MD 20892

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) (US Code Civil Liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment) (US Code Criminal Liablity).

Appendix A

Research Project

Project Title: The Impact of Dialysis on Quality of Life for African Americans: A Cohort Study

Requestor's Name: Gudeta Fufaa

Requesting Institution's Name: WALDEN UNIVERSITY

Other Users under the PI:
Cynthia Newell
Latoya Benjamin

Names of any independent collaborators and their Institutions:

Description of Research: Several researchers have studied the impact of ESRD on individuals' quality of life (QoL), as well as their social, psychological, and mental functionalities The number of studies that have systematically assessed the impacts of dialysis on QoL among racial and ethnic minority populations are limited. Therefore, there is a need to quantify the impact of dialysis on the QoL of underrepresented populations such as African Americans. The problem is that individuals on dialysis often face difficulties and challenges with regard to the management of their health resulting in low QoL but the full, quantified extent of this QoL toll is not yet fully understood. Further research is needed to quantify the burdens of CKD with respect to social factors. In addition, studies with larger sample sizes are needed to better understand the effects of dialysis on racial minorities. The only data source is the CRICS dataset. Once retrieved, the data will be stored using encrypted computerized software that is only accessible by PI, the other researcher under the PI and the student researcher. This software will be stored in a safe data structure which is password protected on the student researcher's computer. The data from this study will serve to help quantify the socioemotional burdens of ESRD and dialysis in a way that may help inform future health policy. Through the findings of this study, practitioners and public health policymakers may gain a better understanding of how a person's social ecology combines with causes of ESRD and specific types of treatment to shape patients' QOL. This may in turn contribute to the development of policies or practices to better serve those members of the African American population most affected in terms of QOL.

