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DOCTOR OF NURSING PRACTICE (DNP) PROGRAM

A DNP PROJECT

TITLE: The Implementation of the Generalized Anxiety Disorder-7 (GAD-7) Screening Tool in Primary Care

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Abstract

Purpose of Project: The aim of the DNP project was to improve early detection of Generalized Anxiety Disorder in the primary care setting by routine screening of adult patients with the Generalized Anxiety Disorder -7 (GAD-7) screening tool.

Methodology: The project was conducted at two different primary care practices located in Budd Lake, New Jersey and Freehold, New Jersey. It began with a one-month preintervention chart review to examine the number of patients identified with Generalized Anxiety Disorder. Then, twenty-five participants from each site, regardless of their chief complaint, completed the GAD-7 survey. Majority of participants were middle-aged Caucasian men.

Results: Eight percent of participants scored an eight or higher on the screening tool thus prompting a discussion with their provider.

Implications for Practice: The project demonstrated the importance of utilizing the GAD-7 tool in primary care to address underdiagnosis and undertreatment of this disease, which in turn may improve medical, mental, and quality of life outcomes.

Keywords: Generalized Anxiety Disorder, GAD-7, Screening, Screening Tool

Introduction

Affecting approximately 40 million adults in the United States, anxiety disorders are the most common form of mental illness among adults. Of that, 6.8 million adults, or 3.1% of the population, in the United States suffers from Generalized Anxiety Disorder. Although a treatable condition, only 36.9% of those suffering seek and receive treatment ("Facts & Statistics," 2018). Generalized Anxiety Disorder can begin gradually and intensify over one's lifespan, making early detection a key component in treatment. In order to improve early detection and prompt initiation of treatment, all adults, regardless of chief complaint, should be screened for Generalized Anxiety Disorder in the primary care setting.

Background and Significance

Apprehension, uncertainty, and stress are common feelings to have as a part of everyday life. Generalized Anxiety Disorder is distinguished by disproportionate and persistent worry about various things when there is little or no cause for concern ("Understanding the Facts: Generalized Anxiety Disorder (GAD)," 2018). Becoming excessively worried and overwhelmed about work, money, family, and health are indicative of Generalized Anxiety Disorder. Those suffering from Generalized Anxiety Disorder worry more than seems necessary about actual or anticipated situations and have difficulty controlling their worry ("Facts & Statistics," 2018). To differentiate between Generalized Anxiety Disorder and normal anxiety or worry, a person suffering from Generalized Anxiety Disorder experiences symptoms and the inability to control their worry on more days than not for six months ("Understanding the Facts: Generalized Anxiety Disorder (GAD)," 2018). Additionally, Generalized Anxiety Disorder is unmanageable worry that is overwhelming, disabling, and interferes with every

day activities. Effective treatment for Generalized Anxiety Disorder exists, however; early detection is a key component to improving the lives of those suffering.

Generalized Anxiety Disorder is approximately twice as common in women than it is in men and is the most common anxiety disorder among the elderly (Baldwin, 2018). Prevalence of Generalized Anxiety Disorder tends to decrease in men overtime, however, increases in women (Kavan, Elsasser, & Barone, 2009). Epidemiologic studies have shown that the lifetime prevalence of Generalized Anxiety Disorder is approximately 11.9 percent in the United States (Baldwin, 2018). Those suffering from Generalized Anxiety Disorder at an early age of onset have a more extensive and complicated course that contributes to other mental illness comorbidities, including depression (Baldwin, 2018). Predictors of Generalized Anxiety Disorder include female sex, chronic physical or mental illness, parental loss, limited childhood support, and history of mental illness among parents (Baldwin, 2018). Others predictors include, unmarried status, lower education level, and presence of life stressors (Locke, Kirst, & Shultz, 2015). Additionally, the median age of Generalized Anxiety Disorder is thirty years of age, although onset can occur at various ages (Locke et al., 2015).

Currently, annual screening for depression with the Patient Health Questionnaire (PHQ-9) in adults is covered by Medicare; inclusive of an evaluation and management bundle (Physicians, 2012). Depression screenings are considered preventative treatment and are commonly completed in private practice offices by a health care provider (Physicians, 2012). In many cases of Generalized Anxiety Disorder, comorbidities such as depression and additional anxiety disorders have been accompanied by Generalized Anxiety Disorder. A nationally represented survey of adults in the United States showed that 66 percent of those suffering with Generalized Anxiety Disorder had at least one other coexisting disorder (Baldwin, 2018). Disorders included social phobia with approximately 34.4 percent of those surveyed; specific phobias with 35.1 percent; and panic disorder with approximately 23.5 percent

(Baldwin, 2018). Major depression along with Generalized Anxiety Disorder are associated with a poorer prognosis, have a more relentless and prolonged course of illness, and have more severe functional impairment (Baldwin, 2018). The National Comorbidity Survey also found that those with Generalized Anxiety Disorder as well as major depression were undoubtedly more likely to meet the criteria of Generalized Anxiety Disorder ten years later as evidenced by follow up studies (Baldwin, 2018). Patients, however, are not screened for Generalized Anxiety Disorder as it is not a requirement for healthcare providers, patients go undiagnosed and untreated, therefore creating a longer and more difficult recovery.

Untreated Generalized Anxiety Disorder leads to functional impairment, similar to that seen in major depression (Baldwin, 2018). Findings show that Generalized Anxiety Disorder develops separately of major depression, however, effects of Generalized Anxiety Disorder are comparable to that of major depression (Baldwin, 2018). Generalized Anxiety Disorder causes distress, physical symptoms, sleep disturbances, restlessness, muscle tension, chronic headaches, and gastrointestinal symptoms (Locke et al., 2015). Patients who are suffering from Generalized Anxiety Disorder may present to primary care facilities with complaints of headaches or gastrointestinal pain and be sent for further testing and work up. This creates time lost for the provider and patient as well as higher healthcare costs for unnecessary testing. While studies prove the need for screening all patients for depression in the primary care setting, as well as findings consistent with Generalized Anxiety Disorder being just as debilitating as depression, little has been done to necessitate the need for Generalized Anxiety Disorder screening in primary care.

Current treatment for anxiety includes pharmacologic and non-pharmacologic treatment. Non pharmacological treatment includes yoga, meditation, guided imagery, deep breathing exercises, stress management techniques, psychotherapy, support groups, and cognitive behavior therapy.

Pharmacologic treatment includes antidepressants and anxiolytics. However, there is a rise of opioid abuse which leads to substance misuse. Those suffering from anxiety are at risk of developing depression and other mental health disorders and are at an even greater risk for substance abuse and overdose. Early detection of Generalized Anxiety Disorder will decrease the risk of the development of additional mental health disorders or substance abuse disorders.

Generalized Anxiety Disorder is associated with self-medicating with alcohol and drugs as well as suicidal ideation (Kavan et al., 2009). Anxiety disorder sufferers have been found to be two to three times more likely to have alcohol or substance abuse disorders over their lifespan as compared to the overall population ("Understand the Facts: Substance Use Disorders," 2018). Additionally, approximately 20 percent of Americans with an anxiety disorder have an alcohol or substance abuse problem ("Understand the Facts: Substance Use Disorders," 2018). Those suffering from Generalized Anxiety Disorder may use substances such as drugs and alcohol to alleviate symptoms of anxiety and feelings of constant excessive worry. Since symptoms of Generalized Anxiety Disorder may mimic those of alcoholism or drug abuse, it is difficult to determine where one illness begins and ends. When Generalized Anxiety Disorder goes undiagnosed, severe complications associated with substance abuse may escalate causing more severe symptoms and debilitating behavior.

Generalized Anxiety Disorder is connected to poor cardiovascular health, coronary heart disease, and cardiovascular mortality. Generalized Anxiety Disorder has been shown to cause diminished heart rate variability as well as prolonged elevated heart rates (Baldwin, 2018). Additionally, Generalized Anxiety Disorder has been linked to elevated blood pressure, an increase in hypertension diagnoses, and an increase in antihypertensive medication use in those who are not truly suffering from hypertension or coronary heart disease (Baldwin, 2018). The misdiagnosis of Generalized Anxiety Disorder has led to over prescribing of medications that were unnecessary.

Further, results of a ten-year cardiovascular mortality study showed that current Generalized Anxiety Disorder predicted greater cardiovascular mortality independently of other metabolic syndromes and cardiovascular risk factors (Butnoriene et al., 2015). The literature also reveals a growing relationship between Generalized Anxiety Disorder and coronary heart disease. There is a strong association between Generalized Anxiety Disorder, coronary heart disease, and heart rate variability that have been proven to be instrumental in cardio pathogenesis and the negative impact on cardiovascular functioning (Tully, Cosh, & Baune, 2013). Three studies proved the link between Generalized Anxiety Disorder and poor prognosis of coronary heart disease, independent of depression; while additional literature revealed Generalized Anxiety Disorder was associated with fatal and nonfatal coronary heart disease in otherwise healthy adults (Tully et al., 2013).

The GAD-7 is a validated diagnostic tool used to screen and assess severity of Generalized Anxiety Disorder. The GAD-7 scale was developed and validated based on DSM-IV criteria and has been proven clinically useful in aiding the diagnosis of Generalized Anxiety Disorder (Locke et al., 2015). The GAD-7 is a simple seven question, self-report, screening tool that is easily administered to screen for Generalized Anxiety Disorder. The higher a patient score on the GAD-7, the more functional impairment the person may suffer (Locke et al., 2015). A score of eight or higher represents a realistic cut off when screening for Generalized Anxiety Disorder ("Generalized Anxiety Disorder 7-item (GAD-7)," 2019). This is due to a 92% sensitivity and 76% specificity when using a cut off score of 8 to diagnose Generalized Anxiety Disorder ("Generalized Anxiety Disorder 7-item (GAD-7)," 2019). The GAD-7 has an overall sensitivity of 89% and specificity of 82%, with a positive likelihood ratio of 5.1 ("Generalized Anxiety Disorder 7-item (GAD-7)," 2019). While some may argue that the Penn State Worry Questionnaire is also useful in aiding in the assessment and diagnosis of Generalized Anxiety Disorder, evidence shows that it is less sensitive than the GAD-7 (Baldwin, 2018).

Needs Assessment

Generalized Anxiety Disorder is one of the most common mental health disorders that is seen in primary care settings and is associated with an increased use of health services and cost, however; Generalized Anxiety Disorder is underdiagnosed and undertreated (Baldwin, 2018). Approximately 58% of people diagnosed with Generalized Anxiety Disorder go untreated (Patel & Fancher, 2013). Generalized Anxiety Disorder causes decreased life satisfaction, decreased work productivity, and an increase in health-related problems (Patel & Fancher, 2013). Evidence suggests that misdiagnosis of Generalized Anxiety Disorder is high due to symptoms often being described as physical causes (Locke et al., 2015). The utilization of the GAD-7 screening tool can improve misdiagnosis and initiate prompt interventions and treatment.

Mental health disorders as well as substance abuse disorders are under-reported making it difficult to determine the true prevalence and disease burden. Underreporting also makes it difficult to determine the true economic cost of mental health disorders. In 2016, anxiety disorders accounted for four percent of the global population equating to approximately 275 million people (Ritchie & Roser, 2018). This made anxiety disorders the most prevalent mental health or neurodevelopmental disorder globally (Ritchie & Roser, 2018). In 2017, anxiety disorders ranked seventh on health problems that cause the most disability in the United States ("United States," 2018). The Institute for Health Metrics and Evaluation, ranked anxiety disorders eighth in New Jersey for problems that cause the most disability from 2007 to 2017 (2019). Alcohol use disorder and drug use disorder often accompany anxiety disorders and is an important risk factor for those suffering from Generalized Anxiety Disorder. Alcohol use disorder accounted for 1.4% of the global population or 100 million people while drug use disorder accounted for 0.9% of the population or 62 million people in 2016 (Ritchie & Roser, 2018).

Those suffering from mental health comorbidities, such as depression and anxiety, are more likely to experience opiate use disorder and overdose (Prevention, 2016). The Centers for Disease Control and Prevention also reported that those suffering from anxiety disorders are more likely to be prescribed benzodiazepines (2016). Benzodiazepines can exacerbate opioid induced respiratory depression and increase the risk of overdose. The prevention and early detection of Generalized Anxiety Disorder has the potential to decrease the need for benzodiazepine therapy, thus decreasing the risk of opioid induced respiratory depression and possible overdose.

Generalized Anxiety Disorder is associated with significant healthcare related economic burden. Approximately $42 billion annually, or one third of the total health expenditures in the United States, is attributed to anxiety disorders (Kehoe, 2017). One study revealed that the median cost for patients with Generalized Anxiety Disorder was $2,375 compared to $1,448 for patients without Generalized Anxiety Disorder (Kehoe, 2017). The longer it takes to diagnose and treat those suffering from Generalized Anxiety Disorder, the more it will cost in the long run. The implementation of the GAD-7 screening tool in primary care will help to decrease subsequent health, functioning, and economic impacts associated with misdiagnosis of Generalized Anxiety Disorder.

Problem Statement

Generalized Anxiety Disorder is associated with many complications including impaired mental and physical health, impaired social functioning, inability to achieve daily activities, as well as physical pain (Kavan et al., 2009). Despite the various screening tools available, it is not mandated to screen for Generalized Anxiety Disorder in the primary care setting. Although patients report feelings of anxiety to their primary care physician, Generalized Anxiety Disorder remains undetected and undertreated. Improved detection of Generalized Anxiety Disorder is critical in improving problems

with underdiagnosing and undertreating Generalized Anxiety Disorder. Interventions that focus on early detection will lead to decreased healthcare costs, improved patient outcomes and quality of life.

Clinical Question

The clinical question that guided the project was: Does routine screening with the Generalized Anxiety Disorder 7 item scale (GAD-7) administered to patients 18 years of age and older, regardless of chief complaint, increase early diagnosis of Generalized Anxiety Disorder in comparison to no screening at all?

Aims and Objectives

The aim of the project was to improve early detection of Generalized Anxiety Disorder within the adult primary care patients. In order to achieve this aim, objectives and several goals were met:

1. Initiate evidence based Generalized Anxiety Disorder-7 screening tool in the primary care setting
2. Administer the Generalized Anxiety Disorder-7 scale (GAD-7) Screening tool to all adults 18 years of age and older in the primary care setting regardless of chief complaint
3. Compare data from two geographically different sites
4. Offer educational materials on Generalized Anxiety Disorder in order to improve understanding of the illness as well as ways to effectively manage feelings of anxiety, sources of more information, and resources available

Review of Literature

An extensive review of current literature was performed to support the implementation of routine screening with the Generalized Anxiety Disorder 7 item scale (GAD-7) in primary care.

Electronic data bases including Pubmed, OVID, CINAHL, PsycINFO, UpToDate, and EBSCO were searched to identify research that supports the implementation of the GAD-7 screening tool. Key words used to search the databases included *"GAD7"*, *"GAD-7"*, *"GAD7 in primary care"*, *"GAD-7 screening"*, *"validity*", *"generalized anxiety disorder screening"*, *"anxiety"*, *"generalized anxiety disorder"*, *"anxiety screening tools"*, and *"impact of anxiety"*. Articles considered for inclusion were published between dates occurring from 2006 through current.

