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Family Consultation To Reduce Early Hospital Readmissions Among Patients With End-Stage Renal Disease: A Randomized Clinical Trial

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FAMILY CONSULTATION TO REDUCE EARLY HOSPITAL READMISSIONS AMONG PATIENTS WITH END-STAGE RENAL DISEASE: A RANDOMIZED CLINICAL TRIAL

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CHAPTER 1 INTRODUCTION

Background on Renal Failure

Chronic kidney disease is a general term for a variety of different disorders affecting kidney structure and function. In the United States, the development of chronic kidney disease is associated with old age, diabetes, hypertension, obesity, and cardiovascular disease (Levey & Coresh, 2012). When unmanaged over long periods of time, these conditions cause damage to and destroy the nephrons, the functional units of the kidney. The diagnosis of chronic kidney disease is made through the presence of either kidney damage or decreased kidney function (as measured by glomerular filtration rate, GFR) below certain markers for a period of at least three months. When the kidney is functioning so weakly that dialysis or transplantation is necessary for the patient to survive (usually GFR < 15 mL/m^2), the condition is labeled as "kidney failure," also known as "end stage renal disease" (ESRD) or "stage 5 chronic kidney disease." Prevalence is approximately 1,800 cases per million across the total population of the United States, and most patients survive only 3-5 years.

For the majority of patients, ESRD is the end result of a progressive deterioration in kidney function over a period of months or years. Although it is possible to reverse the course of disease progression through treatment, that outcome is uncommon. The major focus of treatment is to slow the progression of the disease and manage complications. Most patients with ESRD undergo hemodialysis (as opposed to peritoneal dialysis) in which a machine serves about 15% of the function of healthy kidneys, but this process requires a time commitment of 3 days per week for 3-4 hours each time. Additionally, most patients with ESRD have other complex medical complications such as

cardiovascular disease and diabetes, which require a strict medication regimen to be controlled. This places the responsibility of strict medication adherence in the hands of the patients, in addition to their other burdensome requirements of undergoing dialysis, and consuming reduced amounts of fluids and sodium. Finally, renal transplantation offers better long-term outcomes than dialysis, but the supply of available kidneys is limited.

Early Readmissions

Readmissions within 30 days after discharge from the hospital are an increasingly important metric for evaluating the effectiveness of medical treatment. Hospital admissions are the single most expensive episodes in healthcare, and early readmission has been targeted as indicating a likely failure of appropriate care and/or discharge preparation. In fact, the Affordable Care Act has instituted a policy of fining hospitals for high 30-day readmission rates as means of incentivizing those hospitals to provide quality care. Yet, the ESRD patient population has the highest rate of 30-day readmissions of all patients in the Medicare/Medicaid population, averaging over 30% across all hospitals (Medicare Payment Advisory Commission, 2007). Therefore, interventions that reduce these early readmission rates could make an enormous difference in both improving care for patients with ESRD while also saving money for hospitals. Yet, few interventions have ever been developed or empirically tested via a randomized controlled trial (RCT) to modify this outcome variable. An added benefit of reducing hospital admissions is that it keeps patients out of danger from medical errors, which have been estimated to result in over 210,000 deaths per year in the United States (James, 2013). The following sections present five major behavioral risk factors (shown in Figure 1) for early

readmissions in patients with ESRD, although as I discuss below, only social support may be amenable to adaptive change with a brief intervention.

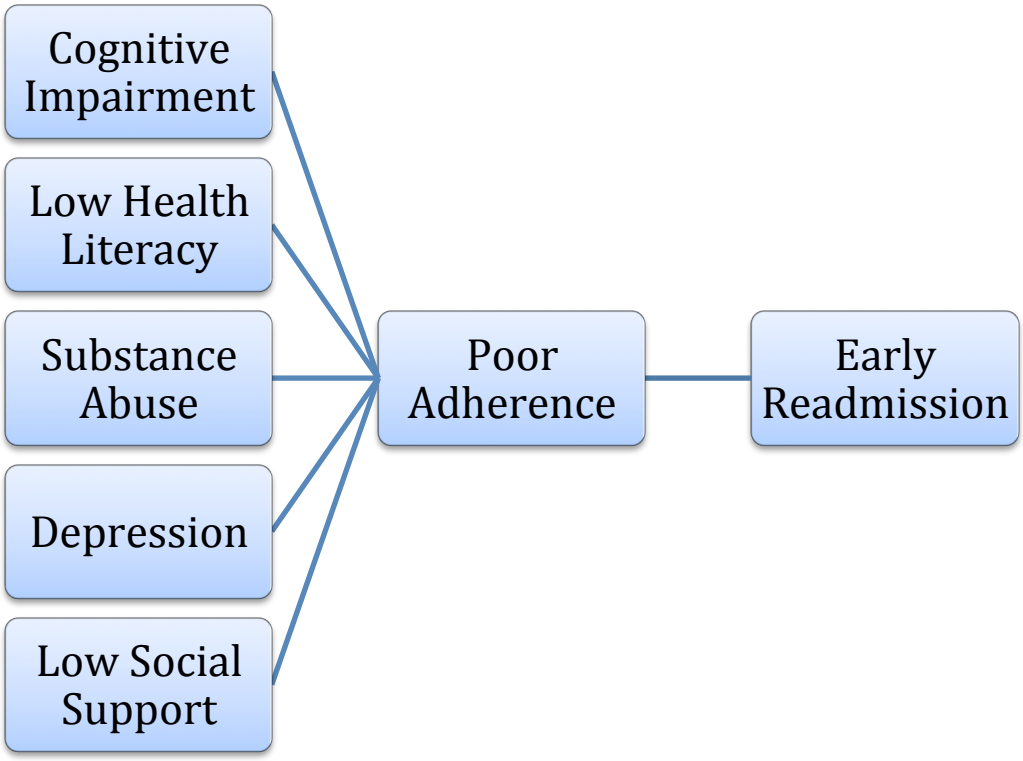


Figure 1. Proposed Model

Risk Factors

Cognitive Impairment

Cognitive impairment, an umbrella term that includes both chronic and acute deficits in cognitive functioning, is increasingly recognized as a primary psychosocial risk factor for excessive healthcare utilization and hospital admissions. In general, the most common cause of cognitive impairment is the normal aging process. Patients with ESRD are particularly at risk due to their high comorbidity with medical conditions that affect the central nervous system, such as hypertension, diabetes, smoking, and

atherosclerosis (Ketterer, Soman, & Mossallam, 2014). Furthermore, patients with ESRD are also at risk for delirium resulting from various causes, such as encephalopathy due to the failing kidney (increased uremia, hyperkalemia, hyperphosphatemia, and acidosis) and side effects from medications. Delirium, which is characterized by confusion, disorientation, and attention problems that fluctuate over time, has been shown to have particularly negative consequences for both patients and support members (O'Malley, Leonard, Meagher, & O'Keeffe, 2008). Cognitive impairment has been found to be related to poor self-care adherence (Cameron et al., 2010) and to prospectively predict readmission and mortality (Dodson, Truong, Towle, Kerins, & Chaudhry, 2013; Watson et al., 2011). Cognitive impairment also may be the principle factor for early readmission in at least some populations, such as those with congestive heart failure (Ketterer, Draus, McCord, Mossallam, & Hudson, 2014). Preliminary analyses have replicated these findings in the very hospital where I conducted this study. A prospective study assessed patients with ESRD for a variety of different risk factors when they were initially admitted to the hospital, and found that cognitive impairment, substance abuse, and low health literacy at baseline predicted 30-day readmissions (Ketterer, Soman, et al., 2014). Additionally, an unpublished retrospective review of medical records of patients with ESRD that I conducted showed that the presence of one or more positives on a "cognitive composite" index (history of delirium, positive head CT or MRI, history of seizures, history of hypoxia) was significantly related to the presence of a 30-day readmission within the past year (Jasinski, Lumley, Soman, Yee, & Ketterer, in press). Unfortunately, cognitive impairment is rarely identified in healthcare settings, and usually remains unattended to in this population (Tamura & Yaffe, 2011). Therefore, simply raising

awareness about cognitive impairment in patients with ESRD might help their physicians, other medical staff, and support people plan for appropriate home care after discharge.

Depression

Patients with ESRD face unique psychological stressors due to their extreme dependence on technology for survival as well as the time-consuming demands on their health behaviors (Christensen & Ehlers, 2002). Living with ESRD entails a variety of chronic, recurrent stressors, significant change in lifestyle, disruption of familial roles and social identity, and threatened personal control, mainly due to the requirements for dialysis. Psychological distress and disorder represent a significant detriment to ESRD patient quality of life. Estimates of the prevalence of depression in this population are that 20-25% of ESRD patients meet diagnostic criteria for major depression (Kimmel, Cukor, Cohen, & Peterson, 2007). The loss of control that comes with ESRD has been identified as an important contributing factor to this depression. Illness intrusiveness, which is very high due to the requirements of hemodialysis, has also been shown to be a contributor to depression (Christensen & Ehlers, 2002). Additionally, depression may be under recognized and under treated in this population, and even when intervention attempts are made, treatment has often been unsuccessful (Fallon, 2011).

Substance Abuse

Cocaine and other substances have been identified as causes and exacerbating factors of renal failure (Norris et al., 2001). Accordingly, substance abuse is very prevalent in patients with ESRD, in spite of the fact that it accelerates the deterioration of their health (Kimmel, Thamer, Richard, & Ray, 1998). In general, substance abuse has been linked with greater health care utilization, especially in populations with low socio-

economic status (Kushel, Vittinghoff, & Haas, 2001). In a study conducted at Henry Ford Hospital, where I conducted this dissertation, substance abuse prospectively predicted early readmissions in patients with chronic kidney disease. Finally, although the impact of substance abuse on interventions with inpatients is largely unknown, it could be an important moderating variable. For example, substance abuse could potentially be a barrier to the success of the intervention.

