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PROBLEM-SOLVING THERAPY FOR DEPRESSED OLDER HEMODIALYSIS PATIENTS: A PILOT RANDOMIZED TRIAL

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Abstract
Depression is the most common mental health problem reported among dialysis patients. Problem-Solving Therapy (PST) is effective for treating depression in patients with chronic illness, but its acceptability has never been reported in older hemodialysis patients, and its association with health-related quality of life is unknown. We investigated the feasibility and effectiveness of PST in HD patients by assessing changes in depressive symptoms and health related quality of life after six weeks' PST therapy at a single, hospital-based chronic hemodialysis unit in central Pennsylvania. Thirty-five patients were randomly assigned to either six weekly sessions of PST-Usual Care or Usual Care. Depression, quality of life, and problem-solving ability were measured at baseline and post-treatment. Thirty-three subjects completed the study; one subject died and one subject withdrew due to illness (both randomized to the PST intervention group). At baseline, subjects in each arm were similar except that patients in the intervention group were more likely to have a history of depression (control group (16.6%), intervention group (53.5%). At six weeks, there were no significant differences in mean PHQ and BDI scores between the groups; however, mean change-from-baseline scores were significantly improved in the intervention group relative to the control group. When adjusted for baseline depression scores, mean 6-week BDI and PHQ scores were significantly lower in the intervention group. Results of this pilot study suggest that PST provided to maintenance hemodialysis patients on-site holds promise for reducing depressive symptoms, though more extensive studies need to be conducted.

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Dedications

This research study is dedicated to the 33 individuals who so graciously volunteered their time to participate in this study and provided me with a better understanding and appreciation of all of the challenges that they face in dialysis and in life. Although I have spent the last 15 years working with dialysis patients and their families, this study provided me with new insight into coping with chronic illness and an unforgettable opportunity to engage in innovative practice with a population that I care deeply about.

I also dedicate this dissertation to the thousands of renal caregivers, including medical providers, family members, friends, and communities, who daily devote their lives to caring for individuals with chronic kidney disease. It is the support of these individuals and the resilience of patients that provide hope for continued progress in effectively treating depression and improving overall quality of life in dialysis patients.

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ABSTRACT

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Shiloh D. Erdley

Dissertation Mentor and Chair, Zvi Gellis, PhD

Depression is the most common mental health problem reported among dialysis patients. Problem-Solving Therapy (PST) is effective for treating depression in patients with chronic illness, but its acceptability has never been reported in older hemodialysis patients, and its association with health-related quality of life is unknown. We investigated the feasibility and effectiveness of PST in HD patients by assessing changes in depressive symptoms and health related quality of life after six weeks' PST therapy at a single, hospital-based chronic hemodialysis unit in central Pennsylvania. Thirty-five patients were randomly assigned to either six weekly sessions of PST-Usual Care or Usual Care. Depression, quality of life, and problem-solving ability were measured at baseline and post-treatment. Thirty-three subjects completed the study; one subject died and one subject withdrew due to illness (both randomized to the PST intervention group). At baseline, subjects in each arm were similar except that patients in the intervention group were more likely to have a history of depression (control group (16.6%), intervention group (53.5%). At six weeks, there were no significant differences in mean PHQ and BDI scores between the groups; however, mean change-from-baseline scores were significantly improved in the intervention group relative to the control group. When adjusted for baseline depression scores, mean 6-week BDI and PHQ scores were significantly lower in the intervention group. Results of this pilot study suggest that PST provided to maintenance hemodialysis patients on-site holds promise for reducing depressive symptoms, though more extensive studies need to be conducted.

Keywords: problem-solving therapy, depression, randomized trial, older dialysis patients

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Chapter 1: Introduction

1.1 Statement of the Problem

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. In order to survive, patients diagnosed with ESRD must either choose dialysis, a medical treatment that removes wastes and fluid from the body, or kidney transplantation. Only thirty percent of dialysis patients receive transplants due to medical ineligibility or low supply of available donor kidneys. In 2008, it was estimated that 16 percent or 33 million Americans were living with chronic kidney disease (USRDS, 2010). Of patients on dialysis, those aged 75 and older represent the fastest-growing group of dialysis patients, whereas the 45-to-63 year old group drives the total number of new ESRD cases (USRDS, 2008). Additionally, Medicare expenditures for ESRD in 2008 in the United States were $26.8 billion, comprising 5.9 percent of the total Medicare budget (USRDS, 2010). The rise in the number of older dialysis patients, combined with the individual and societal cost of ESRD, makes addressing the mental health needs of this population a priority.

Depression is the most common mental health problem reported for dialysis patients (Cohen & Germain, 2005). In older patients, depressive symptoms are often underreported and misdiagnosed (Chilcot, Wellsted, Da Siva-Gane & Farrington, 2008; Gellis, 2009). These patients present with diverse and complex mental and physical concerns that make managing their needs one of the greatest challenges in the profession. Geriatric dialysis patients are characterized by high symptom burden, multiple comorbidities, and high mortality rates (Lopes, Albert, Young, Satayathum, Pisoni,

Andreucci, et al., 2004). The disease trajectory of this population is similar to that of patients with cancer, lung disease, and advanced heart failure (Swidler, 2010).

Additionally, complications introduced by the hemodialysis treatment are compounded by the functional and cognitive impairments with which these patients initially present (Anand, Kurella Tamura, & Chertow, 2010). Older patients frequently report symptoms of depression associated with loss of independence, changes in diet, fewer social support systems, and increased reliance on family members, medical teams, and community programs to maintain an adequate quality of life. Besides dependence on a dialysis machine for survival, changes in transportation access, finances, employment status, and relationships can also lead to compounding life stressors. In short, this life-sustaining, resource-weighted treatment involves innumerable lifestyle changes that introduce barriers to improved health in this population, resulting in higher demands on renal care teams and the healthcare industry. An in-depth understanding of patients' coping skills and problem-solving ability will help patients manage their daily living activities related to their medical condition and reduce daily stressors.

Scant literature exists on the coping and problem-solving abilities of older dialysis patients. Previous studies propose that there is a link between coping, problem-solving ability, and depression among dialysis patients (Takaki et al., 2005; Welch & Austin, 2001). Cos (2008) found that, in general, dialysis patients who use effective coping strategies experience lower rates of depression. Despite limited research on coping in dialysis patients, the relationship between coping, problem-solving ability, and depression has been well documented in chronically ill populations who present with disease trajectories comparable to those of dialysis patients (Gellis & Bruce, 2010; Gellis & Kenaley, 2008;

Malouff, Thorsteinsson, & Schutte, 2007; Nezu, A., Nezu, C., Felgoise , McClure & Houts, 2003). Some studies suggest that depressive symptoms potentially weaken daily problem-solving abilities by affecting learning, memory, reasoning, and speed of processing (Yung-Chieh, Rebok, Gallo, Jones & Tennstedt, 2011). Several models have expanded on coping skills: one that clearly seems to be relevant for chronically ill older patients is Social Problem Solving (SPS). This model fits this population well because older patients are required to deal with daily living stressors and cope with many physical and emotional side effects of the chronic illness.

By systematically analyzing cognitive and behavioral strategies, SPS model explains how individuals cope with daily-life problems (D'Zurilla & Goldfried, 197; Nezu, Maguth-Nezu, & D'Zurilla, 2010). This approach focuses on both problem-solving orientation and problem-solving style in relation to how patients react to and manage these problems. Research on SPS demonstrates that different styles of coping often mediate the relationship between elevated stressors and depression (D'Zurilla, Nezu, & Maydeu-Olivares, 2004). In dialysis patients, Cos (2008) found that SPS can help to buffer the effects of stressors on symptoms such as depression. Given these findings, it is clear that effective interventions that target individual coping and problem-solving ability are needed.

Problem-solving therapy (PST), developed by Nezu and D'Zurilla, is an evidence-based intervention grounded in the social-problem-solving SPS model. PST trains clients to use adaptive problem-solving attitudes and skills to reduce psychopathology and improve quality of life (Gellis & Nezu, 2011; Nezu, Maguth-Nezu,, & D'Zurilla, 2010). PST has demonstrated effectiveness in older geriatric samples, specifically with medically ill patients with similar disease trajectories, such as cardiac and cancer patients (Gellis &

Bruce, 2010; Doorenbos, Given, Given, Verbitsky, Cimprich & McCorkle, 2005). Additionally, PST shows promising results in reducing depression in older in-home medical patients (Gellis et al., 2008). Given the success of this intervention with comparable populations, PST appears to be a suitable depression intervention for older dialysis patients and can be provided by trained renal social workers.

Chapter 2: Literature Review

2.1 Overview of Chronic Kidney Disease (CKD)

According to the 2010 USRDS report, Medicare expenditures for ESRD in 2008 were $26.8 billion, comprising 5.9 percent of the total Medicare budget (USRDS, 2010). Moreover, while CKD patients represent only 10.3 percent of the general Medicare population they use 28.4 percent of the Medicare budget. According to the United States Renal Data System (USRDS), CKD is a public health problem that affects over 33 million Americans, or 16 percent of the U.S. population (USRDS, 2011). According to 2008 data, there are approximately 550,000 combined dialysis patients and kidney transplant recipients, and kidney failure remains the ninth leading cause of death in the United States, claiming 88,620 lives in that year. (Minino, Xu, & Kochanek, 2010).

Description of CKD

CKD occurs when the kidneys are no longer fully capable of achieving their tasks of cleansing the blood of toxins and maintaining fluid, electrolyte, and hormone balance. Although genetic diseases and birth defects can cause kidney disease, diabetes is the leading cause of failure, with high blood pressure as the second most common. Individuals diagnosed with CKD are classified into five stages, depending upon their level of kidney function, as expressed in terms of glomerular filtration rate (GFR). GFR estimates how much blood flows through the filtering units, called glomeruli, of the kidneys. As kidney function declines, so does the GFR [see Table 1].

Table 1: Classification of the Stages of CKD

Stage 1	Kidney damage with normal or increased GFR	GFR >90 mL/min/1.73 m^2
Stage 2	Kidney damage with mild reduction in GFR	GFR 60-89 mL/min/1.73 m^2
Stage 3	Moderate reduction in GFR	GFR 30-59 mL/min/1.73 m^2
Stage 4	Severe reduction in GFR	GFR 15-29 mL/min/1.73 m^2
Stage 5	Kidney failure	GFR < 15 mL/min/1.73 m^2 (or dialysis)

2002, K/DOQI

According to the National Kidney Foundation, a normal GFR is 90 to 120 milliliters per minute per 1.73 m^2 (mL/min). Patients in stages 1 to 2 have a normal or mildly reduced GFR. Individuals with a GFR less than 60 mL/min for more than three months are considered to have CKD and will fall into the remaining stages, 3 through 5. A GFR of less than 60 mL/min indicates a loss of 50 percent or more of normal adult kidney function (Peter, 2007). Patients with a GFR of less than 15 mL/min are classified into stage 5 CKD, which is also considered to be End Stage Renal Disease (ESRD). These patients are faced with treatment options of renal replacement therapy (RRT), kidney transplantation, or medical management with eventual end-of-life support.

Incidence and prevalence of ESRD

ESRD census projections for 2020 reveal significant implications for clinical practitioners and for policy-makers. The various social forces expected to drive up the overall incidence and prevalence include an increasing rate of diabetes, the aging of the baby boomer population, and improvements being made in CKD treatments. The Third National Health and Examination Survey (NHANES III) estimates that CKD is trending upwards in stages 1 through 3, with approximately 50 percent representing stage 3, while

trends for ESRD, or stage 5, have leveled off (USRDS, 2011). The fact that many in the stage 3 CKD group undergo early death caused by cardiovascular diseases provides an explanation for the slow growth of the ESRD population since 2008 (USRDS, 2011).

The impact of CKD on public health is compounded by various medical burdens involved with this population. In 2008, over 110,000 Americans began treatment for ESRD, and for every ten new cases, seven had diabetes or hypertension (HTN) listed as the primary cause of kidney failure (USRDS, 2011). Diabetes (44 percent) and HTN (28 percent) account for 72 percent of all new ESRD cases in the United States (USRDS, 2010). Chronic diseases such as diabetes, HTN, and cardiovascular disease (CVD) share a complex relationship whereby each can either cause or contribute to the development of the other. This is primarily explained by the similar risk factors such as obesity, old age, family history, and ethnicity that these conditions share. These comorbidities in patients often lead to increased disease severity, greater complications in clinical management, and increased healthcare costs (CDC, 2010; USRDS, 2010).

Age, race, and ethnicity additionally play a role in the prevalence of CKD. Almost 50 percent of U.S. patients who have CKD in stages 1 through 3 are age 65 and older, and almost half of new ESRD cases are in this same age group (USRDS, 2010). Age remains the primary predictor of CKD in people age 65 and older, with diabetes as a secondary predictor of CKD in this population (USRDS, 2010). In regards to ethnicity, U.S. CKD rates are higher among minority populations when compared to Caucasians. In particular, African Americans are nearly four times more likely than Caucasians to progress to kidney failure earlier and more quickly (USRDS, 2010).

Comorbidities/disease severity

The severity of illness in the dialysis population is often defined as the extent to which one's kidney disease affects individual functional ability as well as how it impacts the family and society at large (Weisbord et al., (2005). Many symptoms associated with ESRD make quantifying and qualifying the disease severity challenging. Despite efforts to clarify the prevalence, severity, and clinical significance of symptoms in ESRD patients, understanding of symptoms burden in the renal community remains incomplete (Abdel-Kader et al., 2009; Weisbord et al., 2005).

Disease severity in dialysis patients includes the comorbid medical conditions associated with kidney disease such as diabetes; peripheral vascular disease (PVD); heart disease; and the side effects of dialysis treatment, including blood pressure, excessive thirst, nausea, and vomiting. However, renal failure alone is a dramatic risk factor for cardiovascular death. Furthermore, rates of all-cause mortality (adjusted for gender and race) are 6.7 to 8.5 percent higher than for the general population and are representative of a group of patients with incurable cancer (Arnold & Zeidel, 2009; USRDS, 2009).

Multiple aspects of ESRD make this condition difficult to treat. The myriad of physical and medical complications faced by this population creates a cycle of illness in which the cause or effect of a problem is not easily identified or resolved. A link to ameliorating disease severity and slowing the progression of the disease is early referral to a nephrology team for management of CKD. Large-scale educational efforts are being made to inform the general public about and screen for CKD.

Medical treatment options for ESRD

Once an individual reaches ESRD, medical intervention or renal replacement therapy (RRT) is imminent. Options for treatment include hemodialysis (HD) or peritoneal dialysis (PD), either of which can be performed in a variety of settings, in-center or in-home. During HD, a dialysis machine using a special filter called a dialyzer cleans the toxins (metabolic waste products) from the patient's blood. The patient requires a surgically created "access," usually in the arm, by which to easily and safely enter their blood vessels to pump blood through the dialyzer. In PD, the patient's peritoneal lining acts as a natural filter. After having a catheter surgically placed into the abdomen, several daily "exchanges" are performed, whereby dialysate is drained in and out of the peritoneal cavity as toxins are filtered across the peritoneal membrane.

Table 2: Types of Renal Replacement Therapy for End Stage Renal Disease

Hemodialysis (using a surgically created "access" in the arm)	In-center	Advantage: treatments are performed by staff Disadvantage: dietary restrictions are severe
	In-center nocturnal	Advantages: treatments are performed by staff, easier clearance of fluid and phosphorus, blood pressure generally better controlled Disadvantage: patients sleep at the unit three nights per week
	In-home	Advantages: patients can be dialyzed in the comfort of their own home, not reliant on unit schedules or transportation, slightly fewer dietary restrictions Disadvantage: intensive training to learn how to perform treatments
Peritoneal Dialysis (using a surgically placed catheter into the patient's peritoneal cavity)	In-home Continuous Ambulatory Peritoneal Dialysis (CAPD)	Advantages: fewer staff, less restricted diet, patients can be dialyzed in the comfort of their own home Disadvantage: intensive training to learn how to perform treatments
	In-home Continuous Cycling Peritoneal Dialysis (CCPD)	Advantages: fewer staff, liberalized diet, patients can be dialyzed in the comfort of their own home Disadvantage: intensive training to learn how to perform treatments

Numerous factors go into deciding the most suitable RRT choice for an individual [refer to Table 2]. In-center HD and in-home PD are two of the most commonly utilized choices. In-center HD is typically done in a clinic thrice weekly for three to four hours per treatment. It can also be performed nocturnally, whereby the patient sleeps at the clinic thrice weekly as they are dialyzed for approximately six to eight hours per treatment. The benefit to this option is longer time in which blood can be filtered and fluid removed, resulting in a gentler and more effective "cleaning" of the blood. One must be comfortable, however, sleeping at the unit three times per week. Both of these HD options require dialysis staff to perform the treatment. Certain patients may opt for in-home HD, using a portable hemodialysis machine. This requires the patient to be able to provide self-care, as it involves extensive medical training on how to carry out the procedure.

Patients who choose, or who are only medically appropriate for, in-center HD have significant fluid and dietary restrictions that they must follow in order to remain stable and healthy. Because dialysis does not fully compensate for healthy kidneys, fluid, potassium, sodium, and phosphorus can accumulate in patients between their treatments, which can lead to detrimental health effects. Consequently, patients generally need to limit their intake of fluids, salts, and phosphorus. Dietary restrictions may include avoiding enjoyable foods such as chocolate, potatoes, bananas, ice cream, and tomatoes. Fluid restrictions can be as low as 32 to 40 ounces per day. Patients who do not adhere to their diet and fluid restrictions can experience uncomfortable dialysis treatments that involve severe muscle cramping and drops in blood pressure. More importantly, noncompliance with phosphorus and potassium restrictions can lead to painful bone disease or cardiovascular events, including cardiac arrest and even death.

In-home PD is performed independently or with the assistance of a caregiver or aide. The two major types of PD are Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD). CAPD is a manual procedure that involves the patient completing four to five exchanges of dialysis fluid daily. CCPD involves the removal of wastes through the peritoneal cavity via a special machine called the cycler and is completed throughout the evening hours while the patient sleeps. PD provides a certain amount of flexibility over in-center HD, as patients can perform the exchanges in the comfort of their home. Additionally, PD is performed every day, lending to fewer fluid and dietary restrictions when compared to patients utilizing HD as a form of RRT.

2.2 ESRD Among Older Adults

The rate of growth in the numbers of older hemodialysis patients, coupled with the multitude of complex social and medical issues, warrants further exploration of the psychosocial needs of this frail group. To provide effective interventions resulting in positive outcomes, renal health care teams working with older dialysis patients may benefit from an expanded knowledge base in geriatrics. This understanding could help older dialysis patients maintain independence and quality of life through optimal mental capacity and physical functioning.

Comorbidities

In the general population, people over the age of 75 are typically diagnosed with more than three chronic medical problems (Anand et. al, 2010; American Society of Nephrology, on line). The addition of dialysis to the existing course of aging results in a disease trajectory that involves frequent hospitalizations, acute physical complications, multiple comorbidities, high symptom burden, caregiver stress, and advancing declines in

mental health (Swidler, 2010). Older patients experience a multitude of symptoms such as pain, fatigue, insomnia, unintentional weight loss, neuropathy, and depression. As CKD and ESRD prevalence rises in this population, the incidences of functional disability, cognitive dysfunction, and depression increase (Swidler, 2010).

Studies have demonstrated high rates of frailty in older dialysis patients and have reported a significant correlation between symptoms of frailty and increased morbidity, hospitalization, nursing home placement, and mortality (Jassal & Watson, 2009; Rothman, Leo-Summers & Gill, 2008; Rockwood, 2005, Kutner, 2008). Fried et al. (2001) define frailty as a person who exhibits three of five symptoms: (1) unintentional weight loss, (2) self-reported exhaustion, (3) slow gait, (4) weakness, and (5) low physical activity. Studies suggest that older patients with impaired renal function are at higher risk for frailty than older individuals with normal renal function (Shlipak et al., 2004).

