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Does Social Problem-solving Moderate the Relationship Between Physical Functioning and Depression in ALS Patients?

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DOES SOCIAL PROBLEM-SOLVING MODERATE THE RELATIONSHIP BETWEEN PHYSICAL FUNCTIONING AND DEPRESSION IN ALS PATIENTS?

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Submitted in Partial Fulfillment of the Requirements of the Degree of Doctor of Psychology
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PHILADELPHIA COLLEGE OF OSTEOPATHIC MEDICINE
DEPARTMENT OF PSYCHOLOGY

Dissertation Approval

This is to certify that the thesis presented to us by Melissa D. Horowitz on the 24th day of June, 2008, in partial fulfillment of the requirements for the degree of Doctor of Psychology, has been examined and is acceptable in both scholarship and literary quality.

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Abstract

Amyotrophic lateral sclerosis (ALS), commonly known as Lou Gehrig’s disease, is a progressive and ultimately fatal neurological disease that interferes with the normative functions of the upper and lower motor neurons in the brain and spinal cord. Depression has been found across disease stages in some ALS patients, but not all. Investigations that examined the association between physical functioning and depression in ALS patients produced mixed findings. To date, the role of social problem solving has not yet been explored in the ALS population. Thus, the current study examined the relationship between social problem solving, physical functioning, and depression in ALS patients. A total of 71 ALS patients participated in the study. The ALS patients were administered the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revise, Manual Muscle Test, Brief Symptom Inventory 18, the Center for Epidemiologic Studies Depressed Mood Scale, and the Social Problem-Solving Inventory – Revised Short. Data were analyzed using two separate correlations and one multiple regression. Results from the current study concluded: (a) clinically significant levels of depression were found in 15 – 32.3% of the ALS subjects, (b) there was a positive correlation between poor social problem solving skills and depression, (c) there was a small correlation between poor physical functioning and depression, (d) bulbar functioning was not correlated with depression, and (e) negative problem orientation predicted 26.8% of the total variance for depression. Overall, the results from this investigation demonstrated negative problem orientation not physical function was a predictor of higher levels of depression in ALS patients. The implication from this study suggests that empirically supported treatment approaches such as problem-solving therapy may reduce depression in ALS patients.
Table of Contents

Abstract .............................................................................................. iii
List of Tables ....................................................................................... vi

Chapter 1
Introduction .......................................................................................... 1
  Statement of Objectives ..................................................................... 2
  Amyotrophic Lateral Sclerosis ............................................................ 2
    Prevalence ...................................................................................... 3
    Classification .................................................................................. 4
    Diagnostic criteria .......................................................................... 5
    Diagnostic categories ...................................................................... 8
  Symptom management ....................................................................... 9
  Physical Functioning ......................................................................... 10
  Psychosocial Considerations ............................................................ 12
  Coping, Adaptation, and Emotional Distress ..................................... 16
  Depression and ALS ......................................................................... 20
  Social Problem Solving Theory .......................................................... 23
    The social problem-solving model .................................................... 27
    Social problem solving and depression .......................................... 30
    Social problem-solving and depression in medical populations ...... 32
  Summary .......................................................................................... 38
  Hypotheses ...................................................................................... 39

Chapter 2
Method ................................................................................................ 40
  Participants ...................................................................................... 40
  Measures ........................................................................................... 41
    Physical functioning ....................................................................... 42
    Physical strength ........................................................................... 42
    Affect .............................................................................................. 43
    Mood .............................................................................................. 44
    Social problem solving ................................................................... 45
  Design and Procedures ...................................................................... 46

Chapter 3
Results ................................................................................................ 48
  Descriptive Statistics ....................................................................... 48
  Hypothesis 1 ..................................................................................... 51
  Hypothesis 2 ..................................................................................... 53
  Hypothesis 3 ..................................................................................... 54
  Summary of Findings ....................................................................... 55

Chapter 4
Discussion ........................................................................................... 57
Conclusions ........................................................................................ 57
Study Implications ............................................................................. 65
Limitations of Study .......................................................................... 68
Future Directions...........................................................................................................70
References.....................................................................................................................72
Appendices
   Appendix A: Patient Participation Letter and Informed Consent..................84
   Appendix B: ALS QOL Demographic Sheet.........................................................101
   Appendix C: Manual Muscle Test .................................................................103
   Appendix D: ALS Functional Rating Scale Revised.................................105
   Appendix E: Center for Epidemiologic Studies depressed Mood Scale......107
   Appendix F: Brief Symptom Inventory 18.......................................................109
   Appendix G: Social Problem-Solving Inventory - Revised: Short..............110
List of Tables

Table 1  Correlation Coefficients (Pearson $r$) of Measurements and Subscales .................................................... 52
Table 2  Correlation Coefficients (Pearson $r$) of Bulbar Function and Depression ................................................ 54
Chapter 1

Introduction

Amyotrophic lateral sclerosis (ALS), commonly known as Lou Gehrig’s disease, is a progressive and ultimately fatal neurological disease that interferes with the normative functions of the upper and lower motor neurons in the brain and spinal cord (Cwik, 2001; Shaw, 2006). An estimated 30,000 individuals in the United States are living with ALS at one time. Death occurs in approximately 75% of those affected within 2 to 5 years following the presentation of symptoms (www.alsa.org). The age range of onset is between 40 and 70, with an almost equal incidence in both genders. Currently there is no cure for ALS; treatment is focused on slowing the progression of the degeneration of neurons and improving the overall quality of life.

It is generally assumed by many health care professionals and caregivers that depression is commonplace among individuals diagnosed with a terminal illness (Rabkin, Glenn, Wagner, & Del Bene, 2000). Although the psychological impact of ALS can affect the patient’s mood, depression may be less common than initially believed. Research findings thus far suggest that depression at the clinical and subclinical levels may be present in some, but not in all, individuals diagnosed with the illness (Felgoise, Chakraborty, Bond, Bremer, Walsh, & Simmons, 2005, 2005; Ganzini, Johnston, McFarland, Tolle, & Lee, 1998). Furthermore, investigations examining the association between physical functioning and depression in ALS patients have produced mixed findings (Goldstein, Atkins, Landau, Brown, & Leigh, 2006).
Social problem-solving skills have been shown to predict and mediate depression in persons with other chronic medical illnesses, such as cancer (Nezu et al., 1999) and spinal cord injury (Elliott, 1999). However, the role of social problem-solving skills in depression for ALS patients has not been explored. To address this important gap in the literature, this study aims to examine the relationship between social problem solving, physical functioning, and depression in ALS patients. If social problem-solving skills are shown to be predictive or influential of depression in the ALS population, then existing empirically supported, manualized treatments using social problem-solving skills to decrease depression for other medical populations could be modified and adapted to meet the needs of persons with ALS. Therefore, understanding depression and the role of social problem-solving skills as they relate to physical functioning in persons with ALS may be important for treatment planning.

Statement of Objectives

1. Determine if there is a relationship between poor social problem solving and depression in ALS patients;

2. Determine if physical functioning predicts depression in ALS patients;

3. Examine the interaction between social problem solving, physical functioning, and depression.

Amyotrophic Lateral Sclerosis

The medical term *amyotrophic lateral sclerosis* (ALS) was derived from the Greek term *amyotrophiːc* a stands for no or negative, *myo* references muscle, and
trophic is nourishment. When the terms are brought together, they signify “no muscle nourishment.” Lateral refers to the region of the spinal cord in which the nerves send messages to specific muscle groups; sclerosis is the breakdown or hardening that occurs in the spinal region (www.alsa.org).

Prevalence.

ALS is a debilitating and eventually fatal progressive neurodegenerative disease, which produces rapid muscle weakness, paralysis, and respiratory failure (Brooks, 1996; Rabkin et al., 2000). It has been estimated that ALS is diagnosed in 1/100,000 to 2/100,000 individuals annually. In the United States, approximately 5,600 cases are newly diagnosed each year, with an estimated 75% of individuals dying from complications related to the disease within 2 to 5 years of diagnosis (www.alsa.org).

The average age of onset is 40 to 70, with a mean age of 55. Generally, those diagnosed with sporadic ALS tend to experience the onset of disease between the ages of 58 and 63, while familial cases tend to develop in those between 47 and 52 years old. In addition, individuals in their 20’s and 30’s have also been diagnosed, though it is less common (www.alsa.org). ALS has a 1.7:1 male:female ratio, meaning that men are at an increased risk of developing ALS, but the gender ratio diminishes with older age (Haverkamp, Appel, & Appel, 1995; Cwik, 2001). Currently, 93% of reported cases diagnosed are of White individuals. For the most part, ALS is believed to affect individuals equally worldwide after controlling for
classification system was developed for ALS based on three categories: clinical syndromes, mode of acquisition, and degree of diagnostic certainty (Cwik, 2001). ALS clinical syndromes vary depending upon the clinical presentation, symptoms, and prognostic indicators. Classic ALS is discernible by damage to the upper and lower motor neurons. When these two motor neurons are damaged, it causes the individual to experience muscle spasticity, exaggerated or diminished reflex movements, and weakness and/or degeneration of the muscle. However, some individuals with ALS may present with damage to only the upper motor neuron, only the lower motor neuron, or damage only in one muscle region.

The mode of acquisition is essentially the way ALS develops. Generally, ALS is sporadic, familial, or Guamanian. Sporadic ALS is the most common and is diagnosed in 90% to 95% of all cases in the United States. The characteristics of this include a break- down of the upper and lower motor neurons. A great majority of ALS patients with sporadic ALS present with limb-onset disease, 25% with bulbar-onset disease, and 8% to 10% with lower motor neuron decline (Mitumoto, 1997). Familial ALS is generally diagnosed in 5% to 10% of cases. A small percentage of individuals diagnosed with familial ALS were found with a defect in the gene for
superoxide dismutase (Siddique, Nijhawan, Hentati, 1996; Cwik, 2001). Lasty, Guamanian ALS was detected and named based on the high number of cases reported in Guam and other U.S. Territories in the 1950s (www.alsa.org).

The degree of diagnostic certainty refers to how a diagnosis of ALS is determined. Unfortunately, ALS has yet to be diagnosable based on one laboratory test finding. Instead, the diagnostic formulation is determined by physical symptoms, laboratory tests, differential diagnosis, and symptom onset during the disease progression (Cwik, 2001).

Diagnostic criteria.

Prior to receiving a formal diagnosis of ALS, patients tend to seek medical attention in the early phases of the disease for noticeable muscle weakness in an outer extremity such as an arm or leg (Mitsumoto, 1997, 2001). They frequently report problems with buttoning clothing, picking up or carrying objects, unsteady gait, tripping or stumbling while walking or running, difficulty climbing stairs, foot dragging, struggling with getting up out of a seated position, muscle cramps, fatigue, and/or weight loss (www.alsa.org).

The course of ALS often begins to manifest in one of four muscle regions (bulbar, cervical, thoracic, and lumbosacral). Each region controls different muscle movements. The bulbar region includes the facial, tongue, jaw, and larynx muscles. Twenty percent to 25% of individuals diagnosed with ALS present with bulbar symptoms (Mitsumoto, 2001). Bulbar weakness has also been found to be more prevalent in females and in those aged 70 and older (Haverkamp, Appel, & Appel,
The cervical region includes muscle movement in the diaphragm, hands, and arms. Approximately one third initially develop weakness in the arm (Mitsumoto, 1997, 2001). The thoracic region controls the abdominals as well as back muscles. Lastly, the lumbosacral region includes legs, feet, abdominal, and back muscles (Mitsumoto, 1997). It has been estimated that one third of ALS patients present with weakness in the leg (Mitsumoto, 1997, 2001). Though less common, some individuals experience diffuse weakness in the bulbar, arm, and leg muscles. In general, ALS tends to progress asymmetrically early on before it manifests into contralateral limbs. Muscle weakness tends to be a slow and steady progression.

The Revised El Escorial World Federation of Neurology (Brooks, 1994; Forbes, Colville, & Swingler, 2001) are the internationally recognized diagnostic criteria used to determine the presence of ALS. In order to meet these criteria, historical information pertaining to symptom onset, disease progression, past medical history, family history, sphincter problems, mental status, and sensory complaints need to be examined (Mitsumoto, 1997). In addition, neurologic examinations are used to determine the functionality in the upper motor neuron and lower motor neuron regions.

Upper motor neuron damage can cause symptoms including: (a) loss of dexterity, which affects voluntary and reflex movements of fine motor skills, as a result, ALS patients may experience stiffness, delayed movement, or clumsiness in fingers, feet, lips, or tongue, (b) loss of muscle strength, the primary sign and symptom of ALS and generally less severe in the upper motor neuron as compared to the lower motor neuron, (c) spasticity, which is described as muscle tension, (d)
pathologic hyperreflexia, an exaggerated reflex muscle response, (e) pathologic reflexes, defined as abnormal reflex responses, and (f) spastic bulbar palsy, weakness in the bulbar region that produces problems with speech, chewing, and swallowing. In addition, ALS patients tend to experience emotion dysregulation such as impulsive crying and laughter (Mitsumoto, 2001).

Lower motor neuron damage can cause symptoms including: (a) loss of muscle strength, which is generally more severe in the lower motor neuron and affects the outer extremities, (b) muscle atrophy, a decreased muscle size occurring in the hands, forearm, lower leg, and foot muscles, (c) muscle hypotonicity, decreased muscle resistance, which causes the muscles to become motionless, (d) fasciculations, muscle twitches that tend to occur often, and (e) muscle cramps, involuntary muscle contractions that occur across various muscle regions including the calf, thigh, arms, abdomen, and neck (Mitsumoto, 2001).

In terms of cognitive functioning and ALS, studies have identified cognitive decline in upwards of one third to one half of ALS patients diagnosed with sporadic or familial ALS. Researchers have found more than one type of cognitive impairment in this population. Frontotemporal dementia is the most commonly found and researched form of dementia detected in ALS patients (Ringholz, Appel, Bradshaw, Cooke, Mosnikm, & Shultz, 2005; Rippon, Scarmeas, Gordon, Murphy, Albert, Mitsumoto et al., 2006; Robinson, Lacey, Grugan, Glosser, Grossman, & McCluskey, 2006; Wheaton, Salamone, Mosnik, McDonald, Appel, & Schmolck, 2007).
Diagnostic categories.

The diagnostic categories of ALS include definite ALS, probable ALS, probable ALS – lab supported, possible ALS, and suspected ALS. Definite ALS is based upon the clinical detection of lower and upper motor neuron degeneration in the bulbar as well as two additional regions or in three spinal regions. Probable ALS is based upon the clinical detection of lower and upper motor neuron degeneration in a minimum of two regions. Probable ALS – Lab Supported includes both upper motor neuron and criteria for only one region of the lower motor neuron or a minimum of one upper motor neuron region and electromyography nerve blockage in two or more outer extremities. Possible ALS is based upon the clinical detection of lower and upper motor neuron degeneration in only one region or detection in only the lower or only the upper neurons. Suspected ALS is diagnosed when it is only detected in two or more regions of the lower motor neuron (Brooks, 1994; Forbes, Colville, & Swingler, 2001).

In addition, four categories were developed to classify the types of progressive lower and upper motor neuron degenerations: Sporadic ALS, which occurs in isolation; Coexistent sporadic ALS, which presents intermittently and co-occurs with other preexisting diseases in conjunction with ALS; ALS-related syndromes, which occur with the epidemiologic findings of the progression of ALS; and ALS variants, which occur with clinical, genetic, or epidemiological findings that parallel the disease (Brooks, 1994).
Symptom management.