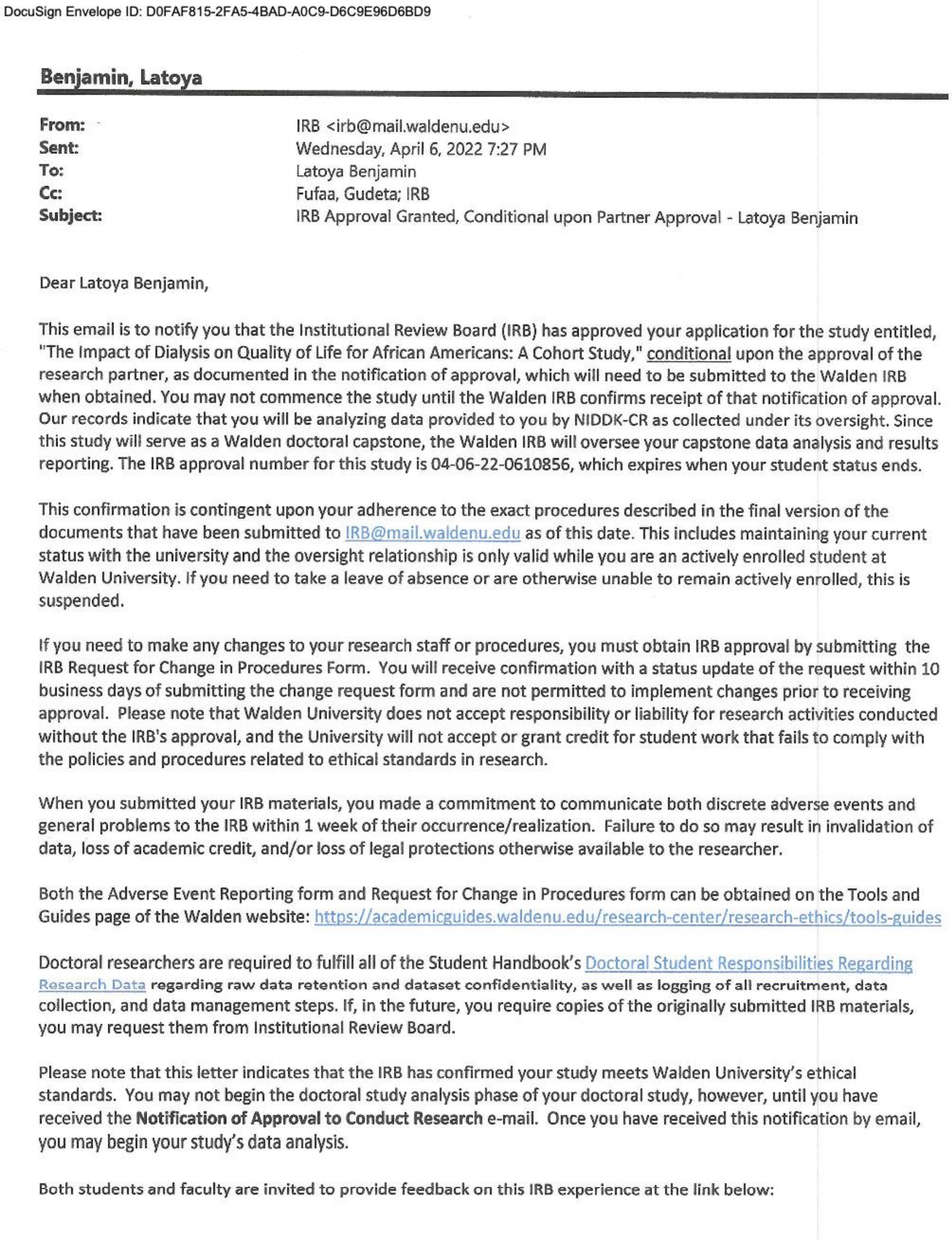
Research objectives and design: The proposed study will be quantitative in nature. Using closed-ended questions, quantitative researchers can gather and analyze data from large sample sizes with relative efficiency.The specific research design for the proposed study will be that of a cohort or historical study dataset containing the relevant data—namely, the CRICS dataset. The following quantitative research questions are proposed in alignment with the purpose of the study. Corresponding null and alternate hypotheses accompany each research question. RQ1: Is there a significant relationship between demographic variables and health-related QOL in African American ESRD patients? H01:There is no significant relationship between demographic predictors (i.e., age, gender, length of time for treatment, family history, and occupation) and health-related QOL in African American ESRD patients. HA1:There is a statistically significant relationship between demographic predictors (i.e., age, gender, length of time for treatment, family history, and occupation) and health-related QOL in African American ESRD patients. RQ2: Is there a significant relationship between the length of time on dialysis and health-related QOL in African American ESRD patients? H02:There is no significant relationship between type of dialysis and health-related QOL in African American ESRD patients. HA2:There is a statistically significant relationship between type of dialysis and health-related QOL in African American ESRD patients. RQ3: Do the variables of length of time for treatment on dialysis, types of dialysis, family history, and occupation, moderate the relationships between dialysis and health-related Kidney Disease and Quality of Life (QoL) in African American ESRD patients? H03:Variables of length of time on dialysis, types of dialysis, family history, and occupation, do not moderate the relationships between type of dialysis and health-related QOL in African American ESRD patients. HA3:Variables of length of time on dialysis,types of dialysis, family history, and occupation, do moderate the relationships between type of dialysis and health-related QoL in African American ESRD patients. The CRICS data offers extensive external validity. The CRICS is a multisite study conducted at a large scale, with a resultingly high sample size. Although this sample still may have incurred self-selection bias, the size and breadth of the sample offers a much greater likelihood of representativeness than a sample collected by a single researcher directly would allow for. Hence, the use of secondary data will greatly enhance the proposed study's external validity.