Health Literacy

Another psychosocial factor attracting much attention is "health literacy," defined as the ability of patients to understand the language used to educate them regarding their medical conditions as well as the medical treatments used to manage their health (Kindig, Panzer, & Nielsen-Bohlman, 2004). Low health literacy has been associated with various adverse outcomes including an increase in hospital admission/readmission rates (Baker, Parker, Williams, & Clark, 1998; Mitchell, Sadikova, Jack, & Paasche-Orlow, 2012). In the case of patients with ESRD, increased mortality has also been found to be associated with low health literacy (Cavanaugh et al., 2010). However, the mechanism by which health literacy impacts outcomes is unclear, and the possibility of a third factor such as socioeconomic status that confounds or mediates any observed association must be considered and controlled or eliminated. For example, research has shown that the improvements assumed to occur with greater health literacy—better disease knowledge, healthier behaviors, more use of preventive care, and compliance—could not account for a relationship between health literacy and use of hospital services (Cho, Lee, Arozullah, & Crittenden, 2008). Most important of all, there have been no randomized controlled trials providing evidence that health literacy is a causal variable (Ketterer, Mahr, &

Goldberg, 2000). In summary, education-focused and behaviorally-based interventions focus on helping patients by improving their health literacy, which is certainly an important variable. Some of these interventions have even included family and friends to a certain extent.

Social Support

Although there are many variables that are risk factors for poor outcomes in patients with ESRD, social support serves as a protective factor. Additionally, whereas there is little or no evidence that we can use brief bedside interventions to attenuate the above risk factors and improve outcomes in patients with ESRD, there is evidence that psychosocial interventions involving family members can reduce patient and caregiver burden, and improve mood in these patients with various chronic illnesses (Martire, Lustig, Schulz, Miller, & Helgeson, 2004). In general, health literacy and individual differences in health behavior are often implicated as potential mediators of the association between social support and physical health (S. E. Cohen & Syme, 1985). Therefore, an increase in social support could help compensate for the presence of these risk factors. Also, a supportive family environment has been identified as a particularly important protective factor for chronically ill individuals in terms of self-management of their health behaviors such as diet (Gallant, 2003). As is the case with other clinical populations, various indices of the quantity and perceived quality of social support have been associated with more favorable psychological adjustment and reduced risk of mortality among patients with chronic kidney disease (Christensen, Wiebe, Smith, & Turner, 1994; S. D. Cohen et al., 2007). Perceived social support is also associated with less depressive and suicidal thoughts among patients with ESRD (Soykan, Arapaslan, &

Kumbasar, 2003).

Potential Mediator: Medication and Dialysis Adherence

Patients with ESRD have a reputation for being "difficult" to work with, because their medical cases are usually complex, and adherence is commonly lower than among patients with other diseases (Christensen & Ehlers, 2002). One explanation for low adherence involves the high burden experienced by patients with ESRD. For example, patients on hemodialysis are required to commit to three dialysis sessions per week, which take a few hours each time. In addition, patients are prescribed dietary restrictions that significantly limit their food options. Therefore, it is unsurprising that many patients say that they feel "over-doctored" and overwhelmed by the amount of self-care that is necessary for them to survive (Levy, Cohen, & Tessier, 2006). Studies examining the prevalence of nonadherence among renal dialysis patients have typically observed that between 30% and 60% of patients do not adhere to diet, fluid-intake, and medication regimens (Bame, Petersen, & Wray, 1993). These studies have relied almost entirely on cross-sectional, self-report assessment of patient characteristics and adherence outcomes.

Adherence to health behaviors such as taking medications as prescribed and attending dialysis sessions has been proposed as the primary mechanism by which the various risk factors described above lead to early readmissions, and represents a mediator by which risk factors translate into poor health outcomes. Patients with ESRD have a unique set of clinical, socio-demographic, and psychosocial factors that have been examined as potential correlates or determinants of adherence behavior, including cognitive impairment, family support, depression, health beliefs, and health literacy (Cameron et al., 2010; Karamanidou, Clatworthy, Weinman, & Horne, 2008). Simply,

patients who are too forgetful or confused to take their medications regularly experience negative health effects (including mortality) as a result, and, therefore, require hospitalization in order to recover (Kimmel, Peterson, et al., 1998; Kimmel et al., 2000; Leggat et al., 1998). For example, cognitive impairment, depression, substance abuse, and younger age have all been linked to worse hemodialysis adherence (Mellon, Regan, & Curtis, 2013).

Social Support and Adherence

Limited research is available regarding the relationship between social support and adherence among patients with ESRD. For example, there is a large body of research in other populations that suggests that many different aspects of social support (emotional, practical, etc.) are important correlates of regimen adherence (DiMatteo, 2004). Christensen et al. (1992) examined the effects of family social support and illness-related stress on hemodialysis patient adherence. Patients who reported a more supportive family environment, characterized by greater cohesion and expressiveness among family members and less intrafamilial conflict, exhibited significantly more favorable adherence to fluid-intake restrictions than did patients reporting less family support. Likewise, being married has been linked to increased adherence to hemodialysis (Alkatheri et al., 2014).

A major limitation of the research is that family and social support interventions have not been tested within patients with ESRD to determine how they might impact medication adherence or the specific health outcome of early readmissions after hospital discharge. On the other hand, this lack of data presents an opportunity to test the ability of health care professionals to mobilize social support, which may be more amenable to change than the other risk factors of early readmission, such as cognitive impairment,

health literacy, depression, and substance abuse. Additionally, across the literature, the impact of social support has been assessed using a variety of different measures, which means that there is robust evidence that shows social support to be a protective factor in patients with ESRD. But, the downside is that social support is a broadly defined construct, so it is difficult to determine which specific factors might carry the most impact in a potential intervention.

Interventions for adherence

Given the prevalence of ESRD and clinical importance of adherence among patients diagnosed with this condition, the design and evaluation of interventions to improve adherence is critically important. The ESRD population has been identified as ripe for specific interventions designed to mobilize social support (Chisholm-Burns, Spivey, & Wilks, 2010; Cukor, Rosenthal, Jindal, Brown, & Kimmel, 2009). However, most interventions in this population have not attempted to utilize social support, and no interventions have been tested for their ability to reduce early readmissions in patients with ESRD. Therefore, in this section I will review interventions that have aimed to improve my primary hypothesized mediator variables, medication and dialysis adherence.

Most ESRD adherence intervention studies (at least 10 in total) have used behaviorally-oriented techniques. There is evidence to suggest that a range of behavioral strategies (e.g., self-monitoring, behavioral contracting, and positive reinforcement) are associated with small to medium effect size improvements in adherence among hemodialysis patients (Matteson & Russell, 2010). However, many of these studies are limited to single-subject or very small sample designs, and conducted over multiple sessions with outpatients. For example, a pre-post design study showed that a 3-month

motivational interviewing intervention improved dialysis attendance as well as biomarkers of kidney health at follow-up (Russell et al., 2010). Also, Binik et al. (1993) reported that a brief, enhanced-education intervention focusing on increasing patient knowledge about the basic pathophysiology of kidney disease, and options for treatment strategies led to a delay in the need to initiate renal dialysis compared with a standard-education control group. Cukor et al. (2013) conducted a large cognitive behavioral therapy (CBT) intervention that occurred while patients were seated at their hemodialysis appointments, and found that the CBT group demonstrated significantly higher adherence to fluid intake restrictions (among other psychosocial improvements), but no improvement with adherence to prescription medications, when compared to a wait-list control group. These interventions, although somewhat encouraging, would not be as feasible with inpatients, particularly those with cognitive impairment, who, in comparison, are much sicker than those in outpatient dialysis units.

Putting it all together: Considerations for intervention

In terms of the focus of the intervention, there are several risk factors that have been previously targeted for intervention in this population, including depression and substance abuse. However, these variables have already been investigated, and usually take many recurring sessions of treatment before any improvement is noticeable. Therefore, this study, although not ignoring these variables, placed an emphasis on domains that have not yet been tested, such as compensating for cognitive impairment. A key aspect of this study is that we targeted patients who had already demonstrated the lack of capacity for proper adherence, and are most at risk for poor adherence and readmissions, in order to work with those who need the most help and use the most

resources. These patients likely would not respond very well to the CBT interventions that have already been tested. Of the five risk factors for poor adherence and early readmissions mentioned above, social support is the one with the most potential to be modified by a brief family consultation. Thus, mobilizing family support to help patients adhere to their medication schedule is something that can potentially be achieved in one brief psychoeducation session. In addition, family involvement could help benefit patients with low health literacy as well.

There are several other considerations for the process of the intervention. First, the consultation-liaison literature has demonstrated that bedside psychiatric consultations can maximize efficiency as well as reducing patient burden (Griffith & Gaby, 2005). Accordingly, we kept the intervention brief to minimize the burden on patients and their support people, as well as reducing the potential cost of this intervention in a real-world setting. Importantly, pragmatic research methods like this would allow this study to achieve the goal of being more on the effectiveness side of the spectrum as opposed to efficacy. Second, health literacy issues will need to be considered as a common concern in this population. Interventions to improve health literacy have included advocating the importance of use language that is easy to understand, promote empowerment in patients, and mobilize social support (Gazmararian, Jacobson, Pan, Schmotzer, & Kripalani, 2010). However, the goal of the intervention is to compensate for low health literacy, rather than to try to change health literacy. Therefore, as part of this intervention, it will be important to use words that patients can understand and do not provoke defensive responses, such as discussing “forgetfulness” instead of “cognitive impairment” or “dementia.” We also utilized motivational interviewing techniques as necessary when

patients were resistant or skeptical of the intervention (Levy et al., 2006; Miller & Rollnick, 2012). Furthermore, although attending to medications and dialysis will be the main focus of the intervention, it would be efficient to mention the importance of managing any evident depression symptoms and abstaining from alcohol and other substances.

There is some debate regarding the optimal way to quantify the outcomes of this study. We used 30-day inpatient readmissions as a dichotomous variable as our main outcome because that is the statistic currently attracting attention due to its use by CMS to determine fines for high readmission rates. This metric is also easy to understand and face valid for explaining to patients and other people who are not versed in the complexities of hospital procedures. However, return visits for observation or to the emergency department are also clinically relevant and important metrics for patient health and quality of life as well as evaluating hospital performance and funding. Therefore, we created a second variable to encompass whether or not a patient had any type of return visit. Finally, readmission status at three months was also assessed as a secondary outcome variable.