Cognitive impairment in older hemodialysis patients appears to increase over time in conjunction with kidney disease progression and the introduction of comorbid medical problems such as diabetes, peripheral vascular disease, cerebrovascular disease, and anemia (Jassal & Watson, 2008; Kurella, Chertown, Luan, & Yaffe, 2004; Murray, Tupper, Knopman, Gilbertson, Pederson, Smith et al., 2006). Murray et al., (2006) discovered that in a study involving 338 hemodialysis patients over the age of 55, 36% had moderate and 37% had severe cognitive impairment, and that furthermore severe cognitive impairment was 3.5 times more frequent in hemodialysis patients than in age-matched controls.

Given the disease trajectory of this population, it is no surprise that many older patients suffer from regular depressed moods. High symptom burden in older hemodialysis patients and the resulting life-altering changes in daily activities often result in decreased

quality of life and increased reports of psychological distress (Davison, 2007). More than cognitive impairment or age, depression in older dialysis patients is linked with a higher risk for falls and poor outcomes, such as decreased daily functioning and social interactions (American Geriatric Society, 2001; Kamholz & Unutzer, 2007). The physical and mental symptoms of older hemodialysis patients can have a substantial impact on both the patient and society when they are not adequately recognized, diagnosed, or treated in this population. This critical area of practice will need to be a priority for renal health care professionals over the next decade (Davison, 2003; Davison, 2007; Weisbord et al., 2005).

Consequences of ESRD in older adults

The use of hemodialysis to support older patients diagnosed with ESRD continues to rise in response to the growing numbers of older patients and improvements in life expectancy (Anand et al., 2010). How this growth is managed will have significant individual and social consequences. In comparison to hemodialysis patients aged 65 and younger, those over the age of 65 utilize on average 10-35% more per patient dialysis expenditures (Wright, 2009). Additionally, studies demonstrate that this phenomenon in older hemodialysis patients is expected to contribute to a significant increase in hospitalizations, medical complications, truncated life expectancy, and nursing home placement over the next 20 years (Cook & Jassal, 2008: Desmet, Beguin, Swine & Jadoul, 2005; Brunori, Viola, Maiorca, & Cancarini, 2008).

Furthermore, older dialysis patients in nursing home settings are at greater risk for mortality and disease-related problems than are their non-nursing home counterparts, including loss of functional ability and decreased mental status (USRDS, 2004). Moreover, decreased activity, sleep disturbances, and reduced kidney function can also contribute to

negative changes in nutritional status in this population. Older patients are more likely to present with decreased caloric and protein intake, increasing risk for malnutrition and mortality (Lacquaniti, Bolignano, Campo, Perrone, Donato, Fazio, et al., 2009). Moderate-to-severe malnutrition is a prevalent cause of death in older dialysis patients, occurring in 10 to 30 percent of this group. Evidence suggests that the myriad of physical, cognitive, and mental health problems that older hemodialysis patients experience are major challenges to their quality of life (Kutner, 2008). Therefore it is essential for renal health care professionals to recognize the mental and physical aspects of hemodialysis treatment in older patients in order to provide effective interventions.

2.3 Depression in the ESRD Population

Incidence and prevalence of depression in the general ESRD population

Research suggests that 20-25% of prevalent ESRD patients have a comorbid diagnosis of clinical depression, and that least 35% more present with symptoms that put them at risk for depression (Cukor, Peterson, Cohen, & Kimmel, 2006; Cukor, 2007). Depression in ESRD patients is often multifactorial and typically attributed to feelings of loss and dependence (Davison, 2007). Further, studies indicate that, in comparison to the general population, ESRD patients experience more frequent depressive symptoms (Kessler et al., 2003; Tossani, Cassano, & Fava, 2005; Watnick, Wang, Demadura, & Ganzini, 2005). Increasingly, evidence points to depression being the most common mental health problem faced among dialysis patients (Lopes et al., 2004; Wilson et al., 2006).

Despite reports of high depression rates in this population, few patients receive treatment for their symptoms (Chilcot, Wellsted, & Farrington, 2008; Guzman & Nicassio, 2003; Sledge et al., 2011). Additionally, depression is reported more frequently among in-

center hemodialysis patients than in those being treated via in-home dialysis modalities and is linked to mortality and morbidity (Chilcot, Wellsted, & Farrington, 2008). Reasons for this difference include the unique challenges faced by hemodialysis patients, including loss of independence, dietary restrictions, the monotony of thrice-weekly treatment, and changes in functional status (Cournos & Goldfinger, 2007). Given the correlation between depressive symptoms and adverse outcomes such as mortality, hospitalization, and patient quality of life, overcoming barriers to identification and treatment of depressive symptoms in ESRD patients is of great importance.

Although depressive symptoms are reported by a large percentage of dialysis patients, it is important to recognize that being depressed is not a "normal" aspect of treatment. Dialysis patients may report feelings of distress related to their treatment needs, but may not experience clinical depression as defined in the DMS-IV. Depression can be accurately identified in most dialysis patients and successfully treated (Prescott, 2006; Cohen et al., 2007). Furthermore, findings suggest that an increased depressive affect alone in this population can result in poor outcomes, warranting expanded efforts for assessment and treatment (Kimmel & Peterson, 2005).

Depression among older hemodialysis patients

Little information is available regarding prevalence of depression in older dialysis patients. What is known is that the majority of individuals starting dialysis are age 65 and older, and that depression is the most commonly encountered mental health problem in the general dialysis population (Cukor et al., 2008; Cukor et al., 2006; Kimmel & Peterson, 2006). These factors alone indicate that older dialysis patients are at high risk for developing depressive symptoms. In order to provide adequate care and prevent adverse

outcomes, a better understanding of this subpopulation's depressive symptoms and treatment needs is a priority for the renal-care profession.

Several factors likely influence the degree to which older patients experience depressive symptoms; however, high symptom burden appears to be a risk factor (Davison, Jhangri, & Johnson, 2006). Research indicates that approximately 50 percent of dialysis patients over the age of 55 experience chronic pain; only 18 percent report mild or no pain (Weisbord, et al., 2005; Davison, 2003). Furthermore, depression is associated with increased morbidity and mortality in older dialysis patients (Balogun, R., Turgut, Balogun, S., Holroyd, & Abdel-Rahman, 2011; Giordano et al., 2007; Watnick et al., 2005). Research suggests that the degree of mental symptoms, such as anxiety and depression, reported by older dialysis patients is similar to symptoms reported by hospitalized cancer patients receiving palliative care, making therapeutic intervention a vital mission in this population (Davison et al., 2006).

Consequence of depression in ESRD

Literature suggests that depressive symptoms in ESRD patients can lead to a level of physical and mental unrest unlike that of any other chronically ill population (Boulware et al., 2006). Social support, severity of illness, perceptions of illness, and stigma associated with illness and mental health symptoms are all factors associated with depressive symptoms in ESRD patients (Roberts & Johnstone, 2006). ESRD patients with depression are likely also to present with poor concentration and motivation that may cause them to forget important information about their condition. Depression in this population can also present as secondary to decreased functional and cognitive ability, financial and family

stress, reduced sexual function, and various lifestyle changes including dietary and daily routine.

A significant amount of research conducted on ESRD patients demonstrates a link between depression, health-related quality of life scores, adherence to treatment, suicide, and mortality (Drayer et al., 2006; Hedayati, Bosworth, Briley et al., 2008; Khalil & Frazier, 2010; Kimmel et al., 2005; McCool et al., 2011). Patients can experience decreased motivation to participate in their care, ultimately leading to poor medical and psychological outcomes. Patients may experience increased hospitalizations, increased discomfort in treatment stemming from nonadherence to diet and medication regimens, less satisfaction with social and family relationships, greater exploration of withdrawal from treatment, and death. As renal providers gain a clearer understanding of the multiple ways in which depression can affect dialysis patients, they can devise protocols that specifically target problem areas.

Little information to explain the high incidence of nonadherence in ESRD exists. However, some available information suggests that a myriad of factors may influence patient adherence, including individual demographics combined with psychosocial factors, such as depression and lack of social support (Taskapan et al., 2005). Hemodialysis patients are required to follow a strict treatment regimen that requires a commitment to thrice-weekly dialysis, harsh renal diet and fluid restrictions, and a complex medicine schedule (Sharp, Wild, & Gumley, 2005). Nonadherence to these treatments can result in poor short-term and long-term outcomes, such as frequent hospitalizations, development of additional comorbidities, and death (Denhaerynck et al., 2007; Khalil & Frazier, 2010). Despite these consequences, approximately 50 percent of patients with ESRD are partially

or totally nonadherent to their dietary prescriptions (Kugler, Valmick, Haverich, & Maes, 2005).

In addition to various other adverse events, depression is reported to be a significant predictor of withdrawal from dialysis (McDade-Montez, Christensen, Cvengros, & Lawton, 2006). Withdrawal of dialysis treatment occurs in 20 percent of patients before their deaths and is reportedly highest among older dialysis patients (Cohen & Germain, 2005). Although typically, withdrawal from treatment is considered a rational decision made according to patients' right to self-determination, it is very important that these patients receive careful assessment for depression. Diagnosing depression in the context of a terminal disease such as ESRD is complicated at best. "It is unclear whether the wish to die is normative for some—or even most—individuals who want an end to an unpleasant or unrecognizable existence" (Cohen, Dobscha, Hails, Penelope, Pekow & Chochinov, 2002, p. 893). Some research suggests that the psychological experiences of ESRD patients with multiple comorbidities can be best described as anticipatory grief rather than depression (Cohen et al., 2002). Despite the differing views over diagnosing depression in dying dialysis patients, most agree that more research is needed in this challenging area.

Historically, depression has also been associated with increased healthcare costs and utilization of services (Edgede, Zheng, & Simpson, 2002; Evans et al., 1997; Welch, Czerwinski, Ghimire, & Bertsimas, 2009). Kimmel (2002) found that 10 percent of the total ESRD population was hospitalized with a psychiatric disorder, and that these patients were more likely to be hospitalized for depression than patients with heart or cerebrovascular disease. Using data from the large Dialysis Outcomes and Practice Patterns (DOPPS) study, Lopes et al (2004) concluded that all levels of depressive symptoms were associated with

increased morbidity and mortality in both incident and prevalent population. Despite the need for further research in this complex area of nephrology care, it is clear that the treatment of depression in dialysis patients, particularly older dialysis patients, is warranted and is likely to have profound effects for the individual patient and the overall society.

2.4 Current Best Practices for Depression in the Hemodialysis Setting

Best-practice interventions for depression in ESRD

Despite the prevalence of depression in ESRD, there is no standard of practice for treatment of depressive symptoms in outpatient dialysis centers. Historically, hemodialysis patients have been treated with pharmacotherapy and selective serotonin reuptake inhibitors when clinically indicated (Cohen et al., 2007). More recently, it has been recognized that HD patients presenting with depression who are treated with antidepressant medications can additionally benefit from psychoeducational support (McCool et al., 2011). However, large, randomized, controlled clinical trials are needed to further support psychoeducational intervention in this population.

The link between depressive symptoms in ESRD patients and adverse medical outcomes has focused increased attention on effective models for screening and managing depression. Current Best Practices include: (a) identification and management of depressive symptoms through monthly interdisciplinary team meetings involving review of social work assessment and recommendations, (b) the use of on-site short term psychoeducational interventions by the licensed unit social worker, (c) the use of good, valid screening tools administered in the dialysis unit setting by trained social workers, (d) a dialysis-clinic-based approach to treatment, and (e) social-worker-initiated depression

management interventions combined with medication management by the nephrologist. Some examples of Best-Practice interventions include Cognitive Behavioral Therapy, Motivational Interviewing, and Symptom-Targeted Intervention. Cognitive-Behavioral Therapy (CBT) has demonstrated positive results in reducing depressive symptoms through individual and group intervention for patients with ESRD (Cournos & Goldfinger, 2007; Cukor, 2007; Duarte, Miyazaki, Blay, & Sesso, 2009). Although CBT has been demonstrated to be a successful intervention in the dialysis population, this form of treatment often requires referrals to outside mental health providers and involves longer sessions. Moreover, this form of therapy is often not optimal for "real-world" settings due to cost, stigma, and limited accessibility, particularly for rural patients who have limited flexibility given the multitude of appointments and other treatments that they undergo. However, studies demonstrate improvement in health related quality of life in dialysis patients when patient centered forms of CBT such as Symptom-Targeted Intervention (STI) and Motivational Interviewing are provided on-site (Sledge, et al., 2011, Kimmel & Peterson, 2006, Johnstone 2007).

The role of renal social workers

Dialysis unit Masters-level Social Workers (MSW) are trained to recognize the signs and symptoms of mental health problems, including depressive symptoms, and are qualified to provide on-site clinical intervention to their patients. The Centers for Medicare and Medicaid recognize in their scope of coverage for dialysis centers that a primary role for MSWs is to help patients cope with their condition and achieve optimum outcomes for them (Centers for Medicare and Medicaid Services, 2008). In fact, the Medicare prospective payment reimburses dialysis clinics for the services provided by MSWs that are aimed at

reducing psychosocial barriers to treatment outcomes (Lowrie, Curtin, LePain, & Schatell, 2003). Renal social workers are a value-added service to dialysis clinics because they: (a) have the necessary training and access to patients to provide effective evidence-based interventions, (b) have access to validated psychometric tools designed specifically for the dialysis population that can effectively monitor the physical and mental health needs of the hemodialysis population, (c) are accessible to patients, and (d) have existing relationships with patients that decrease the stigma that is often associated with being referred to an outside therapist. Social work services must be reflected in patient care plans and monitored through the use of a standardized health related quality of life survey, known at the KDQOL-36. Mental and physical component scores from this survey must be integrated into patient care plans to help patients overcome adverse outcomes like hospitalization and death. As a member of the care team, MSW's can directly and indirectly aid in the intervention process for depressed patients.

Studies indicate that most dialysis patients prefer to receive treatment for depression from their unit social worker because of barriers accessing community mental health treatment (McCool et al., 2011; Roberts & Johnstone, 2006). In addition to accessibility, an important trust is developed through the social work patient relationship that can be powerful part of the process. McCool et al., (2011) discovered that older dialysis patients reported increased comfort with receiving mental health support from their unit social worker, and that patients prefer to be asked for help rather than actively seeking out help for themselves.

Psychoeducational interventions in the dialysis-unit setting continue to gain attention in the renal community because of the high growth and demands of this

population. Furthermore, the dialysis literature suggests that evidence-based interventions can be most effective when provided by the nephrology social worker because of accessibility, trust, and specialized knowledge of the renal social worker (Johnstone 2005; McCool et al., 2011; Merighi & Ehlebracht, 2004).

2.5 Problem-Solving Therapy (PST) as a Potential Depression Intervention in Dialysis

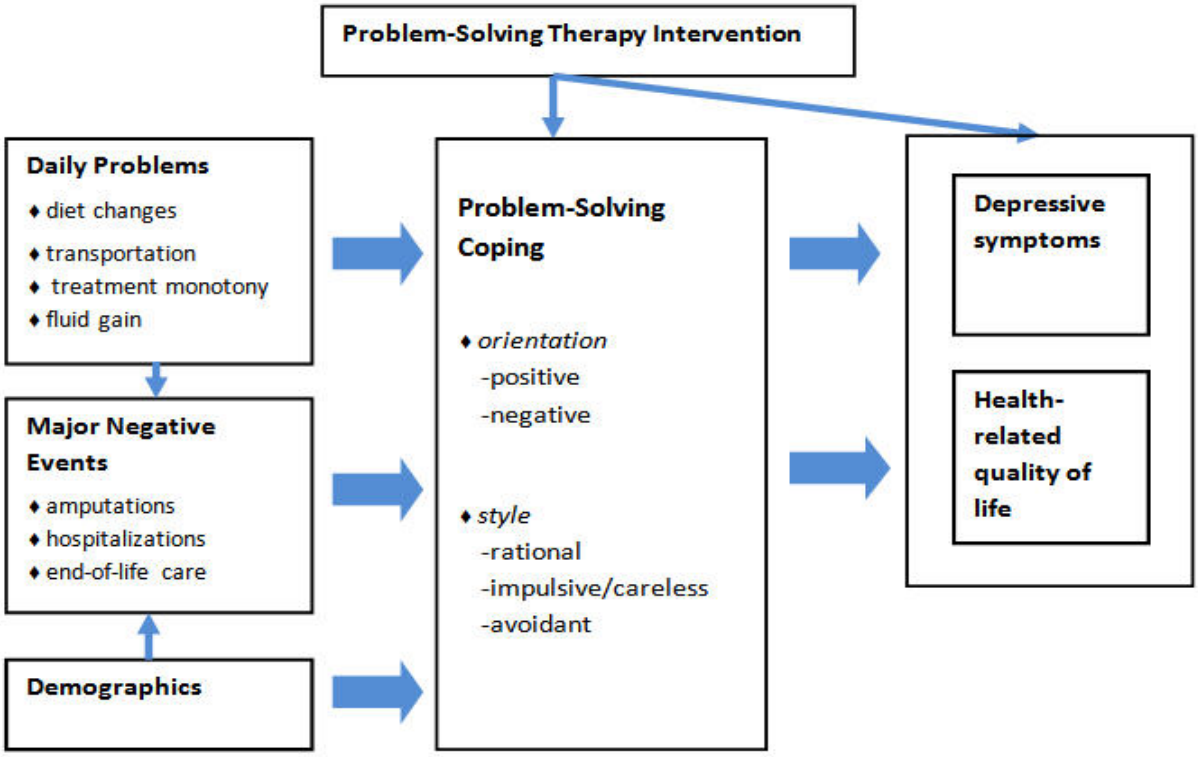
Conceptual framework: Social Problem Solving (SPS)

In 1971, D'Zurilla and Goldfried provided a theoretical rationale for PST known as Social Problem Solving (SPS) theory. SPS builds upon previous approaches such as Perlman's social casework process and the task centered model introducing problem-solving orientation. Whereas these approaches were concerned primarily with problem-solving skills and subsequent solutions, D'Zurilla and his colleagues identified problem orientation as a valuable component of problem solving (Shier, 2011). D'Zurilla and Goldfried affirmed that SPS social problem solving is a "conscious, rational, effortful, and purposeful activity and that SPS model could be aimed at changing the problematic situation for the better, reducing the emotional distress that it produces, or both" (Chang, D'Zurilla, & Sanna, 2004, p. 12). SPS model identifies problem-solving skills as the ability of one to define problems, identify solutions, and then verify that the solutions are effective (D'Zurilla et al., 2004).

PST is an intervention grounded in the problem-solving model of stress. It proposes that individual problem-solving skills moderate how patients experience psychological distress or symptoms of depression. The PST model contends that patients who have chronic medical conditions often experience their medical problems as daily life stressors

and the root cause of their daily problems. In this model, problem-solving skills are recognized as a moderator that can lessen the likelihood that one will experience stress even when confronted by chronic medical stress. The major concepts of SPS include problem-solving dimensions that involve: (1) problem orientation, which can involve either a positive problem orientation or a negative problem orientation, and (2) problem solving style that can be either rational, impulsive/careless, or avoidant. The conceptual framework of SPS allows for flexible, tailored interventions in a dialysis-unit setting (Figure1, next page). The figure implies that individual problem-solving coping may mediate the relationship between problem-solving therapy and patient outcomes such as depressive symptoms and overall health related quality of life. It further suggests that individual problem solving skills may moderate the relationship between stress experienced by dialysis patients and depressive symptoms and health-related quality of life.