The studies analyzed were conducted in different outpatient clinical settings, with one study including the emergency department and one in the household setting. The studies were also conducted throughout various countries including Spain, Germany, Finland, United Kingdom, Iran, Italy, and the United States. Additionally, all studies (except for one that studied patients 14 years of age and older) had a sample study population of at least 18 years of age or older. The Johns Hopkins Evidence Based Practice Model was used to evaluate the level of evidence and quality of the studies. Most of the studies were placed into levels I and III. The articles used for consideration provided a substantial amount of evidence of the reliability and validity of the GAD-7 as a screening tool to be used in the early detection of Generalized Anxiety Disorder. Other themes included the prevalence of Generalized Anxiety Disorder, the economic relationship and impact of Generalized Anxiety Disorder, comorbid conditions, as an outcome measure of disability, anxiety correlations, and interventions. Each of the studies limitations are listed out in the Table of Evidence, see Appendix B.

Validity & Reliability

Generalized Anxiety Disorder is frequently chronic and often undiagnosed, however, patients experiencing Generalized Anxiety Disorder typically present with somatic symptoms in primary care settings. N. Herr and colleagues performed a systematic review in order to accurately identify the most

precise screening tools for Generalized Anxiety Disorder in order to improve early detection and support early intervention. After an in-depth review of 76 articles with low risk bias, nine screening instruments were identified. The studies all included patients 18 years of age and older that were treated in primary care settings, geriatric clinics, women's health clinics, and emergency departments (Herr, Williams Jr., Benjamin, & McDuffie, 2014). Of the nine screening tools identified, the GAD-7 was the best performing. With a cutoff point of greater than or equal to 10, the GAD-7 had a sensitivity of 89%, specificity of 83%, and the highest LR+ (5.1; 95% Cl, 4.3-6.0) out of all screening tools (Herr et al., 2014). The GAD-7 also had the highest test retest reliability with an intraclass correlation of 0.83 (Herr et al., 2014). This study revealed that the GAD-7 is the most efficient, reliable, and easy to use screening tool in the primary care setting. As Generalized Anxiety Disorder goes underdiagnosed and misdiagnosed, the implementation of the GAD-7 is the most accurate tool to implement in primary care.

In a unique study the objective was to identify if there was a prevalence of anxiety disorders, impairment and comorbidities, as well as evaluate the use of the GAD- 7 scale. The study found anxiety disorders were indeed prevalent and debilitating as well as being untreated in the primary care setting (Kroenke, Spitzer, Williams, O. Monahan, & Lowe, 2007). Of the 965 patients, 19.5% had at least one anxiety disorder (95% CI, 17.0% to 22.1%) and 7.6% had Generalized Anxiety Disorder (CI, 5.3% to 9.4%) (Kroenke et al., 2007). Additionally, 41% of patients with anxiety disorder reported no current treatment (Kroenke et al., 2007). The study found positive validity in the GAD- 7 scale, however, the study of 965 random patients in fifteen primary care clinics had limitations of non-random sampling of select primary care patients.

Many studies have been performed to determine the validity of the GAD-7 to screen and diagnose Generalized Anxiety Disorder according to the DSM-IV criteria. In a study performed by

Kujanpaa et al., 286 patients, considered "high utilizers of healthcare", were administered the GAD-7. The study was conducted in four outpatient health centers in Northern Finland. Participants had to be over the age of 18 and have at least eight visits per year to their general health practitioner or four or more visits per year to the University Hospital (Kujanpaa et al., 2014). Exclusion criteria included pregnancy/delivery, consecutive treatment for same illness, cancer, hospice, patients with a history of mental illness, mental retardation, and inability to give informed consent (Kujanpaa et al., 2014). The study resulted in 100.0% sensitivity of GAD-7 and specificity of 82.6% of the GAD-7 in which the cutoff point was a score of seven or greater on the screening tool scale (Kujanpaa et al., 2014). ROC analysis was performed and proved that the area under the curve for the GAD-7 was 0.96 (95% CI 0.91-1.00) (Kujanpaa et al., 2014). The overall results of the study proved the usefulness of the GAD-7 for early detection of Generalized Anxiety Disorder among primary healthcare patients as well as its usefulness for diagnosis among high utilizer patients.

While mental health disorders affect nearly 61.5 million people in Europe; in Spain, approximately 9.4% of the population suffers from anxiety disorders with a one year prevalence of 5.7% (Munoz-Navarro et al., 2017). Out of the numerous types of anxiety disorders, Generalized Anxiety Disorder is the most common found in primary care settings (Munoz-Navarro et al., 2017). In a study performed by Munoz-Navarro and colleagues, the use of a computerized version of the GAD-7 was administered to patients to detect Generalized Anxiety Disorder among Spanish primary care centers. The study was conducted among fourteen primary care settings between January 2014 and December 2014. Participants comprised of primary care patients between the ages of 18 and 65 totaling a sample of 178 participants. Once participants completed the computerized GAD-7 screening tool, they were interviewed by a trained psychologist who was blinded from the results of the GAD-7 (Munoz-Navarro et al., 2017). Each of the seven psychologists that performed the clinical interviews

were trained by senior clinical psychologists (Munoz-Navarro et al., 2017). Results of the study revealed that the GAD-7 performed well. A ROC curve analysis was performed and showed the area under the curve of .86 (Munoz-Navarro et al., 2017). A cut value of 10 on the GAD-7 screening tool had the highest sensitivity of .87 and specificity of .74, proving that the implementation of the computerized version of the GAD-7 is an exceptional screening tool for detecting Generalized Anxiety Disorder in Spanish primary care settings (Munoz-Navarro et al., 2017).

A systematic review of literature was performed to identify studies that validated the GAD-7 and GAD-2 screening tools against other methods of diagnoses, such as Structured Clinical Interviews or Revised Clinical Interviews, to diagnose Generalized Anxiety Disorder. Electronic data bases searched included MEDLINE, PsycINFO, CINAHL, and the Cochrane library. The study population included adults, ages sixteen years and older, that were administered the GAD-7 and GAD-2 questionnaires through telephone, computerized, and face to face contact, in order to screen for anxiety disorders (Plummer, Manea, Trepel, & McMillan, 2016). The systematic review yielded fourteen citations, twelve independent samples, that were eligible to include in the review (Plummer et al., 2016). In all studies, the GAD-7/GAD-2 were administered through self-report. A cutoff score of eight for the GAD-7 had the highest sensitivity and specificity balance. Heterogeneity for a cutoff score of eight was moderate (I^2=61.3%) (Plummer et al., 2016). Out of ten studies, the AUC of the GAD-7 compared to other methods of diagnosing Generalized Anxiety Disorder ranged from 0.650 (95% CI 0.590-0.730) to 0.963 (95% CI 0.942-0.984) (Plummer et al., 2016). In addition, out of the eleven studies, seven had an AUC of above 0.8 while three had an AUC above 0.9 (Plummer et al., 2016). The systematic review revealed that the GAD-7 has an increased sensitivity and specificity with cutoff points of eight or nine (Plummer et al., 2016). The GAD-7 proved to be an acceptable screening tool in the identification of Generalized Anxiety Disorder with a cutoff score greater than

seven. The systematic review revealed the profound accuracy of the GAD-7 in identifying Generalized Anxiety Disorder.

To investigate the validity and reliability of the GAD-7 not only in the primary care setting, the survey questionnaire was administered in German households between May 5th and June 8, 2006. 5,030 participants ages fourteen years and older were administered the GAD-7 screening tool. The demographic characteristics of the study closely reflected characteristics of both German and American populations because study data was compared from federal data of the entire German population as well as data from U.S. NCS-R (Lowe et al., 2008). Confirmatory analysis substantiated the one dimensional structure of the GAD-7 (Lowe et al., 2008). The study generated results showing women had significantly higher scores of Generalized Anxiety Disorder than men [3.2 (3.5) vs. 2.7 (3.2); $P<0.001$] (Lowe et al., 2008). In addition, about five percent of participants scored ten or greater on the GAD-7 scale while one percent scored fifteen or greater (Lowe et al., 2008). When taking the conciseness of the GAD-7 into consideration, the internal consistency of the GAD-7 was satisfactory ($\alpha = 0.89$) (Lowe et al., 2008).

In 2014 a second study was completed and published among 438 elderly adults between the ages of 58 and 82 living at home in Germany. Of that, 55% of participants were women and 52% of participants were 65 to 74 years of age (Wild et al., 2014). The aim of the study was to appraise the validity of the GAD-7 for detecting Generalized Anxiety Disorder in the elderly community. This was done by providing the GAD-7 during an in-home visit in the presence of the study doctor. Then, a structured clinical interview was performed by a blinded interviewer (Wild et al., 2014). With a cutoff score ten or more, the GAD-7 produced a sensitivity of 0.89 and a specificity of 0.82 in primary care patients (Wild et al., 2014). However, a cutoff score of five or greater had a sensitivity of 0.63 and specificity of 0.9 (Wild et al., 2014). Area under the curve was 0.88 (95% CI: 0.83-0.93) and

Cronbach's α for GAD-7 was 0.82 demonstrating acceptable internal consistency (Wild et al., 2014). The study proves that the GAD-7 is an acceptable tool for detecting Generalized Anxiety Disorder among the elderly population, however, cutoff points should be lower for the elderly. Evidence from both the studies supports the use of the GAD-7 as a valid and reliable screening tool to measure Generalized Anxiety Disorder in the population.

Prevalence of Generalized Anxiety Disorder

The purpose of the National Epidemiologic Survey by Mackenzie et al., (2011) was to establish a prevalence and correlation of Generalized Anxiety Disorder by incorporating Wave 2 data; which questioned 12,312 adults over the age of 55. The study also attempted to identify the prevalence of Generalized Anxiety Disorder in one year including medical comorbidities, quality of life, and chances of self-reporting of symptoms (Mackenzie, Reynolds, Chou, Pagura, & Sareen, 2011). Out of 12,312 individuals, there was a 2.8% prevalence of Generalized Anxiety Disorder with 28.3% suffering from comorbidities and 18% without (Mackenzie et al., 2011). According to this study there was a positive correlation between the importance of Generalized Anxiety Disorder treatment and improvement of quality of life. On the contrary, the investigators were unable to decipher if Generalized Anxiety Disorder was a cause or consequence of another condition, thus limiting the study. Another limitation was self-reporting of Generalized Anxiety Disorder and the diagnosis was made based off hierarchical rules (Mackenzie et al., 2011). In conclusion, there was a positive identified need for prevention latent Generalized Anxiety Disorder by screening early.

Economics

There are many economic impacts to patients diagnosed with Generalized Anxiety Disorder. In a systematic review and quality assessment performed by Bereza and colleagues, a positive correlation to major economic and humanistic impacts on patients suffering from Generalized Anxiety Disorder

was found through a review of thirty six articles (Bereza, Machado, & Einarson, 2009). The economic impacts are related to medication regimens and the presence of pain. The patients who suffered from Generalized Anxiety Disorder primarily sought help from their primary care providers. Many of the patients had comorbidities and poor quality of life scores. The review also discovered the positive relationship between Generalized Anxiety Disorder and somatic disorders such as Parkinson's Disease and Heart failure. Economic impacts were due to undertreatment and underdiagnosis of Generalized Anxiety Disorder and increased length of time before a clinical evaluation. The economic evaluations of the study addressed 55.3% to 68.4% of 38 items on a quality of life checklist (Bereza et al., 2009). Additionally, Generalized Anxiety Disorder acquired a larger marginal health care cost compared to other anxiety disorders; a difference of approximately $2,138 (Bereza et al., 2009). The study also found patients with Generalized Anxiety Disorder who suffered from severe pain incurred significantly higher healthcare costs than those with pain, but not suffering from Generalized Anxiety Disorder (Bereza et al., 2009). The review revealed a significant burden on economic and humanistic impact on patients and healthcare systems (Bereza et al., 2009).

As an Outcome Measure of Disability

The effects of Generalized Anxiety Disorder on functionality and health related quality of life are greater than that of Major Depression and associated ailments cannot be accounted for by accompanying diseases (Ruiz et al., 2011). With the initiation of the GAD-7 as a simple to use screening tool, patient and provider burden has been reduced. The objective of one study performed by Ruiz et al., was to explore the validity of the GAD-7 as an outcome measure of disability in the primary care setting. The study was also used to evaluate the functionality of Generalized Anxiety Disorder as well as the relationship between the GAD-7 and the WHO-DAS II scales in the primary care setting. The GAD-7 questionnaire was administered to a sample of 212 patients and controls

along with the Hamilton Anxiety Scale and the WHO-DAS II disability questionnaire between June 2008 and January 2009. The average age was 47.59 years while 72.6% of the participants were women. The study included participants from geographically diverse locations, different cultural and economic backgrounds as well as accounting for sex and age to match the control group. When compared to other tools, the study validated that the GAD-7 is a significant instrument for exploring patients with Generalized Anxiety Disorder, determining severity, and associating the degree of disability in areas such as self-care, interpersonal relationships, and healthcare resource utilization (Ruiz et al., 2011). Strong ($p<0.001$) correlations were made between the GAD-7 and HAM-A and WHO-DAS II predominantly in areas of participation in society ($r=0.852$), understanding communication ($r=0.679$), and life activities ($r=0.638$) (Ruiz et al., 2011). Significant associations were also made between GAD-7 score and number of primary care visits ($r=0.393$) (Ruiz et al., 2011). Finally, an overall association between GAD-7 severity levels and disability scores [$F(3,208)=25.4$, $p<0.001$] was observed with higher disability values correlating to higher severity scores (Ruiz et al., 2011). The study determined that the GAD-7 is not only a useful tool for screening for Generalized Anxiety Disorder, but also a strong predictor of functional impairment.

Comorbidities - GAD-7 Screening in Established Diseases

Generalized Anxiety Disorder may be prevalent before or after a diagnosis. A systematic review conducted between May 2015 and April 2017 found approximately twenty percent of patients post stroke endure different levels of anxiety and worry (Rafsten, Danielsson, & Sunnerhagen, 2018). The publications and references reviewed by Rafsten and colleagues, revealed that out of 13,756 stroke patients; 29% had anxiety during the first-year post stroke. Limitations to the study included occasional small sample sizes in different publications and stroke settings were all different (Rafsten et

al., 2018). However, the study revealed the importance of screening for Generalized Anxiety Disorder in stroke patients is essential in maintaining a good quality of life.

A systematic review and meta-analysis was performed to decipher the difference between individuals with diabetes and anxiety versus individuals without a diagnosis of diabetes and elevated symptoms of anxiety (Smith et al., 2013). Out of twelve studies including 12,626 people with diabetes, there was a positive and significant correlation between diabetic patients with anxiety and elevated of symptoms (Smith et al., 2013). Limitations included self-reporting of a diabetes diagnosis as well as different anxiety disorders were part of the study as opposed to narrowing in on one. However, the study found that Generalized Anxiety Disorder and panic disorder were the most common types of anxiety in the individuals with diabetes. The study also supported that diabetes is associated with an increased probability of having an anxiety disorder and increased anxiety symptoms (Smith et al., 2013).