Analysis Plan: The collected data will be analyzed using descriptive statistics and multiple linear regression analysis. All data analyses will be carried out using SPSS statistical analysis software. The descriptive analysis will be used to characterize the sample and the variables. It will include the calculation of means, medians, ranges, and other statistical properties. Some of the data may also be graphed against demographics to indicate their distribution within the sample. To answer RQ1, an initial multiple linear regression model will be developed. First, the assumptions of multiple regression will be tested. If the assumptions cannot be validated, appropriate transforms will be attempted, and, failing those, nonparametric regression will be used instead. Then, a regression model with the demographic variables of age, gender, length of time for treatment, family history, and occupation as predictors and health-related quality of life will be developed. Provided that the overall multiple R2

of the regression model is significantly different from 0 and at least one predictor has a statistically significant coefficient of regression, the null hypothesis for RQ1 may be rejected. Then, RQ3 will be tested, which will entail adding the factors of demographics and type of dialysis to the model developed in RQ1. As before, the assumptions will be verified and appropriate steps taken if they are not met. Then, it will be determined whether the overall R2 of the new model is significantly different from 0 and significantly greater than the multiple R2 achieved with just the demographics. If the multiple R2 increases, then the null hypothesis RQ3 may be rejected if the coefficient of regression for the type of dialysis is significantly different from 0. In the estimation of the sample size, as per the population and sample size section, the minimum necessary sample is expected to be 200, well exceeded by the 5,112 participants in the dataset.

Please include a one-two (1-2) paragraph Research Use Statement which may be made publicly available.

The purpose of this quantitative, nonexperimental, cohort study is to examine the effects and different types of hemodialysis on patient QoL outcomes above and beyond demographic predictors of QoL in African American ESRD patients. I will use data from the CRIC Study of renal disease, which includes key outcome data for renal disease patients such as kidney disease-related QOL data, which is an 11-dimension construct that is measured using the Kidney Disease Quality of Life (KDQOL)-36 instrument. The results of this study will serve to help quantify the social-emotional burdens of ESRD and dialysis in a way that may help inform future health policy. Through the findings of this study, practitioners and public health policymakers may gain a better understanding of how a person's social ecology combines with causes of ESRD and specific types of treatment to shape patients' QOL. This better understanding, in turn, may contribute to the development of policies or practices to better serve those members of the African American population most affected in terms of QOL. Not all participants in the CRICS are at the ESRD stage and hence on dialysis. As this study is concerned with ESRD and not kidney disease more generally, only those participants with ESRD will be included. Data consisting of participants with less severe chronic kidney disease, will not be included.



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Benjamin, Latoya

From:	IRB <irb@mail.waldenu.edu>
Sent:	Wednesday, April 6, 2022 7:27 PM
To:	Latoya Benjamin
Cc:	Fufaa, Gudeta; IRB
Subject:	IRB Approval Granted, Conditional upon Partner Approval - Latoya Benjamin

Dear Latoya Benjamin,

This email is to notify you that the Institutional Review Board (IRB) has approved your application for the study entitled, "The Impact of Dialysis on Quality of Life for African Americans: A Cohort Study," conditional upon the approval of the research partner, as documented in the notification of approval, which will need to be submitted to the Walden IRB when obtained. You may not commence the study until the Walden IRB confirms receipt of that notification of approval. Our records indicate that you will be analyzing data provided to you by NIDDK-CR as collected under its oversight. Since this study will serve as a Walden doctoral capstone, the Walden IRB will oversee your capstone data analysis and results reporting. The IRB approval number for this study is 04-06-22-0610856, which expires when your student status ends.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the documents that have been submitted to IRB@mail.waldenu.edu as of this date. This includes maintaining your current status with the university and the oversight relationship is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 10 business days of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