Ongoing ALS research continues to search for a cure; however, none has been found thus far. For now, ALS patients are encouraged to receive treatment at an ALS-specific clinic close to home. In this setting, ALS patients are able to receive comprehensive treatment from a team of professionals including one of more of the following: neurologist, nurse coordinator, physical therapist, occupational therapist, speech pathologist, dietitian, and social worker. A comprehensive treatment approach reduces the frequency of visits, but may increase the length of time spent in the clinic (Jacobs & Mitsumoto, 2001).

Presently, the medication riluzole is the only FDA-approved disease-specific treatment available in the United States used to decrease the loss of muscle strength, prolong survival rates by a couple of months, and increase the overall life span of some individuals with ALS (Bensimon et al., 1994). With only one FDA-approved medication on the market, ALS patients have the option to receive treatment of their symptoms of the disease. Some common ALS symptoms include: muscle cramps and spasms, excessive crying or laughter, urinary urgency or frequency, excessive saliva, thick phlegm/post nasal drip, jaw quivering/clenching, laryngospasm, acid reflux, nasal congestion, sleep disturbance, depression/anxiety, shortness of breath, pain, nausea, agitation/anxiety, communication difficulties, and terminal management (Gelinas, 2001). The detailed information describing symptoms and treatment options is beyond the scope of this study.
In the literature, the findings on the association between physical functioning and mood have been mixed (Goldstein, et al., 2006). The following studies reflect the absence of a relationship between physical functioning and mood. Rabkin et al. (2000) examined depression and distress related to the degree of ALS disease progression and functional impairment in 56 ALS patients, as measured using several questionnaires. The study concluded that distress and depressive symptoms were not associated with time, physical manifestations, or progression of ALS.

Norquist, Kenkinson, Fitzpatrick, Swash, and the ALS-HPS Steering Group (2003) examined factors predictive of physical and mental health based on health status from an assessment at baseline and 12 months later. One thousand one hundred eighteen subjects completed the SF-36, the General Well-Being Scale, the Caregiver Strain Index, and the Amyotrophic Lateral Sclerosis Functional Rating Scale at baseline, while 918 of the initial subjects also completed the same measures 12 months later. Results from this study found while physical functioning declined by 15% over the 12-month period, no significant changes to mental health scores were identified.

In another study (Robbins, Simmons, Bremer, Walsh, & Fischer, 2001) of 60 subjects (53.3% male and 46.7% female, with a mean age of 58.5), researchers examined physical functioning and quality of life using self-report quality of life measures, including the McGill Quality of Life measure and the ALS Functional Rating Scale, at baseline, 3-month and 6-month intervals. Results of this study revealed that while physical functioning declined patients’ quality of life remained
stable. Neudert, Wasner, and Borasio (2004) also examined quality of life factors specifically related to physical functioning and psychosocial factors during the progression of ALS. The researchers concluded that as the disease progressed, physical functioning declined while psychosocial factors remained stable.

Conversely, some research studies have found an association between aspects of physical functioning and mood. Hillemacher et al. (2004) examined the factors that predict or influence depression in ALS patients. Forty-one ALS patients completed a self-report depression questionnaire and the Amyotrophic Lateral Sclerosis Functional Rating Scale. Results did not find a significant relationship between decreased general physical ability and depression. However, the researchers did identify reactive depression as a result of bulbar and respiratory symptoms.

In another investigation, Goldstein et al., (2006) explored predictors of psychological distress and low self-esteem and to determine whether these change over time in ALS patients. Fifty ALS patients participated in the study by completing questionnaires during the first interview, 32 participated for the second interview, and 26 participated in the third interview. The questionnaires completed were the Close Persons Questionnaire, Marital Intimacy Scale, ALS Severity Scale, Sickness Impact Profile, Emotional Liability Questionnaire, the Dysexecutive Questionnaire, the Short Inventory of Minor Relapses, Hospital Anxiety and Depression Scale, and the Self-esteem Scale. Results from the first interview found bulbar impairment predicted psychological distress.
Psychosocial Considerations

In general, many patients with a chronic medical condition are able to adjust adequately to psychosocial aspects surrounding their illness. Meanwhile, an estimated 20% to 25% experience psychological distress secondary to their health status (White, 2001). The potential for psychological distress associated with chronic illness can result from the gradual onset, lengthy duration, progressive decline over time, unclear diagnosis and prognosis, absence of a cure, and symptom severity (Holman & Lorig, 2000). Often chronic illness signifies a lifestyle change from independent living toward physical, emotional, and financial dependency upon others.

Developing a chronic medical condition is considered a major life event. When this occurs, individuals become more susceptible to psychological vulnerabilities. Unlike other chronic medical conditions such as cancer or spinal cord injury that may or may not be life threatening, ALS is a progressively debilitating and fatal illness which may produce its own unique psychological vulnerabilities. Psychosocial stressors found among ALS patients tend to become more pronounced during different phases of the disease progression and may encompass changes within social interactions, spiritual and/or religious beliefs, mood fluctuations, and lifestyle adjustment (Nelson, Trail, Van, Appel, & Lai, 2003).

Psychosocial palliative care addresses how ALS patients respond to the disease-related stressors. The core aspects of psychosocial palliative care include: attachment, loss, meaning, and equity (Sheldon, 1997). While these core aspects are not unique to ALS, an emphasis is often placed on the disease-specific elements ALS patients often encounter. Psychosocial palliative care begins as soon as the patient is
formally diagnosed with ALS and continues through the progression of the disease. Some of the more distinct psychosocial stressors in ALS patients relate to hope, loss, control, and outside support (Gallagher & Monroe, 2006).

Patients are informed about their ALS diagnosis by their neurologist. The diagnosis, prognosis, and treatment options are generally presented in a private office setting while in the company of family. At this stage, the goal of the neurologist is to provide honest, accurate, and detailed information. The tone of the discussion is calm, empathic, hopeful, and supportive. Given the disease course, the neurologist is careful not to overwhelm the patient with too much information when first learning of their condition. Instead, written material is provided with the intention that the patient will read about ALS at their own pace, with their loved ones, and after the initial shock of their diagnosis decreases some. The patient is also encouraged to contact members of the ALS multidisciplinary team with questions and for ongoing support (Gallagher & Monroe, 2006).

Hope has been defined as an inner power or strength that can enhance lives and facilitate individuals to look beyond their pain, suffering, and turmoil (Urquhart, 1999). A research study investigated hope in cancer and motor neuron patients and identified factors that encourage and discourage hope (Buckley & Herth, 2004). This study concluded hope was comprised of several factors including: interpersonal connectedness, spirituality, goal setting, maintaining independence, positive relationships, self-worth, humor, personal attributes, and positive memories. Alternatively, factors of hopelessness included: abandonment, social isolation, loss of independence, loss of control, and devaluation of personhood. Being able to assess
for the degree of hope often begins when the neurologist informs the patient of the
diagnosis, prognosis, and treatment options. The goal is to understand what hope
means to the patient, what helps to sustain their hope, what causes them to lose hope,
and how hope changes during the course of the disease. Ganzini et al. (1998) found
that ALS patients with suicidal thoughts experienced greater hopelessness when
compared to ALS patients without suicidal thoughts.

Throughout the course of the disease, ALS patients experience varying
degrees of loss (Gallagher & Monroe, 2006). This may be related to physical
challenges such as age of onset, severity of symptoms, length of illness, and rate of
physical decline. Another form of loss includes isolation from family, friends,
attending events, going to work, and interacting with nature. Additional losses may
include loss of traditional role, financial concerns, or restrictions in leisure activities.

ALS patients' sense of control varies across patients and may change on a
daily basis. Control is assessed early on by the multidisciplinary team in order to
identify potential response patterns as the disease progresses. These patterns are
monitored and addressed as needed. One approach in maintaining healthy control is
to continually reinforce an internal locus of control rather than an external one. An
example of this is when the patient is formally diagnosed with ALS. It is during this
time the neurologist discusses with the patient what he/she should anticipate
happening and encourages the patient to become part of the decision-making process
when considering treatment options (Gallagher & Monroe, 2006).

Aside from the ALS multidisciplinary team, the ALS patient’s support
network, generally comprised of a caregiver, family members, and friends, is a crucial
element in providing physical, emotional, and financial support during the disease progression. While the support network helps address some of the psychosocial stressors the ALS patient is confronted with, it can also pose its own set of stressors. Family members and caregivers described their experience of daily support as a cyclic process in which their daily responsibilities include committing to take care of everyday tasks, tackling unexpected demands and crisis situations, problem solving, asking for additional help at times from others, occasionally taking a break, and relying heavily on hope and courage to make it through each day (Kuckelman-Cobb, Reckling, & Fernengel, 2001).

Outcome findings from the ALS Patient Profile Project (McDonald, 2001) suggested eight key areas are important in order maintain psychological, interpersonal, and spiritual well-being and self-esteem while living with ALS. First, maintain hope that life can still be meaningful and worthwhile despite living with an incurable disease. Second, use inner strength, meaning, and purpose to live each day. Third, maintain a nurturing support system. Fourth, shift focus from disease-related symptoms to focusing in the present and share meaningful experiences with loved ones. Fifth, develop a respectful relationship with others and be comfortable expressing thoughts and feelings with them. Sixth, develop and maintain family and social activities for the ALS patient to participate in. Seventh, utilize support from the multidisciplinary team. Eighth, pursue treatment or counseling if necessary for ALS patient, caregiver, or family member.
Coping, Adaptation, and Emotional Distress

Coping has been described as a process used to manage emotional or cognitive distress associated with diseases (Lazarus, 1984). Individuals with chronic illness and/or disabilities (CID) often experience stress, crisis, loss and grief, body image distortions, negative self-perception, stigma, uncertainty, unpredictability, and a compromised quality of life more frequently than non-medical populations. Specific coping characteristics, such as state and trait determinants, degree of control, locus of control, affect regulation, cognitions, and behavior styles have a direct relationship with individual coping strategies.

In the CID literature (Tobin, Holroyd, Reynolds, & Wigal, 1989; Livneh & Antonak, 2005), two types of coping strategies have been identified. First, disengagement coping, which is a maladaptive means of coping through the use of avoidance, passivity, denial, self-blame, blaming of others, and substance abuse. Second, engagement coping is an adaptive, direct, focused, goal-oriented means, which incorporates problem solving, planning techniques, and the ability to utilize a support network style. Among these two strategies, researchers found engagement coping improved overall well-being, acceptance of illness, and adaptability.

Hecht et al. (2002) examined the subjective experiences of patients with ALS to better understand how these individuals cope. In their study, 41 patients diagnosed with probable or confirmed ALS using the revised World Federation of Neurology ALS criteria, with disease duration of 16 months and a median ALS Functional Rating Scale score of 25, agreed to respond to three subjective questions and complete a self-report depression measure on two occasions. The subjective questions
and most common responses included the following: (a) “In your personal experience, what are the worst aspects of the disease?” The most common responses were “reduction of speech,” “reduction of mobility,” “knowledge of poor prognosis,” and “becoming dependent on other person.” (b) “Who or what most efficiently lightened the burden of these aspects?” The most common responses included “the family,” “unspecific coping mechanisms” (i.e., “thinking positive” and “technical aids”); (c) “Who or what could help you in addition?” The most common responses included “more effective therapy” and “better technical aids.” For all three subjective questions, the same responses were ranked similarly upon second administration.

When these same subjects were asked to complete the Trierer Coping Questionnaire (TCQ), results noted religion as the most common and strongest mode of coping and the recurring theme of family support to be a major benefit to those diagnosed with the disease.

In addition to coping styles, adaptation is also an important consideration with ALS patients because unlike other chronic illnesses, the course of ALS is one that requires the individual to continually adjust to lifestyle changes (Mitsumoto & Munsat, 2001). Adaptation is defined as patients’ ability to actively accept their prognosis, the ability to accommodate both their environmental demands and subjective desires, and possessing the skills to learn how to reconstruct their lives in a positive manner (Livneh, 2001). Individuals who are unable to adapt in a functional way tend to become dependent on others, feel helpless or hopeless, and may be in denial of their prognosis.
Unlike other chronic illnesses, such as cancer and spinal cord injury, ALS patients are faced with a disease sequence that includes progressive muscle decline, physical limitations, lack of curative treatment options, and death. So while other illnesses such as cancer may ultimately lead to death, there are treatments available to slow down or eliminate the disease progression in a greater proportion of those inflicted. This is not the case with ALS. While some treatment approaches with medication or specific therapies appear to prolong survival via slowing disease progression during the early phases of the illness, there is no treatment available to slow the disease in the later stages or eliminate ALS altogether (Gelinas, 2001).

Livneh (2001) stated that the ability to adapt to life with a chronic illness and disability is a predictor of overall quality of life. This idea is based on several hierarchical domains, including intrapersonal functioning (health status, psychological state, satisfaction, view of self), interpersonal functioning (interpersonal relationships, family dynamics, marriage and intimacy, and peer interaction), and extrapersonal functioning (education, employment, and recreation). Adaptation styles in ALS patients are often detected during the early phase of the illness. Newly diagnosed individuals tend to experience anger, denial, bargaining, depression, anxiety, and acceptance. They also may interpret the news with feelings of intolerance or sadness or view ALS as an opportunity for a spiritual journey. For this reason, many ALS interdisciplinary clinics strongly recommend that the patient utilize their support network upon initial diagnosis and through the course of the illness (www.alsa.org).
Generally, the best predictor of one’s ability to adjust to life with ALS is based upon how individuals were able to adjust to past lifestyle changes. A qualitative research study (Young & McNicoll, 1998) identified two common themes regarding positive adaptation strategies. Participants in this particular study reported that the key to adapting occurred through humor and a positive outlook. Moreover, these same participants also described additional effective adaptation strategies, including the use of cognitive reappraisal techniques to help them accept what they could control in their life versus what was out of their control, looking for alternative ways of how to perceive their situation, reframing techniques, thought control, looking for the positives, living in the here and now, and using imagery.

Trail, Nelson, Van, Appel, and Lai (2004) investigated emotional distress in ALS patients by examining physical domains (muscle weakness, mobility problems), psychosocial domain (financial stress, depression, lack of family support), and existential domains (worry about the future, loss of faith in religion, worries about illness progression). Findings suggested that most subjects expressed concerns central to existential and physical domains. In addition, the investigators found the three most common stressors reported by ALS subjects were (a) worries about the illness progression and dependency issues, (b) problems speaking, and (c) muscle weakness. This study concluded that specific stressors have the potential to trigger adaptive or maladaptive coping styles.

Heijmans (1999) proposed that patients who view chronic illness as serious, unremitting, and unmanageable are more likely to become passive and experience increased limitations, more social discord, and mood fluctuations. Lacroix et al.
SPS and ALS 20

(1991) suggested schematic processing can provide an understanding of how cognitive processing influences the patient’s interpretation of the disease diagnosis and progression. This concept of schematic processing may provide a better understanding of the mechanisms by which ALS patients experience the process of coping, adaptation, and emotional distress, as compared to others with a medical illness.

Depression and ALS

Depression in individuals with a chronic illness has often been associated with distress due to physical limitations, loss of independence, decrease in pleasurable activities, denial, pessimism, communication difficulties, swallowing, breathing, and disease progression (Hogg, Goldstein, & Leigh, 1994; Rabkin et al., 2000; Hillemacher et al., 2004). Many health care professionals, caregivers, family, and friends assume depression is common among individuals diagnosed with an incurable and progressive disease such as ALS. Even though the psychological impact of ALS can affect the patient’s mood, depression may be less common than once thought.