In a longitudinal study conducted to analyze the psychometric properties of the GAD-7 scale in participants suffering from Multiple Sclerosis as well as to analyze the correlations with Generalized Anxiety Disorder, 513 participants were randomly chosen from the Greater Northwest Chapter of the National Multiple Sclerosis Society (Terrill, Hartoonian, Beier, Salem, & Alschuler, 2015). A cross sectional study was performed between April 1 and August 31, 2007 with participants all 18 years of age and older. The participants completed a four month follow up survey online (n=119) or on paper (n=394) (Terrill et al., 2015). The GAD-7 internal consistency was appraised by Cronbach α, which indicated good reliability (0.75) (Terrill et al., 2015). Internal validity and construct validity were also confirmed findings to support GAD-7 as a measure of anxiety for individuals suffering from Multiple Sclerosis. Additionally, the study exposed significant relationships between GAD-7 and demographic variables, disease related variables, and secondary symptoms (Terrill et al., 2015). The study

established that GAD-7 is a valuable screening tool of symptoms and will help improve detection of Generalized Anxiety Disorder.

Generalized Anxiety Disorder is a common ailment amongst migraine sufferers. Screening with the GAD-7 for Generalized Anxiety Disorder in patients suffering from migraines has been proven a valid instrument by a study conducted by Seo and Park (2015). 146 patients with known diagnoses of migraine headaches participated from December 2014 through May 2015 and were administered the GAD-7 questionnaire (Seo & Park, 2015). Reliability and validity of the GAD-7 was measured by a neuropsychologist who examined Generalized Anxiety Disorder using the MINI International Neuropsychiatric Interview Plus (MINI) Version 5.0.0 as well as the Beck Anxiety Inventory (BAI), the Migraine Disability Assessment Scale (MIDAS), the Headache Impact Test-6 (HIT-6), and the Migraine-Specific Quality of Life (MSQoL) (Seo & Park, 2015). Results of the study revealed an excellent internal consistency with a Cronbach's α of 0.915 (Seo & Park, 2015). ROC analysis of GAD-7 revealed area under the curve 0.849 (95% CI = 0.775-0.923; SE = 0.038; $p < 0.001$) (Seo & Park, 2015). With a GAD-7 cutoff score of five, sensitivity of 78.1% and specificity of 74.6% was achieved (Seo & Park, 2015). Valid and reliable, the GAD-7 is an excellent screening tool for Generalized Anxiety Disorder for migraine suffers.

Interventions

After the discovery of a Generalized Anxiety Disorder, interventions would need to be put in place. Of the varying interventions, the following interventions have been noted to be effective: psychotherapeutic and pharmacological treatment, non-pharmacological treatment via home-based problem solving, and cognitive behavior therapy. These interventions improve the mental wellbeing of anxiety sufferers. In one systematic review performed to review the efficacy of controlled

interventions for adults with Generalized Anxiety Disorder, revealed patients who are diagnosed with Generalized Anxiety Disorder do not follow up on their treatment plan and would benefit from a repeat screening with an appropriate screening tool (Goncalves & Byrne, 2012). The study also reported older adults to be less apt to seeking help for Generalized Anxiety Disorder, however, they are the more inclined to trying psychotherapeutic and pharmacological treatments. A second study reviewed fourteen trials with 2099 participants in the home and community setting to assess the effectiveness of a non-pharmacological intervention of problem solving in ages 60 and over (Frost, Bauernfreund, & Walters, 2018). The study reported problem solving to be effective as a non-pharmacological problem in patients with anxiety and depression.

After an extensive review and synthesis of the literature, evidence supports the implementation of the GAD-7 screening tool in primary care to aid in the early diagnosis and treatment of Generalized Anxiety Disorder.

Theoretical Framework

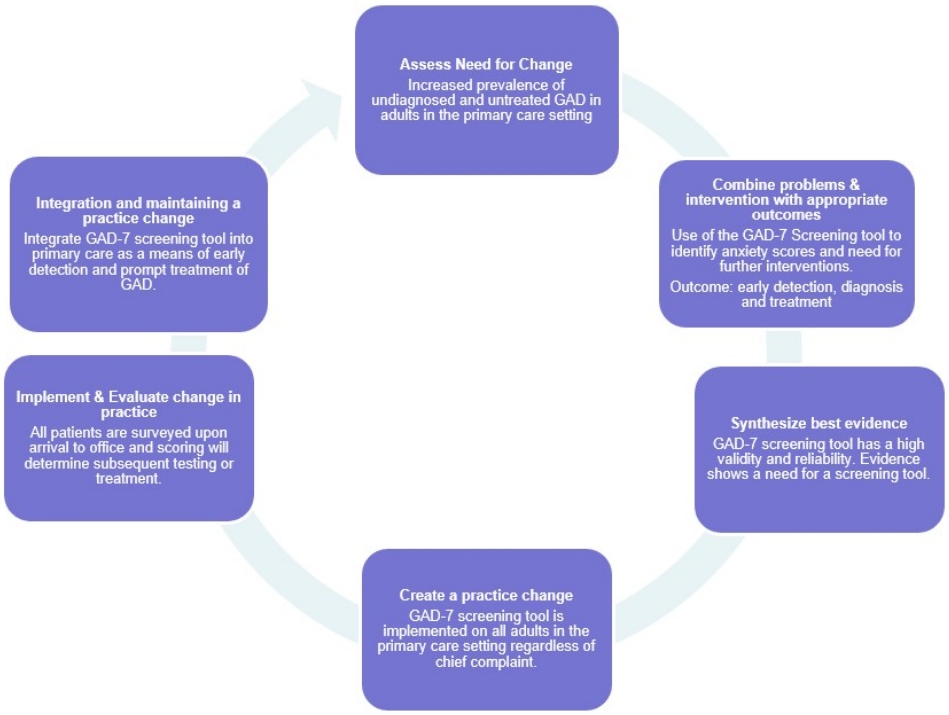
The theoretical framework that guides the project is the Model for Evidence Based Practice Change. The goal of the Model for Evidence Based Practice Change is to improve the health and safety of patients. The model is comprised of six steps. The first step is a needs assessment for practice change. This includes collecting data about the current practice and identifying the problem (Larrabee, 2004). Currently, there are no practice guidelines for the screening and management of Generalized Anxiety Disorder. Patients must self-report symptoms of anxiety, but they may not be aware that their symptoms may be consistent with Generalized Anxiety Disorder, leading to misdiagnosis and delay of treatment. The needs assessment was conducted prior to the implementation of the DNP study. Step two requires linking the problem with interventions and desired outcomes

(Larrabee, 2004). The potential interventions include utilizing a screening tool in primary care for early detection of Generalized Anxiety Disorder in primary care.

Steps three and four include synthesizing the best evidence and designing a practice change (Larrabee, 2004). A comprehensive review of literature was conducted to critique and synthesize the best current evidence. Research revealed that the GAD-7 was the most valid and reliable tool for assessing Generalized Anxiety Disorder. Planning practice change included analyzing the current practice of screening for Generalized Anxiety Disorder in primary practice, recognizing the need for change, and the implementation of the GAD-7 screening tool into primary practice regardless of the patient's chief complaint.

The fifth step includes implementing and evaluating change in practice while the sixth and final step includes integrating and maintaining change in practice (Larrabee, 2004). Step five comprises of the implementation of the GAD-7 screening tool upon patient arrival to the primary care office and being screened for Generalized Anxiety Disorder, regardless of chief complaint. Depending on the score, the patient may be recommended for additional screening and treatment. A mandatory screening tool in primary care practice can implement change within the practice by ensuring the screening of every patient to decrease the amount of undiagnosed and untreated patients. Upon completion of the study, the sixth step will be completed after evaluation and recommendation of the practice change have been made.

Conceptual Framework Image



Methodology

The purpose of the project was to describe the implementation of a Generalized Anxiety Disorder screening tool in order to screen for Generalized Anxiety Disorder. The methodology used for the project is a pre/post-intervention design. The study began with a one-month chart review to examine the number of patients identified with Generalized Anxiety Disorder that were recommended or provided additional treatment for the month prior to the implementation of the GAD-7. Following the implementation of the GAD-7 screening tool, the number of patients identified with Generalized Anxiety Disorder was calculated in a month time period post implementation. The patients who are screened positively were provided information on Generalized Anxiety Disorder as well as ways to receive help in treating the disorder.

Setting

The location of the project was in two primary care offices, [redacted] New Jersey and a private practice in Freehold, New Jersey.

Study Population

The study population included the primary care clinicians and 50 patients, 18 through 64 years of age, seen at the primary care offices regardless of their chief complaint. The sample population included established and new patients of any race, ethnicity, gender, educational level, or marital status, that are cognitively intact. Patients also were included regardless of insurance provider or self-pay and must have been able to read and write in English. Excluded from the study were patients who had a history or prior diagnosis of Generalized Anxiety Disorder.

Study Interventions

The study intervention began with provider education on the purpose and benefits of the GAD-7 in primary care. A chart review was conducted for the month prior to the implementation of the project, August 2019 through September 2019, to determine how many patients were diagnosed with Generalized Anxiety Disorder prior to the use of the screening tool. The study interventions included administering the GAD-7 screening tool to patients upon their arrival to the medical office. Patients filled out the screening tool and those patients who scored an eight or higher were provided with educational materials on Generalized Anxiety Disorder (see Appendix) as well as treatment resources.

Outcome Measure

The purpose of the study was to analyze whether routine screening with the GAD-7 would increase early detection of anxiety. The dependent variable was the number of patients scoring an eight or greater on the GAD-7 after the GAD-7 was administered in the primary care setting. The

GAD-7 scores were analyzed using bivariate analysis of the screening tool as well as the covariates or independent variables (age, gender, etc.). The outcomes to be measured included:

- The number of patients screened for GAD
- The score of each patient's screening tool
- The number of patients receiving patient education
- The number of patients who were positively screened for Generalized Anxiety Disorder within one month compared to the previous month

Risks or Harms

There were no significant risks in participating in the project. There was a potential low risk in the disclosure of personal information which was minimized by ensuring each patient, including all personal data, be exchanged as early as possible to a coding system via an excel document on a password protected computer, properly and securely stored, and destroyed in accordance with Rutgers IRB data removal once coding was correctly completed. The information can only be accessed by the investigators of this project. There was a low potential psychological risk in which patients may be triggered by uninformed perceptions towards anxiety. There was also a low potential social risk in which patients may have felt embarrassed by the questions. Patients were reminded of confidentiality and that no judgement was made prior to signing consent. The patients were also reminded of the low risk of potential identifiers. There were no economic or physical risks for participants. Participants were reminded of their rights to protection against injury or illegal invasions of privacy and all participants were able to change their mind and refuse to answer any question on the GAD-7 screening tool as well as withdraw themselves from the study at any point in time.

Subject Recruitment

The process of recruiting was done with flyers that included a description of the study, criteria for eligibility, locations of research sites, contact information, and benefits and risks of the study. The flyers were placed in easy to view areas such as the waiting room and handed out upon patient check in to their appointments. The flyers were typed in English with little to no medical jargon or abbreviations.

Consent Procedure

The implementation of the GAD-7 is a practice change project and all eligible patients were asked to sign consent prior to participation in the project. The consent was in accordance with Rutgers IRB requirements. Participation was voluntary and all questions were answered prior to obtaining signatures on the consent form. Risks, benefits, and purpose of the DNP project was verbalized to each potential participant prior to signing the consent form.

Subject Costs and Compensation

A questionnaire was used which did not generate any costs for the practice. There was no compensation for study participants. There were no costs to the participants as the assessment tool was provided to them via pen and paper.

Project Timeline

The goal of the project was to submit for IRB approval May 2019 and begin recruitment in September 2019. The project intervention was to last for one month. After the intervention phase was completed; data analysis and interpretation were conducted. The final project dissemination and presentation will be conducted in 2020.

Resources Needed/Economic Considerations

Very little resources were needed during this project. Access to the practice and patient demographic information was needed. The questionnaire used did not generate any costs for the practices. An estimated cost of $60 for investigators included printed materials.

Data Maintenance/Security

After IRB approval was obtained, data collection was to start as soon as possible. De-identified data was collected and no patient names were disclosed on the questionnaire. Each participant was given a code. The key with the codes and completed screening tools were not kept together. Data was entered in an excel document, stored, and analyzed at the practice on a password protected computer. All screening forms were also stored in a locked box in the private practice offices and analyzed at the practices on a password protected computer. After study completion, screening forms and all related information were destroyed in agreement with Rutgers policy. Only principal investigators had access to the forms.

Data Analysis

Descriptive statistics was used to describe the study sample. The project was a pretest/ posttest in which the number of patients identified for additional assessment or treatment of Generalized Anxiety Disorder is examined pre and post intervention. Patient identifiers were not collected (name, birthdate, or medical record number). Descriptive data including; age, gender, race, marital status, education level, and employment status were analyzed. SAS statistical package was used for analysis.

Findings

The pre intervention chart review was conducted between August 1 to 31, 2019 at two primary care offices in New Jersey. Of the 240 charts reviewed at the Budd Lake office, 18 people (7.5%) were diagnosed and actively being treated for Generalized Anxiety Disorder (GAD) with none being

referred to specialists and of the 220 charts reviewed at the Freehold office, 13 patients were diagnosed and treated with two patients referred to a specialist.

In the preintervention chart review phase, the majority of the charts reviewed were male charts, 54.17% (N=130) in Budd Lake and 53% (N= 116) in Freehold. Of the charts reviewed in Budd Lake, 34.17% of patients fell into the 60-69 age range followed by 40-49, then 30-39. The Freehold location saw predominant age range of 50-59 years (26%) followed by 60-69 as the second highest. Figure 1 further describes the comparison. In both locations, the charts reviewed were predominantly Caucasian, Budd Lake with 58.33% and Freehold 62.7%. Figure 2 shows a complete breakdown of race demographics. In both locations, a majority of the charts reviewed showed patients were married; Budd Lake 44.17% and Freehold 65.5%; followed by never married as the second most frequent (Figure 3). Both locations also revealed that a majority of the charts reviewed, a larger number of people had a Bachelor's level degree; Budd Lake 41.25% and Freehold 32%, as seen in Figure 4. Over half of the charts reviewed at both locations showed full time employment status, followed by part time employment (Figure 5). Both sites revealed that patients predominantly were seen for a physical, Budd Lake 35%, Freehold 16%. A complete breakdown of reasons for the visit can be viewed in Figure 6.

In the preintervention chart review, 18 people at the Budd Lake location and 13 people at the Freehold location were diagnosed and actively being treated for Generalized Anxiety Disorder. Data from the pre-intervention chart review recognized that of the patients being actively treated for Generalized Anxiety Disorder, the Budd Lake location had a majority, 55.56% (N=10), were male compared to female (N=8) as did the Freehold site (N=8) for male and (N=5) for female. Other demographic information included that a majority of the patients at both locations were between the ages of 50-59 (N=6) for Budd Lake and (N=4) for Freehold. The sites varied by ages that followed.

Predominantly, the treated patients were Caucasian at both sites followed by African American. Additionally, a majority of the patients diagnosed and treated with GAD were married at both locations. None of the patients being treated at either location were widowed. The treated patients primarily held a Bachelors level degree, N=7, at both intervention sites. Employment status at both locations were also largely similar. Both sites showed, N=10, for full time employment while part time employment revealed (N=8) in Budd Lake and (N=3) in Freehold. None of the patients with a diagnosis and on active treatment were retired or on disability. The reasons for the office visits of those diagnosed and treated for Generalized Anxiety Disorder varied, however, patients were predominantly seen for a physical (N=6) at the Budd Lake location. Patients in the Freehold office were seen for either cough (N=2) or follow up of lab results (N=2). Of note, three of the reasons for their visit at the Budd Lake office were for anxiety. Meaning, the patients made an appointment to be seen for possible anxiety where they received some form of treatment.

