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Examination of Cranial Electrotherapy Stimulation (CES) on Depressive and Anxiety Symptoms of Caregivers: A Double Blind Experimental Study

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EXAMINATION OF CRANIAL ELECTROTHERAPY STIMULATION (CES) ON DEPRESSIVE AND ANXIETY SYMPTOMS OF CAREGIVERS: A DOUBLE-BLIND EXPERIMENTAL STUDY

A

DISSERTATION

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St. Mary's University in Partial Fulfillment
Of the Requirements
For the Degree of

DOCTOR OF PHILOSOPHY
in
Counselor Education and Supervision

By
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San Antonio, Texas
November, 2020

EXAMINATION OF CRANIAL ELECTROTHERAPY STIMULATION (CES) ON DEPRESSIVE AND ANXIETY SYMPTOMS OF CAREGIVERS: A DOUBLE-BLIND EXPERIMENTAL STUDY

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Abstract

EXAMINATION OF CRANIAL ELECTROTHERAPY STIMULATION (CES) ON DEPRESSIVE AND ANXIETY SYMPTOMS OF CAREGIVERS: A DOUBLE-BLIND EXPERIMENTAL STUDY

Reginald Gerard Jefferson

St. Mary’s University, 2020

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The caregiver population has recently been recognized in society as a population highly susceptible to problems related to increased anxiety, burden, and abnormal psychological well-being. This experimental pretest post-test 2-group double-blind study was designed to measure the efficacy of cranial electrotherapy stimulation (CES) on anxiety and depressive symptoms of caregivers. Changes in anxiety and depressive symptoms were identified using pre- and posttest measures of State-Trait Anxiety Inventory and Beck Depression Inventory. Caregivers were assigned a pre-coded CES device. Neither the researcher nor the caregiver knew whether a device was active or sham until the completion of the entire study. This experimental design used a repeated measure t-test for quantitative statistics. Following an analysis of the data, the researcher’s hypotheses that CES would help reduce symptoms of anxiety and depression more significantly than a placebo were not supported. Both the treatment and control groups experienced decreased anxiety and depressive symptoms, but the treatment group’s decrease was not significantly greater than the control group’s decrease.

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Chapter 1

Introduction

Improvements in public health, medical advances, and the graying of the "baby boomer" generation have contributed to the aging of the U.S. population (Chyung, LePiane, Shamsy, & Radloff, 2018). Those aged 65 and older are expected to increase in population from 10.9 % to 15.7% from 2010 to 2050 (Colby & Ortman, 2017), an increase of 35 million people. Life expectancy of those aged 90 and older comprise 4.7 % of this older population, and this population is expected to quadruple over the next four decades (Colby & Ortman, 2017). In addition, more seniors are opting to remain in their homes longer rather than to live in skilled nursing facilities (Chyung et al., 2018). With these current trends, the need for caregivers will increase. However, current research has shown that caregivers have higher risks of adverse health and psychological effects because of their caregiving role (National Alliance for Caregiving [NAC], 2015). Additionally, few studies have investigated the effects of stress reduction interventions for caregivers. It was this researcher's purpose to investigate cranial electrotherapy stimulation (CES) as a stress-reducing intervention for caregivers.

Throughout the progression of providing care, caregiving transitions may lead to triggers for increased anxiety for caregivers (NAC, 2015). As caregivers assume their caregiving role, they sometimes must relinquish or modify prior responsibilities. Changes in family responsibility for caregivers can be stressful which could lead to dynamics in the family changing significantly (Lorig, Ritter, Laurent, & Yank, 2017; Schulz, & Czaja, 2018). Additionally, the transition to a nursing home, or employing home care, may be difficult. Caregiver compassion can lead to distress and increased anxiety if the caregiver feels they are unable to adequately provide care and relieve suffering of their loved one

(Brooks, Fielding, Beattie, Edwards, & Hines, 2018). This distress is especially true for end-stage caregiving as it carries the greatest burden for caregivers. High levels of stress are typically associated with decisions for palliative care, life-sustaining technology, or to withdraw care. All these issues lead to a problem with stress for caregivers. They need anxiety-reducing interventions to help them deal with stressors within their caregiving role.

Statement of the Problem

In numerous studies, multiple researchers have reported that caregivers have higher risk of adverse health, psychological, and financial effects because of increased anxiety in their caregiver role (Ashley, O’Connor, & Jones, 2011; Harris, Durkin, Allen, DeCoster, & Burgio, 2011; King, Ainsworth, Ronen, & Hartke, 2010; MacNeil et al., 2010; Martin et al., 2011; Pioli, 2010; Schulz, & Czaja, 2018; Turner et al., 2010). Researchers have conducted studies that introduce interventions to reduce anxiety and depressive symptoms for caregivers (Epstein-Lubow, McBee, Darling, Armey, & Miller, 2011; Lopez, Crespo, & Zarit, 2007; Lorig et al., 2017; O'Connell, Heslop, & Fennessey, 2010; Williams et al., 2010;). To reduce anxiety and depressive symptoms in caregivers, researchers in previous studies focused on two types of interventions: reduce caregiving time or provide information and develop coping skills (NAC, 2015).

To date, no other research study offers a potential intervention to reduce anxiety and depressive symptoms in the caregiver population outside of the aforementioned two types of interventions. Given the body of research over the past decade for interventions, limitations exist in prior studies. Reducing levels of stress for caregivers does not necessarily reduce anxiety and depression in caregivers (Brooks et al., 2018; Gottlieb & Johnson, 2010). Caregivers who provide intermittent care based on the progression of care commitment may still experience anxiety and depressive symptoms regarding their caregiving responsibility. In addition, interventions regarding increased knowledge and providing coping skills also fall short in reducing stress and depression (Brodaty, Green, & Koschera, 2003). These types of interventions have traditionally relied on professional seminars and forums to disseminate information. This requires time away from caregiving and competes with caregivers' already packed schedules. Due to low participation rates and high attrition, these types of interventions have historically not been very successful. Given the limitations of previous research for these types of interventions, it is imperative to examine alternative methods of anxiety and depressive symptom reduction for caregivers.

Purpose of the Study

This researcher sought to explore the effectiveness of cranial electrotherapy stimulation (CES) as an alternative treatment for caregivers to anxiety and depressive symptoms. A reduction in anxiety and depressive symptoms can lead to a reduction in caregiver burnout, the promotion of better family relations, and the experience of less stress and depression (Brodaty et al., 2003; Dickinson et al., 2017; Schulz, & Czaja, 2018). Success in assisting care recipients' sense of self-worth and increased motivation are also benefits in reducing stress and depression for caregivers.

Research Questions and Hypotheses

This study examined the following research questions:

RQ1: Did caregivers receiving active CES treatments experience a greater reduction of anxiety symptoms than caregivers receiving the CES sham treatment?

H_o1: Participants who received active CES treatments experienced a reduction of anxiety as evidenced by the reduction of STAI scores against subjects in the CES sham group.

RQ2: Did participants receiving active CES treatments experience a greater reduction of depressive symptoms as evidenced by the reduction of the Beck Depression Inventory (BDI) scores against subjects in the CES sham group?

H_o2: Participants who received active CES treatments experienced a reduction of depression as evidenced by the reduction of the BDI scores against subjects in the CES sham group.

RQ3: Is there a relationship between anxiety symptoms and depressive symptoms in caregivers?

H_o3: There is a relationship between STAI scores and BDI scores.

Rationale and Justification of the Study

Caregiving roles can be stressful and burdensome (Harris et al., 2011; Roth, Fredman, & Haley, 2015) and have all the features of chronic stress experiences. Over long periods of time, a caregiver role creates physical and psychological strain. Such a role also has high levels of uncontrollability, lacks predictability, and could create multiple stressors in work and family relationships. Caregiving requires high levels of mindfulness (Harris et al., 2011; Roth et al., 2015).

Medical advances including home care technology, shorter hospital stays, and limited discharge planning, have placed increased demands on caregivers (NAC, 2015). However, their duties and responsibilities may be stressors in their lives that may increase anxiety and depression. Duties include assisting with activities of daily living (ADL) including toiletry issues, bathing, dressing, and may provide help with mobility such as getting out of bed and walking. Some undertake medical duties like administering medication or changing dressings (NAC, 2015). Duties may also include assisting with instrumental activities of daily living (IADL) like supervising and monitoring the care-recipients, as well as taking them to their appointments. Other IADLs include shopping, cooking, and cleaning, along with assisting with financial matters and other paperwork. Caregivers often provide these responsibilities around the clock while juggling other personal responsibilities. This may cause high levels of anxiety in caregivers that could lead to increased anxiety, depression, and other physical or psychological ailments.

Anxiety is a reaction to long-term stress that has both psychological and physical features (McLeod, 2010). The brain works differently when it becomes anxious. Brain structures typically stay the same, but how the brain processes that information is different. Brain functioning occurs across many different parts, but with anxiety, the main part is the limbic striatal loop (McLeod, 2010). When this loop is in overdrive, feelings and emotions may seem overly important. Each part of this system plays an important role in anxiety, and it starts with the stress response (McLeod, 2010).

Stress is a bio-psychological response that we experience when encountering a threat that we perceive we do not have adequate resources to handle (McLeod, 2010). Stressor are the stimulus causing the stress, e.g., caregiving role and responsibility. First, the body decides if a situation is stressful. If so, the hypothalamus, the part of the brain responsible for stress response, activates and sends a signal to the adrenal medulla and the pituitary gland (McLeod, 2010). Once triggered, signals are sent to the pituitary gland and adrenal medulla. The fight-or-flight response sends a signal through the sympathomedullary pathway (SAM). However, the hypothalamic pituitary-adrenal system (HPA) processes long-term stress (McLeod, 2010).

When a stressor activates the HPA, the pituitary gland is stimulated by the hypothalamus and secretes adrenocorticotropic hormones (ACTH). These hormones produce cortisol, which enables the body to sustain the steady supply of blood sugar needed to cope with continued stressors (McLeod, 2010). During this process, the immune system is suppressed. Sustained levels of cortisol due to chronic stress can lead to unhealthy bone and muscle structure. High, sustained levels of cortisol may (a) slow normal cell regeneration and healing, (b) reduce the biochemical necessary to making vital hormones, (c) impair digestion and metabolism, (d) diminish mental functioning, (e) interfere with endocrine functions, and (f) weaken the immune system (McLeod, 2010).

Caregiver anxiety is the state of long-term chronic stress due to caregiving roles and responsibilities (McLeod, 2010). Some caregivers face years or decades of caregiving responsibility. Increased stress may persist if there is no hope that the care-recipient is getting better. Without support and adequate interventions, the stress of caregiving may leave caregivers to a wide range of physical, psychological, and emotional problems, ranging from heart disease and depression to death (Jain, 2014). Caregivers who provide care for dementia care recipients are 63% more likely to have an increased risk of death because related to their caregiving role than any other type of caregiver (Tremont, 2011).

Limitations

Research methodologies have limitations (Krathwohl, 2009). Researchers should be able to recognize and determine if the benefits outweigh the cost of the study (Krathwohl, 2009). The researcher identified the following limitations that may reduce efficacy of treatment and of identified solutions. A limitation is the possibility there will not be a true randomization process to the identified population. This study will recruit participants from the Houston area. Due to caregiving work schedules, there may be a lack of available caregivers willing to participate. Additionally, there may be constraints because CES may seem uncomfortable to some caregivers or they may not have interest in the study. Another limitation is that some participants may not complete the full 21-day protocol for using the CES device.

Definitions of Terms

The following definitions enhance the understanding of this study.

Anxiety symptoms. The uneasy feelings with apprehension from a real or perceived threat of imminent danger (McLeod, 2010). In this study, caregiver anxiety symptoms were measured using STAI scores.

Caregiver. The two types of caregivers are formal and informal. Formal caregivers are paid or volunteer and provide care through service systems that include non-profit or for-profit home care agencies, assisted living facilities, intermediate care facilities, nursing homes, community services, hospice organizations, churches, or charity service groups (NAC, 2015). Informal caregivers include family members, friends, and neighbors who provide unpaid caregiving services out of friendship, love, respect, or obligation, to disabled or chronically ill individuals (NAC, 2015). In this study, the term, “caregiver” were used to reflect both informal and formal caregivers over the age of 18.

Cranial electrotherapy stimulation (CES). Introduced to the United States of America over 50 years ago, CES is “any small electrical current that is passed across the head for therapeutic purposes” (Kirsch, 2002, p. 3). Other names found in the literature for CES are *electrosleep, transcranial electrical stimulation, or cerebral electrostimulation* (Kirsch, 2002). In this study, CES devices, known as Alpha-Stim, were used to administer the CES treatment.

Depressive symptoms. Feelings of intense sadness, including helplessness, and feeling hopeless or worthless (Beck, Steer, & Garbin, 1988). These feelings may last from many days or weeks to several months (Beck et al., 1988). They may also keep one from functioning normally. In this study, caregiver depressive symptoms were measured using Beck's Depression Inventory scores.