Summary and Goals of Study

A variety of risk factors cause poor medication and dialysis adherence in patients with ESRD, but increased family support may be able to counteract these limitations and improve adherence. The main goal of this study was to use a randomized clinical trial to test the efficacy / effectiveness of a brief family meeting consultation aimed at improving the health behaviors of patients with ESRD to prevent early readmissions to the hospital. We will also analyze observation status and emergency department visits as outcomes

because although they are not yet being targeted by the Affordable Care Act, they represent clinically relevant outcomes. As secondary goals, we investigated the mediators of this process by monitoring changes in social support, medication and dialysis adherence, and mood and their relation to the outcome variables. Baseline cognitive impairment and history of substance abuse were examined as moderators.

Finally, I sought to replicate our preliminary study linking cognitive impairment with 30-day readmissions because these findings are relatively novel in the literature and may have important implications for potential mechanisms of this intervention. This was done by examining if baseline cognitive impairment indicators from the chart review predicted readmissions for the sample as a whole, ignoring experimental condition assignment.

Hypotheses

I hypothesized that:

(1) The intervention group would have significantly fewer 30-day (and 3 month) readmissions and hospital visits than the medical treatment-as-usual control group.

(2) Social support and adherence would increase more in the intervention group than the control group, and would mediate the relationship between condition assignment and outcomes.

(3) Baseline cognitive impairment and history of substance abuse were run as exploratory moderator analyses, so no hypotheses were made.

(4) Measures of cognitive impairment from the chart review and baseline assessment would positively predict 30-day readmissions.

CHAPTER 2 METHODS

Participants

Participants were 120 adults who had end stage renal disease and were hospitalized at Henry Ford Hospital in Detroit, Michigan. Inclusion criteria were a current admission to the Nephrology unit and willingness to contact a family member or friend who was expected to be available and responsive to the consultant, if the patient was randomized into the experimental condition. To maximize generalizability of this sample to the larger population of patients with ESRD, there were few exclusion criteria: delirium, unavailability/discharge before recruitment and informed consent, and inability to speak English. Patients were paid $40 for their participation in the study ($20 at baseline and $20 at follow up).

Procedure

Risk Factor Screening Chart Review

A chart review was used as a screening measure to identify the patients admitted to the Nephrology unit who are most at risk for readmission. A pilot study (Jasinski et al., in press) found that age and cognitive impairment variables (such as history of delirium and positive brain imaging results) can be used as screening variables to identify which patients in the nephrology unit are at higher risk for being readmitted to the hospital within 30 days. The experimenter tried to recruit all patients with ESRD, but, given time constraints, when multiple patients were available for recruitment simultaneously, priority was given to patients who screened positive for one or more risk factors for early readmission.

Recruitment and Randomization

This trial was registered at clinicaltrials.gov (NCT02504021) prior to recruitment, which ran from August 2015 to April 2016, with outcome assessment completed in May 2016. The randomization scheme was created before recruitment began by an independent research assistant. Randomization was conducted using randomization.com; it was stratified by patient gender (male or female), conducted in randomized blocks of 6 or 8, and the assignments were placed in sealed envelopes. Figure 1 presents the flow of patients through the trial. All recruitment and intervention procedures were conducted by a trained, male, clinical psychology doctoral student, who was supervised by a doctoral psychologist with extensive experience in health psychology interventions. Patients were approached at bedside, and those who met study criteria provided written, informed consent to the IRB-approved protocol. Patients then completed an initial assessment using several questionnaires, some of which informed the subsequent family consultation (see below). Questionnaire items were read aloud by the researcher to assure the patient's understanding, given concerns about literacy in this population. Following the assessment, the researcher unsealed the envelope to determine the assigned condition; patients and the researcher were blind to condition assignment prior to this.

As part of the screening process at the initial meeting, we carefully discussed with the patients whether or not they had a reliable family member or friend (ideally living in the same household) who might be willing to come meet with us at the hospital. Those participants who potentially met study criteria and remained interested were invited to review the study procedures, provide written, informed consent, and complete baseline questionnaires. Then, they were randomized into the experimental or control condition.

Finally, the researcher verbally assessed stress level and stage of change regarding openness to having someone help with their medications (Miller & Rollnick, 2012). This information was used in planning for the family consult, which was designed to remain flexible as would be consistent with a motivational interviewing approach.

For patients randomized into the consultation condition, the researcher spoke with them about selecting a family member or friend to come to meet them in the hospital and agreeing to participate in the study. We also scheduled a time for the appointment and confirmed with the support people that they could attend. However, in-person family meetings were often not feasible, so to maximize participation and feasibility, some family consultations occurred by telephone. In such cases the consultation was conducted with the family member over the phone, and patients were briefed about the content of the discussion. Then, the family meeting was conducted as soon as possible, ideally before the patient was discharged. Support people were provided with information sheets when meetings were in-person, and provided verbal consent for consults that were done over the phone. Family meetings were conducted in-person when the family was already present at the hospital. Method of contact was recorded for analysis as a potential moderator.

At follow-up, a chart review was conducted by a member of the research team one month after the discharge of each participant to determine if he or she was readmitted to the hospital within that time frame (which represents the window where hospitals are financially penalized). Other variables such as observation status admissions and emergency department visits were also recorded. All codes for readmissions were independently confirmed by a senior hospital psychologist who was blinded to patient

randomization. We reviewed the charts again at three months to assess longer-term readmission status as a measure of health. There was little data available about readmissions to hospitals outside of the Henry Ford, so it was not included. Patients in both the consultation and control conditions were called to administer the follow-up measures after 1 month, and if patients could not be reached via phone after three attempts, were mailed with return envelopes.

Family Consultation Condition

The family consultation consisted of one relatively brief session. To maintain trial integrity and avoiding confounding by the medical team, the doctoral student / family consultant worked independently from the rest of the health care team on the unit, leaving them essentially blind to patient consultation condition.

The consultation had several components. The consultant:

1) introduced himself and informed the patient and family member that the health care team is working to improve post-discharge care by communicating better with the patient's support people;
2) built rapport by providing empathy regarding the burden of managing ESRD;
3) reviewed patient and family understanding of events that caused the hospital admission;
4) educated patient and family about of the level of cognitive impairment that the patient was experiencing by discussing the results of the initial cognitive assessment;
5) discussed ways for the support person to assist the patient with his or her medication adherence, even when the patient displayed no overt signs of cognitive impairment;

6) tailored the consultation to each patient by including other risk factor data from the initial assessment (i.e., health literacy, social support, and adherence) as indicated; and
7) used motivational interviewing techniques, as indicated, such as asking permission to make recommendations, and reflecting ambivalence over treatment adherence.

The detailed protocol is included in Appendix A.

Control Condition

After the initial patient assessment, control participants engaged only in their medical treatment as usual (TAU). No family consultation was conducted.

Screening and Predictor Measures (Baseline only):

Demographic and Medical Status Variables

A researcher conducted the review of the following variables: age, gender, race, history of substance abuse, history of delirium, history of seizures, history of hypoxia, history of psychiatric history, presence of psychiatric medications, number of past year hospital readmissions, length of time on dialysis, comorbid health conditions, serum creatinine, BUN level, and phosphorous.

Cognitive impairment

Cognitive impairment and education was assessed with The Montreal Cognitive Assessment (MoCA; (Nasreddine et al., 2005)), which is a brief (~10 minute), easily administered and scored screening instrument to detect cognitive impairment among patients in medical settings. It was designed to provide physicians a method of assessment for dementia that can be done quickly and requires minimal training to administer and score. The measure assesses: a) executive function (after being given a

full sheet of paper with a large circle drawn on it, patients are instructed, “Draw me a clock, put all the numbers on it and make it say 10:15”); b) naming (“What are these three animals?”); c) immediate memory (“Repeat these three numbers: 2, 1, 8, 5, 4”); d) language (world fluency and sentence repeat); e) abstraction (similes); f) short-term memory (after a 5 minute delay during which the patient was distracted: “What were those five words I read to you earlier you?”); and g) orientation (“Name the current date & building we are in.”). Finally, 1 point is added to the score of patients who have no education beyond a high school level.

Health Literacy

The Rapid Estimate of Health Literacy in Medicine (REALM) (Davis et al., 1993) is a brief screening instrument designed for use in medical settings to assess patients’ reading level. The instrument consists of having patients read two lists of 8 and 7 words aloud and usually takes less than 2 minutes. Patients are scored one point for each word that they pronounce correctly. Scores are interpreted in terms of grade equivalent reading level, with a perfect score corresponding to an above 9^{th} grade level reading capability.

Outcome Measures:

Outcome Measure: Early Readmissions

The outcomes for this trial were obtained from the electronic medical record of each patient. The primary outcome variable for this study was early (30-Day) hospital readmissions. We operationalized this variable in two ways. First, we calculated the percentage of study patients who had another inpatient readmission within 30 days of discharge. This metric is easy to understand and directly relates to the financial penalties levied by the Affordable Care Act, but may be lacking in nuance and fail to capture the

range of negative events. Thus, we also calculated the percentage of patients who had any unplanned return visit to the hospital (inpatient readmissions, observation unit visits, and emergency department visits) within 30 days of discharge. We believe that the observation and emergency department visits represent clinically relevant outcomes and therefore should also be studied in an effort to prevent them. All outcome data were initially retrieved by the consultant, and then independently retrieved by a senior staff member who was blinded to experimental condition. Complete agreement between the two coders was over 98%; the few differences were resolved by discussion and consensus.

Social Support

At both baseline and follow-up, perceived social support was assessed using items from the Modified Scale of Social Support-5 (MSSS), which is an abbreviated version of the full-length MSSS (Sherbourne & Stewart, 1991). This self-report questionnaire takes about 2-3 minutes to complete and has a Cronbach's alpha of .87 (Sherbourne & Stewart, 1991). Items are rated on a scale of 1 (None of the time) to 5 (All of the time). Higher scores indicate greater perceived social support. Item domains include emotional/informational support, tangible support, affectionate support, and positive social interaction. This questionnaire has been used in important studies linking social support with adherence in patients with ESRD (Chisholm-Burns et al., 2010). Internal consistency in this sample was $\alpha = .77$ at baseline and $\alpha = .73$ at 1-month follow up.