The different locations of where the pre-intervention chart reviews were conducted yielded similar results in their demographic data of patients actively being treated for Generalized Anxiety Disorder. A complete breakdown between the two sites can be viewed in Table 1.

Following the implementation of the GAD-7 screening tool, the data revealed that most of the participants were women, 58%. Of the 50 participants, a majority of participants, 36%, were aged between 50-59, followed by 20% in the 30-39 age group, 16% were in the 40-49 age group and 16% were also in the 60-69 age group, and finally 12% in the 20-29 age group. Additionally, 70% were White, 12% African American, 12% Hispanic, and 6% of another race. 60% of participants were married, 28% were never married, 20% were widowed, and 10% were divorced. The most frequent educational findings showed 54% of participants held a Bachelor's degree and 36% had a High School Diploma. 84% of participants were employed full time while 10% were employed part time (Table 2).

About a quarter, 24%, of participants had a history of depression and none had a history of Generalized Anxiety Disorder. The reason for the visit to the primary care offices varied, however, a majority of the patients, approximately 26%, were for a physical exam, followed by 10% for medication checks, and 8% for preoperative clearance. A full list of reason for visit can be viewed in Table 2.

Scores of the GAD-7 screening tool, participants ranged from 0-11 (Figure 7). Of the 50 patients screened, 8% of patients resulted in a score of 8 or higher, which prompted a discussion with the provider during their office visit. Despite their GAD-7 scores, all patients were provided with a handout on identifying Generalized Anxiety Disorder, causes of Generalized Anxiety Disorder, and treatment recommendations. Women had a higher average GAD-7 score (4.3) compared to men (3.6) (Table 4). Participants who were never married averaged a GAD-7 score of 4.5 followed by married (4.1), widowed (4.0), and divorced (2.0). Participants with a graduate level education averaged a GAD-7 score of 5.5, followed by some college, high school, associate degree, and then bachelor degree (Table 4). Retired participants had a higher GAD-7 score (5.0) compared to those who worked full time, part time, or were disabled. The post intervention average GAD-7 score by characteristic can be viewed in Table 4.

Results of the GAD-7 screening tool revealed scores ranging from minimal anxiety to moderate in severity. A majority of the participants, 54%, scored minimal anxiety, while 42% scored mild anxiety. The results can be viewed in Table 3. In just one month of implementing the screening tool on various days, 8% of those that participated scored an 8 or higher on the GAD-7 screening tool, thus proving the need to incorporate the GAD-7 screening tool into routine office visits. Had those patients not been screened, an opportunity would have been missed to educate or treat these patients for Generalized Anxiety Disorder.

Overall demographics between the two different locations post intervention were largely similar. The gender of respondents, however varied. In Budd Lake, 68% of the respondents were female, while Freehold had more than half of its respondents, 52%, were male. Both sites had an overwhelming number of Caucasian participants, 76% in Budd Lake and 64% in Freehold. The majority of respondents between the sites fell between the ages of 50-59 years old, 32% in Budd Lake and 40% in Freehold. Of the respondents, 64% in Budd Lake and 56% in Freehold were married. More than half of the participants in the post intervention stage held a Bachelors level degree, 56% in Budd Lake and 52% in Freehold. High school diploma followed as the second highest degree held between the sites, 28% of respondents from Freehold and 44% of respondents in Budd Lake. Employment status results mirrored each other both 84% in both Budd Lake and Freehold. The reasons for the patients visit varied between the two sites, however, the majority of patients were for physicals, 24% Budd Lake and 28% in Freehold. The characteristics of respondents between both sites was fairly uniform, however, the post intervention demographic comparisons between both sites is further broken down in Table 5.

The average Generalized Anxiety Disorder severity between both locations also was unwavering. A majority, 56% in Budd Lake and 60% in Freehold, scored between 0-4 on the GAD-7 scale, resulting in minimal severity of Generalized Anxiety Disorder. Mild anxiety was the second most prevalent at both sites (Table 6). None of the participants in Budd Lake scored moderate anxiety, however, 8% of respondents in Freehold scored moderate anxiety on the GAD-7 scale. A full comparison of post intervention GAD-7 scores is accounted for in Figure 8. The mean GAD-7 score in Budd Lake was 3.88 (with a standard deviation of 2.26) while the mean score in Freehold was 4.08 (with a standard deviation of 2.84).

Women averaged a higher GAD-7 score and both sites were largely similar, 4.2 in Budd Lake and 4.3 in Freehold. Males averaged a GAD-7 score of 3.1 in Budd Lake and 3.8 in Freehold. Those who were never married averaged a higher GAD-7 score in Budd Lake, 5.0, while those who were married in Freehold averaged a higher GAD-7 score, 4.7. Having a high school diploma resulted in a higher GAD-7 score (4.6) in Budd Lake while a Graduate level degree averaged a higher GAD-7 score (5.5) in Freehold. Those who were retired in Budd Lake had a higher GAD-7 score (5.0), whereas those employed full time had a higher average GAD-7 score (4.3) in Freehold. Table 7 presents the complete breakdown.

Although located in two different areas of New Jersey, the patient demographics and results of the GAD-7 were largely similar between the two locations. Because of this, we can confidently say that the GAD-7 is a useful screening tool to implement in order to screen for Generalized Anxiety Disorder.

The preintervention chart review revealed that three patients that were diagnosed and treated for Generalized Anxiety Disorder at the Budd Lake office practice made an appointment with their physician with complaints of anxiety. It is unknown how long those patients had been suffering from symptoms of anxiety, however, had they been screened prior, an earlier diagnosis could have been made.

The extensive literature review provided strong and sufficient evidence supporting the implementation of the GAD-7 screening tool in the primary care setting. The results of the study revealed that by integrating the GAD-7 into routine screening during primary care visits, regardless of chief complaint, early detection and prompt initiation of treatment for Generalized Anxiety Disorder will be improved. Not only will the implementation of the GAD-7 into routine screening improve

problems with underdiagnosing and undertreating; it will also lead to a decrease in healthcare costs and improved patient outcomes and quality of life.

Discussion

To date, there is no recommended screening for Generalized Anxiety Disorder, however, some literature supports the reliability and validity of the GAD-7 screening tool as well the importance of early detection of Generalized Anxiety Disorder. By screening for Generalized Anxiety Disorder, prompt recognition and treatment can be implemented. With a higher rate of Generalized Anxiety Disorder screening, more patients may be able to receive treatment with cognitive -behavioral strategies rather than pharmacological treatments.

Overall, the project was successful. By comparing the pre intervention chart review to the number of positive GAD-7 scores during the implementation phase, the data revealed that screening initiated early detection of Generalized Anxiety Disorder. The screening tool was only implemented over a four-week period from September 2019 to October 2019. The study provided 8% (N=4) of participants with a positive screen of 8 or higher on the GAD-7 screening tool, prompting a discussion with their providers. The findings of the project suggest possible benefits of the implementation of the GAD-7 screening tool in primary care to improve quality of care for Generalized Anxiety Disorder.

The implementation of the GAD-7 screening tool prompted discussions between patients and their providers that would not have happened otherwise. Regardless of their score on the GAD-7, participants were interested and willing to accept educational materials and discuss Generalized Anxiety Disorder with their providers. None of the participants had a history of Generalized Anxiety Disorder, yet because of the implementation of the GAD-7, 8% of participants were found to have a score of 8 or higher thus prompting a conversation with the practitioner, the need to monitor for an

increase in severity, or some sort of treatment. Had the GAD-7 screening tool not been administered, participants may not have been aware of their anxiety until it was severe. By implementing the GAD-7, early interventions with nonpharmacologic treatment can be initiated.

Limitations

Due to the screening tool ending after one month of participation, only 50 participants were recruited and evaluated. With a larger sample size and longer time frame, the study would have been able to recognize a larger effect. A better representation of the population affected by Generalized Anxiety Disorder would have been identified with a larger sample size.

A small sample size was partially due to cancellation of appointments and stigma associated with psychiatric conditions. Due to cancellations or rescheduled appointments, there were fewer opportunities to recruit participants. Since the investigators were only implementing the screening tool on certain days, fewer participants were able to be included than had they kept their original appointments. Participants may also fear the social stigma of Generalized Anxiety Disorder or mental health disorders and that may have interfered with patient responses to screening or towards a discussion with the provider.

Although the DNP project established feasibility of implementing the GAD-7 into primary care practice, further alterations in the process of administration of the tool and educating clinical staff may be needed in order to improve rates of screening and successful identification and treatment of Generalized Anxiety Disorder. It would also be compelling to see future studies on the barriers and motivators of clinicians or patients to pursue additional testing and treatments for Generalized Anxiety Disorder.

Despite the limitations, the study was able to demonstrate that screening with a brief and validated screening tool can help to identify a significant number of people with Generalized Anxiety Disorder, who would otherwise would have gone overlooked. The project results are also supported by the current literature. For example, a systematic review of literature validated the GAD-7 screening tool against other methods of diagnoses to analyze Generalized Anxiety Disorder in the adult population. A cutoff score of 8 or higher had the highest sensitivity and specificity and proved to be a reliable screening tool for Generalized Anxiety Disorder (Plummer et al., 2016). Further, Dr. Mark Ebell from the University of Georgia assessed the best tool for assessing anxiety in the primary care setting. After testing several screening tools, he determined that the GAD-7 had an excellent negative predictive value and recommended a cutoff score of eight yielded the best results (Ebell, 2008). Dr. Ebell also recommended confirmatory interviewing to validate the self-administered screening (Ebell, 2008). Finally, in a third study conducted by Seo & Park (2015), the GAD-7 was administered to migraine suffers. The reliability and validity of the GAD-7 was measured by a neuropsychologist. The results of the study determined that the GAD-7 had an excellent internal consistency and was a superior method to screen for Generalized Anxiety Disorder (Seo & Park, 2015). Regular health screenings are the best methods to discovering medical problems and to prevent them from becoming more serious medical conditions.

In addition, investigators found that despite participants scoring on the lower end of the GAD-7 scale, participants were interested in receiving educational documents and were inquisitive to having a discussion about Generalized Anxiety Disorder. Since Generalized Anxiety Disorder is nearly as prevalent as depression and causes an impact on medical and psychiatric outcomes, screening with the GAD-7 may be beneficial. Investigators recommend also utilizing the GAD-7 screening tool in high risk populations (depression, trauma, alcohol and drug misuse) and those with chronic comorbidities,

such as diabetes, multiple sclerosis, or heart disease, in order to improve clinical outcomes of patients with chronic medical conditions.

Implications

Economic Implications

The economic burden of Generalized Anxiety Disorder is significant not only for the individual, but for society as well. For the individual, the median cost for patients suffering from Generalized Anxiety Disorder was approximately $2,375 (Kehoe, 2017). Additional costs to those suffering from Generalized Anxiety Disorder include time away from work and lost wages, cost of additional mental health and physical comorbidities, cost of treatments, and cost of adverse effects from treatments. Furthermore, because Generalized Anxiety Disorder causes physical symptoms in addition to emotional distress, patients are often misdiagnosed causing time lost for the provider and higher healthcare costs related to unnecessary diagnostic testing or medication.

For society, $42 billion of health expenditures in the United States are spent on anxiety disorders (Kehoe, 2017). These costs may be related to reduced productivity, absenteeism from work, and increased medical and mental health care costs. Implementing the GAD-7 screening tool into primary care visits is of no cost to the office practice. Utilizing the GAD-7 screening tool in primary care practices may reduce economic and healthcare costs by increasing early detection, aid in accurately diagnosing Generalized Anxiety Disorder, and initiating evidence-based treatment plans or referrals to appropriate clinicians.

Quality and Safety

The quality improvement project illustrates that a significant amount of people experience Generalized Anxiety Disorder and primary care providers are in advantageous position to provide an initial intervention. Research suggests that early intervention and treatments of Generalized Anxiety Disorder are essential in improving long-term outcomes.

Those who are suffering from Generalized Anxiety Disorder may not seek help from mental health professionals, but rather turn to their primary care physicians for help. A mental health professional may not be easily accessible to them or may be difficult to find due to insurance restrictions. Because primary care physicians are on the front lines of patient care, routinely screening for Generalized Anxiety Disorder may help reduce or eliminate barriers and make recovery more achievable. Additionally, because patients establish a relationship with their primary care physicians, it is important for clinicians to educate on the prevalence, risk factors, symptoms, and implications of Generalized Anxiety Disorder to help improve patient outcomes.

Implementing a screening tool will help to initiate conversation about Generalized Anxiety Disorder. A screening tool detects and assess severity of anxiety and create a platform for the diagnostic evaluation. The patient is an active participant in the diagnostic and therapeutic process thus validating him/her as being a contributor to their health and mental wellness. Screening tools are a feasible way to detect the disease and help those suffering get immediate treatment and shorten the length of recovery. Early interventions through non pharmacological interventions or pharmacological therapies can help to reduce the burden of Generalized Anxiety Disorder.

Research proves that Generalized Anxiety Disorder, like many mental health disorders, can cause or worsen physical symptoms or illnesses. Generalized Anxiety Disorder is also often

overlooked, requiring patients to receive additional, unneccesarry testing, causes misdiagnoses, and/or causes the patient to be inappropriately treated. Incorporating the GAD-7 into routine practice would also provide practitioners with a symptom monitoring tool. Measuring longitudinal changes and tracking patient progress are essential to better quality of care and patient outcomes. The GAD-7 will not only alert practitioners of a patient's progress, but guide treatment and assist in differential diagnoses. By routinely administering the rating scale, the clinician can monitor for improvement or changes in mental health symptoms thus providing best practice and optimal care.

The implementation of the GAD-7 screening tool will not only aid in the early detection of Generalized Anxiety Disorder, but it will also help prompt discussion as well as early treatment interventions. The screening tool comes at no cost to the provider and requires less than five minutes to administer. The GAD-7 screening tool can also be utilized in monitoring of the severity of Generalized Anxiety Disorder. Additionally, by allotting time for patients to be screened for Generalized Anxiety Disorder, healthcare providers can allow for timely treatment, thus aiding in quality and safety of patients. By implementing the screening tool, significant changes can be made to the healthcare system as well as to patient outcomes.

Research and Policy

Generalized Anxiety Disorder is the most common anxiety disorder in the United States as well as the most common anxiety disorder presented in primary care settings (Munoz-Navarro et al., 2017). Generalized Anxiety Disorder is a disabling condition that is often accompanied by additional comorbidities including depression. Although a common mental health condition, Generalized Anxiety Disorder has received less attention than that of depression. Presently, the U.S. Preventative Services Task Force (USPSTF) and the Affordable Care Act recommends screening for depression in

the adult population, while it is mandated and paid for by Medicare (Physicians, 2012). This, however, is not the same for Generalized Anxiety Disorder. Although research reveals that those suffering from Major Depression Disorder are more likely to develop Generalized Anxiety Disorder, screening is not recommended (Baldwin, 2018). By identifying the need for screening, practice guidelines can be established and quality of care enhanced.