Chapter 2

Literature Review

Caregivers are a critical resource to national healthcare. However, the current body of research and clinical observation has shown that assuming a caregiving role can increase anxiety that may cause adverse health effects (Ashley et al., 2011; Harris et al., 2011; King et al., 2010; Lockenhoff, Duberstein, Friedman, & Costa, 2011; MacNeil et al., 2010; Martin et al., 2011; Pioli, 2010; Turner et al., 2010; Wooden, 2013). Physical and psychological strain occurs over time, with caregiving, accompanied by high levels of unpredictability and uncontrollability. Such strain can create secondary stress across work and family relationships (Schulz & Sherwood, 2008).

Formal Versus Informal Caregivers

There are two types of caregivers: informal and formal. Known as home care workers, home health aides, or personal care aides, formal caregivers are increasingly in demand as the older population increases (U.S. Bureau of Labor Statistics [BLS], 2016). Families of loved ones needing care are hiring formal caregivers to provide in-home care. Formal caregivers help those who are disabled, chronically ill, or cognitively impaired and need assistance (BLS, 2016). The employment rate of formal caregivers is expected to increase to 69% by 2020. The BLS (2016) reported that formal caregiver positions are growing faster than most occupations. However, this high demand does not translate into high wages for formal caregivers. In practice, formal caregiver occupations are among the lowest paid occupations in the nation (BLS, 2016). In some states, wages fall below the federal poverty line. Of the 2.5 million formal caregivers in the U.S., most are disproportionately female immigrants or women of color and on public assistance like food stamps or Medicaid (Colby & Ortman, 2017).

In contrast, informal care giving is unpaid and provided by a family member, friend, or neighbor out of love, respect, or obligation (Chyung et al., 2018)). This type of caregiver outnumbers formal caregivers. Estimates for total number of informal caregivers range from 20 to 50 million people. This number represents 20% of the population providing full or part-time care (NAC, 2015). Colby and Ortman, (2017) reported that the typical informal caregiver is a female in her mid-40s with a full-time job. This type of caregiver provides care for an average of 18 hours a week.

Among informal caregivers aged 20 to 75, 38% care for parents while 11% care for their spouse (BLS, 2016). Two-thirds of caregivers who care for people 50 years old or older and who work part-time or full-time reported rearranging their work schedule, decreasing hours, or taking unpaid leaves to meet caregiving responsibilities (NAC, 2015). A recent study estimated that informal caregivers have lost about $660,000 in wages over their lifetime due to work sacrifices (Chyung et al., 2018). The loss of productivity to businesses due to caregivers taking time off is between 11 and 29 billion dollars yearly. Informal caregivers' mean time to provide care is approximately 4.5 years; however, at least 20% are providing care five years or longer (NAC, 2015).

A progression of care commitment exists between informal and formal caregivers. That progression is through intermittent, part-time, and full-time care. As caregiving needs increase in intensity along with the number of hours required for care, the need for formal caregiving increases. This in part is due to their training – or lack of training – to address certain situations within their caregiving role. However, some informal caregivers are unwilling to stop providing care for their loved one or family member even when caregiving needs increase, and fail, or are unwilling, to realize they have reached the time for formal caregiving to begin. (NAC, 2015). Unfortunately, informal caregivers may recognize the need for formal care, but the money does not exist to pay for it (NAC, 2015). This type of overload can cause increased anxiety, depression, or physical ailments regardless of the level of commitment necessary when providing intermittent, part-time, or full-time care.

Informal caregivers providing intermittent care give occasional attention to patients who are still living in their home. These caregivers would typically live or work close by and would stop by for occasional visits. Although the care is intermittent, a level of daily stressors still exists because of the caregiving role.

Caregivers may provide part-time care if no extensive medical condition exists. In this type of care, the care-recipient and informal caregiver usually live together. The caregiver maintains a consistent work schedule while providing care. However, levels of anxiety and stressors can still affect the caregiver. Caregivers who provide full-time care often live with the care-recipient. Both informal and formal caregivers can provide this type of care. Due to the demands of this type of care, caregivers often suffer depression, social isolation, and other possible physical ailments (NAC, 2015). Usually during this point in the progression of commitment, the caregiver must decide whether to go completely with formal care or continue with informal care. These transitioning times are also stressors for caregivers (NAC, 2015). To fully understand the effects of the caregiving role on caregivers, one must have a basic understanding of the history of stress and anxiety research.

Pioneers of Stress and Anxiety Research

During the early twentieth century, Walter Cannon, a Harvard Medical School psychologist, and physiologist, first described the body’s reaction to stress (Cannon, 1932). While studying the physical reaction of lab animals when they are under stress, he noticed changes in their stomach function when the animals were frightened or scared (Cannon, 1932). Cannon continued to study physiological reactions to stress in the body and identified the stress reaction as the fight or flight response. This reaction is also known as acute stress response (Cannon, 1932). Cannon defined fight or flight response as the body preparing itself when facing a threat; it either stands ground and fights or runs away (Cannon, 1932).

The endocrinologist Selye (1975) first defined stress as the body's nonspecific response to demands made upon it. While observing changes in the body of lab rats exposed to stressors, stress reactivity was summarized as general adaptation syndrome, a three-phase process. Selye called the first phase the alarm reaction, explaining that in this phase the body begins to show changes that are characteristic of exposure to a stressor. Simultaneously, the body's resistance to handle the stressor diminishes. Stressors that are significantly strong, like extreme temperature, can ultimately cause death. Selye called the second phase the state of resistance. In this phase, the body adapts to the exposure of the stressor and resistance maintains. The bodily changes characteristic of exposure to the stressor have disappeared and levels of resistance rise above normal (Selye, 1975).

Selye (1975) described the third stage of stress reactivity exhaustion. In this phase, the body is no longer able to adjust or adapt to the long-term exposure of the stressor. As a result, signs of the alarm reaction reappear, but this time the signs are irreversible. Selye explained that stress can result from a good experience, like a promotion, or from a bad experience, like a loss of a loved one. Both are experienced physiologically, and we must learn how to adapt (Selye, 1975). Cannon (1932) and Selye (1975) are not the only researches to study this topic.

Other researchers have added to Selye and Cannon’s body of research to illuminate how the body handles stress. One such scientist was Simeons (1961), who was responsible for the link between stress and psychosomatic illness. Simeons (1961) theorized that stress is due to a lack of inner peace. The neurologist Harold Wolf (1953) contributed his understanding of the connection between the nervous system and diseases like ulcers, colitis, and hypertension. He was first to establish a separate category of illness he defined as psychosomatic. Cardiologists Friedman and Rosenman (1958) developed their theory while observing patients with heart conditions while in the waiting room of their office. Some of their patients were unable to sit for long periods of time but rather sat on the edge of their seats and leapt up frequently.

Friedman and Rosenman (1958) went on to label this behavior as Type A personality. People with Type A personality had a higher risk of heart disease and high blood pressure than other personality types (Friedman & Rosenman, 1958). Simonton, Matthews-Simonton, and Sparks (1980) developed a model for the emotional support of cancer patients. They introduced the concept that a positive state of mind could influence one’s ability to survive cancer. Cardiologists Benson and Klipper (1975) pioneered mind-body medicine when they introduced spirituality and healing into medicine. Psychiatrists Holmes and Rahe (1967) examined the medical records of patients to determine if stressful events caused illnesses and found 43 life events that were based on a relative score. A positive correlation was found between their patients’ life events and illnesses. Those results were published as the Holmes and Rahe Stress Scale (1967).

The link between stress and illness may explain why caregivers’ experience adverse health effects in their caregiving role, as caregivers certainly experience stress in carrying out their duties. Definitions differentiating stress and anxiety can be unclear at times. This lack of clarity is even found in the 2013 edition of the APA’s DSM-V. One such reason is that the DSM-V has approximately 13 different diagnoses categorized under anxiety disorder. In addition, there is overlap of symptoms between each diagnosis. Another reason is that the two words are often interchangeable in the DSM-V. McLeod (2010) found that symptoms of stress include headache, chest pain, increased blood pressure, muscle aches, and shortness of breath, to name a few. The DSM-V lists symptoms of stress for a panic attack as “palpitations, heart pounding, sweating, trembling, shortness of breath, choking feeling, chest pain” (p. 432). Although the symptoms are similar, they require different diagnoses. Stress is typically short-term and resolved when the causing stressor is removed. In contrast, anxiety symptoms are usually long-term and remain after the causing stressor is removed. Stress is the body’s physical response to events and circumstances, whereas anxiety is the uneasy feeling regarding apprehension from threat or imminent danger (Mayer, 2011). Mayer’s definition would further imply that stress can lead to anxiety.

Caregiving touches almost every family in different ways. It is, therefore, important to have interventions that reduce anxiety and depression in caregivers. To find possible interventions, it would be helpful also to understand the physiological aspects. To further understand how the body processes anxiety, one must first understand neurotransmitters – the brain elements that comprise the brain messaging system.

Neurotransmitters

Neurotransmitters are chemicals in the brain that convey information throughout the brain and body and signal nerve cells to tell the heart to beat, the lungs to breathe, and the stomach to digest, as well as other body functions (Neurogistics, 2014). Neurotransmitters also affect the body’s mood, sleep function, concentration, and weight.

Neurotransmitters can cause unfavorable symptoms when out of balance (Neurogistics, 2014). In addition, stress can cause neurotransmitter levels to be out of their most efficient range. The neurotransmitters responsible as stress indicators are: Epinephrine, Norepinephrine, Dopamine, Serotonin, GABA, Glutamate, and PEA (Neurogistics, 2014).

Researchers place neurotransmitters into two categories: inhibitory and excitatory. Inhibitory neurotransmitters-serotonin, GABA, and dopamine-help calm the brain by preventing excitatory neurotransmitters from over stimulating the brain (Neurogistics, 2014). Excitatory neurotransmitters—dopamine, norepinephrine, epinephrine, and glutamate—stimulate the brain and are responsible for many stimulatory processes in the body (Neurogistics, 2014). When any of these neurotransmitters fall above or below optimal levels, adverse health symptoms can occur (Neurogistics, 2014). Table 1 shows clinical correlations of specific neurotransmitters to indications of stress and anxiety when the neurotransmitters are not at optimal levels.

Chronic stress and anxiety increase the level of excitatory neurotransmitters in the body. In response, the brain increases inhibitory neurotransmitters levels to bring balance to neurotransmitters levels. When stress and anxiety persist, increased levels of inhibitory neurotransmitter response may be inadequate to regain balance (Neurogistics, 2014). In such cases, additional neurotransmitter support through diet or dietary supplements may be indicated. If the balance is not restored, risks for complicating health issues and immune challenges are increased (Neurogistics, 2014).

Table 1

Neurotransmitter Clinical Correlations for Specific Disease State

Neurotransmitter	High Levels	Low Levels
Epinephrine (adrenaline)	Anxiousness, focus and concentration issues, sleep difficulties	Focus and concentration issues, fatigue, low libido, weight issues
Norepinephrine	Anxiousness, focus and concentration issues, low mood, pain, sleep difficulties, weight issues	Focus and concentration, low mood, fatigue, low libido, memory issues, weight issues
Dopamine	Focus and concentration issues, sleep difficulties	Urges, impulsivity, cravings, anxiousness, focus and concentration issues, low mood, fatigue, low libido, memory issues
Serotonin	Intestinal complaints, low libido	Anxiousness, low mood, intestinal complaints, low libido, pain, sleep difficulties, weight issues
GABA	Excessive energy, anxiousness, sleep difficulties	Anxiousness, sleep difficulties,
Glutamate	Urges, cravings, focus and concentration issues, low mood, intestinal complaints, pain, sleep difficulties, weight issues	Fatigue, focus and concentration
PEA	Sleep difficulties, mind racing, anxiousness	Focus and concentration issues, fatigue, memory issues, weight issues, difficulty thinking clearly

Neurogistics (2014).

Prevalence of Caregiving in the United States

The National Alliance for Caregiving (2015) in collaboration with the American Association of Retired Persons (AARP) conducted a study to present a portrait of caregivers in the United States. The three-part study series examined caregiving trends. The first phase of the study took place in 2004 and had a core focus on care-recipients. The second and third phases of the study took place in 2009 and 2015. The later phases focused more on caregivers and their caregiving role. For purposes of this study, the researcher will only use findings from the 2009 and 2015 phases because the findings of those phases align more with the research goals of this study.

Under the direction of Naiditch and Weber-Raley (2009), the core research areas examined in the 2009 and 2015 were demographic characteristics of caregivers; caregiving situation regarding responsibilities, intensity, and duration of care; and the effect of the caregiver role on their personal life and health. Quantitative interviews were conducted nationwide with 1,480 (N = 1,480) caregivers in 2009 and 1,248 (N = 1,248) caregivers in 2015. Naiditch and Weber-Raley (2009) explained that comparisons should not be drawn between the 2009 and 2015 findings. Although the 2015 study builds itself from prior research phases, it was conducted during a technological shift requiring online data collection. Prior research phases conducted data collection utilizing landline telephones only. The researchers concluded that the 2009 and 2015 findings should be viewed as isolated studies showing the prevalence of caregiving in the United States without drawing comparisons. Table 2 shows the key findings in the 2009 and 2015 phases, respectively.