Figure 1: Conceptual Framework – Mediation



In the SPS model, stressful life events have a direct or indirect effect on well-being through problem-solving coping (Nezu et al., 2010). There are two types of stressors: major negative events and daily problems. A major negative event is often a life-changing experience that requires individuals to make significant adjustments in their lives, such as the death of a loved one or diagnosis of chronic illness. A daily-life problem is more often a specific stressful event such as loss of income or nutritional changes due to illness. These two types of problems do not always occur simultaneously, but they can be directly related. The diagnosis of a chronic illness can lead to loss of employment, decreased financial resources, dietary changes, psychological stress, and depression. The accumulation of unresolved daily problems can equally contribute to major negative events.

The SPS model utilizes Lazarus's model of stress and coping to understand how stress is both experienced and viewed in problem solving. Lazarus and Folkman (1984) contend that stress is experienced when the demands of an individual's environment exceed her or his coping ability and resources. Lazarus's model details how stress affects individuals differently through their cognitive appraisal and their coping processes. Nezu et al. (2010) view the amount of stress an individual experiences as a product of the interplay between stressful life events, emotional stress, and problem-solving coping.

Problem-solving coping. According to D'Zurilla and Goldfried, (1971), problem-solving coping is composed of two independent components: (a) problem-solving orientation and (b) problem-solving style. Problem-solving orientations are recognized as either positive or negative; problem-solving styles include rational, impulsive, and avoidant. Nezu et al. (2010) establish that the interchange between problem-solving orientation and style can result in either negative or positive personal and social outcomes.

Problem-solving orientation. Individuals with positive problem-solving orientation often engage in constructive cognitive problem-solving activities; these include affirmative appraisal of a problem, belief in ability to solve it (Bandura's (1977) problem-solving self-efficacy—see below), and commitment to solving it (D'Zurilla et al., 2004, p. 21). Individuals with negative problem-solving style, however, often engage in dysfunctional cognitive problem-solving that involves low self-efficacy or disbelief in their ability to solve problems.

Problem orientation is a derivative of Bandura's (1977) self-efficacy theory. According to Bandura, *self-efficacy* is a person's belief in his or her ability to succeed in a specific situation (Bandura, 1977). Individuals measure the effects of their actions, and

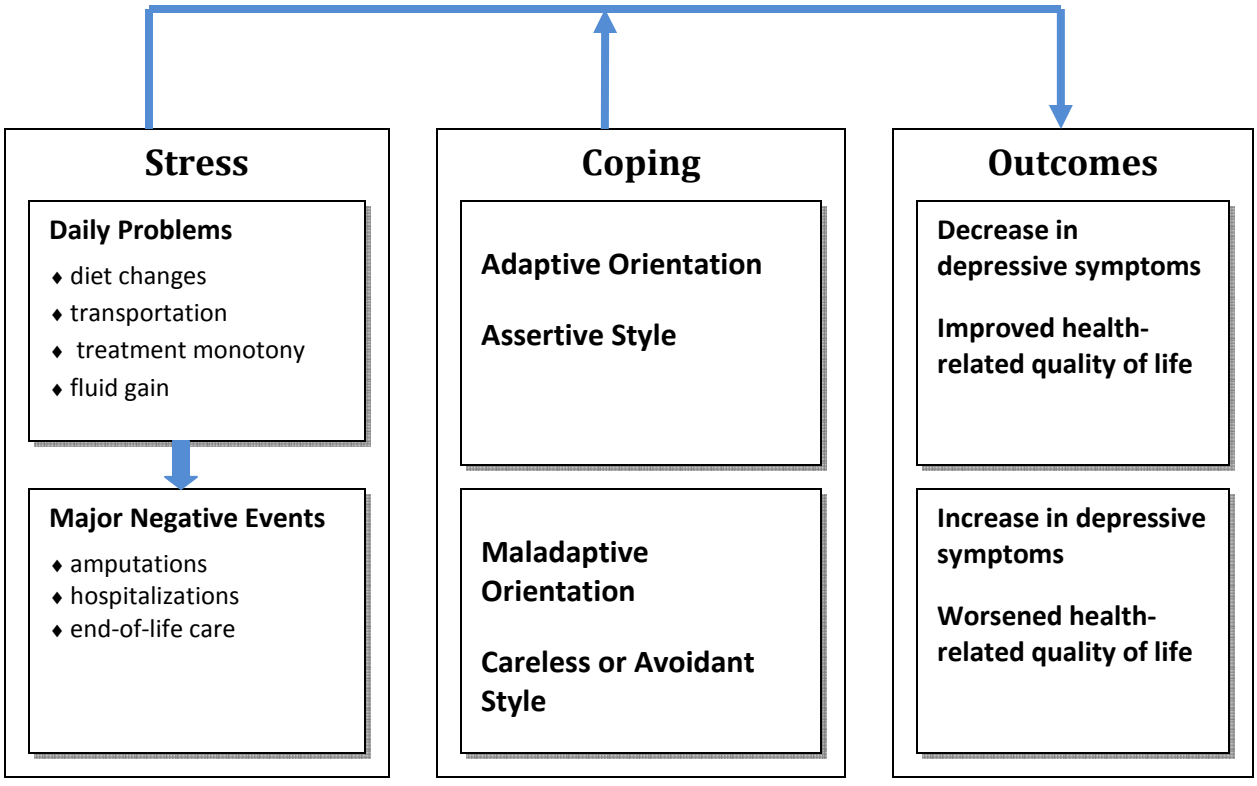
their interpretations of these effects help create their efficacy beliefs (Bandura, 1995). Bandura argues that "efficacy expectations determine how much effort people will expend and how long they will persist in the face of obstacles and aversive experiences" (Bandura, 1977, p. 194). Bandura (1995) further argues that self-efficacy beliefs are developed from behavioral and cognitive tasks. The notion that perception of one's problem-solving self-efficacy can be linked to problem-solving behaviors ultimately provides the clinician with a wider lens with which to work when collaborating with clients to solve problems. Self-efficacy is one component of problem-solving orientation that distinguishes SPS from other problem-solving approaches (D'Zurilla et al., 2004).

Problem-solving style. There are three problem-solving styles in the SPS model that are viewed as either constructive or dysfunctional. (1) *Rational problem solving*, a constructive problem-solving style, involves a careful and systematic review of facts combined with realistic goal-setting and implementation of solutions. (2) *Impulsive/careless problem-solving* style is characterized as dysfunctional because it involves a less careful and systematic approach to solving problems. Individuals who engage in impulsive problem-solving are likely to make quick decisions that lead to negative outcomes. (3) *Avoidance style* is also characterized as dysfunctional and involves very little commitment on the part of the individual. This style is regarded as a passive and dependent style that can lead to negative personal and social outcomes.

In the SPS model, problem-solving coping acts as both a mediator and moderator of the relationship between stressful life events and well-being. Knowledge of these variables can aid the clinician and provide a wider view of how people cope with and solve problems, and how these variables can affect treatment outcomes. Mediating and moderating

variables influence the relationship between social problem solving and psychological adjustment (Chang et. al, 2004). *Moderating variables* can direct us to better understand why certain individuals are more effective problem-solvers. For example, Nezu, A.M., Nezu, C.M., Saraydarian, Kalamar, and Ronan (1988) found that individuals who were more effective problem-solvers experienced less depression from stressful life events. *Mediating variables* are those that can intervene between the problematic situation and the problem-solving process and explain differences in social problem-solving. Affectivity, optimism, pessimism, hope, perfectionism, life span development, gender, ethnicity and social context are examples of variables that may likely contribute to shaping the outcomes of social problem-solving (Rich and Bonner, 2004).

Figure 2: Conceptual Framework – Moderation



This framework provides a deeper understanding of the link between individual well-being and daily or traumatic life stresses by better explaining how individuals engage cognitively and behaviorally in problem-solving. This nuanced approach to understanding individual problem-solving also offers an innovative approach to clinical assessment and therapeutic intervention known as PST.

Problem-solving Therapy (PST)

PST is an evidence-based depression intervention designed to increase positive problem orientation and rational problem solving, while reducing careless/impulsive, and avoidant problem-solving styles (Nezu et al., 2010). It is a derivative of cognitive behavioral therapy: a type of cognitive-behavioral intervention that involves training clients to adopt and use adaptive problem-solving attitudes and skills, and that aims to reduce psychopathology and improve overall quality of life (Nezu et al., 2010). The goal of PST is to prevent recurrence of daily-life problems—or the development of new problems—by helping clients enhance psychological and behavioral functioning.

After a thorough assessment of the client's problem-solving strengths and weaknesses, PST can be applied. PST involves teaching clients how to use a step-by-step process to solve common life problems. In order to do this, PST works to help clients clearly define their problems and set realistic and tangible goals. The two processes taught to clients can be broken down as follows: how to apply a problem-solving orientation to life, and how to use rational problem-solving skills.

Application of problem-solving orientation involves collaborating with clients in order to help them appraise problems as solvable challenges, think that problems can be solved, and recognize the need for time limits (Nezu, 2004). In order for clients to

effectively solve their problems, they must also develop a sense of self-determination. The eight steps of rational problem-solving skills are as follows: (1) clarify and identify the problem, (2) define the problem, (3) understand the problem, (4) set realistic goals related to the problem, (5) generate multiple solutions, (6) evaluate and choose the best solution, (7) implement the solution, and (8) evaluate the efficacy of the problem-solving effort (D'Zurilla & Nezu, 1999). Generally, interventions are short-term, ranging from six to sixteen sessions lasting one to two hours each, as recommended by the originators of PST (D'Zurilla & Nezu, 1999). Clients collaborate with the clinician to solve real-life problems by engaging in oral and written presentation of the problem-solving steps.

Empirical support for PST

There is significant empirical support for PST as an intervention strategy for a multitude of populations and problems (Gellis & Kenaley, 2008; Nezu et al., 2010). In a meta-analysis of 32 studies, Malouff et al. (2007) concluded that PST was as effective as other psychosocial treatments and significantly more effective than no treatment. Cuijpers, Straten & Warmerdam (2007) also concluded that PST was an effective treatment for depression. Several studies demonstrate the efficacy of PST among various depressed adult samples, including depressed primary care patients, adult cancer patients, depressed community-dwelling older adults, and homebound geriatric patients (Alexopoulos, Raue, & Arean, 2003; Ciechanowski et al., 2006; Gellis et al., 2008; Malouff, Thorsteinsson, & Schutte, 2007; Nezu et al., 2003). PST offers an approach to practice that is empirically based and appropriate for diverse populations, and which can be applied individually, in groups, and even over the telephone.

Goodness of fit of PST with Renal Social Work

Social workers engage with clients in ways that aim to solve client's life problems. Since the inception of casework, social workers have worked with clients and systems to practice of problem solving. Problem solving is at the root of what social workers do and continues to provide a unifying connection among all social-work professionals despite their varying approaches to practice. The theoretical framework for problem solving in social work relies on the "basic assumption that all human living is a problem-solving process" and that social-work clients are people whose normal problem-solving capabilities and resources have become impaired (Perlman, 1971, p. 1207).

The changing demographics of the dialysis-unit setting require increased attention to the individual and systematic barriers that prevent older patients from receiving adequate mental health services. The overall number of older hemodialysis patients with mental health disorders will increase as the dialysis population ages. Older patients in rural settings, moreover, are often reluctant to seek mental health services because they (a) have limited access to providers; (b) want to decrease the number of appointments they have outside of dialysis treatment; and (c) are often in denial of their problems. Beyond these barriers, older dialysis patients are often faced with gaps in care due to miscommunication among providers and a shortage of healthcare professionals who can adequately assess and treat mental-health symptoms. The consequences of depressive symptoms in older dialysis patients are far reaching for the individual, the family, and the healthcare system. Left untreated, depression in older dialysis patients can result in decreased quality of life, compounding medical problems, increasing healthcare costs, and death. Hence it is essential for health care providers and renal social workers to focus their attention on best-

practice interventions that will minimize the effects of mental health problems on such adverse outcomes.

PST offers a specific on-site therapeutic problem-solving intervention for renal social work that is of great value for older hemodialysis patients. The application of PST in the hemodialysis setting has significant implications for reducing depressive symptoms in older patients who are confronted with daily and major life stress that accompanies ESRD. If on-site PST intervention provided by renal social workers can help to reduce depressive symptoms in older dialysis patients, the outcome will be a significant decrease in barriers to mental health services for older adults living with kidney failure. In addition, favorable outcomes from PST intervention will help to guide new standards for how mental health services are provided now and in future for this high-needs population. PST offers an evidence-based approach to practice that enables renal social workers to competently confront the challenges of providing on-site intervention to older dialysis patients over the next decade.

Chapter 3: Hypothesis

The primary aim of this study is to test in a randomized controlled trial design the efficacy of Problem-Solving Therapy (PST) in reducing depressive symptoms in older dialysis patients in the dialysis-unit setting. A secondary aim is to acquire an in-depth understanding of PST intervention in the dialysis-unit setting by examining case vignettes. The overall goal is to translate evidence-based approaches into routine care to improve patient-health-related quality of life.

It is hypothesized that older dialysis patients receiving six one-hour sessions of PST in addition to their usual care will experience significantly reduced depressive symptoms, improved health-related quality of life, and improved coping skills compared to a Usual Care (UC) group.

Chapter 4: Method

4.1 Study Aim

The overarching goal of this randomized, controlled pilot trial was to explore a clinically meaningful, patient-centered approach to reducing stressors and improving patient-health-related quality of life in older dialysis patients. The study had two aims: (1) to test the feasibility of PST intervention on symptoms of depression, health related quality of life and problem-solving coping, and (2) to understand patients' perceptions of the usefulness of PST intervention.

4.2 Study Site

The Geisinger Medical Center outpatient dialysis unit was the setting for this pilot project. This dialysis unit is a not-for-profit dialysis center affiliated with the Geisinger Medical Center in Danville, PA. The 21-seat chair facility provides outpatient dialysis treatment to residents in five counties in central Pennsylvania and is capable of servicing approximately 80 dialysis patients. It provides treatment to dialysis patients Monday through Saturday and is staffed with three Nephrologists, 22 dialysis nurses and technicians, three dietitians, and one licensed social worker.

4.3 Recruitment

Participants

Thirty-five patients were recruited to participate in this study. Participating and consenting patients were actively receiving outpatient hemodialysis treatment at Geisinger Medical Center for a minimum of three months. Given that the literature denotes higher levels of depressive symptoms and lower levels of quality of life in HD as compared to

other forms of Renal Replacement Therapy, only outpatient hemodialysis patients were selected for this study.

Inclusion criteria

Individuals were eligible to participate in this study if they met the following criteria: (1) had been diagnosed with End-Stage Renal Disease (ESRD); (2) were currently receiving outpatient hemodialysis at Geisinger Medical Center at a minimum of 3 months; (3) were 60 years of age or older; (4) had consented to allow the research team to access disease-severity indicators from their medical records; and (5) had consented to receiving six weeks of PST or UC, combined with a follow up 60-minute qualitative interview.

Exclusion criteria

Patients were not eligible for this study if they did not meet all of the aforementioned criteria. Additionally, the following factors made a patient ineligible from participating in this study: (1) Chart diagnosis of Cognitive Disorder, Dementia or Alzheimer-related diseases, Psychotic Disorder, or Mild Cognitive Impairment (MCI); and/or (2) they were already receiving psychological counseling.

Procedures

Recruitment of patients was conducted at the Geisinger Medical Center (GMC) outpatient Hemodialysis Center. The patients who meet the inclusion criteria were offered an opportunity to learn about the study upon receiving approval from the GMC Institutional Review Board (IRB) and the University of Pennsylvania IRB. The recruitment procedure involved a safe and uncoerced procedure that included the following three steps: (1) The dialysis unit secretary provided a flyer (See Appendix B) to the patients when they arrived for their weekly treatment at the Hemodialysis Center; (2) the secretary informed

the patients who took the flyer that they would be contacted by the Primary Investigator (PI) within three days to discuss and answer any questions regarding the study; (3) The PI met in her office with interested patients prior to the start of their dialysis treatment, reviewed the form, answered questions, and obtained consents (See Appendix C).

Upon obtaining consent, the PI provided pretest study self-report measures to participants during their hemodialysis treatment. Additionally, research participants were given the opportunity to complete self-measures in a private room before or after their dialysis treatment if they so chose. All participants were instructed not to put their names on the forms given to them by the PI. In order to maintain individual confidentiality and to minimize bias, all measures were stamped with a study identification number that matched the number stamped on the participant's informed consent document. Once the participant completed the questionnaire, the PI briefly reviewed each measure to ensure that all items were completed.

Additionally, the PI checked for any responses on measures involving sensitive items that identified subjects who were at risk for suicide or potential harm to self or others. It is not uncommon for older individuals, especially those with chronic illness and disability, to experience feelings of sadness or grief when answering sensitive questions about their health and emotions. Subjects were followed closely by the PI and the renal care team during the study to ensure medical and mental health stability and safety.

The Procedure for the PST intervention followed the PST Manual (Gellis, 2010) and involved the PI meeting with the subject once weekly in the Hemodialysis Center for approximately one hour. During each weekly visit, the PI completed the following steps with each participant who was selected for the PST intervention: (1) orientation to problem solving, (2) identification of problem and goals, (3) brainstorming solutions, (4) evaluating and choosing

solutions, and (5) identifying steps to achieve solutions to the identified problem. (See Table 1 in Appendix for detailed description of PST intervention.)

Randomization

The eligibility of each dialysis patient was established before allocation to treatment or control condition. The actual treatment condition given to an in-center dialysis patient was determined by a random scheme produced by computer software that incorporated a standard procedure for generating random numbers with an allocation ratio of 1:1—that is, to either the PST + Usual Care group (n=15) or the Usual-Care-only control group (N=18). No stratification or blocking factors were used. This pilot study used an unblinded design, and participants were informed of their allocation sequence upon completing their baseline measures. The generation of the allocation sequence and the assignment of participants were performed by the Hemodialysis Center secretary.

4.3 Variables

The *independent variables* in this study are the two conditions: the experimental treatment (Problem-Solving Therapy) and the control (Usual Care). The *dependent variables* in this study were measures of depression, quality of life, and coping skills ability. These variables were used to assess the effects of PST on depressive symptoms and overall health related quality of life.

Chapter 5: Measures

5.1 Demographic information

A data dictionary was created in order to obtain relevant sociodemographic and medical information. Upon consent, participants completed a brief demographic questionnaire with information about their gender, age, self-defined ethnicity, employment status, estimated household income, social support systems, marital status, and education. Additionally, medical information was obtained from the participants concerning length of time on dialysis treatment, length of time diagnosed with ESRD, and comorbid medical illnesses.

Primary outcomes were the effects of the six-week PST on depressive symptoms of older maintenance hemodialysis patients. Secondary outcomes were measurements of changes in health-related quality of life. Primary outcomes with respect to efficacy of PST were assessed by means of two instruments: the Beck Depression Inventory (BDI) and the Patient Health Questionnaire-9 (PHQ-9).

5.2 Depression

Beck Depression Inventory

Beck Depression Inventory (BDI): The BDI was used to measure depressive symptoms (BDI: Beck, Steer, & Garbin, 1998). Widely used in ESRD research, the BDI is a 21-item self-administered questionnaire with a test-retest reliability of 0.75 (Beck et al., 1988; Stehouer, 1987; Hedayati, Minhajuddin, Toto, Morris & Rush, 2009). Researchers using this tool have observed statistically significant positive associations with other psychological constructs: for example, with impaired quality of life and coping (Vazquez,

Valderrabano, Fort, Jofr, Lopez-Comez, Moreno et al., 2005). In their study, Hedayati et al. (2009) validated the BDI against a gold-standard structured psychiatric interview, suggesting a BDI score of greater than or equal to 11 as an optimal cut-off for significant depressive symptoms (84 percent sensitivity, 93 percent specificity).