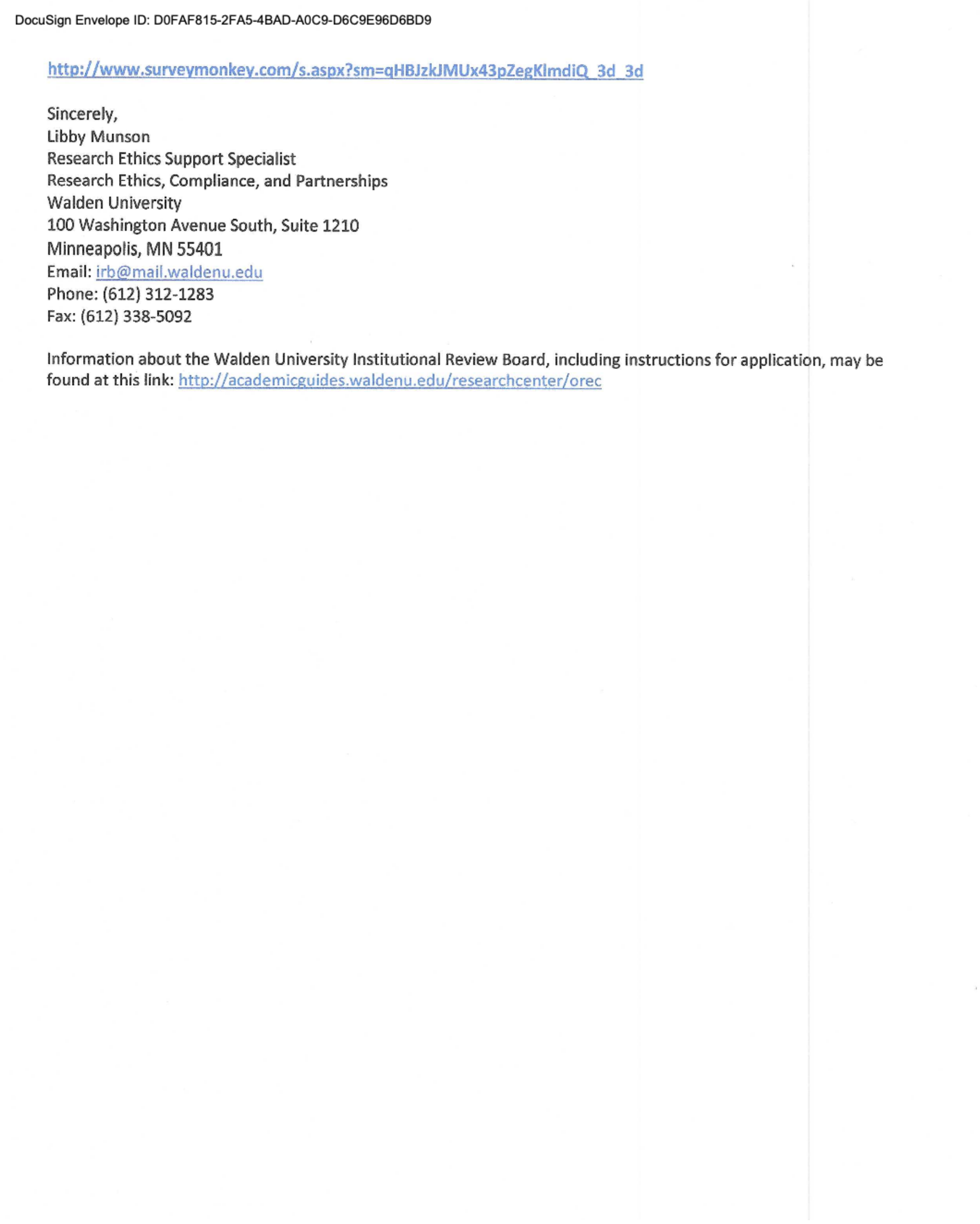
When you submitted your IRB materials, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained on the Tools and Guides page of the Walden website: https://academicguides.waldenu.edu/research-center/research-ethics/tools-guides

Doctoral researchers are required to fulfill all of the Student Handbook's Doctoral Student Responsibilities Regarding Research Data regarding raw data retention and dataset confidentiality, as well as logging of all recruitment, data collection, and data management steps. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Please note that this letter indicates that the IRB has confirmed your study meets Walden University's ethical standards. You may not begin the doctoral study analysis phase of your doctoral study, however, until you have received the **Notification of Approval to Conduct Research** e-mail. Once you have received this notification by email, you may begin your study's data analysis.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:



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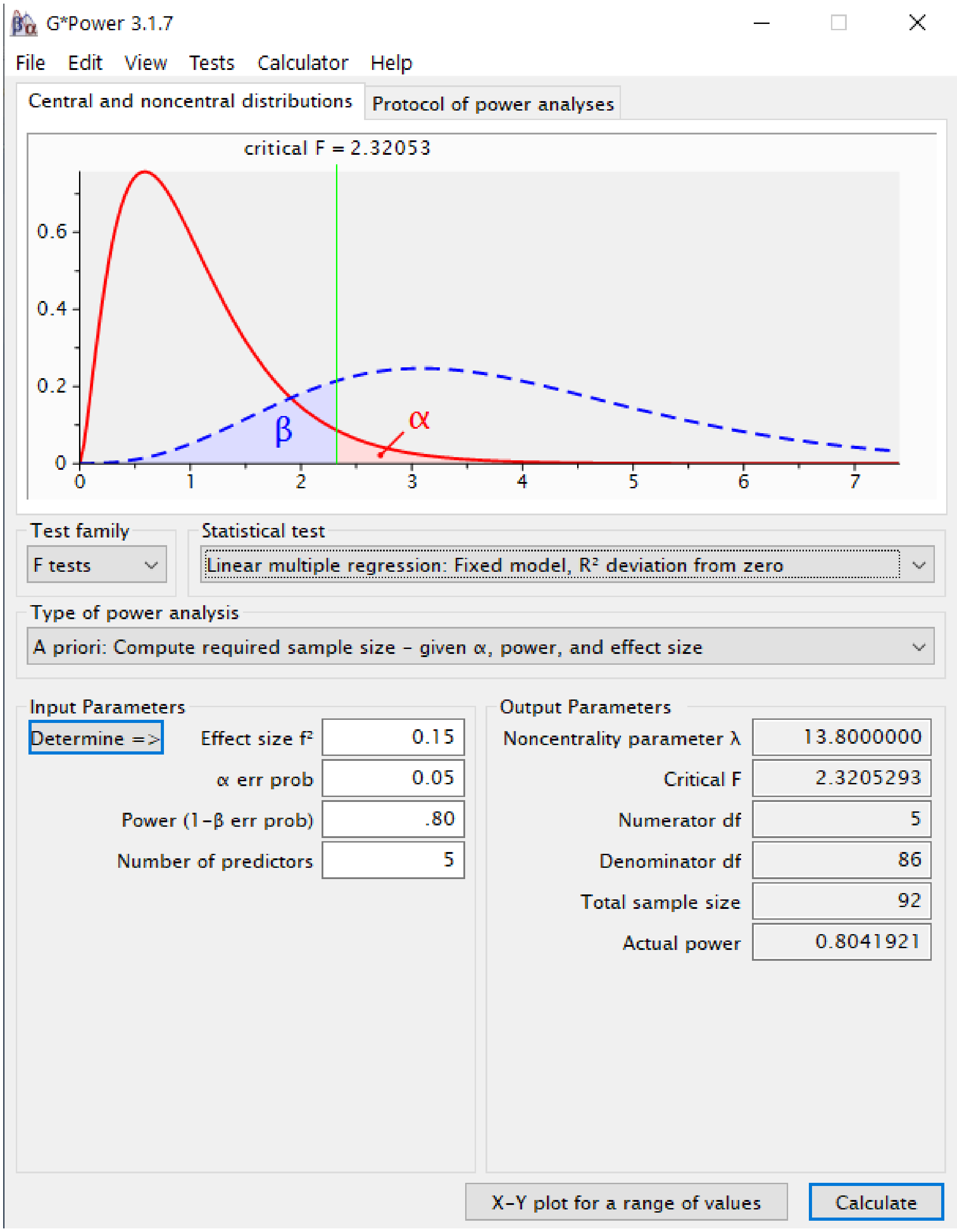
http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Sincerely,
Libby Munson
Research Ethics Support Specialist
Research Ethics, Compliance, and Partnerships
Walden University
100 Washington Avenue South, Suite 1210
Minneapolis, MN 55401
Email: irb@mail.waldenu.edu
Phone: (612) 312-1283
Fax: (612) 338-5092