Table 2

Key Demographic Findings

	2009 Study	2015 Study
Gender		
Male	34%	40%
Female	66%	60%
Age		
18 to 34	22%	23%
35 to 49	29%	23%
50 to 64	35%	34%
65 to 74	9%	12%
75 or older	4%	7%
Race / Ethnicity		
White	72%	62%
African-American	13%	13%
Hispanic	12%	17%
Asian-American	2%	6%
Other	1%	2%
Marital Status		
Married	58%	57%
Living with partner	5%	8%
Single, never married	16%	19%
Separated, divorced	14%	9%
Widowed	7%	7%
Caregiver Household Income		
Less than $49,999	42%	47%
$50,000 to $99,999	61%	30%
$100,000 or more	19%	23%
Employment Status		
Employed providing care	57%	60%
Not employed providing care	43%	40%
Duration of care provided		
Less than 6 months	16%	31%
6 months to 1 year	18%	19%
1 to 4 years	33%	27%
5 to 9 years	13%	13%
10 years or more	20%	10%

(National Alliance for Caregiving, 2015)

Caregiver Roles Across Different Care Recipient Diagnoses

Caregiving experiences vary with the type of illness, disorder, or disability of the caregiving recipient. However, caregiving research over the past decade does not cover all possible caregiving experiences. The NAC (2015) identified three distinct illness categories for people with progressive chronic illness: “gradual decline, steady progression followed by a relatively clear short-lived terminal phase, and gradual decline punctuated by brief episodes of accelerated decline followed by some recovery” (NAC, 2015, p. 4). These three categories are illness trajectories described for people with chronic illness. Common chronic illnesses are Alzheimer, cerebrovascular accident, cancer, congestive heart failure, and HIV/AIDS. Each of these illnesses impact the characteristics of the care given by a caregiver.

Prolonged Gradual Decline

Alzheimer’s Disease and Related Disorders. Most research studies focus on caregivers for Alzheimer’s disease or related disorders (ADRD). Of the four million Americans living with ADRD, three million live at home (NAC, 2015). Alzheimer’s cases are expected to reach 13.2 million by the year 2050. Caregiving for dementia is the most difficult and time-consuming of all the types of caregiving. Twenty-four percent of caregivers of dementia patients work upwards of 40 hours per week versus 16% of nondementia caregivers (NAC, 2015).

Caregivers of dementia patients are under more stress, and spend less time socializing with family and friends, than any other caregiver. This is largely due to the “cognitive impairment, neuropsychiatric abnormalities, dysphoria, disinhibition, delusions, and problematic behavior” that is typical with the disease (NAC, 2015, p. 8). It was also found that caregivers of dementia patients have worse emotional and physical health than caregivers for other illnesses (NAC, 2015).

Cerebrovascular Accident (CVA) or Stroke. In the United States, nearly 700,000 people suffer from strokes each year with 25% dying each year (American Heart

Association, 2018). Survivors are usually dependent on long-term care. In fact, the NAC (2015) reported stroke as the leading cause for long-term disability. The sudden unexpected nature of strokes rarely leaves much time for preparing for caregiving roles. Due to this sudden onset, caregivers often feel a lack of support from others. High caregiving demands for this type of patient, mixed with caregivers feeling a lack of support, can negatively impact their mental and physical health (Low, Payne, & Roderick, 1999).

Steady Progression Followed by a Short-Lived Terminal Phase: Cancer

Cancer is the second leading cause of death in the United States (NAC, 2015). Although cancer treatment has advanced, the five-year survival rate for all cancers is only 65% (Edwards et al., 2014). As with caregivers of patients with chronic disabilities, cancer caregivers are at risk for psychological morbidity. Researchers found the rates of depression of cancer caregivers increase from 20% when newly diagnosed to 50% when the patient is terminally ill (Sherwood et al., 2008; Tomarken et al., 2008).

Cancer caregiving varies depending on the stage of illness. These stages include diagnosis, treatment, remission, or palliative care. Caregivers typically try to obtain information about the disease after diagnosis but are usually ignored by health care providers (Rees & Bath, 2010). In the treatment phase, caregivers focus less on their own needs and more on the needs of the patient for support. They also attempt to obtain information on treatment procedures, side effects, and prognosis (Luker, Beaver, Leinster, & Owens, 1996). During remission, caregiver stress decreases (Northouse, Mood, Templin, Mellon, & George, 2010). However, a recurrence of the illness causes continual caregivers’ psychological distress and social adjustments. During this time, the palliative phase demands more extensive personal care causing caregivers depression and burdens to increase while their quality of life decreases (Grunfeld et al., 2011).

Pain is a major concern in cancer patients (McGuire, 2009). Although there have been advances in treatment, 70% of patients with a terminal illness experience pain (McGuire, 2009). Pain is viewed as a precursor to physical deterioration. Because of this pain, caregivers report working with cancer patients as the most stressful human experience (Powe & Finnie, 2003). This type of caregiver has higher levels of depression and mood disturbances than those caregivers with pain-free patients (Hasson-Ohayon, Goldzweig, Braun, & Gallinsky, 2010). In addition, caregivers deal with fears of patient medication addiction and side effects (Hasson-Ohayon et al., 2010).

Gradual Decline With Brief Episodes of Accelerated Decline and Some Recovery

Congestive Heart Failure (CHF). Patients with severe CHF have the worse quality of life of all chronic diseases; however, two-thirds of CHF hospitalizations are preventable (Juenger et al., 2002). The researchers stated that patients do not follow medical advice or do not seek help when symptoms occur. Strong relationships between caregivers and patients decreases the number of readmissions (Juenger et al., 2002). Empowering caregivers and allowing them to take part in discharge planning makes them more accepting of the caregiving roles (Bull, Hansen, & Gross, 2000).

HIV/AIDS. The introduction of better medication has transformed acquired immune deficiency syndrome (AIDS) from a rapid progressive illness to a chronic illness (Welch & Morse, 2012). This improved survival rate results in a greater need for more informal caregivers and palliative care. Patient and caregiver deal with comorbid diseases like chronic obstructive pulmonary disease, diabetes, hypertension, and congestive heart failure (Welch & Morse, 2012). Additionally, homophily explains the aspects of caring for a person living with HIV/AIDS (PLHA). This principle states that contact among similar people occurs more often than between dissimilar people (McPherson, Smith-Lovin, & Cook, 2001). Seventy-five percent of HIV/AIDS patients are men. As a result, over half of PLHA caregivers are men when compared to caregivers of other illnesses (Centers for Disease Control and Prevention [CDC], 2016; NAC, 2015).

HIV is more common with ethnic minorities, IV drug users, and the poor (CDC, 2016; Karon, Fleming, Stekette, & DeCook, 2010). The CDC (2016) reported that 70% of newly diagnosed cases are nonwhite. Because of the limited resources for receiving formal care services available to nonwhites, ethnic minority caregivers provide the most intensive AIDS care (Turner, Catania, & Gagnon, 2013). Twenty percent of cases are IV drug users (CDC, 2016). It is typical for drug abusers to deplete their own resources and be supportive of other's emotional and financial resources. As a result, drug abusers are more likely to rely on friends rather than family for caregiving (NAC, 2015). Burden for this type of caregiver is increased because the caregiver often does not have legal rights or benefits (NAC, 2015).

The CDC (2016) reported that AIDS is prevalent in youth and a leading cause of death among 25 to 44-year olds. As a result, parents or those acting as surrogates for minor children typically are the caregivers. However, since HIV/AIDS is unfortunately a highly stigmatizing disease, caregivers may perceive stigma as guilt by association. They may find themselves unwilling to disclose the patient's diagnosis or the prevalence of disease to avoid unwanted social reactions. In addition, they may feel socially distant from family and friends when support is needed. They may even delay their own medical needs for fear of stigmatization (Stetz & Brown, 2004).

Other Illnesses

Additional caregiving roles of care recipients not included in the body of literature would include those with a severe mental health diagnosis including Autism Spectrum Disorder. As with AIDs, caregivers providing for this type of care recipient are typically informal caregivers due to the stigma placed on those with mental health issues (Saunders, 2013). Sometimes even the caregiver themselves feel marginalized and the stigma placed on them. Often, they too feel inadequate or unprepared to handle the episodic stressors that come with their caregiving role (Saunders, 2013).

Regardless of the illness cared for, caregiver outcomes have individual differences. The stress process model explains these differences as that model has identified risk and protective factors (Pioli, 2010). The components of the stress process model are primary stressors, secondary stressors, and appraisal (Pioli, 2010).

Caregiver Stressors That May Lead to Increased Anxiety

Primary stressors include those stressors that directly impact the caregivers' physical well-being. Stressors include the severity of patient illness and the required physical task necessary to render the specific care. Caregivers typically help patients with activities of daily living (ADL) (BLS, 2016). These include bathing, dressing, grooming, eating, toileting, and transferring patients from bed or chair. In some cases, they additionally provide instrumental activities of daily living (IADL) like food shopping, meal preparation, housework, and transportation (BLS, 2016). The BLS (2016) also stated that 15% of all caregivers administer medications and change dressings.

Patient suffering also impacts caregiver well-being (Papastavrou et al., 2011). Researchers found that caregiver perception of patient suffering contributes to caregiver depression more than patient's severity of illness, behavior, or time in care. Furthermore, changes in patient suffering were associated with caregiver's depression and burdens (Papastavrou et al., 2011). Compassion derives from a sense of shared suffering coupled with the caregiver's desire to help alleviate it. Compassion can cause distress if the caregiver feels an inability to relieve the patient's suffering (Papastavrou et al., 2011).

Primary stressors typically overlap into a second set of stressors that include feelings of being underappreciated, social, and financial pressures, and transitions. The BLS (2016) reported that 62% of caregivers are married or have a live-in partner, 59% have additional jobs, and 37% are parents who are raising children. These demands often conflict with providing care for patients because of conflicting roles and challenging demands. In addition, researchers found that caregivers report they have no time to socialize and incur substantial financial responsibility. Preoccupation with financial obligations may cause caregivers to be less attentive to patient care (Jardim & Pakenham, 2009).

Caregiving transitions are also stressors for caregivers (Jardim & Pakenham, 2009). For example, as the dynamics of care changes so does caregiving responsibilities. With changing responsibilities, caregivers relinquish or modify their roles that can often lead to greater challenges for other family members and friends (Jardim & Pakenham, 2009). Caregivers of dementia patients are at risk for depression following their patient's nursing home placement, as the caregiving role does not end (MacNeil et al., 2010). Caregivers continue to visit the patient and may provide physical care during those visits. Poor communication and negative interactions with nursing home staff can have an impact on caregivers' well-being (MacNeil et al., 2010). Additionally, end-stage caregiving often thrusts caregivers into their greatest burden. The NAC (2015) reported that caregivers at this stage spend from 100 to 125 hours a week providing care for hospice patients. Furthermore, they typically handle decisions dealing with life-sustaining technology.

In addition to primary and secondary stressors, appraisals impact caregiving outcomes. Appraisals are how caregivers handle or react to stressors. It plays a greater role in their well-being than primary or secondary stressors (Haley et al., 2011). As they perform their caregiving, caregivers are constantly appraising the impact and demand on themselves and judging whether their resources are adequate to cope with that impact. Emotional and behavioral responses are created that can contribute to health outcomes (Haley et al., 2011). Additionally, the ethnicity of the caregiver can affect those health outcomes.

Ethnic differences exist in appraisals. Researchers found that African American caregivers report more positive caregiving and less stress than other ethnicities (Chyung et al., 2018). Because they were not found in noncaregivers, they also found that appraisal differences due to ethnicities are specific to caregivers. Factors such as motivation for providing care, coping strategies to deal with caregiving experiences, and greater availability for support all play a part in these differences (Chyung et al., 2018). Researchers also found ethnic differences in attitudes toward caregiving that affected appraisals (Pinquart & Sorensen, 2005). Western cultures value individualism, whereas non-western cultures value collectivism such as familism (Pinquart & Sorensen, 2005). Compared to White caregivers, African American and Hispanic caregivers generally report a stronger caregiving ethic and cultural reasons for caregiving (Pinquart & Sorensen, 2005).

Although a greater network of support implies greater availability of resources, researchers found that kinship networks among Hispanic caregivers can cause greater distress (Pinquart & Sorensen, 2005). Latino caregivers report less support is available to them than White caregivers because they are less willing to ask for advice or discuss their feelings with their support network (Pinquart & Sorensen, 2005). These kinship networks could be a barrier to seeking formal caregiving if the family keeps problems, they consider to be potentially embarrassing to the family, to themselves.

Although differences in caregiving outcomes depend on the interaction between caregiver and recipient, studies show caring for individuals with an illness contributes to psychiatric and physical morbidity. Pinquart and Sorensen (2005) found that caregivers experience more stress, depression, and lower well-being than non-caregivers. Additionally, differences were significant for spousal caregivers and women. Researchers found spousal caregivers to have worse outcomes because they provide higher intensity hands-on care. Additionally, women are at higher risk because they are more conscious of their emotions, tend to be more sympathetic, and are willing to report negative feelings (Baider & Bengel, 2010).

Providing care for others may influence physical health (Pinquart & Sorensen, 2005). Caregivers may ignore self-care needs and not engage in preventative health behaviors (Schulz & Sherwood, 2008). Additionally, researchers found that caregiver chronic stress may compromise immunity to disease, cardiovascular reactivity, wound healing (Schulz & Sherwood, 2008). Schulz and Sherwood (2008) found there to be a 63% higher mortality risk in caregivers than non-caregivers.