Patient-Health Questionnaire-9

Patient-Health Questionnaire (PHQ-9): The PHQ-9 was used to measure depressive symptoms (Kroenke, Spitzer & Williams, 2001). The PHQ-9 was specifically developed and validated for use in a primary care setting in 1999 and was later discovered to be an attractive alternative to the BDI in the dialysis population given its short length (Watnick et al., 2005). The PHQ-9 is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. It is a depression module, which scores each of the 9 DSM-IV criteria as 0 ('not at all') to 3 ('nearly every day'). The PHQ-9 has a high internal reliability of 89. In their study, Watnick et al. (2005) validated the PHQ-9 against the BDI and the DSM-IV criteria and concluded that the PHQ-9 is a valid screening measure that performs optimally at a cutoff value of 10 or greater for a diagnosis of depressive disorder.

The two measurements were completed before and after the six-week trial by all the participants in both groups.

5.3 Quality of Life

Kidney Disease Quality of Life-36

Kidney Disease Quality of Life (KDQOL-36): Secondary outcomes of health related quality of life were assessed by means of the KDQOL-36 (KDQOL-36: Hays, Kallich, Mapes, Coons, & Carter, 1994). This instrument measures patients' perceptions of physical and

mental adjustment to dialysis treatment, assessing eight aspects of health-related quality of life. It is a 36-item questionnaire that has internal reliability scores of 0.70 or higher for each of the scales (Hays et al., 1994). The KDQOL-36 survey is currently being used by MSWs to identify depression in dialysis patients in dialysis clinics annually and 90 days after the start of treatment as required by CMS; it demonstrates that an increase in the mental component summary by even one point can reduce the risk of death and hospitalization (Lowrie et al., 2003). Patients with low mental component scores are more likely to be depressed, nonadherent to treatment schedule and diet, and have worse outcomes (McCool et al., 2011).

5.4 Coping

Jaloweic Coping Scale

Jaloweic Coping Scale (JCS): The JCS was used to measure individual coping skills ability (JCS: Jaloweic, Murphy, & Powers, 1984). This tool has demonstrated reliability in multiple populations with chronic illness, including dialysis patients (e.g., Shu-Chuan & Hsueh-Chih, 2007). Using a four-point Likert scale (0= never used, 1= seldom used, 2= sometimes used, and 3= often used), the JCS has a reported test-retest reliability of 0.79 for total coping scores and 0.85 for affective-oriented scores, with coefficient alpha levels ranging from 0.81 to 0.96 (Jaloweic, Murphy, & Powers, 1984). The scale covers 32 different coping behaviors, condensed into five subscales, which include: problem-oriented ('looking objectively at a problem' or 'making a plan of action'), emotion-oriented ('using worry or blame to understand the problem'), support-seeking ('talking through a problem with family, friends, or God'), avoidance-oriented ('drank or smoked more than usual'), and isolated thoughts ('getting away from the problem').

Social Problem Solving Inventory-R

Social Problem Solving Inventory, Revised Short Form (SPSI-R): The SPSI-R was used to examine subject-perceived social-problem ability across 5 dimensions. The SPSI-R is a 25-item self-report measure that examines perceived social problem-solving ability across five dimensions. The first two dimensions focus on a person's orientation to problematic situations and can be either positive or negative. The remaining dimensions focus on the strategies used to solve problematic situations, including: "Rational Problem Solving," "Impulsive/Careless Problem Solving," and "Avoidant Problem Solving." Respondents are asked to rate items on a five-point Likert type scale ranging from 0 ("not at all true of me") to 4 ("extremely true of me"). This measure produces five subscales for each of the dimensions, and a weighted total social problem-solving score. Research with the SPSI-R has demonstrated considerable reliability. An internal consistency for the total score was calculated at a Chronbach's alpha of 0.95. The test-retest reliability for the total score in a college (three weeks) and nursing student sample (six weeks) was found to be 0.93 and 0.89, respectively. The SPSI-R is based on theoretical research and factor analysis, with strong support for its structural validity, as well as convergent and divergent validity. The SPSI-R has been shown to have strong predictive validity, in particular, to distress measures, such as the BDI. Research demonstrates its sensitivity to treatment effects for individuals in problem-solving therapy (Nezu, Nezu, & Lombardo, 2003). All tools can be found in Appendix A.

Chapter 6: Analysis

Statistical analysis was conducted by the author, the sub-investigator, and a biostatistician from the Geisinger Medical System, Henry Hood Center for Health Research, using SPSS, SAS, and STATA software.

Prior to inferential analyses, descriptive statistics, including distributions, means, standard deviations, skewness, kurtosis, and frequency counts were obtained for all variables. Tests for differences on the depression, health quality of life and coping survey variables were carried out using T-tests and Wilcoxon Rank Sum tests. Primary analysis involved analysis of variance (ANOVA) to estimate the efficacy of treatment. Manipulation checks included tests of randomization and comparability across conditions. Randomization was tested by performing a series of ANOVAs, Chi-square tests, and Fisher's exact tests to compare the groups on demographic and initial clinical variables. Additionally, a secondary analysis was conducted using a linear regression model to examine the effects of problem solving coping skills on depression scores (BDI and PHQ9).

6.1 Descriptive Statistics

Descriptive statistics are presented below for all the study measures via written summaries and tables. Means, score ranges, and standard deviations are utilized for all continuous variable study measures (BDI, PHQ-9, KDQOL-36, JCS, SPSI). Sociodemographic and medical information, obtained via the demographic questionnaire, is presented with the statistics of means, standard deviations, and ranges when appropriate. Two sample t-tests and Wilcoxon rank sum tests were completed to compare continuous variables for the PST intervention group with the usual-care control group. Frequency tables were produced

for categorical variables and Chi-square tests or Fisher's exact tests were used to test for differences between the two groups.

6.2 ANOVAs

We submitted scores on the PST intervention to an ANOVA with pre- and posttest scores treated as repeated measures. Intervention assignment (e.g., PST + Usual Care versus Usual Care) served as the between-subjects variable; pre- and post- measures of the depression and quality of life scores (6 weeks, pretest versus posttest) served as the within-subjects variable. We hypothesized that the PST + Usual Care group would experience more of a decrease in depressive symptoms and an increase in health related quality of life as compared to the Usual Care group post PST intervention and that those experiencing less depressive symptoms would have more adaptive and positive coping styles as indicated by the SPSI and the JCS.

6.3 Correlational Analysis

Correlational analyses were conducted to examine how the post-survey score variables are interrelated. A correlational analysis of post-survey scores for depression, health-related quality of life, and coping skills surveys for all 33 patients was completed using Pearson product-moment correlation coefficients in SAS.

6.4 Linear Regression Model

A secondary analysis of this study involved linear regression models to examine the study aim of whether there is a moderating role for each of the five social problem-solving scales (SPSI-R) between depression and Problem-Solving Therapy Intervention. Linear

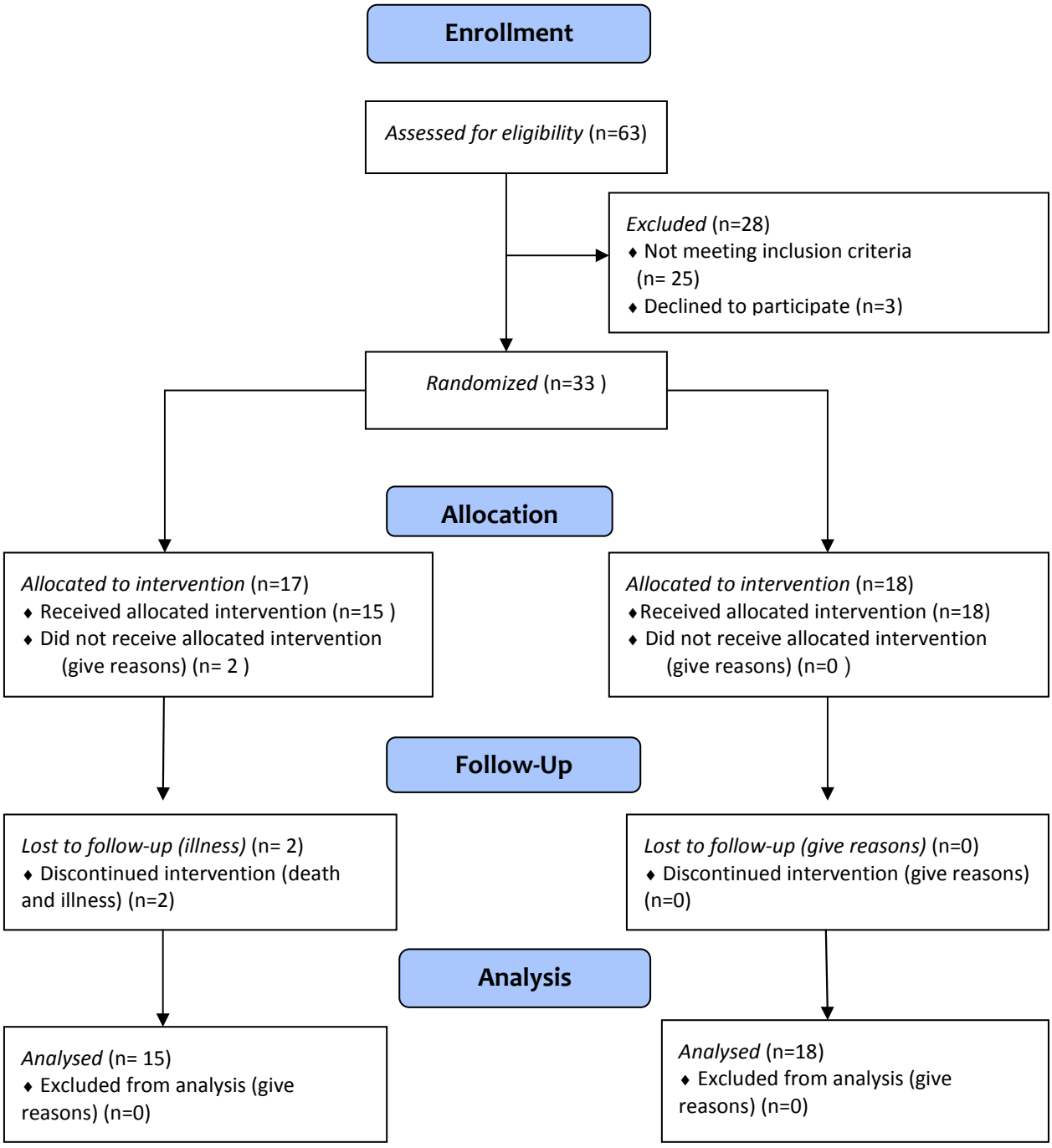
regression models were used to examine if problem solving coping skills had an effect on patient depression scores (PHQ9 or BDI).

Chapter 7: Results

7.1 Participant Flow and Recruitment

Figure 3 (on next page) shows numbers of recruitment, exclusions, refusal, and dropouts throughout the study. Among the 63 patients who were assessed for eligibility for the trial, 25 subjects did not meet the inclusion criteria and three declined participation in the study. Post randomization, one participant in the intervention group withdrew due to illness and a second participant died shortly after completing pretest measures. Participants were recruited from January 1, 2012 through January 31, 2012. The trial was initiated on February 1, 2012 and ended on May 1, 2012.

Figure 3: Study flow diagram



7.2 Baseline Participant Characteristics

Thirty-three patients (21 men, 12 women with a mean age of 73.9 (S.D. 7.26)) years completed the 6-week trial. They ranged in age from 62 to 88 years old. Of the 33 patients, most were Caucasian (94%), were males (64%), were living with a spouse, child, or other family member (58%), in a nursing home (12%) or other supported setting such as a group home or personal care home (9%), and had a mean of 12 or more years of education (79%). Overall, baseline characteristics of participants in the two groups were similar, with the exception that patients in the intervention group were more likely to have a history of a depression diagnosis (control group (16.6%), intervention group (53.5%)). It is interesting to note that although there were fewer subjects in the control group with a diagnosis of depression, patients' medical records indicated that three of the control group subjects were taking psychiatric medication, including Zoloft, Lorazepam, and Celexa, with no charted diagnosis of depression. Comparisons of comorbid conditions were not significantly different between the two groups.

Additional demographic statistics are summarized in Table 3 on the next page.

Table 3: Descriptive Statistics for Study Variables

Characteristic	PST-Usual Care (n=15)	Usual Care (n=18)	P-value
Sex			
Male	10(66.6%)	11(61%)	1.00
Mean age (SD)	72.2(5.6)	75.3(8.28)	
Marital Status			0.72
Single	1(6.6%)	3(44.4%)	
Married	8(53.3%)	11(61%)	
Divorced	4(26.6%)	2(11%)	
Widowed	2(13.3%)	2(11%)	
Living Arrangements			0.45
Lives alone	5(33.3%)	2(11%)	
With Caregiver	8(53.3%)	11(61%)	
Nursing Home	1(6.6%)	3(16.6%)	
Other	1(6.6%)	2(11%)	
Race			1.00
White	13(86.6%)	18(100%)	
African American	1(6.6%)		
Native American	1(6.6%0		
Education			.0.16
<12 years mean (SD)	4(26.6%)	3(16.6%)	
12 or more years mean (SD)	11(73.3%)	15(83.3%)	
Months on Dialysis mean (SD)	43.93(33.7)	40.89(41.8)	
Transplant Candidate	1(6.6%)	1(5.5%)	1.00
Religious Affiliation (yes)	14(93.3%)	17(94.4%)	1.00
Public Transportation (yes)	9(60%)	13(72.2%)	0.48
Diabetic (%)	10(66.6%)	12(66.6%)	1.00
CHF (%)	5(33.3%)	10(55.5%)	0.29
PVD (%)	2(13.3%)	3(16.6%)	1.00
Malignancy (%)	5(33.3%)	6(33.3%)	1.00
MDD Depression Diagnosis (%)	8(53.3%)	3(16.6%)	0.06
# of psychiatric medications			0.70
1	6(40%)	8(44.4%)	
2	3(20%)	2(11%)	
3	1(6.6%)		
GAD Anxiety Diagnosis (%)	3(20%)	3(16.6%)	1.00
Meds prescribed mean (SD)	16.13(5.34)	16.72(7.410	

7.3 Mean differences at baseline and 6 weeks

Table 4 (on next page) displays the mean score changes for the PST and Usual Care groups for Depression (PHQ-9 and BDI), Health Related Quality of Life (MCS and PCS), and Coping (SPSI and JCS) surveys. T-tests and Wilcoxon Rank Sum tests were used to test the null hypothesis of no difference in score changes between the two groups. When the score changes followed a normal distribution, t-tests were used to test for significant differences. When the score changes did not follow a normal distribution, Wilcoxon Rank Sum test were used to test for differences.

Overall data indicate that mean scores for the intervention group improved as hypothesized as compared to the control group. The PST and control groups showed significant differences with respect to the change in scores on the surveys for BDI, PHQ-9, MCS, PPO, NPO, RPS, ICS, AS, Confrontive, Optimistic, and Supportant. Results indicated that at six weeks there were no significant differences in mean PHQ and BDI scores between the usual care and intervention group (PHQ 5.8 vs. 3.3, P=0.1; BDI 11.3 vs. 9.3, P=0.6).

Table 4: Section Means and Standard Deviations of Baseline and Posttest Outcomes Measures

	PST+ Usual Care Group (N=15)				Usual Care Group (N=18)			
	Baseline	6 Weeks	Mean Change	Paired t-test p-value	Baseline	6 Weeks	Mean Change	Paired t-test p-value
BDI	15.67 (8.06)	9.33 (3.15)	-6.33	**0.0040**	10.67 (5.99)	11.28 (7.42)	0.61	0.6628
PHQ-9	10.47 (4.87)	3.27 (1.91)	-7.20	**< 0.0001**	6.11 (4.14)	5.83 (4.22)	-0.28	0.7492
KDQOL-36 MCS	43.69 (10.92)	54.10 (10.23)	10.41	**0.0061**	52.20 (7.76)	51.39 (9.72)	-0.81	0.8035
KDQOL-36-PCS	34.03 (7.95)	37.05 (11.07)	3.02	0.3660	35.33 (10.42)	33.77 (8.53)	-1.57	0.5467
SPSI-R (PPO)	11.13 (2.59)	16.73 (2.74)	5.60	**< 0.0001**	11.72 (2.97)	12.56 (3.65)	0.83	**0.0432**
SPSI-R (NPO)	9.00 (5.78)	3.53 (3.09)	-5.47	**0.0011**	7.28 (4.62)	6.72 (4.51)	-0.56	0.3212
SPSI-R (RPS)	11.53 (3.07)	17.47 (2.47)	5.93	**< 0.0001**	13.83 (2.43)	14.94 (2.31)	1.11	**0.0263**
SPSI-R (ICS)	7.40 (3.40)	3.80 (2.65)	-3.60	**0.0020**	6.50 (2.64)	5.33 (3.25)	-1.17	**0.0424**
SPSI-R (AS)	11.27 (3.58)	5.73 (3.65)	-5.53	**0.0002**	9.56 (3.20)	9.17 (3.05)	-0.39	0.4079
JCS-Confrontive	15.20 (6.11)	21.33 (4.08)	6.13	**0.0007**	16.72 (6.30)	17.89 (5.35)	1.17	0.3076
JCS-Evasive	15.60 (7.68)	14.20 (6.64)	-1.40	0.4755	15.89 (6.56)	14.50 (6.11)	-1.39	0.2141
JCS-Optimistic	16.73 (2.76)	21.27 (3.33)	4.53	**< 0.0001**	18.56 (3.82)	18.56 (4.25)	0.00	1.0000
JCS-Fatalistic	5.33 (2.06)	4.93 (2.15)	-0.40	0.4860	3.28 (2.16)	4.22 (2.44)	0.94	0.1514
JCS-Palliative	5.80 (3.08)	6.93 (3.28)	1.13	0.2948	7.67 (5.37)	8.06 (4.54)	0.39	0.4930
JCS-Supportant	7.80 (3.03)	10.60 (1.72)	2.80	**0.0098**	8.94 (2.07)	9.39 (2.28)	0.44	0.4953
JCS-Reliant	12.53 (3.11)	13.60 (2.03)	1.07	0.1608	11.89 (4.20)	11.67 (4.21)	-0.22	0.6952
JCS-Emotive	5.67 (2.97)	5.20 (2.88)	-0.47	0.3443	4.39 (2.25)	4.06 (1.95)	-0.33	0.5282

7.4 Intervention Effects on Depression and Coping Outcomes

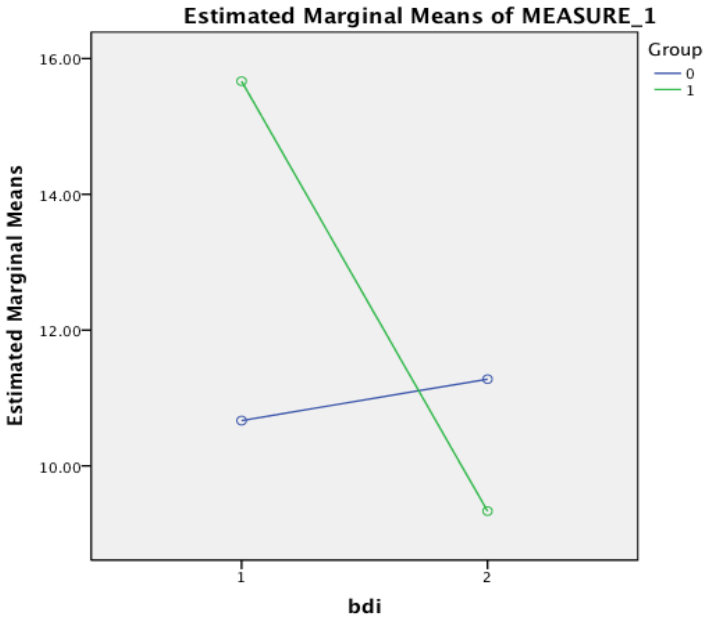
Table 5 (below and the next five pages) presents the results of a repeated measure ANOVA for depression assessment scores (BDI and PHQ9) and health-quality-of-life survey score (MCS and PCS). The Between-subjects effects assess main-effect group differences for the overall survey test means. The within-subjects effects assess the differences in the pre- and posttest scores, and the within-subjects interaction assesses whether the PST intervention group is significantly different from the group that received standard treatment (see Table next page).