Major depressive disorder (MDD), as it is defined by the American Psychiatric Association’s diagnostic and statistical manual of mental disorders, fourth edition, text revision (DSM-IV) (American Psychiatric Association, 2000), states the individual must experience five out of the nine criteria for a minimum of 2 weeks and report a depressed mood and/or decreased interest in once pleasurable activities. Additionally, the individual experiences a clinically significant level of emotional distress, causing possible impairment to daily functioning. The level of
depression may vary from mild to severe, be present with or without psychotic features, or be considered as recurring or in remission. The *DSM-IV-TR* also states a diagnosis is not warranted if the symptoms are directly associated with substance or drug abuse, side effects from prescribed medication or medical treatments, or exposure to toxic chemicals.

The prevalence of depression in the ALS population is difficult to estimate. This may in part be the result of variations (age, stage of disease, psychiatric history) within subject pools as well as varying methodologies and measures used to assess symptoms (Bungen, Piquard, Pradat, Salachas, Meininger, & Lacomblez., 2005; Rabkin et al., 2005). Another consideration is that while ALS patients tend to experience elevated levels of depression when compared to non psychiatric populations, not all experience depression. This means that some might experience clinical depression, subthreshold depression, or no depression (Ganzini et al., 1998; Rabkin et al., 2000; Felgoise et al., 2005).

In a longitudinal study examining 80 late-stage ALS patients, researchers found that less than 10% of subjects presented with major depression, while other subjects were reported to experience transient depressive symptoms. Furthermore, the researchers did not find depression and nearness of death to be concurrent with all subjects (Rabkin et al., 2005). Consistent findings were also established in a study using the Center for Epidemiologic Studies Depressed Mood Scale (CES-D) self-report, in which no correlation between disease duration and lowered scores of psychological well-being were present (Lou, Reeves, Benic, & Sexton, 2003).
In another investigation by Rabkin et al. (2000), 56 patients were examined over time through clinical interview and questionnaires to assess depression as well as other disease-related considerations in an ALS-specific subject pool. The prevalence rates in the study’s subject pool consisted of the following: 88% no clinical depression, 2% current major depressive disorder, 7% subthreshold major depression, and 4% minor depression. After 5.5 months, subjects were reevaluated using the same measures. Results did not find increased levels of depression over time for the sample as a whole. When subjects were asked if a mood change occurred, 15 remained non depressed, 1 remained depressed, and 4 reported changes to their mood (2 improved and 2 worsened). Overall findings suggest that distress and depressive symptoms were not associated with time since diagnosis, changes in physical state due to the illness, or illness progression.

In another investigation (Ganzini, Johnston, & Hoffman, 1999) which examined perceived suffering, pain, overall quality of life, depression, and hopelessness in ALS patients, the researchers found 11 out of 100 patients met criteria for depression based upon the *DSM-IV* criteria. Moreover, Hillemacher et al. (2004) compared depression scales, the ALS Functional Rating Scale, disease duration, gender, age, and level of education in 41 ALS subjects. The results from this study did not support an association between depression and general physical functioning. The study did, however, find reactive depression upon initial diagnosis and with communication and breathing difficulties.

With prevalence of depression still unclear, research findings show some ALS patients are experiencing subthreshold depression or clinical depression. Based on
this data, the European Federation of Neurological Societies (EFNS) task force identified pharmacotherapy treatment for depression using the ALS Care Database. The listing of antidepressant medication consisted of paroxetine, fluoxetine, amitriptyline, and sertraline, with amitriptyline providing the greatest amount of symptom relief (Andersen et al., 2005). The database also revealed that of the ALS patients presenting with depression, less than half were treated with pharmacotherapy and data was unavailable for those receiving psychotherapy.

In terms of psychotherapy research, researchers examined optimism as it related to well-being and depression in ALS patients and their caregivers through mediation factors of appraisal and coping style. This study found ALS patients and their caregivers who were able to give up control were more optimistic and less depressed (Mock, Gabriel, Turnbull, & Wethington, 2004). Other studies attempting to understand the mechanisms of adaptive coping found optimism, sense of control, use of humor, utilizing a support network, cognitive reappraisal, reframing, and intellectual stimulation increased ALS patients’ ability to accept their diagnosis and prognosis (Young & McNicoll, 1998; Trail, Nelson, Van, Appel, & Lai, 2004).

Social Problem Solving Theory

association in which demands are appraised by the person to determine if they are equipped with sufficient coping resources and whether their well-being is at risk. According to this model, a person experiencing a stressful event greatly influences the quality and intensity of their response to stress through two processes: coping appraisal and coping.

Coping appraisal is the process by which a person determines the meaning or personal significance of a stressful encounter with the environment. The two types of appraisal include primary appraisal, which refers to the self-evaluation and significance of the situation and its impact on overall well-being. Secondary appraisal refers to the person’s appraisal of his/her coping choices and resources.

Coping refers to the various cognitive and behavioral activities by which the person attempts to manage stressful situational demands as well as the emotions that may be generated. The two primary coping methods include problem-focused coping and emotion-focused coping. The first method, problem-focused coping, refers to improving a stressful situation, while the second method, emotion-focused coping, refers to the ability of regulating emotions resulting from the situation. Problem-focused coping often occurs when stressful situations are appraised as changeable or controllable, while emotion-focused coping generally occurs in situations appraised as unchangeable or uncontrollable.

The relational model of stress defines problem solving as a type of problem-focused coping in which problem-solving goals are equated with control over environment or mastery goals. Problem-solving is considered maladaptive when stressful situations are perceived as unchangeable or uncontrollable.
The second model, relational/problem-solving model of stress (D’Zurilla & Nezu, 1999; Nezu, et al., 2004), maintains the fundamental framework of the relational model of stress, but also incorporates a greater emphasis on problem solving. As such, the second model describes stress as a function of the reciprocal relationship across three variables: stressful life events, emotional stress response, and problem-solving coping. Stressful life events are life experiences to internal and external demands that require readjustment. The two types of stressful life events consist of a major negative event and a daily problem. A major life event is a global life experience that generally demands readjustment. Examples of this include: divorce, job loss, major medical illness, injury, or death. A daily problem is a specific life experience during which there is perceived imbalance between adaptive demands and a sufficient coping response.

*Emotional stress response* is the initial emotional response (negative or positive) to a stress life event based on appraisal and coping. Negative emotional responses tend to occur when the problem is appraised as a direct threat to well-being, there is self-doubt in ability to effectively cope with situation, or the individual engages in ineffective or maladaptive coping. Alternatively, positive emotional responses occur when the problem is perceived as a challenge or opportunity, the individual believes they have the capability to cope effectively, and they are utilizing effective coping response. Lastly, the relational/problem-solving model of stress identifies problem-solving coping to include problem-focused goals, emotion-focused goals, or both, based on the specific problem and how it is defined and appraised.
The relational/problem solving model of stress (D’Zurilla, Nezu, & Maydeu-Olivares, 2004) defines social problem-solving as a self-directed cognitive-behavioral process individuals use in order to identify possible effective or adaptive coping strategies when problems occur in daily living. Social problem solving encompasses several domains, including impersonal problems (e.g., insufficient finances), intrapersonal problems (e.g., cognitive, emotional, behavioral, or health-related concerns), interpersonal problems (e.g., relationship problems, marital discord, family-related concerns), and societal problems (e.g., crime, racial discrimination).

The definition of problem is “any life situation or task, either present or in the near future, that requires a response for adaptive functioning but no effective response is immediately apparent or available to the person or people confronted with a situation, because of the presence of one or more obstacles” (D’Zurilla et al., 2004, p. 12). Such obstacles may include uncertainty, unpredictability, skill deficits, or limited resources. A problem could be time limited, a sequence of events, or chronic. Moreover, the obstacles to problem resolution may stem from within the individual or may be a product of the environment.

A solution is a cognitive or behavioral response pattern that is the product or outcome of the problem-solving process when it is applied to a specific problematic situation. To reach an effective solution means that the individual is able to achieve his or her problem-solving goal while maximizing positive consequences and minimizing negative consequences.

Problem solving and solution implementation are two additional aspects of the social problem-solving model (D’Zurilla & Nezu, 1999; D’Zurilla et al., 2004).
Problem-solving is the act of searching for solutions to specific problems, and solution implementation is defined as the act of executing those solutions within problematic situations. Problem-solving skills are considered to be general, while solution implementation skills tend to vary based upon the type of problem and solution.

The social problem-solving model.

The original model of social problem solving was first developed by D'Zurilla and Goldfried (1971) and later modified by D'Zurilla and Nezu (1999). According to the revised model, there are two mechanisms of problem-solving: problem orientation and problem-solving proper. Problem orientation is a relatively stable cognitive-emotional schema that reflects the thoughts and feelings of an individual in terms of problem development and one’s ability to solve problems. Furthermore, problem orientation is a motivational component of the problem-solving process. Problem-solving proper is a rational method of searching for an effective or adaptive solution to a specific problem via the use of problem-solving strategies. Problem orientation is a general awareness of one’s attribution style, perception, self-efficacy, appraisal of problems, and one’s ability to problem solve (D’Zurilla & Nezu, 1999). Positive problem orientation tends to evoke a positive or constructive approach in which the individual views a problem as a challenge, exudes optimism and/or confidence in their ability to solve a problem, exercises patience during the problem-solving process, and maintains focus and motivation to solve the problem at hand. Negative problem orientation often presents as low self-efficacy, negative affect, low
frustration tolerance, anticipation of a negative outcome, and a lack of motivation in the presence of a problem.

In general, problem orientation is comprised of a few factors. The first factor, *problem perception*, is the awareness and intention to address problems as they develop. The second factor, *problem attribution*, is the meaning the individual attaches to the problem. Individuals who possess a positive attribution style may deem the problem changeable and may not attribute the problem to personal limitations. Alternatively, individuals with a negative attribution style are likely to identify the problem as fixed or unchangeable and attribute its occurrence to their own perceived deficits. The third factor, *problem appraisal*, tends to be based upon individual attribution style and self-efficacy, i.e., when a problem develops, some individuals will see it as either an opportunity for growth and development or as a threat.

Problem-solving proper is a problem-solving skill set that increases the likelihood that individuals will be able to effectively solve problems. D'Zurilla and Nezu (1999) identify four skills in the set: problem definition and formulation, the generation of alternative solutions, decision making, and solution implementation and verification. The first skill, problem definition and formulation, is the ability to identify a problem, obtain viable and accurate information, understand the problem, establish reasonable goals, and assess the costs and benefits associated with the problem.

The second skill, the generation of alternative solutions, is the process of generating as many reasonable options as possible. When this task is done efficiently,
individuals minimize their reliance on heuristics or old patterned responses of problem-solving and maximize effective solutions using creativity. The generation of alternative solutions is rooted within three primary principles: quantity, affirmative judgment, and variety. The first is the quantity principal, which states that the more solutions generated increase the probability that an effective solution will be produced. Second, the affirmative judgment principle is the idea that sound solutions are not more likely to occur when individuals have the time to process their thoughts during the problem-solving task. Third, the variety principal states that the production of a broad range of ideas enables the problem solver to generate multiple strategies in attempts to solve the problem. After several strategies have been considered, the problem solver is more equipped to narrow the list of possible solutions.

The third skill, decision making process, refers to choosing the best possible solution from the pool of generated ideas. The main objective here is to utilize a cost-benefit analysis to determine the utility of each alternative. During this stage, the individual engages in a cost-benefit analysis by examining temporal factors, affective considerations, predicted consequences, and whether the selected solution resolves the stated problem.

The fourth skill, solution implementation and verification, consists of assessing if the final outcome meets the anticipated goal. Given the variation among individual belief systems and interpersonal obligations, the outcome during this step may require a reevaluation and modification if a more effective solution is deemed necessary.
Within the social problem-solving framework, three primary response styles have been identified. Rational problem-solving is defined as systematic, rational, and thoughtful methods skillfully applied to problematic situations. This skill set enables individuals to find adaptive solutions or effective coping responses to specific problems. Impulsive or careless style occurs when problem solving is conducted in a haphazard or unsystematic way. For example, the problem-solving approach tends to be impulsive, careless, hurried, and incomplete. Avoidant style is the absence of solving problems either by choice or due to the lack of identifying a problem exists. For example, the problem-solving approach often consists of passivity, procrastination, and a reliance on others’ problem-solving abilities to address the problem at hand.

Social problem solving and depression.

The social problem-solving model examines how individuals approach everyday problems and stress. More specifically, do individuals use constructive or unconstructive strategies to address everyday problems and stress. Researchers have been studying the relationship between the components that comprise social problem solving and the impact it has on psychological distress and depression across the life span (Nezu, Nezu, Saraydarian, Kalmar, & Ronan, 1986; Nezu, 1987; Nezu & Ronan, 1988; D’Zurilla, Chang, Nottingham, & Faccini, 1998; Reinecke, DuBois, & Schultz, 2001).

In a study by Nezu et al. (1986), the investigators hypothesized that social problem solving moderates negative stressors and depression and that problem-
solving abilities account for the variation when predicting symptoms of depression beyond negative stressors. Four hundred sixty-two undergraduate students enrolled in introductory level courses completed the Beck Depression Inventory (a self-report depression inventory), the Life Experiences Survey (a measure identifying perceived stress levels secondary to major life changes), and the Problem Solving Inventory (a measure assessing problem-solving behavior and attitudes). Using a multiple regression analysis, researchers determined that in individuals confronted with negative life events, effective problem solvers tended to present with better coping abilities and were less likely to experience depressive symptoms, while ineffective problem solvers were identified as more likely to experience depressive symptoms secondary to negative life events. The authors suggest social problem solving be considered an important factor when explaining reactive depression subsequent to a major life event. As such, if ALS is considered a major life event, further exploration of social problem-solving skills in ALS patients may be predictive of coping abilities and depression.

In another investigation, Nezu and Ronan (1988) examined social problem solving as a moderator of stress linked to depressive symptoms using a prospective analysis. One hundred fifty undergraduate and graduate students voluntarily completed the Beck Depression Inventory (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), the Life Experience Survey (Sarason, Johnson, & Siegel, 1978), the Problem Solving Inventory (Heppner & Peterson, 1982), and the Means End Problem-Solving procedure (Platt & Spivack, 1975). This study concluded: (a) effective problem solvers were less likely to experience depressive symptoms as a
result of negative life events, whereas ineffective problem solvers are more likely to experience depressive symptoms resulting from major negative life events; (b) social problem solving predicted future distress in individuals experiencing negative life events and; (c) problem-solving therapy can be used as an effective coping approach when confronted with stress. Since the subject pool was comprised of students with no known medical histories, further research examining social problem solving as a moderator of stress and depressive symptoms with the ALS population is needed.

Priester and Clum (1993) replicated previous research findings (Nezu & Ronan, 1988) in order to reexamine the association between problem-solving appraisal and depression, hopelessness, and suicidal ideation. Three hundred thirty-nine college freshmen were recruited for participation. Participants were asked to complete the Beck Depression Inventory, Beck Hopelessness Scale, the Modified Scale for Suicidal Ideation, the Problem Solving Inventory, and the Life Experiences Survey prior to taking an examination and again after finding out their grade on the examination. Results from this study supported previous research findings (Nezu & Ronan, 1988) that problem-solving appraisal was a moderator of stress/depression and stress/hopelessness when stress was measured by examination grade. The investigators concluded that a relationship exists between perceived problem-solving ability, depression, and hopelessness but not suicidal ideation.

Social problem solving and depression in medical populations.

Individuals diagnosed with chronic medical conditions, such as vision impairment, diabetes, cancer, spinal cord injury, and the human immunodeficiency
virus (HIV) which is the cause of the acquired immunodeficiency syndrome (AIDS), are often confronted with unique experiences such as psychological distress, behavioral demands/restrictions, drug treatments regime, and overall lifestyle changes during the course of medical treatment. The emotional and behavioral reaction styles and problem-solving abilities across individuals can vary greatly.