Medication Adherence

At both baseline and follow-up, adherence to medication was assessed using a modified version of the Immunosuppressant Therapy Adherence Scale (ITAS)

(Chisholm, Lance, Williamson, & Mulloy, 2005). The only change to this scale was to change the language from immunosuppressant medication to include all medications. Several studies have provided evidence for the validity of this measure to assess adherence in organ transplant populations and has specifically been used in patients with ESRD. The 4 items refer to behaviors over the past month: "How often did you forget to take your medications?; How often were you careless about taking your medications?; How often did you stop taking your medications because you felt worse?; How often did you miss taking your medication for any reason?" The four response options for each item are 0% of the time, 1-20%, 21-50%, and over 50% of the time. Internal consistency was found to be Cronbach's α = .81 during initial development. (Chisholm et al., 2005). A fifth item, "How often did you miss your planned dialysis sessions?," was also added for this study. Including this item, internal consistency was α = .78 in this sample at baseline, and α = .74 at 1-month follow up.

Depression

At both baseline and follow-up, depression was assessed using the Patient Health Questionnaire-8 (PHQ-8) (Kroenke, Spitzer, & Williams, 2001). This measure is one of the most widely used assessment tools in healthcare settings. It consists of 8 items based on the diagnostic criteria for major depressive disorder, with response options ranging from 0 (Not at all) to 4 (Almost every day) asking about the patients' experiences over the past two weeks. Higher scores indicate greater depression. Cronbach's alpha for this measure was .89 during initial validation, and in this sample was .81 at baseline and .82 at 1-month follow up.

Anxiety

At both baseline and follow up, anxiety was assessed using the Generalized Anxiety Disorder 7-Item Scale (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006). The measure is one of the most widely used assessment tools for anxiety. Items are rated from 0 (Not at all) to 3 (Nearly every day); higher scores indicate greater anxiety. Cronbach's alpha for this measure during initial validation was .89, and in this sample was .84 at baseline and .91 at 1-month follow up.

Researcher Ratings Post-Consultation

A rating scale was developed for this project to characterize and describe the family meetings. The first section of the scale contained 9 items ranging from 0 (not at all) to 4 (a lot) that allowed the consultant to subjectively rate the interactions with the family and perceived success of the meeting. Example items referring to the perceived reactions of the support people were "developed greater awareness of barriers to adherence" and "seemed to appreciate the consult."

Statistical Analysis

The trial was powered to detect a difference between consultation and control conditions of 20%, which we estimated to be a clinically meaningful effect. To obtain power of .80 using a chi-square test and 1-tailed (directional) alpha of .05 indicated that at least 55 patients per condition were needed (that is, at least 110 patients). Recruitment also targeted and achieved equal numbers of men and women. Initial analyses examined the success of randomization by comparing background demographic, medical, and psychosocial measures between the consultation and TAU control conditions.

Primary, intent-to-treat analyses of the effects of the consultation versus control condition on the presence / absence of readmission were conducted with 2x2 chi square tests. Treatment effects on continuous variables (i.e., social support, anxiety, depression, adherence) variables were tested using repeated measures ANOVA comparing baseline to 1-month follow up scores. As detailed below, three patients never received their randomly assigned consultation, so in addition to intent-to-treat analyses of all randomized patients, we also ran "per protocol" analyses, comparing those patients who received the consultation to all controls.

For statistical tests with hypothesized direction (consultation condition vs. TAU in readmission and return hospital visits), we used 1-tailed tests with an alpha of .05; all other tests were 2-tailed with alpha at .05.

For effect sizes, I calculated number needed to treat (NNT); that is, the number of patients who would need the consultation to prevent a negative outcome (an early readmission or unplanned hospital visit), compared to TAU. I also calculated effect sizes for all 1-month self-report outcomes. The between-condition effect size for secondary outcome variables were calculated at follow-up using the following equation: [(Family Consultation follow-up *M* – baseline *M*) – (TAU follow-up *M* – baseline *M*)] / *SD* of the pooled baseline scores. Effect sizes of 0.2 SD, 0.5 SD, and 0.8 SD are considered small, medium, and large, respectively.

A few analyses were run in an exploratory fashion: regressions to test cognitive impairment as a moderator, and the predictive value of therapist post-session ratings. Also I ran t-tests and Chi-squares to examine if any of the baseline variables predicted 30-day readmissions. Finally, I ran some supplementary medical cost offset analyses to

estimate the amount of money potentially saved by this intervention, as a function of the difference in days of inpatient stays resulting from readmissions between the two groups.

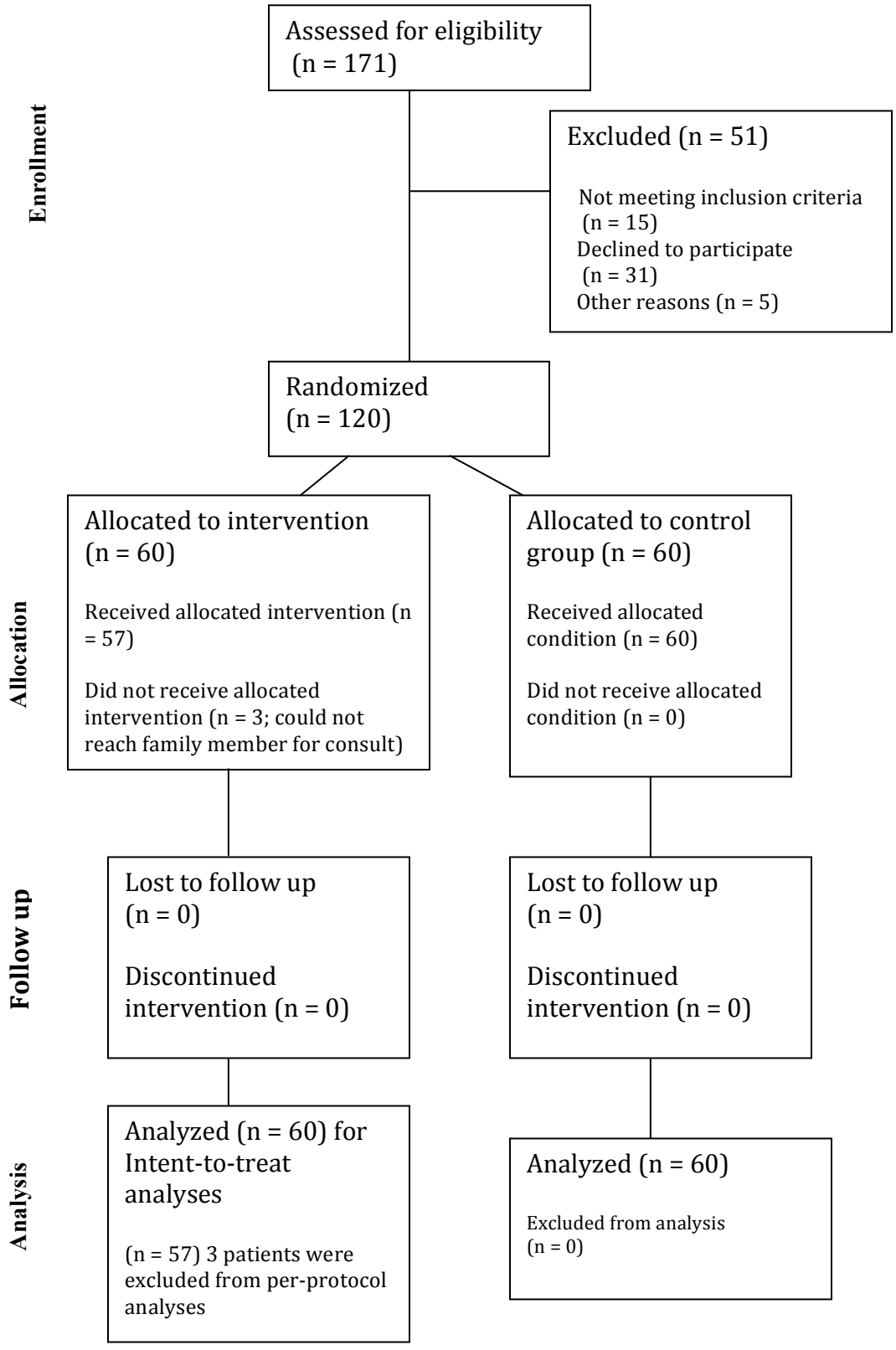
CHAPTER 3 RESULTS

Sample Descriptives

As shown in Figure 1, we screened 171 patients and randomized 120 of them. I approached 51 other patients about participation, and 15 did not meet study criteria, 31 declined to participate, and 5 were excluded for miscellaneous reasons. As shown in Table 1, the randomized sample was half male and half female, had a mean age of 57.5 years (*SD* = 14.4; range = 24-88), was predominantly African American (85.8%), and less than half (42.5%) had education beyond high school. In addition to their ESRD diagnosis, most patients had many medical comorbidities, some of which are shown in Table 1. The two conditions were compared on these background variables to determine the success of randomization; none of the variables differed significantly between conditions. Note: Based on statistics available from this hospital, the 30-day readmission rate for patients with ESRD is around 25%, which is slightly below the national average. The 30-day readmission rate in this sample was 32% in the TAU control group, therefore it is possible that this sample was slightly more at-risk than the usual hospital population.

The consultation was conducted as planned for 57 of the 60 patients randomized to the family consultation condition. Family consultations did not occur for 3 patients, for whom the interviewer was unable to reach any support person, even after three attempted telephone calls. The 57 consultations were relatively brief, averaging about 8 min (*SD* = 5.0 min, range: 2 to 30 min); 23 consultations (40%) were conducted with the family at bedside, and the rest were conducted over the telephone. Consultations involved a variety of different support people: 17 (30%) spouses, 12 (21%) children, 10 (16%) parents, 6 (11%) siblings, 6 (11%) multiple people, 6 (11%) non-relatives.

Figure 2. CONSORT Flowchart



Randomization Check

Table 1 presents the sample data on 30 baseline variables that were compared across treatment groups to determine the success of randomization. At a confidence level of $p < .05$, there were no significant differences between the two groups, and therefore we deemed the randomization to be successful.