Depression Among Caregivers

Multiple studies recognized that caregiver burden was detrimental to caregiver mental health and caused depression rates between 20% and 80%, compared to 13% for the general population, (Cameron et al., 2016; Geng et al., 2018). Depression rates were a function of severity of physical and psychological impairment of patient, duration of care, and degree of lifestyle changes (Cameron et al., 2016; Pinquart & Sorensen, 2005). Depressive symptoms extend beyond well beyond the period of caregiving (Cameron et al., 2016). Research indicated that 41% of former caregivers of a spouse dementia experienced mild to severe depression three years after termination of caregiving responsibility (Denno et al., 2013). A longitudinal study of 280 caregivers found that one year after completed caregiving for stroke victims the caregiver depression rate remained three times greater than the general population (Cameron et al., 2016). Actual caregiver depression rates are moderated by several factors (Pinquart & Sorensen, 2005). Subjective well-being, physical health quality and quantity of non-caregiver social roles, social roles, socioeconomic status, quality of social relations, health promoting habits, personality, and genetic factors moderate caregiver burden and depression.

Some caregivers with symptoms of depression do not recognize the symptoms in themselves, while others have difficulty admitting they feel depressed (Geng et al., 2018). Lingering stigma regarding mental illness can make depressive thoughts and feelings difficult to express for fear of judgment from others (Geng et al., 2018). Depression is a normal pervasive response to caregiver burden. Caring burden is a broad term covering ministering to the ill and may be compounded by: (a) illness-related behavioral problems, disorientation, and shifts in personality; (b) increased need for supervision and loss of spare time; (c) isolation from friends and family: (d) patients inability to appreciate the sacrifice involved in caregiving; and I progressive deterioration of the care receiver, which reduces the potential for positive outcomes from caregiving sacrifices (Denno et al., 2013).

Researchers research indicated that depression rates for cancer caregivers increase from 20% for newly diagnosed and expand to 50% for terminally ill patients (Sherwood et al., 2008). Cancer patient caregivers significantly influence the patient’s disease management and palliation, which may adversely affect their mental and physical health in the longer run (Geng et al., 2018). Increasing caregiver stress during prolonged caregiving produced measurable changes in neurohormonal and inflammatory processes that quadruple the risk of depression and may increase morbidity and mortality among caregivers (Geng et al., 2018).

Prolonged patient suffering erodes caregiver resiliency and empathy manifests in feelings of despair (Papastavrou et al., 2011). Researchers found that caregiver perception of patient suffering contributes to caregiver depression more than patient’s severity of illness, behavior, or time in care (Sherwood et al., 2008). Normal deterioration in patient health and increases in suffering were associated with caregiver’s depression. Compassion derives from a sense of shared suffering coupled with the caregiver’s desire to help alleviate it, which may cause feelings of helplessness from the inability to relieve patient suffering (Papastavrou et al., 2011).

Caregiving transitions produce incremental stressors from logistical, financial, and emotional sources (Jardim & Pakenham, 2009). As the caregiving setting evolves, so do caregiving challenges. Caregivers may relinquish or modify their roles in a manner which causes the need to manage other caregivers in the family or professionally. For example, movement of a patient into a nursing home evokes feelings of bereavement for the loss of a family member’s capability, and because it is the beginning of a new set of responsibilities and challenges (MacNeil et al., 2010). Caregivers nursing home visits with the patient and may involve physical care, interaction with staff, searches for alternative therapies or the need for final arrangements. Poor communication and negative interactions with nursing home staff and family members adversely affect caregivers (MacNeil et al., 2010). End-stage caregiving often thrusts caregivers into their greatest burden with caregivers spending from 100 to 125 hours a week providing hospice care.

Differences in caregiving outcomes often depend on factors well beyond caregiver’s capacity and evokes a sense of failure, which contributes to depression and a variety of psychiatric and physical maladies (Geng et al., 2018). Research indicated that caregivers experience significantly more stress, depression, and lower well-being than family-related non-caregivers. Women were significantly more likely to experience depression than their male peers. Women are at higher risk because they are more conscious of their emotions, tend to be more sympathetic, and are willing to report negative feelings (Baider & Bengel, 2010). Also, at high risk for poor health outcomes were spousal caregivers because they provide higher intensity hands-on care.

Past Caregiving Interventions by Category

Considering the impact of caregiving, researchers have conducted few studies on interventions for caregivers. A review of literature within the past decade reveals four studies on caregivers of those diagnosed with dementia or Alzheimer’s. Furthermore, the research shows past caregiving interventions fall into two categories: (a) reducing amount of caregiving and (b) providing information and improving coping skills. All four studies fall within the category of providing information and improving coping skills.

Reducing Amount of Caregiving

Respite care is temporary substitute relief for caregivers. There are two basic types of respite care. Centered-based programs are a type of respite care that provide day or night care for a certain number of hours. In contrast, institutional respite care provides care when caregivers need multiple days of relief for holidays, sickness, or when caregiving responsibilities interfere with personal demands (Gottlieb & Johnson, 2010). The National Alliance for Caregiving (2015) reported that to date no clear evidence supports the conclusion that respite care reduces the burden on caregivers or improves their mental health. One probable cause of this conclusion is that caregivers typically use respite care as a last resort when responsibilities become overwhelming (Gottlieb & Johnson, 2010). Additionally, caregivers may see respite as unacceptable because they do not want to leave the patient (Gottlieb & Johnson, 2010).

Providing Information and Improving Coping Skills

Support groups build understanding between participants surrounding topics, so they feel comfortable discussing their problems, successes, or feelings about caregiving. They are vehicles to disseminate information, psychosocial support, or education. However, Brodaty et al. (2003) found that increased caregiving knowledge is not related to social or psychological outcomes. Psychoeducational programs information and resources to caregivers regarding the disease process and train them on how to provide adequate services.

Additionally, some psychoeducational interventions include some form of psychotherapy. The major disadvantage of this type of intervention is its intensive professionally-led nature. Self-reliance and independence are important values to caregivers (McMillan et al., 2006). Therefore, many of these intervention programs have low participation rates and high attrition rates (McMillan et al., 2006).

Lopez et al. (2007) examined a stress management program for informal caregivers. Participant requirements were (a) age 18 and older, caring for a dependent individual over the age of 60 who scored a 1 on the Katz Index of Activities of Daily Living which measures level of disability, (b) lived at same residence as patient, (c) was solely responsible for providing care, and (d) had provided care for patient for at least six months. Additionally, participants must not have received any other treatment and have shown some evidence of emotional distress as measured by Beck Depression Inventory (BDI) or the Hospital Anxiety and Depression Scale. One hundred twenty-three caregivers were assessed. Of that number, 14 (11%) did not meet requirements and 18 (15%) declined to participate. Ninety-one (*N* = 91) caregivers were used for the sample.

A multigroup experimental design was used with repeated measures (Lopez et al., 2007). Participants were randomly grouped into one of three groups: (a) a group that received the program through a traditional format, (b) a group that received the program with minimal therapist contact, and (c) a control group that was placed on a waiting list (Lopez et al., 2007). Likewise, professionals were randomly selected to facilitate each treatment. Treatment lasted two months for all groups.

The traditional group received eight 60-minute weekly sessions. Participants were in direct contact with a therapist. They received written exercises and homework between sessions. In contrast, the minimal therapist contact group received three 90-minute sessions at four-week intervals. Between sessions, caregivers were directed to review strategies learned and to go over new ones. The waiting list group did not receive any type of treatment or help. Participants were administered both pre- and posttreatment with the Katz Index of Activities of Daily Living, Hospital Anxiety and Depression Assessment, BDI, Zarit Burden Interview, and the Maladaption Scale (Lopez et al., 2007). Data analysis showed caregivers in the traditional group experienced the greatest reduction in anxiety and depression compared with caregivers in the minimal therapist contact group (Lopez et al., 2007).

Limitations to the Lopez et al. (2007) study included the absence of a blind interview for performing assessments. There might have been possible bias since the interviewer knew the participant's experimental assignment. Another limitation was that there was only one measure posttreatment. Therefore, it is unclear if treatment effects were short-term or continued.

Williams et al. (2010) analyzed a video-based coping skills (VCS) training program for Alzheimer's disease and related dementia (ADRD) patients. Their objective was to decide if VCS with telephone coaching would reduce psychosocial and biological distress in caregivers (Williams et al., 2010). One hundred sixteen (*N* = 116) ADRD caregivers were recruited over a two-year interval through advertisements, support groups, and referrals from an Alzheimer's disease research center in North Carolina (Williams et al., 2010). Participants were screened for medical problems and those who were non-caregivers. Then they were randomly placed into two groups: a VCS training group or a waiting list control group.

On day one, participants in the VCS group were given study materials and informed of the telephone coaching they would be receiving (Williams et al., 2010). Psychological and biological distress markers were immediately tested, and then again at seven weeks, three months, and six months. Test measurements used were the CES-D, Minnesota Multiphasic Personality Inventory-based Cook–Medley Hostility Scale, Perceived Stress Scale, Pittsburgh Sleep Quality Index, Revised Scale for Caregiving Self-Efficacy, Spielberger STAI, and the Spielberger State-Trait Anger Inventory (Williams et al., 2010). Participants received $30 for each module completed and $60 for the fourth visit (Williams et al., 2010). The VCS program consisted of ten 7-minute video modules that taught 10 coping skills that dealt directly with caregivers (Williams et al., 2010). Coping skills taught were (a) changing reactions, (b) evaluating reactions, (c) empathizing, (d) listening, I increasing awareness and objectivity, (f) increasing positive interactions, (g) problem solving, (h) using assertion, (i) speaking clearly, and (j) saying no (Williams et al., 2010). Participants watched a dramatization of a caregiving situation that was linked to a specific coping skill. They were required to complete two modules a week and all exercises and homework assignments for each module.

VCS participants also received telephone coaching during the five-week duration of the program. Trained telephone coaches called participants weekly to teach that week is two coping skills (Williams et al., 2010). Telephone coaches followed a structured format including the 10 coping skills and coaching goals. Videos presented caregiving scenarios with stress-producing circumstances. They were used to normalize caregiving experiences and to enable caregivers to admit or verbalize difficult thoughts or behaviors (Williams et al., 2010). The wait list control group were tested at the seven-week, three-month, and six-month intervals, but received no treatment.

Williams et al. (2010) researchers found that VCS training with the inclusion of telephone coaching was statistically significant in reducing psychosocial and biological measures of distress in ADRD caregivers. The main limitation with this study dealt with the treatment effects. It was unclear if there was a true effect or response bias because participants were paid to complete the study. Also, this study did not show whether treatment effects were short-term or continued after treatment.

O’Connell et al. (2010) evaluated a wellness guide for new older caregivers living in a community setting. The Health and Wellbeing Project was initiated in 2003 at a major university in the United States and was conducted in three stages. In the first stage, researchers identified specific needs of caregivers by performing health needs assessments. Surveys were mailed to 226 caregivers in a region with an invitation to one of two focus groups. In the second stage, researchers collected the data from the focus group and developed a wellness guide based on recurring themes using qualitative analysis. In the third stage, new caregivers evaluated the wellness guide for its usefulness and effectiveness as well as its impact on their health and well-being. O’Connell et al. (2010) found that caregiver wellness guides based on caregiver needs assessment is an acceptable source for new caregivers. However, a major limitation of the wellness guide was whether it continued to have lasting effects on addressing the needs of new caregivers.

Epstein-Lubow et al. (2011) investigated a mindfulness-based stress reduction training program for caregivers. Nine (*N* = 9) female caregivers ages 48 to 73 participated in 80 thirty-minute weekly classes geared toward mindfulness-based stress reduction. Mindfulness mediation is a type of meditation that allows one to focus their attention on bodily sensations and thoughts in the present with a goal to reduce anxiety. Depressive symptoms, burdens, perceived stress, anxiety, general health, and mindful attention were all measured at pre-intervention, post-intervention, and one-month follow-up.

Results revealed a decrease in depressive symptoms, perceived stress, and burden during the eight-week intervention. Stress and burden continued to reduce after the one-month follow-up, while depressive symptoms returned to baseline. Mindful attention increased for the duration of the study. Additionally, participants reported continued use of mindfulness techniques during the one-month follow-up. Limitations to this study included the challenge of identifying subpopulations of caregivers that would utilize mindfulness techniques. All these interventions relied upon various forms of behavior and psychological modifications with some sort of therapist involvement. One intervention does not rely so much on behavior modification as it does on a physiological method: cranial electrotherapy stimulation.

Cranial Electrotherapy Stimulation (CES)

An alternative anxiety reduction method that has gained attention in literature is Cranial Electrotherapy Stimulation. CES uses small electrical impulses that pass across the head from electrodes placed on, or near, the ears. Pulse rates can vary from .5 to 100 HZ in different CES devices, and stimulation intensities can range from 0 – 1.5 mA via sinusoidal or modified square waves (Regence Blue Cross Blue Shield, 2018). A review of the literature on CES is more challenging due to the variety of names given for the same method. Other names include *transcranial electrical stimulation, cerebral electrostimulation, electrosleep, and alphasleep* (Gibson & O'Hair, 1987; Kirsch, 2002; Kirsch & Smith, 2004).