Dreer, Elliott, Fletcher, and Swanson (2005) investigated social problem solving and its relationship to emotional distress, depressive symptoms, well-being, overall functional abilities, and possible gender differences in 45 subjects diagnosed with vision impairment (macular degeneration, cataracts, glaucoma, diabetic retinopathy, and optic nerve atrophy). Each subject completed the Social Problem-Solving Inventory – Revised: Short, the Tactile Analogue Scales, the Center for Epidemiological Studies Depression Scale, the Satisfaction with Life Scale, and a modified version of the National Eye Institute Visual Function Questionnaire.

The investigators concluded: negative problem orientation was associated with emotional distress and depression, and rational problem-solving skills were positively correlated with life satisfaction. This finding suggests that individuals with vision impairment tend to be better adjusted when they possess sufficient problem-solving skills, higher levels of motivation, increased treatment adherence, and the ability to follow through on daily tasks. The results from this study propose using social problem-solving framework when assessing psychological distress and functional abilities in individuals with medical conditions. Replication of this study with ALS patients would provide perspective on emotional distress, depression, and overall functioning abilities when problem orientation (positive or negative) and
problem-solving style (rational problem solving, impulsive/careless style, and avoidant style) are examined.

In another study, 542 Black patients with type 2 diabetes were examined to determine if a relationship exists between social problem solving in glycemic control and health behaviors (Hill-Briggs et al., 2006). Subjects completed the Social Problem-Solving Inventory – Revised: Short, the Hill Bone Compliance Therapy scale, a measure to assess medication adherence, the Atherosclerosis Risk in Communities/ Baecke Leisure Time Activity Scale, a measure of routine engagement in physical activity, the Center for Epidemiologic Studies of Depressed Mood Scale, a single item question to assess self-monitoring of blood glucose, and blood via venipuncture. Results from the study concluded: (1) a normal distribution of social problem solving across Black patients with type 2 diabetes, (2) problem orientation and rational problem-solving style was not associated with health behaviors and glycemic control, (3) ineffective problem solvers were identified with an impulsive/careless style, while decreased glycemic control was identified with avoidant style, and (4) avoidant style was associated with variations found in blood sampling.

The researchers concluded a relationship exists between ineffective problem-solving styles and glycemic control, while no significant relationship was determined with problem orientation or rational problem-solving style. In addition, problem-solving styles may be a predictor of glycemic control in diabetic patients. Generalizability of these findings to the ALS population could provide valuable prevention/intervention strategies. For example, conducting efficacy research in
order to examine problem orientation and rational problem solving abilities in ALS patients may facilitate the development of effectively addressing treatment adherence issues.

In another investigation, Glasgow, Fisher, Skaff, Mullan, and Toobert (2007) explored problem-solving skills in a culturally diverse sample of 506 diabetic subjects. The researchers hypothesized that problem solving was associated with self-management, diet, emotional distress, and depression across ethnic groups. The results from this study did not suggest a significant relationship between patient characteristics (race/ethnicity, gender, or level of education) and self-management behaviors. The investigators also found problem-solving abilities of individuals with diabetes were associated with disease-related distress and depressive affect. This study demonstrates that problem-solving ability likely plays a role in disease-related distress and depression. While the chronicity of diabetes and potential for physical limitations is somewhat similar to ALS, future studies specific to ALS patients would afford more understanding of the mechanism that maintains emotional distress and depression.

Nezu et al. (1999) conducted two separate investigations to examine various aspects of the association between problem-solving ability and levels of distress in cancer patients. In the first study, researchers studied the relationship between problem solving and distress of cancer patients. One hundred and five recently diagnosed cancer (breast, leukemia, non-Hodgkin’s lymphoma, colon, ovarian, cervical, prostate, bladder, and rectal) patients being treated at both inpatient and outpatient oncology departments within an urban medical center enrolled in the study.
Each subject completed the Social Problem-Solving Inventory – Revised, Brief Symptom Inventory, and the Cancer Rehabilitation Evaluation System Form. Study 1 concluded a significant relationship between effective problem-solving and psychopathology. In the second study, researchers examined the role of problem solving in predicting distress in the years following breast surgery in survivors of breast cancer. Sixty-four breast cancer survivors completed questionnaires including the Negative Impact subscale in the Life Experiences Survey and the Social Problem-Solving Inventory – Revised. Study 2 concluded that high scores on the Negative Problem Orientation and Rational Problem-Solving subscales of the Social Problem-Solving Inventory – Revised found significant distress in their sample. Outcome findings from both studies were able to support the hypothesis that poor problem-solving ability is associated with higher levels of cancer-related distress. Replication of a study with ALS patients could provide an understanding of the association between problem-solving ability, coping, and ALS-related distress.

Elliott (1999) studied the relationship between social problem-solving abilities, psychological adjustment, and physical health among individuals with recent onset spinal cord injury currently enrolled in an inpatient medical rehabilitation program. More specifically, the researcher examined: (a) problem orientation and acceptance of disability, (b) the association between problem orientation and career decisional needs following discharge, and (c) whether problem solving skills predict the rate of pressure sores 1 year following discharge from the program. One hundred eighty-six subjects diagnosed with tetraplegia, paraplegia, and lower spine injuries completed the Inventory to Diagnose Depression, the Social Problem-Solving
Inventory – Revised, the Acceptance of Disability Scale, the Career Factors Inventory and received a physical examination by a psychiatrist to determine the presence of pressure sores. Findings from this study suggest acceptance of a physical disability includes cognitive, affective, and motivational components often identified in those with a positive problem orientation. The researcher also determined that disabled individuals with impulsive or careless problem-solving styles were less likely to accept their prognosis as compared to those with a more rational problem-solving style. Replication of this study with ALS subjects would provide an understanding of the role of problem-solving abilities and its association, if any, with psychological distress.

In another investigation, Johnson et al. (2006) examined antiretroviral therapy (ART), a highly effective treatment to decrease HIV-related mortality, to determine the influence, if any, among treatment adherence, social problem solving, and psychosocial health. Moreover, this study examined components of problem orientation and problem-solving styles. Eight hundred sixty-seven subjects completed the Social Provisions Scale, Beck Depression Inventory, Positive States of Mind Scale, Social Problem-Solving Inventory – Revised, ART Adherence survey, and a demographic questionnaire. Researchers concluded: (a) a constructive problem-solving style was associated with more favorable psychological adjustment and treatment adherence in HIV positive individuals, (b) a dysfunctional problem-solving style was associated with less than optimal psychological adjustment and treatment adherence, and (c) poor problem solving was associated with psychological distress and poor treatment adherence. Generalizability of these results may provide an
understanding of how patients problem solve through issues related to ALS. In addition, this study offers a direction to examine further what type of problem-solving interventions could be used to improve medication adherence.

Presently, there are no known studies on problem orientation or problem-solving styles in the ALS population. As such, future investigations examining the role of social problem solving, physical functioning, and depression in ALS patients is needed.

Summary

The literature review provides an overview of ALS and includes other psychosocial factors associated with the disease. Factors consistently associated with ALS include physical functioning (Rabkin et al., 2000; Robbins et al., 2000; Hillemacher et al., 2004; Neudert, 2004), psychosocial considerations (Nelson et al., 2003), adaptation (Trail et al., 2004), coping (Young & McNicoll, 1998; Mock et al., 2004; Trail et al., 2004), emotional distress (Trail et al., 2004), and depression (Ganzini et al., 1998; Rabkin et al., 2000). One factor that has yet to be examined in ALS patients is social problem solving. Research already exists on social problem solving in other chronic medical patients with vision impairment (Dreer et al., 2005), diabetes (Hill-Briggs et al., 2006; Glasgow et al., 2007), cancer (Nezu et al., 1999), spinal cord injury (Elliott, 1999), and HIV (Johnson et al., 2006), among others. As such, the relationships between depression, social problem-solving skills, and physical functioning in ALS patients are important to examine to effectively address depression in this population.
Hypotheses

This study examines the relationship between social problem solving, physical functioning, and depression in ALS patients. Specifically, this study aims to test the following hypotheses:

1. There is a positive correlation between poor social problem solving and depression;
2. There is a negative but small correlation between physical functioning and depression;
3. The interaction between social problem solving (positive problem orientation, negative problem orientation, and rational problem solving) and physical functioning will significantly predict unique variance in depression.
Chapter 2

Method

Participants

The present research utilized data collected from a larger study of ALS patients focusing on quality of life in patients who attended appointments at ALS-specific multidisciplinary clinics nationwide. Three clinics located in rural or urban Pennsylvania and Minnesota collected data on the variables examined, indicating social problem solving, physical functioning, and depression in this study.

Inclusion criteria for each participant consisted of: age 18 years or older; diagnosis of definite, probable, or probable laboratory-supported ALS; fluency in English at the sixth grade level or higher; and capable of providing informed consent. Exclusion criteria for patients consisted of: younger than 18 years old; the presence of dementia and or other cognitive impairments, as detected by a physician or psychologist; and a lack of or refusal to sign informed consent.

The demographic data consisted of: gender, age, ethnicity, marital status, level of education, household income, and employment status. Other information such as onset of illness, living arrangement, and psychotropic medication use was also obtained.

A total of 71 subjects from urban (63.4%) or rural (23.9%) Pennsylvania and Minnesota (12.7%) participated in the study. The sample of ALS patients reflected more males \( (n = 47, 66.2\%) \) than females \( (n = 24, 33.8\%) \) and a mean age of 60.72 \( (SD = 10.22) \). The ethnic composition of the ALS subjects included White \( (n = 63, 88.7\%) \), Black \( (n = 4, 5.6\%) \), Hispanic \( (n = 3, 4.2\%) \) and other \( (n = 1, 1.4\%) \). Most
participants were married \((n = 52, 73.2\%)\). The participants scored a mean of 4.64 \((SD = 1.87)\) across eight levels of education. Thus, the average ALS patient completed “some college” or “2 year college degree.” The annual household income ranged from $20,000 to $39,999 \((n = 22, 31\%)\), $40,000 to $59,999 \((n = 17, 23.9\%)\), $80,000 or greater \((n = 11, 15.5\%)\), less than $20,000 \((n = 6, 8.5\%)\), or “prefer not to answer” \((n = 6, 8.5\%)\). The majority of ALS subjects were retired \((n = 35, 49.3\%)\), while the remainder were on disability \((n = 21, 29.6\%)\), were employed full-time \((n = 9, 12.7\%)\) or part-time \((n = 3, 4.2\%)\), or retired and on disability \((n = 1, 1.4\%)\).

The duration of illness for participants ranged from 1 year to 21 years \((n = 59; M = 5.10, SD = 3.85)\) while the remainder were unknown \((n = 12)\). A greater proportion of the ALS subjects in the sample lived with their spouse/partner \((n = 51, 71.8\%)\), followed by living alone \((n = 8, 11.3\%)\), living with a relative \((n = 6, 8.5\%)\), living in a long-term care facility \((n = 4, 5.6\%)\), or living with a friend or other \((n = 4, 2.8\%)\). Lastly, many of the ALS subjects were not taking psychotropic medication \((n = 28, 39\%)\), while the remainder were taking one or more psychotropic medications such as an SSRI, bupropion, quetiapine, benzodiazepine, duloxetine, or mirtazapine \((n = 24, 34\%)\), or the psychotropic medication detail was unknown \((n = 19, 27\%)\).

**Measures**

Demographic information (see Appendix C) from the larger study in conjunction with various specific questionnaires was completed by study participants orally or by pointing or blinking while the data collector circled their responses. One measure assessing muscle strength was completed by the physician and/or medical
staff. All of the questionnaires were completed during the participants’ scheduled clinic appointments and were administered in a set order.

**Physical functioning.**

Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS – R) is a 12-item self-report questionnaire assessing noticeable physical abilities in activities of daily living in ALS patients (Cederbaum, 1999). The domains on the ALSFRS-R include gross motor abilities, fine motor abilities, and bulbar and respiratory function. More specifically, some examples of physical abilities assessed by the questionnaire include: speech, salivation, swallowing, dressing and hygiene, walking, and respiratory insufficiency. Each of the item responses are scored using a 0 to 4 point scale, ranging from normal functioning to inability to carry out task on own. Outcome scores are calculated by adding the up the points endorsed for each item. Composite totals in the upper limits indicate a higher level of functioning than scores in the lower limits. The internal consistency values were .73 for raw and .71 for standardized. The questionnaire also has good construct validity. Administration time is approximately 5 to 10 minutes. For purposes of this study, the ALSFRS - R total score and the three questions assessing bulbar function (speech, swallowing, and salvation) were analyzed.

**Physical strength.**

Manual Muscle Strength Test (MMT) measures strength in four muscle groups (arm abductors, wrist extensors, hip flexors, and ankle dorsiflexors) in both
the upper and lower extremity muscle groups on the left and right side (Her Majesty’s Stationary Office, 1976). Strength is scored using a 0 to 5 scale (weakest to strongest, respectively) for each of the muscle groups. Scores are determined by adding up the total score and dividing by 8. The MMT is an objective measure administered by a physician and/or medical staff to validate subjective ratings obtained in the ALSFRS-R.

Affect.

Brief Symptom Inventory – 18 (BSI – 18) is an 18-item self-report inventory intended to detect the presence of psychological distress and psychiatric disorders in medical populations over the age of 18 (Derogatis, 2001). The questionnaire assesses psychiatric symptoms on three dimensions comprised of somatization, depression, and anxiety. Symptoms are scored using a 0 to 4 scale ranging from not at all to extremely distressing and scored by adding up the numbers endorsed for each item. Some example items from the depression dimension include “feeling no interest in things,” “feeling lonely,” “feeling blue,” “feeling of worthlessness,” “feeling hopeless about the future,” and “thoughts of ending your life.” The Global Severity Index represents the overall level of distress and is calculated by adding up total scores on each dimension. Internal consistency for the three dimensions ranged from .74 to .89. Internal consistency on the depression dimension was .84. Test-retest reliability research has yet to be conducted on the BSI – 18. However, the estimated comparisons from the Brief Symptom Inventory (BSI) are considered to be within a sufficient range. The BSI test-retest reliability for the General Severity Index was .90 and the depression dimension was .84 (Derogatis, 2001). Initial research outcomes
found the BSI - 18 was highly correlated with the Symptoms Checklist 90. The BSI - 18 takes approximately 5 minutes to complete. For purposes of this study, the depression dimension of the BSI - 18 was used in the data analysis.

**Mood.**

The Center for Epidemiologic Studies Depressed Mood Scale (CES-D) is a 20-item self-report questionnaire initially created for epidemiology research measuring depression in nonclinical and psychiatric populations (Radloff, 1977). Symptoms are scored using a 0 to 3 scale ranging from *rarely or none of the time (less than 1 day)* to *all of the time (5-7 days)*. Some sample questions include “I felt depressed,” “I had trouble keeping my mind on what I was doing,” “I thought my life had been a failure,” “I was happy,” and “I enjoyed life.” Depression levels are determined by reverse scoring items 4, 8, 12, and 16 and adding the scores on these and the remainder of items on the questionnaires. Scores range from 0 to 60, with a score of 16 or higher indicating depressive symptoms. The questionnaire has an internal consistency of .85 for the nonclinical population and .90 for psychiatric populations. Split-half and Spearman-Brown reliability coefficients ranged between .77 and .92, and test re-test reliability was .51 to .67 over a 2 - week to 2- month period. The CES-D also has good concurrent validity. Administration time is approximately 5 minutes.
Social problem solving.

