

## Creating Healthy Work Environments 2019

### Effects of Cognitive Behavioral Therapy and Selective Serotonin Reuptake Inhibitor Protocol on Generalized Anxiety Disorder

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**Purpose:** Generalized anxiety disorder (GAD) has a high lifetime prevalence of reportedly at least 12% in the United States with 264 million individuals suffering from an anxiety disorder worldwide (Edmund & Sheppard, 2018; World Health Organization, 2017). Despite many invisible and intangible characteristics of GAD, it can cause significant distress, debilitation, decreased quality of life, and increased morbidity and mortality throughout the lifespan (Bystritsky, Khalsa, Cameron, & Schiffman, 2013). In addition, depression as well as alcohol and drug abuse are highly correlated with GAD (Edmund & Sheppard, 2018). Anxiety is considered the sixth largest contributor to global disability (World Health Organization, 2017). Proper attention and treatment to GAD is lacking (Bystritsky et al., 2013). Barriers to current treatment include a lack of available therapists and sessions, transportation constraints, cost-prohibitive services, and inappropriate use of potentially addictive medications (Bystritsky et al., 2013; Edmund & Sheppard, 2018). The purpose of this project is to improve treatment of GAD by implementing an evidence-based protocol that includes self-administered cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitor (SSRI) use.

**Sample:** The target population includes adults ages 18 years old and older with a diagnosis of GAD based on The American Psychiatric Association's (2013) *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) criteria. Additional inclusion criteria include the ability to speak and understand spoken and written English. Those with comorbid mental disorders are eligible for participation in order to allow for generalizability as many patients with GAD have comorbid diagnoses (Edmund & Sheppard, 2018). Patients taking anti-anxiety medications in addition to SSRIs, such as benzodiazepines, also remain eligible as it would be illogical, unethical, and unsafe to expect patients taking these medication to cease their administration and change to only SSRI therapy immediately. Participants will be recruited during their appointments, either initial or follow up, at an NP-owned family practice clinic in Northwest Indiana. Exclusion criteria includes individuals with current suicidal ideation, psychosis, cognitive impairment, and/or an inability to speak or understand English. Pregnant women and individuals younger than the age of 18 are also excluded.

**Methods:** High quality and high level evidence strongly supports the combination of self-administered CBT and SSRIs for anxiety symptom reduction. Approximately 81% of patients with GAD have responded well to combination CBT and pharmacotherapy compared with a 60% response rate for CBT alone and 55% response rate for pharmacotherapy alone (McBride, 2015). CBT is a form of psychotherapy that aims to modify thinking in order to combat dysfunctional thinking, encourage positive thoughts, and develop coping strategies for anxiety (Bystritsky et al., 2013; McBride, 2015). Antidepressant medications in the form of SSRIs are considered first-line therapy for GAD (Edmund & Sheppard, 2018). A best practice protocol was developed in accordance with the literature. In fulfillment of the protocol, a CBT workbook for anxiety will be administered in combination with the prescribing of an SSRI medication for each participant. Participants will complete the workbooks independently and take the medication as directed over an implementation period of 12 weeks. Stakeholders, including NPs, office managers, patients, and the community, are supportive of this endeavor. The Neuman Systems Model and Stetler Model were selected to aide in project implementation based on their applicability to core components.

**Results:** Multiple outcomes were selected for measurement in accordance with the literature, including one primary outcome and four secondary outcomes. The primary outcome to be measured is anxiety symptoms via the GAD-7 Scale, a valid and reliable tool for measuring anxiety symptom severity via patient self-report (Beard & Bjorgvinsson, 2014; Spitzer, Kroenke, Williams, & Lowe, 2006). A secondary outcome of depression symptoms will be measured via the Patient Health Questionnaire (PHQ-9), a self-

report tool for determining depressive symptom severity also with high validity and reliability (Kroenke, Spitzer, & Williams, 2001). Change in GAD status is to be measured via the Clinical Global Impressions-Improvement (CGI-I) Scale, which measures improvement or worsening of the disorder (Busner & Targum, 2007). Patient acceptability via the attrition rate, or the percentage of participants lost to follow up, will be measured. Patient satisfaction will be measured via the Patient Satisfaction Questionnaire (PSQ), a tool developed by the project manager to assess participant's level of satisfaction with use of the CBT workbooks regarding the concepts of convenience, ease of use, efficacy, overall satisfaction, worthiness, and engagement (McClanahan, 2018). The GAD-7 Scale and PHQ-9 will be measured at baseline, 4 weeks after the start of the intervention, 8 weeks after the start of the intervention, and 12 weeks after the start of the intervention. The CGI-I Scale will be measured 4 weeks, 8 weeks, and 12 weeks post-intervention. Patient acceptability and patient satisfaction will be measured upon project completion at 12 weeks post-intervention. Pre-intervention and post-intervention data will be analyzed via a paired *t*-test.

