Anxiety is Something to Worry About: the Effects of a Cognitive Behavioral Therapy and Selective Serotonin Reuptake Inhibitor Intervention Protocol on Generalized Anxiety Disorder

Alesha E. McClanahan
Valparaiso University

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ANXIETY IS SOMETHING TO WORRY ABOUT: THE EFFECTS OF A COGNITIVE BEHAVIORAL THERAPY AND SELECTIVE SEROTONIN REUPTAKE INHIBITOR INTERVENTION PROTOCOL ON GENERALIZED ANXIETY DISORDER

by

ALESHA E. MCCLANAHAN

EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions of Valparaiso University, Valparaiso, Indiana in partial fulfillment of the requirements For the degree of

DOCTOR OF NURSING PRACTICE

2019

Alesha E. McClanahan 4/25/19
Student Date

Christine Brown 4/25/19
Advisor Date
DEDICATION

This project is dedicated to my loving family. To my incredible mother, Trish Dempsey, you beautiful soul and my Lorelai Gilmore, thank you for your unwavering support of my goals, achievements, and above all else, my happiness through not only this program, but also my entire life. You are more of an asset to this world and to my life than you will ever know. I would never have been able to accomplish this were it not for the way you have inspired me, taught me, sacrificed for me, and made me want to be a better person. To my wonderful husband, Zachary McClanahan, thank you for not only sharing your last name with me, but also for sharing in all the challenges as well as the triumphs throughout my entire time in this DNP program. Your patience and understanding, willingness to take on an extra workload, insistence that I finish what I set out to do, and relentless belief in me are the reasons that I was able to obtain a doctoral degree. To my husband’s kind family, thank you for welcoming me into your homes and your hearts, for your love and support, and for the joy and laughter that you have brought to my life.

I would like to thank my cherished loved ones who are watching over me from heaven: Dad, Nana, Pop-Pop (Cyril Schaad), and Uncle Mark (Dr. Mark Schaad). To my strong and stoic father, William Dempsey, who could not contain his excitement upon hearing of my plans to enter the DNP program and passed only days before he would have seen me start classes, thank you for dedicating your life to working hard for our family, for making my endeavors possible, and for loving my mother throughout 33 years of marriage. To my saint of a Nana, Patricia Schaad, thank you for teaching me your strength, kindness, and positive attitude. You taught me everything except how to live without you.

Thank you for all you do for me. I love you all very much. I am fortunate to know you and proud to call you my family. You are all the reason I was able to obtain a doctoral degree.
ACKNOWLEDGMENTS

I would like to thank my incredible project advisor, Dr. Christina Cavinder, for her immense expertise, patience, kindness, humor, warmth, guidance, and support throughout this project. I have the utmost respect and admiration for her and her contributions to the nursing profession through her work as a neonatal nurse practitioner (NP) and nurse educator. She has been a guidepost to me since the very beginning of my DNP journey when I was first considering whether to become an NP. She kindly allowed me to shadow her in her role as an NP without even knowing me. I would like to sincerely thank her for contributing to my decision to become an NP, helping me grow throughout the DNP program, and supporting me as life comes full circle through completion of my EBP project and DNP. Getting to know her has truly been a pleasure. I cannot thank her enough for all the laughs we have had, the amazing time we had on the Ireland Spring Break Trip, and for sharing so much of her vast nursing knowledge and skills with me. She is an NP, educator, and person that I admire very much through her dedication to the profession, tireless efforts, and kindness to all.

I would like to thank Sigma Theta Tau Zeta Epsilon Chapter for providing me with a generous grant for this project. Thank you to the College of Nursing and Health Professions, Dean Allen, and faculty for the experience of presenting my project at Sigma’s Creating Healthy Work Environments Conference, for being instrumental in guiding this project, and for so much support, kindness, knowledge sharing, and exemplary efforts. I also want to thank my site facilitators for believing in the need for this project and allowing me to interact with their patients. I want to thank the participants for their time and feedback. I want to thank my classmates and friends for always rooting for one another to succeed, building each other up, and supporting each other. You all filled classroom time, library visits, study sessions, and get togethers with great memories. I’m grateful for the lifelong friendships we have created. I would like to extend a final thank you to my coworkers and friends.
PREFACE

May this project aide in taking our worries away, decreasing the number of lives lost to suicide, and allowing us all to live our lives to the fullest and enjoy every day.

“We love them. We miss them. We grieve them. And so, we live our lives to make them proud.”
– Anonymous

“Those we love don’t go away; they walk beside us every day, unseen, unheard, but always near, still loved, still missed, and very dear.” - Anonymous
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEDICATION</td>
<td>iii</td>
</tr>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>iv</td>
</tr>
<tr>
<td>PREFACE</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vi</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>viii</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>ix</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>x</td>
</tr>
<tr>
<td><strong>CHAPTERS</strong></td>
<td></td>
</tr>
<tr>
<td>CHAPTER 1 – Introduction</td>
<td>1</td>
</tr>
<tr>
<td>CHAPTER 2 – Theoretical Framework and Review of Literature</td>
<td>15</td>
</tr>
<tr>
<td>CHAPTER 3 – Implementation of Practice Change</td>
<td>83</td>
</tr>
<tr>
<td>CHAPTER 4 – Findings</td>
<td>95</td>
</tr>
<tr>
<td>CHAPTER 5 – Discussion</td>
<td>116</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>136</td>
</tr>
<tr>
<td>AUTOBIOGRAPHICAL STATEMENT</td>
<td>141</td>
</tr>
<tr>
<td>ACRONYM LIST</td>
<td>142</td>
</tr>
<tr>
<td><strong>APPENDICES</strong></td>
<td></td>
</tr>
<tr>
<td>APPENDIX A – NIH Certificate of Completion</td>
<td>145</td>
</tr>
<tr>
<td>APPENDIX B – Johns Hopkins Tools Permission For Use</td>
<td>146</td>
</tr>
<tr>
<td>APPENDIX C – Evidence-Based Practice Project Explanation</td>
<td>147</td>
</tr>
<tr>
<td>APPENDIX D – Informed Consent Form</td>
<td>148</td>
</tr>
</tbody>
</table>
APPENDIX E – Demographic Form .......................................................151
APPENDIX F – Code Sheet .................................................................153
APPENDIX G – Generalized Anxiety Disorder 7-item (GAD-7) Scale .................................................................154
APPENDIX H – Patient Health Questionnaire (PHQ-9) ..................156
APPENDIX I – Clinical Global Impressions-Improvement (CGI-I) Scale .................................................................158
APPENDIX J – Patient Satisfaction Questionnaire (PSQ) ..............160
APPENDIX K – Patient Instructions ....................................................163
APPENDIX L – Best Practice Intervention Protocol .........................164
APPENDIX M – Institutional Review Board Approval .................165
APPENDIX N – Handout for Sustainability .........................166
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1.1 Anti-Anxiety Medications</td>
<td>7</td>
</tr>
<tr>
<td>Table 2.1 Evidence Search Table</td>
<td>28</td>
</tr>
<tr>
<td>Table 2.2 Levels of Evidence</td>
<td>30</td>
</tr>
<tr>
<td>Table 2.3 Appraisal of Evidence</td>
<td>33</td>
</tr>
<tr>
<td>Table 4.1 Demographic Characteristics</td>
<td>97</td>
</tr>
<tr>
<td>Table 4.2 Repeated Measures ANOVAs with Means and Standard Deviations ( n = 10 )</td>
<td>107</td>
</tr>
<tr>
<td>Table 4.3 PHQ-9 Post Hoc Paired ( t ) Tests ( n = 10 )</td>
<td>108</td>
</tr>
</tbody>
</table>
**LIST OF FIGURES**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 4.1 Gender Pie Chart</td>
<td>99</td>
</tr>
<tr>
<td>Figure 4.2 Race Pie Chart</td>
<td>99</td>
</tr>
<tr>
<td>Figure 4.3 Marital Status Pie Chart</td>
<td>100</td>
</tr>
<tr>
<td>Figure 4.4 Health Insurance Pie Chart</td>
<td>100</td>
</tr>
<tr>
<td>Figure 4.5 Highest Level of Education Pie Chart</td>
<td>101</td>
</tr>
<tr>
<td>Figure 4.6 Employment Status Pie Chart</td>
<td>101</td>
</tr>
<tr>
<td>Figure 4.7 Annual Household Income Pie Chart</td>
<td>102</td>
</tr>
<tr>
<td>Figure 4.8 Improvement in Mean Anxiety (GAD-7) and Depression (PHQ-9) Symptom Severity with Combination Therapy ($n = 10$)</td>
<td>109</td>
</tr>
<tr>
<td>Figure 4.9 Patient Satisfaction Questionnaire Convenience Pie Chart</td>
<td>111</td>
</tr>
<tr>
<td>Figure 4.10 Patient Satisfaction Questionnaire Ease of Use Pie Chart</td>
<td>111</td>
</tr>
<tr>
<td>Figure 4.11 Patient Satisfaction Questionnaire Worthwhile Pie Chart</td>
<td>112</td>
</tr>
<tr>
<td>Figure 4.12 Patient Satisfaction Questionnaire Satisfaction with Impact on Anxiety Symptoms Pie Chart</td>
<td>112</td>
</tr>
<tr>
<td>Figure 4.13 Patient Satisfaction Questionnaire Satisfaction Overall</td>
<td>113</td>
</tr>
</tbody>
</table>
ABSTRACT

Generalized anxiety disorder (GAD) is highly prevalent in the United States with at least 12% of the population affected (Edmund & Sheppard, 2018). GAD can pose significant distress and debilitation throughout the lifespan (Bystritsky, Khalsa, Cameron, & Schiffman, 2013; Edmund & Sheppard, 2018). Barriers to treatment include adverse effects, inaccessibility, and expense. The purpose of this project was to implement an evidence-based protocol involving combination therapy with self-administered cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitor (SSRI) medication in order to improve patient outcomes through more accessible, affordable, and standardized treatment of GAD. The Neuman Systems Model and Stetler Model were utilized to guide this project among a sample population of 20 adults with GAD at a nurse practitioner-owned family practice clinic in Northwest Indiana. In fulfillment of the protocol, each participant was prescribed an SSRI in combination with independent completion of a CBT workbook for anxiety over 12 weeks. Anxiety symptoms via the Generalized Anxiety Disorder 7-item (GAD-7) Scale and depression symptoms via the Patient Health Questionnaire (PHQ-9) were measured at baseline, week 4, week 8, and week 12. A one-way repeated-measures analysis of variance (ANOVA) indicated that while mean GAD-7 scores decreased from baseline ($M = 4.20, SD = 4.32$) to week 12 ($M = 1.60, SD = 2.12$), there was no statistically significant decrease found ($F(3,27) = 1.94, p > 0.05$). Mean PHQ-9 scores decreased from baseline ($M = 4.80, SD = 3.58$) to week 12 ($M = 1.90, SD = 2.81$), and there was a statistically significant decrease found ($F(3,27) = 4.34, p < 0.05$). Participants were satisfied (44.4%), very satisfied (33.3%), and extremely satisfied (22.2%) with self-administered CBT. Providers are recommended to implement combined self-administered CBT and SSRI medication as a cost-effective, accessible, and effective method to decrease anxiety and depression symptoms among patients with GAD.
CHAPTER 1
INTRODUCTION

Background

As one of the most common psychiatric illnesses addressed in the primary care setting, generalized anxiety disorder (GAD) is highly prevalent in the United States as well as in other countries and poses a significant problem for not only adults, but also for children and adolescents (Edmund & Sheppard, 2018). As many as 264 million people suffered from an anxiety disorder worldwide in 2015 (World Health Organization, 2017). This indicated a 15% rise since 2005 in the number of individuals affected with further rise expected. The lifetime prevalence of GAD alone is reportedly 12% in the United States with a higher prevalence suspected due to a lack of care sought by affected individuals (Edmund & Sheppard, 2018). Despite many invisible and intangible characteristics of GAD, it can cause significant debilitation (Bystritsky, Khalsa, Cameron, & Schiffman, 2013). GAD is "...characterized by excessive worry or anxiety about everyday events and problems to the point at which the individual experiences considerable distress and difficulty in performing day to day tasks" (Campbell, 2016, p. 1). Decreased quality of life, decreased productivity, negative impact on well-being, increased morbidity and mortality, and increased abuse of drugs and alcohol are often associated with GAD (Bystritsky et al., 2013; Edmund & Sheppard, 2018). Approximately 32.3% of individuals with GAD reportedly have serious impairment, 44.6% have moderate impairment, and 23.1% have mild impairment (National Institute of Mental Health, 2017). Anxiety is considered the sixth largest contributor to global disability (World Health Organization, 2017). The impact of anxiety on functional impact has led to a total of 24.6 million years lived with disability according to 2015 data.

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) provides specific diagnostic criteria for GAD (American Psychiatric Association, 2013). In order
to classify as a diagnosis of GAD, A) such excessive anxiety and worry about multiple events or activities must be present for a majority of days throughout a time period of at least 6 months, B) the worry is difficult to control, C) the anxiety and worry are associated with three or more of the following six symptoms in adults or one or more of the following six symptoms in children: 1. feeling restless or on edge, 2. easily fatigued, 3. difficulty concentrating or remembering thoughts, 4. irritability, 5. muscle tension, 6. sleep disturbance (trouble falling or staying asleep, restlessness during sleep, feeling unsatisfied with sleep), D) significant impairment in functioning, social, and/or occupational aspects, E) the anxiety, worry, and symptoms are not associated with the use of a substance (drug abuse or medication use) nor another medical condition, F) there is a lack of a better explanation for such difficulty including another medical disorder, mental disorder, or anxiety disorder (American Psychiatric Association, 2013).

There is evidence to support the influence of both environmental and genetic factors associated with GAD. Individuals with parents who have been diagnosed with an anxiety disorder are more likely to develop an anxiety disorder themselves (Edmund & Sheppard, 2018). Overprotective or overcontrolling and negative or highly critical parenting styles can also contribute to the development of GAD in adolescents. Disturbances among norepinephrine, serotonin, and gamma-aminobutyric acid may also be responsible. Data support that dysregulation in areas of the brain that control emotional processing, such as the anterior limbic network, may contribute to the development of GAD (McBride, 2015). Such brain structures among individuals with GAD react easily to stimuli that elicit fear and other strong emotions among individuals with GAD. The development of GAD is associated with behavioral inhibition, which is defined as the likelihood to feel distress and to withdraw from unfamiliar or new stimuli.

The median age of onset of GAD is characterized as 30 years old, but symptoms may begin years sooner (Edmund & Sheppard, 2018). Women are affected twice as often as men. Poverty, loss, other mental disorders, and life events perceived as negative increase the likelihood of GAD development. There are conflicting data regarding the relationship of
socioeconomic status and the risk of GAD development with some studies indicating that lower occupational status, income, and education level are associated with higher risk of GAD development and others indicating that lower socioeconomic status is linked to lower rates of GAD than those of higher statuses (McBride, 2015). Additional risk factors for GAD include personality characteristics of behavioral inhibition, negative affect, low self-esteem, decreased adaptability, and poor self-regulation. Conflict among parents and children or among siblings as well as interparental violence, separation, and divorce can increase GAD risk. Report of suicidal ideation and past attempts of self-harm are more common among adolescents with GAD than those without. Additional risks associated with GAD in adolescence include alcohol and cigarette abuse, academic difficulties, conflicts at home, struggles in social situations, negative self-image, rejection by peers, and being left out of activities with peers. Adolescents with GAD may have fewer friendships and be less liked by their peers as a result of such relationship struggles. Being the victim of bullying, in particular, is the most influential factor among peer relationships in the development of GAD. Depressive disorders are highly correlated with GAD (Edmund & Sheppard, 2018). The correlation is so great that coexisting depression among patients with symptoms of GAD is not only possible, but likely probable. In 2015, approximately 322 million individuals suffered from depression worldwide (World Health Organization, 2017). Depression also strongly correlates with suicide deaths, which total approximately 800,000 per year. Common psychiatric comorbidities of individuals with GAD include substance use/abuse, social anxiety disorder, obsessive compulsive disorder, post-traumatic stress disorder, and bipolar disorder (Edmund & Sheppard, 2018).

**Statement of the Problem**

**Data from the Literature Supporting Need for the Project**

Anxiety disorders are the most prevalent mental health disorders, which supports the need to make them a priority to help a large number of individuals (Bystritsky et al., 2013). Anxiety disorders are such a significant problem in the United States, yet they often do not
receive as much recognition and care as other psychological disorders. There are a multitude of challenges associated with understanding, diagnosing, and treating GAD in primary care. Many symptoms of GAD can be associated with other disorders, such as anemia, hyperthyroidism, cardiac dysrhythmias, or substance abuse, contributing to the misdiagnosis and underdiagnosis of GAD that often occurs (Edmund & Sheppard, 2018). The physical symptoms that patients with GAD report may be nonspecific, confusing, or ill-defined, and they may be variable, disappearing on the weekends or during vacations (McBride, 2015). In addition, other health conditions and comorbidities often take priority over the treatment of GAD, leading to a lack of timely and proper treatment. Another challenge is the lack of affected individuals seeking care with only a reported one third of individuals with GAD presenting for help (Edmund & Sheppard, 2018). Further adding to these dilemmas include the barriers associated with treatment, such as a lack of cognitive behavioral therapy (CBT) therapists or cost-prohibitive CBT services (Bystritsky et al., 2013). These challenges lead to the underdiagnosis and undertreatment of GAD.

According to the American Psychiatric Association, combination pharmacotherapy and psychotherapy, especially CBT, elicits great response rates in the majority of patients (Edmund & Sheppard, 2018). Such combination therapy has been shown to yield the best results and helps to reduce relapse, relieve symptoms, and develop coping strategies (Edmund & Sheppard, 2018; McBride, 2015). 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). Therefore, patients with GAD should be provided with these options for treatment.

CBT is a form of psychotherapy that aims to modify thinking in order to combat dysfunctional thinking and encourage positive thoughts (Bystritsky et al., 2013; McBride, 2015). It allows patients to change their negative and distorted thoughts into more positive and realistic ones and to confront the situations and beliefs that cause them to feel anxious and fearful. Side
effects of CBT are minimal but may include emotional vulnerability, emotional discomfort, frustration, crying, anger, feeling physically drained, temporary stress, and temporary anxiety as a result of addressing such sensitive thoughts (May Clinic, 2018a). CBT is a long-term therapy that typically yields success with higher patient engagement and attendance (Bystritsky et al., 2013). It often involves the use of manuals or daily homework to promote the learning of methods to reduce negative reactions to anxiety, modification of irrational thoughts, and development of coping skills. There are many different types of CBT programs. However, efficacy and long-term outcomes are comparable among those most commonly used (McBride, 2015). Due to the lack of available CBT therapists and affordable sessions, there is a call for making CBT more accessible in primary care through education and training (Bystritsky et al., 2013). Self-administered CBT currently serves to help fill this void. There is evidence to support the effectiveness of self-administered CBT, and its efficacy via different methods of dissemination continues to be further explored through research and evidence-based practice (EBP).

Evidence supports the effectiveness of pharmacologic therapy for GAD with selective serotonin reuptake inhibitors (SSRIs), which are classified as antidepressant medications (Edmund & Sheppard, 2018). SSRIs are considered first-line therapy. Several weeks of SSRI use may be necessary to achieve maximal effects. SSRIs work by increasing serotonin activity (Hirsch & Birnbaum, 2019). Serotonin, or 5-hydroxytryptamine (5-HT), is a neurotransmitter released in the brain. The pharmacodynamics of SSRIs allows them to decrease action of the presynaptic serotonin reuptake pump by 60-80%, increasing the amount of time that serotonin is thus available at the synapse. This, in turn, increases serotonin activity by increasing the number of receptors occupied by serotonin at the postsynaptic neuron. Examples of SSRI medications include fluoxetine, paroxetine, citalopram, escitalopram, and sertraline. Side effects of SSRIs may include gastrointestinal symptoms such as nausea and diarrhea, sexual dysfunction such as decreased libido or erectile dysfunction, insomnia, headache, blurred
vision, drowsiness, dry mouth, nervousness, agitation, restlessness, dizziness, and possible weight gain (Edmund & Sheppard, 2018; Mayo Clinic, 2018b). Drug interactions, serotonin syndrome, and pregnancy risks are associated with some SSRIs. Paroxetine and escitalopram are the only Food and Drug Administration (FDA) approved SSRIs. Other medications often used in the treatment of GAD that are not first-line agents include serotonin-norepinephrine reuptake inhibitors (SNRIs) and benzodiazepines. Examples of SNRIs include venlafaxine, desvenlafaxine, and duloxetine. SNRIs may cause side effects including weight gain, nausea, insomnia, constipation, sweating, and increased blood pressure. Venlafaxine and duloxetine are the only FDA approved SNRIs. Buspirone is another medication often used. However, it is often incorrectly prescribed as needed rather than on a scheduled basis. Despite its efficacy, it can increase the risk of serotonin syndrome in patients taking additional serotonergic medications. Benzodiazepines also are effective yet pose a multitude of risks including the potential for dependence, tolerance concerns, difficulty weaning or discontinuing, and adverse reactions of amnesia, rebound anxiety, diminished psychomotor performance, or withdrawal symptoms. Additional information regarding anti-anxiety medications is presented in Table 1.1 (Bystritsky, 2019; Hirsch & Birnbaum, 2019).
<table>
<thead>
<tr>
<th>Medication</th>
<th>Class</th>
<th>Use</th>
<th>Examples</th>
<th>Risks</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Anti-depressant</td>
<td>First line</td>
<td>Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline</td>
<td>Generally well tolerated and safe; risks – serotonin syndrome, drug interactions, pregnancy</td>
<td>Gastrointestinal symptoms such as nausea and diarrhea, sexual dysfunction such as decreased libido or erectile dysfunction, insomnia, headache, blurred vision, drowsiness, dry mouth, nervousness, agitation, restlessness, dizziness, weight gain</td>
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<tr>
<td>Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)</td>
<td>Anti-depressant</td>
<td>NOT first line</td>
<td>Desvenlafaxine, Duloxetine, Levomilnacipran, Milnacipran, Venlafaxine</td>
<td>Weight gain, nausea, insomnia, constipation, sweating, increased blood pressure</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Sedative/ Hypnotic/ Anxiolytic</td>
<td>NOT first line</td>
<td>Alprazolam, Clonazepam, Diazepam, Lorazepam</td>
<td>Potential for dependence, tolerance concerns, difficulty weaning or discontinuing</td>
<td>Amnesia, rebound anxiety, diminished psychomotor performance, or withdrawal symptoms</td>
</tr>
</tbody>
</table>
| Serotonin Modulators | Anti-depressant | NOT first line | Nefazodone  
| | | | Trazodone  
| | | | Vilazodone  
| | | | Vortioxetine  
| | | | Drowsiness, orthostatic hypotension, QTc prolongation, gastrointestinal upset, weight gain, sexual dysfunction  
| Tricyclic and Tetracyclic Antidepressants (TCAs) | Anti-depressant | NOT first line | Amitriptyline  
| | | | Amoxapine  
| | | | Clomipramine  
| | | | Desipramine  
| | | | Doxepin  
| | | | Imipramine  
| | | | Maprotiline  
| | | | Nortriptyline  
| | | | Protriptyline  
| | | | Trimipramine  
| | | | Anticholinergic effects, drowsiness, insomnia, agitation, orthostatic hypotension, QTc prolongation, gastrointestinal upset, weight gain, sexual dysfunction  
| Atypical Agents | Anti-depressant | NOT first line | Agomelatine  
| | | | Bupropion  
| | | | Mirtazapine  
| | | | Drowsiness, anticholinergic effects, insomnia, agitation, QTc prolongation, gastrointestinal upset, weight gain, sexual dysfunction  
| Monoamine Oxidase Inhibitors | Anti-depressant | NOT first line | Isocarboxazid  
| | | | Phenelzine  
| | | | Selegiline  
| | | | Tranylcypromine  
| | | | Anticholinergic effects, drowsiness, insomnia, agitation, orthostatic hypotension, gastrointestinal upset, weight gain, sexual dysfunction |
### Azapirones

<table>
<thead>
<tr>
<th>Anxiolytic/Antipsychotic</th>
<th>NOT first line</th>
<th>Buspirone Gepirone Ispaprione</th>
<th>Dizziness, nausea, headache, insomnia, agitation</th>
<th>I upset, weight gain, and sexual dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Azapirones</strong></td>
<td>Anxiolytic/Antipsychotic</td>
<td>NOT first line</td>
<td>Buspirone Gepirone Ispaprione</td>
<td>Dizziness, nausea, headache, insomnia, agitation</td>
</tr>
</tbody>
</table>
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 call also includes a need for more knowledgeable administration of effective interventions in primary care and the communication of such effective treatment to the public (Bystritsky et al., 2013). It is important to raise awareness that GAD is treatable and to widely disseminate best practice (McBride, 2015). There is overwhelming support that the best treatment for GAD is the combination of an SSRI and CBT. The development of a trusting relationship between the provider and patient with a team-based approach including patient involvement in treatment decisions has been shown to be beneficial (Edmund & Sheppard, 2018). Effective treatment requires time and effort on behalf of both the provider and patient. There is much evidence to support a need for this project, which includes all of these necessary components based upon best practice and aims to improve these shortcomings in current clinical practice.