The Social Problem-Solving Inventory-Revised: Short (SPSI – R: S) (D’Zurilla, Nezu, & Maydeu-Olivares, 2002), a 25-item brief questionnaire, assesses an individual’s ability to identify and learn adaptive solutions to everyday living problems. The SPSI – R: S has two domains: (1) Problem-Solving Orientation is comprised of two subscales each with five items: Positive Problem Orientation (“Whenever I have a problem, I believe it can be solved”) and Negative Problem Orientation (“I feel nervous and unsure of myself when I have an important decision to make”), (2) Problem-Solving Style is made up of three subscales each with five items: Rational Problem Solving (“When I have a decision to make, I try to predict the positive and negative consequences of each option”), Impulsivity and Carelessness Style (“I am too impulsive when it comes to making decision”), and Avoidant Style (“I spend more time avoiding my problems than solving them”). Scores are determined by using a 0 to 4 Likert scale ranging from not at all true of me to extremely true. Each scale and subscale has a standardized mean of 100 and a standard deviation of 15. The scores are added and then converted in standard scores. Scores of 145 or greater are considered extremely above norm group average and scores 55 or below are considered extremely below norm group average. The internal consistency ranged from .60 to .90, test-retest reliability ranged from .68 to .91, and the standard error of measurement of the standard scores ranged from 3.00 to 9.49. Furthermore, the SPSI – R: S is highly correlated with the Social Problem-Solving Inventory Revised: Long (SPSI – R: L). The questionnaire possesses sufficient structural, predictive, convergent, and discriminate validity. Administration time is
approximately 10 minutes. For purposes of this study, the SPSI - R: S total score and its subscales Positive Problem Orientation, Negative Problem Orientation, Rational Problem Solving, Impulsivity/Carelessness Style, and Avoidant Style were analyzed.

Design and Procedures

This study was a cross-sectional design that examined the relationship between social problem solving, physical functioning, and depression in ALS patients. The data were analyzed using correlation coefficients and a multiple regression analysis to test the study's three hypotheses.

The following procedures were standardized from a larger ALS quality of life study. On the day of the ALS patient's regularly scheduled appointment, the potential participants were informed about the research being conducted at the clinic and were asked for their voluntary participation. The information about the larger study was conveyed verbally by health care professionals, including physicians, nurse practitioners, research coordinators, and volunteer staff, and through a flyer distributed in the clinic to potential subjects.

When an ALS patient expressed interest in the study, one of the individuals assigned to collect data went into the examination room after the patient had already met with his/her physician. At that time, the data collector described the study in more detail. Patients who agreed to voluntarily participate were asked to sign the consent form in order to proceed (see Appendix A). When a caregiver was present in the examination room, he/she was asked to wait in the waiting area until the data collection process was complete. The data collectors were comprised of master’s
level and advanced doctoral students in clinical psychology from the Philadelphia College of Osteopathic Medicine, clinic nurses, or other research assistants. Data collection occurred under the supervision of a clinical psychologist or physician. Each individual data collector was required to follow a standardized protocol and was provided written instruction in addition to observing a trained data collector.

Seventy-one ALS subjects participated in the study during one of their scheduled clinic appointments in a hospital-affiliated setting located in urban or rural Pennsylvania or Minnesota. Patients recruited for this study completed questionnaires about physical functioning, mood, and social problem solving responding orally, by pointing, or blinking. In addition, one measure assessing muscle strength was completed by the physician and/or medical staff during that same clinic appointment. These participants represented a convenience sample. Participation in this study was voluntary and no financial compensation was provided. The study was open to patients across all stages of the ALS illness.
Chapter 3

Results

The purpose of this investigation was to examine the relationship between social problem solving, physical functioning, and depression in ALS patients. Data were initially inspected to evaluate the normalcy of the variables. The analyses for this study were conducted using SPSS software version 16.0.

Descriptive Statistics

The Social Problem Solving Inventory – Revised Short (SPSI – R: S) assesses an individual’s ability to identify and learn adaptive solutions to problems in everyday living. Scores are determined by using a 0 to 4 Likert scale ranging from not at all true of me to extremely true. The scores are added and then converted to standard scores. Scores of 145 or greater are considered extremely above norm group average and scores 55 or below are considered extremely below norm group average. Each scale and subscale has a standardized mean of 100 and a standard deviation of 15. The means and standard deviations for the SPSI – R: S total score were categorized by age group. The age distributions of ALS subjects in this study were: young adults (YA) ages 17 to 39 (2.8%), middle age adults (MA) 40 to 55 (42.3%), and elderly adults (EA) ages 60 to 80 (54.9%).

In this sample, SPSI – R: S scores ranged from 64 to 131; means (with standard deviations in parentheses) for YA, MA, and EA were 104.5 (24.75), 102.63 (11.67), and 106.0 (15.15), respectively. The YA ALS sample was difficult to compare with the normative sample as a result of having a small sample size (N = 2).
After comparing the ALS subject samples scores on the SPSI – R: S total score to the age adjusted normative scales, no significant differences were found between the samples.

Results from the three subscales of the SPSI – R: S included Positive Problem Orientation (PPO) had a mean score of 106.03 (SD = 15.88), with a low score of 63 and a high score of 135. The subscale Negative Problem Orientation (NPO) had a mean score of 96.14 (SD = 15.59), with a low score of 78 and a high score of 141. The mean score on the Rational Problem Solving subscale (RPS) was 104.80 (SD = 14.01), with a low score of 58 and a high score of 137. The subscale Impulsivity Carelessness (ICS) had a mean score of 100.90 (SD = 13.37), with a low score of 77 and a high score of 137. The mean score on the Avoidance Scale (AS) was 101.10 (SD = 16.85), with a low score of 76 and a high score of 157. Higher scores are indicative of more effective problem-solving abilities.

The Center for Epidemiologic Studies Depressed Mood Scale (CES – D) measures depression in nonclinical and psychiatric populations. Symptoms are scored using a 0 to 3 scale ranging from rarely or none of the time (less than once a day) to all the time (5-7 days). The mean score was 13.25 with a standard deviation of 9.06. Twenty-five percent of the sample scored 6 or less and 75% scored 18.75 or higher. In this sample, approximately 32.3% of subjects scored within the clinically significant range.

The Brief Symptom Inventory 18 (BSI – 18) assesses psychological distress and psychiatric disorders in adult medical populations. For this study, only the depression subscale was utilized. This measure is scored using a 0 to 4 scale ranging
from not at all to extremely distressing. The lowest score was 0 and the highest score was 23. A higher score reflects an increased tendency for depressive symptoms. Raw scores were converted to T-scores, based on the manual. The norms provided for oncology patients indicate that T-scores of 63 or above are clinically significant (Derogotis, 2001). In the sample, ALS subjects had a mean raw score of 3.49 ($SD = 4.35$) which is equivalent to a T-score of 54. There were no significant differences between the ALS sample and the normative sample. Twenty-five percent of the ALS sample scored 0, and 75% of the sample scored above 4. A raw score of 4 is equivalent to a T-score of 58. In this sample, approximately 15% of subjects scored within the clinically significant range.

The Manual Muscle Test (MMT), a measure of physical strength, was administered by a physician and/or medical staff to measure strength on the left and right side muscle groups (arm abductors, wrist extensors, hip flexors, and ankle dorsiflexors). Strength is scored on a 0 to 5 scale from weakest to strongest. The lowest score was .50 and the highest score was 5.00. The mean was 3.70 ($SD = 1.10$).

On the Amyotrophic Lateral Sclerosis Rating Scale - Revised (ALSFRS – R), both a composite measure of physical functioning and a score reflecting only bulbar function (speech, swallowing, and salivation) were used. This scale is scored using a 0 to 4 scale ranging from normal functioning to an inability to carry out a task independently. The lowest score was 14 and the highest score was 48 on the ALSFRS – R total score, with a mean score of 31.84 ($SD = 7.42$). On the bulbar functioning subscale, the scores ranged from 1 to 12, with a mean score of 9.77 ($SD = 2.32$). A higher score means a greater level of physical functioning.
Hypothesis 1

*There is a positive correlation between poor social problem solving skills and depression.*

The hypothesis was supported, and there was, in fact, a positive correlation between poor social problem-solving skills and depression. The first hypothesis was evaluated using Pearson product-moment correlation (Pearson $r$) in order to demonstrate the strength and direction of the relationship between the variables (George & Mallery, 2003). The Pearson correlation coefficients were computed between social problem solving as measured by the Social Problem Solving Inventory–Revised Short: (SPSI – R: S) total score and the Positive Problem Orientation (PPO), Negative Problem Orientation (NPO), Rational Problem Solving (RPS), Impulsivity and Carelessness Style (ICS), and Avoidance Style (AS) subscales and depression as measured by the Center for Epidemiologic Studies Depressed Mood Scale (CES – D) and the depression dimension subscale from the Brief Symptom Inventory 18 (BSI – 18).

The correlation matrix is presented in Table 1. The table illustrates that both the SPSI – R: S total score, NPO, and ICS are significantly correlated with both depression measures. All values were evaluated using a significance level of .05 and were two-tailed. The SPSI – R: S total score is significantly negatively correlated with the CES – D ($r = - .41, p < .01$). The NPO subscale is significantly positively correlated with the CES – D ($r = .52, p < .01$). The ICS is significantly positively correlated with the CES – D ($r = .25, p = .38$). Similarly, the SPSI – R: S total score is significantly negatively correlated with the BSI – 18 depression dimension...
The NPO is significantly positively correlated with the BSI – 18 depression dimension ($r = .34, p < .01$). The ICS is significantly positively correlated with the BSI – 18 depression dimension ($r = .26, p = .32$). Therefore, higher levels of depression are related to lower levels of social problem-solving abilities and higher NPO and ICS scores. Also, as seen in Table 1, there was no significant correlation between PPO, RPS, AS and the depression measures, although the correlation between the PPO and the CES – D approached significance ($r = -.23, p = .06$).

Table 1. *Correlation Coefficients (r) of Measurements and Subscales*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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</thead>
<tbody>
<tr>
<td>1. SPSI-R:S</td>
<td>1.00</td>
<td>0.43**</td>
<td>-0.58**</td>
<td>0.44**</td>
<td>-0.41**</td>
<td>-0.58**</td>
<td>0.23</td>
<td>0.18</td>
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<tr>
<td>2. PPO</td>
<td>0.43**</td>
<td>1.00</td>
<td>-0.29*</td>
<td>0.67**</td>
<td>-0.23</td>
<td>-0.08</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>3. NPO$^b$</td>
<td>-0.58**</td>
<td>-0.29*</td>
<td>1.00</td>
<td>-0.21</td>
<td>0.52**</td>
<td>0.34**</td>
<td>-0.04</td>
<td>-0.19</td>
</tr>
<tr>
<td>4. RPS</td>
<td>0.44**</td>
<td>0.67**</td>
<td>-0.21</td>
<td>1.00</td>
<td>-0.13</td>
<td>-0.08</td>
<td>0.15</td>
<td>-0.04</td>
</tr>
<tr>
<td>5. CES-D</td>
<td>-0.41**</td>
<td>-0.23</td>
<td>0.52**</td>
<td>-0.13</td>
<td>1.00</td>
<td>0.76**</td>
<td>-0.10</td>
<td>-0.26*</td>
</tr>
<tr>
<td>6. BSI-18</td>
<td>0.58**</td>
<td>-0.08</td>
<td>0.34**</td>
<td>-0.08</td>
<td>0.76**</td>
<td>1.00</td>
<td>-0.14</td>
<td>-0.22</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>7. MMT$^c$</td>
<td>0.23</td>
<td>0.02</td>
<td>-0.04</td>
<td>0.15</td>
<td>-0.10</td>
<td>-0.14</td>
<td>1.00</td>
<td>0.61**</td>
</tr>
<tr>
<td>8. ALSFRS-R</td>
<td>0.18</td>
<td>0.03</td>
<td>-0.19</td>
<td>-0.04</td>
<td>-0.26*</td>
<td>-0.22</td>
<td>0.61**</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*Note. *$p < .05$, **$p < .01$*

$^a n = 70$

$^b n = 71$

$^c n = 69$
Hypothesis 2

There is a negative but small correlation between poor physical functioning and depression.

The second hypothesis was once again evaluated using Pearson product-moment correlation (Pearson $r$). The Pearson correlation coefficients were computed between physical functioning as measured by the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS – R) composite score, a separate score derived from three questions measuring bulbar function from the ALSFRS – R, and depression as measured by the Center for Epidemiologic Studies Depressed Mood Scale (CES – D) and the depression dimension subscale from the Brief Symptom Inventory 18 (BSI – 18).

Correlation coefficients and significance levels are presented in Tables 1 and 2. Once again, all analyses were two-tailed and evaluated at the .05 level. The ALSFRS – R was significantly negatively correlated with the CES – D ($r = -.26, p < .05$). The correlation between the ALSFRS – R and the BSI – 18 depression dimension was approaching significance ($r = -.22, p = .07$). This result suggests that as physical abilities decline, depression levels increase. This finding, however, was only significant on the CES – D. As seen in Table 2, the correlations between the bulbar functioning subscale, CES – D, and BSI – 18 depression dimension were not significant. Overall, there was partial support for hypothesis 2 in that a significant correlation between poor physical functioning and depression as measured by the CES – D was demonstrated. However, no significant correlation was found between poor physical functioning and depression as measured by the BSI – 18. Additionally,
bulbar function (speech, swallowing, and salivation) was not significantly correlated with either depression measure.

Table 2.

*Correlation Coefficients (r) of Bulbar Function and Depression (n = 71)*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CES-D</td>
<td></td>
<td>0.76**</td>
<td>-0.10</td>
</tr>
<tr>
<td>2. BSI-18 Depression</td>
<td></td>
<td>0.76**</td>
<td>0.03</td>
</tr>
<tr>
<td>3. ALSFRS-R Bulbar</td>
<td>0.10</td>
<td>0.03</td>
<td></td>
</tr>
</tbody>
</table>

*Note. *p < .05, **p < .01

Hypothesis 3

*The interaction between social problem solving (positive problem orientation, negative problem orientation, and rational problem solving) and physical functioning will significantly predict unique variance in depression.*

A multiple regression analysis was conducted to evaluate if social problem solving moderated the relationship between physical functioning and depression. Multiple regression analysis examines the relationship between two or more predictor (independent) variables and a criterion (dependent) variable (George & Mallery, 2003). For hypothesis 3, the subscales Positive Problem Orientation (PPO), Negative Problem Orientation (NPO), and Rational Problem Solving (RPS) from the Social Problem Solving Inventory—Revised: Short (SPSI – R: S) and the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS – R) were used as the
predictor variables and depression as measured by the Center for Epidemiologic Studies Depressed Mood Scale (CES – D) was used as the criterion variable. The correlation coefficients are presented in Table 1.

All predictor variables were entered into the regression analysis using a forward method. By virtue of the forward method, variables were entered one at a time. The model is complete when there are no additional variables that explain a significant portion of additional variance. The NPO was the only variable that met entry requirements, whereas PPO, RPS, ALSFRS – R and the interaction between NPO and physical function did not. The overall regression was significant ($R^2 = .27$, adjusted $R^2 = .26$, $F(1, 67) = 24.56, p < .001$). The $\beta$ values indicate the relative influence of the entered variables with the negative problem orientation as the variable exerting the most effect, $\beta = .52$. This model predicts 26.8% of the variance in CES – D. The multiple regression analysis results suggest that a negative problem orientation (e.g., when confronted with a problem, it could be perceived as a threat and may respond with avoidance or poor motivation to address the problem) predicts a significant proportion of levels of depression. Since the CES – D was not related to the SPSI – R: S subscales, other than NPO, and the SPSI – R: S scales were not related to the ALSFRS – R, testing for a moderator relationship was not indicated. This hypothesis, therefore, was not supported.