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link: http://academicguides.waldenu.edu/researchcenter/orec

Appendix B: G*Power Analysis



Test family: F tests

Statistical test: Linear multiple regression: Fixed model, R² deviation from zero

Type of power analysis: A priori: Compute required sample size – given α, power, and effect size

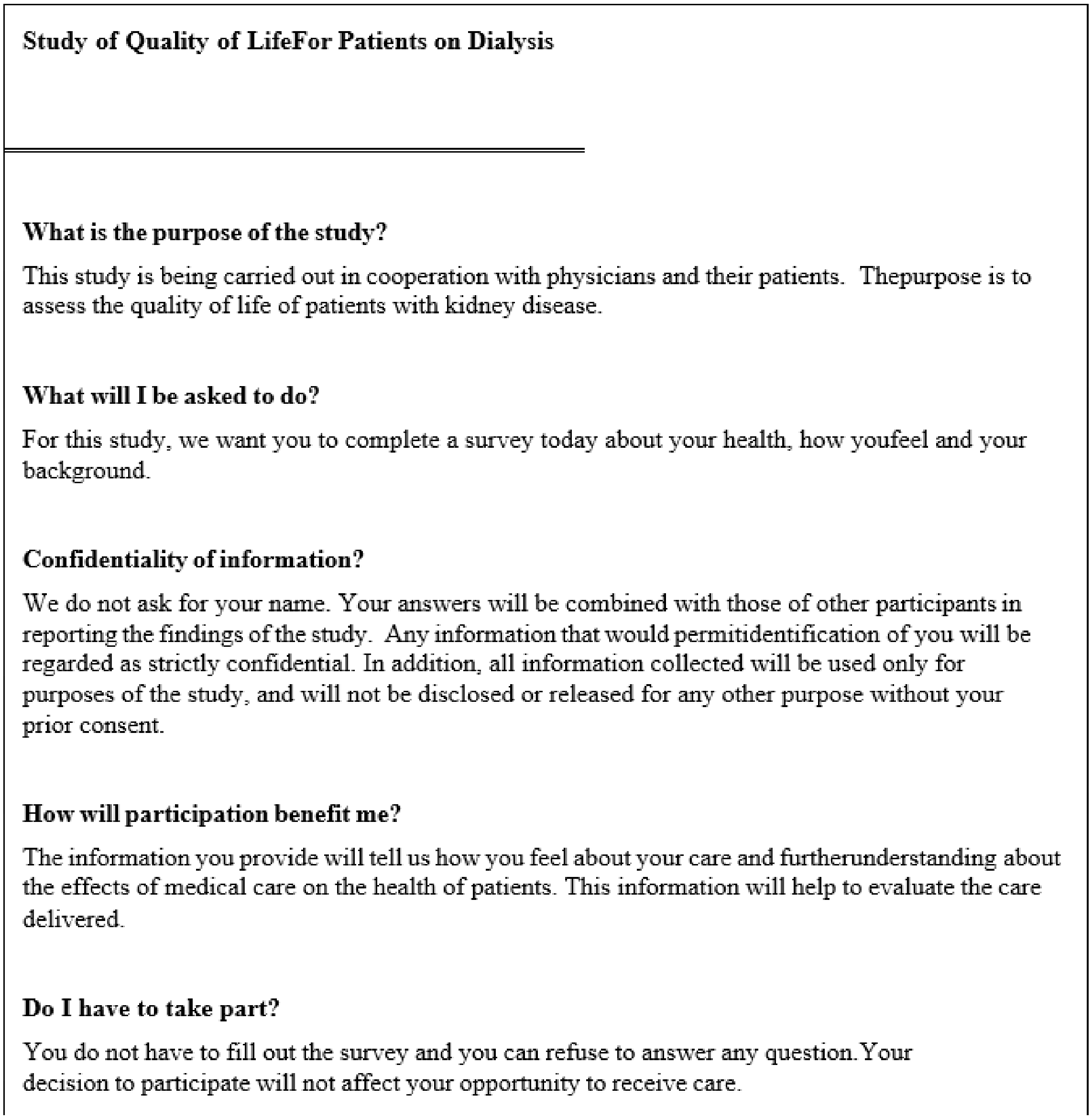
Input Parameters

Effect size f²	0.15
α err prob	0.05
Power (1–β err prob)	.80
Number of predictors	5

Output Parameters

Noncentrality parameter λ	13.8000000
Critical F	2.3205293
Numerator df	5
Denominator df	86
Total sample size	92
Actual power	0.8041921

Appendix C: Kidney Disease Quality of Life Questionnaire



Study of Quality of LifeFor Patients on Dialysis

What is the purpose of the study?

This study is being carried out in cooperation with physicians and their patients. Thepurpose is to assess the quality of life of patients with kidney disease.