Data from the Clinical Agency Supporting Need for the Project

The clinical agency where this EBP project was conducted was a family practice clinic in Northwest Indiana (E. Strutz, personal communication, July 10, 2018). This clinic is owned by a nurse practitioner (NP) who is the sole provider in office. A collaborative agreement with a physician located outside of the practice is in place who reviews 5% of the patient charts. Two medical assistants also provide patient care. The NP and office manager approved the project and served as the site facilitators. Clinical agency data were provided by the office manager. This primary care office was opened in April 2012. Care is provided to an age range of infants to adults, from birth to death. Approximately 105 patients are seen in the office each week, and approximately 15% of these patients have depression and/or anxiety, with data remaining rather consistent throughout the entire year.
The rural town in which this clinical agency is located has a population of approximately 909 residents with a diversity index of 20, which represents the likelihood on a scale from 0 to 100 that two people selected at random from the town will be of different race or ethnicity (Home Town Locator, Inc. 2018). A population consisting of only one race and one ethnic group would have a diversity index of 0, indicating a lack of diversity. When there is an even distribution of two or more race or ethnic groups in an area, the diversity index is 100. When compared to other Indiana towns, this town is considered to be within the upper quartile for diversity. The average household income of residents is $54,153, the average home value is $146,272, and the average family size is three (Home Town Locator, Inc., 2018). The unemployment rate in this town is 7.6%, and 8.7% live in poverty. Approximately 45.5% of residents have obtained a high school diploma, and approximately 6.2% have obtained a bachelor’s degree. The median age of town residents is 29.6 compared to 37.4 for the state of Indiana (Stats America, 2016). The clinical agency provides care to patients from this town as well as neighboring towns.

The office manager, NP, and medical assistants at this office have passionately supported this EBP project, its goals, and its great need in practice since initial contact and proposal of the project (L. K***, personal communication, June 11, 2018). They discussed that a significant number of patients present to their office with GAD, and the stigma and barriers to treatment pose great challenges. They have mentioned their struggles with and reservations in prescribing benzodiazepines for patients as well as the reluctance of some patients to fulfill their referrals to psychiatric care and counseling. As a result of such challenges, they have expressed their difficulty in consistently following best practice recommendations. A protocol such as the one developed by this EBP project has not been previously implemented nor currently exists at the practice. The staff has expressed their interest in the help that this project can provide them in effectively treating patients with GAD and improving patient outcomes. The project manager and staff at the clinical agency believe that this project can be very beneficial to this practice, make a difference in the quality of life and symptomology of their patients with
GENERALIZED ANXIETY DISORDER PROTOCOL

GAD, and help serve as a guide for NPs to facilitate such positive outcomes and proper treatment plans. This is congruent with the mission statement of the clinical agency which expresses this practice’s commitment to high quality of life (K. Family Medicine, 2018).

Purpose of the Evidence-Based Practice Project

Compelling Clinical Question

The purpose of this EBP project titled, Anxiety is Something to Worry About: The Effects of a Cognitive Behavioral Therapy and Selective Serotonin Reuptake Inhibitor Intervention Protocol on Generalized Anxiety Disorder, was to improve treatment of GAD by developing and implementing an evidence-based protocol including CBT and SSRI use. Thus, a protocol for NPs and other providers to utilize in order to provide proper and consistent treatment of patients with GAD via SSRI use and CBT to yield best patient outcomes was provided. The project explored the effects of SSRI use and self-administered CBT on symptoms of GAD experienced by patients across much of the lifespan. The aims of the project included decreasing patient symptoms of GAD, increasing knowledge of providers regarding appropriate care of patients with GAD, and raising awareness for GAD and its treatable nature. EBP involves the translation of the best available evidence into clinical practice in order to foster the highest quality of care and best patient outcomes. It begins with clinical inquiry, which entails gathering data to evaluate available treatment in order to determine the best choice. Such clinical inquiry led to the development of the following compelling clinical question (Melnyk & Fineout-Overholt, 2015). What is the best way to decrease symptoms of generalized anxiety disorder (GAD) among affected adults in primary care?

PICOT Question

Clinical questions are often clearly posed in PICOT format with (P) standing for patient population/disease of interest, (I) for intervention or issue of interest, (C) for comparison intervention or issue of interest, (O) for outcome of interest, and (T) for time over which the population is observed (Melnyk & Fineout-Overholt, 2015). The following PICOT question was
developed to guide the EBP project: 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 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)?

**Significance of the EBP Project**

As treatment of GAD often begins in primary care, providers in this setting have a vital role in ensuring that those affected receive proper care. This project aimed to implement a practice change based on current, quality evidence-based practice recommendations. Such practice change consisted of a protocol including SSRI and CBT use for the best treatment of patients affected by GAD in the family practice setting. This EBP project aimed to fight the stigma associated with mental illness and to give GAD the recognition it deserves in order for individuals with GAD to receive timely care that allows them to live healthier lives. Accurate measurement of outcomes provided greater understanding of interventions and their effects on a multitude of different aspects, including symptom severity, comorbid depression, acceptability of treatment, and much more. The project ultimately served to significantly reduce worry, decrease the rate of suicide, and allow individuals affected by GAD to gain back control of their lives and enjoy every day. As application of this protocol expands to other family practice settings, it can assist providers in gaining further knowledge and skills regarding appropriate treatment of GAD and thus, better equip them to care for this population. This will aide in continuity and quality of care provided, as there is currently much discourse and lack of unity in the treatment of GAD. In addition, this will support early treatment of GAD and help to prevent delays in care. Finally, by implementing such best practice recommendations, patients can receive greater relief of GAD symptoms, which may translate into improvement of many areas
of their lives, including greater quality of life. By facilitating a focus on self-care, wellness can be achieved.
CHAPTER 2
THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

Theoretical Framework

After thorough review of many theoretical frameworks and EBP models, the Neuman Systems Model and Stetler Model respectively, were selected to aide in the development of this EBP project based on their applicability to the core components of the project. The Neuman Systems Model was highly applicable due to its premise of environmental stressors eliciting a reaction in a person based in part on his or her ability to cope with such stressors as well as the model’s aim for the person to achieve their highest level of wellness possible (Neuman & Fawcett, 2011). These components are important as this project included the incorporation of best practice for the treatment of GAD in order to help patients learn to cope with stressors that cause them anxiety to yield improved quality of life. The Stetler Model served as a guide for the EBP process of this project with its five detailed steps for development, implementation, and analysis in order to foster successful integration of practice change and worthwhile conclusions (Melnyk & Fineout-Overholt, 2015). A comprehensive review of the literature was performed in order to determine best practice interventions for the treatment of GAD as well as details regarding their efficacy and the best methods of implementation. A description, appraisal, and synthesis of such literature will be presented in order to disseminate best practice recommendations in the form of a protocol for patients with GAD.

Overview of Theoretical Framework

The Neuman Systems Model was utilized to guide this endeavor due to its ideal relevance to examining the influence of the use of SSRIs and self-administered CBT among patients presenting with GAD. This model’s development began in 1970 by Betty Neuman after her efforts in teaching University of California, Los Angeles (UCLA) graduate students led her to the conclusion that nurse educators and practitioners were in need of a comprehensive
framework to guide a variety of nursing contexts (Neuman, 1982). It served an initial purpose as a teaching tool and a way to unify student learning (Neuman & Fawcett, 2011). The model was first published in 1972 in an article in Nursing Research, and in 1982, Neuman published the first edition of a book detailing the model and its application to nursing.

A holistic, wellness-oriented focus can describe the Neuman Systems Model, which has an overall nursing goal to “facilitate optimal wellness for the client through retention, attainment, or maintenance of client system stability” (Neuman & Fawcett, 2011, p. 3). Optimal wellness is deemed the highest degree of system stability at any given point in time, and wellness is gauged on a continuum from the highest degree of wellness to severe illness or death (Neuman & Fawcett, 2011). The client is viewed as an open system and can refer to individuals, groups, families, communities, or societies. The client system considers a holistic perspective that includes the following five variables: physiological, psychological, sociocultural, developmental, and spiritual. The model is based on the client’s continuous relationship with and potential reaction to stressors within the environment. The open system includes input, output, and feedback and allows for an individual to adjust to internal and external environmental stressors. Thus, flexibility and change exist to help the client conquer challenges and meet the model’s goal of attaining stability.

The model is pictorially represented by a centrally located basic structure that is surrounded by concentric circles depicting lines of resistance and defense (Neuman & Fawcett, 2011). The basic structure possesses characteristics common to all organisms, including human processes, genetic features, and survival factors, as well as characteristics that are unique to each client, including the five aforementioned variables. The lines of resistance surround the basic structure. The normal line of defense surrounds the lines of resistance. The flexible line of defense surrounds the normal line of defense. A greater degree of protection is provided amongst the outer most concentric circle as compared to the inner most concentric circle. The lines of resistance are called to action when the normal line of defense has been invaded by
stressors. These resistance lines, which are made of internal and external resources that the client may be consciously aware of or unaware of, strive to protect the integrity of the system. The normal line of defense denotes the stability and integrity of the system and is dynamic as the client faces different stressors at different times of life. The flexible lines of defense are also dynamic and form a protective barrier to prevent stressors from impacting the client’s state of stability. When such lines of defense are unsuccessful in preventing penetration by stressors, a reaction is elicited by the client. Coping methods, lifestyle, and developmental, spiritual, and cultural factors influence the success or failure of the lines of resistance and defense.

**Application of Theoretical Framework to EBP Project**

There is a strong relationship between the concepts of stress and anxiety. Stress can be defined as the interaction between environmental stimuli, or stressors, and stress response systems. Anxiety is characterized by behavioral, cognitive, and physiologic responses that occur when faced with uncertain or threatening stimuli (Chen, George, & Liberzon, 2017). Anxiety may characterize a client’s response to stress or may serve as a potential stressor. The Neuman Systems Model “takes into account all variables affecting a client’s possible or actual response to stressors and explains how system stability is achieved in relation to environmental stressors imposed on the client” (Neuman & Fawcett, 2011, p. 3). Thus, the Neuman Systems Model is applicable to this EBP project centered upon utilizing best practice interventions implemented by NPs to decrease symptoms and feelings of anxiety among patients presenting with GAD in the family practice setting. Thus, the best practice interventions of SSRIs and CBT contribute to the model’s goal of attaining stability as their purpose is to help patients identify, respond to, and cope with their environmental stressors in a healthy manner that can be maintained.

Neuman believed in using her philosophy of “helping each other live” in order to contribute to the development of this model (Neuman & Fawcett, 2011). This philosophy is upheld by the NPs assessing, diagnosing, treating, and evaluating patients with GAD as their goal is to help patients with anxiety live better and achieve and maintain an optimal level of
wellness through coping with and reducing anxiety levels. The Neuman Systems Model can help guide practicing nurses and NPs caring for patients with GAD as it allows them to explore complexities of the individual and develop assessment and intervention skills that stem from such nursing model. It is also useful in guiding the education and practical training of nursing students and helps teach them to treat clients as individuals. GAD is often unique to each individual and complex in nature to treat due to a multitude of factors, including the challenge of addressing the mind, which can be considered intangible and invisible. Thus, use of the Neuman Systems Model can greatly aide in the treatment of GAD.

**Strengths and Limitations of Theoretical Framework for EBP Project**

Strengths of the use of the Neuman Systems Model as the theoretical framework for the EBP project include its global applicability, which allows for its use among the variety of cultures present at the project site as well as for generalizability across all cultures (Neuman & Fawcett, 2011). In addition, the model has a holistic perspective, which is at the forefront of the discipline of nursing. The four concepts of the nursing metaparadigm, including human beings, environment, health, and nursing, are related to the main concepts of the model. The model’s goal of forming a relationship between clients and caregivers and establishing desired “goals for optimal health retention, restoration, and maintenance” is consistent with the goal of the EBP project (Neuman & Fawcett, 2011, p. 12). The EBP project aimed to establish a trusting relationship between patient and NP in the treatment of GAD utilizing best practice interventions and patient motivation in order to minimize the damage cause by stressors by decreasing anxiety. This was achieved through the use of this model due to such congruent values.

Limitations of the use of the Neuman Systems Model include the risk of oversimplifying its application and failing to address all parts and subparts of the system as well as their relationship to one another and the environment (Neuman & Fawcett, 2011). “When used correctly, however, a systems model dramatically and convincingly demonstrates the nature of a process, which leads to better understanding and more accurate prediction of outcomes”
(Neuman & Fawcett, 2011, p. 9). Thus, this advocates for proper use of the theoretical framework and the consideration of complex phenomena, such as that of GAD. It may be difficult to view client system variables and boundaries clearly due to their dynamic and ever-changing nature. However, each part and subpart of the system must be studied individually in order to understand its role in relationships and stability of the whole system. Thus, continually adapting to changing stressors and causes of anxiety throughout the patient’s lifespan is vital to maintenance of stability and optimal wellness.

**Evidence-based Practice Model**

**Overview of EBP Model**

In addition to a theoretical framework, an EBP model, the Stetler Model, was also selected to facilitate this EBP project. The Stetler Model has transformed through numerous revisions since its debut in 1976 and has broadened its focus from that of research utilization to evidence-based nursing practice (Melnyk & Fineout-Overholt, 2015). While the model originally only referred to the application of research findings to practice, the latest version encompasses research findings, quality improvement data, operational data, and “…the consensus of recognized experts and affirmed experience to substantiate practice” [Stetler et al., 1998, p. 49]” (Melnyk & Fineout-Overholt, 2015, p. 279). The inclusion of external evidence, which results from rigorous research, as well as internal evidence, which results from projects within the clinical practice setting is a key component. The model is centered 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.

It “outlines a series of steps to assess and use research findings to facilitate safe and effective evidence-based nursing practice” (Melnyk & Fineout-Overholt, 2015, p. 279). These five steps are clearly delineated and described and include 1) preparation, 2) validation, 3) comparative evaluation/decision making, 4) translation/application, 5) evaluation, which contribute to the ease with which this model can be followed in order to implement an EBP
project successfully (Melnyk & Fineout-Overholt, 2015). Detailed graphics of these steps provided by the model aide in its understanding. The preparation phase is characterized by determining a need worth addressing and beginning a relevant literature search. The validation phase includes a critical appraisal of each piece of evidence as well as synthesizing this evidence. During the comparative evaluation/decision making phase, utilization criteria are used to determine whether evidence should be used for the practice change. The next phase of translation/application requires planning and implementing an EBP change by converting findings into operational use. Finally, during the evaluation phase, goals are evaluated for completion, and implementation of the plan is reviewed.

There are many important assumptions of the Stetler Model (Melnyk & Fineout-Overholt, 2015). The model assumes that research findings can be utilized in the clinical setting. Consideration of patient individuality and preferences is necessary to implement the model appropriately for each patient. Practitioners who are competent in research utilization and EBP can use this model to improve practice, alter ways of thinking, and develop new strategies. Advanced-level practitioners are better equipped to accomplish such advances in clinical practice due to their advanced critical thinking skills and knowledge. Baccalaureate-prepared providers should be encouraged to contribute to these endeavors in collaboration with advanced-level providers. Another assumption of the model is the ability to use research findings and other evidence in varying ways. Strength of the evidence must be considered for safe use of evidence in multiple ways.

**Application of EBP Model to EBP Project**

The Stetler Model is applicable to this EBP project for a variety of reasons. The evidence supporting the interventions of CBT and an SSRI for the reduction of anxiety symptoms among with GAD strongly calls for the inclusion of patient preferences, which is also a central component of this model (Melnyk & Fineout-Overholt, 2015). Facilitating safe and effective evidence-based nursing practice through the translation of evidence to practice describes the
purpose of the Stetler Model, which also is the purpose of the EBP project with an aim to change current treatment of GAD in accordance with best practice recommendations to yield the most effective outcomes.

The five steps of the Stetler Model served as a detailed guide for the project. During the preparation phase, the project manager identified a problem with current treatment of GAD and a need to address this after experience in the clinical setting with a significant number of patients presenting with GAD. An exhaustive literature search was completed in order to determine best practice that included a search of seven databases as well as citation chasing. The validation phase of the model fostered a critical analysis, quality appraisal, and summary of the evidence by the project manager, which yielded sources of good and high quality evidence that supported best practice via combined CBT and SSRI use. Throughout the comparative evaluation/decision making phase, the evidence was organized and a decision to use the evidence was made based on sufficient, strong, and current available evidence. The translation/application phase allowed the project manager to apply these findings to practice and implement a feasible plan in a family practice clinic with the support of NPs who were greatly invested in the project. Finally, the evaluation phase was utilized to evaluate outcomes of the practice change, attainment of goals, success of the implementation, overall effect of the intervention on symptoms of anxiety and other measures, and sustainability of the practice change.

**Strengths and Limitations of EBP Model for EBP Project**

Limitations of the use of the Stetler Model to guide the EBP project include its complex appearance via graphic representation including the five steps, numerous components within each step, and multi-directional arrows to indicate fluidity (Melnyk & Fineout-Overholt, 2015). A thorough review of the model is necessary to facilitate understanding and obtain clarity. While the model helps to anticipate important needs and aspects regarding the intended practice change, certain variables may be unpredictable. Thus, despite adequate use of the five phases
of the Stetler Model, a level of flexibility must be maintained, and changes to the original plan may be necessary. For example, the model was used by Romp and Kiehl (2009) in order to improve a nursing preceptor program at a large medical facility. After careful development using the appropriate stages of the model, it was discovered during implementation that many preceptors were unable to attend scheduled classes while interest in the classes continued. Thus, additional classes as well as both individual and group sessions were scheduled to aid in this unforeseen problem that occurred.

Strengths of the Stetler Model as a guide for the EBP project include its revisions to remain current and encompass not only research findings, but also EBP (Melnyk & Fineout-Overholt, 2015). The model is useful for individual practitioners, including NPs with knowledge in their area of practice, and also for groups to translate research to practice (Snyder et al., 2011). Its detailed steps emulate the nursing process and can be followed to increase the likelihood of successful practice change and to answer the clinical question at hand. In addition, the model encourages the evaluation of such practice change and promotes further research. The model strongly supports critical thinking as well as changes in ways of thinking (Snyder, Facchiano, & Brewer, 2011; Stetler, 2001). It involves making decisions regarding feasibility, applicability, and the substantiality of evidence and aims to reduce barriers to practice change. The study by Romp and Kiehl (2009) showed that by exploring a multitude of aspects among each of the five phases of the Stetler Model, considerations that may have been otherwise overlooked were able to be addressed in order to help avoid challenges and failures. Successful outcomes were yielded as the Stetler Model helped to develop a detailed plan, thoughtful preparation, and effective application of EBP to increase nurses’ satisfaction with their preceptors and ultimately, increase rates of nurse retention with an improved nursing preceptor program. Positive outcomes were also elicited by another study conducted by Snyder and colleagues (2011) in which the Stetler Model was followed in order to change practice by increasing screening for anxiety among patients with Parkinson’s Disease. This model allowed
for several quality aspects to be upheld through this translation of EBP to practice, including patient safety, effectiveness of interventions, patient-centered care, timely and early recognition and treatment, efficient utilization of best practice, and equal opportunity for care.

**Literature Search**

**Sources Examined for Relevant Evidence**

An exhaustive relevant literature search was performed in order to support the spirit of inquiry regarding best practice for the treatment of GAD in the family practice setting by NPs. A total of seven databases were searched, including CINAHL, ProQuest, MEDLINE via EBSCO, Joanna Briggs Institute, National Guideline Clearinghouse, PsycINFO, and Cochrane Library. CINAHL, ProQuest, and MEDLINE were selected based on their ability to yield large volumes of individual studies. The Joanna Briggs Institute and Cochrane Library were utilized due to their inclusion of high levels of evidence of multiple studies. The National Guideline Clearinghouse was selected as it includes clinical guidelines regarding a wide variety of healthcare topics. PsycINFO was utilized based on its applicability to the psychological topic of GAD upon which the project centers. Citation chasing from the results yielded was also utilized in order to explore all relevant evidence. After trialing a multitude of searches in each database, the keywords selected for the final best literature search yielding the most relevant and appropriate quantity of results were “generalized anxiety disorder*” OR “anxiety disorder*” AND (treat* OR manag*) AND (“primary care” OR “family practice”). MeSH (medical subject heading terms) and CINAHL subject headings in CINAHL, MEDLINE via EBSCO, ProQuest Nursing and Allied Health Database, and PsycINFO for generalized anxiety disorder and anxiety disorders were used in the search to encompass all terms describing such topic. Truncation symbols, quotation marks, and parentheses also helped to yield all relevant sources.

Inclusion criteria for the literature search consisted of scholarly, peer-reviewed sources, date range of 2013 to 2018 for sources published within the last five years, English language, and age groups of child: 6-12 years, adolescent: 13-18 years, adult: 19-44 years, middle aged:
45-64 years, aged: 65+ years, and aged, 80 and over. It was decided that such criteria would lead to the most trustworthy, current, understandable, and applicable evidence. Additional inclusion criteria included evidence that pertained to the primary care, family practice, or outpatient setting, a population of children, adolescents, and/or adults, and a population diagnosed with anxiety disorder or generalized anxiety disorder. Exclusion criteria was defined as pertaining to the hospital or inpatient setting, population of infants or children under 6-years-old, outcomes comparing anxiety levels prior to and after surgical procedures, poor initial quality appraisal, and diagnoses of depression only, social anxiety disorder only, panic disorder only, post-traumatic stress disorder only, health anxiety only (also known as hypochondriasis), or mental health disorder with no further classification of generalized anxiety disorder or anxiety disorder specified. Initially, it was determined to exclude sources focused on anxiety related to health conditions or diseases, such as cancer. However, this was revised after further exploration as comorbidities are very prevalent in the United States and often cause or exacerbate anxiety in patients, and a patient’s stated reason for anxiety is always valid as it is his or her own feeling. After a thorough literature search indicated that the majority of available evidence supported interventions including SSRIs and CBT, pieces of evidence detailing treatment focused on diet, exercise, mindfulness interventions, or classes of medications other than SSRIs were excluded. Evidence related to CBT was individually evaluated for relevance to self-administered CBT in the form of workbooks for anxiety and excluded if deemed irrelevant or inapplicable to such administration method. Exceptions were made on a case by case basis when literature was deemed worthy of inclusion despite lack of self-administration method of CBT. Some evidence regarding CBT in general, without specification of administration method, was included.

An initial literature search began in the Joanna Briggs Institute database. A search using the keyword anxiety and a publication date within the last five years (2013 to current) proved too broad as 774 results were yielded. After modifying the search with the keywords generalized
anxiety disorder and the same date range limiter, an acceptable quantity of 21 results to review was populated. However, upon review of titles, it was determined that this search was too narrow. After many different search attempts, the most appropriate, relevant, and inclusive search was deemed as the aforementioned best search, which encompassed both generalized anxiety disorder and anxiety disorder as well as plural forms of the word disorder, the goal of the EBP project to treat or manage the condition, and the intended setting of primary care or family practice. A total of 17 sources were yielded, and four were accepted for inclusion in the final literature review.