**Summary of Findings**

A total of 71 ALS patients responded verbally, pointing, or by blinking to complete a demographic questionnaire (see Appendix C), the Social Problem Solving...
Inventory – Revised: Short (SPSI – R: S), the Center for Epidemiologic Studies Depressed Mood Scale (CES – D), the Brief Symptom Inventory – 18 (BSI – 18) depression dimension, and the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS – R).

In conclusion, the SPSI – R: S total score, NPO, and ICS are significantly correlated with both depression measures. The ALSFRS – R was significantly correlated with CES – D. NPO was the only variable predicting a significant amount of variance in the CES – D. This means that the correlation between poor physical functioning and depression disappears when NPO is controlled for. Therefore, the bivariate correlation between physical functioning and depression is entirely accounted for by the association of poor physical functioning and NPO, rather than a direct association between physical functioning and depression. NPO was not a moderating variable between physical functioning and depression.
Chapter 4

Discussion

This study examined the relationship between social problem solving, physical functioning, and depression in ALS patients. Specifically, it was sought to determine if physical functioning predicts depression and if so, whether there was an interaction between social problem-solving skills, physical functioning, and depression. Three specific hypotheses were explored to answer these questions. Two of the three hypotheses were supported by the data. This chapter will address the following findings: (a) clinically significant levels of depression were found in 15 – 32.3% of the ALS subjects, (b) there was a positive correlation between poor social problem solving skills and depression, (c) there was a small correlation between poor physical functioning and depression, (d) bulbar functioning was not correlated with depression, and (e) negative problem orientation predicted 26.8% of the total variance for depression.

Conclusions

In the current study, 32.3% of the subjects reported with clinically significant levels of depression as measured by the CES – D and 15 % of subjects reported with clinically significant levels of depression on the BSI – 18 depression dimension. The outcome scores on both depression instruments portrayed a positively significant correlation with one another (r = .76, p < .01). This correlation suggests the instruments measured the same construct. The levels of depression as evidenced by the sample were consistent with prior studies that reported lower levels of depression
among ALS patients (Ganzini et al. 1999; Rabkin et al., 2000). The current study found that 33.8% of ALS subjects were prescribed psychotropic medications, while Rabkin et al. (2000) reported only 16%. It is not clear whether these patients in the current study had a preexisting history of depression, if they were prescribed a psychotropic medication on or after disease onset, or whether subjects who endorsed depressive symptoms were taking a psychotropic medication.

Also, both Ganzini et al. (1999) and Rabkin et al. (2000) documented depression in approximately 10% of their samples, while the current study found approximately 15-32.3% ALS subjects reported depression. One explanation for these differences is that in both the Ganzini and Rabkin studies, depression was assessed using objective measures, rather than subjective reports, as used in this investigation. Another potential explanation for the discrepancies in depression ratings may be related to the phrasing of the questions used with ALS patients. For instance, in Rabkin et al.’s (2000) study, certain questions were omitted from the depression scales regarding sleep problems, poor appetite, and psychomotor retardation. The researcher’s rationale for this was to minimize the misinterpretation between symptoms related to ALS and depression.

The first hypothesis was supported and found a positive correlation between poor social problem-solving skills and depression. More specifically, a robust correlation between negative problem orientation and depression was found. Although there are no known studies that correlated social problem solving and depression in ALS patients, there is empirical support for the relationship between depression and social problem solving with other populations (Nezu, 1987). Also,
social problem-solving abilities have been associated with optimal levels of adjustment following chronic disease (Elliott, Grant, & Miller, 2004).

Consistent with the current study, other investigations have documented similar findings that negative problem orientation was predictive of depression (Nezu et al., 1999; Elliott et al., 2004; Dreer et al., 2005; Johnson et al., 2006; Glasgow et al., 2007). In one investigation, Dreer et al. (2005) documented that negative problem orientation was predictive of emotional distress and elevated depression scores in vision impaired patients. Nezu et al. (1999) concluded that effective problem-solving was associated with lower levels of depression and that negative problem orientation was significantly correlated with distress in cancer patients. Elliott et al. (2004) found that effective problem solvers tended to be more psychologically adjusted toward living with a chronic medical condition. Johnson et al. (2006) demonstrated that dysfunctional problem-solving style was associated with poorer psychological adjustment in HIV subjects, which accounted for compromised treatment adherence. Finally, Glasgow et al. (2007) concluded poorer problem-solving ability was associated with disease-related distress and depression.

Another finding in the current study was the low correlation between Impulsivity and Carelessness style and depression. The current study was consistent with the finding from a study conducted by Elliott (1999) demonstrating that impulsivity/carelessness style was associated with decreased levels of acceptance of a spinal cord injury prognosis. Hill-Brigg et al. (2006) also found an association between CES – D scores, Impulsivity and Carelessness style, and glycemic control in type 2 diabetics. One explanation for this finding may be due to the larger sample size
or the nature of the chronic medical conditions examined in each of these investigations as compared to the current study.

The supported findings in hypothesis 1 suggest problem-solving abilities may influence coping in ALS patients. These results are seemingly consistent with theories of coping (Lazarus & Folkman, 1984; D’Zurilla & Nezu, 1999) and its relationship with depression in that it suggests cognitive, affective, and behavioral processes influence coping style. For example, in the relational model of stress, coping appraisal is an important aspect in determining how an individual copes (Lazarus & Folkman, 1984). Similarly, in the relational/problem-solving model of stress, problem solving plays a significant role as a general coping strategy (D’Zurilla & Nezu, 1999; D’Zurilla, Nezu, & Maydeu-Olivares, 2004). In the coping literature (Tobin et al., 1989; Livneh & Antonak, 2005) for individuals with chronic illness and/or disabilities, individual coping strategies have been described as both adaptive and maladaptive based on specific coping characteristics such as locus of control, affect regulation, cognitions, and behavior. Though the current study did not examine specific characteristics of coping, the study found that poor problem-solving coping predicted higher levels of depression. These findings might better be understood when conceptualized within the constructs of the social problem-solving model as aspects of either a positive or negative problem orientation. A negative problem orientation produces negative emotions, avoidance, unproductive worry, diminished effort, and low motivation, while a positive problem orientation tends to produce positive emotions, focus, effort, motivation, persistence, and frustration tolerance, and allow for uncertainty. Accordingly, ALS patients with a negative problem orientation
have the propensity to experience hopelessness, social isolation, loss, and feelings of being physically out of control. Rabkin et al. (2000) examined factors of hopelessness in ALS patients using the Beck Hopelessness Scale, a measure used to assess three aspects of hopelessness (feelings about the future, loss of motivation, and expectations). The study concluded that intensity of hopelessness contributed to the 30% of ALS patients who experienced moderate depression and 13% that experienced severe depression. Additionally, Plahuta et al. (2002) concluded an external locus of control and an absence of meaning in life was a predictor of hopelessness in ALS patients.

Therefore, the ability to improve ALS patients’ positive problem orientation is an important consideration in order to enhance adaptive coping. Young and McNicoll (1998) demonstrated that ALS patients who were able to cope well with the disease were found to possess optimism, humor, adaptive cognitive strategies, and utilize a strong support network. Hecht et al. (2000) demonstrated that adaptive coping included religiosity and family support. Finally, Mock et al. (2004) found ALS patients who were able to give up control were more optimistic and less depressed. Overall, it seems that the use of cognitive-behavioral methods of treating depression by focusing directly on negative problem orientations may be of great benefit to ALS patients.

The second hypothesis was partially supported and found there was a small correlation between poor physical functioning and higher depression. This outcome suggests that as general physical abilities decline, depression levels increase. This relationship was only seen when using the CES-D and not with the BSI-18. As
previously mentioned, the elevated scores on the CES–D in the current study might be better explained by the phrasing of some of the questions which could apply to symptoms of depression and/or symptoms related to ALS.

Consistent with the current study, Hogg et al. (1994) found that poor physical functioning was associated with higher levels of depression, although other studies have found no relationship between physical functioning and depression (Rabkin et al., 2000; Robbins et al., 2001; Norquist et al., 2003; Hillemacher et al., 2004). One explanation may be related to the selection of measures used to assess depression as seen in Rabkin et al. (2000). In their study, subjects were administered measures such as the Patient Health Questionnaire, an instrument developed for medical populations that assesses for the nine DSM-IV criteria, and the Beck Depression Inventory. During the scoring process, three items related to sleep problems, poor appetite, and psychomotor agitation were omitted, as these symptoms are sometimes considered to be directly caused by ALS. This could lead to lower depression scores. Another possible explanation for the inconsistent findings may be that in Robbins et al.’s (2001) study, psychological factors were assessed using general quality of life (McGill Quality of Life questionnaire) and ALS-specific health-related quality of life (SIP/ALS-19) instruments rather than a depression-specific measure. Moreover, in an investigation conducted by Norquist et al. (2003), the subject pool was comprised of 918 subjects spanning 15 countries across Europe, while the current study had 71 ALS participants, all of whom resided in urban or rural Pennsylvania or Minnesota. European cultural differences may have influenced different results as compared to urban and rural Pennsylvania and Minnesota. Although the current study found a
correlation between declining physical function and depression, there may be other influences that also account for depression. Other studies have addressed disease-related stressors, which could have a greater impact on depression beyond physical functioning. Trail et al. (2004) concluded that illness progression and dependency on others, problems speaking, and muscle weakness were their greatest concerns. This suggests other variables, such as receiving the formal diagnosis of ALS by a neurologist (Gallagher & Monroe, 2006), age of disease onset, or ALS and its overall impact on life roles (Kingsnorth, 2006), or coping and adaptation skills to manage lifestyle changes (Hecht et al., 2002; Young & McNicoll, 1998) could all potentially influence a negative mood state. The current study did not entirely account for all of these outside influences.

Another consideration may be that the sample in the current study was not as physically impaired as subjects in the other investigations. In the current study, the mean score and standard deviation on the ALSFRS – R was 31.84 (SD = 2.32) as compared with other studies reporting mean scores and standard deviations of 24.7 (SD = 9.3) (Hillemacher et al., 2004) and 23.3 (SD = 7.8) at baseline and 17.1 (SD = 6.7) at time two (Rabkin et al., 2000). One explanation for the differences in scores could due to the variability of disease progression and stage of illness of ALS participants in the respective investigations.

The current study examined the relationship between bulbar functioning and depression and did not find a significant correlation. The current study was inconsistent with other investigations (Goldstein et al., 2006; Hillemacher et al., 2004) that demonstrated a significant correlation between bulbar functioning (e.g., the
ability to verbally communicate with others, chewing and swallowing food to sustain nutritional balance, and being able to control saliva and drooling), breathing, and reactive depression. Neither study, however, found decreased bulbar functioning and higher levels of depression over time. Respiratory insufficiency was not analyzed separately in this study. Though there is no cure for symptoms related to bulbar functioning, prior research supports the idea that depression symptoms should be monitored as impairment occurs in the bulbar regions (Goldstein et al., 2006).

The third hypothesis stated the interaction between social problem solving (positive problem orientation, negative problem orientation, and rational problem solving) and physical functioning would predict unique variance in depression. In the current study, only negative problem orientation emerged as a significant predictor of depression in ALS patients. Negative problem orientation predicted 26.8% of the total variance for depression as measured by the CES-D. By contrast, no significant associations were demonstrated by positive problem orientation or rational problem solving.

Furthermore, the current investigation was not able to test for a moderator relationship. While other investigations have yet to examine the moderating role of social problem solving in the ALS population, prior research (Nezu & Ronan, 1985; Nezu, 1986; Nezu & Ronan, 1988) has established social problem solving as a moderator of the negative effects of stressful major life events on depression. This suggests a need for future research to continue to examine the role of social problem solving in the ALS population.
In conclusion, the examination of the three hypotheses made two contributions to the literature. First, this study appears to be one of the first to examine the role of social problem solving in ALS patients. Second, results from this current study found negative problem orientation to be a predictor of higher levels of depression, rather than decreased physical functioning in ALS patients.

**Study Implications**

This investigation makes an important contribution to the literature in that it is among the first to examine the relationship between social problem solving, physical functioning, and depression in ALS patients. The outcome of this investigation strengthens the finding that a negative problem orientation, not physical function, is a predictor of higher levels of depression in ALS patients. This finding proposes the usefulness of problem solving therapy (PST) for ALS patients. PST is an empirically supported, formal treatment approach which has been used to treat depression in other chronically ill medical populations such as cancer patients (Nezu, Nezu, Felgoise, McClure, & Houts, 2003).

PST can be modified for ALS patients in order to help reduce depression that is associated with deficits in problem-solving ability. The rationale for selecting PST is to help ALS patients to identify and resolve disease-related stressors that are influencing maladaptive responses and at the same time teach general skills training to adaptive responses to solve problems. Furthermore, since depression not only affects the ALS patient but also influences the family, an integral part of effective work with ALS patients should include their caregiver and/or family members. In
support of this concept, Murphy (2003) identified a positive relationship between problem solving and quality of life/psychological distress in caregivers of ALS. Though the premise of this current study was not examining caregivers or family members, their inclusion in PST could positively influence the problem orientation (motivation level) and problem-solving skill acquisition of the ALS patient. In a cancer population, inclusion of caregivers in PST proved to be beneficial in maintenance of gains from PST training (Nezu et al., 2003). This generally occurs by the caregiver and/or family member’s willingness to make accommodations in the social environment and provide ongoing support during varying phases of ALS (Vuchinich, 2004).

The application of PST occurs through two processes: (a) problem orientation which is a motivational component, and (b) problem-solving proper, which is the method by which the ALS patient would explore adaptive solutions to specific problems through the use of problem-solving strategies. First, the problem-orientation process within social problem solving is a set of responses that influences cognitive, behavioral, and affective responses in the presence of a stressful situation or problem. A positive problem orientation tends to produce positive emotions, focus, effort, motivation, and persistence, frustration tolerance, and allow for uncertainty. Alternatively, negative problem orientation produces negative emotions, avoidance, unproductive worry, diminished effort, and low motivation. PST emphasizes specific problem orientation variables consisting of: problem perception, problem attribution, problem appraisal, personal control beliefs, and approach avoidance style. Two examples of ALS patients with a negative problem orientation are described. In
example one, problem appraisal may occur when receiving the news of the initial diagnosis. At this time, the ALS patient may appraise the problem as being diagnosed with ALS. This problem may lead toward feelings of hopelessness that without a known cure, negative predictions may be generated about his/her future of living with the disease. In example two, perceived control through a negative problem orientation lens is defined as possessing low self-efficacy, viewing problems as difficult, threatening, and lacking motivation to confront the problem. An ALS patient experiencing ongoing decreased physical abilities such as difficulty communicating may determine this problem is not solvable and as a result engage in maladaptive problem solving by avoiding attempts to ameliorate the communication problem.

The next process in PST includes teaching four problem-solving skills to maximize thoughtful problem solving in order to determine the most effective solution to a particular problem. These four problem-solving skills are: problem definition and formulation, generation of alternative solutions, decision making, and solution implementation and verification. In general, PST is facilitated by enhancing motivation in order to utilize the effective problem-solving skills and to promote high self-efficacy in the process.

In summary, treatment goals could focus on: (a) improving ability to recognize the presence of a problem, (b) reducing the influence of emotional distress and negative thought patterns, (c) developing a perspective that uses a systematic approach to problem solving to provide a means of effective coping, (d) aiding in the development of expecting successful coping abilities, and (e) refraining from the temptation of reacting impulsively or avoiding the problem. Clinical psychologists
and other mental health care professionals can provide psychoeducation, treatment planning, and implementation of PST to ALS patients as well as their caregiver and/or family member for the duration of the disease.