Table 5: Summary of Repeated Measures ANOVA for Depression and HRQOL

Source	*SS*	*df*	*MS*	*F*
BDI				
Between-Subjects				
Intervention	38.19	1	38.19	.61
Error	1947.47	31	62.82	
Within-Subjects				
BDI	133.95	1	133.95	6.420*
BDI x Intervention	197.29	1	197.29	9.45**
Error	646.806	31	20.865	
PHQ-9				
Between-Subjects				
Intervention	13.09	1	13.09	.56
Error	725.94	31	23.42	
Within-Subjects				
PHQ-9	228.75	1	228.75	28.25***
PHQ-9 x Intervention	196.03	1	196.03	24.21***
Error	251.006	31	8.097	
MCS				
Between-Subjects				
Intervention	137.67	1	137.67	1.37
Error	3117.07	31	100.55	
Within-Subjects				
MCS	377.10	1	377.10	4.42*
MCS x Intervention	514.28	1	514.28	6.02*
Error	2646.009	31	85.355	
PCS				
Between-Subjects				
Intervention	15.93	1	15.93	.14
Error	3593.56	31	115.92	
Within-Subjects				
PCS	8.64	1	8.64	.128
PCS x Intervention	86.06	1	86.06	1.28
Error	2090.162	31	67.425	

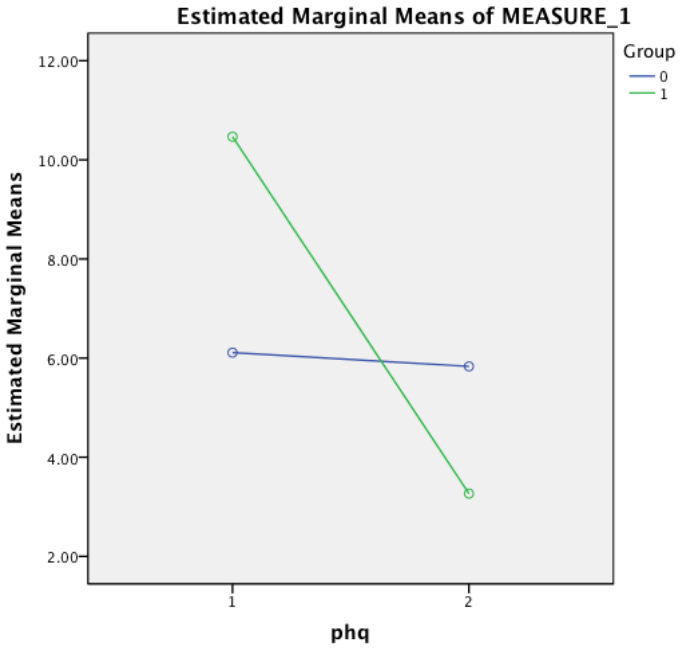
There were no significant differences in BDI scores for the main effect of PST intervention: F (1,31)=.608, P(.441) >.05. The interaction of PST intervention and BDI scores was significant: F (1,31)=9.45, p(.004)<.01. The PST intervention group showed a significant decrease in depression scores from baseline to posttest (baseline mean =15.67; posttest mean = 9.33) as compared to the control group (baseline mean= 10.67; posttest mean = 11.28)

Figure 4: Plot of BDI scores by PST intervention



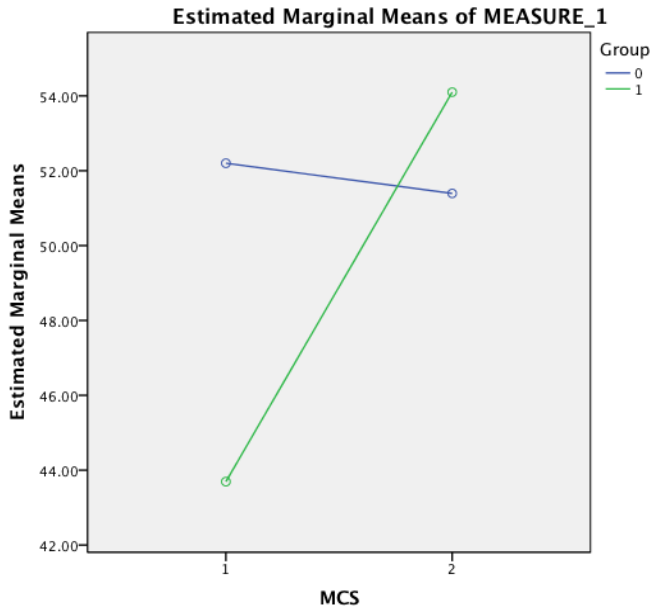
There were no significant differences in PHQ-9 scores for the main effect of PST intervention: F (1,31)=.559, p(.460) >.05. The interaction of PST intervention and PHQ-9 scores was significant: F (1,31)=24.21, p (.000)<.01. The PST intervention group showed a significant decrease in depression scores from baseline to posttest (baseline mean =10.47; posttest mean = 3.27) while the control group showed little change (baseline mean= 6.11; posttest mean= 5.83)

Figure 5: Plot of PHQ-9 scores by PST intervention



There were no significant differences in MCS scores for the main effect of PST intervention: F(1,31)= 1.369, p(.251) >.05. The interaction of PST intervention and MCS scores was significant: F (1,31)=6.02, p(.020)<.05. The PST intervention group showed a significant increase in mental component scores from baseline to post-test (baseline mean =43.69; posttest mean = 54.10) while the control group showed little change (baseline mean= 52.20; posttest mean= 51.39).

Figure 6: Plot of MCS scores by PST intervention



There were no significant differences in PCS scores for the main effect of PST intervention, and the interaction between PCS scores and PST was not significant; F(1,31)=.137, p(.713)>.05. The interaction of PST intervention and PCS scores was not significant: F (1,31)=1.276, p(.267) >.05. Furthermore, there were only small differences in mean scores over the course of the study, as there was a slight increase for the intervention group (baseline mean= 34.02; posttest mean= 37.04) and a slight decrease for control group (baseline mean= 35.33; posttest mean=33.77).

Figure 7: Plot of PCS scores by PST intervention

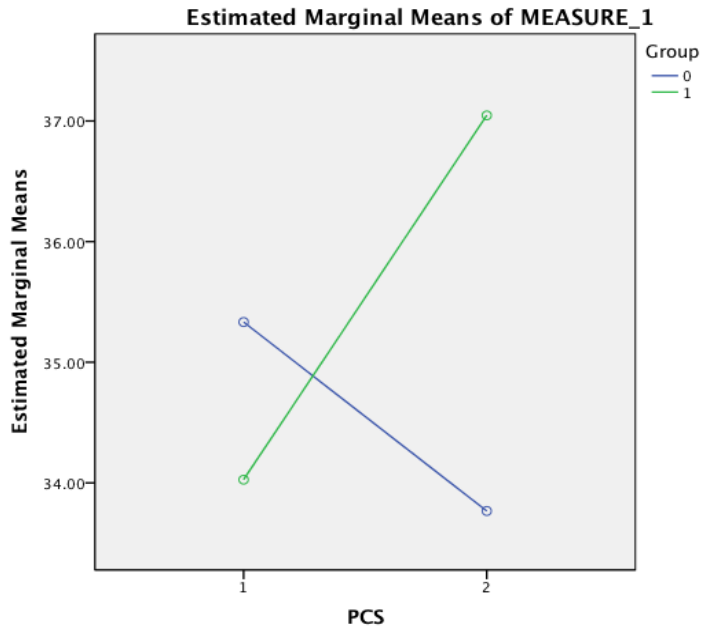


Table 6 (this page and the next four pages) presents the results of a repeated measure ANOVA for SPSI and JCS coping survey scores. The between-subjects effects assess main effect group differences for the overall survey test means. The within-subjects effects assess the differences in the pre- and posttest scores, and the within-subjects interaction assesses whether the PST intervention group is significantly different from the group that received standard treatment.

Table 6**: Summary of Repeated Measures ANOVA for SPSI-R and JCS (Coping)**

Source	***SS***	***df***	***MS***	***F***
SPSI-PPO				
Between-Subjects				
Group	52.69	1	52.69	3.28
Error	497.67	31	16.05	
Within-Subjects				
SPSI-PPO	169.31	1	169.31	68.12**
SPSI-PPO x Group	92.95	1	92.95	37.39**
Error	77.05	31	2.48	

Table 6 (continued)

SPSI-NPO				
Between-Subjects				
Group	8.80	1	8.80	.253
Error	1078.86	31	34.80	
Within-Subjects				
SPSI-NPO	148.36	1	148.36	19.81***
SPSI-NPO x Group	98.66	1	98.66	13.17***
Error	232.08	31	7.48	
SPSI-RPS				
Between-Subjects				
Group	.202	1	.202	.022
Error	283.55	31	9.14	
Within-Subjects				
SPSI-RPS	203.00	1	203.00	50.2***
SPSI-RPS x Group	95.12	1	95.12	23.52***
Error	125.35	31	4.04	
SPSI-ICS				
Between-Subjects				
Group	1.64	1	1.64	.121
Error	420.45	31	13.56	
Within-Subjects				
SPSI-ICS	92.95	1	92.95	20.87***
SPSI-ICS x Group	24.22	1	24.22	5.43*
Error	138.05	31	4.45	
SPSI-AS				
Between-Subjects				
Group	12.13	1	12.13	.697*
Error	539.80	31	17.41	

Table 6 (continued)

Within-Subjects				
SPSI-AS	143.47	1	143.47	27.97***
SPSI-AS x Group	108.26	1	108.26	21.10***
Error	159.00	31	5.12	
JCS-Confrontive				
Between-Subjects				
Group	15.11	1	15.11	.308
Error	1521.00	31	49.06	
Within-Subjects				
JCS-Confrontive	218.00	1	218.00	17.06***
JCS-Confrontive x Group	100.91	1	100.91	7.89**
Error	396.11	31	12.77	
JCS-Evasive				
Between-Subjects				
Group	1.41	1	1.41	.020
Error	2488.33	31	72.52	
Within-Subjects				
JCS-Evasive	31.81	1	31.81	1.76
jCS-Evasive x Group	.001	1	.001	.000
Error	559.93	31	18.06	
JCS-Optimistic				
Between-Subjects				
Group	3.23	1	3.23	.157
Error	638.88	31	20.60	
Within-Subjects				
JCS-Optimistic	84.07	1	84.07	14.65**
JCS-Optimistic x Group	84.07	1	84.07	14.65**
Error	177.86	31	5.73	

Table 6 (continued)

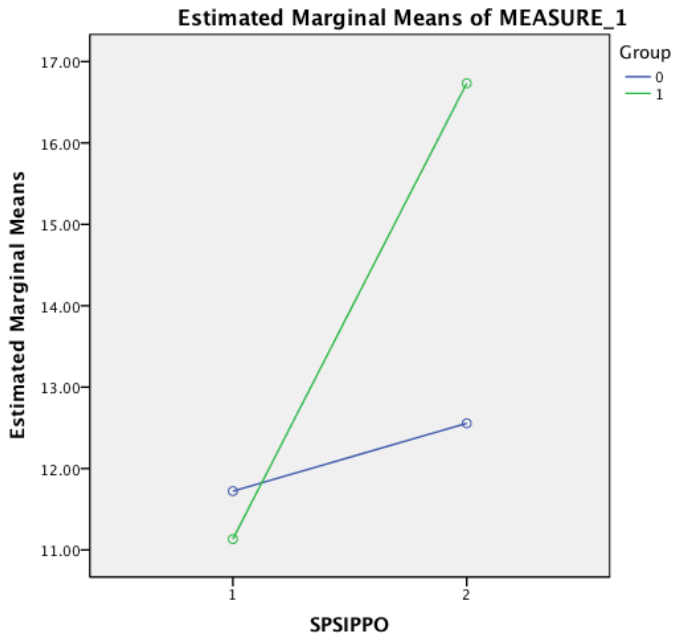
JCS-Fatalistic				
Between-Subjects				
Group	31.31	1	31.31	4.58*
Error	211.71	31	6.83	
Within-Subjects				
JCS-Fatalistic	1.21	1	1.21	.403
JCS-Fatalistic x Group	7.39	1	7.39	2.45
Error	93.27	31	3.00	
JCS-Emotive				
Between-Subjects				
Group	24.00	1	24.00	2.28
Error	326.08	31	10.51	
Within-Subjects				
JCS-Emotive	2.61	1	2.61	1.25
JCS-Emotive x Group	.073	1	.073	.035
Error	64.86	31	2.09	
JCS-Palliative				
Between-Subjects				
Group	36.54	1	36.54	1.17
Error	963.27	31	31.07	
Within-Subjects				
JCS-Palliative	9.47	1	9.47	1.82
JCS-Palliative x Group	2.26	1	2.26	.437
Error	161.00	31	5.19	
JCS-Supportant				
Between-Subjects				
Group	.018	1	.018	.003
Error	176.80	31	5.70	

Table 6 (continued)

Within-Subjects				
JCS-Supportant	43.06	1	43.06	8.64**
JCS-Supportant x Group	22.69	1	22.69	4.55*
Error	154.42	31	4.98	
JCS-Self-Reliant				
Between-Subjects				
Group	27.18	1	27.18	1.21
Error	693.08	31	22.35	
Within-Subjects				
JCS-Self-Reliant	2.91	1	2.91	.886
JCS-Self-Reliant x Group	6.79	1	6.79	2.06
Error	102.02	31	3.29	

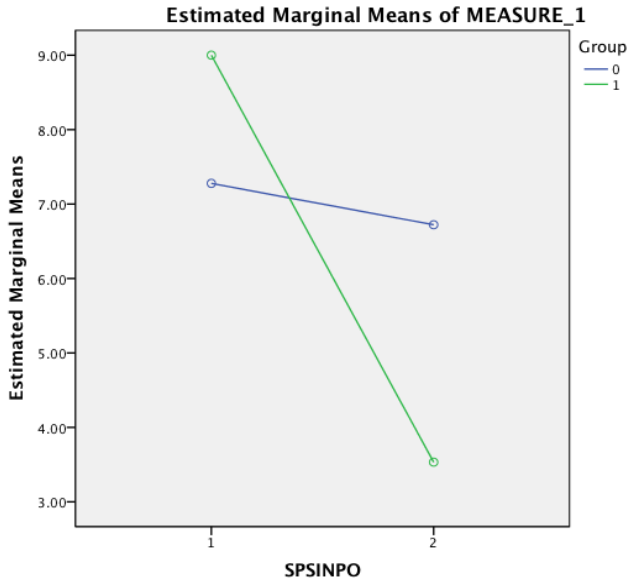
There were no significant differences in SPSI-PPO (Positive Problem Orientation) scores for the main effect of PST intervention: F (1,31)= 3.28, p (.08) > .05. The interaction of PST intervention and SPSI-PPO scores was significant: F (1,31)=37.39, p (.000)<.01. The PST intervention group showed a significant increase in SPSI-PPO scores from baseline to post-test (baseline mean =11.13; posttest mean = 16.73) while the control group showed little change (baseline mean= 11.72; posttest mean= 12.55)

Figure 8: Plot of SPSI-PPO scores by PST intervention



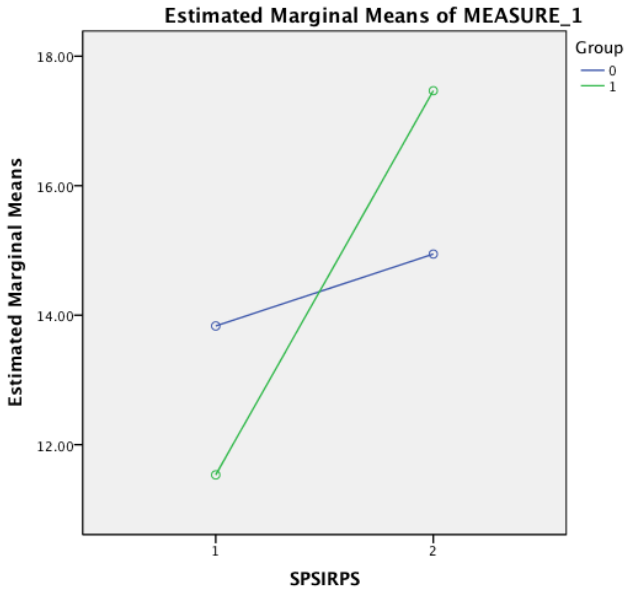
There were no significant differences in SPSI-NPO (Negative Problem Orientation) scores for the main effect of PST intervention, F (1,31) = .253, p (.619) >.05. The interaction of PST intervention and SPSI-NPO scores was significant, F (1,31)=13.17, p(.001)<.01. The PST intervention group showed a significant decrease in SPSI-NPO scores from baseline to post test (baseline mean =9.00; posttest mean = 3.5) while the control group showed little change (baseline mean= 7.27; posttest mean= 6.72)

Figure 9: Plot of SPSI-NPO scores by PST intervention



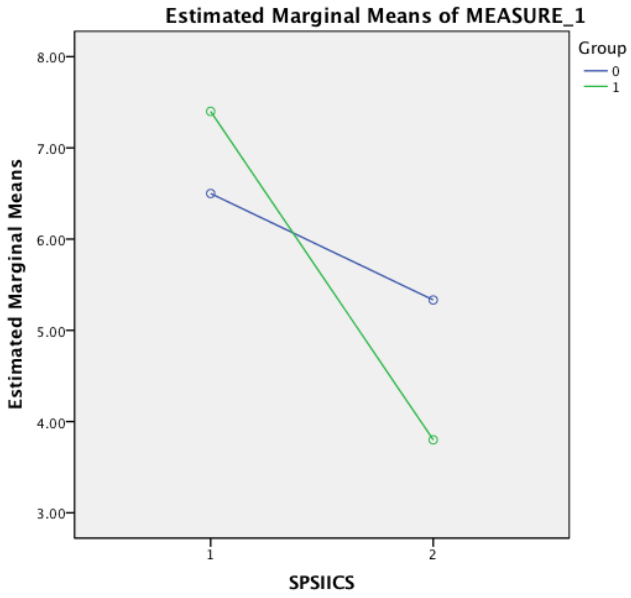
There were no significant differences in SPSI-RPS(Rational Problem Solving) scores for the main effect of PST intervention: F, (1,31)= .022, p(.883) >.05. The interaction of PST intervention and SPSI-RPS scores was significant: F (1,31)=23.52, p(.000)<.01. The PST intervention group showed a significant increase in SPSI-RPS scores from baseline to post test (baseline mean =11.53; posttest mean = 17.46) as compared to the control group (baseline mean= 13.83; posttest mean= 14.94)

Figure 10: Plot of SPSI-RPS scores by PST intervention



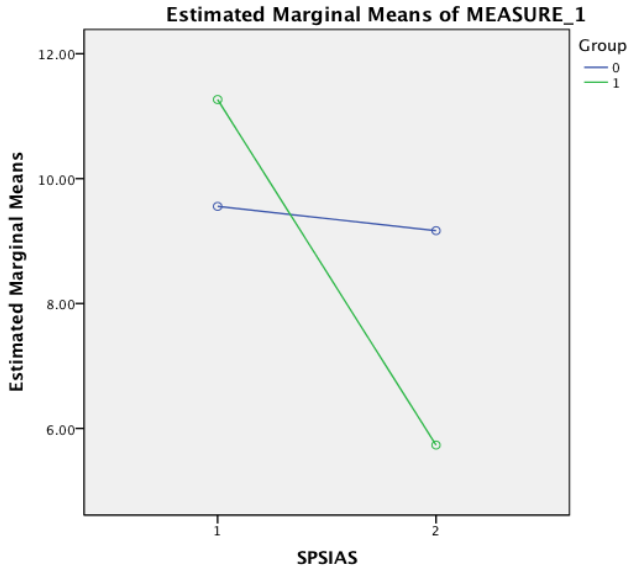
There were no significant differences in SPSI-ICS (Impulsivity/Carelessness Style) scores for the main effect of PST intervention: F, (1,31)= .121, p(.730)> .05. The interaction of PST intervention and SPSI-ICS scores was significant,: F (1,31)=5.43, p (.026)< .01. The PST intervention group showed a significant decrease in SPSI-ICS scores from baseline to post test (baseline mean =7.40; posttest mean = 3.80) as compared to the control group (baseline mean= 6.50; posttest mean= 5.33)