Further research should be conducted on the benefits and risks of screening for Generalized Anxiety Disorder. More studies with a large sample size and prolonged follow up are needed to determine the net benefit of screening and early detection of GAD. Additionally, research should be conducted on the validity and reliability of the GAD-7 screening tool in languages other than English. Future research is also warranted to determine whether screening for GAD can reduce healthcare cost and improve clinical outcomes of patients with chronic medical conditions. Further research will help motivate and inspire the development of primary care-based models to assess, diagnose, and treat prevalent conditions such as Generalized Anxiety Disorder.

Conclusion

Through the process of screening for GAD, healthcare professionals can improve detection of the condition thus enabling earlier intervention and management in the hope to reduce the burden of the disease. Primary care providers are well positioned to identify and treat Generalized Anxiety Disorder. The seven-item Generalized Anxiety Disorder scale, GAD-7, is a validated and reliable tool that can be used in aiding the diagnosis and determining severity of Generalized Anxiety Disorder. Routinely utilizing the GAD-7 tool in primary care can serve as the first step to address underdiagnosis, initiate prompt interventions and improve patients medical, mental, and life quality outcomes.

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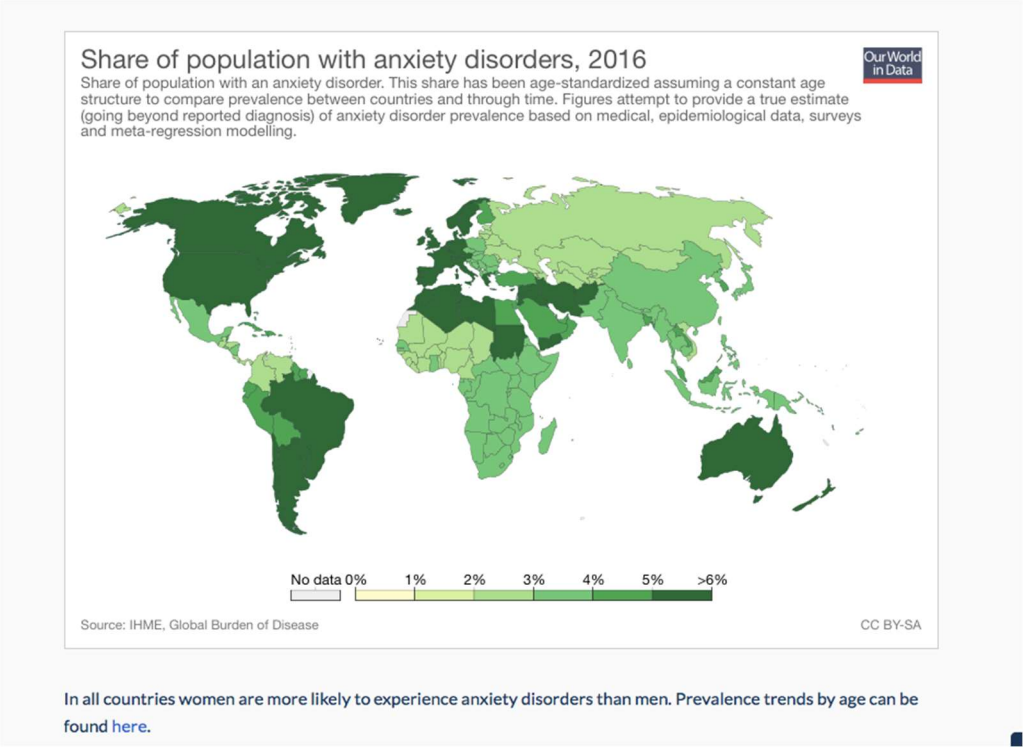
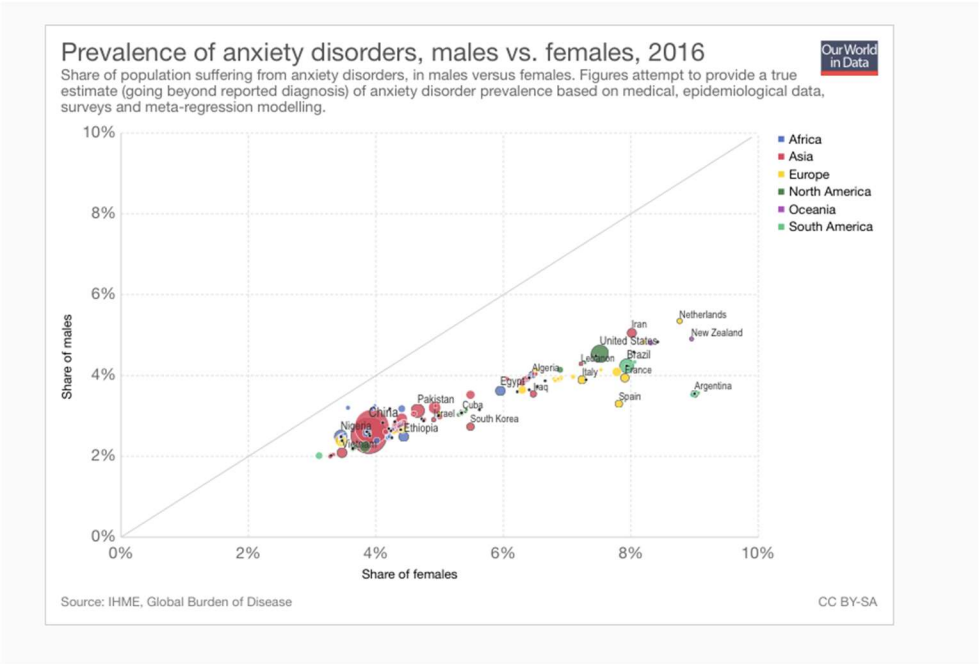
Appendix A: Population & Prevalence of Anxiety Disorders





(Ritchie & Roser, 2018)

Appendix B: Table of Evidence

Article Number	Author & Date	Evidence Type	Sample, Sample Size Setting	Study Findings that help answer the EBP Question	Limitations	Evidence Level & Quality
1.	Herr et al 2014	Systematic Review	Sample Size: Detailed review of 76 articles Total 2785 patients Setting: Primary care offices	GAD-7 had a sensitivity of 89%, specificity of 83%, & the highest LR+ (5.1; 95% Cl, 4.3-6.0) GAD-7 = highest test retest reliability Intraclass correlation = 0.83	Most studies – threshold values for screening tools were specified after analysis of results → replication needed Lack of studies with patient outcomes & societal influence Poor quality studies excluded – possible exclusion of low-level evidence studies Studies were not designed to address differences in subgroups	Level I, A
2.	Kroenke et al 2007	Non-Experimental – criterion study	Sample Size: 965 random patients Setting: 15 U.S. primary care clinics	Of the 965 participants, 19.5% had at least one type of anxiety disorder 7.5% had GAD with impairments of health	The study included a nonrandom sample of selected primary care patients The study did not have information	Level III, B

				Of all participants with anxiety disorders, 41% are without current treatment The study found patients in primary care setting are not being treated for anxiety & a screening tool would help improve the detection of anxiety	on comorbid conditions or number & types of medications that can affect the impairment alone	
3.	Kujanpaa, Tero et al. 2014	Non-Experimental	Sample Size: 286 patients Setting: 4 municipal health centers in Northern Finland	Sensitivity, specificity, positive predictive value, likelihood ratio, Youden's index, and their 95% CI values were calculated In GAD, Youden's index was the highest (0.83) for the cut-off point 7 or more for GAD-7 Prevalence of GAD was 4% in Finnish high utilizers of health care Sensitivity of GAD-7 was 100.0% (95% CI 54.1 – 100.0) & specificity of GAD-7 was 82.6% (95% CI 75.4 – 88.4) (with a	Small sample size Not all 286 patients were high utilizers Few earlier studies exist investigating high utilizers making comparison difficult	Level III, A

				cut-off point of 7 or more)		
4.	Munoz-Navarro et al 2017	Non-Experimental	Sample Size: 178 patients Setting: Spanish Primary Care Centers	A GAD-7 scale result cut-off of 10 yielded a: - sensitivity of .87 - specificity of .78 - positive predictive value of .93 - negative predictive value of .64 - positive likelihood ratio of 3.96 - negative likelihood ratio of .17 - Younden's Index of .65 The GAD-7 with a cut-off value of 10, performed very well	Use of electronic questionnaire – participants must be familiar with computer use Possible for participants to exaggerate answers affecting specificity of results	Level III, A
5.	Plummer et al 2016	Systematic Review & Meta Analysis	12 samples identified 5223 participants 4 samples from predominantly English-speaking countries Various settings:	Pooled sensitivity and specificity values acceptable at a cutoff point of 8 [sensitivity: 0.83 (95% CI 0.71–0.91), specificity: 0.84 (95% CI 0.70–0.92)] Cutoff scores 7–10 had similar pooled estimates of sensitivity/specificity	Did no use 2 independent researchers to select & extract data (could lead to bias) Possible publication bias Cutoff points varied between studies & possibility of	Level I, B

			3 general population 3 primary care 4 secondary care 1 occupational health Remainder – community drug treatment service		pooled estimates of sensitivity & specificity may be inflated	
6.	Lowe et al 2008	Non-Experimental	Sample size: 5,030 patients 56.3% female Setting: Face to face household survey, Germany	Women = higher scores of GAD than men [3.2 (3.5) vs. 2.7 (3.2); P<0.001] 5% = GAD-7 scores of 10 or greater 1% = GAD-7 scores of 15 or greater Internal consistency of GAD-7 (α = 0.89) GAD-7 = lower in patients with higher educational levels compared to lower educational levels, Employed patients = lower GAD-7 scores than unemployed patients	Response rate of 72.9% (however, usual response rate for general surveys within the general population is 70.9%) Representativeness of study sample Generalizability of study results of other countries	Level III, B

				GAD-7 scores = lower in patients with higher household income than lower household income No difference in GAD-7 scores between German & non-German		
7.	Wild et al 2014	Non experimental	Sample size: 438 elderly adults (ages 58-82) Setting: Elderly population living at home in Germany	Cutoff score 10 or more = GAD-7 = sensitivity of 0.89 & a specificity of 0.82 Cutoff score of 5 or more = sensitivity of 0.63 & specificity of 0.9 Area under the curve was 0.88 (95% CI: 0.83-0.93) Cronbach's α for GAD-7 was 0.82	Sample not representative of general German population Possibility those who agreed to participate in home visits were healthier or less impaired compared to those who declined GAD-7 was completed approximately 25 days before diagnostic interview → cannot rule out changes that occurred between self-report and expert assessment	Level III, A

					Presence of M.D. of the study = bias (elderly score lower) because M.D. was there	
8.	Mackenzie et al 2011	Epidemiological Survey	Sample Size: 12,312 adults over age of 55 Completed survey	2.8% prevalence of GAD 18% did not have any comorbidities and 28.3% had comorbidities 7.2% reported not obtaining relief of their symptoms The study found that the treatment of GAD is significant	The study was unable to determine if GAD is a cause or a consequence. The survey does not generalize to older adults in institutions but rather the community population. Another limitation found that GAD was not diagnosed using the hierarchical rules and the data from the survey is self-reported.	Level III, C
9.	Bereza et al 2009	Systematic Review & Quality Assessment	Studies were chosen that had a sample population in which met criteria for quick diagnostic interview, ICD, and DSM 36 articles were included	The study found that GAD is associated with major economic and humanistic impacts on patients and the health care systems. The study also found that there should be more studies performed on the related costs of under diagnosed and under treated GAD.	Some of the studies reviewed were based on summary population data. ICD-9 codes were used for diagnosis criteria which assessed billing claims. Some studies found that GAD was underdiagnosed	Level III, A

					and undertreated while some found that it was not. The quality assessments were subjective.	
10.	Ruiz et al 2011	Non-Experimental Observational Cross sectional study	Sample Size: 212 subjects Setting: Primary Care Clinics in Spain	Strong (p<0.001) correlations were made between the GAD-7 and HAM-A and WHO-DAS II predominantly: Participation in society (r=0.852) Understanding communication (r=0.679) Life activities (r=0.638) Healthcare utilization = primary care visits higher in GAD than control group: 1.98 (1.3) versus 1.11 (0.9) →difference = 0.87 visits, SE = 0.16, p<0.001	Conducted at medical centers in 3 regions – generalization might be considered Use of the abridged version of WHO-DAS II Scale (12 item compared to 36) Cross sectional design = excludes observing progression of disability & disability & anxiety	Level II, A
11.	Rafsten et al 2018	Systematic Review/Meta-Analysis	Sample Size: 13,756 stroke patients 37 Studies	Anxiety was common during the first year after a stroke The study also found routine screening is needed after a stroke as anxiety affects the quality of life and predisposes	Small sample sizes; less than 50 Types of settings were different for the individuals who suffered strokes within the last year.	Level III, A

				individuals to depression.	The scales given to patients were the same however, there were different ways of assessment. Some studies involved research assistant, some patients received home assessment, and some patients had no guidance.	
12.	Smith et al 2013	Systematic Review/Meta-Analysis	Sample Size: 12 studies - 626 individuals with Anxiety and Diabetes	There is a strong association between diabetes and anxiety and elevated anxiety disorders	Only studies in English or French could be assessed. Limitations with publication bias and language bias.	Level III, B
13.	Terrill et al 2015	Non-Experimental Observational Study (Longitudinal)	Sample Size: 513 subjects Setting: [redacted] Chapter of the National MS Society - United States	Support use of the GAD-7 for patients with MS GAD-7 useful addition for clinical and research purposes Cronbach alpha (0.75) = adequate internal consistency for GAD-7 GAD-7 was highly correlated with the Hospital Anxiety & Depression Scale–Anxiety (r = 0.70)	Relied on self-reported data GAD-7 used was the version that is incorporated into the full PHQ rather than the version that has been published as a standalone module (yet are consistent with GAD-7) Small number of study participants (n = 41) met the GAD-7 categorical criteria → analyses examining descriptive	Level II, B

				Higher GAD-7 scores in women & those with secondary progressive MS Higher GAD-7 scores = more depressive symptoms	properties may be skewed	
14.	Seo & Park 2015	Non experimental Cross Sectional	Sample Size: 146 participants Setting: Various Clinics	GAD-7 is reliable & valid for GAD screening in migraine patients Cronbach's α for GAD-7 was 0.915 = excellent internal consistency ROC analysis of GAD-7: area under the curve 0.849 (95% CI = 0.775-0.923; SE = 0.038; p< 0.001) Validity of GAD-7 was determined by correlation with BAI, MIDAS, HIT-6, & MSQoL scores GAD-7 score well correlated with: BAI score (p < 0.001)	Small sample size – may have caused difference in sensitivity & specificity Self-report questionnaire = aid in probable diagnosis → need further eval Cutoff score of 5 = PPV was 46.3 – possible false positive results GAD-7 focuses on 1 type of anxiety disorder	Level III, A

				MIDAS score ($p < 0.001$) HIT-6 score ($p < 0.001$) MSQoL score ($p < 0.001$) GAD-7 comprehended easily by patients		
15.	Goncalves et al 2012	Systematic Review/Meta-Analysis	Sample Size: 2373 adult participants over the age of 55 Setting: Community, rehab, hospital inpatients and psych outpatient within the U.S, Iran, & Italy	The study found pharmacological and psychotherapeutic interventions were beneficial to older adults with GAD	Cognitive function was not addressed The responses were clinical and self-related measures	Level III, B
16.	Frost et al 2018	Systematic Review/Meta-Analysis	Sample Size: 14 trials with 2099 randomized participants People above the age of 60 who have experienced functional difficulties from physical or cognitive comorbidities who also have	The study reported home-based problem-solving therapy can decrease the signs and symptoms of depression, but more information is needed for patients with anxiety	Limitations included finding and involving willing and available caregivers The meta-analysis had inconsistencies in timing and poor study quality	Level III, C

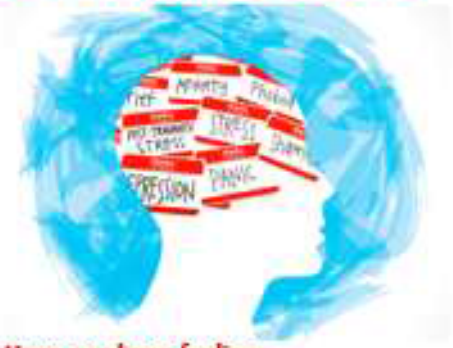
			signs and symptoms of or a diagnosis of depression or anxiety. Setting: In home & community in UK			

Appendix C: Recruitment Flyer

RUTGERS
School of Nursing

The Implementation of the GAD - 7 screening tool in the Primary Care Setting

Feeling anxious?