Electromedicine can be traced back in history for thousands of years. The first reference of electromedicine occurred in 46 A.D. by the Greek physician Scirbonius Largus. He described an application of a black torpedo fish to ease chronic pain (Kirsch, 2002). In 1903, Leduc and Rouseau were the first to experiment with low currents across the scalp. This was called electrosleep. It would later be introduced to the United States in the 1960s (Appel, 1972; Brown, 1975; Gilula & Kirsch, 2005). Since then, researchers experiment with multiple versions of electromedicine. It has now officially become known as cranial electrotherapy stimulation (Anan'ev et al., 1960; Douglas, Larson, & Sances, 1970; Knutson, Tichy, & Reitman, 1956; Robinovitch, 1914).

Food and Drug Administration (FDA) and CES

The FDA currently approves Cranial electrotherapy stimulation for anxiety, insomnia, and depression (Allevia Health, 2014). In 2012, the FDA stated CES is a class II neurological device that applies electrical current to a patient’s head to treat insomnia, depression, or anxiety. This type of device was defined as the most stringent regulatory category for devices. Class II devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls” (FDA, para 9). These devices require pre-market FDA approval which is defined as “the required process of scientific review to ensure the safety and effectiveness of Class” (FDA, para 11). Currently eight companies have FDA approval to sell CES devices (Gilula & Kirsch, 2005). One such company is Electromedical Products International, Inc (EPI). EPI markets their device using the name Alpha-Stim They received FDA approval in May 1992 (Allevia Health, 2014). The 510(k)-pre-market notification number is K903014 (Alpha Stim, 2008). To meet FDA approval, the device must meet certain standards which include:

> A microprocessor controller box and skin electrodes. The small Controller box is software controlled low-intensity output. Current ranges from 0-600 Microamperes typically set at 0.5 Hz. Additional frequencies at 1.5 and 100Hz are available for the physician’s use. The waveform is a bipolar asymmetric rectangle shape with a 50% duty cycle, 0 net current. Current is applied using silver electrodes with self-adhesive pads applied to the ear lobes (Allevia Health, 2014).

Simply stated, the CES unit is a small device that utilizes software to produce low frequency waves conducted through ear clip electrodes.

How CES Works

It is not clear how CES works. However, several researchers have attempted to answer the question (Giordano, 2014). Since the initial studies, researchers proposed several theories. One such theory is that micro current waveforms projected by the CES unit stimulate and change neurological nerve cells that in turn fine-tune the brain. It was hypothesized that the raphe-nuclei is stimulated when ear clip electrodes are clipped to the earlobes near the mastoid bone (Giordano, 2014). Giordano (2014) stated:

> This neurological fine-tuning is called modulation, and occurs either as a result of, or together with the production of a certain type of electrical activity pattern in the brain known as an alpha state which can be measured on brain wave recordings (called electroencephalograms, abbreviated EEG). Such alpha rhythms are accompanied by feelings of calmness, relaxation and increased mental focus. The neurological mechanisms that are occurring during the alpha state appear to decrease stress effects, reduce agitation, and stabilize mood, and regulate both sensations and perceptions of particular types of pain. (p. 1)

Gilula and Kirsch (2005) discussed the CES effect on the limbic system, reticular activating system (RAS), the hypothalamus, and the thalamus on the nervous system. Toriyama (1975) suggested CES works through the parasympathetic nervous system. Smith (2002) stated that “neurotransmitters that are out of homeostasis due to some prior, reasonably prolonged stress reaction, whether it be psychological or physical such as drug abuse, will come back into homeostasis and any concomitant anxiety, depression or sleep problems will subside” (p. 5). Childs and Price (2007) stated that anti-aggressive effects of CES generate due to an increase of alpha waves created. It was also reported that CES may augment prescribed antipsychotics and mood stabilizers.

CES Studies

Currently, there are more than 175 published studies for CES reporting significant results with most of them reporting a positive reduction in anxiety and/or stress. Approximately 75 were designed to measure anxiety reduction using CES. Some of those studies are Briones & Rosenthal, 1973; Feighner, Brown, & Oliver, 1973; Frankel, Buchbinder, & Snyder, 1973; Gibson & O'Hair, 1987; Gilula & Kirsch, 2005; Hearst, Cloninger, Crews, & Cadoret, 1974; Heffernan, 1996; Jemelka, 1975; Kirsch & Nichols, 2013; Krupitsky et al., 1991; Passini, Watson, & Herder, 1976; Phillip, Demotes-Mainard, Bourgeois, & Vincent, 1991; Rosenthal, 1972; Strentzsch, 2009; Taylor, Lee, & Katims, 1991;Von Richthifen & Mellor, 1980; Voris, 1995; Winick, 1999).

Thirty-five studies reported using a double-blind technique. In these studies, participants were divided into two groups: One group received CES and the other received a sham treatment. Eleven of these studies investigated anxiety (Briones & Rosenthal, 1973; Feighner et al., 1973; Hearst et al., 1974; Heffernan, 1996; Jemelka, 1975; Passini et al., 1976; Phillip et al., 1991; Rosenthal, 1972; Von Richthifen & Mellor, 1980; Voris, 1995; Winick, 1999). Additionally, three studies used a placebo control designed to rule out placebo effects during the administration of CES as opposed to sham CES. Neither found placebo effects (Lichtbroun, Raicer, & Smith, 2001; Strentzsch, 2009; Taylor et al., 1991).

Anxiety research that uses CES dates from 1968 to the present. Most of these studies were conducted in the 1970s (Kirsch, 2002). Negative outcome studies were all between 1965 and 1980 (Kirsch, 2002). No Alpha-Stim has ever received a negative outcome (Kirsch, 2002). Most of the negative outcome studies addressed insomnia. Only four measured anxiety (Moore, Mellor, Standage, & Strong, 1975; Passini et al., 1976; Tomsovic & Edwards, 1973; Von Richthifen & Mellor, 1980).

Gilula and Kirsch (2005) examined the effectiveness of CES as opposed to medication in treating depression. The goal of the study was to determine if evidence supported CES as an alternative to pharmaceuticals. Researchers found an equal benefit over placebo for CES opposed to medication. In contrast to pharmaceuticals and its various side effects, CES has no reported serious side effects (Gilula & Kirsch, 2005).

Numerous methods have been used to measure effectiveness of CES, including electrocardiogram (EKG), electroencephalogram (EEG), electromyogram (EMG), skin conductance, blood pressure, pulse, respiration, heart rate, body chemistry, peripheral tension, BDI (Beck et al., 1988), Hamilton Anxiety Scale, Hamilton Depression Scale, Global Evaluations, Minnesota Multiphasic Personality Inventory (MMPI), State/Trait Anxiety Inventory, Taylor Manifest Anxiety Scale, and the Zung Depression Scale (Kirsch, 2002). Few studies have used neurotransmitter levels as an outcome measure (Frankel et al., 1973; Krupitsky et al., 1991; Scherder et al., 2003; Shealy, Cady, Culver-Veehoff, Cox, & Liss, 1998; Shealy, Cady, Wilkie, Cox, & Clossen, 1989).

Summary

This chapter presented cranial electrotherapy stimulation as an alternative method of reducing anxiety and depression in caregivers. The review of literature indicates that multiple research studies of caregiving interventions have been conducted. However, many of these studies failed to show whether treatment effects were short-term or had long lasting effects beyond treatment. The history of cranial electrotherapy stimulation was briefly outlined, and numerous detailed studies supported the FDA-approved device as an effective way to reduce anxiety, depression, and insomnia.

Chapter 3

Methodology

Currently, no other research study has investigated interventions for depression and anxiety symptom reduction for caregivers outside the interventions of reducing the amount of caregiving or providing information and coping skills. The purpose of this experimental pretest post-test two-group double-blind design study was to examine the efficacy of cranial electrotherapy stimulation (CES) to reduce anxiety and depressive symptoms for a sample of 35 caregivers.

Research Design

This study uses an experimental pretest post-test two-group double-blind design. Researchers may unintentionally change research outcomes in a variety of ways. They may offer a smile (which offers a sense of encouragement) for a right answer or offer a frown for a wrong answer (Krathwohl, 1998). This design ensures that both the administrator and those receiving treatment are blind to which group receives the different treatments (Krathwohl, 1998). The sham CES treatment group consists of the participants who are given treatment that was meant to not have an effect, and the active CES treatment group consisted of participants who were given treatment that is meant to have an effect. This study uses an experimental pretest post-test 2-group double-blind design. This design ensures that both the administrator and those receiving treatment are blind to which group receives what (Krathwohl, 1998). Electromedical Products International, Inc. (EPI) provided the CES devices to the researcher. Before delivery to the researcher, EPI coded the devices as active or sham. Neither the researcher nor the subjects knew whether a device was active or sham until the completion of the study.

Assumptions and rationale for design. This study is designed to respond to limitations represented in the current body of literature regarding interventions for anxiety and depressive symptoms in caregivers. CES is an electronic device approved by the U.S. Food and Drug Administration (2018) for reducing symptoms if anxiety, depression, and insomnia. Current literature has identified a primary limitation of a lack of double-blinding experimentation necessary to eliminate researcher bias. To ensure double-blindness, EPI will code all CES devices as either active or sham before sending the devices to the researcher. After completion of the three-week treatment protocol and final data gathering, EPI will inform the researcher which CES devices are active and which are sham.

The researcher selected this population due to multiple studies in the body of literature that found caregivers have high risk of adverse health, psychological, and financial effects because of increased anxiety and depressive symptoms related to their caregiver role (Ashley et al., 2011; Harris et al., 2011; King et al., 2010; MacNeil et al., 2010; Martin et al., 2011; Pioli, 2010; Turner et al., 2010). Traditional treatment methods for reducing anxiety and depressive symptoms for caregivers include either reducing caregiving or providing information and coping skills (NAC, 2015). Because there has been high dropout rates in studies using these traditional treatment methods (McMillan et al., 2006), the researcher believes that this population would benefit most from an alternative treatment method that requires little, if any, modification of the caregiving routine or additional time taken away from caregiving and other usual activities.

Participants. To be eligible, participants must be living in the Houston area, be at least 18 years old, and be currently providing care to an individual who is disabled, chronically ill, or cognitively impaired.

Sampling. This study used a sample size of 40 caregivers in the Houston area. The researcher recruited participants from caregiving agencies and organizations in the Houston area by sending out emailed invitations to invite participants to the study.

Risks. There were both physical and psychological risks to participants. Physical reactions to the skin, dizziness, and nausea may occur when using the CES device. Psychological risk may include re-emergence of negative feelings when taking the Beck’s Depression Index (BDI) and State-Trait Anxiety Inventory (STAI).

Confidentiality and Informed Consent. All data collected was confidential including test results, demographic questionnaires, and tracking sheets. The informed consent is the only place the participants’ names will appear. Names will not appear on the STAI, the BDI, or demographic questionnaire. All final data were used only for publication and research purposes.

Costs. There were no costs associated with this study for participants. However, participants will need to devote time to complete the 3-week CES protocol and track their use of the CES device each day on the tracking sheet (Appendix A).

Role of the Researcher. The researcher’s role is to find participants, ensure integrity of the study, answer questions of the participants, collect data, and interpret findings.

Data Collection Procedures

Prior to data collection. Permission for the study was obtained from the St. Mary’s University Institutional Review Board (Appendix B). An invitation (Appendix C)) and common asked question brochure were then sent out to area caregiver agencies to invite caregivers to be a part of the study in order to reach a sample size of 40 participants. Participants were asked if they have received treatment from a mental health care provider prior to participating in the study. If yes, their data was not used in the study. All participants were given a participation letter, informed consent form (Appendix D), common questions brochure, demographic questionnaire (Appendix E), State-Trait Anxiety Inventory (Appendix F), and Beck's Depression Inventory to complete. If participants receive a score of 20 or above on the State-Trait Anxiety Inventory or Beck's Depression Inventory they were given a referral list of mental health care providers. The consent form and information sheet were kept separate from the data containing each participant's name, contact information, and assigned number identifying each participant. The assigned number will also be placed on participants pre and post surveys. The surveys were kept separate from the consents and information sheets so that the surveys remain unidentifiable.

Participants were asked to use their CES device each day for 60 minutes for three weeks. The researcher will teach participants how to use the CES device when devices are delivered to each participant. See training protocol (Appendix G). Upon completion of the 3-week CES protocol, participants will repeat the test measurements taken at the start of the study. Participants were asked if they received any treatment from a mental health care provider since starting their participation in the study. If yes, their data will not be used in the study. Participants with significant missing data were removed from data analysis. Data collection will continue until participant numbers are met with completed data. After a participant has completed the study and returned the device, the researcher will cut out the participant's name and contact information from the master list and will shred this information.

The STAI is a 40-item scale used to assess two types of anxiety: trait anxiety and state anxiety (Spielberger, 1983). Trait anxiety is how prone one is to perceive stressful situations as threatening. State anxiety is how intensely one will respond to a perceived threatening situation (Spielberger, 1983). Under psychological stress, test-retest reliability ratings for the STAI assessment tool vary between .89 and .94. However, there is a larger variance of .16 and .94 in the populations. Comparing both forms to all populations creates a .65 correlation between all responses (Spielberger, 1983).

The BDI is a 21-item, self-report inventory that measures attitudes and the symptoms of depression (Beck et al., 1988). Developed in several forms, including computerized administration, it can be completed in approximately 10 minutes. A fifth-grade reading level is required to understand the questions (Beck et al., 1988). Internal validity ranges from .73 to .92 with a mean of .86. It demonstrates high internal validity, with alpha coefficients of .86 and .81 for psychiatric and non-psychiatric populations (Beck et al., 1988).