A thorough search of the Cochrane Library was then performed. A minor modification in the search terms utilized for this database was approved by the Valparaiso University library liaison, Kim Whalen, who assisted the literature search process. The terms “primary care” and “family practice” were omitted from the search to allow for inclusion of the most relevant pieces of evidence as several applicable pieces were not yielded when these terms were included. The final search yielded a total of 23 results, and 8 were deemed worthy of further review after assessing titles. Several were eliminated based on method of delivery of CBT intervention inapplicable to the EBP project, protocol only available, and treatment irrelevant to CBT or SSRIs. One was accepted to provide supporting evidence for the EBP project.

The National Guideline Clearinghouse was searched for clinical guidelines to support the EBP project utilizing the initial best search. Although the National Guideline Clearinghouse database was no longer available after July 16, 2018, the EBP project manager decided to take advantage of the limited opportunity remaining as worthwhile, high quality, high level evidence can be obtained from this database. Twenty-two results populated, and upon initial review, it seemed than there were no applicable sources. However, further exploration led to further review and acceptance of two clinical guidelines for inclusion in the literature review.

Upon continuing the literature search, the database CINAHL was searched for relevant evidence. Prior to implementing subject headings into the search, thousands of results were
yielded. Thus, after receiving guidance from Valparaiso University’s library liaison, it was deemed necessary to utilize CINAHL headings, which greatly refined the search. The final search utilizing (MH “Generalized Anxiety Disorder”) OR (MH “Anxiety Disorders”) AND (treat* OR manag*) AND (“primary care” OR “family practice”) with limiters of scholarly, peer-reviewed sources, published within the last five years, English language, and age groups of child: 6-12 years, adolescent: 13-18 years, adult: 19-44 years, middle aged: 45-64 years, aged: 65+ years, and aged, 80 and over yielded a total of 28 results. After further review of 10 pieces of evidence, three were selected for the literature review.

A search of the database MEDLINE via EBSCO included the MeSH subject heading (MH “Anxiety Disorders/CL/DI/DT/NU/PC/TH”). Such abbreviations stand for subheadings that were utilized to further narrow the search and include classification (CL), diagnosis (DI), drug therapy (DT), nursing (NU), prevention and control (PC), and therapy (TH). Such refining of the search helped to yield a sufficient number of relevant articles of which to review. Specifically, 152 articles were yielded. After removing duplicates that had previously been reviewed through CINAHL and reviewing articles that were deemed worthy of further review, two were chosen as supporting evidence for the EBP project.

ProQuest Nursing and Allied Health Database were then searched for applicable evidence using the MeSH subject heading Exact (“Anxiety Disorders”) as well as additional keywords and limiters aforementioned. A total of 42 articles were populated from this search. A total of seven duplicate articles that had already been found in CINAHL and/or MEDLINE were removed. After review of titles and abstracts of several pieces, no articles were deemed worthy of final inclusion.

To conclude the literature search, the database PsycINFO was explored. Subject terms including DE “Generalized Anxiety Disorder” OR DE “Anxiety Disorders” were included in the search. Age groups selected were consistent with the other searches but had minor variances in categorization and those selected were school age (6-12 years), adolescence (13-17 years),
adulthood (18 years and older), young adulthood (18-29 years), thirties (30-39 years), middle age (40-64 years), aged (65 years and older), and very old (85 years and older). This yielded 145 results. Although a large quantity of results, it was deemed that the search was appropriately narrowed and such a large amount of information regarding anxiety disorders could be expected to be found in a database related to psychological topics. After accounting for and removing a large total of 59 duplicates as well as reviewing relevant sources, no pieces were included as evidence for the project.

Nine additional pieces of evidence were obtained via citation chasing from the reference lists of results yielded. Three were deemed worthy of inclusion. One was obtained from a citation chase of a Cochrane Library systematic review. A version of the review published in 2016 was withdrawn from the Cochrane Library due to the review being “passed onto a new group of authors.” A 2003 version of this review was then found via citation chasing of the 2016 piece, and an exception to accept this evidence with an older publication date was granted due to the circumstances and the meeting of inclusion criteria. Another systematic review was citation chased from an accepted evidence summary and met inclusion criteria. A third piece of evidence, a randomized controlled trial (RCT), was found via citation chasing through a relevant excerpt of the study found through CINAHL.

In total, 436 pieces of evidence were yielded from the literature search. A review of titles led to the elimination of many sources due to failure to meet inclusion or exclusion criteria or irrelevance to GAD or the proposed interventions. Duplicate articles were accounted for and removed. Upon further review of titles and abstracts, 74 sources were deemed as warranting further, more extensive review based on inclusion criteria, applicability to the EBP project, and initial quality appraisal. After such review, a decision was made to include 15 of these pieces of evidence in the final literature review based on their ability to provide strong support for the EBP project. Data regarding the evidence search results are depicted in Table 2.1.
Table 2.1

*Evidence Search Table*

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*Note.* Databases are listed in order of searches performed. JBI is Joanna Briggs Institute. NGC is National Guideline Clearinghouse. ProQuest is ProQuest Nursing & Allied Health Source.
Levels of Evidence

In order to rank each piece of evidence appropriately by strength, Melnyk and Fineout-Overholt’s (2015) Hierarchy of Evidence was utilized for this project. Such seven-level ranking system guides categorization among different types of literature in order to appraise the strength of the evidence. Greater strength of the evidence indicates a higher level of confidence that the evidence is likely to reliably answer a clinical question. This Hierarchy of Evidence includes Level I through Level VII evidence listed in order from highest level of evidence to lowest. This is currently depicted as a table with Level I evidence listed at the top as the highest level of evidence and Level VII evidence listed at the bottom as the lowest level of evidence. To begin, Level I evidence is evidence from systematic reviews or meta-analyses of all relevant RCTs, and level II evidence refers to evidence obtained from well-designed RCTs. Proceeding through the table, Level III evidence is characterized as evidence obtained from well-designed controlled trials without randomization while Level IV evidence includes evidence from well-designed case-control and cohort studies. Level V evidence is described as evidence from systematic reviews of descriptive and qualitative studies whereas Level VI evidence is evidence from single descriptive or qualitative studies. Finally, level VII evidence is defined as evidence from the opinion of authorities and/or reports of expert committees. Fifteen total pieces of evidence were included for the final review of literature, including three evidence summaries (Level I), four systematic reviews (Level I), two clinical guidelines (Level I), four RCTs (Level II), one non-randomized controlled trial (Level III), and one evidence summary (Level V). The levels of the selected pieces of evidence are illustrated in Table 2.2.
### Levels of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Included</th>
<th>Quality</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>9</td>
<td>A (6)</td>
<td>Evidence Summary (3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B (3)</td>
<td>Systematic Review (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clinical Guideline (2)</td>
</tr>
<tr>
<td>II</td>
<td>4</td>
<td>A (2)</td>
<td>RCT (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B (2)</td>
<td></td>
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<tr>
<td>III</td>
<td>1</td>
<td>B (1)</td>
<td>Non-Randomized Controlled Trial (1)</td>
</tr>
<tr>
<td>V</td>
<td>1</td>
<td>A (1)</td>
<td>Evidence Summary (1)</td>
</tr>
</tbody>
</table>
In addition to ranking the evidence by level, a critical appraise of the quality of each evidence was also conducted. Quality was appraised using the Johns Hopkins Research and Non-Research Evidence Appraisal Tool as well as the Appraisal of Guidelines for Research & Evaluation (AGREE II) Instrument. Permission was granted to utilize the Johns Hopkins Research and Non-Research Evidence Appraisal Tool, and such documentation is presented in Appendix B. The AGREE II Instrument is allowed to be reproduced and used for education and quality appraisals. The AGREE II Instrument was used for quality appraisal of evidence summaries and clinical guidelines, and the Johns Hopkins Research and Non-Research Evidence Appraisal Tool was used for quality appraisal of the remainder of the evidence, including systematic reviews, randomized controlled trials, and non-randomized controlled trials.

The Johns Hopkins Research and Non-Research Evidence Appraisal Tool provides a thorough algorithm for determining the type of study design and assessing the quality of the evidence through a multitude of yes/no questions about the evidence (Dearholt & Dang, 2017). This tool delineates high quality (A) as evidence with “consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence” (Dearholt & Dang, 2017, p. 286). Good quality (B) is considered evidence with “reasonably consistent results; sufficient sample size for the study design; some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence” (Dearholt & Dang, 2017, p. 286). Low quality or major flaws (C) is defined as “little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn” (Dearholt & Dang, 2017, p. 286). Of the 15 pieces of literature accepted for inclusion, nine were deemed of high quality, six were deemed of good quality, and none were deemed of low quality. Table 2.3 presents a summary and appraisal of the relevant evidence listed in alphabetical order by author.
The AGREE II Instrument provides a detailed structured format consisting of a total of 23 items of consideration within six main domains as well as two items of global rating, or overall assessment, for determining the quality of guidelines (AGREE Next Steps Consortium, 2017). The six domains include scope and practice, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence. The 23 core items are each scored via a 7-point Likert scale with 1 indicating strongly disagree and 7 indicating strongly agree. Domain scores are calculated by adding the scores of the items in each domain and using a mathematical equation including the obtained score and minimum and maximum scores possible to yield a percentage. These scores can be used to compare the quality of different guidelines. However, the tool has not differentiated scores indicating high, good, and poor quality but rather recommends that the user should consider all aspects of the tool and make this decision regarding quality.
Table 2.3

Appraisal of Evidence

<table>
<thead>
<tr>
<th>Citation (APA)</th>
<th>Purpose</th>
<th>Design</th>
<th>Sample</th>
<th>Measurement/Outcomes</th>
<th>Results/Findings</th>
<th>Level/Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andersen, B. L., DeRubeis, R. J., Berman, B. S., Gruman, J., Champion, V. L., Massie, M. J., Holland, J. C., Partridge, A. H., Bak, K. Somerfield, M. R., &amp; Rowland, J. H. (2014). Guideline summary: Screening, assessment, and care of anxiety and depressive symptoms in adults with cancer: An American Society of Clinical Oncology guideline adaptation. Journal of Clinical Oncology, 32(15), 1605-1619. doi:</td>
<td>The purpose of this clinical guideline was to present the best screening, assessment, and care methods that should be utilized in the treatment of anxiety and depressive symptoms among adults with a coexisting diagnosis of cancer.</td>
<td>This was a clinical guideline adapted from the American Society of Clinical Oncology. Pharmacologic and nonpharmacologic as well as psychological and psychosocial interventions were explored.</td>
<td>The target sample population included adults 18 years of age and older with any type of cancer, any disease stage, and undergoing any types of treatments who also were experiencing symptoms of depression and anxiety. A thorough systematic literature search was performed.</td>
<td>The Generalized Anxiety Disorder (GAD)-7 scale was strongly recommended to measure symptoms of anxiety. Anxiety should be measured at the initial visit and at appropriate intervals depending on clinical indication, including change in disease status or transition to palliative care. Preferably, outcomes should be measured once per month, but at a minimum should be measured pre</td>
<td>Patient preferences, shared decision making, and both pharmacologic and nonpharmacologic treatments are recommended. Psychological interventions should be based on treatment manuals that explain content and guide delivery. If there is no improvement in symptomology after 8 weeks of treatment, additional treatments should be added to the treatment regimen.</td>
<td>Level I High quality</td>
</tr>
</tbody>
</table>
### Assessment and Management of Risk for Suicide


The purpose of this clinical guideline was to promote evidence-based management of patients at risk for suicide.

This was a clinical guideline.

Interventions discussed included psychotherapy methods, including CBT, and medications, including antidepressants.

The sample population included adult patients 18 years of age or older at risk for suicide with or without a mental disorder in the Department of Veterans Affairs (VA) and Department of Defense (DoD) clinical settings.

A thorough literature search was performed.

Patients with anxiety disorders should be asked about suicidal thoughts and behavior directly.

Reassessment of suicidal ideation should regularly occur, particularly with changes in circumstances.

Treatments with CBT and antidepressants may be beneficial for patients with anxiety disorders at risk for suicide.

Close monitoring of patients who are prescribed antidepressants is necessary to assess for the emergence or worsening of suicidal thoughts during the initiation phase or after change in dose.

### Calleo, J. S., Bush, A. L., Cully, J. A., Wilson, N. L., Kraus-Schuman, C., Rhoades, H. M.

The purpose of this study was to explore the feasibility, satisfaction, and clinical outcomes.

The study design was a non-randomized controlled trial. Participants engaged in CBT.

The sample included a total of 19 older adults aged 60 years of age and older with GAD who were...

| Novy et al. (2013) | The purpose of this evidence summary was to determine the best evidence for the pharmacologic treatment of GAD. The sample included patients with GAD from seven systematic reviews, one evidence-based guideline, one clinical guideline, one prospective intervention, and one medication. Outcomes measured included the efficacy and tolerability of a multitude of medications including duloxetine (SNRI), fluoxetine (SSRI), and antidepressants. The use of antidepressants for the treatment of GAD was given a Grade A recommendation. Fluoxetine (SSRI) was recommended for anxiety (mean [SD], 3.61 [0.49]). | PSWQ and GADSS scores significantly declined from baseline to 3 months among those who completed treatment. Other anxiety measures did not yield statistically significant effect size changes. There were no significant differences in results among patients treated by ACSs or counselors without training. |

| Campbell (2016) | The purpose of this evidence summary was to determine the best evidence for the pharmacologic treatment of GAD. The sample included patients with GAD from seven systematic reviews, one evidence-based guideline, one clinical guideline, one prospective intervention, and one medication. Outcomes measured included the efficacy and tolerability of a multitude of medications including duloxetine (SNRI), fluoxetine (SSRI), and antidepressants. The use of antidepressants for the treatment of GAD was given a Grade A recommendation. Fluoxetine (SSRI) was recommended for anxiety (mean [SD], 3.61 [0.49]). | PSWQ and GADSS scores significantly declined from baseline to 3 months among those who completed treatment. Other anxiety measures did not yield statistically significant effect size changes. There were no significant differences in results among patients treated by ACSs or counselors without training. |
self-care. CBT, anticonvulsants, antidepressants, and antipsychotic medications were involved in many of the studies included.

trial, and one qualitative study.

escitalopram (SSRI), fluoxetine (SSRI), lorazepam (benzodiazepine), paroxetine (SSRI), pregabalin (anticonvulsant), sertraline (SSRI), tiagabine (anticonvulsant), venlafaxine (SNRI), buspirone, and hydroxyzine.

Anxiety symptoms, response rates, and remission status were also measured.

its associated response and remission, and sertraline (SSRI) was recommended for its tolerability.

SSRIs were found to reduce anxiety symptoms and should be considered first-line treatment for GAD.

CBT was also recommended in the treatment of GAD with a Grade B recommendation.

The addition of CBT to the treatment regimen of patients taking an SSRI led to sustained remission from symptoms of anxiety and prevented long-term pharmacotherapy.
| Freshour, J. S., Amspoker, A. B., Yi, M., Kunik, M. E., Wilson, N., Kraus-Schuman, C., Cully, J. A., Teng, E. Williams, S., Masozera, N., Horsfield, M., Stanley, M. (2016). Cognitive behavior therapy for late-life generalized anxiety disorder delivered by lay and expert providers has lasting benefits. *International Journal of Geriatric Psychiatry, 31*(1), 1225-1232. doi: 10.1002/gps.4431 | The purpose of this study was to explore the effects of CBT delivered by bachelor-prepared lay providers as compared to CBT delivered by PhD expert providers. | This was a randomized controlled trial. Participants were randomly assigned to three groups including CBT administered by lay providers, CBT administered by expert providers, or usual care. | A sample of 112 older adults aged 60 years or older were included and were recruited from internal medicine, family practice, and geriatrics clinics in Texas. | Primary outcomes measured worry via the Generalized Anxiety Disorder Severity Scale and anxiety via the State-Trait Anxiety Inventory and the Structured Interview Guide for the Hamilton Anxiety Scale. Secondary outcomes measured included depression via the Patient Health Questionnaire, mental health quality of life via the Medical Outcomes Study Short Form, and sleep via the Insomnia Severity Index. | Outcomes were measured 6 months and 12 months post initiation of treatment. | There was no significant difference in outcomes among participants who received CBT delivered by bachelor-prepared lay providers and those who received CBT delivered by PhD expert providers (p>0.05). Improvements in worry and anxiety outcomes as well as changes in depression, mental health-related quality of life, and insomnia were maintained at 6 and 12 month follow up. | Level II High quality |
|---|
| The purpose of this study was to explore treatment dose and patient engagement as predictors of treatment outcome. |
| This study design was a randomized controlled trial. |
| A total of 1,004 participants with a diagnosis of panic disorder, generalized anxiety disorder, social anxiety disorder, or posttraumatic stress disorder were enrolled in the study. |
| The primary outcome of anxiety was measured via the Brief Symptom Inventory. |
| Results indicated that at both 12 and 18 months, participants with low attendance in CBT sessions had higher scores on all outcome measures than patients with high attendance (p<0.029). |
| Level II Good quality |

<table>
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<tbody>
<tr>
<td>The purpose of this review was to explore the effectiveness of CBT in the treatment of childhood and adolescent anxiety disorders.</td>
</tr>
<tr>
<td>The study design is a Cochrane systematic review.</td>
</tr>
<tr>
<td>A thorough literature review among multiple databases was performed.</td>
</tr>
<tr>
<td>The primary outcome measured was remission via the Anxiety Disorder Interview Schedule for Parents, Children, and Youth.</td>
</tr>
<tr>
<td>Findings concluded that 58.9% of participants who received CBT achieved remission while 16% of participants who received usual care did not.</td>
</tr>
<tr>
<td>Level I Good quality</td>
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</tbody>
</table>
disorders in children and adolescents (Review).
Cochrane Database of Systematic Reviews, 2, 1-30. doi: 10.1002/14651858.CD004690.pub4

adolescent anxiety disorders. individual, group, or family/parental involvement manualized, or modular, CBT alone or CBT with medication. participants were included in the review. Participants within the studies were ages 4-19, met diagnostic criteria for an anxiety disorder, and were recruited from research settings.

The purpose was to determine the best evidence regarding psychotherapy for patients with GAD. This was an evidence summary. Psychotherapy interventions, including CBT, were utilized in the studies included in the evidence summary. Persons with GAD including children, adolescents, adults, and older adults from two Cochrane systematic reviews, one meta-analysis, two systematic reviews, and five RCTs were

The effect of CBT on anxiety levels, relapse of anxiety symptoms, and secondary symptoms of worry and depression was measured. Use of CBT was determined to be effective for children, adolescents, the working-age population, and older adults with GAD and received a Grade B recommendation. CBT reduced

participants who did not receive CBT achieved remission, but these results were not significant (p=0.23). There were no differences between the outcomes of individual, group, or family CBT nor between the rates of participants lost to follow up among the CBT versus control groups. These findings were significant (p=0.02).


Persons with GAD including children, adolescents, adults, and older adults from two Cochrane systematic reviews, one meta-analysis, two systematic reviews, and five RCTs were

Use of CBT was determined to be effective for children, adolescents, the working-age population, and older adults with GAD and received a Grade B recommendation. CBT reduced Level I High quality

The purpose of this evidence summary was to determine the best available evidence regarding self-help interventions for patients with anxiety disorders.

The study design was an evidence summary. Self-help interventions were explored among the studies reviewed.

The sample included persons with anxiety disorders, including panic disorders, social anxiety disorder, phobias, generalized anxiety disorder, and post-traumatic stress disorder. Five meta-analyses, four systematic reviews, one Cochrane review, and one RCT were included in the evidence summary.

The effectiveness of self-help interventions was the primary outcome. Symptoms of anxiety and depression were measured.

Self-help CBT was found to be effective as compared to controls including wait list, treatment as usual, and placebo, and the effect size did not vary depending on the type of self-help CBT administered, including guided, minimal contact, or self-administered.

Participants should work on self-help materials for at least six weeks.

Self-help bibliotherapy CBT may serve as a low-cost intervention for anxiety levels, symptoms of worry and depression, prevented relapse, and results were maintained at follow up.

Level I High quality
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Title</th>
<th>Study Details</th>
<th>Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kapczinski, F., dos Santos Souza, J. J. S. S., Batista Miralha da Cunha, A. A. B. C., &amp; Schmitt, R. R. S.</td>
<td>Antidepressants for generalised anxiety disorder (GAD) (Review).</td>
<td>The purpose was to assess antidepressants for their efficacy and acceptability in the treatment of GAD. The design of the study was a Cochrane systematic review. Duration of treatment with antidepressants among the included studies ranged from six to 28 weeks. A thorough literature search within multiple databases was performed. A total of 15 RCTs regarding antidepressants were included in the review. Participants in the studies were outpatients. One study included children while all others included adults. Most trials were conducted in the United States. Symptoms were often measured using the HAM-A. GAD changes were measured by the Clinical Global Impression score. Acceptability of treatment was measured via dropout rate and side effects.</td>
<td>Participants who received antidepressants were more likely to exhibit treatment response than those who received placebo. Paroxetine and imipramine showed similar efficacy and were well tolerated by most patients. Sertraline was more effective than placebo in the treatment of GAD among children and adolescents.</td>
</tr>
<tr>
<td>Nguyen, D. H.</td>
<td>Evidence Summary: Generalized anxiety disorder: Management. The Joanna Briggs Institute, 1-4.</td>
<td>The purpose of this piece of evidence was to explore the best available evidence for the management of GAD. This was an evidence summary. The sample included persons with a diagnosis of GAD from three clinical practice guidelines, six Cochrane reviews, two meta-analytic</td>
<td>CBT-based psychological therapy effectively reduced anxiety symptoms and was more effective than placebo. Pharmacological interventions,</td>
</tr>
<tr>
<td>Piacentini, J., Bennett, S., Compton, S., Kendall, P.,</td>
<td>The purpose of this study was to explore response, remission rates,</td>
<td>The design of the study was a randomized controlled trial.</td>
<td>A sample of 488 children and adolescents ages 7-17 years who</td>
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<td>interventions were reviewed, reviews, and one RCT.</td>
<td>Outcomes measured included anxiety symptoms.</td>
<td>including the prescribing of SSRIs, were supported with a Grade B recommendation due to their cost effectiveness, efficacy, safety, and ease of use.</td>
<td>Self-help interventions, including bibliotherapy CBT, were recommended and supported for reducing barriers to traditional CBT.</td>
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</table>

Participants were randomized to four different groups: CBT only (CBT), sertraline only (SRT), sertraline and CBT combined (COMB), or pill placebo (PBO). CBT included adaptation of the “Coping Cat” program. A maximum daily dose of 200 mg of sertraline was established. Participants met DSM-IV criteria for separation, generalized, or social anxiety disorder were included in the study. They were recruited from six geographically diverse sites.

(CGI-I) measured response. The Pediatric Anxiety Rating Scale (PARS) and the Clinical Global Impressions Severity Scale (CGI-S) measured anxiety severity. The Children’s Global Assessment Scale measured overall functional impairment.

CBT, SRT, and COMB were all superior to PBO. Despite excellent response rates, COMB was unable to achieve statistical significance over SRT and CBT at weeks 24 and 36 due to significant improvement in SRT and CBT groups during that time.

Most participants maintained gains at weeks 24 and 36. There was no significant difference in study attrition rates for each treatment group.
| Sawyer, M. C., & Nunez, D. E. (2014). Cognitive-behavioral therapy for anxious children: From evidence to practice. *Worldviews on Evidence-Based Nursing, 11*(1), 65-71. doi: 10.1111/wvn.12024 | The purpose of the review was to explore available evidence about the effectiveness of individual CBT for children with anxiety disorder. The design was a systematic review. CBT was the primary intervention throughout the studies included. Eight of the ten studies utilized a manualized version of the Coping Cat program. A total of 10 studies were included in the review. Participants within these studies were 7 to 12 years of age, male or female, with varying primary anxiety diagnoses. A range of races and ethnicities were included. A total of 22 different measurements were utilized across the studies and were not mentioned in detail. Diagnostic recovery and rates of anxiety diagnoses were also measured. Individual CBT significantly decreased the rates of anxiety diagnoses as compared to control groups. Diagnostic recovery rates for individual CBT were equal or superior to diagnostic recovery rates of control groups with the exception that combination therapy of sertraline and CBT was significantly more effective than monotherapy. Level I High quality |
| Strawn, J. R., Dobson, E. T., Giles, L.L. (2017). Primary pediatric care psychopharmacology: Focus on medications for ADHD, depression, and anxiety. *Current*. The purpose was to explore psychopharmacologic interventions for the treatment of anxiety, ADHD, and depression in pediatric care. The design of the study was a systematic review. Psychopharmacologic interventions explored included SSRIs, particularly sertraline, SSNRIIs, stimulants, alpha 2 The sample population included youth with depressive disorders, anxiety disorders, and/or ADHD. Several landmark studies were explored in the The sample population included youth with depressive disorders, anxiety disorders, and/or ADHD. Several landmark studies were explored in the Outcomes measured included side effects and tolerability of medications. Remission, response to treatment, and Sertraline effectiveness was not statistically significant from that of CBT but was statistically significant in comparison to placebo. Level I Good quality |
agonists as well as CBT. review, including the CAMS and CAMELS studies. relapse were also measured. Combination therapy with sertraline and CBT led to better outcomes than either treatment alone, and gains were maintained at follow up.