Figure 11: Plot of SPSI-ICS scores by PST intervention



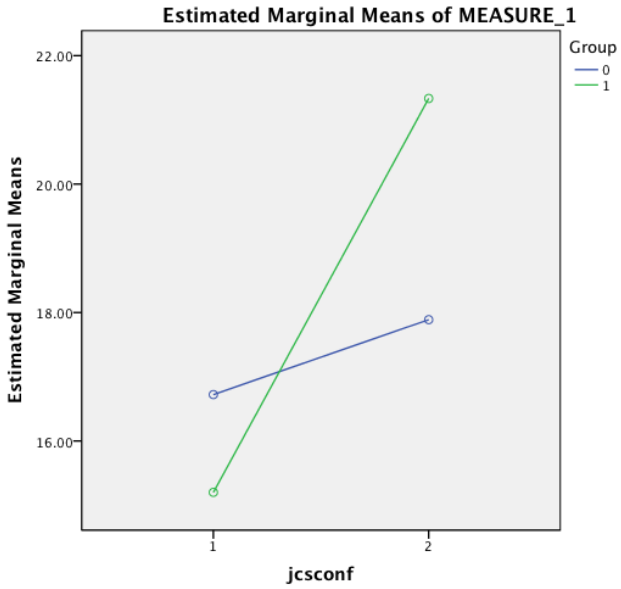
There were no significant differences in SPSI-AS (Avoidance Style) scores for the main effect of PST intervention: F (1,31) = .697, p (.410) >.01. The interaction of PST intervention and SPSI-AS scores was significant: F (1,31) = 21.10, p (.000)< .01. The PST intervention group showed a significant decrease in SPSI-AS scores from baseline to posttest (baseline mean =11.26; posttest mean = 5.73) as compared to the control group (baseline mean = 9.55; posttest mean = 9.16)

Figure 12: Plot of SPSI-AS scores by PST intervention



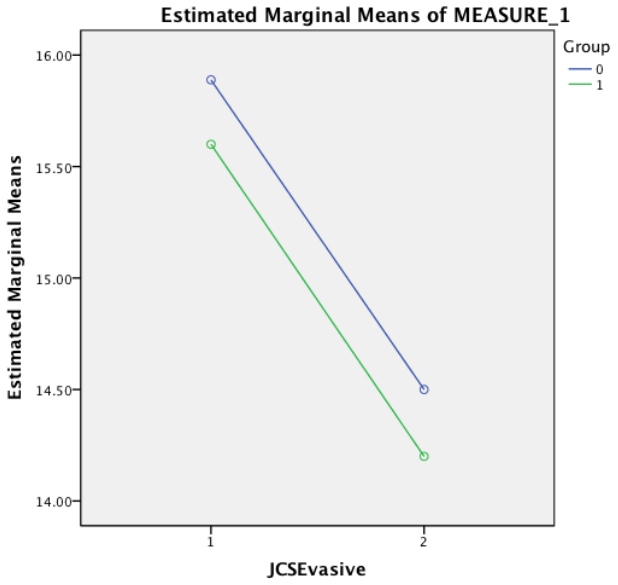
There were no significant differences in JCS-Confrontive scores for the main effect of PST intervention: F (1,31)= .308, p(.583) >.05. The interaction of PST intervention and SPSI-RPS scores was significant: F (1,31)=7.89, p(.009)<.01. The PST intervention group showed a significant increase in JCS-Confrontive scores from baseline to posttest (baseline mean =15.20; posttest mean = 21.33) while the control group showed little change (baseline mean= 16.72; posttest mean= 17.88)

Figure 13: Plot of JCS-Confrontive scores by PST intervention



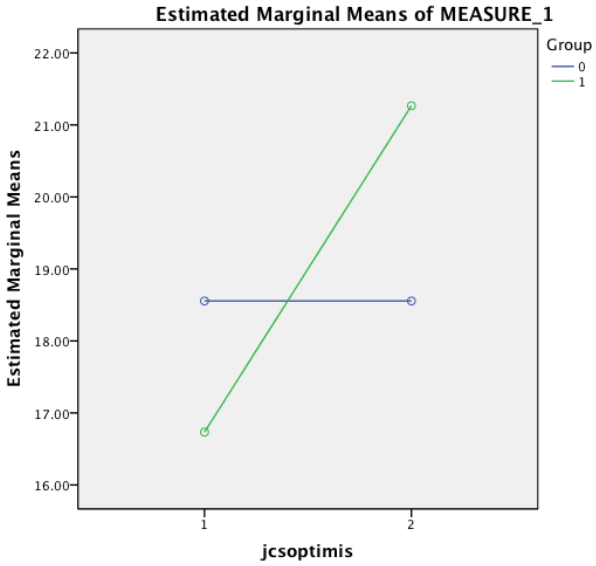
There were no significant differences in JCS-Evasive scores for the main effect of PST intervention and the interaction between PCS scores and PST was not significant; $F(1,31)=.020$, $p(.890)>.05$. The interaction of PST intervention and JCS-Evasive scores was not significant: $F(1,31)=.000$, $p(.996)>.05$. There were no significant differences in mean scores over the course of the study, as there was a slight decrease for the intervention group (baseline mean= 15.60; posttest mean= 14.20) and a slight decrease for control group (baseline mean= 15.88; posttest mean=14.50).

Figure 14: Plot of JCS-Evasive scores by PST intervention



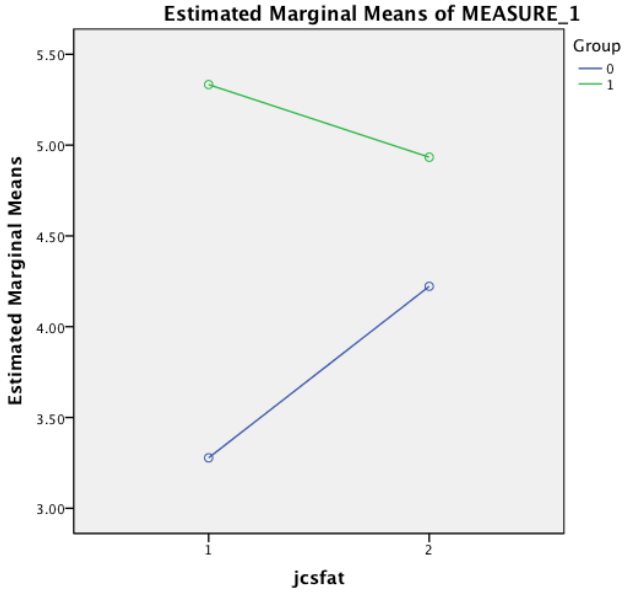
There were no significant differences in JCS-Optimistic scores for the main effect of PST intervention F (1,31)= .157, p(.695) >.05. The interaction of PST intervention and JCS-Optimistic scores was significant, F (1,31)=14.65, p(.001)<.01. The PST intervention group showed a significant increase in JCS-Optimistic scores from baseline to post test (baseline mean =16.73; posttest mean = 21.26) while the control group showed no change (baseline mean= 18.55; posttest mean= 18.55)

Figure 15: Plot of JCS-Optimistic scores by PST intervention



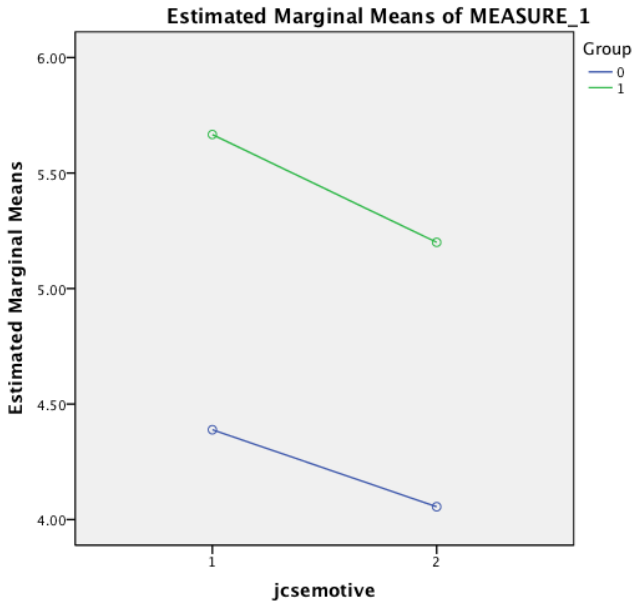
There were significant differences in JCS-Fatalistic scores for the main effect of PST intervention: F (1,31)= .4.59, p<.05. The interaction of PST intervention and JCS-Fatalistic scores was not significant: F (1,31)=2.45, p(.127) >.05.

Figure 16: Plot of JCS-Fatalistic scores by PST intervention



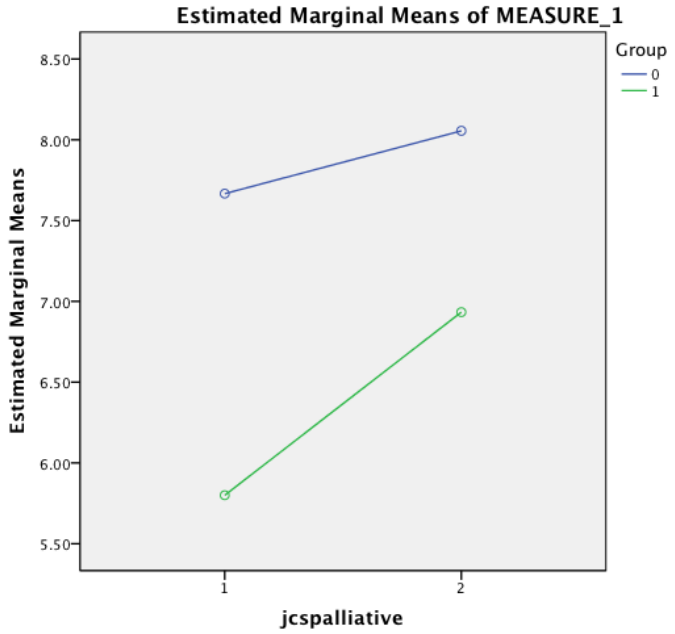
There were no significant differences in JCS-Emotive scores for the main effect of PST intervention: F (1,31)= 2.282, p(.141) >.05. The interaction of PST intervention and JCS-Emotive scores was not significant: F (1,31)=.035, p(.853) >.05.

Figure 17: Plot of JCS-Emotive scores by PST intervention



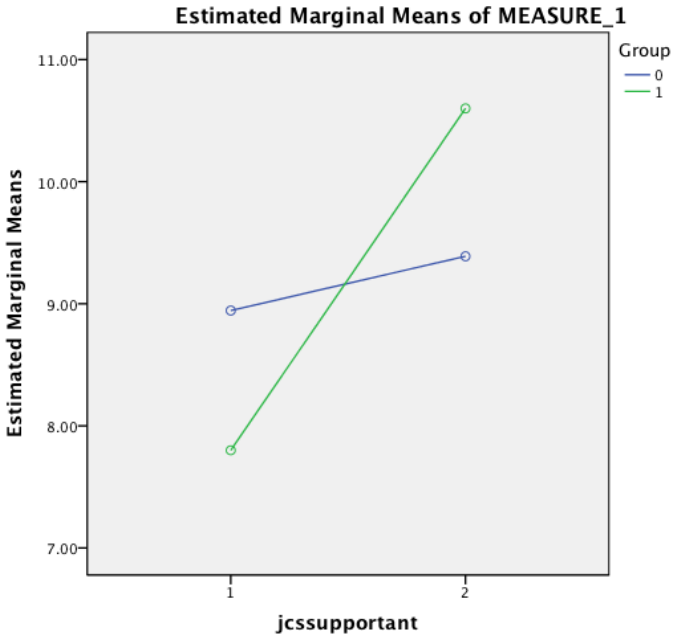
There were no significant differences in JCS-Palliative scores for the main effect of PST intervention, F (1,31)=1.17, p (.287)> .05. The interaction of PST intervention and JCS-Palliative scores was not significant, F (1,31)=.437, p(.514) >.05.

Figure 18: Plot of JCS-Palliative scores by PST intervention



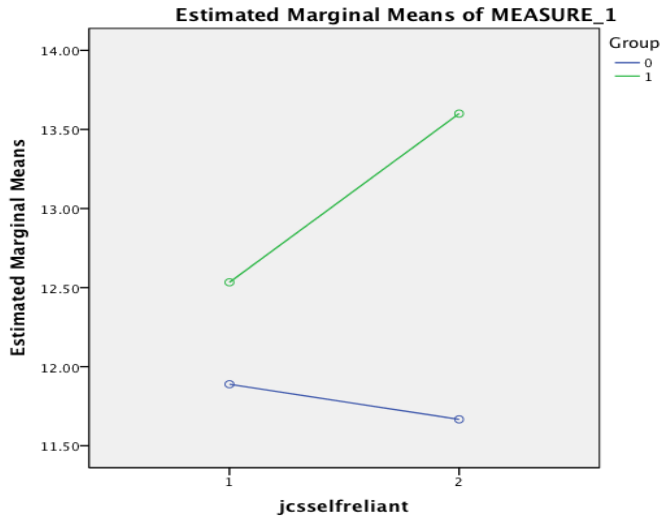
There were no significant differences in JCS-Supportant scores for the main effect of PST intervention: F (1,31)=.003, p(.955) >.05. The interaction of PST intervention and JCS-Supportant scores was significant: F (1,31)=4.55, p(.041)<.05. The PST intervention group showed a significant increase in JCS-Supportant scores from baseline to post test (baseline mean =7.80; posttest mean = 10.60) while the control group showed no change (baseline mean= 8.94; posttest mean= 9.38)

Figure 19: Plot of JCS-Supportant scores by PST intervention



There were no significant differences in JCS-Self-Reliant scores for the main effect of PST intervention, F (1,31)=1.21), p(.279) >.05. The interaction of PST intervention and JCS-Self-Reliant scores was not significant, F (1,31)=.2.065, p(.161) >.05.

Figure 20: Plot of JCS- Self-Reliant scores by PST intervention



7.5 Comparison across Study Measures

In any statistical study, it is crucial to understand interrelationships between variables. Correlation coefficients less than -0.50 and greater than 0.50 are highlighted to facilitate interpretation of the results. There was a strong positive correlation between the post BDI and post PHQ9 variables (r = 0.8095). This indicates that increases in post BDI scores are correlated with increases in post PHQ9 scores. The strongest correlation between post BDI scores and post survey scores for the various coping surveys was for the JCS-Fatalistic survey variable (r = 0.5230). This indicates that increases in post BDI scores are correlated with increases in post JCS-Fatalistic survey scores. The post PHQ9 survey scores did not have correlations greater than 0.50 or less than -0.50 with other survey variables. Other strong and moderately strong correlations occur between pairings of some coping survey variables. For instance, there is a strong negative correlation (r = -0.8047) between the SPSI-RPS and SPSI-AS. This indicates that an increase in one variable results in a decrease in the other. Table 7 (on the following page) represents the interrelationships between study variables via correlational matrices.

Table 7: Correlation Matrix for Post Survey Variables

Name	BDI	PHQ9	MCS	PCS	SPSI-PPO	SPSI-NPO	SPSI-RPS	SPSI-ICS	SPSI-AS	JCS-Confrontive	JCS-Evasive	JCS-Optimistic	JCS-Fatalistic	JCS-Palliative	JCS-Support.	JCS-Self-Reliant	JCS-Emotive
BDI	1.0000	0.8095	-0.3773	-0.1822	-0.1863	0.4354	-0.3861	0.4423	0.3678	-0.2988	0.3632	-0.2005	0.5230	-0.1715	-0.1646	-0.0382	0.0988
PHQ9	0.8095	1.0000	-0.4956	-0.2426	-0.1843	0.2799	-0.3309	0.4337	0.3763	-0.3000	0.2647	-0.3001	0.3038	-0.0482	-0.1816	-0.0978	0.0155
MCS	-0.3773	-0.4956	1.0000	0.0763	0.1371	-0.1215	0.1443	-0.3676	-0.3517	0.1033	-0.1563	0.2509	-0.1546	-0.2150	0.1362	-0.1342	-0.1954
PCS	-0.1822	-0.2426	0.0763	1.0000	0.1054	-0.1542	0.0738	-0.3080	-0.2199	0.2200	0.0578	0.1734	0.0297	0.0053	-0.1737	0.1320	0.2507
SPSI-PPO	-0.1863	-0.1843	0.1371	0.1054	1.0000	-0.6411	0.6791	-0.4220	-0.5879	0.4536	-0.1213	0.3322	0.0733	0.1275	0.1269	0.4552	0.1801
SPSI-NPO	0.4354	0.2799	-0.1215	-0.1542	-0.6411	1.0000	-0.7996	0.6116	0.6389	-0.5270	0.3596	-0.2476	0.3332	-0.2886	-0.1113	-0.5014	0.0329
SPSI-RPS	-0.3861	-0.3309	0.1443	0.0738	0.6791	-0.7996	1.0000	-0.6282	-0.8047	0.4782	-0.3011	0.2190	-0.2364	0.1822	0.2064	0.3895	0.0824
SPSI-ICS	0.4423	0.4337	-0.3676	-0.3080	-0.4220	0.6116	-0.6282	1.0000	0.5467	-0.3947	0.0792	-0.1131	0.2335	-0.0729	-0.1203	-0.2830	0.0038
SPSI-AS	0.3678	0.3763	-0.3517	-0.2199	-0.5879	0.6389	-0.8047	0.5467	1.0000	-0.3965	0.3775	-0.1370	0.2665	0.0254	-0.0231	-0.3442	-0.0189
JCS-Confrontive	-0.2988	-0.3000	0.1033	0.2200	0.4536	-0.5270	0.4782	-0.3947	-0.3965	1.0000	0.0886	0.6824	0.2249	0.4560	0.4611	0.5880	0.1701
JCS-Evasive	0.3632	0.2647	-0.1563	0.0578	-0.1213	0.3596	-0.3011	0.0792	0.3775	0.0886	1.0000	0.3336	0.7073	0.2828	0.2580	0.2024	0.4448
JCS-Optimistic	-0.2005	-0.3001	0.2509	0.1734	0.3322	-0.2476	0.2190	-0.1131	-0.1370	0.6824	0.3336	1.0000	0.4861	0.5492	0.5389	0.5560	0.2845
JCS-Fatalistic	0.5230	0.3038	-0.1546	0.0297	0.0733	0.3332	-0.2364	0.2335	0.2665	0.2249	0.7073	0.4861	1.0000	0.1496	0.2837	0.3150	0.4184
JCS-Palliative	-0.1715	-0.0482	-0.2150	0.0053	0.1275	-0.2886	0.1822	-0.0729	0.0254	0.4560	0.2828	0.5492	0.1496	1.0000	0.2897	0.5664	0.3209
JCS-Support.	-0.1646	-0.1816	0.1362	-0.1737	0.1269	-0.1113	0.2064	-0.1203	-0.0231	0.4611	0.2580	0.5389	0.2837	0.2897	1.0000	0.1364	0.0009
JCS-Self-Reliant	-0.0382	-0.0978	-0.1342	0.1320	0.4552	-0.5014	0.3895	-0.2830	-0.3442	0.5880	0.2024	0.5560	0.3150	0.5664	0.1364	1.0000	0.2544
JCS-Emotive	0.0988	0.0155	-0.1954	0.2507	0.1801	0.0329	0.0824	0.0038	-0.0189	0.1701	0.4448	0.2845	0.4184	0.3209	0.0009	0.2544	1.0000

7.6 Moderating Effects of Coping on Depression Outcomes

The moderating role of the subscales of the Social Problem-Solving Inventory-Revised (SPSI-R) and the Jaloweic Coping Scale (JCS) will be examined in this section using a linear regression analysis. Table 8, Table 9, and Table 10 demonstrate the results for PHQ9 with the linear regression model. If adjusted for all post-primary coping sub-scales (SPSI-PPO, SPSI-NPO, SPSI-RPS, SPSI-ICS, SPSI-AS, PHQ9PRE), only the SPSI-ICS scale affects the post PHQ9 score. The higher SPSI-ICS score corresponds with the higher post PHQ9 score ($p=0.0429$). The treatment group has lower PHQ9 score compared with the control group ($p=0.0057$) (Table 8). In addition, if adjusted only for the SPSI-ICS and PHQ9 pre-scores, the treatment group has a lower PHQ9 score ($p=0.0025$) (Table 9). If adjusted only for the pre PHQ9 score, the PHQ9 score in the treatment group is 4.23 times lower than that in the control group (Table 10).