What will I be asked to do?

For this study, we want you to complete a survey today about your health, how youfeel and your background.

Confidentiality of information?

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permitidentification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

How will participation benefit me?

The information you provide will tell us how you feel about your care and furtherunderstanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

Do I have to take part?

You do not have to fill out the survey and you can refuse to answer any question.Your decision to participate will not affect your opportunity to receive care.

Your Health

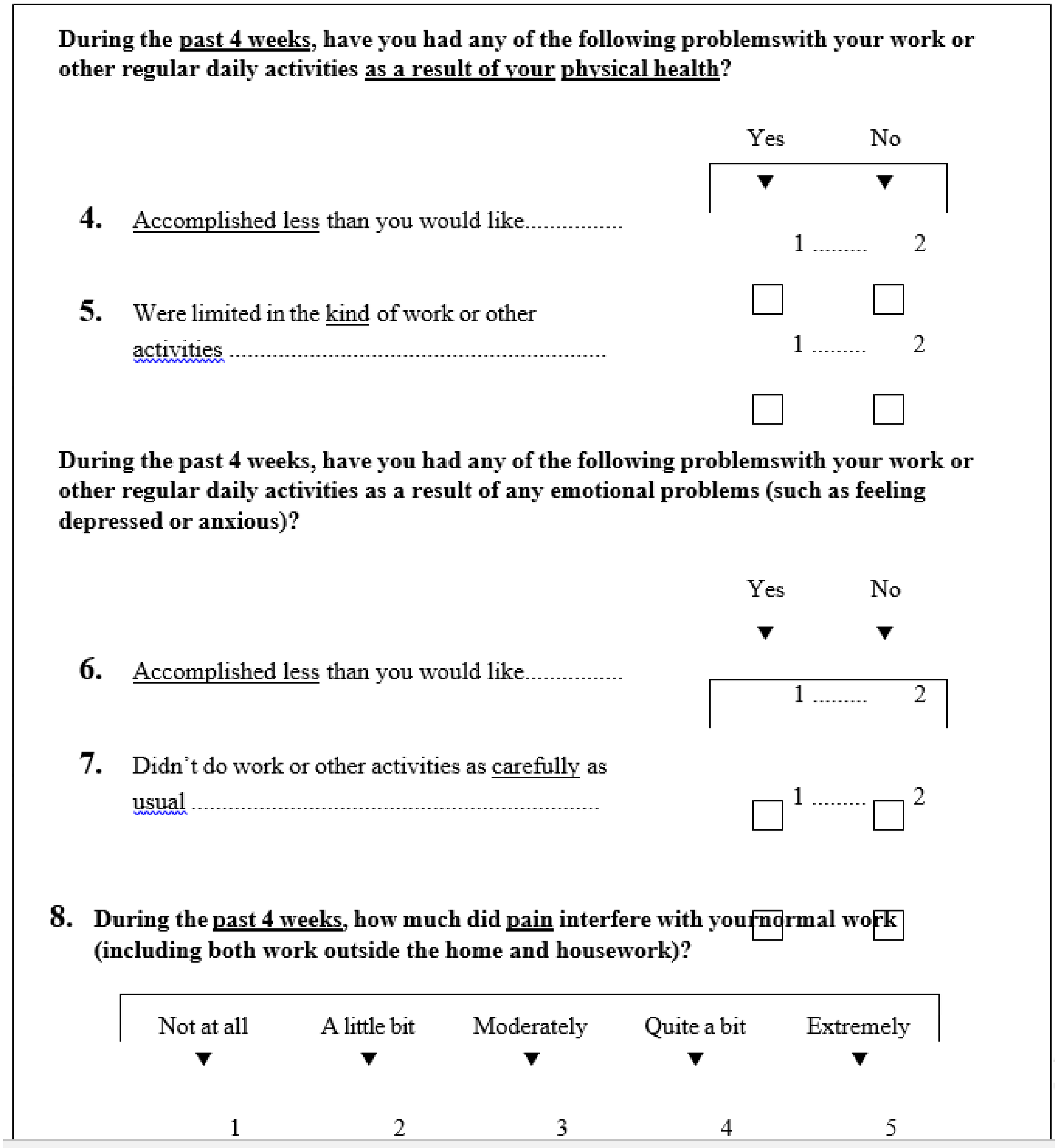
This survey includes a wide variety of questions about your health andyour life. We are interested in how you feel about each of these issues.