SSRIs and SSNRI s have similar side effect profiles among youth, including headaches, nausea, irritability, restlessness, mild disinhibition, and insomnia.

Multiple meta-analyses did not identify a link between antidepressant use and increased risk of suicide, but appropriate caution should be taken.

Wetherell, J. L., Petkus, A. J., White, K. S., Nguyen, H., The purpose of this study was to determine whether the addition of an The study design was a randomized controlled trial. The sample included 73 adults at least 60 years of age with a Anxiety outcomes were measured via the Hamilton Anxiety Rating Based on the results of the Penn State Worry Questionnaire, Level II Good quality

antidepressant medication to the regimen of CBT would increase response and prevent relapse in older adults with GAD.

All participants received escitalopram for 12 weeks and then were randomly assigned to one of four different groups: 1) escitalopram and CBT followed by maintenance escitalopram, 2) escitalopram alone followed by maintenance escitalopram, 3) escitalopram and CBT followed by pill placebo, 4) escitalopram alone followed by placebo.

primary diagnosis of GAD based on DSM-IV criteria. They were recruited from three outpatient clinics.

Scale (HAM-A) every four weeks during the augmentation phase and every two weeks during the maintenance phase.

Outcomes of excessive and uncontrollable worry were measured using the Penn State Worry Questionnaire at the initiation and completion of the augmentation and maintenance phases.

participants who received CBT were three times more likely to respond to treatment than those who did not receive CBT (p<0.05).

The effect size was medium to large regarding CBT and worry symptoms with greater improvements in pathological worry exhibited by participants who received escitalopram augmented with CBT according to the Penn State Worry Questionnaire. According to the HAM-A, participants who received CBT did not show greater improvement in anxiety symptoms.
| Lower relapse rates were exhibited by participants who received maintenance escitalopram or CBT with placebo as compared to participants who did not receive these treatments respectively. |
Level I evidence. Nguyen (2017) published an evidence summary exploring the best available evidence for the management of GAD. This evidence summary included three clinical practice guidelines, six Cochrane reviews, two meta-analytic reviews, and one RCT. It was addressed within this summary that clinical practice guidelines provide support that most often, patients diagnosed with GAD can be well cared for in the primary care setting. Additional conclusions made from U.S. clinical practice guidelines include that psychological therapy provides the longest duration of treatment effect followed by the effects of pharmacological therapy with antidepressants or self-help interventions. Cochrane reviews and clinical guidelines supported that psychological interventions that are grounded in CBT are effective for short-term treatment of GAD, have been shown to reduce symptoms of anxiety, and are more effective than placebo. The addition of CBT to pharmacotherapy also demonstrated usefulness. Effective pharmacological interventions include the use of SSRIs due to cost effectiveness, efficacy, safety, tolerable side effects, and ease of use. There are many barriers to typical therapist-guided CBT, including lack of time, transportation issues, negative stigma, lack of trained clinicians, all of which lead to limited patient access to CBT. Thus, self-help, self-administered, or distance delivery in the form of telephone or the internet has reduced such barriers. Psychological therapy based on CBT principles in the form of books, known as bibliotherapy, is recommended as such type of self-help intervention. A Grade B recommendation was assigned to the use of an SSRI for the treatment of GAD unless contraindicated as well as to instruct patients to take medication as directed to avoid discontinuation or withdrawal symptoms. A Grade A recommendation was given to always taking patient preference in consideration for care.

Thus, the evidence summary provided strong, well-supported, clear recommendations from current sources (Nguyen, 2017). The objectives as well as the target population of the evidence summary were clearly stated. A systematic search of the literature was performed. There was a clear relationship between the evidence, conclusions, and recommendations.
made. Benefits as well as risks were addressed within the recommendations. Multiple options for the management of GAD were provided based on patient eligibility, safety, and preference, and barriers were discussed. Conclusions were consistent, generalizable, based on results, and flowed logically in response to the clinical question. The evidence summary received high scores within all six domains. This can be described as level I evidence of high quality based on Melnyk and Fineout-Overholt’s (2015) Hierarchy of Evidence and the AGREE II Instrument respectively.

**Level I evidence.** An evidence summary published by Jayasekara (2016a) was also included in the review of literature due to its relevance to the EBP project. The purpose of the summary was to answer the clinical question regarding the best evidence regarding psychotherapy for patients diagnosed with GAD. Evidence found that CBT was able to reduce anxiety levels more than treatment as usual for patients on a waiting list, and in addition, CBT effectively reduced secondary symptoms of worry and depression. CBT was also found to help prevent relapse of GAD symptoms. A meta-analysis reviewed found that CBT was more effective than non-cognitive therapy in the treatment of worry and that such positive outcomes were maintained at follow-up. Evidence supported the effectiveness of CBT for the treatment of anxiety disorders in children, adolescents, the working-age population, and older adults. In conclusion, the best practice recommendation for the use of CBT in the treatment of GAD across the lifespan, including children, adolescents, adults, and older adults received a Grade B recommendation.

This evidence summary received a high score for the scope and practice domain with the objectives, clinical questions, and intended population for these recommendation clearly delineated (Jayasekara, 2016). The evidence was well written, and content was easy to find within the document. The stakeholder involvement domain also ranked high as the evidence summary clearly identified that these recommendations were useful for children, adolescents, adults, and older adults with GAD. A systematic search of evidence-based health care
databases was underwent, and details of each piece of evidence were provided leading to a strong score in the rigour of development domain. Details of each study were presented, and one of the Cochrane systematic reviews included 38 RCTs and a total of 3,214 participants. Recommendations were clear and suffice yielding a high score for the clarity of presentation domain. Clear advice regarding implementing recommendations and implications for practice were discussed among the multiple pieces of evidence included, which provided a strong rating for the applicability domain. The editorial independence domain also scored high as it was declared that there were no conflicts of interest. Thus, this level I evidence summary was deemed of high quality with consistent, generalizable results across the lifespan, sufficient sample size, and strong, definitive conclusions. This piece of evidence provided much support for the CBT intervention focus and well as the intended population of the EBP project.

**Level I evidence.** Another evidence summary published by Jayasekara (2016b) reviewed the best evidence for self-help interventions for patients with anxiety disorders. Self-help interventions include patients completing psychological treatment protocols independently. Most of these self-help interventions are based on CBT, including exposure, cognitive restructuring, and relaxation. They can be accessed through books, computers, televisions, videos, or the Internet. It is unnecessary to interact with a therapist in order to participate in the therapy. Five meta-analyses, four systematic reviews, one Cochrane review, and one RCT were included in the evidence summary. Several different types of self-help were included in the studies, including unguided self-help, self-help as partial replacement to face-to-face therapy, and guided self-help. In conclusion, self-help interventions were recommended for the treatment of anxiety disorders and received a Grade A recommendation. Multiple meta-analyses found that bibliotherapy, including written texts, computer programs, or audio/video material, was more effective than waiting lists, no treatment, or placebo. One meta-analysis in particular determined that the effect size did not differ by the type of self-help intervention, including guided, minimal contact, and self-administered. Self-help bibliotherapy can serve as a low-cost effective option
for patients with GAD. However, overall, there are limited data regarding the cost and feasibility of such bibliotherapy. Face-to-face CBT may be clinically superior, but self-help serves as an available treatment option for patients when other services may be inaccessible.

This level I evidence summary included a thorough description of its scope and purpose (Jayasekara, 2016b). The target population, interventions, and comparison were clearly delineated. A comprehensive literature review that included reference to scientific evidence was included, and sources ranged in publication dates between 2001 to 2016. Thus, not only was current evidence included, but data and trends covering a large time period were available. The systematic search was relevant and appropriate for the clinical question. Details of the studies were presented clearly including brief descriptions of design, sample, methods, results, outcomes, strengths, and limitations. Sample sizes for many included studies were large. The evidence presented was strong, clear, and consistent and received a Grade A recommendation. Thus, this evidence summary was appraised as being of high quality.

**Level I evidence.** Kapczinski, dos Santos Souza, Batista Miralha da Cunha, and Schmidt (2003) published a systematic review exploring the efficacy and acceptability of the use of antidepressants in the treatment of GAD. This publication was citation chased from the version published in 2016. The title of the 2016 version was present within the results yielded from the best search. However, the publication was withdrawn from the Cochrane Library Database as it was passed on to new authors. Because the version published in 2003 was the most recent one available at this time, an exception was made to include this piece of evidence. Although it was not published within the last 5 years, it remains published within the last 15 years. This systematic review of RCTs only involved a search of multiple databases, including Cochrane Collaboration Depression, Anxiety and Neurosis Controlled Trials Register, the Cochrane Central Register for Controlled Trials, MEDLINE, and LILACS for publications published from 1966 to 2002. Additional inclusion criteria included relevant RCTs comparing antidepressants to placebo or antidepressants to other pharmacological treatment. Non-
randomized studies and patients with additional Axis I comorbidities other than GAD were excluded. Thorough review was performed by one reviewer, who assessed studies for relevance, inclusion and exclusion criteria, and quality. A total of 15 articles were included in the review. Most of the included trials were conducted in the United States, and all included outpatients. One trial was conducted among children, and the other trials were conducted among adults. Duration of treatment ranged from 6 to 28 weeks.

Each of the trials included outcome measurement of symptoms via various symptoms scales with the most common scale used by the Hamilton Anxiety Scale (HAM-A). Additional outcomes measured included generalized anxiety changes at the end of the trial (extent of response via a Clinical Global Impression (CGI) score) and acceptability of the treatment (dropout rate and specific side effects). Data were analyzed by two reviewers. A third reviewer solved any disagreement between the two primary reviewers. An analysis of results occurred via the use of Review Manager Software 4.1. Relative risk and confidence intervals were calculated. Evidence favored antidepressants over placebo and found that antidepressants were more effective in treating GAD than placebo. Paroxetine and imipramine were compared and shown to have similar efficacy and be well tolerated by most patients with GAD. Sertraline was more effective than placebo in the treatment of GAD among children and adolescents. Side effects more commonly occurred in the groups treated with antidepressants as compared to placebo groups. Side effects included nausea, dry mouth, constipation, and drowsiness. However, because dropout rates were not significant between antidepressant and placebo groups, evidence supports that antidepressants are well tolerated. Therefore, this systematic review provides support for the use of antidepressants in the treatment of GAD across the lifespan and describes the efficacy and acceptability of many different antidepressants in particular, which can aid in appropriate prescribing by NPs and other providers.

A good quality rating was assigned to this systematic review as variables of interest were clearly identified, key search terms were stated, multiple databases were searched, and
exclusion and inclusion criteria were stated (Kapczinski et al., 2003). The data were older than the past 5 years, dating back to the past 15 years. This review excluded participants with additional Axis I diagnoses other than GAD. This provided benefit in that it allowed for the conclusion to be made that the effect of antidepressants to decrease symptoms of anxiety was independent from its effects on depression or dysthymia. However, it hindered the generalizability of the review as about 90% of patients with a diagnosis of GAD also have another psychiatric comorbidity. The sample size for some of the trials, including the one involving children and adolescent participants, was small. Definitive conclusions and consistent recommendations were yielded from the results.

**Level I evidence.** A systematic review performed by Sawyer and Nunez (2014) reviewed literature published between 2007 and 2012 in order to evaluate the effectiveness of individual, manualized CBT for anxiety in the pediatric population. Four databases were searched, including Cochrane, PubMed, CINAHL, and PsycINFO, and 10 studies were selected for final review. Inclusion criteria consisted of evidence from peer-reviewed journals, English language, CBT as the primary intervention, and school-age anxious children ages 7-12. Exclusion criteria included a comorbid diagnosis of autism, disorder-specific CBT, computer-assisted, group only, self-help, or school-based CBT, fewer than 10 participants, CBT in combination with other therapies, only one component of CBT, any adult participants, and only adolescent participants. An exception was made to include this piece of evidence as it was determined to be relevant to the EBP project and self-help CBT as an individual, manualized form of the Coping Cat program was explored. A total of 40 articles met inclusion and exclusion criteria and were further reviewed for level of evidence, quality, and relevance. Of the 10 final articles selected, two were systematic reviews, six were randomized controlled trials, and two were quasi-experimental studies.

The interventions included in this review were individual CBT, with or without parental involvement (Sawyer & Nunez, 2014). Eight of the ten studies utilized a manualized form of
CBT, and most included the Coping Cat program. Coping Cat is a 14-to-20-session program with 60-minute sessions. Additional individual CBT programs utilized in the studies included Facing Your Fears, a 12-session program with 60-to-90-minute sessions and FRIENDS, a 14-session program with 60-minute sessions. CBT sessions were one hour long, and most children participated in at least 12 sessions. A total of 22 different tools were utilized among the studies in order to measure the outcome of symptom reduction. These tools were not discussed in detail but were described as having adequate reliability and validity. Diagnostic recovery was also measured, which can be defined as remission from a disorder and no longer meeting diagnostic criteria for the disorder. Compared to controls of group CBT, family CBT, education or support, and medication, findings supported that individual, manualized, CBT significantly decreased anxiety rates and was superior or equivalent to measures of diagnostic recovery. There was an exception in that the combination of sertraline and CBT was significantly more effective than individual CBT alone. This review called for further dissemination of CBT, cost-effective programs, accessible manuals, training, and as well as evidence-based CBT programs that can be implemented in brief sessions over less visits in the primary care setting in order to overcome barriers. Overall, this systematic review provided strong, high level evidence to support individual, manualized CBT for the treatment of anxiety disorders in children.

This level I systematic review was deemed of high quality after critical appraisal as a result of its heterogeneity with the inclusion of both males and females and a variety of races and ethnicities (Sawyer & Nunez, 2014). Thus, results are generalizable across the pediatric population. An extensive literature review was performed with the inclusion of only high-level sources, specifically level I and level II. Key search terms were stated, multiple databases were searched, and inclusion and exclusion criteria were delineated. Details of included studies were presented, including design, sample, method, results, outcomes, strengths, and limitations. This review identified gaps in knowledge regarding CBT for anxiety, provided supporting evidence to help close those gaps, and recommended further necessary research.
Level I evidence. Andersen and colleagues (2014) presented a clinical guideline that was adapted from the American Society of Clinical Oncology (ASCO). The purpose of the guideline was to address appropriate screening, assessment, and care of symptoms of anxiety and depression in adults who have cancer. The authors of the guideline stated that all patients should be screened for anxiety symptoms when they are diagnosed and onward. Screening at initial visits and times of disease status changes, such as post-treatment, recurrence, progression, palliative, or end-of-life care, was advocated as important. It was also noted that a valid and reliable tool is necessary to both screen and assess for anxiety. The Generalized Anxiety Disorder (GAD)-7 scale was strongly recommended. Providers should be aware of not only anxiety symptoms that patients may present with but also other ways in which the disorder may present including concerns or fears. Although it is expected for patients to have worries regarding cancer, GAD is likely present when such worries do not align with the actual cancer-related risk, including worry about symptoms that are not associated with cancer or cancer treatments. In addition, a patient with GAD has worries about a large variety of other topics, including non-cancer issues. The provider should assess the patient's home environment, relationships, social life, and occupational work to detect any impairments during the time in which they experience anxiety symptoms. Referral to a psychiatrist, psychologist, physician, or equivalently trained professional should occur if the patient expresses a risk of harm to oneself and/or others, severe anxiety or agitation, or psychosis or delirium. Assessments should include identifying signs and symptoms of anxiety (panic attacks, trembling, sweating, tachypnea, tachycardia, palpitations, sweaty palms), symptom severity, potential stressors (impaired daily living), risk factors, times of vulnerability, and potential underlying causes. A confirmation of GAD via the DSM-5 criteria is necessary prior to the initiation of treatment.

Patient preferences and shared decision making should be incorporated into the treatment plan, and both pharmacologic and/or nonpharmacologic interventions should be considered (Andersen et al., 2014). Patients should be warned of potential adverse effects,
tolerability, and potential interactions with other medications if prescribed medications. Benzodiazepines should be used with caution, especially with long-term use, due to increased potential for abuse and dependence and adverse effect of cognitive impairment. Support, education, and information about anxiety, proper management, and when to call the provider should be provided to the patient. Well-supported psychological interventions with clear explanations regarding guided content and structure, delivery method, and duration of treatment should be provided. Outcomes should be measured at various intervals, including a minimum of pre- and post-treatment but preferably once per month or until symptoms subside, in order to determine the effectiveness of the intervention, monitor patient compliance, evaluate the practitioner, assess patient satisfaction with the treatment, and determine solutions to compliance issues. After eight weeks of treatment, if there has been no symptom reduction or poor patient satisfaction, a psychological or pharmacological intervention should be added, the medication should be changed, or the provider should provide a referral to individual or group psychotherapy. Detailed information for the treatment of depression was also discussed in the guidelines but not thoroughly explained within this report due to the project's main focus of GAD. This clinical guideline provided thorough instructions to providers for the screening, assessment, and treatment of GAD among adult patients with cancer and can help to aide in achieving positive outcomes for patients when followed.

This level I evidence was deemed of high quality based on the AGREE II Instrument due to its development by key stakeholders, including a highly regarded organization, the ASCO, and its detailed conclusions (Andersen et al., 2014). Multiple databases were searched and identified, including MEDLINE, EMBASE, the Cochrane Library, and medical specialty websites. The target population was identified including clinical condition and comorbidities. Potential harms and benefits were addressed. Recommendations were clear, grounded in supporting evidence, and provided multiple options patients are likely to accept.
Level I evidence. A clinical guideline by the Assessment and Management of Risk for Suicide Working Group (2013) provided information for the assessment and management of patients at risk for suicide. This is very applicable to patients with GAD, and the link between GAD and risk for suicide is discussed frequently throughout available literature. In addition, in contrast to best practice, benzodiazepines are often utilized in the treatment of GAD. The FDA has added boxed warnings to benzodiazepines as their use combined with opioid medications can lead to slowed or difficult breathing and death. Benzodiazepines should be used with caution when prescribed for patients at risk for suicide due to this risk of respiratory depression as well as addiction effects. This guideline recommends that any patient diagnosed with a mental disorder be assessed for suicide risk. Depression is often a comorbidity with GAD. Patients with high scores on depression screening tools should also be assessed for risk of suicide. When symptoms of anxiety are present, providers should ask patients directly regarding suicidal ideation. It is also important to consider that suicidal ideation can fluctuate, and reassessment should regularly occur when circumstances change. Additional warning signs of potential suicidal behavior includes anxiety in the form of agitation, irritability, angry outburst, wanting to jump out of one’s own skin and dramatic mood changes or lack of interest in usual activities or friends. Protective factors should also be assessed, including a patients’ will and purpose to live and other factors that may decrease the risk of suicide, such as social support, positive personal traits, good coping and problem-solving skills, and access to health care. A detailed mental health history should also be obtained.

CBT and other psychodynamic therapies as well as antidepressants may be beneficial to this patient population (Assessment and Management of Risk for Suicide Working Group, 2013). However, close monitoring of patients who are prescribed antidepressants is warranted for the emergence or worsening of suicidal thoughts. Providers should be aware of overdose risk and only provide a limited amount of medication at a time. There is no evidence to support the use of antipsychotics to reduce suicide risk. In conclusion, there is a call for clinical training
programs for mental health in order to help bridge the gap between research and practice and to help solve the problem of a shortage of clinicians trained to provide evidence-based psychotherapies. In conclusion, this guideline in applicable to the EBP project as it provides important recommendations for treating the patient with GAD holistically, assessing for suicide risk, and appropriately managing GAD via CBT and antidepressants.

After a quality appraisal of this level I clinical guideline was conducted, it was assigned a rating of high quality in accordance with the AGREE II Instrument (Assessment and Management of Risk for Suicide Working Group, 2013). Key terms searched were addressed, including suicide and all related terms. Inclusion criteria were listed as peer-reviewed articles, published in the English language, population of adults 18 years of age or older, and appropriate sample sizes. RCTs, meta-analyses, and systematic reviews of RCTs were included to provide the strongest levels of evidence in support of the guideline recommendations. A total of 35 RCTs and 38 systematic reviews were included. Studies were appraised for quality prior to making decisions to include or exclude. Patient preferences and individual situations were considered. Conclusions were developed through a rigorous approach.

Level I evidence. A Cochrane systematic review by James, James, Cowdrey, Soler, and Choke (2015) served a purpose of examining the effectiveness of CBT for children and adolescents with anxiety disorders as compared to wait lists, non-CBT interventions and treatment as usual (TAU), medications, combination therapy, and placebo as well as the long-term effects of CBT. A search of multiple databases was performed including The Cochrane Library, EMBASE, MEDLINE, and PsycINFO for evidence with a publication date of 1970-2012. Inclusion criteria consisted of children and adolescents ages 4-19, meeting diagnostic criteria of the DSM II or IV or ICD9 or ICD10 for anxiety disorder, research settings (i.e. university outpatient clinics, inpatient services, community clinics, and schools), and comorbidities allowable for anxiety disorders per DSM and ICD rules. Exclusion criteria consisted of PTSD,
OCD, and simple phobias. A total of 41 RCTs met inclusion criteria, and each arbitrarily involved at least nine sessions of CBT and direct contact with children. A total of 1034 participants and 921 controls were included within the 41 studies. Participants were recruited from outpatient clinics, and all had a psychiatric diagnosis of an anxiety disorder ranging from mild to moderate (SAD, overanxious disorder (OAD), SOP, panic disorder (PD), GAD, specific phobia (SP)) while many had comorbid conditions (depression, conduct disorders (CDs), oppositional defiant disorder (ODD), attention-deficit/hyperactivity disorder (ADHD)).

The intervention within the studies was required to include manualized, or modular, CBT alone, or CBT with medication (James et al., 2015). Individual, group, or family/parental involvement were ways in which CBT was administered. CBT was aimed at helping children recognize feelings of anxiety and somatic reactions, clarify cognitions, develop coping skills, and learn exposure training. Participants in waiting list, treatment as usual, treatment without CBT, and placebo groups served as the controls. Placebo treatment included education or bibliotherapy without CBT elements. The primary outcome measured was remission, which was measured using the Anxiety Disorder Interview Schedule for Parents (ADIS-P), the Anxiety Disorder Interview Schedule for Children (ADIS-C), or the Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP). The interviews were not carried out by the treatment team to allow for blinding. The Clinical Global Impressions (CGI) Scale was also utilized to assess treatment response. Acceptability was measured by the number of participants lost to follow up. Reduction in anxiety symptoms was also measured using multiple scales. Outcomes were assessed at follow up periods between 6 months and 24 months. Demographic data, including heterogeneity between trials (age, gender, diagnosis, duration and severity, comorbidities), were assessed using the Chi test and the I statistic. Only modest variability was found. Meta-regression was utilized to determine the influence of disorder severity prior to initiation of treatment on outcome.
To summarize the results, 58.9% of participants who received CBT achieved remission compared to 16% of controls, but these results were not significant (OR 1.51, 95% CI 0.77 to 2.96, Z=1.21, P=0.23) (James et al., 2015). The study supported a clear benefit for CBT (95% CI), and there were no differences in outcomes for individual, group, or family CBT. There was also no difference between the rates of participants lost to follow up among the CBT intervention and control groups. Findings were significant and supported the efficacy of CBT over active controls (OR 0.52, 95% CI 0.31 to 0.91, Z=2.28, P=0.02). Group and family/parental formats of CBT were associated with greater reduction in symptoms than those produced by individual CBT formats alone, but findings were not significant (Z=1.66, P=0.1).