Have you been feeling:

- anxious?
- nervous?
- on the edge?
- restless?
- trouble relaxing?
- irritable?
- trouble sleeping?
- uncontrollable worrying?

If you are between the ages of 18 and 64, without a previous diagnosis of anxiety, you may be eligible to participate in this research study involving the screening of Generalized Anxiety Disorder! Additional criteria include: established or new patients of any race, ethnicity, gender, educational level, or marital status, that are cognitively intact. Participants will also be included regardless of insurance provider or self-pay and must be able to read and write in English.

Study Activities include filling out a brief questionnaire in the waiting room or privately inside exam rooms. Participation in this study is less than 5 minutes. There is no compensation for this study.

[redacted]

Invitation to Participate in Research Study!

Anxiety

Anxiety disorders are the most common mental illness in the U.S., affecting 40 million adults. Only ⅓ of those suffering from anxiety receive treatment. 56% of people with anxiety say it interferes with their work performance. Women are 60% more likely than men to develop anxiety. Generalized Anxiety Disorder causes distress, physical symptoms, sleep disturbances, restlessness, muscle tension and chronic headaches to name a few. Generalized Anxiety Disorder affects your overall wellbeing. Although a treatable condition, only 36.9% of those suffering seek and receive treatment.

Generalized Anxiety Disorder - 7 Screening Tool

The purpose of the study and of the Generalized Anxiety Disorder - 7 screening tool is to aid your healthcare provider in identifying level of anxiety severity, if any, as well as a diagnosis of Generalized Anxiety Disorder. Upon voluntary participation of this study, you will be provided with a 7-question screening tool. You and your healthcare provider can privately discuss the results and your options, if any. The purpose of this study is to raise awareness on the purpose of prompt identification of anxiety and treatment to improve mental wellbeing. The purpose of this study is to incorporate this screening tool into the primary care setting.

Participation is needed!

Join us in participating in the screening of Generalized Anxiety Disorder regardless of the purpose of your visit today. The purpose of participating in the project is to describe the implementation of a Generalized Anxiety Disorder screening tool in order to identify those suffering from undiagnosed Generalized Anxiety Disorder as well as to determine if the Generalized Anxiety Disorder 7 item scale screening tool will increase early detection of anxiety. You can get the help you need and improve your mental health starting today.

To learn more, contact:

[redacted]

Version 4, July 28, 2010

Rutgers, The State University of New Jersey

Appendix D: Demographic Survey

Generalized Anxiety Disorder Demographic Survey

Age:

18-20 _____ 21-29 _____ 30-39 _____ 40-49 _____

50-59 _____ 60-69 _____ 70-79 _____ 80 years or greater _____

Gender

Male _____ Female _____ Other (specify) _____

Race

White _____ Asian _____

African American _____ Native Hawaiian/Pacific Islander_____

American Indian or Alaskan Native _____ Other (please specify) _____

Marital Status

Married _____ Widowed _____ Divorced _____

Never Married _____

Education

Less than high school degree _____ High school or equivalent (GED) _____

Some college (no degree) _____ Associate degree _____

Bachelor degree _____ Graduate degree _____

Employment Status

Full Time _____ Part Time _____ Unemployed _____ Disability _____

Reason for Todays Visit _____

Version 2, July 9, 2019

Appendix E: GAD-7 Screening Tool

GAD-7 Anxiety

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid, as if something awful might happen	0	1	2	3

Column totals _____ + _____ + _____ + _____ =

Total score _____

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

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Source: Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD-PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues. For research information, contact Dr. Spitzer at ris8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission

Scoring GAD-7 Anxiety Severity

This is calculated by assigning scores of 0, 1, 2, and 3 to the response categories, respectively, of "not at all," "several days," "more than half the days," and "nearly every day."
GAD-7 total score for the seven items ranges from 0 to 21.

0–4: minimal anxiety

5–9: mild anxiety

10–14: moderate anxiety

15–21: severe anxiety

Appendix F: Anxiety & Depression Association of America (ADAA) Education Tools

Which Is It?

Everyday Anxiety	Anxiety Disorder
Worry about paying bills, landing a job, a romantic breakup, or other important life events	Constant and unsubstantiated worry that causes significant distress and interferes with daily life
Embarrassment or self-consciousness in an uncomfortable or awkward social situation	Avoiding social situations for fear of being judged, embarrassed, or humiliated
A case of nerves or sweating before a big test, business presentation, stage performance, or other significant event	Seemingly out-of-the-blue panic attacks and the preoccupation with the fear of having another one
Realistic fear of a dangerous object, place, or situation	Irrational fear or avoidance of an object, place, or situation that poses little or no threat of danger
Anxiety, sadness, or difficulty sleeping immediately after a traumatic event	Recurring nightmares, flashbacks, or emotional numbing related to a traumatic event that occurred several months or years before

Appendix G: Anxiety & Depression Association of America (ADAA) Education Tools

Generalized Anxiety Disorder

ADAA
ANXIETY AND DEPRESSION ASSOCIATION OF AMERICA

Generalized Anxiety Disorder

Relationships, health, money, deadlines, traffic, world affairs, climate change, arriving on time to work or an appointment — you name it. We all have plenty to worry about. But people who have generalized anxiety disorder, or GAD, experience persistent, excessive, and unrelenting worry that goes on every day, most of the day.

Those with GAD don't know how to stop the worry cycle, which they feel is beyond their control, and it interferes with daily living. They often expect the worst, and they worry disproportionately about real concerns. Physical ailments often accompany the worrying: muscle tension, fatigue, irritability, gastrointestinal symptoms, and headaches. Many people experience having repetitive circular internal dialogues between their anxious mind and their rational mind that interfere with sleep and enjoyment of life. Others repeatedly seek reassurance.

GAD affects men and women, and it can begin at any time. No laboratory tests exist to specifically diagnose this or another anxiety disorder. A mental health provider diagnosing GAD asks questions about your medical history. He or she will try to determine if your symptoms are part of another mental disorder or due to a substance or medical issue.

GAD is diagnosed if you've worried chronically on more days than not about a variety of everyday problems for at least six months. A diagnosis of GAD is determined if chronic worrying interferes with daily living, such as causing you to miss work or school or causes significant mental distress. Further, if you have a very difficult struggle to regain control, relax, or manage anxiety and worry, that usually indicates GAD.

GAD is also diagnosed if for most days over the previous six months you have experienced three or more of these symptoms that cause clinically significant distress:

- Restlessness or feeling keyed up or on edge
- Being easily fatigued
- Difficulty concentrating or mind going blank
- Irritability
- Muscle tension
- Sleep disturbance (difficulty falling or staying asleep or restless, unsatisfying sleep)

ANXIETY AND GAD

In addition to GAD, the term "anxiety disorder" includes panic disorder and panic attacks, agoraphobia, social anxiety disorder, selective mutism, separation anxiety, and specific phobias.

Obsessive-compulsive disorder (OCD) and posttraumatic stress disorder (PTSD) are closely related to anxiety disorders; anxiety is one of the symptoms. Some people may experience either of these disorders along with depression and other related disorders at the same time.

Each disorder has specific symptoms. For more details, visit the ADAA website at **www.adaa.org**.

Unrelenting worry
physical ailments
struggle
chronic anxiety
distress

NORMAL ANXIETY VS. GAD

An important part of living, anxiety is a normal emotional reaction to stress, which is a biological response to a threat. Anxiety helps us get out of harm's way and prepare for important events, and it warns us when we need to take action.

When anxiety is persistent, excessive, seemingly uncontrollable, overwhelming, and disabling or when it interferes with daily activities, you may have an anxiety disorder.

NORMAL ANXIETY	GAD
Muscle aches or tiredness related overexertion at the gym, a stressful day at work, or sitting too long at the computer	Restlessness, muscle tension, and fatigue that persist for six months or more not related to a specific physical or emotional problem
Worry about a work deadline, school exam, or upcoming medical appointment	Constant and chronic worry that disrupts social activities and interferes with work, school, family, and relationships
Difficulty relaxing, sleeping, or concentrating when faced with an illness, job loss, or relationship difficulties	Irritability, sleep disturbance, or difficulty concentrating on more days than not for at least six months

EFFECTS

When worrying goes on every day, possibly all day, generalized anxiety disorder can disrupt social activities and interfere with work, school, family, relationships, and your general sense of well-being. GAD is also a risk factor for depression; these two disorders frequently occur together.

According to a national survey conducted by ADAA, seven out of 10 people with GAD agreed that their chronic anxiety had an impact on their relationships with spouses and significant others and two-thirds reported that GAD had a negative effect on their friendships.

CAUSES

Although the precise cause of GAD is unknown, scientific studies show that a combination of biological, genetic, cognitive, and environmental factors (stress, negative life events) play a role in GAD. Even the stress of positive events, such as buying a new house or getting married, can trigger symptoms in those who are predisposed to this disorder.

TREATMENT

Most people who seek treatment for GAD see significant improvement and enjoy a better quality of life. Treatment is individualized, but standard approaches have proved effective.

A variety of treatment options are scientifically proven to be effective. These evidence-based treatments include psychotherapy such as cognitive-behavioral therapy (CBT). This short-term treatment actively involves you in learning skills to help change your thinking and behavior patterns. It teaches you how to control your worry, decrease the impact of anxiety on your life, and learn new responses to stressful events, often within 12 to 16 weeks. In addition, medications such as benzodiazepines and SSRIs may be prescribed. One or a combination of treatments may be recommended.

Relaxation and breathing techniques, meditation, yoga, and exercise may also become part of your treatment plan.

Learn about effective treatments on the ADAA website at **www.adaa.org**.

There is no single "right" treatment. What works for one person may not be the best choice for you. Ask your treatment provider for an explanation of why a particular type of treatment is recommended, other available options, and what you must do to fully participate in your recovery.

MANAGE YOUR ANXIETY

Whether you have normal anxiety, GAD, or another anxiety disorder, these strategies will help you cope:

- Talk to someone: spouse, significant other, friend, child or doctor.
- Exercise: Go for a walk, jog, do yoga, dance, or just get moving!
- Keep a daily journal. Become aware of what triggers your anxiety.
- Eat a balanced diet. Don't skip meals. Avoid caffeine, which can trigger anxiety symptoms.
- Contact ADAA at **www.adaa.org**: Let us help you help yourself.

GETTING HELP

Suffering from GAD can interfere with many aspects of your life. Visit ADAA at **www.adaa.org** to find qualified mental health professionals using the *Find a Therapist* directory.

ADAA also provides resources and connections to help you and your loved ones better understand anxiety disorders and depression. Look over the questions to ask a mental health provider as you explore treatment, find resources and books, and locate support groups in your area.

ADAA serves as a comprehensive resource for education about the causes, symptoms, and treatments of anxiety, depression, and related disorders. We are here to help you find answers and make the best decisions for your health care so you can move forward with your life.

HELP ADAA HELP OTHERS.

You can make a difference by helping ADAA expand its efforts to reach those with anxiety disorders, depression, OCD, PTSD, and related disorders. Your contribution supports ADAA's efforts to increase awareness and provide education that improves the lives of all people who suffer from anxiety or depression. Your donation also supports research and allows ADAA to advocate for improved treatments and access to care.

Donate *online* at **www.adaa.org**,
on the *phone* (240-485-1001),
or by *mail* to ADAA,
8701 Georgia Avenue, Suite 412
Silver Spring, MD 20910.

All donations are tax-deductible.

About ADAA

The Anxiety and Depression Association of America (ADAA) is a national 501(c)(3) nonprofit organization whose mission is to promote the prevention, treatment, and cure of anxiety, OCD, PTSD, depression, and related disorders and to improve the lives of all people who suffer from them.

Help ADAA help others. Please donate at **www.adaa.org**.

For more information visit **www.adaa.org** or contact
8701 Georgia Avenue, Suite 412 – Silver Spring, MD 20910
Phone: 240-485-1001

overwhelming
Disabling
persistent
Effects
Causes
Treatment
Let us help
www.adaa.org you find treatment.

Appendix H: What is Anxiety Education

What is Anxiety?

Anxiety is a mental and physical reaction to perceived threats. In small doses, anxiety is helpful. It protects us from danger, and focuses our attention on problems. But when anxiety is too severe, or occurs too frequently, it can become debilitating.

Symptoms of Anxiety

- uncontrollable worry
- excessive nervousness
- sleep problems
- muscle tension
- poor concentration
- increased heart rate
- upset stomach
- avoidance of fear

Types of Anxiety

Generalized Anxiety: An excessive amount of anxiety or worry in several areas of life, such as job responsibilities, health, finances, or minor concerns (e.g. completing housework).

Phobias: A very intense fear of a specific situation or object, which is out of proportion to its actual threat. For example, a fear of giving speeches, or of spiders, could be considered a phobia.

Panic: An extreme anxious response where a person experiences a panic attack. During a panic attack, the individual experiences numerous physical symptoms, and is overwhelmed by a feeling of dread.

How Does Anxiety Grow?

Anxiety drives people to avoid the things that scare them. When a "scary" thing is avoided, there is an immediate but short-lived sense of relief. However, the next time a similar threat arises, it feels even scarier. This creates a harmful cycle of avoidance, and worsening anxiety.

Anxiety Treatments

Cognitive Behavioral Therapy (CBT)

CBT is a very effective treatment for anxiety. During CBT, the unhealthy thinking patterns that create anxiety are identified, and challenged. Oftentimes, CBT will also include components of exposure therapy and relaxation skills.

Exposure Therapy

During exposure therapy, the therapist and their client create a plan to gradually face anxiety-producing situations, thus breaking the cycle of avoidance. With enough exposure, the anxiety loses its power, and the symptoms diminish.