Data Analysis Procedures

The data collected from the pre- and posttest results of the STAI scores, BDI scores, and demographic data sheet were entered in a dataset using SPSS. Descriptive statistics and frequency tables were executed using information gathered from the demographic questionnaire. After completing descriptive analysis, inter-item reliability analysis were conducted on the STAI and BDI measures to determine reliability in the sample. After reliability analysis, a repeated measure multivariate analysis of variance (MANOVA) were conducted to address variance between pre- and posttest scores for the STAI and Beck's Depression Inventory scores. Results will then be examined for the relationship between outcome measures related to anxiety and depressive symptoms. On.

Security and Confidentiality of Data

This study will require paper records of the informed consent form, demographic questionnaire, State-Trait Anxiety Inventory, Beck Depression Inventory, and the tracking sheet. The informed consent were kept separate from all other data in order to ensure confidentiality. They were sent to the Sponsored Programs Academic Research and Compliance office at St. Mary's University where they were stored and disposed of according to federal regulations. All other hard copy data were stored in a locked cabinet in a locked room in the researcher's house and will have codes associated with the participants data forms. All electronic data forms were password protected. All data were kept for five years and then shredded by the researcher. No follow up treatment was offered to any participants.

Chapter 4

Data Analysis

The purpose of this experimental pretest post-test two-group double-blind design study was to examine the efficacy of cranial electrotherapy stimulation (CES) to reduce anxiety and depressive symptoms for a sample of 35 caregivers. The research design required that neither the administrator or those receiving treatment knew which CES device was active and which were sham. To ensure double-blindness, Electromedical Products International, Inc. (EPI) coded all CES devices as either active or sham prior to sending devices to the researcher. After completion of the three-week treatment protocol and final data gathering, the researcher opened the sealed envelope from EPI that informed the researcher which CES devices were active and sham based on serial numbers. The researcher was then able to identify the participants who were in the treatment group and those who were in the control group.

Participants had been trained on how to use the CES device and instructed to use the CES device each day for 60 minutes for three consecutive weeks. Prior to the first CES session, each participant completed both the Beck Depression Index (BDI) and State-Trait Anxiety Inventory (STAI) to create a bassline. Upon completion of the there-week CES protocol, participants again completed the BDI and STAI. This chapter includes a discussion of the data analysis results. Descriptive statistics were employed to characterize the study sample demographically and summarize study variable data for the treatment and control groups.

Data Collection

The study sample included 35 caregivers willing to follow the CES protocol for a three-week period and complete the BDI and STAI pre and post CES protocol. Eighteen caregivers were randomly assigned CES devices. All participants completed the CES protocol, BDI, and STAI. Two participants chose not to provide certain demographic data and were included in the study. Otherwise, no other data issues emerged.

Findings

Tables 3 through 11 summarize demographic data distributions for control and treatment groups based on age, caregiver status, caregiver hours, caregiver experience, ethnicity, gender, income, marital status, and, number of individuals cared for, and patient's illnesses. As shown in Table 3, for gender distribution, of the 35 participating caregivers, the sample included 24(68%) females, 10(29%) males, and 1(3%) who provided no gender data. Control and distribution groups included similar distributions by gender with approximately two-thirds female.

Table 3

Gender Distribution by Group

Group	Gender	*n*	%
Control	Female	12	70.6
	Male	4	23.5
	Unknown	1	5.9
	Total	17	100.0
Treatment	Female	12	66.7
	Male	6	33.3
	Unknown	0	0.0
	Total	18	100.0

As shown in Table 4, both groups contained a wide range of ages, from 18 to 30 age group through the 60+ age group. The age distributions between the control group and treatment group were similar. Approximately two-thirds were between age 31 and 50.

Table 4

Age Distribution by Group

Group	Age	*n*	%
Control	18 to 30	2	11.8
	31 to 40	4	23.5
	41 to 50	7	41.2
	51 to 60	2	11.8
	60+	2	11.8
	Total	17	100.0
Treatment	18 to 30	2	11.1
	31 to 40	3	16.7
	41 to 50	9	50.0
	51 to 60	0	0.0
	60+	4	22.2
	Total	18	100.0

Table 5 details caregiver status by group. Caregiver status distributions between the control group and treatment group were similar. Between 82.4% and 94.4% were informal caregivers.

Table 5

Caregiver Status Distribution by Group

Group	Caregiver Status	*n*	%
Control	Formal	3	17.6
	Informal	14	82.4
	Total	17	100.0
Treatment	Formal	1	5.6
	Informal	17	94.4
	Total	18	100.0

As shown in Table 6, the ethnicity distribution contained various ethnicities. The ethnicity distributions between control and treatment groups were similar. Black and Latino represented 64.7% and 89%, respectively.

Table 6

Ethnicity Distribution by Group

Group	Ethnicity	*n*	%
Control	Asian	1	5.9
	Black	9	52.9
	Latino	2	11.8
	P. Islander	1	5.9
	White	2	11.8
	Unknown	1	5.9
	Total	17	100.0
Treatment	Asian	0	0
	Black	12	66.7
	Latino	4	22.2
	P. Islander	0	0
	White	1	5.6
	Unknown	1	5.6
	Total	18	100.0

As shown in Table 7, the marital status distribution between the control and treatment groups were similar. In the control group, 35.5% of the participants were married or cohabitating. In the treatment group, 44.4% of the participants were married or cohabitating.

Table 7

Marital Status Distribution by Group

Group	Marital status	*n*	%
Control	Single	8	47.1
	Cohabitating	3	17.6
	Married	3	17.6
	Divorced	1	5.9
	Widowed	1	5.9
	Unknown	1	5.9
	Total	17	100.0
Treatment	Single	7	38.9
	Cohabitating	2	11.1
	Married	6	33.3
	Divorced	2	11.1
	Widowed	0	0.0
	Unknown	1	5.6
	Total	18	100.0

As shown in Table 8, in the control group 12 (70.0%) participants reported providing more than 11 hours of caregiving per week, while in the treatment group only 8 (50%) participants reported providing more than 11 hours of caregiving per week. The number of caregiver hours was somewhat greater for the control group. The overall sample commits substantial proportions of their week to caregiving.

Table 8

Caregiver Hours Distribution by Group

Group	Caregiver hours	*n*	%
Control	1 to 10 hours	5	29.4
	11 to 20 hours	5	29.4
	31 to 40 hours	4	23.5
	Greater than 40 hours	3	17.6
	Unknown	0	0.0
	Total	17	100.0
Treatment	1 to 10 hours	9	50.0
	11 to 20 hours	4	22.2
	31 to 40 hours	3	16.7
	Greater than 40 hours	1	5.6
	Unknown	1	5.6
	Total	18	100.0

As shown in Table 9, the treatment group was more varied in the amount of caregiving years. The treatment group had more relatively new caregivers and a greater number of longer experienced caregivers than the control group. Most of the control group had between 2 and 5 years of experience.

Table 9

Years as Caregiver Distribution by Group

Group	Years as caregiver	*n*	%
Control	Less than 2 years	5	29.4
	2 to 5 years	11	64.7
	Greater than 5 years	0	0.0
	Unknown	1	5.9
	Total	17	100.0
Treatment	Less than 2 years	10	55.6
	2 to 5 years	3	16.7
	Greater than 5 years	4	22.2
	Unknown	1	5.6
	Total	18	100.0

As shown in Table 10, both the treatment group and control had similar numbers of patients for whom they provided care. The control group had three participants who provided care to three or more patients. The treatment group had more participants who provided care to two patients, but this group had no participants who provided care to three or more patients.

Table 10

Number Cared for Distribution by Group

Group	Number cared for	*n*	%
Control	1	13	76.5
	2	1	5.9
	3	2	11.8
	Greater than 3	1	5.9
	Total	17	100.0
Treatment	1	14	77.8
	2	4	22.2
	3	0	0.0
	Greater than 3	0	0.0
	Total	18	100.0

As shown in Table 11, the control group income primary distribution was as follows: 13 (76.6%) reported income between $31,000 and $69,000, while the treatment group had 9 (50%) report income between $31,000 and $79,000. The treatment group income skewed somewhat higher than the control group.

Table 11

Income Distribution by Group

Group	Income	*n*	%
Control	Less than 30K	1	5.9
	31k to 39k	4	23.5
	40k to 49k	2	11.8
	50k to 59k	4	23.5
	60k to 69k	3	17.6
	70k to 79k	1	5.9
	80k to 89k	1	5.9
	90k to 99k	1	5.9
	Total	17	100.0
Treatment	Less than 30K	3	16.7
	31k to 39k	0	0.0
	40k to 49k	2	11.1
	50k to 59k	7	38.9
	60k to 69k	1	5.6
	70k to 79k	2	11.1
	80k to 89k	3	16.7
	90k to 99k	0	0.0
	Total	18	100.0

Statistical Assumptions

Paired sample *t*-test were conducted to assess hypotheses 1 and 2, and Pearson correlation was employed to test hypothesis 3. The assumption is that pre and post BDI and STAI data for both the control and treatment groups were approximately normally distributed, and a scatterplot reveals a linear relationship. Parametric statistical methods such as Pearson correlation and paired sample *t*-tests, assume that dependent variable data (BDI score and STAI score) are approximately normally distributed and linear.

As shown in Table 12, Shapiro-Wilk's was conducted on the eight subsets of dependent data depicted to test for normality and linearity (Leedy, Ormrod, & Johnson, 2019).Correlation statistics demonstrated that Pre-BDI, Pre-STAI, Post-BDI data for both treatment and control groups met the assumptions for linearity. None of the eight Shapiro-Wilk's tests for normality were significant at $p < .05$, meaning that all eight subsets of dependent variables depicted in Table 12 met the assumption for normality.

Table 12

Test of Normality

Shapiro-Wilk's		Statistic	df	Significance
Control	Pre-BDI	.923	17	.164
	Pre-STAI	.961	17	.648
	Post-BDI	.803	17	.119
	Post-STAI	.814	17	.112
Treatment	Pre-BDI	.932	18	.208
	Pre-STAI	.938	18	.263
	Post-BDI	.946	18	.360
	Post-STAI	.946	18	.372

Hypothesis Tests

RQ1: Did caregivers receiving active CES treatments experience a greater reduction of anxiety symptoms than the caregiver control group?

> **H_o1**: Participants who received active CES treatments did not experience significantly greater anxiety reduction, as measured by STAI scores, as compared to the control group.
>
> **H_a1**: Participants who received active CES treatments experienced significantly greater anxiety reduction, as measured by STAI scores, as compared to the control group.

Table 13 reports pre and post STAI score mean, standard deviation, and standard error for the control and treatment groups. A paired-samples *t*-test was conducted to compare control group STAI score before and after CES treatment. For the control group, the 10.53 mean difference in STAI scores between pre (M = 42.18, SD = 13.28) and post

(*M* = 31.65, *SD* = 5.65) treatment was statistically significant; *t*(16) = 3.119, *p* = .001. A paired-samples *t*-test was conducted to compare treatment group STAI score before and after CES treatment. For the treatment group, the 12.05 mean difference in STAI scores between pre (*M* = 43.61, *SD* = 10.99) and post (M = 31.56, *SD* = 4.11) treatment was statistically significant; *t*(17) = 4.189, *p* = .001. However, there was no significant difference in pre and post STAI score improvement (Mean difference = 1.52) between the treatment group and the control group *t*(34) = .345, *p* = .732. Therefore, the null hypothesis was accepted, there was no difference in anxiety symptom reduction between the control group and the treatment group.

Table 13

STAI Scores by Group

Group	Dependent Variable	Mean	Mean Diff.	*n*	*SD*	Std. Error
Control	Pre-STAI	42.18	--	17	13.28	3.22
	Post-STAI	31.65	10.53	17	5.65	1.37
Treatment	Pre-STAI	43.61	--	18	10.99	2.59
	Post-STAI	31.56	12.05	18	4.11	0.97

RQ2: Did participants receiving active CES treatments experienced a greater reduction of depressive symptoms, as measured by BDI scores, compared to the control group?

> **H_o2**: Participants who received active CES treatments did not experience greater depressive symptom reduction, as measured by BDI scores, as compared to the control group.
>
> **H_a2**: Participants who received active CES treatments experienced significantly greater depressive symptom reduction, as measured by BDI scores, as compared to the control group.

Table 14 reports pre and post BDI score mean, standard deviation, and standard error for the control and treatment groups. A paired-samples *t*-test was conducted to compare control group BDI score before and after CES treatment. For the control group, the 9.12 mean difference in BDI scores between pre (*M* = 18.41, *SD* = 13.12) and post (*M* = 9.29, *SD* = 7.29) treatment was statistically significant; *t*(16) = 4.139, *p* = .001. A paired-samples *t*-test was conducted to compare treatment group BDI score before and after CES treatment. For the treatment group, the 10.39 mean difference in BDI scores between pre (*M* = 16.11, *SD* = 11.31) and post (*M* = 5.72, *SD* = 3.89) treatment was statistically significant; *t*(17) = 4.189, *p* = .001. However, there was no significant difference in pre and post BDI score improvement (Mean difference = 1.57) between the treatment group and the control group *t*(34) = .415, *p* = .675. Therefore, the null hypothesis was accepted, there was no difference in depressive symptom reduction between the control group and treatment group.