Overall, this review offers support for the usefulness of CBT as well as its acceptability in the treatment of anxiety disorders in children and adolescents (James et al., 2015). CBT was shown to be superior to waiting list controls, but its superiority as compared to active controls (psychoeducation, bibliotherapy, treatment as usual) could not be confirmed. It was unclear whether children younger than 6 years of age have the cognitive maturity to participate in CBT.

This level I systematic review was deemed of good quality (James et al., 2015). The use of multiple outcome scales did add complexity and posed some challenges to making comparisons. All scales utilized were found to have good reliability, validity, and efficacy. Included studies involved an age range of 4 to 18 years, but children younger than 7 years old were underrepresented. Generalizability was enhanced by inclusion of both genders, a range of socioeconomic classes, and multiple comorbidities. However, nine studies did not provide details of ethnicity of participants, and generalization to those with severe anxiety was limited as only mild to moderate cases were included in the review. A small sample size of 41 studies was included. Details of the studies were clearly depicted. There was a potential for bias as participants could not be blinded. Conclusions logically flowed from the results of the review and were consistent with those of other reviews and meta-analyses.
Level I evidence. Strawn, Dobson, and Giles (2017) recently published a systematic review addressing psychopharmacologic interventions utilized in pediatric care for the treatment of anxiety as well as attention deficit hyperactivity disorder (ADHD) and depression. Medication classes, including SSRIs, SNRIs, stimulants, and alpha 2 agonists, side effects and tolerability concerns, and landmark trials of antidepressant medications in children and adolescents were reviewed. The Child/Adolescent Anxiety Multimodal Study (CAMS) is one of the largest trials of its kind and supports that sertraline has the greatest efficacy in the treatment of GAD in children and adolescents. This study included 488 patients, and 78% of them had a primary diagnosis of GAD. Randomization to groups occurred, and intervention groups included CBT only, sertraline only, or CBT and sertraline in combination. Results indicated that sertraline effectiveness was not statistically significant from that of CBT, but was statistically significant in comparison to placebo. Combination treatment led to better outcomes than either treatment alone, and patients maintained gains at follow up. After completing the 12-week CAMS trial, approximately 60% of those patients participated in the Child/Adolescent Anxiety Multimodal Extended Long-term Study (CAMELS). A total of 82 patients who had received combination therapy of sertraline and CBT, 79 who received sertraline monotherapy, 83 who received CBT monotherapy, and 44 who received placebo continued into this trial. Six years following the initiation of the study, approximately 47% of patients were in remission. Response to acute treatment was determined to be a predictor of long-term outcomes. However, relapse also occurred in about 48% of patients, as anxiety often fluctuates. In additional studies, lower likelihood of remission after treatment with pharmacotherapy was found to be associated with older age, female gender, minority status, lower socioeconomic status, poor family functioning, and severe anxiety at baseline.

SSRIs and SSRNIs have similar side effect profiles among youth, including headaches, gastrointestinal side effects (nausea), and activation, which is characterized by irritability, mild disinhibition, increased restlessness, and insomnia (Strawn et al., 2017). Activation occurs more
commonly in youth treated with SSRIs than with adults. Multiple meta-analyses did not identify a link between antidepressant use and increased risk of suicide, but appropriate caution should be taken. Paroxetine and venlafaxine may be more associated with this risk of increased suicide due to their short half-lives, and as a result, are not first-line interventions for the treatment of anxiety disorders in youth. Within the study, CBT was found to help mitigate the suicidality-related adverse events associated with venlafaxine.

This review supported the importance of early treatment of GAD in youth and celebrated the growing volume of evidence for psychopharmacologic interventions in youth with anxiety disorders (Strawn et al., 2017). It calls for providers to be astute regarding medication-specific tolerability concerns and warnings when prescribing antidepressants. It also provides further evidence for the effectiveness and sustained effects of combined CBT and antidepressant use, specifically including the SSRI sertraline.

After critical appraisal, this level I systematic review was deemed of good quality (Strawn et al., 2017). Information regarding key search terms, databases searched, and inclusion and exclusion criteria were lacking. Details of included studies were briefly described. Methods for appraising the strength of the evidence were not disclosed. Sample sizes of many included studies were adequate and allowed for generalizable results across youth ages 7 to 17 years. Adequate control was maintained among groups. Definitive conclusions and consistent recommendations were based on scientific evidence and provided worthwhile contributions to practice.

**Level II evidence.** Wetherell, Petkus, White, Nguyen, Kornblith, Andreeescu, Zisook, and Lenze (2013) conducted a randomized controlled trial exploring the effects of antidepressant medication augmented with CBT for the treatment of GAD in the older adult population. The purpose of the study was clearly stated as examining whether such interventions improve symptom outcomes (boost treatment response) and decrease relapse rates in this population. A sample of 73 adults greater than or equal to 60 years of age with a DSM-IV principal diagnosis
of GAD participated in the study. Recruitment of participants occurred between 2008 and 2010 at primary care practices, mental health clinics, and advertisements at three sites in Pittsburgh, San Diego, and St. Louis. Patients with comorbid depression or other anxiety disorders were included in the study provided that GAD was their principal diagnosis. Exclusion criteria included a history of substance abuse without a minimum of 6 months of full remission, lifetime history of psychosis or bipolar disorder, cognitive impairment, current suicidal ideation, ongoing psychotherapy, and medical instability. Psychotropic medications were tapered off two weeks before the start of the study, and benzodiazepines and sleep aids were also tapered off or continued at a consistent, lower dosage throughout the study. Participants were given a thorough description of the study and provided written informed consent.

Treatment throughout the study was administered in three phases: acute, augmentation, and maintenance (Wetherell et al., 2013). During the acute phase, participants received 12 weeks of treatment with escitalopram, an antidepressant categorized as an SSRI, starting at a dosage of 10 mg per day. If symptoms were not improving, the dosage was increased to 20 mg per day as tolerated after four weeks of treatment. After 12 weeks, participants were randomly assigned to one of four groups provided that they received at least a 20% improvement in symptoms: 1) escitalopram for 16 weeks and 16 CBT sessions (augmentation phase), followed by escitalopram for 28 weeks (maintenance phase); 2) escitalopram for 16 weeks without CBT, followed by escitalopram for 28 weeks; 3) escitalopram for 16 weeks with CBT, followed by pill placebo for 28 weeks; 4) escitalopram for 16 weeks without CBT, followed by pill placebo for 28 weeks. The CBT protocol, which was administered by six therapists with doctoral degrees, included education modules regarding psycho-education/self-monitoring, relaxation training, cognitive therapy, and problem-solving skills. Participants could invite one family member to attend one session with them in order to educate them as well and provide support for the participant.
Anxiety outcomes were measured using the Hamilton Anxiety Rating Scale (HAM-A), a 14-item scale conducted via interview by the clinician that measures anxiety by assessing somatic symptoms, every four weeks during the augmentation phase and every two weeks during the maintenance phase (Wetherell et al., 2013). The HAM-A is considered a gold standard for measuring outcomes regarding GAD treatment with pharmacotherapy and has excellent reliability with a correlation coefficient of 0.93. Outcomes of excessive and uncontrollable worry were measured using the Penn State Worry Questionnaire at the initiation and completion of the augmentation and maintenance phases. This self-report scale consisting of 16 items is most commonly used in psychotherapy studies for GAD and has high internal consistency with a Cronbach’s alpha of 0.87.

The study began with a total of 86 participants enrolled (Wetherell et al., 2013). Thirteen participants withdrew from the study due to medication side effects or lack of efficacy or were lost to follow up. A total of 69 of the 73 randomly assigned participants, or 95%, completed the entire protocol. Demographic information of the treatment groups was clearly described and depicted in a table. There was no difference among the four groups regarding demographic variables, anxiety level, or worry level at pretreatment. It was determined that age, education, and age at onset of diagnosis of GAD did not affect the results. Statistical analyses included chi-square tests for group differences at baselines, Kaplan-Meier survival analysis for HAM-A scores and relapse rates, logistic regression for Penn State Worry Questionnaire data, and linear mixed models for measuring improvement in anxiety and worry symptoms. Based on the results of the Penn State Worry Questionnaire, participants who received CBT were three times as likely to exhibit response to treatment in terms of improved symptoms than those who did not receive CBT (odds ratio=3.19, 95% CI=1.00-10.14, p<0.05). A medium to large effect size of CBT on worry symptoms was found. Participants who received escitalopram augmented with CBT exhibited greater improvements in pathological worry than those who received escitalopram only (p=0.01). Based on HAM-A scores, participants who received CBT did not
exhibit greater improvements in anxiety symptoms (p=0.15). Participants who received maintenance escitalopram had significantly lower relapse rates than those receiving placebo (p<0.001). Participants who received CBT with placebo had lower relapse rates than those who did not receive CBT (p=0.009). There was no statistical significance among relapse rates between the participants who received maintenance medication without CBT and participants who received CBT without maintenance medication (p=0.11). A total of 34.0% of participants receiving placebo relapsed, while no participants receiving maintenance medication relapsed. Regarding participants receiving placebo, 42.9% of those who did not receive CBT relapsed while 25.0% of those who received CBT relapsed.

This study provides strong evidence to support the combined use of CBT and SSRIs (Wetherell et al., 2013). This sequenced combination treatment led to improved symptoms of worry, although not improved symptoms of anxiety in this population. Both maintenance medication and CBT were highly able to prevent relapse. Based on these results, the augmentation of CBT can improve response to treatment and worry levels when an SSRI is insufficient and may allow patients to discontinue long term medication use while remaining in good control of GAD. Use of CBT and a maintenance SSRI also provides a safer and more efficacious alternative to benzodiazepine use. The relapse prevention findings among older adults in this study were found to also be generalizable to the young adult and middle-aged population. In conclusion, this RCT provided much support for the addition of CBT after initiation of an SSRI for the treatment of GAD in older adults. This was very applicable to the EBP project as many patients with GAD at the facility had been taking an SSRI prior to the implementation of the project, and thus, the addition of CBT was appropriate at the start of the project for such patients. The results were also applicable to the project’s included population of older adults as well as young and middle-aged adults.

Overall, this level II RCT was found to be of good quality after critical appraisal (Wetherell et al., 2013). Moderate control was allocated to the groups as the demographics
were similar in both the control and intervention groups, and the settings were similar as
aforementioned. The instruments utilized to measure data were reliable with a Cronbach’s alpha
greater than 0.70, and instrument validity was discussed. A high response rate of 95% was
achieved. Results were clear and consistent, and definitive conclusions were made. Limitations
of the study were discussed, including the small sample size, lack of control for the CBT
intervention, and moderately short maintenance phase of 7 months.

**Level II evidence.** Glenn and colleagues (2013) performed an RCT that examined
predictors of outcomes of CBT for anxiety disorders in regard to treatment dose and patient
engagement. A total of 1,620 patients with GAD, panic disorder, social anxiety disorder, or
posttraumatic stress disorder were recruited from primary care settings in the United States, and
1,004 of these were eligible for the study. Potential applicable participants were directly referred
for the study by primary care providers and clinical nursing staff. A trained clinician then
determined eligibility based on inclusion criteria including the requirements of attendance at a
participating clinic, age 18-75 years old, meeting of DSM-IV diagnostic criteria for the included
disorders, and a score on the Overall Anxiety Severity and Impairment Scale (OASIS) indicating
moderate or clinically significant anxiety symptoms. Exclusion criteria included patients with
unstable conditions, marked cognitive impairment, active suicidal intent or plan, psychosis, or
Bipolar I disorder, drug or alcohol dependence (abuse was permitted), patients already
receiving CBT, and patients who could not speak English or Spanish.

Using an automated program and stratified permuted block randomization, participants
were randomized to groups (Glenn et al., 2013). About half of the participants, 503 in total,
received the intervention. Participants could select their preference to receive pharmacotherapy,
computer-assisted CBT, or both. A total of 43 of the 503 participants chose to receive
pharmacotherapy only, 166 chose CBT only, and 273 chose both CBT and pharmacotherapy.
The CBT intervention was based on Coordinated Anxiety Learning and Management (CALM)
tools and contained eight modules in which the clinician and patient both viewed the program on
the screen at the same time. CBT principles included cognitive restructuring, exposure, self-monitoring, psychoeducation, fear hierarchy, breathing retraining, and relapse prevention. Clinicians did not have expertise in anxiety management or CBT. Some had patient care experience, and 8 of 14 had prior mental health experience. Six were social workers, five were registered nurses, two were master’s-level psychologists, and one was a doctoral-level psychologist.

Variables included number of CBT sessions attended, number of CBT modules in which exposures were conducted to interoceptive cues, trauma memories, catastrophic images, or feared or avoided situations, clinician rating of homework adherence, and clinician rating of patient overall commitment to CBT per session (Glenn et al., 2013). The Brief Symptom Inventory (BSI) 12-item scale was utilized to measure primary outcomes of psychic and somatic anxiety and has high internally reliability and validity. Secondary outcomes measured included depression via the PHQ-9 and functional status via the Sheehan Disability Scale (SDS). The PHQ-9 has high internal reliability with a Cronbach’s alpha of .86 to .89 and high construct, external, and criterion validity. The SDS measures impairment in work/school, social life, and home life/family and has adequate internal reliability, construct validity, sensitivity, and specificity among patients with anxiety disorders. Propensity score weighting was utilized to eliminate differences in baseline characteristics between patients in the low and high CBT dose and engagement groups. Demographics characteristics identified included ethnicity, age, education, gender, and comorbidities.

Results included that participants who had lower attendance scored significantly higher on all outcome measures (ps < 0.029) at both 12 and 18 months than those who had high attendance. Patients who did not complete exposure modules were significantly more symptomatic (ps < 0.004) across all measures at 12 and 18 months in comparison with those who did complete exposure modules. Patients who were less adherent to homework scored significantly higher (ps < 0.012) across all measures at 12 and 18 months than those who were
more adherent to homework. Patients who exhibited low commitment to CBT scored significantly higher across all measures at 18 months (ps < 0.006) but not at 12 months than those who exhibited high commitment to CBT.

Findings supported that greater learning and storage strength of learning during CBT occurred with greater treatment dose and engagement (Glenn et al., 2013). In addition, greater reduction in symptoms and improvements in functioning occurred with higher CBT dose and engagement, including completing at least one exposure exercise, having a high attendance rate, and completing assigned homework. As a result of exposure completion and higher attendance predicting better outcomes, the value of these aspects of CBT as predictors of outcomes was emphasized. Further endeavors to make CBT more interesting, understanding, and useable, such as through mobile phone applications or computer programs, were recommended.

A quality rating of good was applied to this level II RCT (Glenn et al., 2013). The purpose of the study and data collection methods were described clearly. The instruments were reliable with a Cronbach’s alpha greater than 0.70. Tables were presented and consistent with the narrative content. A thorough literature review was performed, but sources dated as far back as 1992. Limitations of the study were discussed, including overlap of variables, a lack of assessment of the quality of homework, and some missing data due to clinician error. A sufficient sample size was utilized, and results were generalizable due to the inclusion of varying cultural and educational demographic information. Consistent recommendations were yielded.

**Level II evidence.** A randomized controlled trial by Freshour and colleagues (2016) explored the long-term effects of CBT delivered by bachelor-prepared lay providers and CBT delivered by PhD expert providers on GAD severity, anxiety, quality of life, and other outcomes among older adults. The lay providers were trained and supervised by a licensed psychologist. Study participants included adults age 60 years or older who were recruited from internal
medicine, family practice, and geriatric clinics in Texas. Inclusion criteria included meeting diagnostic criteria for GAD as a principal or co-principal diagnosis. Exclusion criteria included patients with active suicide intent, current psychosis or bipolar disorder, substance abuse within the past month, or cognitive impairment. A total of 223 participants were enrolled in the study, and 112 were randomly assigned to CBT and completed post-treatment assessments. Groups included participants randomly assigned using a random number generator to CBT administered by lay providers, CBT administered by expert providers, and usual care. CBT was administered for a time period of 6 months. The first two sessions were administered in person, and subsequent sessions were administered in person or via telephone in accordance with patient preference. The first 3 months of CBT included education, awareness training, motivational interviewing, deep breathing, coping self-statements, behavioral activation, exposure, sleep management, problem solving, progressive muscle relaxation, thought stopping, and cognitive restructuring. Patients were called weekly for the following month and biweekly for the final two months of CBT to provide support and review of skills.

Outcomes were assessed using various scales (Freshour et al., 2016). Worry was measured via the Generalized Anxiety Disorder Severity Scale (GADSS), a 6-item clinician rated scale measuring DSM criteria with adequate reliability and validity among older adults. Anxiety was measured using the trait subscale of the State-Trait Anxiety Inventory (STAI-T), a 20-item self-report measure of general anxiety with a Cronbach’s alpha of 0.92, as well as the Structured Interview Guide for the Hamilton Anxiety Scale (SIGH-A), a clinician-rated scale aimed at increasing the reliability of the Hamilton Anxiety Scale. Both scales demonstrate good sensitivity when used with adults experiencing late-life anxiety. Secondary outcomes measured included depressive symptoms via the Patient Health Questionnaire-8 (PHQ-8), mental health quality of life via the Medical Outcomes Study Short Form (SF-12), and severity of insomnia via the Insomnia Severity Index (ISI). Telephone calls by independent evaluators who were unaware of the treatment assignments were used to measure outcomes 6 months and 12
months after treatment. Demographic variables, clinical characteristics, and psychototropic medication use at post-treatment was analyzed via t-tests and chi-square analyses. Growth-curve models were created to analyze the effects of time, treatment group, and the interaction among them.

Results indicated that improvements in both worry and anxiety outcomes were maintained at both six- and 12-month follow up and that scores were equivalent for both CBT administered by lay providers and CBT administered by expert providers (Freshour et al., 2016). Therefore, this study provided support for the sustainable, long-term benefit of CBT for the treatment of anxiety among older adults as well as for its administration by lay providers trained and supervised by experts. This can allow for expanded access to CBT, a reduction in barriers to proper treatment of GAD, and decreased costs of mental health services. In addition, as experts can help determine patient appropriateness for CBT and provide training and supervision of bachelor-prepared providers, the shortage of geriatric mental health experts can, in part, be overcome.

This recently published level II RCT can be described as high quality (Freshour et al., 2016). A power analysis indicated that the sample size was sufficient to detect a medium effect size for differences among the groups with 97% power. Adequate control among the groups was established. Instrument reliability and validity were discussed, and Cronbach’s alpha was greater than 0.70. Well-qualified independent evaluators were utilized to measure outcomes and were blinded to treatment assignments. They were well qualified in that they were masters-level graduate students in clinical psychology and supervised by a licensed psychologist. Results were presented clearly, and definitive conclusions were drawn from results.

**Level II evidence.** Piacentini and colleagues (2014) conducted the largest RCT to date comparing the effects of CBT, SSRIs, and their combined treatment for childhood anxiety. This study was aforementioned within the systematic review by Strawn and colleagues (2015). The purpose of this study, which is known as the Child/Adolescent Anxiety Multimodal Study
(CAMS), was to evaluate response, remission rates, and anxiety severity changes among participants within the different groups. A total of 488 children and adolescents ages 7-17 years who met DSM-IV criteria for separation anxiety disorder, GAD, and/or social phobia and lived in six different geographically diverse areas were included in the study. Comorbid mood, psychotic, or pervasive developmental disorder, one prior CBT trial failure, or two SSRI trial failures for anxiety described the exclusion criteria.

Randomization to four different groups occurred: CBT only (CBT), sertraline only (SRT), a combination of CBT and SRT (COMB), or pill placebo (PBO) (Piacentini et al., 2014). Blinding occurred within the SRT and PBO groups while the COMBO and CBT groups included masking to independent evaluator but not to patients and therapists. The CBT intervention was the “Coping Cat” program adapted for the CAMS study and included fourteen 60-minute long sessions throughout the 12 weeks of the acute phase (Phase I). Therapists were trained in the “Coping Cat” program and received supervision throughout the study. The SRT group included eight 30-minute long sessions discussing anxiety severity, treatment response, and adverse events. A maximum daily dose of sertraline and matching placebo for these participants was 200 mg, and clinical response and tolerability were considered for dosing. Pharmacotherapists were certified psychiatrists and nurse clinicians who received supervision throughout the study. Participants in the COMB groups usually received both interventions during the same day. Blinding did not occur among COMB psychiatrists in order to create a collaborate care approach, which has been linked to improved outcomes and lower required medication doses.

An initial phase of acute treatment lasted for 12 weeks and was followed by a phase of 6 months of maintenance treatment (Piacentini et al., 2014). Participants remained in their originally assigned groups for the maintenance period. CBT administered during the acute phase included new material per session, and CBT administered during the maintenance phase included monthly delivery without new material. Medication treatment during the acute phase included weekly or biweekly clinic visits with dose increases when necessary while medication
treatment during the maintenance phase included continuation of the dose established by the end of the acute phase and dose decreases due to side effects if necessary. CBT and medications were administered in ways equivalent to how they would be delivered in primary care. Two adjunctive services/attrition prevention (ASAP) sessions were allowed during each study phase. These additional sessions aimed to address emergent issues, such as significant symptom worsening or environmental stressors that endanger safety or increase the risk of study attrition. Participants who did not respond to acute phase treatment were referred to community providers, and participants who did not respond to placebo were allowed to select their choice of CAMS treatment. The study allowed participants to use off-protocol, or concomitant, interventions during the maintenance phase, but use of these interventions was closely monitored.

Demographic data, anxiety and comorbidities, and psychosocial functioning were reported by participants and their parents at baseline and weeks 4, 8, 12, 24, and 36 (Piacentini et al., 2014). Diagnostic criteria was established using the Anxiety Disorders Interview Schedule for DSM-IV-TR, Child Version. Demographic data for the sample included a mean age of 10.7 years with 74.2% 12 years of age or younger. Most participants were white, middle class with approximately half female and half male. Most had at least two primary anxiety disorders.

Response was measured by the Clinical Global Impression-Improvement Scale (CGI-I), and those who were rated 1 (“very much improved”) or 2 (“much improved”) were considered as responders (Piacentini et al., 2014). The CGI-I also helped to determine a measure of Excellent Treatment Response with a score of 1 (very much improved). Anxiety severity was measured by the Pediatric Anxiety Rating Scale (PARS), which demonstrated good to excellent internal consistency and measures six items for the assessment of anxiety severity, frequency, distress, avoidance, and interference over the previous week. Overall functional impairment was rated via the Children’s Global Assessment Scale. The Clinical Global Impressions Severity Scale (CGI-S) is a clinician rating for anxiety severity and helped determine Remission-Severity as no
or only occasional symptoms and no impairment related to symptoms. Remission-Diagnosis included the absence of GAD diagnosis. Treatment responders were further divided into categories of either Always Responders, Always Non-Responders, New Phase II Responder, Phase II Relapse, Phase II Regained, or Temporary Responders. There were some missing data as 21.8% of participants did not complete 24-week follow-up, and 21.1% did not complete 36-week follow-up.

Results found that significantly higher response rates on the CGI-I were achieved with COMB (80.7%) as compared to either CBT alone (59.7%) or SRT alone (54.9%) (Piacentini et al., 2014). All active treatments were more effective than PBO, and response rates among CBT alone and SRT alone did not differ significantly. Study attrition rates were not found to be significantly different for each treatment group at week 24 (chi-square=1.18, p=0.55) nor week 36 (chi-square=2.50, p=0.29). COMB was superior to SRT alone and CBT alone at week 12. The responded and excellent responder raters for COMB were maintained through weeks 24 and 36. However, the rates for both SRT alone and CBT alone improved so much during weeks 24 and 36 that COMB’s superiority was no longer statistically significant compared to the monotherapies at weeks 24 and 36. Most of the participants who showed response to acute treatment maintained gains at weeks 24 and 36. COMB treatment was superior over CBT and SRT on all outcomes measures (PARS, CGI-S, CGAS) at weeks 24 and 36 with moderate to large effect sizes. SRT only and CBT only participants were more likely to seek new additional psychopharmacological treatments during the maintenance phase than were COMB participants.