Table 1. Characteristics of the full sample and family consultation and control conditions separately

Variable	Total N = 120	Consultation n = 60 (50%)	Control n = 60 (50%)	*t* or χ^2
Demographics				
Age (*M, SD*)	57.5 (14.4)	58.0 (13.9)	56.97 (15.1)	-1.03
Gender (Male)	60 (50.0%)	30 (50.0%)	30 (50.0%)	0.00
Gender (Female)	60 (50.0%)	30 (50.0%)	30 (50.0%)	0.00
Race (Black)	103 (85.8%)	51 (83.0%)	52 (86.7%)	0.08
Race (White)	17 (14.2%)	9 (15.0%)	8 (13.3%)	
Grade > 12th	51 (42.5%)	24 (40.0%)	27 (45.0%)	0.31
Medical risk factors				
Congestive heart failure	58 (48.3%)	28 (46.7%)	30 (50.0%)	0.13
Smoking	71 (59.2%)	35 (58.4%)	36 (60.0%)	0.34
Diabetes	74 (61.7%)	42 (70.0%)	32 (53.3%)	3.53
Hypertension	118 (98.3%)	59 (99.2%)	59 (99.2%)	0.00
COPD	22 (18.3%)	10 (16.7%)	12 (20.0%)	0.22
Blood Urea Nitrogen (*M, SD)*	40.72 (22.65)	38.42 (18.67)	43.02 (26.00)	1.11
Serum Creatinine (*M, SD)*	7.35 (3.65)	6.97 (3.34)	7.74 (3.93)	1.16
Phosphorous (*M, SD)*	4.37 (1.69)	4.12 (1.45)	4.63 (1.88)	1.68
Charlson Comorbidity(*M, SD*)	7.47 (3.14)	7.60 (3.02)	7.33 (3.27)	0.46
Behavioral risk factors				
Psychiatric diagnosis	35 (29.2%)	17 (28.3%)	18 (30.0%)	0.04
Psychiatric medication	30 (25.0%)	14 (23.3%)	16 (26.7%)	018
Substance use history	31 (25.8%)	11 (18.3%)	20 (33.4%)	3.52
Positive tox screen	11 (9.2%)	4 (6.6%)	7 (11.6%)	0.90
Past Year Admissions (*M, SD)*	2.94 (3.06)	2.75 (2.32)	3.13 (3.67)	0.68
Cognitive risk factors				
Delirium	37 (30.8%)	17 (28.3%)	20 (33.3%)	0.35
Positive head imaging	61 (50.8%)	29 (48.3%)	32 (53.3%)	0.30
History of seizures	14 (11.7%)	6 (10.0%)	8 (13.3%)	0.32
History of hypoxia	19 (15.8%)	6 (10.0%)	13 (21.6%)	3.06
Dementia	5 (4.2%)	2 (3.3%)	3 (5.0%)	0.21
Stroke history	10 (8.3%)	4 (6.7%)	6 (10.0%)	0.44
Cognitive impairment	20.5 (4.50)	20.5 (4.79)	20.4 (4.22)	-0.05
Baseline Assessment				
REALM-R (*M, SD)*	5.22 (2.62)	5.29 (2.50)	5.15 (2.75)	-0.29
REALM-SF (*M, SD)*	5.46 (2.11)	5.51 (2.02)	5.42 (2.22)	-0.23
Social Support (*M, SD)*	2.93 (1.00)	2.92 (0.95)	2.94 (1.06)	0.11
Adherence (*M, SD)*	2.38 (0.60)	2.38 (0.57)	2.38 (0.64)	-0.03
Depression (*M, SD)*	6.78 (4.59)	6.88 (4.26)	6.69 (4.94)	-0.22
Anxiety (*M, SD)*	5.29 (4.56)	5.22 (4.13)	5.17 (5.00)	-0.39

Note. *Consultation and control conditions did not differ significantly ($p < .05$) on any of the variables in the table.*

Main Analyses

The 30-day readmission rate for the total sample was 26% (31 patients). As shown in Table 2, there was a marginally lower early readmission prevalence in the consultation (20%) than TAU condition (32%; $\chi^2 = 2.13$, $p = .077$, NNT = 9).

The rate for the presence of any unplanned return hospital visit within 30 days (including inpatient readmissions, emergency department visits, and observation status) was 39% (47 patients). The occurrence of any early hospital return visit was significantly lower in the consultation (32%) than TAU condition (47%; $\chi^2 = 2.83$, $p = .046$, NNT = 7). More specifically, there were 9 more patients with inpatient readmissions in the control condition than in the family consultation condition (27 vs. 14) and 4 more patients with an ED visit (13 vs. 9). There were 3 patients with only observation visits in each group.

For three patients in the treatment group, the intervention could not be completed because we failed to contact a support person for the patient; two of those three were readmitted within 1 month. Excluding these three patients for the per protocol analyses slightly enhanced the condition effects noted above. As shown in Table 3, when those three patients were removed from the analyses, the readmission rate was significantly lower in the treatment group (18%) than in the control group (32%; $p = .039$; NNT = 7). Next, readmission rates were lower in the treatment group (28% vs. 47%) when observation and emergency department visits were added into the equation ($p = .019$; NNT = 6).

Table 2. Main Effect of Condition Assignment on 30-Day Readmissions and Hospital Visits: Intent-to-Treat

	Total Sample (n = 120)	Family Consultation	TAU Control	χ^2	*p*
Intent to Treat Analyses		(n = 60)	(n = 60)		
30-Day Readmit	47 (39%)	12 (20.0%)	19 (31.7%)	2.13	.077
30-Day Any Return Visit	73 (61%)	19 (31.7%)	28 (46.7%)	2.83	.046
Per Protocol Analyses		(n = 57)	(n = 60)		
30-Day Readmit	31 (26%)	10 (17.5%)	19 (31.7%)	3.13	.039
30-Day Any Return Visit	89 (74%)	16 (28.1%)	28 (46.7%)	4.31	.019

The 3-month readmission rate for the total sample was 45% (66 patients). As shown in Table 3, the consultation condition (40%) and the TAU condition (50%; χ^2 = 1.21, p = .141) did not statistically differ on readmission rates. The rate for the presence of any unplanned return visit within 3 months was 61%. For this outcome variable, readmission rates were marginally lower in the consultation condition (55%) and the TAU control (67%; χ^2 = 1.71, p = .075).

Table 3. Main Effect of Condition Assignment on Readmissions and Hospital Visits at Three Months

	Total Sample (n = 120)	Family Consultation	TAU Control	χ^2	*p*
Intent to Treat Analyses		(n = 60)	(n = 60)		
3 Month Readmit	54 (45%)	24 (40%)	30 (50%)	1.21	.141
3 Month Any Return Visit	73 (61%)	33 (55%)	40 (67%)	1.71	.075

One month follow up: Self-Report Measures

We retained 84 patients (70%) for 1-month follow up measures of social support, adherence, depression, and anxiety. The remaining patients were unable to be reached by phone, and did not respond by mail. First, completers (n = 84) and non-completers (n = 36) were compared across all baseline variables. The only significant difference between

groups was that completers were younger than non-completers ($t = 2.06$, $p = .041$). Of the completers, 43 were from the consultation condition, and 41 were from the control group; non-completion was unrelated to experimental condition.

As shown in Table 4, there was no difference in change in social support, adherence, depression, or anxiety between conditions. Furthermore, social support, adherence, depression, and anxiety were meant to be examined as potential mediators of the intervention but were ruled out because the change in these variables at one month was not correlated with the main outcomes.

Table 4. Change in Self-Report Measures Between Groups at One Month Follow-up

	Total n = 84	**Family Consult n = 43**	**Control Group n = 41**	**F**	***p***
Social Support Baseline M (SD)	2.83 (1.08)	2.87 (0.99)	2.79(1.17)	0.19	.662
Social Support 1 month M (SD)	2.94 (0.95)	3.02 (0.90)	2.85 (1.01)		
Social Support Change M (SD)	0.11 (1.04)	0.16 (0.75)	0.06 (1.28)		
Adherence Baseline M (SD)	2.41 (0.59)	2.36 (0.57)	2.45 (0.63)	0.01	.921
Adherence 1 month M (SD)	2.54 (0.50)	2.49 (0.45)	2.60 (0.54)		
Adherence Change M (SD)	0.14 (0.52)	0.13 (0.53)	0.14 (0.51)		
Depression Baseline M (SD)	6.73 (4.67)	7.03 (4.38)	6.41 (5.00)	2.32	.132
Depression 1 month M (SD)	5.60 (4.69)	6.56 (4.90)	4.59 (4.23)		
Depression Change M (SD)	-1.14 (4.09)	-0.48 (4.29)	-1.82 (3.79)		
Anxiety Baseline M (SD)	4.99 (4.52)	5.04 (4.35)	4.93 (4.75)	0.60	.441
Anxiety 1 month M (SD)	4.41 (5.05)	4.81 (5.30)	4.00 (4.81)		
Anxiety Change M (SD)	-0.58 (4.04)	-0.24 (3.77)	-0.93 (4.32)		

Other variables that predicted readmissions

Comorbidities

As shown in Table 5, history of delirium (χ^2 = 11.29, p = .001) and history of positive head imaging (χ^2 = 6.78, p = .009) were both cognitive risk factors that significantly predicted early readmissions.

Baseline Variables

As shown in Table 5, there was a trend such that women were marginally more at-risk for an early readmission than men (p = .061). The MoCA was the only baseline measure that predicted readmissions (p = .015). Baseline social support, adherence, depression, anxiety, and health literacy did not predict readmissions across groups.