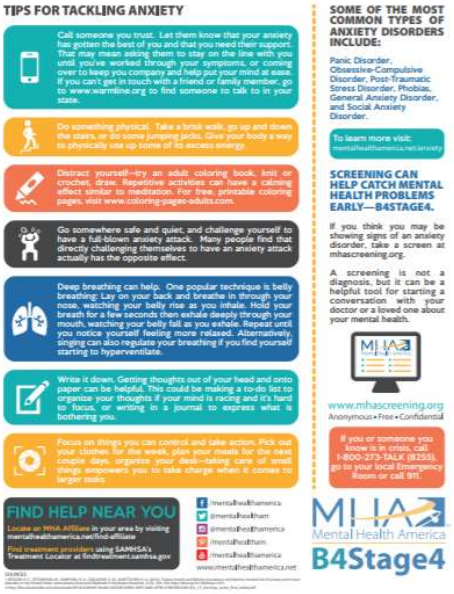
Relaxation Skills

Various techniques—such as deep breathing, progressive muscle relaxation, and mindfulness—provide immediate relief from the symptoms of anxiety. With practice, relaxation skills will become a powerful way to manage anxiety in the moment.

Medication

Medication can help control the uncomfortable symptoms of anxiety. However, because medication does not fix the underlying problems of anxiety, it is typically used in conjunction with therapy. The need for medication varies greatly, case-by-case.

Appendix I: Anxiety Fact Sheet



Appendix K: Coding Sheet

RUTGERS
School of Nursing

Version 1, April 20, 2019

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Appendix L: Consent

CONSENT TO TAKE PART IN A RESEARCH STUDY

Version 4 7/28/2019

TITLE OF STUDY: The Implementation of a GAD-7 Screening Tool in Primary Care

Principal Investigators: Dr. Cara Padovano, DNP, FNP-BC

Co- Investigators: Amanda Boyle, RN, BSN and Delilah Nankoo, RN, BSN

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to identify the need for routine screening to detect anxiety early. If you take part in the research, you will be asked to fill out a screening tool on anxiety. Your time in the study will take approximately 5 minutes to complete. Possible harms or burdens of taking part in the study are not anticipated, however there is a small potential risk of disclosure of personal information, which will be minimized by all personal data being coded and properly stored. Possible benefits of taking part in this study may be possible early identification of anxiety. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?

Dr. Cara Padovano is the Principal Investigator. Amanda Boyle, RN, BSN and Delilah Nankoo, RN, BSN are the Co-Investigators of this research study. The Principal Investigator and Co-Investigators

have the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Cara Padovano can be reached at [redacted]

Amanda can be reached at [redacted]

Delilah can be reached at [redacted]

Why is this study being done?

The purpose of this study is to identify the need for routine screening to detect anxiety early in the primary care setting.

Who may take part in this study and who may not?

1.) Participants should be male or female; 2) age of 18 years to 65 years old; 3) ability to understand English language; 4) no previous diagnosis of anxiety; 5) being cognitively intact. Individuals younger than 18 years old, older than 65 years old will be excluded from the study. All participants who meet the inclusion criteria will be invited to participate.

Why have I been asked to take part in this study?

You have been asked to take part in this study to help identify the need for routine screening to detect anxiety early in the primary care setting. The goal is to improve early detection of anxiety.

How long will the study take and how many subjects will take part?

This study will take approximately 5 minutes to complete including educational materials. About 100 participants are anticipated to be included in this study.

What will I be asked to do if I take part in this study?

Participants will be asked to complete a demographic survey and an anxiety screening tool. Participants will be given educational materials regarding anxiety.

What are the risks and/or discomforts I might experience if I take part in this study?
There are no significant risks in participating in the study. There is a potential low risk in the disclosure of personal information which will be minimized, including all personal data, be exchanged as early as possible to a coding system via an excel document on a password protected computer, properly and securely stored, and destroyed in accordance with removal once coding is correctly completed. The information can only be accessed by the investigators of this project. There is a low potential psychological risk in which you may produce negative feelings towards anxiety. There is also a low potential social risk in which you may feel embarrassed by the questions. There is no judgement based off the answers. There are no economic or physical risks.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be possible detection of anxiety.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take part in this study?

There will be no anticipated cost to participate in this study.

Will I be paid to take part in this study?

You will not be paid to take part in this study.

Who might benefit financially from this research?

There is no financial benefit for any of the parties involved in this research study

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Information obtained about you for this study will be kept private to the extent allowed by law. De-identified data will be collected and no patient names will be disclosed on the questionnaire. Each participant will be given a code. Data will be entered in an excel document, stored, and analyzed at the practice on a password protected computer. All screening forms will also be stored in a locked box in the private practice office and analyzed at the practice on a password protected computer. After study completion, screening forms and all related information will be destroyed in agreement with Rutgers policy. Only principal and co investigators will have access to the forms.

What will happen to my information or biospecimens collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the doctor will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Who can I call if I have questions?

If you have questions about taking part in this study or if you feel you may hae suffered a research related injury, you can call the study doctor: *Dr. Cara Padovano, Rutgers Graduate School of Nursing at* [redacted]

If you have questions about your rights as a research subject, you can call the IRB Director at: *Newark Health Sciences (973)-972-3608*.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

Appendix M.

Figure 1. Pre-Intervention Chart Review Age Demographics Comparison

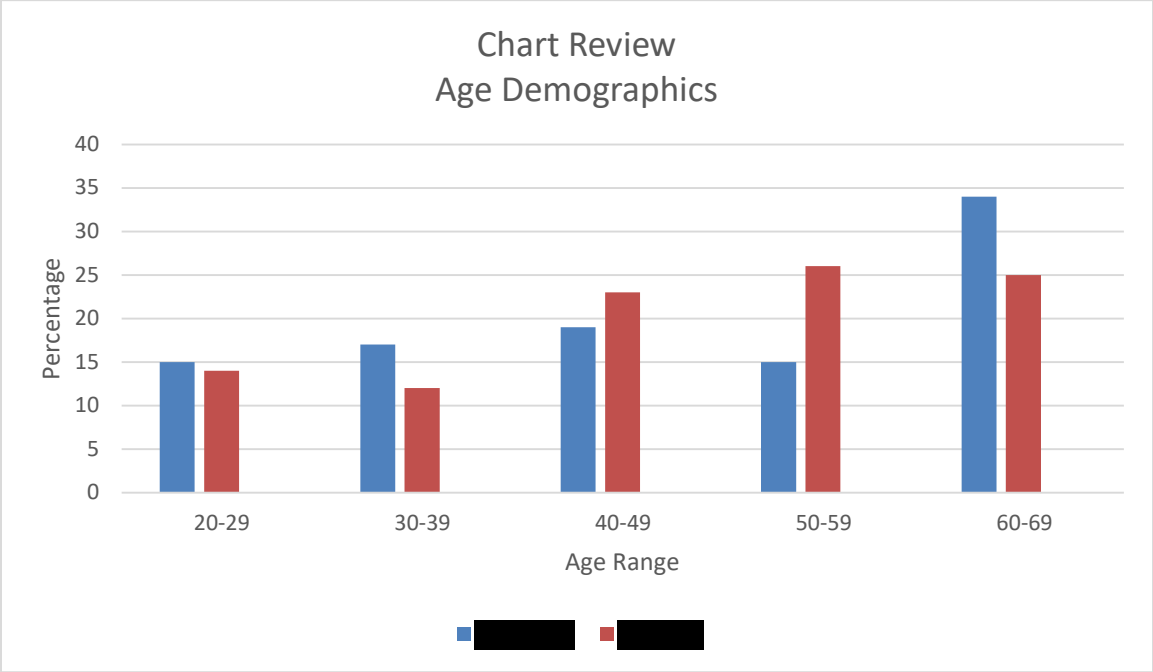
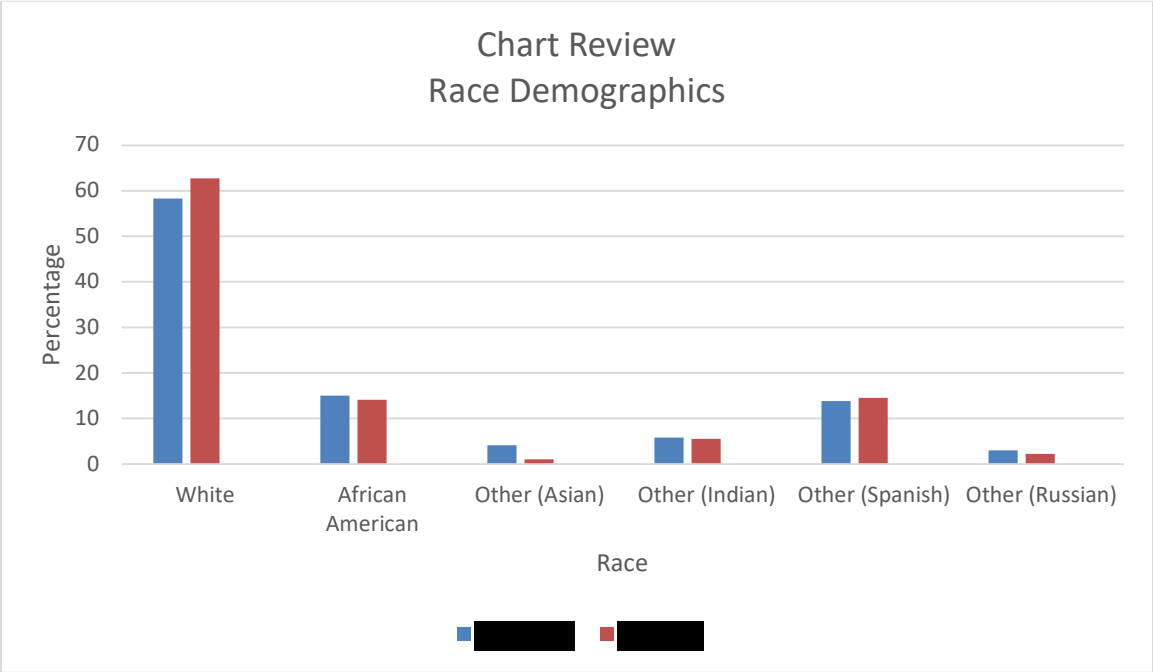


Figure 2. Pre-Intervention Chart Review Race Demographics Comparison



Appendix N.

Figure 3. Pre-Intervention Chart Review Marital Status Comparison

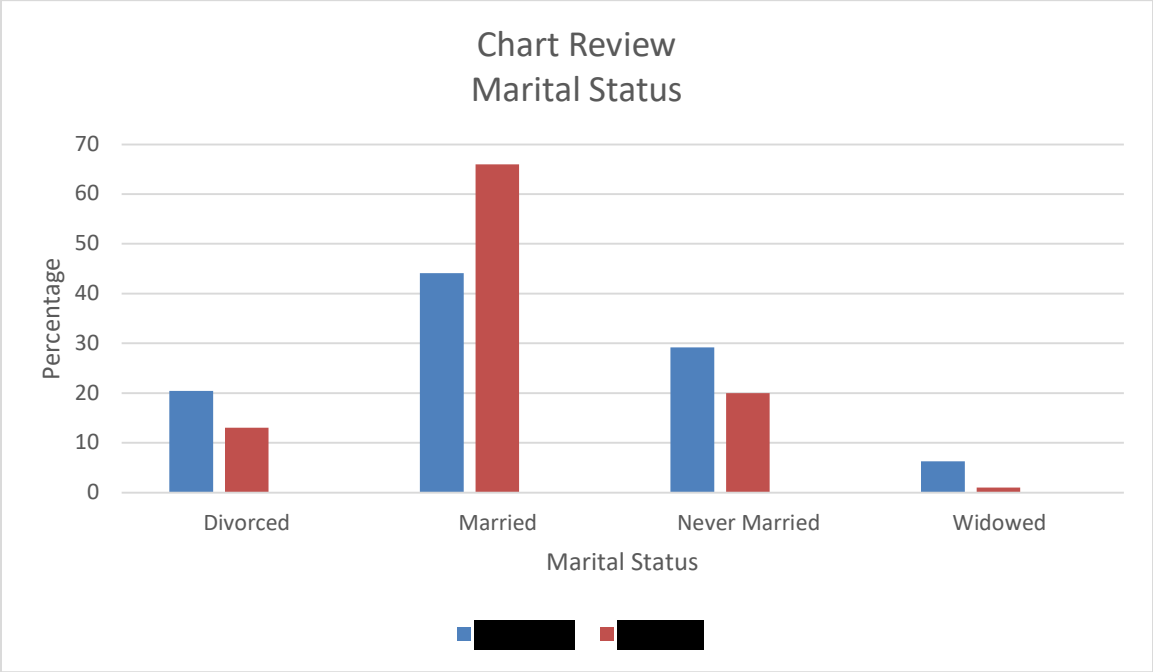
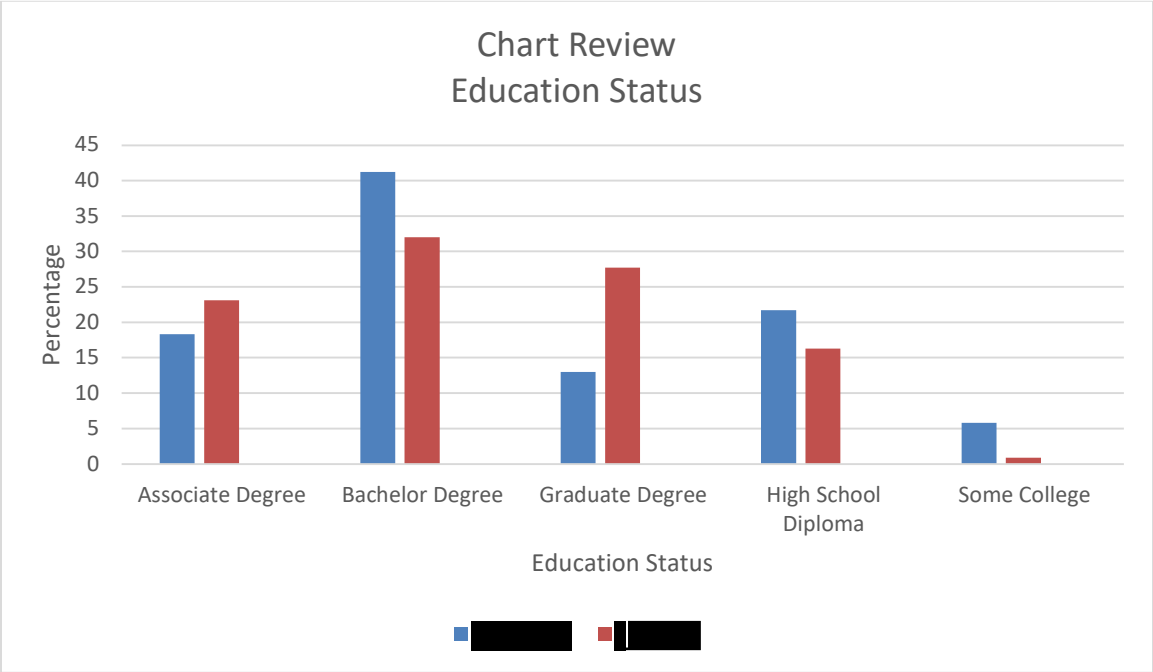


Figure 4. Pre-Intervention Chart Review Education Status Comparison



Appendix O.