This study’s significant strength and value contributed positively to the EBP project. In conclusion, the efficacy and durability of the use of CBT and an SSRI were greatly supported for treatment of severe childhood anxiety disorders (Piacentini et al., 2014). Combined CBT and an SSRI was deemed as the best treatment for prompt benefit, but CBT only and an SSRI only also gave promising benefits after 6 months of treatment. Therefore, these three interventions
are all viable treatment choices, and availability, cost, burden, and family preference should also be considered among deciding factors.

This level II RCT received a high quality appraisal after review. The sample size was adequate and the largest to date of its kind (Piacentini et al., 2014). Generalizability of findings was enhanced by high subject retention, age distribution, diverse population sample, broad eligibility criteria, geographic distribution of study sites, and replication of “real world” delivery of treatment. Study limitations were addressed including concomitant treatment usage and lack of a placebo comparison group at weeks 24 and 36. Offering participants in the placebo group to select treatment if they desired supported ethical care and beneficence. Characteristics and demographics were similar among the four different groups. Instruments utilized were described in detail and were valid and reliable. The majority of participants completed the follow up questionnaires and outcomes measurements. Consistent recommendations and definitive conclusions were drawn.

**Level III evidence.** A non-randomized controlled trial published by Calleo and colleagues (2013) examined outcomes of CBT delivered by experienced and nonexperienced counselors for older adults with GAD including feasibility, satisfaction, and clinical measures. This pilot study was conducted prior to a similar study by Freshour and colleagues (2016) that was previously discussed within level II evidence. A total of 47 participants recruited from primary care clinics in the United States agreed to participate, and 19 received treatment based on eligibility. At their initial visit, participants signed an informed consent, answered questions regarding demographic information, and completed anxiety screening. Inclusion criteria, exclusion criteria, and intervention were mirrored in the RCT by Freshour and colleagues (2016). However, important differing outcomes were measured in each study, which provides a rationale for the inclusion of both pieces.

Inclusion criteria included patients who were diagnosed with a principal or coprincipal diagnosis of GAD. Exclusion criteria included patients who had mental impairment, active
suicidal intent, active substance use, psychosis, or bipolar disorder. The CBT intervention was delivered over a period of 3 months and included up to 10 skills-based sessions lasting 30-40 minutes each. The first two sessions were conducted in person with the remaining sessions conducted via telephone or in person in accordance with patient preference. CBT homework included workbook pages and practice exercises. All patients received anxiety education, awareness training, motivational interviewing, deep breathing, and coping self-statements. Additional skills that patients could select included behavioral activation, exposure, sleep management, problem solving, progressive muscle relaxation, thought stopping, and cognitive restructuring. CBT was administered by anxiety counselor specialists who had training and experience in CBT, late-life mental health, or anxiety disorders or by counselors with no previous mental health training or experience. Ten patients received CBT via an anxiety counselor specialist with training, and nine patients received CBT via a counselor without training. Ongoing communication with the primary care provider occurred.

Outcomes that were measured included feasibility, satisfaction, and worry/anxiety outcomes (Calleo et al., 2013). Feasibility of the treatment was assessed via content and patient delivery choice, attrition rates, comparison of provider/EMR and self-referral procedures, and treatment credibility-expectancy. An exit interview with a 4-point Likert scale assessed patients’ satisfaction with the treatment and included topics such as how useful the program was in helping them manage anxiety, how confident they were that they would continue to use the skills, how well their therapist understood their anxiety, and how helpful they found written materials. Positive outcomes were indicated by higher scores. The Penn State Worry Questionnaire (PSWQ) was used to assess worry. This scale consists of 16 items and has adequate psychometric properties for use among older adults. The Generalized Anxiety Disorder Severity Scale (GADSS), a six-item, clinical-rated scale with adequate internal consistency and validity, was used to assess GAD symptom severity. The Beck Anxiety Inventory (BAI), a 21-item self-report scale, measured anxiety severity. The Structured Interview
Guide for the Hamilton Anxiety Scale (SIGH-A) is a 14-item, clinician rated scale with higher reliability than the Hamilton Anxiety Rating Scale and was also used to assess anxiety severity. Outcomes were measured at baseline, 3 months after treatment initiation, and 6 months after treatment initiation.

Data were analyzed using descriptive statistics and nonparametric tests for treatment characteristics, attrition, and satisfaction (Calleo et al., 2013). Demographic information included age, education, gender, ethnicity, comorbidities, and medication use. Approximately 57.8% were Caucasian, 31.6% were African American, and 10.5% were Hispanic. Approximately 52.6% were female. In terms of feasibility, most patients perceived the treatment as highly credible after the first session (mean [SD], 7.29 [1.76]) and believed that the treatment would be successful (mean [SD], 6.79 [2.12]). A total of 75% of participants completed the exit interview. Results indicated that patients reported that the treatment did successfully help them manage anxiety (mean [SD], 3.61 [0.49]). Scores on the PSWQ and GADSS declined significantly from baseline to 3 months for those who completed treatment. The other anxiety measured did not yield statistically significant effect sizes changes. Patients who received CBT treatment by ACSs and counselors experienced no significant differences in ratings of treatment expectancy and credibility (credibility: mean, 7.39 for ACSs and 7.21 for counselors, p = 0.70; and expectancies: mean, 6.33 for ACSs and 7.13 for counselors, p = 0.41).

In conclusion, this modified CBT intervention is promising for reducing worry and sustaining outcomes in older adults with GAD (Calleo et al., 2013). Gains were maintained at 6 months. Patient preferences allowed for shared decision making and patient-centered care. Television sessions provided improved access to treatment for patients with financial, health, and geographic barriers. This study provided support that counselors with a bachelor’s degree or less who have not had extensive mental health experience are still a viable option for the administration of CBT and can provide a more cost-effective option. The feasibility,
acceptability, and effectiveness of CBT were upheld by this study and provide valuable information for culturally diverse primary care clinics across the country.

A quality rating of good was assigned to this level III non-randomized controlled trial (Calleo et al., 2013). The results are generalizable and were shown to be consistent with a larger primary care study previously conducted. However, the sample size of 19 participants was small. Further limitations of the study were also described, including lack of control. Instrument validity and reliability was discussed and was adequate for the outcomes measured. Interrater agreements between evaluators were good. Definitive conclusions were appropriately drawn from results.

**Level V evidence.** Campbell (2016) explored the best available evidence regarding pharmacotherapy for patients with GAD via an evidence summary. This is considered a level V piece of evidence due to the inclusion of one qualitative study. Among the other pieces of literature included in the summary were seven systematic reviews, one evidence-based guideline, one clinical guideline, and one prospective trial. There was strong support for the use of SSRIs as first-line treatment for GAD. Fluoxetine (SSRI) was most strongly recommended for its outcomes related to response and remission, and sertraline (SSRI) was most strongly recommended for its tolerability as compared to other medications including duloxetine (SNRI), escitalopram (SSRI), lorazepam (benzodiazepine), paroxetine (SSRI), pregabalin (anticonvulsant), tiagabine (anticonvulsant), and venlafaxine (SNRI). Duloxetine also had high rates of response, escitalopram was effective for remission, and pregabalin had high tolerability. SSRIs and SNRIs elicited comparable outcomes of improved anxiety symptoms and response rates. Benzodiazepines should not be used as first-line treatment. The evidence supported not only pharmacotherapy for the treatment of GAD, but also psychological therapy and self-care. The addition of CBT enhanced remission rates from symptoms of anxiety while omitting the need for long-term pharmacotherapy. The use of CBT received a Grade B recommendation, and the use of antidepressants (imipramine, venlafaxine, paroxetine, fluoxetine, sertraline,
duloxetine, and escitalopram), second-generation antipsychotic (quetiapine) and anticonvulsant pregabalin with individual consideration for each clinical situation received a Grade A recommendation. Thus, this evidence summary provided great detail regarding the effectiveness and tolerability of many specific medications used in the treatment of GAD and made a strong case for the inclusion of SSRIs in treatment. This provided more clarity and knowledge for the prescribing details of the intervention. Support was also expressed for the CBT portion of the intervention.

A high-quality appraisal rating utilizing the AGREE II Instrument was assigned to this level V evidence summary as the six domains received strong ratings, and the overall assessment indicated such high quality as well as a recommendation to use this guideline for research and practice (Campbell, 2016). The design, sample, and outcomes of included studies were presented briefly, but clearly. The guideline recommended that clinical situation, risks, and benefits be taken into account. Current literature yielded from a systematic search was utilized. Recommendations were clearly linked to the corresponding source of evidence. Definitive conclusions were stated and were logical based upon the outcomes of the included studies.

**Construction of Evidence-based Practice**

**Synthesis of Critically Appraised Literature**

The thorough literature review yielded overall consistent results and recommendations. As only good and high quality evidence and a majority of high level pieces were included, strong evidence was available to support best practice for GAD treatment across the lifespan. Several common themes, or subtopics, were apparent within the literature selected. These recurrent subtopics included a target population of school-age children through older adults, the use of many of the same interventions throughout the literature, including CBT and SSRIs, and outcome measurements of reduced anxiety symptoms and decreased GAD severity.

**Population.** The literature was consistent in including children aged 7 years and above, adolescents, adults, and older adults 60 years of age and older within the population sample. As
it was unable to be determined whether children ages 6 years and younger possess the cognitive maturity to participate in CBT, they were often excluded (James et al., 2015). A diagnosis of GAD according to DSM criteria was required for inclusion. Comorbidities were often allowed to enhance generalizability as most patients with GAD have comorbidities. Patients with active suicidal thoughts were frequently excluded. Patients recruited from outpatient primary care or family practice settings were included while patients in inpatient settings were excluded.

**Interventions.** Although there was some variability in the format and delivery method of CBT utilized among the evidence, there was a consensus that CBT was effective in reducing anxiety symptoms, associated with long-term maintenance of gains, and acceptable to patients (Calleo et al., 2013; James et al., 2015; Jayasekara, 2016a; Jayasekara, 2016b; Nguyen, 2017; Piacentini et al., 2014; Sawyer & Nunez, 2014; Wetherell et al., 2013). Individual CBT administered via bibliotherapy format using either guided self-help or unguided self-help methods was found to not only be beneficial for patients with GAD, but also decreased barriers associated with therapist-administered CBT, increased cost-effectiveness, and improved access to and feasibility of CBT. CBT was not found to be more effective when delivered by expert counselors (Freshour et al., 2016). Greater engagement in CBT materials was associated with better outcomes (Glenn et al., 2013).

The literature also supported use of pharmacotherapy in the form of antidepressants for treatment of GAD (Campbell, 2016; Kapczinski et al., 2003; Nguyen, 2017; Piacentini, et al., 2014; Strawn et al., 2017; Wetherell et al., 2013). SSRIs were shown to be most effective, and many pieces of evidence favored the effectiveness, tolerability, and safety of sertraline in particular for children, adolescents, and adults. There was support for the effectiveness of monotherapy CBT and monotherapy SSRI use. However, there was overwhelming support within the literature that better outcomes were achieved with combination therapy of CBT and an SSRI (Nguyen, 2017; Piacentini et al., 2014; Wetherell et al., 2013). Sequenced use of an SSRI followed by CBT was shown to be effective. However, there was greater support for
tandem CBT and SSRI use, which was linked to more prompt benefit. To support patient-centered care, patient preferences should be considered and discussed.

**Outcomes.** A significant number of both primary and secondary outcomes utilizing a multitude of measurement tools were discussed among the included evidence (Calleo et al., 2013; Campbell, 2016; James et al., 2015; Jayasekara, 2016a; Jayasekara, 2016b; Kapczinski et al., 2003; Nguyen, 2017; Piacentini et al., 2014; Sawyer & Nunez, 2014; Strawn et al., 2017; Wetherell et al., 2013). Such primary outcomes often included reduction in anxiety symptoms, improved GAD severity, response to treatment, and remission. Secondary outcomes measured often included reduction in depressive symptoms, improvement in worry severity and general mental health, relapse rates, changes in GAD status, reduced rates of anxiety diagnoses, diagnostic recovery, improvements in mental health quality of life and sleep, long-term maintenance gains in worry, acceptability of treatment, reductions in worry, and improved functioning. Many different scales were discussed to measure these outcomes, including the HAM-A, PSWQ, GAD-7, PHQ, Mental Wellness Scale, Insomnia Severity Index, Hamilton Anxiety Scale Revised, CGI-I, CGI-S, GADSS, Beck Anxiety Inventory and Structure Interview Guide for Hamilton Anxiety Scale, 12-Item Brief Symptom Inventory, Sheehan Disability Scale, PARS, Children’s Global Assessment Scale, and more. The evidence supported at least a minimum measurement of outcomes at pre-intervention and post-intervention, but monthly measurement was preferred.

High levels of evidence supported the use of the Generalized Anxiety Disorder 7-Item (GAD-7) Scale to measure anxiety symptoms (Andersen et al., 2014). The Clinical Global Impression-Improvement (CGI-I) Scale was often used within the literature to measure changes in GAD status, such as “very much improved” (James et al., 2015; Kapczinski et al., 2003). Much support was present for use of the Patient Health Questionnaire (PHQ-9) to measure depressive symptoms. Acceptability of treatment was frequency measured within the literature via the number of participants who dropped out prior to the completion of the study (James et
al., 2015). Patient satisfaction upon completion of treatment was also measured via Likert scale format (Calleo et al., 2013).

**Best Practice Model Recommendation**

The synthesis of critically appraised literature indicated that current best practice for the treatment of GAD in the target population includes combination therapy with CBT, particularly individual, self-help via bibliotherapy, and pharmacotherapy, particularly SSRI use. In accordance with best practice, bibliotherapy in the form of CBT workbooks for GAD was utilized as well as the prescribing of an SSRI, sertraline with a maximum daily dose of 200 mg, if acceptable. *The Cognitive Behavioral Workbook for Anxiety: A Step-By-Step Program* (2014) written by licensed psychologist, William J. Knaus, EdD, with over forty years of experience in the treatment of anxiety and depression was utilized for adults 18 years and older. Education was provided to patients, and close monitoring by providers occurred. Outcomes were measured at baseline and monthly and included assessment of anxiety symptoms, depressive symptoms, GAD status, acceptability, and patient satisfaction. This best practice intervention protocol described was created in a document by the project manager from the best available evidence and is presented in Appendix K.

**How the Best Practice Model will Answer the Clinical Question**

Based on this best practice recommendation, a protocol for the treatment of GAD in adults 18 years of age and older, including treatment with CBT and an SSRI was developed to answer the clinical question regarding the best treatment for decreasing symptoms of anxiety in this target population. This best practice model sought to incorporate patient preferences, effective interventions supported by quality evidence, and organized delivery of feasible and accessible treatment. The implementation phase took place over a period of 12 weeks. In accordance with the literature, participants received monthly telephone calls in order to provide them with support, discuss progress, and measure outcomes. Clear measurements were obtained prior to implementation of the intervention (baseline) and at monthly increments.
throughout the implementation phase until the completion of the intervention to assess outcomes. These measurements were interpreted to provide definitive results and conclusions.
CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

By creating and implementing an evidence-based protocol including SSRI and CBT use for the best treatment of adult patients with GAD, a worthwhile practice change was initiated. The project included the project manager’s collaboration with a family practice NP, office manager, and medical assistants (MAs) who greatly value the significance and intent of the practice change. A multitude of barriers, including the stigma associated with mental illness, lack of available and affordable CBT, and inappropriate prescribing and use of medications contribute to the hindrance of the provision of best practice recommendations in the management of GAD. This EBP project aimed to help eliminate these barriers, educate providers about best practice interventions, provide better treatment of patients with GAD, decrease patient symptoms of GAD through the implementation of best practice, and improve overall quality of life of affected patients. The purpose of this project was to improve treatment of GAD by implementing an evidence-based protocol that includes CBT and SSRI use.

Participants and Setting

Conduction of the EBP project took place in a rural family practice office that provides primary care services to patients across the lifespan. This facility is located in Northwest Indiana and was the only site of project implementation. A masters-prepared NP who owns the office in addition to two MAs provide care in this practice. The owner has 15 years of experience as an NP and extensive experience as a registered nurse. The project manager is not and has never been employed within this facility, which helped to eliminate the potential for selection bias. Written permission for the project’s implementation was granted on May 21, 2018 by the facility’s office manager who clearly stated her belief in the need for this project, its congruence with the facility’s aims and patient population, its feasibility at this primary care location, and her staff’s interest and welcoming attitude toward the project.
Participants who were eligible to participate were recruited during their appointments, either initial or follow up, at the family practice office from September 25, 2018 to December 6, 2018. The project manager and NP reviewed patient charts to determine initial eligibility based on diagnosis and age. The patient was seen by the project manager and NP, and a diagnosis of GAD based upon the DSM-5 criteria was confirmed or negated. Patients without a diagnosis of GAD were excluded from the project. In addition to a diagnosis of GAD, inclusion criteria for participation was an age of 18 years or older and the ability to speak and understand spoken and written English.

The presence of comorbid anxiety and/or mental disorders, including depression, panic disorder, social anxiety disorder, active substance abuse or dependence, current participation in CBT outside of the project and/or sessions with a licensed therapist, and the use of other classes of medications for the treatment of GAD were also allowed, but disclosed. This decision was made on the premise of many factors. Many patients with GAD have comorbid diagnoses. There is also a higher likelihood that patients with GAD have substance abuse and dependence problems. Thus, excluding these patients would limit the sample size, hinder generalizability, and limit important data that could be gathered among this population. Treatment with SSRI medication prior to the start of project implementation was also allowed as many patients are treated with SSRIs for GAD in the clinical setting and as this would still allow for the implementation of both SSRIs and CBT.

It has become apparent through experience with patients with GAD that despite seeing therapists and taking medications for anxiety for significant periods of time, symptoms of anxiety may still persist, and further treatment is necessary. Thus, it is believed that this project had the potential to benefit these patients by providing them with the additional treatment they needed. It is illogical, unethical, and unsafe to expect patients, such as those taking benzodiazepines, SNRIs, and other medications for anxiety, to cease current anxiety medications and change to
only SSRIs immediately. These patients may benefit from the addition of CBT and SSRI use, and their exclusion from participation could have significantly limited the sample size.

Additional exclusion criteria included patients with current suicide intent, psychosis, cognitive impairment, inability to understand and speak English, and current pregnancy. Such participants were excluded for safety reasons, time constraints, as well as lack of ability to properly participate in the activities of the project. Patients eligible for participation were provided a handout explaining the project. This explanation of project document for patients is presented in Appendix C. After reviewing the information and having any questions answered, patients decided whether or not they wanted to participate in the project. Upon deciding to participate in the project, patients were asked to read and sign the informed consent document, which is displayed in Appendix D. After providing their written informed consent, participants of the project were asked to complete a demographic questionnaire, which is available in Appendix E.

**Outcomes**

Multiple outcomes were selected for measurement in accordance with the literature. The primary outcome measured was a reduction in anxiety symptoms via the GAD-7 scale. Secondary outcomes measured included changes in GAD status as measured by the Clinical Global Impression-Improvement (CGI-I) Scale, a reduction in depressive symptoms as measured by the Patient Health Questionnaire (PHQ-9), patient satisfaction via the Patient Satisfaction Questionnaire (PSQ), and acceptability of treatment measured by attrition rates, including the number of participants who dropped out prior to completion of the entire implementation phase and outcomes measurement. The GAD-7 and PHQ-9 Scales were participant-reported scales that were completed via written documentation during each participant’s initial appointment prior to the implementation of the intervention, and once every month (every four weeks) during the three-month implementation period of the intervention via telephone calls with the project manager. During such telephone follow up sessions every four
weeks, the project manager recorded participant-reported answers for the GAD-7 and PHQ-9. The CGI-I Scale was completed by the project manager monthly after the initiation of treatment and was not applicable at baseline. The PSQ and attrition rates were measured upon completion of the three-month implementation period. The project manager recorded participant-reported answers for the PSQ during the final telephone follow up session and calculated the attrition rate as a percentage of the total participant population. The pre-intervention scores and post-intervention scores were compared to determine whether the intervention had an effect on GAD symptoms, GAD status of illness, and depressive symptoms. Scores throughout the implementation phase were also compared to determine the progression of the effect, including the amount of time necessary for noticeable change to begin.

**Intervention**

The intervention consisted of the development of a protocol based on best practice recommendations from good and high quality pieces of evidence. The intervention protocol included combination CBT bibliotherapy and an SSRI. The literature provided the most support for the effectiveness of combination therapy, but also provided support for the effectiveness of CBT monotherapy and SSRI monotherapy. Providers should also consider shared decision making and patient safety. Because combination therapy was most effective and considered best practice, it was implemented for this project.

Each participant who consented to participate in the project received combination SSRI and CBT use. They were provided with self-help CBT bibliotherapy in the form of an age-appropriate CBT workbook for GAD at their initial appointment. The appropriate workbook administered to adults 18 years of age and older throughout this project was *The Cognitive Behavioral Workbook for Anxiety: A Step-By-Step Program* (2014) by licensed psychologist, William J. Knaus. Participants were provided with written information from the project manager describing CBT as well as its purpose, including restructuring of thoughts to allow for a more positive mindset to cope with anxiety. Participants were also provided with further instructions
regarding assigned workbook chapters and completion due dates. *The Cognitive Behavioral Workbook for Anxiety: A Step-By-Step Program* for adults is divided into four parts. Therefore, based on the 12-week period of the intervention, participants were instructed to complete Part I by week 3 of the implementation phase, Part II by week 6, Part II by week 9, and Part IV by week 12. To clarify via example, week 3 of the implementation phase is approximately 3 weeks after the initiation of the intervention for the participant. Participants had different initiation dates based on varying appointment dates throughout the implementation phase. In addition to CBT, participants were prescribed an SSRI at their initial appointment. They were then required to go to their selected pharmacy to pick up their prescription. They were educated about potential side effects and adverse effects as well as when and how to take their medication including dosage and frequency. They were advised to take their medication as directed and to not stop taking it abruptly. Education was provided to patients verbally as well as via a written document created by the project manager. This education document is presented in Appendix K.

The participants were informed that follow up would occur every four weeks by telephone sessions with the project manager. Initially, follow up was planned via either in person sessions or telephone sessions based on patient preference. However, this was not feasible within the family practice office due to time and billing constraints per the NP. If patients had appointments at the office during such designated follow up times, follow up could be obtained at those appointments rather than by phone call. Patients’ follow up telephone sessions and workbook homework completion schedule were included along with their education documents. Follow up telephone sessions included completion of the GAD-7, PHQ-9, CGI-I, and PSQ when appropriate. The project manager answered any questions that the participants had and provided support and encouragement to the participants, but the main purpose of the follow up telephone sessions was outcomes measurement. Additional topics covered included discussion of patient thoughts, symptoms, functional impairment, and progress as well as inquiry of side effects of SSRI medication and CBT, and assessment of workbook completion. The participants
were scheduled for in-person follow up visits with the NP per clinic policy. For example, if SSRIs were initiated for the first time at the start of project implementation, follow up visits with the NP occurred after six weeks. If patients had been already been taking SSRIs at the start of project implementation, follow up visits with the NPs occurred after 3 months.

Planning

A significant amount of time and effort was devoted to the planning phase of this EBP project to ensure its completeness, strong grounding in evidence, and likelihood of successful implementation. A need for practice change and best practice recommendations were determined based on clinical practice experience and a thorough literature search of current evidence. The project manager met and engaged with key stakeholders, including the family practice NP, office manager, and MAs, and an overview of the intended project was discussed. During this time, best practice information was shared with key stakeholders, and they reviewed the protocol and provided their input for suggestions and changes. Support for the project and permission to implement the project at the family practice clinic was granted by key stakeholders in May 2018 at the beginning of project development. Project planning continued with input from the project manager, key stakeholders, project advisor, program professors, further research, available interventions, and additional worthwhile sources.