Table 5. Relationship of Baseline Variables with Presence of 30-Day Readmission

Variable	Total N = 120	Readmit n = 31 (25.8%)	No Readmit n = 89 (74.2%)	*t* or χ^2
Demographics				
Age (*M, SD*)	57.5 (14.4)	60.32 (14.8)	56.5 (14.2)	-1.27
Gender (Male)	60 (50%)	11 (35.5%)	49 (55.1%)	3.52†
Gender (Female)	60 (50%)	20 (64.5%)	40 (44.9%)	3.52†
Race = Black	103 (85.8%)	29 (93.5%)	74 (83.1%)	2.21
Race = White	15 (12.5%)	2 (6.5%)	15 (16.9%)	
Grade > 12th	51 (42.5%)	15 (48.4%)	36 (40.4%)	0.59
Medical risk factors				
CHF	58 (48.3%)	18 (48.4%)	40 (44.9%)	1.59
Smoking	71 (59.2%)	16 (51.6%)	55 (61.8%)	0.99
Diabetes	74 (61.7%)	19 (61.2%)	55 (61.8%)	0.00
Hypertension	118 (98.3%)	29 (93.5%)	89 (100.0%)	N/A
COPD	22 (18.3%)	5 (16.1%)	17 (19.1%)	0.14
Blood Urea Nitrogen	40.72 (22.65)	36.68 (20.87)	42.12 (23.19)	1.15
Serum Creatinine	7.35 (3.65)	6.84 (3.72)	7.53 (3.62)	0.92
Phosphorous	4.37 (1.69)	4.27 (1.92)	4.41 (1.62)	0.38
Charlson Index	7.47 (3.14)	8.32 (2.98)	7.17 (3.15)	1.78
Behavioral risk factors				
Psychiatric diagnosis	35 (29.2%)	9 (29.0%)	26 (29.2%)	0.00
Psychiatric medication	30 (25.0%)	6 (19.4%)	24 (27.0%)	0.71
Substance use history	31 (25.8%)	9 (29.0%)	22 (24.7%)	0.22
Positive tox screen	11 (9.2%)	4 (12.9%)	7 (7.9%)	0.70
Past Year Admissions	2.94 (3.06)	3.94 (4.32)	2.60 (2.42)	-1.64
Cognitive risk factors				
Delirium	37 (30.8%)	17 (54.8%)	20 (22.5%)	11.29**
Positive head imaging	61 (50.8%)	22 (71.0%)	39 (43.8%)	6.78**
History of seizures	14 (11.7%)	4 (12.9%)	10 (11.2%)	0.06
History of hypoxia	19 (15.8%)	6 (19.4%)	13 (14.6%)	0.39
Dementia	5 (4.2%)	2 (6.5%)	3 (3.4%)	0.55
Stroke history	10 (8.3%)	4 (12.9%)	6 (6.7%)	1.14
MoCA Total	20.47 (4.50)	18.79 (5.66)	21.06 (3.88)	2.47*
Baseline Assessment				
REALM-R	5.22 (2.62)	5.10 (2.92)	5.26 (2.52)	0.27
REALM-SF	5.46 (2.11)	5.24 (2.37)	5.58 (2.01)	0.97
Social Support	2.93 (1.00)	3.01 (0.97)	2.91 (1.02)	-0.47
Adherence	2.38 (0.60)	2.45 (0.59)	2.35 (0.60)	-0.79
Depression	6.78 (4.59)	6.52 (4.10)	6.88 (4.77)	0.38
Anxiety	5.29 (4.56)	4.06 (4.14)	5.58 (4.66)	1.61

Note. † < .10 *p <.05, ** p<.01; N/A – does not meet criteria for Chi Square test

Therapist Post-Session Ratings

The therapist session ratings were analyzed in an exploratory fashion of predictors of readmissions within the family meeting condition. Only one item ("seemed to appreciate the consult") predicted lower risk of an early readmission ($t = 2.26$, $p = .046$).

Moderation Analyses

There was a trend of a moderation that the intervention worked better for patients with higher baseline MoCA scores, but the effect failed to reach significance ($p = .116$). In the consultation condition, readmitted patients had numerically lower cognitive functioning scores ($M = 16.8$, $SD = 6.6$) than patients who were not readmitted ($M = 21.4$, $SD = 3.8$), whereas, in the control group, cognitive functioning scores were similar for patients who were ($M = 20.0$, $SD = 4.7$) and were not ($M = 20.6$, $SD = 4.0$) readmitted. There was also a trend that the intervention worked better for patients with no history of substance abuse (n = 89), but the effect failed to reach significance ($p = .105$). In patients without a history of substance abuse (n = 89), there was a lower readmission rate in the family consult group (16%) versus the control group (35%; $p < .042$). In the 31 patients with a history of substance use, the readmission rate was surprisingly significantly higher ($p = .042$) in the treatment group (36%) versus the control group (25%). Gender and method of contact for the intervention (in person versus phone) did not moderate the efficacy of the intervention.

CHAPTER 4 DISCUSSION

A brief behavioral intervention—consulting with the patients' family members about the patient's cognitive status and other risk factors and the need for better medication adherence—reduces early hospital readmissions and all unplanned hospital visits among patients with ESRD. Many patients with ESRD are at substantial risk for early readmission, particularly due to cognitive impairment, low health literacy, and subsequent nonadherence to medications and dialysis. Intervening with family members in a manner that addresses these deficits reduces the likelihood of early readmission.

The effect size of this family consultation on early readmissions (reducing early readmissions from 32% to 20%) was clinically significant. The effect size (NNT) obtained in this study suggests that only 6 or 7 patients need to receive this consultation to reap the benefits of one patient avoiding an early readmission. We can find no other study demonstrating a comparable reduction in readmission rates in patients with ESRD. On a practical level, the brevity and simplicity of the intervention means that an effect size of the magnitude achieved in this study would be more than enough for the savings of this intervention would outweigh its costs. In this case, a psychology doctoral student conducted the initial assessment, which required about 20 minutes to obtain data on cognitive impairment, health literacy, and social support, and then less than 10 minutes, on average, to provide the consultation. Including time for note writing and chart review, the actual billing in most medical settings would be for one hour, with an estimated cost of $220 for a psychologist in this setting. The average cost per inpatient day in Michigan is $2132 dollars, with a median length of stay of 4.0 days, and the average cost of an emergency room visit is $1233 (Kshirsagar, Hogan, Mandelkehr, & Falk, 2000). Thus,

the total net savings of this intervention are roughly estimated to be at $81,752 for this sample (n = 60), or an average of over $1200 per patient. Beyond the economics, however, are the benefits of improving the health outcomes of substantial numbers of patients.

Notably, this trial has substantial generalizability or external validity in that it excluded few patients, was conducted with high feasibility—at bedside or via telephone—and did not rely on special resources or high involvement from other providers within the nephrology unit. Furthermore, the sample was one that is often viewed as particularly high risk: urban, largely African American patients, with multiple social, economic, and behavioral risk factors. Therefore, we believe that this intervention can readily be implemented on other nephrology units, and perhaps other hospitalized populations with chronic disease and high risk for readmission.

Additionally, I believe that the impact of the intervention was likely attenuated by the lack of integration of the psychologist consultant with the rest of the team in the nephrology unit. Integrated care has been identified as a key predictor of success in behavioral health interventions; therefore, we expect that a greater reduction in early readmissions might occur if the psychologist worked more closely with other providers on the unit, attended interdisciplinary care meetings, and documented behavioral medicine notes in the EHR (Bridges et al., 2015; Crosson, 2009).

It is disconcerting that this basic assessment and family consultation rarely happens in hospitals. Many patients and family members in this trial remarked that no one had ever explained to them that cognitive impairment was common in patients with ESRD, and that such impairment puts them at risk for missing medications and dialysis

treatments, resulting in further hospital care. In addition, some patients reported some mistrust of their providers, which is consistent with the literature on difficult patient-provider relationships in patients with chronic illnesses (Kammerer, Garry, Hartigan, Carter, & Erlich, 2007). With these concerns in mind, it is imperative that providers listen to patients' concerns, assess their risk factors, engage the family in the patient's health care, and build trust to increase their motivation to follow through on discharge recommendations. More research is need to determine how to address this issue, which could result in substantial improvement in care both in patients with ESRD and in the national healthcare system in general.

This study was designed with an effectiveness rather than efficacy framework, and thus did not rely on special conditions, resources, or even above average levels of cooperation from other providers within the nephrology unit. Therefore, we believe that this same intervention could easily be implemented on any nephrology unit. We believe that effectiveness studies are an especially important step in translating research into clinical practice (Glasgow, Lichtenstein, & Marcus, 2003). There is already an abundance of trials demonstrating the efficacy of behavioral health interventions in medical populations such as congestive heart failure and liver disease, but there remains a lack of implementation (Brownson, Colditz, & Proctor, 2012).

One limitation of this study is that we do not know which social, emotional, or behavioral changes family members and patients might have made after the consultation that reduced early readmission rates. Our hypotheses that the family meetings improved adherence by way of social support compensating for patient cognitive impairment or poor health literacy was not supported by the 1-month follow up self-report measures.

The findings (or lack thereof) in the previous paragraph require some explanation. One possibility is that our assessment measures for social support and adherence may have had shortcomings in terms of their validity. For social support, it would have been useful to obtain reports from the family members who participated in the meeting, because it was their behavior that we were actually intending to change. This also would have been useful for a manipulation check about the success of the psychoeducation piece of the meeting. For adherence, we were working with patients with cognitive impairment and a low education level. Therefore, by definition we know that they are likely to be poor historians when reporting on their ability to take their medications on time. More accurate measures of adherence such as electronic pill-boxes or records of dialysis attendance would have been preferable. Overall, the limitations of these assessment measures prevented us from drawing meaningful conclusions regarding the mechanisms of change in this intervention.

Therefore, we suspect that the consultation led the family member or support person to help patients remember to take their medications, even though the self-reported adherence and social support scores in this study do not support this. More than half of the patients with ESRD in the nephrology inpatient population have some cognitive impairment, so it is not surprising that they have difficulty with medication adherence. Although willful nonadherence to the treatment regimen may occur for some patients with ESRD, cognitive deficits remain woefully undetected and unmanaged when discharge planning, and these impairments appear to be a key factor in early hospital readmissions (Jasinski et al., in press). Furthermore, most of the patients in this sample, and many of those with ESRD in general, come from disadvantaged socioeconomic

backgrounds. We believe that this family consultation raises awareness of barriers to adherence such as cognitive impairment and low health literacy, and encourages support people to help patients compensate—and the patient to accept the help—for these challenges. We believe that this family consultation raises awareness of barriers to adherence such as cognitive impairment and low health literacy, and allows support people to help patients compensate for these challenges.