**Nursing Implications:** Results will provide worthwhile information to benefit nursing practice regarding the effectiveness of combined CBT and SSRIs for GAD treatment. Such intervention is anticipated to reduce anxiety symptoms among affected individuals. There is a call among the literature for providers to be more aware of the prevalence and severity of GAD, express greater sensitivity in the treatment of mental health, be more diligent and knowledgeable in assessing and diagnosing those affected, make treatment of GAD a priority, and provide better and earlier management of GAD among children, adolescents, and adults (McBride, 2015). This evidence-based practice project can aid in such advancements within the nursing profession regarding GAD.

**Conclusions:** Should the intervention protocol demonstrate a reduction in anxiety symptoms, providers will be encouraged to incorporate this protocol into practice to provide safe, accessible, effective treatment for GAD and improve anxiety/depression symptoms, GAD status, and quality of life. There is overwhelming support within the literature that combination therapy via CBT and SSRIs is best practice and yields the best outcomes. Evidence also greatly supports a need for this practice change, which incorporates the necessary components of best practice and aims to improve shortcomings in current clinical practice.

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**References:**

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### **Abstract Summary:**

An evidence-based protocol, including the combination of cognitive behavioral therapy (CBT) bibliotherapy and selective serotonin reuptake inhibitor (SSRI) medication, was implemented among adults diagnosed with generalized anxiety disorder (GAD) in order to assess the protocol's effectiveness on anxiety symptoms, depression symptoms, change in GAD status, acceptability, and patient satisfaction.

### **Content Outline:**

#### **1. Introduction**

- 1. Statement of Problem:** Anxiety disorders are the most prevalent mental health disorders, which supports the need to make them a priority in order to help a large number of individuals (Bystritsky, Khalsa, Cameron, & Schiffman, 2013). Approximately, a reported 12% of the United States population is affected by generalized anxiety disorder (GAD) (Edmund & Sheppard, 2018). This percentage is likely greater as GAD is often underdiagnosed and undertreated, and only one third of individuals with GAD seek

help (Bystritsky et al., 2013; Edmund & Sheppard, 2018). There is a need to raise awareness for the treatable nature of GAD and combat the current lack of proper attention and treatment (Bystritsky et al., 2013). Despite many invisible and intangible characteristics of GAD, it can cause significant debilitation among children, adolescents, and adults, including decreased quality of life and increased morbidity and mortality (Bystritsky et al., 2013; Edmund & Sheppard, 2018). Evidence highly supports the combination of self-administered cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitor (SSRI) medication as the best treatment for GAD (Nguyen, 2017). Despite such strong evidence, best practice is often not followed in the clinical setting. There are many barriers to existing treatment, including lack of available therapists and sessions, transportation constraints, cost-prohibitive services, and inappropriate use of potentially addictive medications. Thus, implementing best practice can aid in reducing barriers, improving accessibility, and yielding better outcomes for patients.

2. **PICOT:** Among adults presenting with generalized anxiety disorder (GAD) in the family practice setting (P), does the introduction of an intervention protocol to treat patients with combination therapy involving a selective serotonin reuptake inhibitor (SSRI) and self-administered cognitive behavioral therapy (CBT) via bibliotherapy (I) compared to the current practice of no protocol (C), improve GAD symptoms as measured by patient-reported scores on the Generalized Anxiety Disorder 7-item (GAD-7) Scale (O) over a 12-week period (T)?
2. **Theoretical Framework**
    1. **Theory:** The Neuman Systems Model was selected to facilitate this project based on its applicability to the topic of GAD and its wellness-oriented, wholistic focus (Neuman & Fawcett, 2011). The model considers the concepts of stress and the client's reaction to stress. Its goal is to achieve and maintain optimal wellness with wellness gauged on a continuum from the highest degree of wellness to severe illness or death.
    2. **EBP Model:** The Stetler Model was used to guide this project as the model focuses on the movement of evidence to practice, utilization of critical thinking, improvement in current practice, change in current ways of thinking, and implementation of safe and effective findings (Melnik & Fineout-Overholt, 2015). The model's five steps are clearly delineated and described and contribute to the ease with which this model can be followed in order to implement an EBP project successfully.
- **Review of Literature**
    1. **Systematic Search:** An exhaustive systematic search of the literature was performed via seven database, including CINAHL, ProQuest, MEDLINE via EBSCO, The Joanna Briggs Institute, National Guideline Clearinghouse, PsycINFO, and Cochrane Library. Citation chasing was also utilized. Key words included "generalized anxiety disorder\*" OR "anxiety disorder\*" AND (treat OR manag\*) AND ("primary care" OR "family practice"). Limiters included scholarly, peer reviewed sources, a publication date between 2013 and 2016, written in English language, and ages of child: 6-12 years through aged, 80 and over. Inclusion criteria included primary care, family practice, or outpatient setting, a population of children, adolescents, or adults, a diagnosis of anxiety disorder or GAD, and CBT and/or SSRI intervention. Exclusion criteria included hospital or inpatient setting, a population of infants or children under 7 years, poor quality, lack of GAD or anxiety disorder diagnosis, interventions other than CBTs or SSRIs, and inapplicable outcomes, such as comparison of anxiety levels before and after surgery.
    2. **Evidence Obtained:** The review of literature and quality appraisal yielded 15 relevant pieces of evidence. For comprehensiveness, no evidence was eliminated on the basis of level. The majority of evidence included was Level I and of high quality
      1. **Hierarchical ratings:** Leveling was determined using Melnyk and Fineout-Overholt's (2015) Hierarchy of Evidence in order to rank each piece of evidence by strength. A total of 9 Level I, 4 Level II, 1 Level III, and 1 Level V pieces were included.