 Furthermore, the role of a clinical psychologist on the multidisciplinary team may prove valuable for a variety of reasons. First, they could provide ongoing assessment of cognitive changes, coping strategies, and mood incongruence. Second, they are able to assess for depression and provide referrals to other mental health professionals such as psychiatrists for dual treatment along with psychotherapy and pharmacotherapy, if recommended. Third, they would be able to improve communication between medical staff and ALS patients in order to address any ongoing concerns the ALS patients may have regarding their medical treatments.

Limitations of Study

Several limitations were identified in the current investigation. The number of individuals in the sample was small ($N = 71$), contributing to a potentially decreased statistical power. Other studies examining social problem solving and psychological distress in medical populations with chronic conditions used samples with over 500 subjects (Hill-Briggs et al., 2006; Johnson et al., 2006; Glasgow et al., 2007). However, it is important to note that these studies were not examining patients with ALS, but rather patients with other chronic medical conditions who tend to experience more symptom variability, treatment options, and greater life expectancy. Though limited by the sample size, the current study does provide valuable information on the effects of social problem-solving abilities and depression in ALS.
Another study limitation was that participant recruitment consisted of patients receiving treatment at one of three ALS hospital-affiliated clinics located in rural (63.4%) or urban (23.9%) Pennsylvania or Minnesota (12.7%). Also, the majority of subjects in the sample were White (88.7%). Therefore, these results may be difficult to generalize to other ethnicities or geographical regions.

Another limitation of this study includes the use of self-report measures to assess problem-solving skills and depression. This use of subjective measures versus objective measures places great emphasis on the ALS patient’s perceived rather than actual state.

Even though this study documented subjects who were prescribed a mood-stabilizing medication at the time of data collection, information regarding the patients’ history of depression prior to ALS onset was not known.

Another limitation of this study was not obtaining a coping history of ALS subjects. Clinically, this information is often considered to be predictive of one’s ability to adjust to lifestyle changes.

Finally, this study did not account for the number of potential subjects who declined participation. Patients often schedule their clinic appointment with their multidisciplinary treatment teams approximately four times a year. During these visits, patients often expect to remain in the clinic for a few hours. The combination of physical symptoms as a result of ALS and general fatigue might have played a role in the limited number of patients who volunteered to participate in the study.
Future Directions

Future studies of ALS patients could consider the following changes in the design of the study or other areas for further investigation: First, when studies are limited to just one group, the generalizability to all groups is low. Future studies would be better if they included a larger sample size of ALS patients with more ethnic minorities from diverse parts of the country.

Second, subject recruitment may pose a challenge due to the nature and course of ALS. Future studies may want to assess reasons for nonparticipation in order to develop alternative data collection approaches. For instance, telephone interviews or home visits may be an alternative method of ensuring greater participation in research studies from ALS patients.

Third, coping patterns of ALS patients tend to influence depression levels. Future investigations may benefit from obtaining a history of specific coping patterns in ALS patients across stages of the disease.

Fourth, the ALS patients’ perceived social support from caregivers, spouse, family, and friends may also impact depression levels. Future investigations may consider examining aspects of these relationships and their association with depression.

Fifth, depression is an important construct to examine in ALS patients as it influences cognitive and emotional coping responses. Future investigations could benefit from obtaining a detailed history of depression, which may prove to be useful for group comparison research. Additionally, using both subjective and objective
measures (e.g., clinical interviews, Structured Clinical Interview for DSM-IV Disorders) may reflect more precise levels of depression in ALS patients.

Lastly, there seems to be a gap in the literature regarding empirically supported treatments for depression in ALS patients. Future investigations examining the application of problem-solving therapy, a standardized treatment model, to address potential cognitive and coping skill deficits may prove to be an important approach for treating depression in ALS patients.
References


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Medical Research Council (1976). *Memorandum No. 45. Aids to the examination of the peripheral nervous system.* London: Her Majesty’s Stationery Office.


Dear ALS Clinic Patient:

You may be familiar with our studies of quality of life and have participated in them in the past. Based on our results to date, we are beginning a new study on quality of life in individuals with ALS. The current study is also being conducted at 8 other ALS centers across the country. We are writing to inform you about this study. If you choose to participate, it will require approximately 45-50 minutes of your time in the clinic, during which we will ask you a series of questions regarding your quality of life. No blood tests or other procedures are involved, and there is no additional cost to you.

Enclosed you will find a consent form. Please look at this, and bring it with you to clinic. If you choose to participate, we will explain the study in more detail, answer any questions which you may have, obtain your signature on the consent form, and conduct the interview.

Your participation is entirely voluntary. We would like you to consider participation in this study. If you have any questions about this research study, you may contact me at 717-531-1802, or you may contact the Research Coordinator, Beth Stephens, at 717-531-0003, ext. 283395.

Sincerely,

Zachary Simmons, MD
Professor and Vice-Chair of Neurology
Director, Neuromuscular Program & ALS Clinic

This research study has been approved by the Institutional Review Board, under federal regulations, at Penn State Milton S. Hershey Medical Center (IRB No: 21184EP)

Version Date: 6/20/2005
Title of Project: Measuring Quality of Life in Individuals with Amyotrophic Lateral Sclerosis and their Caregivers: Patient Consent Form

Principal Investigator: Zachary Simmons, MD

Other Investigators: Kevin Scott, MD, Helen E. Stephens, MA, Susan Walsh, RN, McKenzie Walker, Diana Brown, Andrea Weller

Participant's Printed Name: ________________________________

This is a research study. Research studies include only people who want to take part. This form gives you information about this research, which will be discussed with you. It may contain words or procedures that you don't understand. Please ask questions about anything that is unclear to you. Discuss it with your family and friends and take your time to make your decision.

1. Purpose of the Research:
You are being offered the opportunity to take part in this research because you are an individual who has been diagnosed with amyotrophic lateral sclerosis (ALS).

The purpose of this research is to better understand those factors which contribute to quality of life in individuals with ALS, and to use this information to develop a brief, accurate questionnaire for future use. This questionnaire will be specifically designed to evaluate quality of life in individuals with ALS.

This is a multi-center study that is occurring at 9 university-affiliated ALS clinics. Approximately 280 people will take part in this research nationwide and 40 people are expected to take part at the Hershey Medical Center.

2. Procedures to be Followed:
If you consent to this study, then at one of your ALS clinic appointments, you will be asked to complete a series of questionnaires or be interviewed about your physical limitations, emotions, coping abilities, values, interests, desires, goals, the support that you receive from others, and the role of religion in your life. These questionnaires will also include
questions on the importance of emotional intimacy (sharing deep, private thoughts; feeling connected), physical intimacy (for example, touching, hugging, kissing), and sexual intercourse on your quality of life, although you will not be asked for the names or relationships of others with whom you share such intimacy. You are free to skip any questions that you would prefer not to answer. If you become fatigued while completing the questionnaire, you may take short breaks.

The questionnaire will be administered by an advanced doctoral student in clinical psychology from the Philadelphia College of Osteopathic Medicine, the institution that is coordinating this multi-center study. This information will be collected only once, and will take 50 minutes of additional time beyond the usual time needed for your ALS clinic appointment. If there is information missing from the questionnaire, you may receive a phone call from one of the investigators to request complete information.

Information will be collected from your medical record about your neurological disorder.

3. **Discomforts and Risks:**

There is no physical discomfort, and there are no physical risks associated with this study. You may experience emotional discomfort and become upset due to thinking about how all these factors impact on your life with ALS. You may decline to respond to a particular question or a questionnaire, but you may be asked by an investigator why you chose not to respond.

You may experience fatigue. You may request breaks as needed. You may also stop your participation in answering the questionnaire at any time.

4. **Possible Benefits:**

a. **Possible benefits to the participant:**

Your doctors may develop a better understanding of those factors that affect your quality of life, and may be able to use this information to improve the quality of your existence. However, no benefit is guaranteed.

b. **Possible benefits to others:**

This study may lead to a better understanding of those factors which affect the quality of life in other patients with ALS, and may lead to the development of a questionnaire that accurately assesses this for other persons with this disease.

5. **Other Options that Could be Used Instead of this Research:**

You do not have to take part in this research study.

6. **Time Duration of the Procedures and Study:**
If you agree to take part in this study, your involvement will last approximately 50 minutes. You may receive a phone call to confirm answers when some of the information on the questionnaire is incomplete. The phone call will take a few minutes.

7. **Statement of Confidentiality:**
   a. Privacy and confidentiality measures

Your research records that are reviewed, stored, and analyzed at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) will be kept in a locked file in the office of Dr. Zachary Simmons in the Department of Neurology, or on a password-protected computer file accessible to Dr. Simmons and to Beth Stephens, the coordinator of the study.

For research records sent to the Philadelphia College of Osteopathic Medicine, you will not be identified by name, social security number, address or phone number. The records will include a code number. The list that matches your name with the code number will be kept in a locked file in Dr. Simmons' office or on a password-protected computer file accessible to Dr. Simmons.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. The use of private health information:

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the HMC Privacy Notice. If you have not received this notice, please request a copy from the researcher. At The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the research team to use your health information. If you do not want us to use your protected health information, you may not participate in this research.

Your permission for the use, retention, and sharing of your identifiable health information will expire upon completion of the research study. At that time the research information not already in your medical record will be destroyed. Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to Dr. Simmons and let him know that you are withdrawing from the research study. His mailing address is:

Zachary Simmons, MD,
Department of Neurology, H037
Penn State Milton S. Hershey Medical Center
500 University Drive
Hershey, PA 17033.

If you withdraw your permission:

• We will no longer use or share medical information about you for this research study, except when the law allows us to do so.
• We are unable to take back anything we have already done or any information we have already shared with your permission.
• We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
• We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

• Information from your medical records about your neurological disorder
• The information you provide during the questionnaire interview

Representatives of the following people/groups within HMC/PSU may use your health information and share it with other specific groups in connection with this research study.

• The principal investigator, Dr. Zachary Simmons
• The HMC/PSU Institutional Review Board
• The HMC/PSU Human Subjects Protection Office
• Members of the research team

The above people/groups may share your health information with the following people/groups outside HMC/PSU for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original PSU/HMC records.

• The Office of Human Research Protections in the U. S. Department of Health and Human Services
• Stephanie Felgoise, PhD, Philadelphia College of Osteopathic Medicine, a co-investigator of this study.
• The advanced doctoral students in clinical psychology at the Philadelphia College of Osteopathic Medicine who are data collectors for this study.

8. Costs for Participation:
You will not experience extra expense for participation in this study.

You are not waiving any legal rights you may have by signing this form.

9. Compensation for Participation:
You will not receive any compensation for being in this research study.
10. **Research Funding:**

This institution and the investigators are not receiving any funds to support this research study.

11. **Voluntary Participation:**

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include completing a questionnaire. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are entitled. Your medical care will not be affected.

12. **Contact Information for Questions or Concerns:**

You have the right to ask any questions you may have about this research. If you have questions or concerns or believe you have developed an injury that is related to this research, contact Dr. Simmons at 717-531-1802.

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or about your privacy and the use of your personal health information, contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about the Institutional Review Board (IRB), a group of people who review the research to protect your rights, please visit the HMC IRB’s Web site at http://www.hmc.psu.edu/irb. Included on this website, under the heading “Participant Info”, you can access information about the protection of human research participants. If you do not have access to the internet, copies of these regulations are available by calling the HSPO at (717) 531-5687.

**Signature and Consent/Permission to be in the Research**

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

**Participant:** By signing this consent form, you indicate that you are voluntarily choosing to take part in this
**Person Explaining the Research:** Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

Signature of person who explained this research  Date  Time  Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)
Dear ALS Clinic Patient:

You may be familiar with our studies of quality of life and have participated in them in the past. Based on our results to date, we are beginning a new study on quality of life in individuals with ALS. The current study is also being conducted at 8 other ALS centers across the country. We would greatly appreciate your cooperation in this study. If you choose to participate, it will require approximately 45-50 minutes of your time in the clinic, during which we will ask you a series of questions regarding your quality of life. No blood tests or other procedures are involved, and there is no additional cost to you.

Enclosed you will find a consent form. Please look at this, and bring it with you to clinic. If you choose to participate, we will explain the study in more detail, answer any questions that you may have, obtain your signature, and conduct the interview.

Again, participation is entirely voluntary. However, we believe that this is a very important study, and would greatly appreciate your participation.

Sincerely,

Leo McCluskey, MD Lauren Elman, MD Robert Kalb, MD

Enclosure
Title: Measuring Quality of Life in Individuals with Amyotrophic Lateral Sclerosis

Sponsor: Stephanie H. Felgoise, Ph.D., ABPP
Department of Psychology
Philadelphia College of Osteopathic Medicine
4170 City Avenue
Philadelphia, PA 19131
215-871-6543

Investigator: Leo McCluskey, MD
Department of Neurology
330 South 9th Street
Philadelphia, PA 19107
215-829-3053

PURPOSE

The purpose of this study is to understand what adds to quality of life in individuals with Amyotrophic Lateral Sclerosis (ALS), and to use this information to test a brief questionnaire designed to assess quality of life in individuals with ALS.

The doctors and scientists at Philadelphia College of Osteopathic Medicine (PCOM) do research on diseases and new treatments. The interview you are being asked to volunteer for is part of a research project.

Even though this research study is looking at specific aspects of ALS, such as physical limitations, emotions, coping abilities, values, interests, desires, goals, the support that you receive from others, and the role of religion in your life, no one can say that this will improve your usual treatment.

If you have any questions about this research, you can call Dr. Stephanie Felgoise at (215) 871-6543 or Dr. Leo McCluskey at 215-829-3053.
DESCRIPTION OF THE PROCEDURES

This consent form gives you information about the research study. This information will also be discussed with you. Once you learn about the study, you will be asked whether or not you would like to participate. If you would like to participate, you will be asked to sign this form. A copy of this signed form will then be given to you for your records. If your doctor has diagnosed you with dementia, cognitive problems, or if you do not agree to this informed consent, you cannot be in this study.

If you agree to participate in this study, then at one of your ALS clinic appointments, you will be asked to complete a series of questionnaires about your physical limitations, emotions, coping abilities, values, interests, desires, goals, the support that you receive from others, and the role of religion in your life. All questionnaires will be read to you in interview form. Also, please know that you may refuse to respond to a particular question or questionnaire at anytime.

During your participation in the study, you may get tired. If this occurs, you may request breaks as needed. You may also stop your participation in the study at anytime.

This information will be collected only once, and will take 45-50 minutes of additional time beyond the usual time needed for your ALS clinic appointment.

POTENTIAL BENEFITS

Your doctors may develop a better understanding of quality of life for persons with ALS. This study may lead to a future questionnaire that accurately measures quality of life for other persons with ALS. A questionnaire of this nature will help researchers’ and clinicians’ to develop medical and psychosocial interventions according to their patients’ needs and be able to monitor patient change.

You may not benefit from being in this study. However, other people in the future may benefit from what the researchers learn from the study.

RISKS AND DISCOMFORTS

There is no physical discomfort, and there are no physical risks associated with this study. However, you may experience emotional discomfort and become upset due to thinking about how life has changed with ALS.

There are no known risks or discomforts from being in the study.

ALTERNATIVES

Your other choice is to not be in this study and continue with your regular treatment by your doctor at the ALS clinic without prejudice.

Version 1, 2/7/06
PAYMENT

You will not receive any payment for being in this study.

CONFIDENTIALITY

All information and medical records relating to your participation will be kept in a locked file. Only the doctors, members of the Institutional Review Board, and the U.S. Food and Drug Administration will be able to look at these records. If the results of this study are published, no names or other identifying information will be used.

REASONS YOU MAY BE TAKEN OUT OF THE STUDY WITHOUT YOUR CONSENT

If health conditions occur that would make staying in the study possibly dangerous to you, or if other conditions occur that would damage you on your health, your doctor or his/her associates may take you out of this study. In addition, the entire study may be stopped if dangerous risks or side effects occur in other people.