The lack of significant moderating variables suggests that this intervention would be effective across a wide range of patients. However, there were two trends that merit comment. It was surprising that patients with less cognitive impairment seemed to benefit more from the intervention than those with more severe CI. Perhaps instead of this intervention working by family members compensating for patients who were incapable of caring for themselves, this intervention works best through family members helping patients who still have some ability to actively participate in their care and coordinate ways that their support people can help them adhere to their medication regimen. Second, although the moderation did not reach significance, it appeared that the intervention may have worked better in patients with no substance abuse history. This intervention did not target substance abuse, and therefore the same rate of reduction in readmissions may not occur with patients who are actively using. It is possible that substance use overrides any benefits that might be obtained by improved adherence.

Patient-Provider Relationships

These results have implications for the issue of patient-provider relationships. There has been a robust literature linking better patient-provider relationships with better treatment adherence. The idea is that when patients trust their providers more, they are

more likely to follow through on recommendations (Ciechanowski, Katon, Russo, & Walker, 2001). Although it might seem that trusting one's provider should be automatic, our fragmented healthcare system has created situations where providers have little time to actually speak to patients (Nam, Chesla, Stotts, Kroon, & Janson, 2011). This has led to many patients having a great deal of frustration, as the healthcare system often does not meet their expectations (Naidu, 2009).

There are several reasons why patient-provider relationships for patients with ESRD are particularly at-risk for being troublesome. First, research has shown a negative correlation between the complexity of the condition that a patient has and their relationship with their physician (Porcerelli, Murdoch, Morris, & Fowler, 2014). Patients with ESRD are often the most complex cases within the health care system; therefore, it is not surprising that the problem is so glaring in this population. Second, there is a stigma about having ESRD, given that the disease usually results from long-term unmanaged diabetes and hypertension or substance abuse (Hopper, 1981). Therefore, there is a belief that these patients are responsible for their declining health, and they are often reported as being "difficult" to work with. Third, patients with ESRD are disproportionately represented by low SES African Americans, whereas their physicians are more likely to be high SES people of European, Middle Eastern, or Asian descent (Smedley, Stith, & Nelson, 2003). Sometimes, these significant differences in demographics can breed mistrust on the side of the patient.

Although the problems with patient-provider relationships may sound grim, the identification of this problem represents an opportunity for improved care. In fact, it is possible that one of the mechanisms of success of this intervention was through

increasing the trust of patients and their support people support people in the treatment team. As part of the protocol, the researcher spoke to the patients and listened to their concerns, which unfortunately is not something that these patients always encounter. Therefore, it may be that the improved trust might motivate patients to adhere to their treatment plans. Future research should consider the patient-provider alliance as a mediator for this type of intervention.

Iatrogenic Effects of Medicine

Another important reason for decreasing hospital utilization is that there are often iatrogenic effects of hospital stays. For example, there are many infections, such as C. Difficile that are common in hospitals, but patients would rarely be exposed to in their daily lives (Hidron et al., 2008). Additionally, the rate of mistakes by healthcare providers is higher than most people would expect (Naveh, Katz-Navon, & Stern, 2005). In our country, there is a misconception that hospitals are places of healing, when in reality patients are much safer at home, and hospitals should only be used when totally necessary (Lafont, Gérard, Voisin, Pahor, & Vellas, 2011). Yet, the effect of the intervention implies a fundamental lack of attention to discharge planning that would seem to be common sense to most people. With the results of this study exposing these simple flaws in our healthcare system, there will be a greater understanding in public perception regarding the risks of hospitalization.

Socio-Economic Status

Socio-economic status is an issue that factors into the health behaviors of patients with ESRD. This sample of this study would not be appropriate for testing the moderating effects of SES, given that the same was relatively homogenous with mostly

low-income, inner-city African Americans. However, the results demonstrate that an intervention based on psychoeducation can be effective within this population. These patients generally had below average health literacy, and the fact that the intervention was able to work in spite of this is promising. It will be important to continue to develop and test interventions that work with low SES populations, in order to reduce the health disparities nationwide (Goldman & Smith, 2002).

Cognitive Impairment as a Predictor of Readmissions

Hypotheses were confirmed that three indicators of cognitive impairment were predictive of early readmissions: delirium, positive head imaging, and low scores on the Montreal Cognitive Assessment. No other biological/medical risk factors (such as serum creatinine or BUN) predicted early readmissions. There were fewer baseline predictors of readmissions than we expected, although it is possible that the effect of the intervention might have diluted some of these effects. Although this type of study is novel within the kidney disease population, the findings are consistent with a growing cardiology literature showing that cognitive impairment is one of the key factors in early hospital readmissions, but is often ignored in medical settings (Cameron et al., 2010; Dodson et al., 2013; Huijts et al., 2013; Ketterer, Draus, et al., 2014; McLennan, Pearson, Cameron, & Stewart, 2006; O'Donnell et al., 2012). Finally, in addition to confirming that cognitive impairment predicts early readmissions, the results demonstrated that it is possible to identify patients who are at risk and intervene in a way that compensates for cognitive deficits to actually prevent readmissions.

Limitations

First, our outcome measure did not account for readmissions or hospital visits to external health care systems. This means that there might be some missing readmissions in our tally, which would skew our main outcome data, and not be consistent with the method that CMS uses for calculating readmission penalties. However, through phone conversations with patients at follow up, we have reason to believe that such external readmissions were rare, and that they would be randomly distributed across experimental conditions even if they did occur.

Second, only one psychologist was used to conduct the family meetings. The literature has shown that the individual ability of therapists can have a major impact on outcomes, but we did not have other consultants available (Crits-Christoph & Mintz, 1991). Therefore, it is possible that other psychologists might have different levels of success with this intervention. Yet, the therapist's level of training (master's degree) and supervision in this study are roughly consistent with what might be expected from providers administering this intervention in real world settings. Therefore, generalization to other consultants would need to be demonstrated in replication studies.

Next, specific reasons for readmission are complex and not well delineated in medical records. These patients are generally very ill, and linking the intervention to changes in adherence or family relations, and subsequently to health changes needs further study. Finally, it is likely that this intervention is most effective with subsets of patients, such as those with a certain degree of cognitive impairment or certain types of family relations, but our sample was not large enough to reliably test such moderators.

In terms of the implementation of the intervention, we were limited by the inability to contact support people for three patients. However, this likely reflects the reality of clinical practice; overall, we were pleased with the overall rate of contact with support people. Similarly, we would have preferred to have conducted more of the interventions face-to-face. Again, it was important to prioritize completing the intervention over its location, so conducting a portion of them over the phone was expected. However, it is possible that if the intervention were a routine part of the standard of care, that more could have been conducted at bedside.

Conclusions

The results of this study represent the potential for a "win-win" scenario; an intervention that improves patient care while reducing health care expenditures. Therefore, there is a compelling argument for rapidly moving forward to promote and disseminate such interventions of this nature. The next objective would be to run a replication study with a methodology that addresses the aforementioned limitations and greater integration with the rest of the health care team. From a long-term perspective, these results support greater involvement of behavioral medicine in treatment planning. This intervention was carried out by a graduate student in clinical psychology, who was supervised by a senior clinical health psychologist. Therefore, we believe that this intervention could be implemented by mid-level providers such as physician assistants, nurses, and social workers, who are trained and supervised by a health psychologist. Additionally, episodic, longer term follow-up may be necessary in order to maintain the benefits of the intervention. We also think that this same type of family meeting will be successful with other populations of inpatients with chronic diseases where cognitive

impairment is common, such as congestive heart failure or liver disease. As our national health care system shifts from a fee-for-service based model to one that is focused on value, interventions such as this one will become increasingly vital.

APPENDIX A. STUDY DETAILS

FAMILY CONSULT PROTOCOL

1) Introductions:
    a. Introduce self and obtain names of support people present and their relationship to the patient.
    b. Make efforts to establish rapport and trust.
2) Rationale
    a. Friends and family can make a major difference for patients with ESRD in terms of health and quality of life.
    b. Non-threatening language such as "improving stress and coping" to cite rationale for study
    c. *Patients on dialysis have a high rate of being in and out of the hospital over and over. The goal is to keep you healthy and out of the hospital.*
3) History
    a. Review patient/family understanding of events that caused the hospital admission
    b. Empathize with frustration about the burden that their care requires (costs, travel, side effects, insurance, etc.)
    c. To patient: *Many patients on dialysis say that they feel burdened by all of the things they need to do to take care of their health. Do you ever feel that way?*
    d. To support: *How aware are you of the effort [patient] puts in to manage the ESRD condition?*
    e. Assess how involved the support people currently are in terms of managing ESRD
4) Medications
    a. Have patient do clock draw so support people can observe (Goal is to make support people aware of the severity of cognitive impairment)
    b. Discuss practicality of support people helping with medication adherence.
    c. Recommend use of pillbox, and assess how patient refills medications.
5) Cognitive Impairment
    a. Explain how risk of "forgetfulness" or "confusion" increases with renal failure.
    b. "Blame the illness or medications" for these symptoms, in order to avoid stigmatization
    c. Assess subjective experience of cognitive impairment, from patient and support people perspective.
    d. Discuss findings from baseline cognitive screening.
    e. Explain the cognitive symptoms, and how family/friends might notice it before the patient.
6) Wrap Up
    a. Offer to answer any other questions.
    b. Help direct patient and family member to appropriate member of medical staff if I cannot answer the question.
    c. Ask participants to reflect on the meeting
7) As needed: Motivational Interviewing Techniques

a. Throughout the meeting, be mindful of stage of change for both patients and support people in terms of health behaviors (especially medications)
b. Roll with patients/families who display resistance, and/or those in the pre-contemplative stage of change
c. Pros and Cons technique
d. Explore barriers to social support collaboration to medication adherence and communication with patient.
e. Remind participants that the decision is theirs

CONSENT FORM

Mark W. Ketterer, PhD
Henry Ford Hospital/A2
2799 West Grand Boulevard
Detroit, MI 48202

1. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word "you" refers to you throughout the consent form.

You have been asked to take part in a research study because you have spent time as an inpatient in the Nephrology unit at Henry Ford Hospital. The purpose of this research study is to determine how talking about your health care with a family member or friend influences your health.

There will be approximately 150 people in this research study at Henry Ford Health System (HFHS).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin).

Your participation in this study will last up to one month after your discharge from the hospital. As part of this study, you will have no additional visits to the clinic, but will be visited by our research staff once or twice during your hospital stay, and once after your discharge.