Table 8: Linear regression model for PHQ9 adjusting all post primary coping scales

Parameter	Estimate	Standard Error	P-value
Intercept	-2.902479508	8.35991858	0.7314
Group	-3.742975889	1.23703411	0.0057
SPSI-PPO	0.116124561	0.18964719	0.5459
SPSI-RPS	0.041360758	0.40925739	0.9203
SPSI-NPO	-0.167766452	0.20785422	0.4272
SPSI-ICS	0.450626146	0.21128059	0.04
SPSI-AS	0.310493818	0.22513006	0.1801
PHQ9PRE	0.415296249	0.11353106	0.0012

Table 9: Linear regression model for PHQ9 and SPSI-ICS

Parameter	Estimate	Standard Error	P-value
Intercept	1.180567904	1.26269230	0.3575
Group	-3.575061251	1.08127663	0.0025
SPSI-ICS	0.432606349	0.16163074	0.0121
PHQ9PRE	0.383814257	0.10800316	0.0013

Table 5: Linear regression model for PHQ9 only

Parameter	Estimate	Standard Error	P-value
Intercept	3.505892556	1.00603041	0.0015
Group	-4.225497184	1.15679746	0.0010
PHQ9PRE	0.380853945	0.11857402	0.0031

Table 11 and Table 12 demonstrate the results for BDI with the linear regression model. Table 11 indicates that none of the primary coping scales have any significant effects on the post BDI. If adjusted only for the pre-BDI score, the treatment group has lower post BDI score (p=0.0029).

Table 6: Linear regression model for BDI adjusting all post primary coping scales

Parameter	*Estimate*	*Standard Error*	*P-value*
Intercept	0.451362147	16.30609344	0.9781
Group	-2.269998081	2.46525063	0.3660
SPSI-PPO	0.166932189	0.37751878	0.6622
SPSI-RPS	0.003233319	0.79537936	0.9968
SPSI-NPO	0.146690581	0.42990136	0.7358
SPSI-ICS	0.362242978	0.41689478	0.3932
SPSI-AS	0.266321295	0.43415384	0.5451
BDIpre	0.311516375	0.16215399	0.0662

Table 7: Linear regression model for BDI

Parameter	*Estimate*	*Standard Error*	*P-value*
Intercept	6.712032568	1.86106792	0.0011
Group	-4.084637512	1.91891210	0.0416
BDIpre	0.428038613	0.13219853	0.0029

7.7 Adjusted Outcomes

When adjusting for baseline depression scores, it was found that mean six-week BDI and PHQ scores were significantly lower in the intervention group. Results indicated that mean change-from-baseline depression scores were significantly improved in the intervention group relative to the usual care group (change in PHQ 7.2 vs. 0.3, P<0.001; change in BDI 6.3 vs. –0.6, P=0.008).

7.8 Additional outcomes of interest

Patient satisfaction questionnaires

In response to the patient satisfaction questionnaire subjects in the PST +Usual Care group (N=15) reported overall satisfaction with the PST intervention, agreed that in-center treatment was comfortable, and led to better problem-solving skills for managing dialysis treatment. Patients in the treatment group also agreed that the PST intervention helped to improve coping with problems associated with dialysis treatment and illness.

Participation in PST Homework

While we don't know how many in-home pleasurable activities subjects were engaging in prior to the study, outcomes from the study suggest that subjects in the experimental group were receptive to this aspect of PST intervention. When given the goal of completing two pleasurable activities daily, subjects in the PST group (N=15) completed a mean of (11.64) activities weekly.

7.8 Case Study exploratory review of PST intervention

The following seven case vignettes were generated from actual PST intervention participants in the study. The names have been changed to abbreviations, and identifiers have been omitted to safeguard confidentiality. While the case information is incomplete, the vignettes are designed to provide a profile of participants and to delineate patients' experiences with dialysis, chronic illness, problem solving, and PST intervention.

Case#1: AB

AB is a 63-year-old divorced Caucasian male who presented for six weeks of Problem Solving Therapy (PST) in the outpatient dialysis unit setting. At the start of PST, AB had received five months of outpatient hemodialysis treatments. His medical history included End Stage Renal Disease (ESRD), type 2 diabetes, insomnia, heart failure, and a left-leg below-knee amputation (BKA). AB was prescribed 11 medications. Prior to starting on dialysis, he was hospitalized for two months with renal failure, at which time he also underwent his amputation. After hospitalization, AB was admitted to an extended care facility for one to two months. He was then discharged to home with outpatient physical rehabilitation services and support from his brother and extended-family members.

On presentation, AB's main support systems included his brothers, sister, close friends, and neighbors. He had no children. He resided alone in a one-story home that was handicap-accessible. He was a high-school graduate who had been working full time prior to starting dialysis. Due to medical problems, he was unable to return to work and received a limited monthly Social Security income. At the start of PST, the patient did not have adequate insurance or prescription coverage.

AB presented for PST treatment with moderately severe depression [Patient Health Questionnaire-9 (PHQ-9) score of 18; Beck Depression Inventory-II (BDI-II) score of 23]. At the start of PST, he reported mild coping problems, frustration about medical problems, and worries about finances. Although expressing that he felt overwhelmed by his poor health and limited resources, AB was receptive to PST orientation, which involved a discussion about how his attitude toward solving problems and his problem-solving skills

impacted his ability to manage stressful problems. During the initial orientation session, AB was agreeable to completing homework assignments, including identifying and documenting pleasurable activities. Over the course of the PST intervention, AB continued to be open to this approach and engaged in more than 80 documented pleasurable activities.

AB identified post-amputation goals, such as feeling stronger, being more confident, ambulating in his home with a prosthetic leg, and coping with and adjusting to multiple lifestyle changes. Specifically, AB defined realistic goals that focused on increasing the number and duration of times during which he would walk independently or with a walker, cane, or prosthetic leg in his home. He also identified realistic short-term goals that might help him reduce financial stress in his life. At the end of therapy, AB's short-term goals resulted in improvements in confidence, coping, and adjustment, as well as in reduced symptoms of depression. At the end of six weeks of PST intervention, he completed physical rehabilitation, was confidently ambulating with a walker, and made plans for future travel. AB's post measures for depression revealed a PHQ-9 score of 3 and BDI-II score of 5, indicating a decline in depressive symptoms. During the final session, he reported having "one of the best days in a long time," and feeling "motivated, excited, involved, and eager to get stronger."

Case#2: CD

CD is a 69 -year-old married Caucasian male who presented for six weeks of PST in the dialysis unit setting. At the start of PST, CD had been undergoing dialysis treatments for five years. His medical history included ESRD, type 2 diabetes, obesity, congestive heart

failure (CHF), coronary artery disease (CAD), obstructive sleep apnea, retinal edema, pulmonary hypertension, and depressive disorder. He was taking Paxil once daily as well as 21 other prescribed medications. He presented with limited ability to complete activities of daily living (ADLs) due to multiple medical problems and cumbersome ambulation using a cane or walker.

CD resided in a handicap-accessible home with his wife, who was his primary caretaker and main support. He had limited support systems and, due to past family conflicts, reported minimal contact with his three children. The patient had completed ten years of education and presented with a fair understanding of his medical condition and treatment needs. He was unemployed and received Social Security disability (SSD) as his main source of income. Although he did not receive in-home services, he did utilize county transportation for his dialysis treatments.

CD presented for PST therapy with mild depression (PHQ-9 score 9; BDI-II score 6) and a KDQOL Mental Component Summary (MCS) score of 55.9. The patient's baseline SPSI-R indicated a higher score (17) for avoidant coping style, and his JCS indicated a higher score (9) on the evasive scale. Upon initiation of PST, he reported feeling mild difficulty in coping and a desire to be more independent and active at home. During orientation to problem solving, he expressed feeling overwhelmed about a recent hospitalization and reported feeling confused about how much physical activity he was able to do safely.

CD was receptive to PST and was agreeable to homework assignments. Over the course of the PST intervention, the patient completed 77 pleasurable activities as part of

the assignments. He reported that his wife enjoyed working with him on his homework, and he felt encouraged by the progress that he was making throughout the therapy. During the six-week trial, CD was able to identify measurable goals, including: (1) increasing activity in his home by 10%, and (2) reducing his fluid intake by 12 ounces a week. The patient was able to identify several barriers to accomplishing his goals including: (1) relying on his wife to manage his fluid intake, (2) succumbing to cravings, and (3) using avoidant and sometimes careless coping skills. At the end of six weeks of PST intervention, the patient reported over a 10% increase in activities at home and a 1 kg decrease in weight gains between some dialysis sessions.

CD's post measures for depression revealed a PHQ-9 score of 4, indicating a decline in depressive symptoms. Upon completing PST intervention, the patient also presented with an increase in his overall health-related quality of life (MCS score of 64.1) and his coping scores suggested more rational (18) and positive (19) coping, and less avoidant (6) and fatalistic (1) coping.

Case #3: EF

EF is a 69-year-old, married, Caucasian female who had been receiving hemodialysis treatments for two years at the start of PST intervention. Her medical history included type 2 Diabetes, CHF, gout, and a recent stroke with mild left-side paralysis. She was also diagnosed with depression with no other symptoms. She was taking Celexa once daily, as well as 30 other prescribed medications. As a result of her stroke, EF reported a recent change in her lifestyle and decreased ability to complete ADLs.

EF resided in a handicap-accessible home with her husband, the primary caretaker and main support. Between her husband and children, she had an adequate support system, and reported having a very close relationship with her daughter, as well as with her grandchildren. She had completed 12 years of education and presented with a fair understanding of her medical condition and treatment needs. EF was unemployed and received SSD as her main source of income. She did not receive in-home services, and she relied on her husband to transport her to dialysis treatments. She reported recent major lifestyle changes as a result of her stroke, including an inability to drive as well as poor concentration and memory. In addition, paralysis from her stroke had limited her ability to sew and knit, activities that had provided her with great enjoyment.

EF presented for PST therapy with moderately severe depression (PHQ-9 score 15; BDI-II score 17) and a KDQOL Mental Component Summary (MCS) score of 38.1. Her baseline SPSI-R indicated higher scores for negative (8), impulsive (9), and avoidant (13) coping styles and her JCS indicated higher scores on the evasive (23) and confrontive (24) scale.

At the start of PST, she reported feeling moderate difficulty with coping and a desire to be more independent and active at home. During orientation to problem-solving, she expressed that she felt overwhelmed by her recent stroke and sad about how her life had changed as a result of it. EF was receptive to PST orientation and was agreeable to homework assignments. Over the course of the PST intervention, the patient completed 52 pleasurable activities as part of the assignments. Upon completing the PST intervention at six weeks, EF asked to continue with homework assignments, specifically those that

involved reporting pleasurable activities. During the six-week trial, the patient was able to identify measurable goals such as devising a plan to visit with her daughter and identifying and completing activities in the home that were enjoyable and productive. EF was able to identify several barriers to accomplishing her goals, including: (1) dependence on her husband, (2) physical and mental limitations resulting from her previous stroke, and (3) recent symptoms of depression. During the six-week trial, the therapist and patient co-developed a "Positive Coping Card" that EF would carry to reinforce her strengths, goals, and accomplishments. The wallet-sized, 2x2-inch card read, "Great job. Small little steps help. Things are turning out better than I expected. I can do it."

The patient's post measures for depression revealed a PHQ-9 score of 4, and a BDI-II score of 9, indicating a decline in depressive symptoms. EF also demonstrated an increase in her overall health-related quality of life (MCS score of 55.0). In addition, her coping scores suggested more rational (19) and positive (20) coping, and less avoidant (4) and evasive (14) coping. At the end of six weeks of PST intervention, the patient reported less dependence on her husband, reduced symptoms of depression, and an improved quality of life. In summation, she stated:

> Although I am still uncertain about my future, I feel as though I can take the bull by the horns and get things done. I feel less sad about dialysis treatments, and believe that I have the ability to have a happy life and do things that are important and meaningful. Working through my concerns with you has been very helpful, and I feel more confident about tackling problems in the future. I know that, given my health condition, I will be facing a life time of challenges.

Case#4: GH

GH is an 82-year-old married Caucasian male who, at the start of PST intervention had been receiving hemodialysis treatments for two years. His medical history included ESRD, CAD, CHF, diabetes, and adjustment disorder with depressed mood. During the six-week trial, GH was taking Celexa once daily as well as 14 other prescribed medications. The patient reported a recent change in his lifestyle as a result of his wife's admission to an extended care facility related to her Alzheimer's disease.

GH had limited support systems, though he identified a male neighbor as his main support, to whom he had given medical and financial power of attorney (POA). He reported that his son, whom he had long ago placed in adoption, had recently contacted him. He described this relationship as comfortable but acknowledged that he did not rely on his son for support. GH resided alone in a large two-story home, which he could not maintain on his own. He was on a waiting list to move into retired and disabled housing. The patient had completed 12 years of education and had served for four years in the armed forces. He presented with a fair understanding of his medical condition and treatment needs. GH's main source of income was his pension and SSD. He did not receive in-home services and was able to transport himself to and from dialysis treatments.

GH had experienced recent major lifestyle changes as a result of his wife's medical and mental health condition and subsequent extended-care placement. In addition, he reported difficulty sleeping, poor appetite, and symptoms of depression. Although he understood his wife's need for 24-hour care, the depression, he believed, resulted from feelings of guilt surrounding his decision to place her in an extended care facility.

The patient presented for PST therapy with moderate depression (PHQ-9 score of 10; BDI-II score of 8) and a KDQOL Mental Component Summary (MCS) score of 35.5. The patient's baseline SPSI-R indicated higher scores for negative (16), impulsive (9) and avoidant (11) coping styles and his JCS indicated higher scores on the evasive (23) scale.

At the start of PST, the patient reported feeling moderate difficulty in coping. He expressed a desire to feel less sad about his wife's placement and an interest in making long-term alternative living plans. During the introduction to problem-solving orientation, he conveyed feeling overwhelmed about the tasks required in finding more suitable housing. GH was receptive to PST orientation and was agreeable to homework assignments. Over the course of the PST intervention, he completed 46 pleasurable activities and was very receptive to the assignments, with the exception of one week during the trial for which he was hospitalized. Despite his hospitalization, however, the patient completed six full weeks of PST intervention. During the six-week trial, GH was able to identify measurable goals such as finding more suitable housing and learning and understanding more about his wife's Alzheimer's diagnosis. He identified several barriers to accomplishing his goals including: (1) financial obstacles, (2) physical limitations resulting from previous hospitalization, and (3) recent symptoms of depression.

The patient's post measures for depression revealed a PHQ-9 score of 5, indicating a decline in depressive symptoms. GH revealed an increase in his overall health-related quality of life (MCS score of 43.2). His coping scores suggested more rational (18) and positive (18) coping and less avoidant (5), negative (2), and evasive (17) coping. At the end of the six-week intervention, GH reported a better understanding of his wife's medical

condition and decreased symptoms of depression. In addition, he completed all the necessary steps to secure a veteran's grant to reside in an assisted living facility close to his dialysis unit and his wife's extended-care home.

Case#5: IJ

IJ is a 68-year-old divorced Caucasian female who had been receiving hemodialysis treatments for eight years at the start of PST intervention. Her medical history included ESRD, CHF, diabetes, obesity, and Depressive Disorder. During the six-week trial, IJ was taking Celexa once daily, as well as 17 other prescribed medications.

The patient presented with adequate support systems, identifying her son and daughter-in-law as her main support and her POA. IJ resided in handicapped-accessible housing and received in-home services from the Area Agency on Aging (AAA). She also received transportation assistance to dialysis through the AAA's Shared Ride Program. The patient completed had seven years of education and reported some difficulty in reading and writing. Overall, she presented with a fair understanding of her medical condition and treatment needs. IJ was retired and received SSD as her main source of income.

The patient presented for PST therapy with moderately severe depression (PHQ-9 score of 17; BDI-II score of 18) and a KDQOL Mental Component Summary (MCS) score of 38. Her baseline SPSI-R indicated higher scores for negative (14), impulsive (13), and avoidant (15) coping styles, and her JCS indicated higher scores on the evasive (23) and self-reliant (13) scales.

At the start of PST, IJ reported feeling sad and frustrated about her poor health and her increasing dependence on her son and daughter-in-law for support. She expressed

feeling a lack of purpose and a desire to improve her ability to complete ADLs. The patient was receptive to PST orientation and was agreeable to homework assignments. Over the course of the intervention, IJ completed 70 pleasurable activities and was very receptive to the assignments. While she reported difficulty documenting her homework without assistance of her daughter-in-law, she successfully accomplished this goal during the last two weeks of therapy, completing the forms on her own. During the six-week trial, the patient was able to identify measurable goals such as walking without assistance from her daughter-in-law and developing a more positive coping style. She was able to identify several barriers to accomplishing her goals, including: (1) dependence on her son and daughter-in-law, (2) physical limitations resulting from medical problems, and (3) recent symptoms of depression.

IJ's post measures for depression revealed a PHQ-9 score of 2 and a BDI-II score of 12, indicating a decline in depressive symptoms. She also demonstrated an improvement in her overall health-related quality of life (MCS score of 66.6). At the completion of the six-week PST intervention, the patient's coping scores suggested more rational (20) and positive (18) coping and less avoidant (0), negative (6), and evasive (12) coping. At that time, IJ reported being able to walk independently in her apartment with her walker and to complete more tasks around her home, including her PST homework assignments. The patient talked about feeling more positive about her problems, more purposeful in her life, and less dependent on her family.

Case #6: KL

KL is a 76-year-old single Caucasian male who had been receiving hemodialysis treatments for three years at the start of PST intervention. His medical history included ESRD, diabetes, HTN, and Bipolar Disorder. During the six-week trial, he was taking Celexa, Depakote, and Lamictal, as well as 24 other prescribed medications.

The patient presented with limited support systems and identified his brother and his sister as his support. KL resided in handicap-accessible housing in a personal-care home with his brother. He received transportation to dialysis through the AAA's Shared Ride Program. The patient had completed seven years of education and reported significant barriers with reading and writing. Overall, he presented with a limited understanding of his medical condition and treatment needs. KL was retired and received SSD as his main source of income.

The patient presented for PST therapy with moderate depression (PHQ-9 score of 14; BDI-II score of 30), and a KDQOL Mental Component Summary (MCS) score of 31.3. His baseline SPSI-R indicated higher scores for negative (15), impulsive (6), and avoidant (14) coping styles and his JCS indicated higher scores on the evasive (24), self-reliant (16) and fatalistic (9) scales.