Table 14

BDI Statistics by Sample

		Mean	Mean Diff.	*n*	*SD*	Std. Error
Control	Pre-BDI	18.41	--	17	13.12	3.18
	Post-BDI	9.29	9.12	17	7.29	1.76
Treatment	Pre-BDI	16.11	--	18	11.31	2.66
	Post-BDI	5.72	10.39	18	3.89	0.91

RQ3: What is the relationship between anxiety symptoms, as measured by the STAI, and depressive symptoms, as measured by the BDI, in caregivers?

H$_o$3: There is no significant relationship between STAI scores and BDI scores for caregivers.

H_a3: There is a significant relationship between STAI scores and BDI scores for caregivers.

Pearson correlation statistics were conducted to address Research Question 3. Table 15 depicts correlations and significance for the pre BDI – STAI relationship and the post BDI – STAI relationship. The pre-CES treatment BDI- STAI relationship was strong and statistically significant ($r = 0.575$, $p < .000$). The pre-CES treatment BDI- STAI relationship was strong and statistically significant ($r = 0.668$, $p < .000$). Therefore, the null hypothesis is rejected, there was a strong significant correlation between BDI score and STAI score for the overall sample.

Table 15

BDI - STAI Correlations

		Post-BDI	Pre-STAI
Post-STAI	Pearson Correlation	.575**	--
	Sig. (2-tailed)	.000	--
Pre-BDI	Pearson Correlation	--	.668**
	Sig. (2-tailed)	--	.000

Chapter 5

Discussions, Conclusions, and Recommendations

The purpose of this experimental pretest post-test two-group double-blind design study was to examine the efficacy of cranial electrotherapy stimulation (CES) to reduce anxiety and depressive symptoms for a sample of 35 caregivers. To study this phenomenon, the researcher drew data from among 35 caregivers to determine whether CES treatment helped them experience a decrease in anxiety and depressive. The researcher hypothesized that participants who received treatment would experience reductions in anxiety symptoms (as gauged by STAI scores) and depressive symptoms (as gauged by BDI scores).

The methodology chosen used an experimental pretest post-test two-group double-blind design to ensure that both the administrator of the test and those receiving the treatment were blind to which group received the genuine treatment and which received the sham treatment. Data was collected from CES devices used by participants and analyzed for both pre- and post-test results on STAI and BDI scores. The findings of the study, reported in Chapter IV, are discussed in the following sections.

Participant Demographics

A non-random convenience sampling technique was employed to recruit and select participants. More than 80% of all 35 participants were informal caregivers, and there was no publicly available demographic information regarding the general population of informal caregivers in Houston. Thus, the researcher was unable to compare the participants to the general population of informal caregivers in Houston.

Interpretation of the Findings

Three research questions were developed to guide the current study. The first research question for the study was as follows:

RQ1: Did caregivers receiving active CES treatments experience a greater reduction of anxiety symptoms than the caregiver control group?

Findings indicated that there was no statistically significant difference in anxiety symptom reduction between CES treatment and control groups, even though both groups reported experiencing significantly lower anxiety symptoms. As such, CES treatment did not appear significantly more effective in reducing anxiety symptoms than a placebo. The findings were not consistent with proposals regarding CES, which researchers indicated may be useful for addressing a variety of conditions through the stimulation of raphe-nuclei (Giordano, 2014). Researchers previously broadly indicated that the use of CES could influence multiple parts of the brain and nervous system, such as the hypothalamus, thalamus, and totality of the nervous system (Gilula & Kirsch, 2005).

Smith (2002) also indicated that neurotransmitters may fall out of homeostasis because of prolonged stress reactions in response to both physical and psychological stimuli. The use of CES was noted as an effective means of reducing anxiety in numerous studies (Briones & Rosenthal, 1973; Feighner et al., 1973; Frankel et al., 1973; Gibson & O'Hair, 1987; Gilula & Kirsch, 2005; Hearst et al., 1974; Heffernan, 1996; Jemelka, 1975; Kirsch & Nichols, 2013; Krupitsky et al., 1991; Passini et al., 1976; Phillip et al., 1991; Rosenthal, 1972; Strentzsch, 2009; Taylor et al., 1991; Von Richthifen & Mellor, 1980; Voris, 1995; Winick, 1999). As such, it was anticipated from the existing literature that CES would help to address anxiety symptoms in caregivers.

Despite all the evidence suggesting that CES should be useful in treating anxiety, the current study did not seem to yield similar results. Consequently, that places the current study as the outlier regarding the rest of the literature. The findings suggest there may be specific conditions among caregivers that influence their anxiety that the use of CES does not address.

RQ2: Did participants receiving active CES treatments experience a greater reduction of depressive symptoms, as measured by BDI scores, compared to the control group?

Findings indicated that there was no statistically significant difference in depressive symptom reduction between CES treatment and control groups, even though both groups reported experiencing significantly lower depressive symptoms. As such, CES treatment did not appear significantly more effective in reducing depressive symptoms than a placebo. This finding was inconsistent with the expectations generated from the literature. Past research suggested that CES should help address negative mental health conditions. However, this was not found in the current study. Once again, this suggests that caregivers may have unique situations that lead to depressive symptoms, meaning that alternatives to addressing those symptoms may be necessary rather than employing CES. Given the above findings, the research produced within the current study contradicted previous indications in the literature that CES may help.

RQ3: What is the relationship between anxiety symptoms, as measured by the STAI, and depressive symptoms, as measured by the BDI, in caregivers?

After testing to determine the relationship between anxiety symptoms and depressive symptoms in caregivers, the researcher found that there was a strong association between both types of symptoms among caregivers as gauged using STAI and

BDI scores. Previous indications from the National Alliance for Caregiving (2015) indicated that caregiving work may lead to both anxiety and depression, therefore, the findings that both occurred among caregivers was consistent with the previous literature. However, there was little else identified in the literature suggesting that the two may occur in tandem. As such, the current findings were relatively novel when contextualized within the larger literature and added a unique contribution to the existing research.

Limitations of Study

The choice of various research methodologies can have limitations (Krathwohl, 2009). It is up to researchers to recognize and determine if the benefits of the chosen study design outweigh the cost of the chosen approach (Krathwohl, 2009). Within the context of the current study, the choice of research design was deemed of greater benefit than the associated costs. Regardless, the identified limitations may have reduced the efficacy of the study, though steps were taken to address these limitations to the greatest degree possible.

One limitation recognized was the lack of a true randomization process for sampling the identified population. For this study, participants were recruited from the Houston area. However, owing to variation in caregiving work schedules, there was a lack of available caregivers willing to participate at any given time. As such, sampling could not be randomized. A second limitation to the study was the nature of the topic. The topic of CES may have seemed uncomfortable to some caregivers, who may not have felt inclined to participate (biasing the sample), or who answered without full honesty during the study.

The small size sample due to the practical limitations limited generalizability of study findings, and the non-random sampling technique suggests the sample may not be representative of caregivers in the Houston area. The following practical limitations limit findings. First, participant sessions were not monitored, so it was possible that some participants did not use the devices as required for the study. Second, it is possible that caregiving could have changed during the use of the device or that the caregivers experience stressors during the study affecting their posttest scores. Third, participants could have guessed that they had been given active or sham devices, which affected their posttest scores. Fourth, although the samples were somewhat similar, the control sample reported spending more hours giving care and more years of experience giving care than the treatment group. It is possible that these differences affected the outcome. Fifth, the treatment protocol was for 21 days with immediate posttest at the end without follow-up. it was not known if additional change could have occurred with longer term CES usage.

Recommendations

The fact that both groups improved in both symptoms suggests that caregivers can reduce their anxiety and depressive symptoms with minimal intervention. Caregivers may just need to believe they are doing something or feel hope that improvement can occur. This would imply that any intervention could result in improvement. A few practical recommendations can be made from the current study. In short, it did not seem that CES helped to address either anxiety or depression in caregivers significantly more than the placebo. Given that as the case, no recommendation could be made suggesting that CES be applied among caregivers as a means of addressing these symptoms. Considering the lack of effectiveness of CES, such devices should not be employed among caregivers for addressing issues of anxiety and depression. As such, the most practical recommendation that could be made based on the current research would be for organizations employing caregivers to seek out alternative methods for addressing both anxiety and depression among these individuals.

Regarding research recommendations, it is clear from the findings that the current research conflicted with the vast amount of literature regarding CES use for anxiety and depressive symptom reduction. The body of literature indicated that CES should have had some statistically significant greater impact on these symptoms than a placebo. Yet, the current research did not reach this objective. Considering that the findings of the current research were in such contrast to the previous findings, further investigation of this population is necessary. First, there is the issue of the small sample drawn for this research. The sample size may have disproportionately impacted the current study findings. As such, expanding the sample to increase the power may yield different results from those reached in the current version of the study. One recommendation for future research is to include a more representative sample of the population in the higher-powered sample.

A second recommendation for future research would be to examine the nature of the sample. Research could explore whether there are specific characteristics that distinguish the jobs of caregivers from roles that others fill in other careers. If so, this may help to explain why the use of CES did not provide greater help in addressing the anxiety and depressive symptoms experienced among this sample. A qualitative investigation of these caregivers could yield data on unique phenomenon common to their roles that may make caregivers more resistant to positive outcomes from CES treatment.

A third recommendation for future research would be to analyze the nature of the currently completed research itself. The current research, given its outlier status, may necessitate replication to determine whether the same results can be achieved. If not, then it may indicate a fundamental flaw in the design of the research that would need to be addressed before the research can be repeated. Considering the outlier status of the findings, it brings to question whether there may have been a design flaw that could have affected the outcomes. As such, replication attempts may help clarify whether the current study’s findings typify the target population.

Another recommendation would be to replicate the study with low cost treatments that would not be time consuming for caregivers. Considering that both CES and a placebo yielded a significant reduction in anxiety and depressive symptoms, it is possible that low cost treatments that do not require great time commitments from caregivers would be effective. For example, training caregivers in breathing exercises and mindfulness, which could be employed during caregiving activities, could assist caregivers in reducing their anxiety and depressive symptoms. One of the reasons for the decision to study CES with this population is because caregivers often do not have the time to devote to attend counseling groups or to participate in self-care activities that take them away from their caregiving responsibilities. If a low-cost treatment that does not take the caregivers’ time were identified, this could help many caregivers.

Implications

Given that CES failed to impact anxiety and depression in the sample drawn for this study, the implication is that CES may not be as successful at addressing these issues as the vast amount of prior literature suggests. If this is the case, then it may necessitate revisiting old literature, and reviewing the studies, to assess the quality of each study’s design to determine whether the findings were valid. A second implication of the study stemmed from the association of anxiety and depression, both occurring among the sample. If anxiety and depression occur together, then it implies they may have similar roots and develop along similar mental pathways. In this regard, the implication is that caregivers may have both anxiety and depressive symptoms manifest as a response to the duties the individuals must complete and the emotional experiences that caregivers have as they care for their patients.

Conclusion

The purpose of this experimental pretest post-test two-group double-blind design study was to examine the efficacy of cranial electrotherapy stimulation (CES) to reduce anxiety and depressive symptoms for a sample of 35 caregivers. To complete this study, 35 participants were recruited into a pretest post-test two-group double-blind study. The underlying hypothesis was that participants who received treatment would experience reductions in anxiety and depressive symptoms.

Following an analysis of the data, the researcher's hypotheses that CES would help reduce symptoms of anxiety and depression were not supported. This contextualized the current study as an outlier against the larger body of literature, which suggested that CES should have a greater positive impact on symptoms than a placebo. The lack of greater improvement through CES suggested that the current study may have included unique features within the research design that produced significantly different findings from those previously found in the literature.

Based on the current research, CES cannot be recommended as a treatment for anxiety and depressive symptoms among caregivers. The study indicated that anxiety and depressive symptoms both occurred among this population and that both the treatment and control groups experienced lowered anxiety and depressive symptoms. As such, there continues to be an ongoing need to address the mental health needs of caregivers and find varying ways to treat anxiety and depressive symptoms in this population. Because both the treatment and the placebo were effective in lowering anxiety and depressive symptoms, counselors and other mental health professionals should keep an open mind to creatively treating caregivers. It is possible that caregivers could lower their anxiety and depressive symptoms just by participating in treatments that they believe will result in change. Thus, future research should investigate low cost treatments that do not require a lengthy time commitment from caregivers to address these symptoms rather than relying on CES to help address anxiety and depressive symptoms among caregivers.

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Appendix A

Daily Tracking Sheet

Tracking Sheet

Days	Start	am/pm	Stop	am/pm
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				

Appendix B

Institutional Review Board Approval

June 3, 2019

Reginald Jefferson
Dept. of Counseling
St. Mary's University

DELIVERED BY EMAIL TRANSMISSION

Dear Mr. Jefferson:

The IRB has approved the study Jefferson (M. Harper, faculty sponsor), An Examination of Cranial Electrotherapy Stimulation (CES) on Anxiety and Depressive Symptoms of Caregivers: A Double-Blind Experimental Study. If research participants have any questions about their rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary's University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu.