Figure 5. Pre-Intervention Chart Review Employment Status Comparison

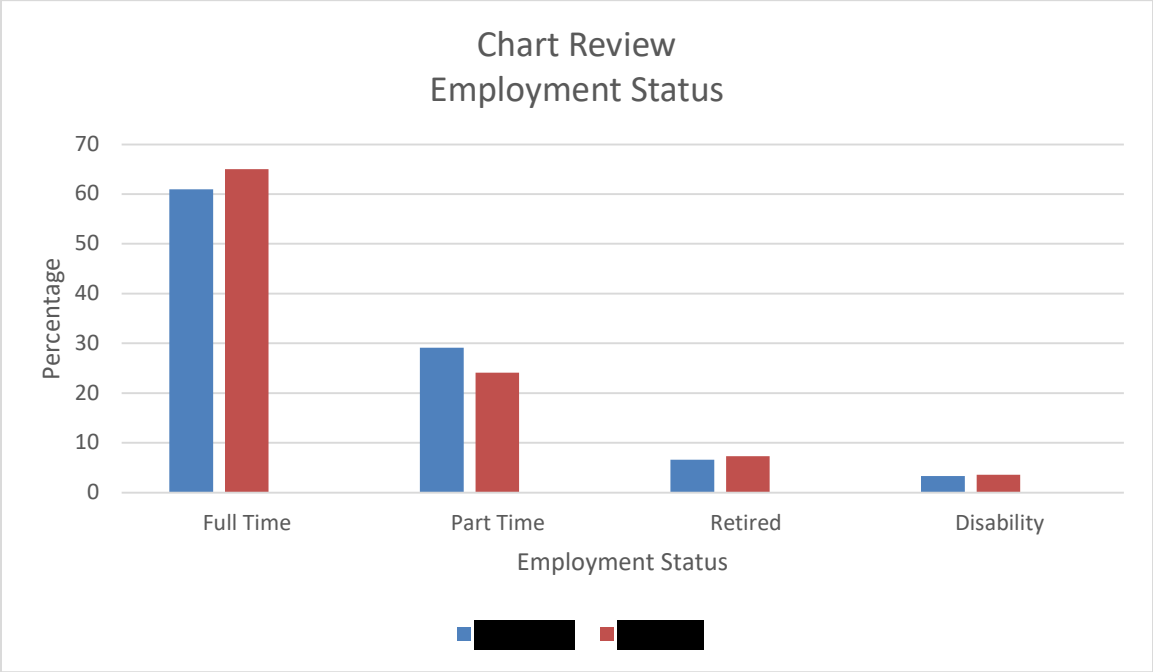
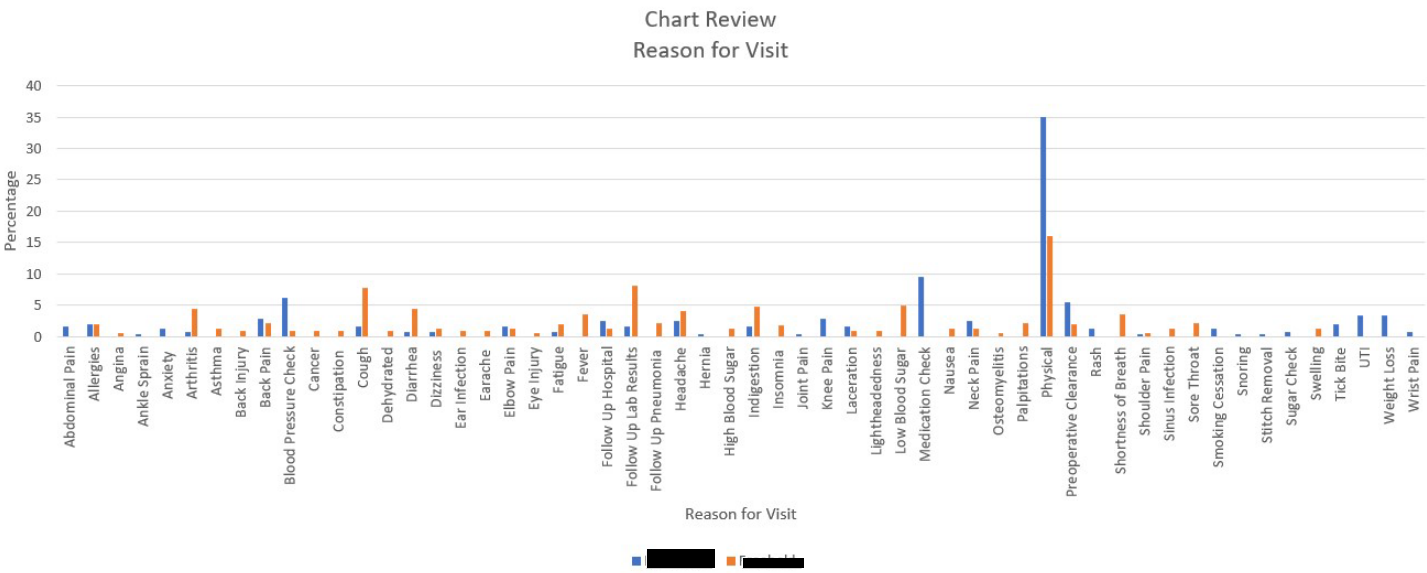


Figure 6. Reason for Visit Comparison



Appendix P.

Table 1 Pre-Intervention Chart Review Characteristics of Patients Treated for GAD Comparison

Characteristics of Treated for Anxiety	[redacted] (N=18)	[redacted] (N=13)
Gender		
Male	10	8
Female	8	5
Age		
20-29 years	2	1
30-39 years	3	3
40-49 years	3	3
50-59 years	6	4
60-69 years	4	2
Race		
White	12	7
Black/African American	3	3
Hispanic	2	2
Other		
Asian	0	0
Indian	1	1
Russian	0	0
Marital Status		
Married	7	10
Divorced	6	0
Widowed	0	0
Never married	5	3
Education		
Associate Degree	4	0
Bachelor's degree	7	7
Graduate Degree	3	5
High School	2	0
Some College	2	1
Employment Status		
Full Time	10	10
Part Time	8	3
Retired	0	0
Disability	0	0

Reason for Visit		
Anxiety	3	0
Ankle Injury	1	0
Arthritis	0	1
Back Pain	1	1
Cancer	0	1
Cough	0	2
Dehydration	0	1
Elbow Pain	0	1
Fatigue	0	1
Fever	0	1
Follow up Lab Results	0	2
Indigestion	1	0
Medication Check	3	0
Neck Pain	1	0
Physical	6	1
Pre-Operative Clearance	2	0
Sinus Infection	0	1

Appendix Q.

Table 2. Post Intervention Demographics of Participants (n=50)

Characteristics of Participants	Percentage (%)	Number (N=50)
Gender		
Male	42	21
Female	58	29
Age		
20-29 years	12	6
30-39 years	20	10
40-49 years	16	8
50-59 years	36	18
60-69 years	16	8
Race		
White	70	35
Black/African American	12	6
Hispanic	12	6
Other		
Asian	2	1
Indian	2	1
Russian	2	1
Marital Status		
Married	60	30
Divorced	10	5
Widowed	2	1
Never married	28	14
Education		
Associate Degree	4	2
Bachelor's degree	54	27
Graduate Degree	4	2
High School	36	18
Some College	2	1
Employment Status		
Full Time	84	42
Part Time	10	5
Retired	4	2
Disability	2	1
Reason for Visit		
Allergies	2	1
Blood Pressure Check	4	2
Back Injury	4	2
Cough	2	1
Diarrhea	2	1
Dizzy	2	1

Elbow Pain	2	1
Follow up Pneumonia	2	1
Follow up Hospital	2	1
Indigestion	2	1
Follow up Lab Results	4	2
Laceration	2	1
Low Back Pain	2	1
Lump in throat	2	1
Medication Check	10	5
Neck Pain	2	1
Physical	26	13
Physical & Hernia	2	1
Pre-Operative Clearance	8	4
Right Knee Pain	2	1
Shoulder Pain	2	1
Sinus Infection	6	3
Sinus Infection/Knee Pain	2	1
Wrist Pain	2	1
Weight Loss	4	2

Appendix R.

Figure 7. Post Intervention Generalized Anxiety Disorder Score Frequency

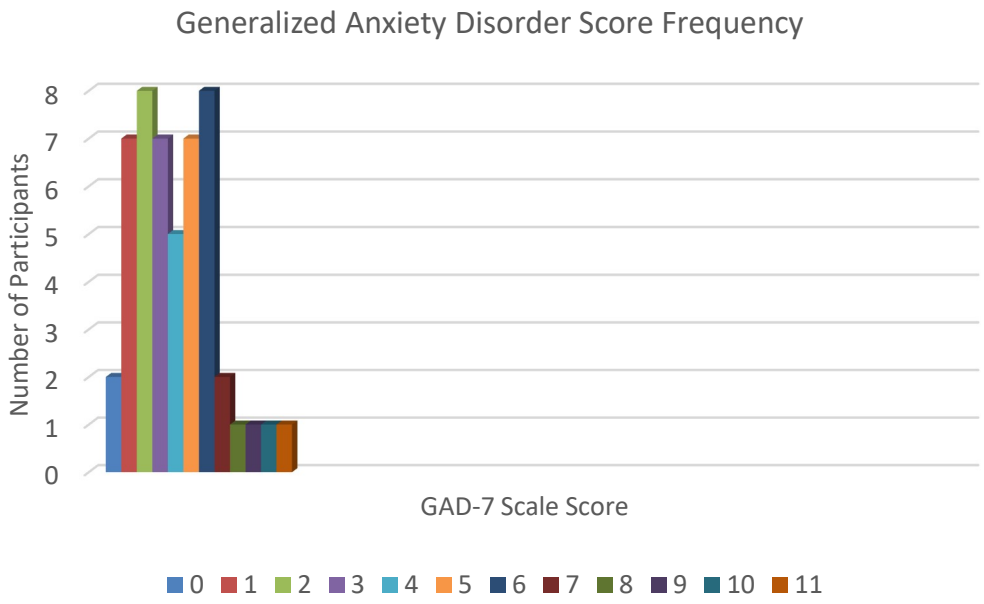


Table 3. Post Intervention GAD-7 Anxiety Severity Frequency

GAD-7 Anxiety Severity Scale	Percentage (%)	Study Group *n=50*
Minimal Anxiety (Gad-7 score 0-4)	54%	27
Mild Anxiety (GAD-7 score 5-9)	42%	21
Moderate Anxiety (GAD-7 score 10-14)	4%	2
Severe Anxiety (GAD-7 score 15-21)	0%	0

Appendix S.

Table 4. Post Intervention Average GAD-7 score by Characteristic

Characteristics of Participants	Average GAD-7 Score
Gender	
Male	3.6
Female	4.3
Marital Status	
Married	4.1
Divorced	2.0
Widowed	4.0
Never married	4.5
Education	
Associate Degree	4
Bachelor's degree	3.6
Graduate Degree	5.5
High School	4.4
Some College	5
Employment Status	
Full Time	4
Part Time	3.6
Retired	5
Disability	2

Appendix T.

Table 5. Frequency of Post Intervention Demographics of Participants by Location

Characteristics Post Intervention Participants by Location	[redacted] (N=25)	[redacted] (N=25)
Gender		
Male	8	13
Female	17	12
Age		
20-29 years	3	3
30-39 years	5	5
40-49 years	4	4
50-59 years	8	10
60-69 years	5	3
Race		
White	19	16
African American	2	4
Hispanic	3	3
Other		
Asian	0	1
Indian	0	1
Russian	1	0
Marital Status		
Married	16	14
Divorced	2	3
Widowed	1	0
Never married	6	8
Education		
Associate Degree	0	2
Bachelor's degree	14	13
Graduate Degree	0	2
High School	11	7
Some College	0	1
Employment Status		
Full Time	21	21
Part Time	2	3
Retired	2	0
Disability	0	1

Reason for Visit		
Allergies	0	1
Anxiety	0	0
Back Pain	0	1
Back Injury	2	0
Blood Pressure Check	2	0
Cough	1	0
Diarrhea	1	0
Dizziness	1	0
Elbow Pain	0	1
Follow up Hospital	0	1
Follow up Lab Results	0	2
Follow up Pneumonia	1	0
Indigestion	0	1
Knee Pain	0	1
Laceration	0	1
Lump in throat	1	0
Medication Check	2	3
Neck Pain	1	0
Physical	6	7
Physical & Hernia	0	1
Pre-Operative Clearance	2	2
Shoulder Pain	0	1
Sinus Infection	3	1
Weight Loss	2	0
Wrist Pain	0	1

Table 6. Post Intervention GAD-7 Anxiety Severity by Location

GAD-7 Anxiety Severity Scale	[redacted] Percentage (%)	[redacted] Percentage (%)
Minimal Anxiety (Gad-7 score 0-4)	56%	60%
Mild Anxiety (GAD-7 score 5-9)	44%	32%
Moderate Anxiety (GAD-7 score 10-14)	0%	8%
Severe Anxiety (GAD-7 score 15-21)	0%	0%

Appendix U.

Figure 8. Post Intervention GAD-7 Scores by Location

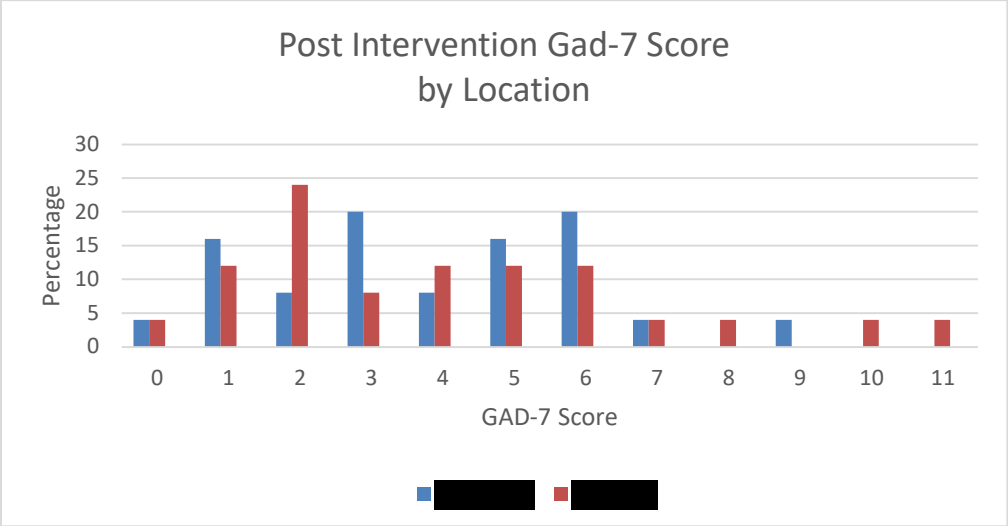


Table 7. Post Intervention Average GAD-7 Score by Location by Participant Characteristic

Characteristics of Participants	Average GAD-7 Score [redacted]	Average GAD-7 Score [redacted]
Gender		
Male	3.1	3.8
Female	4.2	4.3
Marital Status		
Married	3.5	4.7
Divorced	3.5	1.0
Widowed	4.0	-
Never married	5.0	4.7
Education		
Associate Degree	-	4.0
Bachelor's degree	3.3	3.8
Graduate Degree	-	5.5
High School	4.6	4.0
Some College	-	5.0
Employment Status		
Full Time	3.8	4.3
Part Time	4.0	3.3
Retired	5.0	-
Disability	-	2.0