At the start of PST, KL reported feeling upset about recent news that his personal-care home was expected to close and that his brother would be the first resident to transfer to a nursing-home setting. During the first PST intervention, KL said that he was feeling overwhelmed by the changes in his life, including the possibility of being separated from his brother. The patient was receptive to PST orientation and was agreeable to homework

assignments. Given KL's literacy barrier, he agreed during the second week of intervention to be contacted at home to review what daily pleasurable activities he had completed. Over the course of the intervention, KL completed 52 pleasurable activities, although he did struggle with identifying new activities that he could incorporate into his life. During the six-week trial, the patient was able to identify measurable goals such as decreasing his negative thoughts about the impending separation from his brother and improving his adherence to his diabetic medication regime. KL was able to identify several barriers to accomplishing his goals, including: (1) limited financial and family support, (2) limited literacy, and (3) recent symptoms of depression.

KL's post measures for depression revealed a PHQ-9 score of 2 and a BDI-II score of 11, indicating a decline in depressive symptoms. He also demonstrated an improvement in his overall health-related quality of life (MCS score of 58.7). At the conclusion of the PST intervention, KL's coping scores suggested more rational (13) and positive (14) coping and less avoidant (10), negative (11), evasive (16), and fatalistic (6) coping. By that time, KL had followed through with his medical appointments to address his problems with his diabetic medication and was able to work with his personal-care home staff to be transferred to the same nursing home as his brother.

Case#7: MN

MN is a 63-year-old single African-American male who had been receiving hemodialysis treatments for 11 years at the start of PST intervention. His medical history included ESRD, HTN, and Hepatitis C. During the trial, the patient was taking 14 prescribed medications.

The patient presented with adequate support systems and identified his daughters, although they resided out of state, as his main support system. MN resided in handicap-accessible housing in an apartment complex that consisted primarily of older, retired, and disabled individuals. He also received transportation to dialysis through the AAA's Shared Ride Program. The patient had completed twelve years of education and reported no difficulty with reading and writing. Overall, he presented with a good understanding of his medical condition and treatment needs. MN was retired and received SSD as his main source of income.

MN presented for PST therapy with mild depression (PHQ-9 score of 9; BDI-II score of 13) and a KDQOL Mental Component Summary (MCS) score of 50.9. His baseline SPSI-R indicated higher scores for negative (4), impulsive (8), and avoidant (7) coping styles and his JCS indicated higher scores on the evasive (14), supportant (10), and fatalistic (6) scales.

At the start of PST, MN said he was feeling upset about being displaced from his current apartment due to renovations in his apartment complex. He reported anxiety about dealing with change and worries about adhering to his renal diet due to the displacement. MN reported feeling frustrated about not having a car or family members that he could rely on for support. He was receptive to PST orientation and agreeable to homework assignments. Over the course of the intervention, MN completed 52 pleasurable activities, though he did forget to bring his homework to his third intervention. Along with MN's reports of limited financial and family support and his frustration about poor access to transportation, he expressed difficulty in verbalizing solutions to these problems. Despite

this initial struggle, however, MN was able to identify measurable goals, including keeping his potassium levels below 5 while he was staying at the hotel and eating a healthy diet each day of the month during the displacement. MN was able to identify some barriers to accomplishing his goals, including: (1) limited financial and family support, (2) poor coping and adjustment to change, and (3) lack of access to transportation.

MN's post measures for depression revealed a PHQ-9 score of 1 and BDI-II score of 4, indicating a decline in depressive symptoms. He demonstrated an increase in his overall health related quality of life (MCS score of 61.4). On completion of the PST intervention, the patient's coping scores suggested more rational (20) and positive (20) coping and less avoidant (1), negative (1), evasive (6), and fatalistic (3) coping.

Chapter 8: Discussion

8.1 General Findings

The overall purpose of this study was to determine the feasibility and acceptability of PST intervention in the dialysis unit setting. Additionally, this study sought to determine the effects of PST on clinical outcomes in the dialysis unit setting, including depression and health-related quality of life. Additionally, we examined the impact of problem-solving coping on depression scores for individuals receiving in-center maintenance hemodialysis.

The results of this study were promising for the use of PST, an evidence-based intervention, in a dialysis unit setting. PST is a manualized intervention that can be easily learned and implemented by Master's-level renal social workers. This intervention is appropriate to the dialysis unit because it offers a short-term intervention at the dialysis patient's chair-side. Furthermore, dialysis patients were receptive to PST provided by their in-center renal social worker and adhered to the treatment protocol. Attrition rates were low, but some attrition was expected given this population's severity of illness.

In addition, this intervention had positive impact on the variables of interest and shows promise for reducing depressive symptoms, increasing quality of life, and improving problem-solving abilities in older hemodialysis patients. In comparison to the control group, patients receiving PST intervention over the course of 6 weeks were significantly less depressed and reported improved health-related quality of life. Furthermore, patients receiving PST intervention had significantly higher problem-solving ability scores on the SPSI compared to those of the control group post-intervention. Levels of improvement in the PHQ-9 scores in this study were comparable to previous studies aimed at reducing

depression in older adults (Gellis & Bruce, 2012; Gellis, 2010; Gellis et al., 2008; Gellis et al., 2007). Although previous studies recommend an intervention for depression that include both medication and therapy, this study resulted in positive outcomes with therapy alone (Cohen et al., 2007; Koo et al., 2005). Multifaceted depression interventions involving case management, PST, education, and medication support indicate favorable outcomes for reducing depressive symptoms compared to PST alone (Gellis & Kenaley, 2008; Ciechanowski et al., 2004, Doorenbos et al., 2005; Katon et al., 2004). Unlike many treatment disciplines, dialysis practice is interdisciplinary, allowing for a more comprehensive assessment and treatment protocol for depressed patients. Still, many units continue to take inconsistent approaches for treating depressive symptoms in this population. Future research on implementation of PST in dialysis unit settings should include a multidisciplinary approach to address potential benefits of this approach for older dialysis patients.

8.2 Implications

The findings of this study are reassuring for older dialysis patients. Depression is the most reported mental-health symptom among older dialysis patients, and older patients are more likely to experience greater dysfunction as well as barriers to treatment and a poor quality of life. Barriers for older dialysis patients include stigma, access, and cost of services. The inability to overcome such barriers for this population further compounds already existing medical and psychological problems and may result in higher rates of depression. It is also important to note that negative outcomes such as hospitalization and poor quality of life can result when patients with chronic illness report

mild as well as major symptoms of depression (Brenes, 2007; Kimmel et al., 2000; Kelly & Turner, 2000; Lopes et al., 2004).

PST provided to older dialysis patients allows for an effective intervention directed at reducing barriers and depressive symptoms while improving overall health-related quality of life. Such an approach provides significant opportunities for dialysis patients to overcome barriers by allowing for an *on-site* intervention at no cost to them as a part of routine care from their trained renal social worker. Compared to outpatient mental health providers, renal social workers have better access to patients because of the location of their practice; this location affords the opportunity for long-term relationships of trust, safety, and mutual respect. Many dialysis patients are also able to forge relationships with their unit social worker prior to presenting depressive symptoms. These unique relationships may enable patients to overcome the feelings of shame or embarrassment often associated with acknowledging the presence of depressive symptoms. It is also likely, given patients' existing relationships with their renal social workers, that reports of stigma associated with treatment will decrease. In sum, the accessibility of the renal social worker combined with a distinctive helping relationship and environment creates a situation in which PST can be feasibly implemented with the hopes of improving patient outcomes.

Previous research on psychosocial interventions such as PST that are rooted in behavioral-theory principles further suggests that interventions aimed at improving problem-solving coping in older adults are effective for treating minor and major symptoms of depression (Gellis & Nezu, 2011; Gellis & Kenaley, 2008; Gellis et al., (2007; Nezu et al., 2003). The relationship between problem-solving coping and positive outcomes

is important to understand, particularly as it applies to older dialysis patients. The unique nature of dialysis treatment presents various challenges for patients: changes, sometimes drastic, in daily sleeping patterns, diet, fluid intake, medicine regime, and social roles and relationships. PST provides a theoretical foundation that enables social-work clinicians to help older patients identify more adaptive coping styles so the patients can effectively address these many challenges. For dialysis patients especially, the inability to address some of the changes associated with treatment can have deadly consequences. Older dialysis patients who are unable to develop more adaptive coping styles are more likely to continue to experience depression and in some scenarios may be at increased risk of dying. By contrast, the results of this study suggest that the personal application of improved problem-solving coping skills by older dialysis patients can result in positive patient outcomes.

The practical implications of this study will be of particular interest to clinical renal social workers as well as health-care institutions. The consequences of depression in older hemodialysis patients are far-reaching and can result in a level of unrest that extends beyond individual suffering. Adherence to treatment, access to care, and social support are often negatively impacted by depression in older adults and can further be associated with quality of life, hospitalizations, and mortality (Kimmel & Peterson, 2005; Kimmel, 2002; Kimmel et al., 1993). Poor adherence to treatment and diet can be life-threatening in dialysis: noncompliant patients are at risk of declining health, increased medical problems, hospitalizations, and death. This association between nonadherence and negative patient outcomes may further increase demands on caregivers and caregiving institutions. Little information has been gathered regarding a definitive relationship between depression in

older dialysis patients and caregiver stress; however, some have reported that caring for older dialysis patients imposes considerable burden on caregivers given their multiple and complex needs (Belasco et al., 2006). Also, caregivers may face increased responsibilities because of the decreased physical and mental health of the older patient. It is likely that the consequences of depression in older dialysis patients have further disruptive effects on patients' external systems, including caregivers, family members, medical professionals, and healthcare institutions. An intervention such as PST may improve outcomes for these existing external systems in patients' lives, in turn significantly increasing the benefit of the intervention.

A vital aspect of PST is that it teaches patients to develop sustainable problem-solving coping skills so as to better manage their medical condition throughout their life course. This is especially true of older dialysis patients, who often present with multiple medical problems and a complex, lifelong disease process. Developing adaptive coping and positive problem-solving skills early on is likely to have profound implications for older dialysis patients given the trajectory of their illness. This study suggests that the integration of a more positive problem-solving orientation and a more adaptive style of coping in the early stages of the disease will likely lead to improved patient outcomes such as decreased depression and improved quality of life.

8.3 Application to Social Work Practice

This is the first known study of PST intervention for older in-center hemodialysis patients delivered by a clinical renal social worker. The decision to use a short-term (six-week) PST intervention was based on previous reports of effectiveness within this time

frame, organizational constraints, and realistic expectations of renal social workers in providing such an intervention (Gellis, 2011; Hegel, Barret, & Oxman, 2000; Mynors-Wallis, 1996).

The study findings have several implications for clinical renal social workers in the dialysis-unit setting. The finding demonstrate that PST intervention delivered in-center by trained renal social workers may have promise for dialysis patients who present with comorbid depressive symptoms. The accessibility of renal social workers is crucial in successfully implementing PST with older dialysis patients. Of great interest to renal social workers, therefore, is the availability of evidence-based interventions such as PST, given the overarching goal of dialysis centers to meet quality assessment and performance improvement standards. Such manualized treatment models allow social workers to effectively and efficiently monitor clinical outcomes.

RSWs can further utilize the information obtained via PST interventions in an interdisciplinary setting by sharing it with other members of the renal care team, including dietitians, nurses, technicians, and nephrologists. Such information could help to identify potentially high-risk problem areas that may otherwise have gone undetected and led to increased morbidity and mortality.

8.4 Study Limitations

The study has a number of limitations. To begin with, this study was a pilot, randomized controlled trial with a small sample examining depressed older hemodialysis patients. A larger and more diverse sample would help to better determine the generalizability of the findings and would increase the probability of finding significant

differences between the groups. This study is limited to a small, fairly homogeneous sample from a single rural dialysis-unit setting and is not representative of all renal clinic settings. Moreover, this study did not examine the long-term impact of treatment in this patient group. Future data on the long-term benefits of treatment for older adults will be of great value for patients who continue to experience complex problems throughout the course of their illness. Furthermore, there was potential for social desirability, given the relationship of the participants with the researcher.

This study did not address the impact of pretreatment of already existing psychiatric symptoms in patients receiving PST, nor did it address the impact of antidepressant medication in conjunction with PST treatment. Future research will need to examine the potential benefits of the integration of psychiatric consultation with PST intervention.

Another limitation to this study was the lack of information about satisfaction with the intervention protocol from a large sample of renal social workers. The fact that the intervention was confined to a smaller sample size and performed by a single social worker limits our knowledge of how most renal social workers would receive PST intervention in their daily practice. A larger study involving multiple centers and multiple social workers would allow for a more accurate assessment of the intervention's acceptability and likely adoption.

Future research will also need to examine the cost-effectiveness of PST intervention in the dialysis unit setting given the consequences of depression in this population such as increased morbidity and mortality. This information will be of great interest to the renal sector given the anticipated growth of the aging population over the next decade. An

intervention such as PST can lessen depressive symptoms and may ultimately save healthcare costs by reducing hospitalizations.

This study was done to address the lack of evidence on psychosocial treatment of depression in older patients in the dialysis-unit setting. It supports recent assertions that on-site, evidence-based interventions provided by trained RSWs may lead to significantly better outcomes for patients at risk for or presenting with depressive symptoms (Sledge et al., 2011). This study demonstrates a relevant and feasible intervention that is reflective of everyday practice for renal social workers. It is empirically based and flexible, and it provides a short-term effective approach that has profound implications for service delivery and patient outcomes.

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Appendix A: Participant Consent Form

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary—<u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

PROJECT # 2011-0360

Study Title: Problem-solving therapy for rural depressed older hemodialysis patients

PRINCIPAL INVESTIGATOR: Shiloh D. Erdley, MSW
SITE(S): GMC Outpatient Dialysis Unit
PHONE NUMBER: 570-271-6211 xt.54421

24-HOUR PHONE NUMBER: 570-271-6211 (HOSPITAL SWITCHBOARD)

You are being asked to take part in this research study because you are 60 years of age or older on hemodialysis at Geisinger Medical Center.

This is a research study. Research studies include only participants who choose to take part. Please take your time to make your decision and ask questions of the study team.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate the effectiveness of Problem-Solving Therapy (PST) in reducing feelings of depression and improving overall health related quality of life in dialysis patients age 60 and older.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 50 people will take part in this research study at Geisinger Clinic.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this research study, you will have the following tests and procedures:

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in any group.

Your involvement in this study will include the following;

1. Completion of 1questionnaire given prior to PST intervention and again at 6 weeks post intervention.
2. Completion of one questionnaire at the end of the study.

Your involvement in this study may include the following:

3. Weekly problem-solving therapy intervention from your unit social worker for a period of 6 weeks.
4. A 60 minute interview discussing your experience with the study.

Your interview responses or any information collected about your care will be kept completely confidential. No information that can identify you as an individual will be shared with anyone other than study personnel. We are not interested in studying individual persons, only in examining a large group. Any records associated with this study will be kept in a locked file here in the dialysis unit. All records will be given a confidential study number so that no one can identify you.

HOW LONG WILL I BE IN THE STUDY?

You will be in the research study for approximately 9 weeks.

There is no expiration date for the use and disclosure of your protected health information.

WHAT ARE THE RISKS OF THE STUDY?

Risks involving the emotional and psychological aspects of end of life issues could potentially create feelings of sadness, anxiety or depression. Participants may feel upset discussing how psychological or lifestyle factors contribute to their physical symptoms/illness and they may become frustrated if the suggested intervention does not immediately help to reduce symptoms of depression or improve health related quality of life. So, in order to address this, we will have counseling services available from your dialysis social worker

There is a slight chance that your protected health information may be released to someone other than the study staff. All precautions are taken to make sure this does not happen.

For more information about risks and side effects, ask the study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct medical benefit to you. We hope the information learned from this research study will benefit other patients on hemodialysis in the future.

WHAT OTHER OPTIONS ARE THERE?

You do not have to take part in this study. You will continue to receive medical care at Geisinger Clinic even if you do not take part in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Only the study PI and Sub-I will have access to your PHI.

Information from the research study will not be used to target you for marketing or sales communications.

Geisinger Clinic has several departments that are responsible for making sure research is performed according to federal and state regulations. The staff members of these departments may review your medical record and research data for this study. This review will be administrative in nature and no PHI will be sent outside Geisinger Clinic.

You have the right to access your medical records.

The study results will be retained in your research record for data analysis or required governmental review for at least six years or until after the study is completed, whichever is longer. At that time the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results at Geisinger Clinic. Any research information in your medical record will be kept indefinitely.

If data or information from the research study is submitted for publication in a medical journal or is presented at a medical meeting, your identity as a research participant will not be revealed.

WHAT ARE THE COSTS?

You will not be receiving medical care as a part of this research study. Taking part in this research study will not lead to added costs to you or your insurance company. If you request counseling services, you will have the option of receiving counseling intervention from your inpatient unit social worker at no cost.

You do not have to pay anything to be in this research study. There is no payment for this study. However, all participants will be entered into a drawling to be eligible to win one of 5 grocery gift certificates worth $30.

WHAT HAPPENS IF I AM HURT WHILE I AM IN THE STUDY?

No funds have been set aside to compensate you in the event of injury or illness.

By signing this consent form, you will not give up any legal rights.

In the case of injury or illness resulting from this research study, medical treatment is available but will be provided at the usual charge. Immediately contact your study PI, Shiloh D. Erdley at 570-271-6211 ext. 54421.

You or your insurance company will also be charged for continuing medical care and/or hospitalization required for any such injury or illness.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

No funds have been set aside to compensate you in the event of injury or illness.

By signing this consent form, you will not give up any legal rights.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this research study is voluntary. You may choose not to be in the study or withdraw from the study at any time. You may also withdraw your authorization for us to use your data/samples. Data/samples that have already been collected or sent to the University of Pennsylvania cannot be withdrawn.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits. It will not affect your access to health care at Geisinger Clinic. If you do decide to withdraw, we ask that you contact the study doctor in writing to state that you are

withdrawing from the study. Please contact: Shiloh D. Erdley at 570-271-6211 xt. 54421. If you decide to stop participating in the research study, we encourage you to talk to the study doctor and your regular doctor first.

We will also inform you of information that may affect your health or welfare during your participation in this research study.

The study doctor may decide to take you off this research study if your medical status changes and you are not physically or emotionally well enough to participate or if you are hospitalized.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the research study, contact the study PI, Shiloh D. Erdley at 570-271-6211 xt.54421.

For questions about your rights as a research participant, contact the Human Research Protection Program staff of the Geisinger Institutional Review Board (which is a group of people who review the research to protect your rights) at (570) 271-8663.

SIGNATURE

I agree to take part in this research study. By signing this consent form, I have not given up any of my legal rights. You will get a signed copy of this form.

_____ _____

Research Participant's Signature Date

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information.

_____ _____

Person Obtaining Consent Signature Date

Appendix B: Invitation to Participate

GEISINGER
HEALTH SYSTEM

University of Pennsylvania

YOUR PARTICIPATION IS REQUESTED IN A STUDY TO IMPROVE QUALITY OF LIFE

WHO: Hemodialysis patients at Geisinger Medical Center ages 60 and older who have been on treatment for 3 or more months. About 44 people will participate in the study.

WHAT: This study is looking at improving ones quality of life in managing ones medical condition. You will be asked to complete one questionnaire on two separate occasions that will take approximately 60 minutes.

WHEN: From January 2012 through January 2013

WHERE: This study will take place at Geisinger Medical Center Outpatient Dialysis Center during your dialysis treatment. No extra time outside of your treatment will be needed to participate.

WHY: To find ways to help dialysis patients cope with their medical condition and problems associated with their medical condition to improve overall quality of life.

**** Participants enrolled will be entered into a drawing to win one of 5 grocery store gift certificates valued at $30.**

HOW: If you are interested in learning more about this study, or if you would like to consent to participate in this study, please speak further with GMC unit Social Worker, **Shiloh D. Erdley at 570-271-6211 ext.54421.**

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