Dan Ratliff, Ph.D.
IRB Chair
St. Mary's University

The proposal is determined to meet criteria for expedited review [45 CFR 46.110]. The research protocol has been approved by the St. Mary's IRB for the period of May 15, 2019 to May 14, 2020.

You may collect data from human subjects according to the approved research protocol. The approval stamp must appear on any Information Form or Informed Consent Form approved by the IRB (jpeg file attached).

If, at any time, you make changes to the research protocols that affect human participants, you must file a "Changes to Approved IRB Protocol and/or Unanticipated Problems" form. Changes must be reviewed and approved by IRB before proceeding with data collection.

Dan Ratliff, Ph.D.
IRB Chair

CC: Melanie Harper, PhD, Faculty Sponsor
Attachment: IRB Approval Stamp jpeg file

Appendix C

Invitation to Participate in Research Study

Dear Potential Participant,

My name is Reginald Jefferson, and I am currently recruiting participants to be part of a study to increase understanding of the effectiveness an intervention designed to reduce stress in caregivers. To be eligible for the study, participants must be at least 18 years old, live in the greater Houston area, and currently participate in a caregiving role for at least one person who is disabled, chronically ill, or cognitively impaired. As a caregiver you were a huge asset to this study.

You were asked to complete a consent form and demographic information sheet before the study and stress-related symptoms questionnaires before and after the study. The study entails you using a device that is FDA approved to reduce stress, depression, insomnia, and anxiety. You were required to use it for 60 minutes a day for 3 weeks. The device is palm size, functional, and mobile, allowing for easy use. Using this device will not get in the way of caregiving responsibilities.

There is no cost to you for participating in the study. However, you may experience benefits of relief from stress and anxiety symptoms. For participating in the study, you were entered in a drawing for a $50 VISA gift card.

If you are willing to participate, please suggest a day and time when we can meet, and I will make myself available to you. If you have any questions, please don’t hesitate to ask. I can be reached at (713) 452-0614.

Thank you,

Reginald Jefferson, Ph.D. Candidate, St. Mary’s University

Appendix D

Informed Consent for Participation

St. Mary's University

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Title:	An Examination of Cranial Electrotherapy Stimulation (CES) on Depression and Anxiety Symptoms of Caregivers.
Principal Investigator:	Reginald Jefferson, MS, MA, NCC, LPC-S, LMFT Department of Counseling and Human Services St. Mary's University (713) 452-0614

I am being asked to participate in the above-named project. My participation in this study is entirely voluntary and I may refuse to participate or may decide to cease participation once the study has begun. Should I withdraw from this study, which I may do at any time, or should I refuse to participate in the study, my decision will involve no penalty or loss of benefits to which I am otherwise entitled. I am being asked to read the consent form carefully and were given a copy of it to keep. I was told the purpose of the study was to attempt to determine the effectiveness of an alternative method for reducing stress-related depressive and anxiety symptoms in caregivers.

I was also informed of the following research procedures: First, I were asked to fill out a demographic information sheet about age, gender, ethnicity, marital status, work status, type of caregiver, length of time in a caregiver role, illnesses of care recipient(s), and annual income. Next, I were asked to fill out the State-Trait Anxiety Inventory and Beck's Depression Inventory to assess for anxiety and depressive symptoms that I experience. I will then be randomly assigned to one of two groups: active

Appendix D (cont.)

treatment and sham treatment. Neither I nor the researcher will know which group receives the active

treatment. I am asked to follow the treatment protocol of use, which is one hour per day each day for three consecutive weeks.

Every effort was made to maintain the confidentiality of my study records. I have been specifically told that the information gathered in this study were coded to protect my privacy and confidentiality. All data were coded with the number assigned to me at the beginning of the study. The list pairing participant names and participant numbers were kept separate from the data and will only be available to the principal investigator, Reginald Jefferson, MS, MA, LPC-S, LMFT.

I have been advised that the data collected from the study were used for educational and publication purposes; however, I will not be identified by name. The confidentiality of the data was maintained within allowable legal limits. I have been told that the investigator has the right to withdraw me from this study at any time.

The investigator has offered to answer all my questions. If I have additional questions during the course of this study about the research or any related issue, I may contact the principal investigator, Reginald Jefferson MS, MA, LPC-S, LMFT at (713) 452-0614 or via email reginaldjefferson@Stmarys.edu or you may contact Melanie Harper, Ph.D., St. Mary's University, (210) 438-6400.

Appendix D (cont.)

My signature below acknowledges my voluntary participation in this research project. Such participation does not release the investigator, institution, or sponsor from their professional and ethical responsibilities to me. I have read the information provided above and had my questions answered to my satisfaction. I voluntarily agree to participate in this study. After it is signed, I will receive a copy of this consent form.

____
Name (Print)

____ ____________________
Signature of Participant Date

____ ____________________
Signature of Principal Investigator Date

If you have any questions about your rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary’s University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu. ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT ST. MARY'S UNIVERSITY ARE GOVERNED BY THE REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT.

Appendix E

Demographic Questionnaire

ID # ________________

Please do not write your name on this form. It were stored separately from any other information that you complete during this study and will not be linked with your responses in any way. The information will allow us to provide an accurate description of the sample.

For the following items, please select the *one* response that is most descriptive of you or fill in the blank as appropriate.

Age: __________

Gender:

- ○ Male
- ○ Female
- ○ Other

Ethnicity:

- ○ Asian or Pacific Islander
- ○ Black/African American (Non-Hispanic)
- ○ Native American
- ○ Latino/Hispanic
- ○ Asian Indian
- ○ Caucasian/White
- ○ Puerto Rican
- ○ Other________________________________

Appendix E (cont.)

What is your marital status?

○ Single
○ Cohabitating with partner/significant other
○ Married
○ Divorced
○ Widowed
○ Other

Work Status:

○ Part-Time
○ Full-Time

What type of caregiver are you?

○ Informal caregiver
○ Formal caregiver

How long have you been in your caregiving role?

○ Less than 2 years
○ Two to 5 years
○ Greater than 5 years

To what chronic illnesses do you provide care?

○ Alzheimer’s Disease
○ Dementia
○ Vascular Dementia

Appendix E (cont.)

○ Cerebrovascular Accident (CVA) / Stroke
○ Cancer
○ Congestive Heart Failure
○ Mental Illness/Mental Retardation
○ HIV/AIDS
○ Other

What is your annual income (Or combined income if you are married/cohabitating)?

○ Less than $30,000
○ $31,000 to $39,000
○ $40,000 to $ $49,000
○ $50,000 to $59,000
○ $60,000 to $69,000
○ $70,000 to $79,000
○ $80,000 to $89,000
○ $90,000 to $99,000
○ $100,000 and above

.

Appendix F

State-Trait Anxiety Inventory Sample and Permission Letter

For use by Reginald Jefferson only. Received from Mind Garden, Inc. on March 28, 2015

Self-Evaluation Questionnaire

STAIAD Short Form Y-1

Please provide the following information:

Name	Date
Age	Gender (Circle) M F Other

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best. Use the following scale:

1) NOT AT ALL 2) SOMEWHAT 3) MODERATELY SO 4) VERY MUCH SO

1. I feel calm.. 1 2 3 4
2. I am tense... 1 2 3 4
3. I feel at ease... 1 2 3 4.
4. I am presently worrying over possible misfortunes 1 2 3 4
5. I feel frightened.. 1 2 3 4

.

Appendix F (cont.)

For use by Reginald Jefferson only. Received from Mind Garden, Inc. on March 28, 2015

To Whom It May Concern,

The above-named person has made a license purchase from Mind Garden, Inc. and has permission to administer the following copyrighted instrument up to that quantity purchased:

State-Trait Anxiety Inventory for Adults

The four sample items only from this instrument as specified below may be included in your thesis or dissertation. Any other use must receive prior written permission from Mind Garden. The entire instrument may not be included or reproduced at any time in any other published material. Please understand that disclosing more than we have authorized will compromise the integrity and value of the test. Citation of the instrument must include the applicable copyright statement listed below.

Sample Items**:**

I feel at ease
I feel upset
I lack self-confidence
I am a steady person

Copyright © 1968, 1977 by Charles D. Spielberger. All rights reserved in all media.
Published by Mind Garden, Inc. www.mindgarden.com
Sincerely,

Robert Most
Mind Garden, Inc.

Appendix G

CES Training Protocol

Cranial Electrotherapy Stimulation Training Protocol

1. You are asked to complete the 3-week protocol by using your device each day consecutively for the entire 3-week period.
2. The CES device has been preset to run for 60 minutes each time you use it.
3. The manufacturer has preset each device to be active or sham as this is part of the blinding process. Until the study ends, the researcher does not know which devices are set to be active or sham.
4. To use your device, place one drop of saline solution on each ear clip.
5. Place an ear clip on each ear lobe
6. Turn device on.
7. Press Start and let run for 60 minutes.
8. After the device shuts off, remove the clips from your ear lobes.
9. Record daily participation on the tracking sheet.
10. Repeat steps 4-9 daily for 3 weeks.

Vita

REGINALD JEFFERSON, M.A., NCC, LPC-S, LMFT

Education

St. Mary's University - San Antonio, Texas
June 2005 – Present
Doctor of Philosophy in Counseling Education and Supervision student
Specializations in Neurofeedback and Play Therapy
Master of Arts in Community Counseling, Graduated December 2008

Prairie View A&M University - Prairie View, Texas
Master of Science in Human Sciences, Graduated May 2002
Bachelor of Science in Biology, Graduated December 1997

Work Experience

IAH Secure Adult Detention Facility / MTC Medical, Inc. – Livingston, Texas
October 2016 – Present
Mental Health Professional: Oversee all behavioral health programming at IAH Secure Adult Detention Facility. Provide diagnostic behavioral health assessments, treatments plans, and counseling services to ICE detainees in custody and housed at the facility. Provide reports and statistical information to detention facility administrative staff.

United Behavioral Health – Houston, Texas
March 2014 – Present
Care Advocate: A&T Provider Line collaborates with providers and facilities to define precipitants, symptoms, recovery and resiliency needs, desired outcomes and interventions. Determine appropriate levels of care placement based on clinical presentation and risk factors. Conducts focused facility-based reviews effectively and efficiently. Gather consistent clinical information to assess clinical needs. Obtain bio-psychosocial data and co-morbid conditions. Identify needed resources. Demonstrate clinically sound judgment by appropriately authorizing the level of care based on clinical presentation, risk factors, Coverage Determination or Level of Care Guidelines. Initiate discharge planning.

The Bair Foundation – Houston, Texas
June 2012 – February 2013
Therapist: Provide therapeutic services to children, adolescents, adults, and families with mental health issues in the home of the client. Facilitated therapeutic services in accordance to the Bair Foundation's mission and values. Completed diagnostic behavioral health assessments, develops behavioral health treatment plans, performs clinical back-up and administrative duties in the absence of the Director or Supervisor.

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Banyan Tree Family Counseling Center – Houston, Texas
January 2011 – Present
Owner/Therapist: Oversee the daily activities of the counseling center including, but not limited to operations, marketing, strategy, financing, and compliance with safety regulations, sales, and public relations. Provide counseling and mental health wellness services to individuals, families, children, and couples to help them resolve crisis and concerns as well as find balance in mental health status.

Cypress Creek Hospital – Houston, Texas
February 2009 – April 2012
Therapist*:* Provide counseling services to individuals, families, and groups regarding mental illness. Develop treatment plans, completes psychosocial history, and perform other case management duties for assigned patients. Attends team and therapy meetings when appropriate and provide consultation to treatment team including psychiatrists and other clinical staff. Interfaces with Utilization Review on a regular basis to determine patient treatment needs within managed care counseling.

Family Time Foundation, Inc. - Humble, Texas
January 2006 – July 2011
Therapist: Provide outreach and counseling services individuals, couples, children, and families in crisis. Instruct parenting workshops to couples going through divorce involving children and those who have lost their children to Child Protective Services.

Fort Bend County Juvenile Detention Center - Richmond, Texas
August 2004 - January 2005
Counselor*:* Provide counseling services to detainees and their families. Conducted and facilitated group counseling sessions with emphasis on cognitive modification and relaxation techniques. Interviewed and evaluated all individuals for specific services needed. Report findings to detention center staff and court personnel.

Mental Health Mental Retardation Authority of Harris County - Houston, Texas
October 2002 - March 2004
Service Coordinator: Provided mental health services that include, but not limited to: treatment plan implementation, counseling and therapy, group facilitating, referral, linkage, service coordination, rehabilitative services, and community outreach to juvenile and adult ex-offenders (ages 16-adult) with a diagnosis of mild to severe and persistent mental illness. Provide training and support to both clients and their family members in the areas of homelessness, interpersonal skill limitations, medical issues, and all other stress related issues.

Teaching Experience

University of Phoenix Online - Houston, Texas
January 2006 – December 2009
Faculty: Provide online guidance and counseling to students while teaching courses in the areas of Child Development, Adult and Family Development, and Professional, Ethical, and Legal Issues in Human Services.

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Publications

St. Mary's University – San Antonio, Texas
January 2010 – Present
<u>Dissertation in Process:</u> EXAMINATION OF CRANIAL ELECTROTHERAPY STIMULATION (CES) ON DEPRESSIVE AND ANXIETY SYMPTOMS OF CAREGIVERS: A Double-Blind Experimental Study