NEW FINDINGS

If any new information develops that may affect your willingness to stay in this study, you will be told about it.

INJURY

If you are injured as a result of this research study, you will be provided with immediate necessary medical care.

However, you will not be reimbursed for medical care or receive other payment. Pennsylvania Hospital and the University of Pennsylvania Health System will not be responsible for any of your bills, including any routine medical care under this program or reimbursement for any side effects that may occur as a result of this program.

If you believe that you have suffered injury or illness in the course of this research, you should notify Joseph Sherwin, Ph.D., Director of Regulatory Affairs at the University of Pennsylvania at (215) 898-2614.

VOLUNTARY PARTICIPATION

You may refuse to be in this study. You voluntarily consent to be in this study with the understanding of the known possible effects or hazards that might occur while you are in the study. Not all the possible effects of the study are known. You may leave this study at any time. If you drop out of this study, there will be no penalty or loss of benefits to which you are entitled.
I have had adequate time to read this form and I understand its contents. I have been given a copy for my personal records.

I agree to be in this research study.

Signature of Subject: ________________________________

Printed Name of Subject: ________________________________

Date: _____/_____/______

Signature of Investigator or Designee: ________________________________

Printed Name of Investigator or Designee: ________________________________

Date: _____/_____/______
Dear ALS Clinic Patient:

Some of you are familiar with our studies of quality of life and have participated in them in the past (thank you to those of you who have participated). Based on our results to date, we are beginning a new study on quality of life in individuals with ALS. The current study is also being conducted at 8 other ALS centers across the country. We would greatly appreciate your cooperation in this study. If you choose to participate, it will require approximately 45-50 minutes of your time in the clinic, during which we will ask you a series of questions regarding your quality of life. No blood tests or other procedures are involved, and there is no additional cost to you.

Enclosed you will find a consent form. Please look at this, and bring it with you to clinic. If you choose to participate, we will explain the study in more detail, answer any questions which you may have, obtain your signature, and conduct the interview.

Again, participation is entirely voluntary. However, we believe that this is a very important study, and would greatly appreciate your participation.

Sincerely,

William S. David, MD, PhD
Medical Director
Hennepin Faculty Associates
ALSA Certified ALS Center

Enclosure
INFORMED CONSENT FORM

TITLE OF STUDY

Measuring Quality of Life in Individuals with Amyotrophic Lateral Sclerosis

INVESTIGATOR: William S. David, M.D., Ph.D.

SPONSOR OF STUDY: Philadelphia College of Osteopathic Medicine

PURPOSE

The purpose of this research is to better understand those factors which contribute to quality of life in individuals with amyotrophic lateral sclerosis (ALS), and to use this information to validate a brief, accurate questionnaire specifically designed to evaluate quality of life in individuals with ALS. This study will be conducted in nine ALS Clinics across the United States. Each site will enroll 30 participants.

You are being asked to participate in this clinical research study because of your current health condition. Clinical research is the study of human disease in an attempt to improve diagnosis and treatment. In order to decide whether or not you should agree to be part of this research study, you should understand enough about its risks and benefits to make a judgment. This process is informed consent.

This informed consent gives you information about the research study that will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. You will be given a copy of this signed form for your records. If your physician has diagnosed you with dementia, cognitive impairments, or if you do not agree to this informed consent, you cannot be in the study.

DESCRIPTION OF THE PROCEDURES

If you consent to this study, then at one of your ALS clinic appointments, you will be asked to complete a series of questionnaires, you will be interviewed about your physical limitations, emotions, coping abilities, values, interests, desires, goals, the support that you receive from others, and the role of religion in your life.
This information will be collected only once, and will take 45-50 minutes of additional time beyond the usual time needed for your ALS clinic appointment.

**POTENTIAL BENEFITS**

Your doctor may develop a better understanding of those factors that affect the quality of life for people with ALS. However, no direct benefit is guaranteed, and you may not benefit at all from participation in this study. This study may lead to further development of a questionnaire that accurately assesses quality of life for people with ALS. Other people in the future may benefit from what the researchers learn from this study.

**RISKS AND DISCOMFORTS**

There is no physical discomfort, and there are no physical risks associated with this study. You should understand that you may decline to respond to a particular question or questionnaire. You may experience emotional discomfort and become upset due to thinking about how all these factors impact on your life with ALS.

You may experience fatigue. You may request breaks as needed. You may also stop your participation in answering the questionnaire at any time.

**ALTERNATIVES**

The other choice is not to be in this study and to have the usual treatment by your physician at the ALS clinic without prejudice.

**PAYMENT**

You will not receive any payment for being in this study.

**CONFIDENTIALITY**

If you consent to participate in this study, you will be authorizing the use of your private health information for purposes of this study.

By signing this form, you authorize the HFA ALS Clinic and the investigators to use and disclose any information created or collected in the course of your participation in this research protocol.

This information may be given to other researchers in this study (including those at other institutions), representatives of the company sponsoring the study, or private, state, or federal government parties responsible for overseeing this...
research. These may include the Food and Drug Administration, the Office for Human Research Protection or other offices within the Department of Health and Human Services, and the Minneapolis Medical Research Foundation Office for Human Subject Protection.

This information will be given out for the proper monitoring of the study, checking the accuracy of the study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. This authorization lasts until the end of the study. You can, however, revoke it in writing.

You may stop this authorization at any time except if the HFA ALS Clinic needs the information already collected to ensure complete and accurate study results. This might mean the HFA ALS clinic may continue to use your information collected as part of this study even after you have told them to stop.

**REASONS YOU MAY BE TAKEN OUT OF THE STUDY WITHOUT YOUR CONSENT**

If health conditions occur that would make staying in the study possibly dangerous to you, or if other conditions occur that would damage you or your health, your doctor or his associates may take you out of the study. In addition, the sponsor may decide to stop the entire study.

**NEW FINDINGS**

If any new information develops that may affect your willingness to stay in this study, you will be told about it.

**INJURY**

If you are injured as a result of this study, you will be provided with immediate necessary medical care.

However, you will not be reimbursed for medical care or receive other payment. Medical services will be given at the usual charge. Your medical treatment will be billed to your third party payer/insurance or to you.

**YOUR RIGHTS IF YOU TAKE PART IN THE STUDY**
You do not have to take part in this study, but if you do, you can stop at any time. Your medical care at HFA ALS clinic will not be affected now or in the future whether or not you take part in this study. You do not give up any of your rights by taking part in this study. You will be told of any new findings or changes in study procedures that may affect you or your willingness to continue in the study. If the trial results are published, your identity will remain confidential.

WHO CAN ANSWER YOUR QUESTIONS?

You may talk to Dr. William David, M.D., Ph.D. at any time about any question you have on this study. You may contact Dr. David by calling 612-873-7521. You may also contact Pamela Droberg, R.N. in the ALS clinic at 612-347-5224.

You can get further information about your rights as a research subject by contacting the Human Subjects Research Committee at 612-347-8528.

I have had adequate time to read this form. I have read, and to the best of my knowledge understand, this form. I have been given a copy for my personal records. I agree to be in this research study and I authorize the use of the information that is collected for the purposes of this study. By signing this form, I am not giving up any of my legal rights.

Signature of Subject: _____________________________
Date: ___/___/___

Signature of Witness: _____________________________
Date: ___/___/___

Signature of Investigator or Designee _____________________________
(circle one)
Date: ___/___/___
ALS Quality of Life Demographic Sheet

Each of these questions relates to the person with ALS who is enrolled in the current quality of life study. Please complete each question by writing in the information requested or marking the single best answer:

Name: ________________________________

Study ID #: __________________________

Gender (choose one):
  ____ Male
  ____ Female

Age in years: ______________________

Education
  ____ No high school
  ____ Some high school
  ____ High school diploma
  ____ Some college
  ____ 2 year college degree
  ____ 4 year college degree
  ____ Graduate degree
  ____ Trade/Technical degree

Living Arrangements
  ____ Lives alone
  ____ With spouse (husband or wife)
  ____ With other relative
  ____ With friend or other person
  ____ Long term care facility

Marital Status
  ____ Never married
  ____ Currently married
  ____ Divorced
  ____ Separated
  ____ Widowed
**Household Income**

- Less than $20,000
- $20,000 - $39,999
- $40,000 - $59,999
- $60,000 - $79,999
- $80,000 or more
- Prefer not to answer

**Racial Background**

- White/Caucasian
- Hispanic/Latino
- Black/African American
- Oriental/Asian Pacific Islander
- Other
- Prefer not to answer

**Employment Status**

Currently working?

- Yes
- No

If yes

- Part time
- Full time

If no

- Retired
- Unemployed
- On disability
- Not working outside of the home prior to ALS

**Month/Date When You First Became Symptomatic**

______________________

**When were you first diagnosed with ALS (Month/Year)?**

_______________
Manual Muscle Testing

The following muscle groups are to be tested on both sides

- Arm (shoulder) abductors
- Wrist Extensors
- Hip Flexors
- Ankle Dorsiflexors

Grade the strength in each muscle group using the following scale designed by the Medical Research Council (MRC):

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No contraction</td>
</tr>
<tr>
<td>1</td>
<td>Flicker or trace of contraction</td>
</tr>
<tr>
<td>2</td>
<td>Active movement with gravity eliminated</td>
</tr>
<tr>
<td>3</td>
<td>Active movement against gravity</td>
</tr>
<tr>
<td>4</td>
<td>Active movement against gravity and resistance</td>
</tr>
<tr>
<td>5</td>
<td>Normal power</td>
</tr>
</tbody>
</table>

For grades 3, 4, and 5, these measurements may be modified as “+” and “−” (grade 5 can be modified only by “−”) if power is believed to be slightly greater or lesser than that described above. In such cases, the modifier changes the whole number by 1/3 of a grade for purposes of calculation:

- 5− is equivalent to 4.67
- 4+ is equivalent to 4.33
- 4− is equivalent to 3.67
- 3+ is equivalent to 3.33
- 3− is equivalent to 2.67

Measured muscle strength for each muscle group is to be recorded on the attached sheet, with the average of all 8 measurements then calculated to determine the composite MRC score.
Manual Muscle Testing Data Sheet

Subject Name: ________________________________

Study ID #: ____________________________

Date: ________________________________

<table>
<thead>
<tr>
<th>Muscle Group</th>
<th>MRC Rating: Right</th>
<th>MRC Rating: Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm (Shoulder) Abductors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrist Extensors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip Flexors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankle Dorsiflexors</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Composite MRC Score: ____________
ALS Functional Rating Scale – Revised

1. Speech
   4 Normal speech process
   3 Detectable speech disturbance
   2 Intelligible with repeating
   1 Speech combined with nonvocal communication
   0 Loss of useful speech

2. Salivation
   4 Normal
   3 Slight but definite excess of saliva in mouth; may have nighttime drooling
   2 Moderately excessive saliva; may have minimal drooling
   1 Marked excess of saliva with some drooling
   0 Marked drooling; requires constant tissue or handkerchief

3. Swallowing
   4 Normal eating habits
   3 Early eating problems—occasional choking
   2 Dietary consistency changes
   1 Needs supplemental tube feeding
   0 NPO (exclusively parenteral or enteral feeding)

4. Handwriting
   4 Normal
   3 Slow or sloppy; all words are legible
   2 Not all words are legible
   1 Able to grip pen but unable to write
   0 Unable to grip pen

5a. Cutting Food and Handling Utensils (patients without gastrostomy)
   4 Normal
   3 Somewhat slow and clumsy, but no help needed
   2 Can cut most foods, although clumsy and slow; some help needed
   1 Food must be cut by someone, but can still feed slowly
   0 Needs to be fed

5b. Cutting Food and Handling Utensils (alternate scale for patients with gastrostomy)
   4 Normal
   3 Clumsy but able to perform all manipulations independently
   2 Some help needed with closures and fasteners
   1 Provides minimal assistance to caregiver
   0 Unable to perform any aspects of task

6. Dressing and Hygiene
   4 Normal function
   3 Independent and complete self-care with effort or decreased efficiency
   2 Intermittent assistance or substitute methods
   1 Needs attendant for self care
   0 Total dependence
<table>
<thead>
<tr>
<th>ALS Functional Rating Scale – Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Page 2 -</td>
</tr>
</tbody>
</table>

**7. Turning in Bed and Adjusting Bed Clothes**
- 4 Normal
- 3 Somewhat clumsy, but no help needed
- 2 Can turn alone or adjust sheets, but with great difficulty
- 1 Can initiate, but not turn or adjust sheets alone
- 0 Helpless

**8. Walking**
- 4 Normal
- 3 Early ambulation difficulties
- 2 Walks with assistance
- 1 Nonambulatory functional movement
- 0 No purposeful leg movement

**9. Climbing Stairs**
- 4 Normal
- 3 Slow
- 2 Mild unsteadiness or fatigue
- 1 Needs assistance
- 0 Cannot do

**10. Dyspnea**
- 4 None
- 3 Occurs when walking
- 2 Occurs with one or more of the following: eating, bathing, dressing (ADL)
- 1 Occurs at rest, difficulty breathing when either sitting or lying
- 0 Significant difficulty, considering using mechanical respiratory support

**11. Orthopnea**
- 4 None
- 3 Some difficulty sleeping at night due to shortness of breath, does not routinely use more than two pillows
- 2 Needs extra pillows in order to sleep (more than two)
- 1 Can only sleep sitting up
- 0 Unable to sleep

**12. Respiratory Insufficiency**
- 4 None
- 3 Intermittent use of BiPAP
- 2 Continuous use of BiPAP during the night
- 1 Continuous use of BiPAP during the night and day
- 0 Invasive mechanical ventilation by intubation or tracheostomy

**Total Score**
Center for Epidemiologic Studies – Depressed Mood Scale (CES-D)

Using the scale provided, indicate the number which best describes how often you felt or behaved this way-DURING THE PAST WEEK.

DURING THE PAST WEEK:

<table>
<thead>
<tr>
<th></th>
<th>Rarely or none of the time (less than 1 day)</th>
<th>Some or a little of the time (1-2 days)</th>
<th>Occasionally or a moderate amount of time (3-4 days)</th>
<th>Most or all of the time (5-7 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I was bothered by things that usually don’t bother me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. I did not feel like eating; my appetite was poor.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. I felt that I could not shake off the blues even with help from my family and friends.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. I felt that I was just as good as other people.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. I had trouble keeping my mind on what I was doing.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. I felt depressed.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. I felt that everything I did was an effort.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. I felt hopeful about the future.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. I thought my life had been a failure.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. I felt fearful.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Rarely or none of the time (less than 1 day)</td>
<td>Some or a little of the time (1-2 days)</td>
<td>Occasionally or a moderate amount of time (3-4 days)</td>
<td>Most or all of the time (5-7 days)</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>11. My sleep was restless.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. I was happy.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. I talked less than usual.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. I felt lonely.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15. People were unfriendly.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16. I enjoyed life.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. I had crying spells.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18. I felt sad.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19. I felt that people dislike me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20. I could not get “going.”</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Example Questions from Instrument:

How Much Were You Distressed By:

0 = Not at all
1 = A little bit
2 = Moderately
3 = Quite a bit
4 = Extremely

Feeling no interest in things      0  1  2  3  4
Feeling lonely                  0  1  2  3  4

Example Questions from Instrument:

0 = Not at all true of me
1 = Slightly true of me
2 = Moderately true of me
3 = Very true of me
4 = Extremely true of me

I feel nervous and unsure of myself when I have an important decision to make
0 1 2 3 4

I spend more time avoiding my problems than solving them
0 1 2 3 4