At visit 1, you will have the following procedures:

Extra and not experimental:

- *Your records will be reviewed for events that might affect your cognitive status, and your family member may be asked if we may proceed with following you for the study.*
- *You will be asked to complete a series of simple cognitive task in questionnaire form*
- *We estimate the time commitment for you at 20 minutes.*

At visit 2, you will have the following procedures:

Extra and experimental:

- *Within a few days of visit 1, and before you are discharged, we may have a discussion with you and one or more of your family members or friends about how to take care of your chronic illness at home.*
- *We estimate the time commitment for you and your family member at 45 minutes.*
- *This visit applies to only 1 of the 2 randomly assigned groups in the study.*

At visit 3, you will have the following procedures:

Extra and experimental: One month after your discharge from the hospital, we will contact you or your family member by phone to ask a few questions about the self-management of your chronic illness. We estimate the time commitment for you and your family member at 15 minutes.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now.

It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: helping you with self-management of your illness. You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for kidney disease without being in a study, such as the routine care in the Nephrology unit that does not involve meetings with family members or friends.
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Mark W. Ketterer, or his staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Dr. Ketterer at (734-642-8776). Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

You will be paid $20 after completing the first set of questionnaires, and $20 after completing the follow-up phone call. If you complete the study, you will be paid a total of $40. If you do not finish the study, you will be paid for the part that you did complete.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ _____
Signature of Subject Date Time

_____
Print Name of Subject

_____ _____
Witness to Signature Date Time

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date Time

_____ _____

Signature of Person Signing For Subject Date Time

_____

Print Name of Person Signing for Subject and Relationship to Subject*

_____

Print Name of Subject

_____ _____

Witness to Signature Date Time

_____ _____

Signature of Person Obtaining Consent Date Time

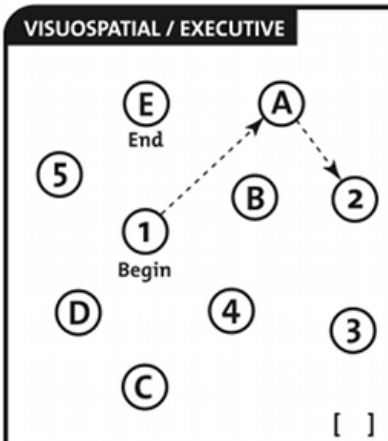
APPENDIX B. MEASURES

MONTREAL COGNITIVE ASSESSMENT

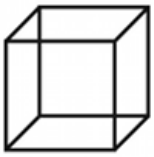
MONTREAL COGNITIVE ASSESSMENT (MoCA)

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS



Copy cube



[ ] [ ]

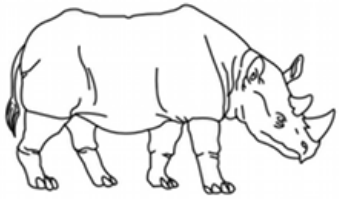
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

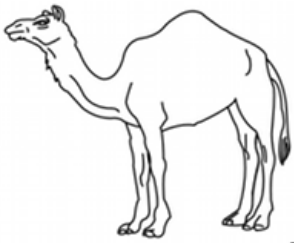
__/5

NAMING

[ ]



[ ]



[ ]

__/3

MEMORY — Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION — Read list of digits (1 digit/sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: 3 2 or 3 correct: 2 1 correct: 1 0 correct: 0

__/3

LANGUAGE — Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency : Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION — Similarity between e.g., banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

		FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUED recall only
	Has to recall words WITH NO CUE	[ ]	[ ]	[ ]	[ ]	[ ]	
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION — [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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06AR34E

Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr education

REALM

REALM-R Examiner Record

Reading Level _____

Patient Name/
Subject # _____ Date of Birth _____ Grade Completed _____

Date _____ Clinic _____ Examiner _____

fat		fatigue	_____
flu		directed	_____
pill		colitis	_____
allergic	_____	constipation	_____
jaundice	_____	osteoporosis	_____
anemia	_____		

Fat, Flu, and Pill are not scored. We have previously used a score of 6 or less to identify patients at risk for poor literacy.

Score _____

REALM-SF Form

Patient name _____ Date of birth_____ Reading level_____

Date _____ Examiner _____ Grade completed _____

Menopause	☐
Antibiotics	☐
Exercise	☐
Jaundice	☐
Rectal	☐
Anemia	☐
Behavior	☐

Instructions for Administering the REALM-SF

1. Give the patient a laminated copy of the REALM-SF form and score answers on an unlaminated copy that is attached to a clipboard. Hold the clipboard at an angle so that the patient is not distracted by your scoring. Say:

   > "I want to hear you read as many words as you can from this list. Begin with the first word and read aloud. When you come to a word you cannot read, do the best you can or say, 'blank' and go on to the next word."

2. If the patient takes more than 5 seconds on a word, say "blank" and point to the next word, if necessary, to move the patient along. If the patient begins to miss every word, have him or her pronounce only known words.

MSSS-5

1. How often is someone available to take you to the doctor if you need to go?

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

2. How often does someone help you take your medications?

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

3. How often is someone available to listen to concerns or worries about your medical care?

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

4. How often does someone help you manage your medical problems?

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

5. How often does someone encourage you to eat the right foods?

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

ITAS-M

1. In the last month, how often did you forget to take your medications?

_____ 0% of the time
_____ 1-20% of the time
_____ 21-50% of the time
_____ More than 50% of the time

2. In the last month, how often were you careless about taking your medications?

_____ 0% of the time
_____ 1-20% of the time
_____ 21-50% of the time
_____ More than 50% of the time

3. In the last month, how often did you stop taking your medications because you felt worse?

_____ 0% of the time
_____ 1-20% of the time
_____ 21-50% of the time
_____ More than 50% of the time

4. In the last month, how often did you miss taking your medications for any reason?

_____ 0% of the time
_____ 1-20% of the time
_____ 21-50% of the time
_____ More than 50% of the time

5. In the last month, how often did you miss your planned dialysis sessions for any reason?

_____ 0% of the time
_____ 1-20% of the time
_____ 21-50% of the time
_____ More than 50% of the time

PATIENT HEALTH QUESTIONNAIRE - 8

Personal Health Questionnaire Depression Scale (PHQ-8)

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?
*(circle **one** number on each line)*

How often during the past 2 weeks were you bothered by...	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3

Scoring

If two consecutive numbers are circled, score the higher (more distress) number. If the numbers are not consecutive, do not score the item. Score is the sum of the 8 items. If more than 1 item missing, set the value of the scale to missing. A score of 10 or greater is considered major depression, 20 or more is severe major depression.

GAD-7

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

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

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Inern Med.* 2006;166:1092-1097.

Stress and Health Interview
Psychologist Post-Treatment Rating Form

Patient ID: Psychologist:

Date of session: Start time: Duration of session (minutes):

Location: Support Present:

Overall Ratings:

(0 = not at all 1 = a little 2 = moderately 3 = quite a bit 4 = a lot)

___ baseline involvement of support
___ was interested or motivated to participate
___ learned the material being taught
___ was focused on and attentive to the session content (rather than tangential or distracted)
___ participant / psychologist interactions were positive
___ developed greater awareness of barriers to adherence
___ seemed to appreciate the consult
___ Lives with someone (1 = yes, 0 = no)

Session Content Checklist:
___ Provided rationale
___ Included reasons why it will benefit the support people for them to help
___ Reviewed patient/family understanding of events that caused the hospital admission
___ Empathized with frustration of managing chronic illness
___ Showed clock draw
___ Practical issues of support people involvement
___ Pillbox and medication adherence
___ Explained how "forgetfulness" can occur with renal failure and medications
___ Anxiety and/or depression
___ Substance Abuse

Additional Comments:

_____

_____

_____

_____

_____

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ABSTRACT

FAMILY CONSULTATION TO REDUCE EARLY HOSPITAL READMISSIONS AMONG PATIENTS WITH END-STAGE RENAL DISEASE: A RANDOMIZED CLINICAL TRIAL

by

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Background: The U.S. Centers for Medicare and Medicaid Services have mandated reducing early hospital readmissions (i.e., within 30 days of discharge) to both improve patient care and reduce expenses. Patients with end-stage renal disease (ESRD) have relatively high early readmission rates, due in part to their complex medical regimens but also cognitive impairment, health literacy problems, and lack of social support. We developed a brief family consultation intervention to address these problems and tested its ability to reduce early readmissions among patients with ESRD.

Method: 120 hospitalized adults with ESRD (*M a*ge = 57.5 years; 50% male; 86% Black, 12% White) were recruited from an urban, inpatient nephrology unit. Patients were randomized to family consultation (FC; n = 60) or treatment-as-usual (TAU) control (n = 60) conditions. Family consultations, conducted either bedside or via telephone, were conducted with 57 of the 60 assigned patients and covered psychoeducation about cognitive and behavioral risk factors for readmission and how to compensate for them. Blinded medical record review was conducted later to determine readmissions within 30 days.

Results: Chi-square tests and logistic regressions tested intervention effects. Per protocol analyses (excluding three FC patients who received no consultation) indicated that FC reduced early readmission (18%) after discharge, compared to TAU (32%; $\chi = 3.13$, $p = .039$), and reduced any early hospital return visit (emergency department, brief observation, or readmission) compared to TAU (28% vs. 47%; $\chi = 4.31$, $p = .019$). Intent-to-treat analyses revealed that FC marginally reduced readmission (20%) compared to TAU (32%; $\chi = 2.13$, $p = .077$), but FC still significantly reduced any hospital visit (32%) compared to TAU (47%; $\chi = 2.83$, $p = .046$).

Discussion: A brief psychosocial intervention with family members can decrease readmissions in patients with ESRD, thereby improving health outcomes and reducing costs.

AUTOBIOGRAPHICAL STATEMENT

The author was born and raised in the Maryland suburbs of Washington, D.C. He attended St. Anselm's Abbey School for high school, the Pennsylvania State University for college, and Wayne State University for graduate school. He is currently completing his predoctoral internship at the John D. Dingell VAMC in Detroit, MI. For 2017-2018, he will be completing his postdoctoral fellowship at the Washington DC VAMC.