Data

Measures. The primary outcome measured was anxiety symptoms via the GAD-7 Scale, a 7-item self-report scale used to measure anxiety symptom severity in the primary care setting (Beard & Bjorgvinsson, 2014; VISN 4 Mental Illness Research, Education and Clinical Center, 2017). This scale involves use of DSM-5 criteria and is an effective tool for assessing GAD cases. It helps to provide important information regarding the patient's overall clinical condition, guide treatment planning, track treatment progress or lack thereof, improve communication between providers, and provide continuity among various patient care services. It may be completed in the office by the patient or via the telephone using an interviewer to
record patient responses. It can be administered via paper and pencil or electronic devices. It is quick to administer, often taking 2-5 minutes to complete. Questions within the GAD-7 ask patients to rate the frequency of their anxiety symptoms that they have experienced within the last 2 weeks via a Likert scale from 0-3 for each of the seven items with 0 indicating not at all, 1 indicating several days, 2 indicating more than half the days, and 3 indicating nearly every day. Total scores indicate anxiety severity and range from 0-21 with 1-4 indicating minimal symptoms, 5-9 indicating mild symptoms, 10-14 indicating moderate symptoms, and 15-21 indicating severe symptoms. Thus, greater levels of symptoms are indicated by greater scores.

The GAD-7 is available in Appendix G. The GAD-7 is considered a valid and reliable tool, and these findings have been supported by numerous studies (Spitzer, Kroenke, Williams, & Lowe, 2006). There is evidence to support its good sensitivity (89%) and specificity (82%) in primary care settings for the assessment of GAD (Williams, 2014). It is also found to have greater sensitivity for identifying changes in symptom severity as compared to other anxiety scales, such as the Penn State Worry Questionnaire for Measuring Response. It has excellent internal consistency with a Cronbach’s alpha of 0.92 and good test-retest reliability with an intraclass correlation of 0.83 (Spitzer et al., 2006). GAD-7 self-reported scores correlate well with clinician-reported scores, indicating good procedural validity, and with similar anxiety scales, indicating good convergent validity. Good construct validity is evident as higher scores are associated with higher levels of functional impairment. Patients with a diagnosis of GAD typically have higher GAD-7 scores as compared to those without a diagnosis of GAD, also demonstrating good construct validity (Kertz, Bigda-Peyton, & Bjorgvinsson, 2013). The GAD-7 can also be described as having good criterion and factorial validity. It is generalizable across the general population with no variation among gender or age (Lippincott William & Wilkins, 2008). Thus, the GAD-7 is useful among both men and women as well as younger and older individuals.
A secondary outcome of depressive symptoms was measured via the PHQ-9, a self-report tool used for diagnosing depressive disorder as well as determining depressive symptom severity (Kroenke, Spitzer, & Williams, 2001). There are many variations of the PHQ, but the PHQ-9 was selected as most appropriate for this project. The PHQ-9 can be administered quickly, making it desirable in busy clinical practice settings. It consists of nine items that address DSM-IV criteria for depressive disorder. Items within the PHQ-9 ask patients to rate the frequency of their depressive symptoms within the last two weeks via a Likert scale from 0-3 for each of the nine items with 0 indicating not at all, 1 indicating several days, 2 indicating more than half the days, and 3 indicating nearly every day. Total PHQ-9 scores range from 0-27 with scores of 0-4 indicating minimal symptoms, 5-9 indicating mild symptoms, 10-14 indicating moderate symptoms, 15-19 indicating moderately severe symptoms, and 20-27 indicating severe symptoms. Higher levels of symptoms are indicated by higher scores. The PHQ-9 is presented in Appendix H.

Like the GAD-7, the PHQ-9 is also a valid and reliable tool (Kroenke et al., 2001). It has a high sensitivity as well as a high specificity of 88% for the assessment of major depression. A study implemented in the primary care setting supported that the PHQ-9 has excellent internal reliability with a Cronbach’s alpha of 0.89 and an excellent test-retest reliability. External validity is also high as findings from this study were able to be replicated among an obstetrics-gynecology patient population. This also supports the generalizability of the PHQ-9 across various outpatient settings. The PHQ-9 highly correlates with other tools used to measure depression symptoms. High PHQ-9 scores correlate with worsening functioning among similar scales, demonstrating high construct validity. The PHQ-9 also has high criterion validity and high positive predictive value.

The CGI-I scale was utilized to measure another secondary outcome of changes in GAD status. The CGI is composed of two scales including the CGI-S, which measures changes in symptom severity, and the CGI-I, which measures improvement or worsening of the disorder as
aforementioned (Busner & Targum, 2007). Only the CGI-I was used for this project as the patient reported GAD-7 scores were used to measure symptom severity, and a concise number of measurements was desired for the project. The CGI-I describes a patient’s change in disorder status as a result of treatment. It represents the provider’s view of the patient’s disorder as responses are provided by the provider based on knowledge of the patient’s history, symptoms, behavior, and functional impact of the disorder. It also provides an overall clinical interpretation beyond symptomology and displays trends in clinical progress and responses. The CGI-I helps to identify interventions that have provided benefit to the patient’s condition as well as identify those that have provided no benefit. The CGI-I can be easily and quickly administered, often taking approximately 1 minute to complete. It consists of a seven-point scale ranging from 1) very much improved since the initiation of treatment to 7) very much worse since the initiation of treatment. Proper use of the CGI-I includes a comparison of the patient’s current clinical presentation to the patient’s clinical presentation at the baseline visit, or the one week period prior to initiation of treatment. Thus, changes are not compared from week to week, but rather always compared to baseline. Important considerations for rating include present symptoms, frequency of occurrence over the past 7 days, severity of symptoms, and functional impact of the symptoms on the patient’s life. Information gathered to determine a CGI-I rating may come from interviews with the patient, chart notes, family members, nurses, school teachers, caseworkers, significant others, or additional sources. The rating is overall given based on clinical judgement. Side effects of treatment should not be included in the rating. The CGI-I is depicted in Appendix I.

The CGI-I is considered a well-established tool for assessing psychiatric disorders, including anxiety and depression (Busner & Targum, 2007). The CGI-I is often used in FDA-regulated and other trials, and its reliability and validity for measuring changes in GAD status based on treatment response are well-supported (Busner & Targum, 2007; James et al., 2015; Kapczinski et al., 2003). It correlates well with similar yet more complex tools, including the
Health of the Nation Outcomes Scales, another clinician-rated scale (Berk, Ng, Dodd, Callaly, Campbell, Bernardo, Trauer, 2008; Busner & Targum, 2007). There is also a high correlation among CGI-S scores and CGI-I scores (Berk et al., 2008). Evidence has supported that the CGI-I is sensitive to change, valid among diverse groups, and reliable when administered appropriately by clinicians.

Patient satisfaction of the self-administered CBT utilized within this project was measured via the Patient Satisfaction Questionnaire (PSQ), a six-item questionnaire developed by the project manager. It addresses important aspects of patient satisfaction including convenience, ease of use, efficacy, overall satisfaction, worthiness, and engagement. As this is a newly developed tool, there is no information regarding its validity and reliability. The PSQ is available in Appendix J.

Acceptability of treatment was measured via the number of participants who dropped out of the project prior to completion or who did not complete outcome measurements, also known as the attrition rate. This was calculated as a total percentage of participants.

**Collection.** Data collection took place both in the clinical setting and via telephone by the project manager from September 25, 2018 to February 28, 2018. It commenced at the initial patient appointment when the patient signed consent and received interventions of combined CBT and SSRI therapy. Data collection included paper copies of instruments utilized for outcomes measurement, including the GAD-7, PHQ-9, CGI-I, and PSQ. During telephone follow up to assess outcomes, patient responses were recorded via paper copies of the scales by the project manager. Data collection was completed at the final follow up after the patient received the intervention for a duration of 12 weeks, or 3 months. As continuous recruitment took place, this completion date varied among participants, but was consistently 12 weeks after treatment commencement for each individual.

Patient confidentiality was protected by coding. Each participant was assigned a code number at random determined by drawing a number from a bag. The code was recorded on all
participant data collected in a designated area of the top right corner of each document including the demographic form, GAD-7, PHQ-9, CGI-I, and PSQ. The code number served as the method by which to identify the patient and was used to compare pre-intervention and post-intervention data. A list of patient names with corresponding codes was kept in a locked box with access to the project manager only. An example of this code sheet is available in Appendix F. The project manager placed data collected in the clinical setting, including patient GAD-7, PHQ-9, and PSQ scales and provider CGI-I scales, with code numbers into a folder clearly marked with the project title located in an authorized personnel only area. The multiple documents for each patient were paper clipped together for organizational purposes and to ensure that each patient’s data gathered remained together. Telephone calls to patients were made by the project manager in the safety of the project manager’s home when no one else was home or in a private room with the door closed to ensure patient confidentiality. Data collected during this time was stored in a folder clearly marked with the project title located in a private and safe area of the project manager’s home with access only to the project manager.

**Management and analysis.** The project manager accessed the designated folder in order to perform data analysis. Patient data with code numbers only was taken from the folder at the office to the project manager’s home while the code list remained safely stored in the locked box aforementioned. Patient names and other identifying information were never disclosed, and only code numbers were referenced in discussions regarding the project. Following completion of the project, including data analysis, the coding list was destroyed. Pre-intervention and post-intervention data were analyzed via a paired t-test. Demographic data were also analyzed via Chi-square. Software utilized to run data analysis was IBM SPSS Statistics Base 24.

**Protection of Human Subjects**

Protection of human subjects was upheld throughout the project. The project manager was properly educated about protection of human subjects and completed an ethics course
within the DNP curriculum during the fall semester of 2017 as well as an online training course through the National Institutes of Health (NIH) titled “Protecting Human Research Participants” in April 2018. A certificate of completion of the NIH course is available in Appendix A. The project manager applied for approval from Valparaiso University’s Institutional Review Board (IRB) by mailing in a detailed application explaining the project on August 12, 2018. Suggestions for revisions to the project were provided by the IRB, and such revisions within the project were made and made known to the IRB. Approval for the project was obtained by Valparaiso University’s IRB on September 21, 2018. Consent from adult participants was obtained. A thorough explanation of the project, including risks, benefits, and time commitment, was provided to potential participants prior to obtaining consent. Questions from potential participants were thoroughly answered. Potential participants were also informed that patient confidentiality would be upheld, participation is voluntary, and participants who do not want to participate will still receive the standard of care. Patients were not coerced, nor pressured into participating. Participants that consented were informed that they could withdraw from the project at any time without retribution. Data were kept in a secure and private location, and the coding list with patient names was destroyed by shredding upon project completion.
CHAPTER 4

FINDINGS

The purpose of this EBP project was to implement an evidence-based protocol involving combination therapy with CBT and SSRI medication in order to improve patient outcomes through more accessible, standardized treatment of GAD. Patient outcomes, including anxiety and depression symptoms, were measured via the GAD-7 Scale and PHQ-9 respectively in order to compare baseline scores to follow up scores over a period of 12 weeks. Additional outcomes, including change in GAD status, patient acceptability, and patient satisfaction were also measured. Both participant demographic characteristics and outcomes were analyzed.

Participants

Size. Upon commencement of project implementation, 20 eligible participants consented to participate, completed the demographic form, and completed self-report baseline measures of the GAD-7 Scale and PHQ-9. SSRI medication was either initiated or continued at this time, and self-administered CBT was initiated in accordance with the developed protocol. Participants agreed to independently administer their SSRI medication as directed and complete the CBT workbook independently as instructed. In total, 12 participants completed follow up at week 4 as well as at week 8 for an attrition rate of 40% at each of these times of measurement. A total number of 10 participants completed the final follow up at week 12 yielding a final attrition rate of 50%.

Characteristics. Demographic characteristics for participants \((n=10)\) were analyzed using descriptive statistics. Pre-intervention demographic data for the initial 20 participants that enrolled in the project and completed baseline data were collected. As outcomes were analyzed for only the 10 participants who completed the project in full, including baseline, week 4, week 8, and week 12 data, demographic data for only the remaining 10 participants were analyzed for consistency. Analysis of the characteristic of age was reported via the mean and range while
the remaining demographic characteristics were reported via frequencies. Participant ages ranged from 18 to 75 years with a mean age of 49.60 years ($SD = 17.86$). The majority of participants were female (70%) (Figure 4.1), Caucasian (100%) (Figure 4.2), and married (60%) (Figure 4.3). The majority also had private insurance (70%) (Figure 4.4), held a high school diploma or GED as their highest level of education (60%) (Figure 4.5), were employed full time (30%) (Figure 4.6), made an annual household income of over $100,000 (30%) (Figure 4.7). Descriptive statistics regarding demographic data are presented in Table 4.1.

**Intervention Information.** As aforementioned, the intervention protocol consisted of combination therapy of an SSRI antidepressant medication with self-administered CBT in the form of a workbook. Sertraline was recommended in accordance with the literature based on its safety and tolerability, but the prescribing of any SSRI was acceptable within this project. Of the 10 participants who completed all follow ups throughout the 12 weeks of project implementation, 60% were prescribed sertraline, 20% were prescribed escitalopram, 10% were prescribed fluoxetine, and 10% were prescribed paroxetine. All participants (100%) within the remaining sample of 10 participants had already been taking an SSRI prior to baseline assessment. A total of 95% of the original sample of 20 participants had been taking an SSRI prior to baseline assessment while 5% of original sample started taking an SSRI immediately after baseline assessment. Thus, CBT was added immediately after the baseline assessment in order to fulfill the protocol of combination therapy. As it would have been unethical and unsafe to discontinue as needed benzodiazepines immediately at the baseline appointment, participants who were taking or began taking an SSRI medication were eligible even if they also had been prescribed an as needed benzodiazepine. A total of 10% of the remaining 10 participants at week 12 had been taking an as needed benzodiazepine.
Table 4.1

*Demographic Characteristics*

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Mean/SD</td>
<td>49.60/17.86</td>
</tr>
<tr>
<td>Range</td>
<td>18 - 75</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Female</td>
<td>7 (70)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>10 (100)</td>
</tr>
<tr>
<td>Native American</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Married</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Divorced</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Widowed</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Health insurance</td>
<td></td>
</tr>
<tr>
<td>No insurance</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Medicare</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Private</td>
<td>7 (70)</td>
</tr>
</tbody>
</table>
### Highest level of education

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High school/GED</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Some college</td>
<td>2 (20)</td>
</tr>
<tr>
<td>2-year degree</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4-year degree</td>
<td>2 (20)</td>
</tr>
</tbody>
</table>

### Employment status

<table>
<thead>
<tr>
<th>Employment Status</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full time</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Part time</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Student</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Retired</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Homemaker</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Unable to work</td>
<td>2 (20)</td>
</tr>
</tbody>
</table>

### Annual household income

<table>
<thead>
<tr>
<th>Income Range</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $20,000</td>
<td>2 (20)</td>
</tr>
<tr>
<td>$20,000 - $34,999</td>
<td>1 (10)</td>
</tr>
<tr>
<td>$35,000 - $49,999</td>
<td>2 (20)</td>
</tr>
<tr>
<td>$50,000 - $74,999</td>
<td>0 (0)</td>
</tr>
<tr>
<td>$75,000 - $99,999</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Over $100,000</td>
<td>3 (30)</td>
</tr>
</tbody>
</table>

GED = General Education Diploma; SD = Standard Deviation
Figure 4.1. Gender Pie Chart

Figure 4.2. Race Pie Chart
Figure 4.3. Marital Status Pie Chart

Figure 4.4. Health Insurance Pie Chart
Figure 4.5. Highest Level of Education Pie Chart

Figure 4.6. Employment Status Pie Chart
Figure 4.7. Annual Household Income Pie Chart
Changes in Outcomes

This EBP project addressed the following PICOT question, “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 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)?” The primary outcome of anxiety symptoms was measured using the GAD-7 Scale at baseline, 4-weeks, 8-weeks, and 12-weeks post-intervention. Secondary outcomes, including depression symptoms via the PHQ-9, change in GAD status via the CGI-I, and patient satisfaction were also measured.

**Statistical testing.** Data were entered into the Statistical Package for Social Sciences (SPSS) Version 25 for analysis. The text titled *How to use SPSS: A step-by-step guide to analysis and interpretation* by Cronk (2017) was utilized to guide the process of analysis and interpretation. A repeated measures ANOVA was used for comparison of anxiety symptoms and depression symptoms at four different times, including baseline, 4-weeks post-intervention, which is also referred to as week 4, 8-weeks post-intervention, which is also referred to as week 8, and 12-weeks post intervention, which is also referred to as week 12. A repeated measures ANOVA was also used to analyze changes in GAD status, which was measured at three different times, including week 4, week 8, and week 12. Statistical significance for all analyses was determined as $p < 0.05$. Patient satisfaction data were measured via the PSQ at 12-weeks post-intervention only and analyzed via descriptive statistics. Patient acceptability data were measured via attrition rate and also analyzed via descriptive statistics.

**Anxiety symptoms.** Anxiety symptoms were scored using the GAD-7, which asked participants to rate 7 items, or anxiety-related problems, on a Likert scale indicating their frequency within the last 2 weeks of 0 (not at all), 1 (several days), 2 (more than half the days),
or 3 (nearly every day). These items were tallied into a total score ranging from 0 to 21 with higher scores consistent with higher levels of anxiety severity. Scores 0-4 indicate minimal symptoms, scores 5-9 indicate mild symptoms, scores 10-14 indicate moderate symptoms, and scores 15-21 indicate severe symptoms. A one-way repeated-measures ANOVA was calculated comparing the exam scores of participants at four different times: baseline, week 4, week 8, and week 12. No significant effect was found (F(3,27) = 1.94, \( p > 0.05 \)). No significant difference exists among baseline (\( M = 4.20, SD = 4.32 \)), week 4 (\( M = 3.40, SD = 2.72 \)), week 8 (\( M = 2.40, SD = 3.13 \)), and week 12 (\( M = 1.60, SD = 2.12 \)) means. Repeated measures ANOVA data with means and standard deviations for anxiety symptoms are presented in Table 4.2. A visual representation of the decreasing trend in mean GAD-7 scores over 12 weeks indicating improvement in anxiety symptom severity is depicted in a line graph in Figure 4.8.

In addition to the one-way repeated-measures ANOVAs that were calculated for total GAD-7 scores, one-way repeated-measures ANOVAs were also calculated for each individual item within the GAD-7 Scale. No significant difference was found among any of the individual items, including Question 1 (F(3,27) = 0.669, \( p > 0.05 \)), Question 2 (F(3,27) = 0.588, \( p > 0.05 \)), Question 3 (F(3,27) = 0.355, \( p > 0.05 \)), Question 4 (F(3,27) = 1.736, \( p > 0.05 \)), Question 5 (F(3,27) = 1.919, \( p > 0.05 \)), Question 6 (F(3,27) = 2.197, \( p > 0.05 \)), Question 7 (F(3,27) = 1.090, \( p > 0.05 \)), or Question 8 (F(3,27) = 1.636, \( p > 0.05 \)).

**Depression symptoms.** Similar to anxiety symptoms, depression symptoms were scored using the PHQ-9, which asked participants to rate 9 items, or depression-related problems, on a Likert scale indicating their frequency within the last 2 weeks of 0 (not at all), 1 (several days), 2 (more than half the days), or 3 (nearly every day). These items were tallied into a total score ranging from 0 to 27 with higher scores consistent with higher levels of depression severity. Scores 0-4 indicate minimal symptoms, scores 5-9 indicate mild symptoms, scores 10-14 indicate moderate symptoms, scores 15-19 indicate moderately severe symptoms, and scores 20-27 indicate severe symptoms. A one-way repeated measures ANOVA was
calculated comparing the PHQ-9 scores of participants at four different times: baseline, 4-weeks post-intervention, 8-weeks post-intervention, and 12-weeks post-intervention. A significant effect was found (F(3,27) = 4.34, p < 0.05). Repeated measures ANOVA data with means and standard deviations for depression symptoms are presented in Table 4.2. Follow-up protected t tests revealed scores decreased significantly from baseline (M = 4.80, SD = 3.58) to week 8 (M = 2.90, SD = 2.02), baseline to week 12 (M = 1.90, SD = 2.81), week 4 (M = 3.90, SD = 2.77) to week 8, and week 4 to week 12. Such post hoc paired t test data for depression symptoms are displayed in Table 4.3. No significant difference exists among baseline and week 4 means or week 8 and week 12 means. A visual representation of the decreasing trend in mean PHQ-9 scores over 12 weeks indicating improvement in depression symptom severity is depicted in a line graph in Figure 4.8.

In addition to the one-way repeated-measures ANOVAs that were calculated for total PHQ-9 scores, one-way repeated-measures ANOVAs were also calculated for each individual item within the PHQ-9. No significant difference was found among any of the individual items, including Question 1 (F(3,27) = 1.615, p > 0.05), Question 2 (F(3,27) = 0.915, p > 0.05), Question 3 (F(3,27) = 1.761, p > 0.05), Question 4 (F(3,27) = 2.374, p > 0.05), Question 5 (F(3,27) = 2.656, p > 0.05), Question 6 (F(3,27) = 0.310, p > 0.05), Question 7 (F(3,27) = 2.769, p > 0.05), Question 8 (F(3,27) = 1.976, p > 0.05), Question 9 (F(3,27) = no change), or Question 10 (F(3,27) = 0.783, p > 0.05).

Change in GAD status. Change in GAD status from baseline was determined using the CGI-I scale and scored by the project manager as 1 (very much improved), 2 (much improved), 3 (minimally improved), 4 (no change), 5 (minimally worse), 6 (much worse), or 7 (very much worse). A one-way repeated measures ANOVA was calculated comparing CGI-I scores of participants at three different times: week 4, week 8, and week 12. No significant effect was found (F(2, 18) = 3.05, p > 0.05). No significant different exists among week 4 (M = 3.60, SD = 1.07), week 8 (M = 2.80, SD = 1.40), and week 12 (M = 2.30, SD = 1.57) means. Repeated
measures ANOVA data with means and standard deviations for change in GAD status are presented in Table 4.2.
Table 4.2

Repeated Measures ANOVAs with Means and Standard Deviations (n = 10)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>F</th>
<th>p</th>
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<tbody>
<tr>
<td>Anxiety symptoms</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Baseline</td>
<td>4.20</td>
<td>4.32</td>
<td>1.94</td>
<td>0.146</td>
</tr>
<tr>
<td>Week 4</td>
<td>3.40</td>
<td>2.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 8</td>
<td>2.40</td>
<td>3.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>1.60</td>
<td>2.12</td>
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</tr>
<tr>
<td>Depression symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.80</td>
<td>3.58</td>
<td>4.34</td>
<td>0.013*</td>
</tr>
<tr>
<td>Week 4</td>
<td>3.90</td>
<td>2.77</td>
<td></td>
<td></td>
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<tr>
<td>Week 8</td>
<td>2.90</td>
<td>2.02</td>
<td></td>
<td></td>
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<tr>
<td>Week 12</td>
<td>1.90</td>
<td>2.81</td>
<td></td>
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<tr>
<td>Change in GAD status</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>3.60</td>
<td>1.07</td>
<td>3.05</td>
<td>0.072</td>
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<tr>
<td>Week 8</td>
<td>2.80</td>
<td>1.40</td>
<td></td>
<td></td>
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<tr>
<td>Week 12</td>
<td>2.30</td>
<td>1.57</td>
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</tbody>
</table>

* = Denotes statistical significance
### Table 4.3

**PHQ-9 Post Hoc Paired t Tests (n = 10)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
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<tr>
<td><strong>Difference</strong></td>
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<tr>
<td><strong>Depression symptoms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline – Week 4</td>
<td>1.33</td>
<td>3.80</td>
<td>1.22</td>
<td>11</td>
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<td>Baseline – Week 8</td>
<td>1.83</td>
<td>2.79</td>
<td>2.28</td>
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<tr>
<td>Baseline – Week 12</td>
<td>2.90</td>
<td>3.93</td>
<td>2.33</td>
<td>9</td>
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</tr>
<tr>
<td>Week 4 – Week 8</td>
<td>1.27</td>
<td>1.56</td>
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<td>10</td>
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<td>Week 4 – Week 12</td>
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<td>2.05</td>
<td>3.08</td>
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<td>Week 8 – Week 12</td>
<td>1.00</td>
<td>1.70</td>
<td>1.86</td>
<td>9</td>
<td>0.096</td>
</tr>
</tbody>
</table>

* = Denotes statistical significance
Figure 4.8. Improvement in Mean Anxiety (GAD-7) and Depression (PHQ-9) Symptom Severity with Combination Therapy ($n = 10$)
Acceptability. Patient acceptability of the combined SSRI and CBT protocol was measured via the attrition rate from pre- to post-intervention, or baseline to week 12. As aforementioned, 20 participants (N = 20) consented to project enrollment and completed baseline measurements. At week 4, the participant response rate was 60% (n = 12) with an attrition rate of 40%. At week 8, the participant response rate and attrition rate did not change from the aforementioned values of week 4. At week 12, the participant response rate decreased to 50% (n = 10) while the attrition rate rose to 50%.