2. **Quality ratings:** Critical appraisal was conducted using the Johns Hopkins Appraisal Tool and AGREE II Instrument. Ratings included high quality (A), good quality (B), and low quality (C) (Dearholt & Dang, 2017). A total of 9 high quality, 6 good quality, and 0 low quality pieces were included.
3. **Decision to Change Practice:** A decision to change practice was made on the basis that there is a lack of evidence-based practice being followed in clinical practice regarding the treatment of GAD. Best practice recommendations include combination therapy via CBT workbooks and SSRI antidepressant medication with patient education and close monitoring for school-age children, adolescents, adults, and older adults with a diagnosis of GAD based on The American Psychiatric Association's (2013) *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) in the outpatient setting. This best practice implementation can eliminate barriers, raise awareness for GAD and its treatable nature, and improve patient quality of life.
4. **Implementation of Practice Change**
  1. **Intervention:** The intervention protocol includes self-administered, bibliotherapy CBT in the form of a workbook for adults titled *The Cognitive Behavioral Therapy Workbook for Anxiety* by licensed psychologist William J. Knaus, EdD in combination with the prescribing of an SSRI medication, preferably sertraline with a maximum daily dose of 200mg. Verbal and written patient education, close monitoring, and outcomes measurement via telephone follow up every 4 weeks in accordance with the literature are also included within the protocol.
  2. **Targeted Outcomes:** Primary outcomes to be measured include anxiety symptoms via the Generalized Anxiety Disorder 7-item (GAD-7) Scale. Secondary outcomes to be measured include depression symptoms via the Patient Health Questionnaire (PHQ-9), change in GAD status via the Clinical Global Impressions-Improvement (CGI-I) Scale, patient acceptability via the attrition rate, and patient satisfaction via the Patient Satisfaction Questionnaire (PSQ). Outcomes will be measured at baseline and monthly for 12 weeks as applicable.
5. **Implications for Nursing:** Results will provide worthwhile information to benefit nursing practice regarding the effectiveness of CBT and SSRIs for GAD. Such interventions are anticipated to reduce anxiety symptoms. Providers are encouraged to incorporate this protocol in order to provide safe, accessible, effective treatment for patient with GAD, leading to improved GAD symptoms and the elimination of barriers.

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**Professional Experience:** 2019: pending graduation, Doctorate of Nursing Practice, Valparaiso University Development of this project began in Spring 2018, and implementation started in Fall 2018. Alesha learned of the extremely high prevalence of GAD while caring for patients in the primary care setting as a DNP student as well as from current literature. She has noted the presence of GAD among many patients in the acute care setting as well throughout her experiences as an RN and recognizes that no population is immune as children, adolescents, adults, and older adults can all be affected by GAD. She has a desire to change practice for GAD treatment, achieve better outcomes, and improve the quality of life of patients as well as her loved ones affected by GAD. 2014 – present: Registered Nurse, Women & Children's Unit 2014: Bachelor of Science in Nursing, Valparaiso University 2012 – 2014: Certified

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**Author Summary:** Alesha McClanahan is a Doctorate of Nursing Practice student at Valparaiso University. She obtained her BSN from Valparaiso University in 2014 and has worked as a registered nurse on a Women and Children's Unit for the past four years. Her interest in GAD is grounded in a desire to decrease the number of lives lost to suicide and allow loved ones and patients to live their lives to the fullest and enjoy every day.