1. **In general, would you say your health is: [Mark an ☒ in the one boxthat best describes your answer.]**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
1	2	3	4	5
☐	☐	☐	☐	☐

The following items are about activities you might do during a typicalday. <u>Does your health now limit</u> you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3



During the past 4 weeks, have you had any of the following problemswith your work or other regular daily activities as a result of your physical health?

	Yes	No
	▼	▼
4. Accomplished less than you would like................	1 .... ☐	2 ☐
5. Were limited in the kind of work or other activities	1 .... ☐	2 ☐

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

	Yes	No
	▼	▼
6. Accomplished less than you would like................	1 .... ☐	2 ☐
7. Didn't do work or other activities as carefully as usual	1 .... ☐	2 ☐

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

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
1	2	3	4	5

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

How much of the time during the past 4 weeks…

	All of the time ▼	Most of the time ▼	A good bit of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
9. Have you felt calm and peaceful?......................	☐ 1........	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1........	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue? .	☐ 1........	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐
1	2	3	4	5

Your Kidney Disease

How true or false is each of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13.	My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14.	Too much of my time is spent dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15.	I feel frustrated dealing with my kidney disease.......	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16.	I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, to what extent were you bothered by eachof the following?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17.	Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18.	Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19.	Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20.	Itchy skin?.............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21.	Dry skin?...............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22.	Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23.	Faintness or dizziness?.............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24.	Lack of appetite?...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25.	Washed out or drained?................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26.	Numbness in hands or feet?........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27.	Nausea or upset stomach?..............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28ª.	(Hemodialysis patient only) Problems with your access site? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28ᵇ.	(Peritoneal dialysis patient only) Problems with your catheter site?..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Some people are bothered by the effects of kidney disease on theirdaily life, while others are not. How much does kidney disease botheryou in each of the following areas?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
		▼	▼	▼	▼	▼
29.	Fluid restriction...	1	☐ 2	☐ 3	☐ 4	☐ 5
30.	Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31.	Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32.	Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33.	Being dependenton doctors and other medical staff?......................	☐ 1	2	3	4	5
34.	Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35.	Your sex life?........	1	2	3	4	5
36.	Your personal appearance?	☐ 1 ☐	☐ 2 ☐	☐ 3 ☐	☐ 4 ☐	☐ 5 ☐
		☐	☐	☐	☐	☐

Thank you for completing these questions!