Patient satisfaction. Patient satisfaction scores were measured at week 12 using the PSQ and analyzed using descriptive statistics, including frequency, mean, and range. One participant declined to complete the PSQ, and thus, nine remaining participants completed the PSQ in total. The majority of participants rated use of the CBT workbook as very convenient (33.3%) (Figure 4.9), easy (44.4%) (Figure 4.10), and very worthwhile (55.6%) (Figure 4.11). The majority also reported their satisfaction with the CBT workbook’s impact on their anxiety symptoms as a tie between satisfied (44.4%) and very satisfied (44.4%) (Figure 4.12) with an overall satisfaction level with the CBT workbook of satisfied (44.4%) (Figure 4.13). Time spent using the CBT workbook per week ranged from 15 minutes to 30 hours as reported by participants. The mean amount of time spent using the CBT workbook per week was 301.11 minutes, or approximately 5 hours, with a standard deviation of 576.21 minutes, or approximately 9.5 hours.
Figure 4.9. Patient Satisfaction Questionnaire Convenience Pie Chart

Figure 4.10. Patient Satisfaction Questionnaire Ease of Use Pie Chart
Figure 4.11. Patient Satisfaction Questionnaire Worthwhile Pie Chart

Figure 4.12. Patient Satisfaction Questionnaire Satisfaction with Impact on Anxiety Symptoms Pie Chart
Figure 4.13. Patient Satisfaction Questionnaire Satisfaction Overall
**Significance.** To summarize, no statistical significance was achieved for evaluation the primary outcome of anxiety symptoms via the GAD-7 Scale \((F(3,27) = 1.94, p > 0.05)\) nor for evaluation of the secondary outcome of change in GAD status via the CGI-I Scale \((F(2, 18) = 3.05, p > 0.05)\). Statistical significance was achieved for evaluation of the secondary outcome of depression symptoms via the PHQ-9 \((F(3,27) = 4.34, p < 0.05)\).

**Reliability and validity.** The reliability and validity of each tool utilized to evaluate outcomes was assessed. The GAD-7 was utilized to evaluate anxiety symptoms. There is much evidence to support the GAD-7’s high reliability and validity (Spitzer et al., 2006). With a high Cronbach’s alpha of 0.92, the GAD-7 demonstrates excellent internal consistency. It is also noted to have good sensitivity (89%) and specificity (82%), good construct and convergent validity, and good criterion and factorial validity (Kertz et al., 2013; Spitzer et al, 2006; Williams, 2014). A Cronbach’s alpha regarding the GAD-7 Scale relative to this project specifically was calculated using SPSS software and found to be 0.87. This is similar to that reported within the literature, and thus, high reliability of the GAD-7 was demonstrated within this project.

Similarly, the PHQ-9, used to evaluate anxiety symptoms, also demonstrates high reliability and validity within the literature (Kroenke et al., 2001). It’s excellent internal reliability is supported with a Cronbach’s alpha of 0.89 reported within the literature. The PHQ-9 also has excellent test-retest reliability, high sensitivity and specificity, and high construct, criterion, and external validity. Specifically regarding use of the PHQ-9 within this project, a Cronbach’s alpha was calculated as 0.90. Thus, again, excellent internal consistency and reliability is supported.

The CGI-I, which was utilized to evaluate GAD status, also boasts high reliability and validity supported by evidence (Busner & Targum, 2007). It correlates well with other tools and has high sensitivity (Berk et al., 2008). It has high validity and is able to be used among diverse groups. It has specific instructions to promote its appropriate use and high reliability.

The PSQ was developed by the patient manager to evaluate patient satisfaction with self-administered CBT. Thus, validity cannot be established for the PSQ as it has not been
reviewed by experts. Reliability tests were performed within SPSS in order to determine the PSQ’s reliability. A Cronbach’s alpha was calculated as 0.84. Thus, this supports good internal consistency and high reliability of the PSQ.
CHAPTER 5

DISCUSSION

This EBP project served the purpose of answering the following PICOT question, “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 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)?” The project examined the impact of the combination therapy protocol involving simultaneous self-administered CBT and SSRI antidepressant medication use on decreasing anxiety and depression symptoms, improving GAD status, and demonstrating patient acceptability and satisfaction among adults presenting to the family practice setting with a diagnosis of GAD. This chapter will detail an explanation and interpretation of project findings as well as an evaluation of the applicability of the theoretical framework and EBP model used to guide the project. Project strengths and limitations will be explored as will consideration of implications for future practice, theory, research, and education.

Explanation of Findings

Project findings support the effectiveness of combination therapy regarding CBT and SSRIs for the treatment of GAD among adults. Such results were consistent with current literature overall. Participant findings, including sample size, demographic characteristics, and intervention information, will be discussed. Outcomes, including anxiety symptoms, depression symptoms, change in GAD status, acceptability, patient satisfaction, and incidental qualitative data, will also be explained.
Participant Findings

Based on information reported within high quality, current literature, including the high prevalence of GAD and larger sample sizes reported in studies within the literature review, a larger participant sample size was expected. The sample size of this project was limited by several factors that will be further discussed later on within this chapter. The sample population was predominantly female (70%) within this project. This was an expected finding as women are affected by GAD twice as often as men (Edmund & Sheppard, 2018). The majority of participants earned an annual household income of over $100,000, which can be considered of high socioeconomic status. Although the link between socioeconomic status and rates of GAD is conflicting (McBride, 2015), the results of this project support that high socioeconomic status could be linked to higher rates of GAD as compared with those of low socioeconomic status. As the majority of participants were already taking an SSRI prior to baseline, this project allowed the effects of the addition of self-administered CBT to be assessed and visible. The majority of participants who completed follow up in its entirety were prescribed sertraline (60%), which was recommended in the literature. Thus, this added strength to the project and also demonstrated that patient safety, medication tolerability, and the best interests of participants were priorities.

A small number of participants had been prescribed an as needed benzodiazepine prior to baseline and had this available for administration during the implantation phase of this project. As aforementioned, it was decided that it would be unethical and unsafe to immediately discontinue the benzodiazepine at baseline. Excluding these participants, those taking an SSRI and benzodiazepine, from the project was decided against as it was determined that these participants could also significantly benefit from the intervention. It was also hoped that the benzodiazepine could eventually be discontinued due to the improvement from combination therapy. As such a minimal number of the remaining participants were taking an as needed benzodiazepine (10%), it is not thought that this had an effect on results. It was also not confirmed as to how often, if at all, the participants were taking benzodiazepines during the
implementation phase. It would have been helpful for the project manager to have asked participants this information during follow up phone calls, but due to human error, this was not done.

**Anxiety Symptoms**

Although a statistically significant decrease in anxiety symptoms was not achieved upon project completion, mean GAD-7 scores did decrease every 4 weeks of project implementation. Therefore, lack of statistical significance does not negate the positive impact of combination therapy on anxiety symptoms and may be accounted for by project limitations. Mean GAD-7 scores indicating anxiety symptom severity among the 10 participants who completed final follow up steadily decreased with mean scores of 4.20 at baseline, 3.40 at week 4, 2.40 at week 8, and 1.60 at week 12. Patient-reported GAD-7 Scale scores range from 0 - 21 with scores of 0 - 4 indicating minimal symptom severity, 5 - 9 indicating mild symptom severity, 10 - 14 indicating moderate symptom severity, and 15 - 21 indicating severe symptom severity. Thus, mean scores were decreased from levels of symptom severity indicating minimal to mild symptom severity at baseline to minimal symptom severity by week 12. This indicated that anxiety symptoms decreased as a result of combination therapy. As these 10 participants had been taking SSRIs prior to project implementation, this specifically indicated that the addition of CBT yielded a positive effect in the form of a decrease in anxiety symptoms. Participants’ use of SSRI medication prior to the implementation of the project may explain why participants’ symptom severity was minimal to mild when beginning the project, which did not allow for large scale improvement. Also, it is important to note that many of the 10 participants who did not follow up until project completion and were not included in data analysis rated high GAD-7 scores at baseline that indicated severe symptom severity. Therefore, results of this project in no way indicate that the impact of GAD anxiety symptomology is less than what is described by current literature. It was surprising that a statistically significant decrease in GAD-7 scores was not achieved as often was reported within current literature. However, this was likely related to
many limitations of the study. The small patient sample and attrition was unable to account for the extreme symptom severity and debilitating potential of GAD, yet many participants reported that their anxiety symptoms prior to project completion interfered with their lives and made it difficult to work, take care of things at home, or get along with other people. Therefore, the decreased anxiety symptoms displayed by steadily reduced mean GAD-7 scores over 12 weeks of project implementation, although not statistically significant, were of great benefit to participants.

**Depression Symptoms**

A statistically significant decrease in depression symptoms was achieved upon completion of project implementation at week 12. Mean PHQ-9 scores indicating depression symptom severity among the 10 participants who completed final follow up steadily decreased with mean scores of 4.80 at baseline, 3.90 at week 4, 2.90 at week 8, and 1.90 at week 12. Patient-reported PHQ-9 scores range from 0 - 27 with scores of 0 - 4 indicating minimal symptom severity, 5 - 9 indicating mild symptom severity, 10 - 14 indicating moderate symptom severity, 15 - 19 indicating moderately severe symptom severity, and 20 - 27 indicating severe symptom severity. Thus, mean scores were decreased from levels of depression symptom severity indicating minimal to mild symptom severity at baseline to minimal symptom severity by week 12. Thus, results indicate that depression symptoms significantly decreased as a result of combination therapy with CBT and SSRIs. Like anxiety symptoms, the low level of depression symptoms at baseline may again be accounted for as the remaining 10 participants were all taking SSRI medication prior to the start of project implementation. The statistically significant decrease in depression symptoms achieved by completion of project implementation supports the significant benefit of combination therapy with self-administered CBT and SSRI medication for the treatment of adults with GAD. Such results also demonstrate the strong link between depression and anxiety that was addressed in the literature and the need to address not only
anxiety symptoms, but also depression symptoms, in patients presenting with GAD at every visit.

**Change in GAD Status**

In congruence with anxiety symptoms, change in GAD status did not achieve statistical significance. Again, the positive impact of combination therapy on change in GAD status is not negated by lack of significance as the 10 remaining participants who completed week 12 follow up demonstrated an improvement in GAD status. It was surprising that statistical significance was not achieved in accordance with current literature. However, again, statistical significant within this project likely would have been achieved had it not been for the limitations of the project. This level of improvement or worsening of disease course was rated by the project manager using the CGI-I Scale with a score of 1 indicating very much improved, 2 indicating much improved, 3 indicating minimally improved, 4 indicating no change, 5 indicating minimally worse, 6 indicating much worse, and 7 indicating very much worse. The CGI-I Scale was utilized appropriately by always comparing change in GAD status to baseline GAD status. Mean CGI-I scores decreased when measured every 4 weeks, indicating improvement in GAD status. Mean scores decreased from 3.90 at week 4, 2.90 at week 8, and 1.90 at week 12. Thus, mean change in GAD status improved from no change/minimally improved at week 4 to much improved/very much improved at week 12. Therefore, project findings support that combination therapy with SSRIs and CBT improves GAD status.

**Acceptability**

Participant acceptance of the combination therapy, particularly the addition of CBT, was determined by the rate of attrition, or the number of participants lost to follow up. Attrition rates were 40% at week 4, 40% at week 8, and 50% at week 12. Typically, attrition rates of 50% and lower are considered acceptably low while attrition rates greater than 50% are considered high (Deke, Sama-Miller, & Hershey, 2015). Thus, the attrition rates for this project are considered low, indicating high levels of acceptability among participants regarding the intervention. The
attrition can likely be explained by difficulties in reaching participants via phone, full or nonfunctioning voicemail boxes, and busy participant schedules limiting availability for follow up. The low attrition rate was expected and similar to that reported within high quality literature.

**Patient Satisfaction**

Patient satisfaction regarding CBT was rated by participant responses to the PSQ created by the project manager. Findings indicated that participants were satisfied with the CBT workbook, which coincides with high patient satisfaction yielded within the literature. The majority of participants found the CBT workbook very convenient to use, easy to use, and very worthwhile to use. In addition, the majority of participants were satisfied or very satisfied with the impact that use of the CBT workbook had on their anxiety symptoms and satisfied with use of the CBT workbook overall. There were large variations reported regarding the amount of time that participants spent utilizing the CBT workbook per week with a wide range of 15 minutes to 30 hours per week. Participants spent an average of 5 hours per week utilizing the CBT workbook. The most common response provided regarding approximate time spent utilizing the CBT workbook per week was 1 hour. Thus, some participants spent a brief time utilizing the CBT workbook per week while others spent extensive time utilizing the CBT workbook per week.

**Qualitative Data**

During initial in-person patient visits at the clinic at baseline as well as follow-up telephone encounters with the project manager at week 4, week 8, and week 12, participants expressed comments regarding use of such combined CBT and SSRI intervention. These patient comments are useful in depicting patients’ unique experiences, thoughts, and beliefs with combination therapy. Several common themes emerged from this incidental qualitative data. Such themes explore effectiveness, understanding, side effects, endorsement, accessibility/ease of transport of self-administered CBT, applicability of self-administered CBT components, and busy lifestyle. These themes will be discussed in further detail as follows.
One common theme was that self-administered CBT and SSRIs were effective in helping participants feel better by minimizing symptoms associated with GAD. For example, participants noted positive changes with comments including, “I feel like the book and medication are helping a lot. I notice a big difference from my last visit,” “The CBT is helping. I’ve noticed a big change in myself. The [SSRI] also helps, and I notice when I don’t take it because I feel more anxious,” and “I like to read the book. It is very beneficial. I feel better with the [SSRI], and I feel the book helps, too.” Participants also reported improved productivity, increased levels of patience, and decreased depression symptoms. One patient expressed, “I accomplish more things now. I am feeling better from the start from talking to you and reading the book. I reevaluate my thoughts. I feel good.” Another stated, “I can see the difference, especially when it comes to irritation. I have more patience.” A third mentioned, “The [SSRI] has changed me around a lot and made me less depressed.”

As a second commonly identified theme, self-administered CBT provided useful education to participants and increased their understanding of GAD and coping skills. Participants were quoted saying, “As I read more of the workbook, I understand generalized anxiety disorder better.” Additional noteworthy patient reports included, “The book has helped me understand a lot more and puts things into perspective,” “I feel like the book is teaching me things I didn’t know and didn’t realize until now,” “It tells me things that I can do when my anxiety comes on,” and “Now, I’m able to work through my anxiety. The workbook taught me things that I wasn’t fully aware of and didn’t know how to do before.” Thus, participants were able to make important realizations through use of self-administered CBT and utilize this learned information to manage their anxiety and depression symptoms. Another participant stated, “I learned everything I wanted to know from the workbook. It’s therapeutic and makes you think” while another expressed, “I’m more conscious of things now because of the workbook.”

Another theme supported that participants experienced minimal to no side effects associated with self-administered CBT and SSRIs. One participant reported, “I was getting
sweaty palms from the [SSRI], but that’s the only side effect I’ve noticed. [The NP] told me to take it at night instead of in the morning to help with this.” Another mentioned, “I haven’t had any side effects.”

It was another commonly identified theme that participants endorsed self-administered CBT through expressions of satisfaction, enjoyment, desire for earlier use, plans to continue use, and plans to share self-administered CBT with others. Satisfaction and enjoyment were supported by participant comments, including “I’m so glad you offered this to me,” “I’ve been using the workbook more, and it’s helped a lot with my symptoms. I’m very satisfied,” “I like the CBT workbook and find it useful. I am pleasantly surprised how much the book has helped. It’s like a breath of fresh air. My symptoms are not as frequent,” and “I notice an improvement from a month ago. I find it interesting. It’s been a while since I had to read a book and study. I enjoy it.” Others shared their desire for earlier self-administered CBT use and intent to continue use with, “I wish I’d had this book a long time ago. So is this all? Are we done? Because I want to keep doing this. I plan to continue using this because I really like it. It was fun. Thank you for this,” as well as “I’m very excited about the workbook. This is great! I wish I had this when I started the medication.” Many participants were excited to share CBT to allow others to benefit from it as exemplified by the following quotations, “I was telling my boss about it and even she is interested in the CBT workbook now,” and “My daughter also has anxiety, and I am going to have her do this with me.” At the beginning of the project, one participant expressed, “I am excited to do this workbook. I work as a nurse at an addiction center and am excited to use this and learn from it in order to help my patients. This would be great for a lot of them,” and at the end of week 12 follow up mentioned, “I have been telling the counselors at work about this CBT and plan to share what I have learned with a class I teach.”

An additional common theme attested that the self-administered CBT was easy to keep nearby the participant and to transport. For example, one participant reported, “I take the book
with me wherever I go, including work and to my mother-in-law’s house.” Another noted, “I’ve been keeping the book by my chair.”

Several participants expressed that some information within the CBT workbook applied to them greatly while other information did not apply to them at all. A participant was quoted as reporting, “Some of the things in this book don’t apply to me, like anxiety around crowds, but I will keep reading it” while another stated, “The chapter about procrastination hit home and helped me. I often procrastinate, which causes me more anxiety.” Another participant felt a combination of these opinions with, “Some parts of the CBT workbook don’t pertain to me, but some are spot on.”

Finally, busy lifestyles and stressful life events making it difficult to use self-administered CBT was a common theme. This also contributed to difficulty achieving follow up and the resulting attrition throughout the project. For example, a participant expressed, “I haven’t done the CBT book yet because things have been so crazy since my accident, but I will get to it.” Similarly, another patient reported, “I had major surgery recently, and I need to focus on physical therapy so I have not used the book much yet.” Another stated, “I am driving now and am busy with my three kids and their activities tonight. I will call you tomorrow.” However, the patient did not call nor return calls. Unfortunately, another participant reported sad family circumstances that hindered his ability for completion and follow up with the statement, “My dad is dying. I read one chapter. Things have been hectic. I can’t answer questions now, but you can call me back in a week.” Follow up was not achieved with this patient. Additional remarks included, “It has been difficult to use because of my busy schedule, but I feel that the book is helpful,” “I’m in the middle of something with my daughter and will call you back in a little bit,” and “I haven’t used the book a lot recently because it’s finals weeks, but it is helping.”

**Evaluation of Applicability of Theoretical and EBP Frameworks**

The Neuman Systems Model served as the theoretical basis of the EBP project while the Stetler Model was the EBP model that guided the project. Use of these models aided in
successful implementation of the practice change by providing frameworks that the project manager could follow. Incorporating such models allowed important components to be upheld throughout the project as the principles of the Neuman Systems Model and the Stetler Model aligned with those of the project.

**Theoretical Framework**

The Neuman Systems Model served as a very effective and applicable theoretical framework to guide this EBP project (Neuman, 1982). Successful implementation of combined self-administered CBT and SSRI medication was able to occur in the family practice setting by utilizing this framework. Strengths of the Neuman Systems Model included its focus on the patient achieving an optimal level of wellness. This was a goal congruent with the EBP project. Through combination therapy to decrease anxiety and depression symptoms and improve GAD status, wellness was promoted within this project. In addition to considering patient wellness, the Neuman Systems Model assisted the project manager in considering lines of resistance and defense. The SSRI medication was able to serve as a defense against any harm to patient wellness through chemical changes within the brain to decrease feelings of anxiety. The CBT workbook was able to provide a defense mechanism through teaching coping skills to deflect stressors within the environment. The Neuman Systems Model brought concepts of the environment, stressors, health, and nursing to the forefront in order to develop a project that strived to address interactions between the patient and stressors within the environment, implement a beneficial nursing intervention to modify the manner in which the patient responds to such interactions, and improve patient’s health and wellness through collaboration via a positive relationship between the patient and nurse practitioner providing care. Weaknesses of the Neuman Systems Model included suggestions for prevention of invasion of stressors into beyond the lines of resistance and defense that were inapplicable to this project. Examples included blood pressure control and exercise. Although these are great interventions for the reduction of anxiety, only CBT and SSRI medications were utilized within this project on the
basis of best practice. In addition, limitations of the Neuman Systems Model include the risk of oversimplifying the theory as a whole during its application. Therefore, the need to thoroughly explore and understand the theoretical framework is necessary in order to use it properly. The Neuman Systems Model can be challenging to implement and consider all parts and subparts addressed within the framework, particularly as there are complexities in considering the interactions among an individual and the environment. Thus, an individual, holistic patient approach and the consideration of a multitude of variables and dynamic nature of GAD is necessary for proper use of the Neuman Systems Model.

**EBP Framework**

It can be concluded that the Stetler Model was a good fit as the EBP framework utilized to guide this EBP project. As the project manager was a novice in regard to implementing practice changes, the detailed steps of the Stetler Model aided in the consideration of important information that otherwise could have been missed or omitted. The Stetler Model is comprised of the following five steps: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation (Melnyk & Fineout-Overholt, 2015). The basic premise of the project was formed using the preparation stage, which provided instructions to determine a practice change that was in great need and perform a literature search. During experiences within the clinical setting in family practice, the project manager noticed that GAD was extremely prevalent and severely affecting the lives of patients. After wondering if there was a better way to treat patients for GAD than the various medications that were being prescribed, lack of follow through with referrals for counseling, or lack of recommendation for counseling provided, the project manager found strong information within the literature to support the need for a change in practice via self-administered CBT and SSRI medication use. Evidence was critiqued during the validation stage, and much good and high quality and high level evidence was utilized to support the project. Throughout the comparative evaluation/decision making stage, the project manager further determined how to utilize the evidence in a feasible and beneficial manner.
Numerous methods of CBT were recommended. However, self-administered CBT was proposed as a cost-effective, accessible, effective method that would be feasible to implement within the family practice setting.

Modifications were made to the plans outlined for the translation/application stage, which included further planning and actual implementation of the project. Initially, the project manager intended to include children ages 7 years of age and older, adolescents, and pregnant women as participants in congruence with current literature. However, due to rigorous IRB requirements for approval to include such vulnerable populations, time constraints regarding start of implementation, and an anticipated small sample of this population at the project site, children, adolescents under the age of 18, and pregnant women were excluded from the project. A further change occurred when translating the plans of the project into practice. It was originally planned that patient preferences would be upheld in the form of allowing participants to choose between interventions of self-administered CBT only, SSRI use only, or combined self-administered CBT and SSRI use. This would have created three different groups within the project. A decision to change the available intervention solely to combination therapy with self-administered CBT and an SSRI was made after the VU IRB suggested that as combination therapy is best practice, it should be the only intervention offered. Additional modifications included provider involvement in project participant recruitment. It was originally planned that the two nurse practitioners in the family practice office at the project site would recruit eligible participants every day that they were present in the office, which would have totaled 5 days per week. This became altered when one NP left the practice shortly before project implementation began. As the remaining NP then was taking on a greater workload unexpectedly, patient recruitment became challenging for her due to time constraints. Therefore, the project manager came to the office more frequently than initially planned in order to recruit participants.

The evaluation stage within the Stetler Model was also very useful to this project. Goals were evaluated as well as the degree to which the project was implemented and adopted.
Overall, the project was implemented in full as planned yet with revisions, and many goals were met, including a statistically significant decrease in depression symptoms and high levels of patient satisfaction reported. Goals that were not met included a sample population of at least 25 adults with GAD and achieving a statistically significant decrease in anxiety symptoms and statistically significant improvement in GAD status. After completion of implementation, adoption of the project at the project site was discussed. As the CBT workbooks were purchased by the project manager using a generous grant from Sigma Theta Tau Zeta Epsilon Chapter, a new method for acquiring the CBT workbooks was discussed with the NP who owns the practice. The combination therapy protocol implemented via this project involving self-administered CBT and SSRI use, patient education, and close monitoring is sustainable. It was decided that the best way to adopt and sustain this practice change would be to provide patients with information regarding self-administered CBT, its benefits associated with GAD treatment, where it is available for purchase, and the potential cost. Best practice via the combined prescribing of SSRI medication and the recommendation of CBT will continue to be incorporated into the treatment of GAD at the project site. Such information will now be provided verbally as well as via a patient handout for all adults with GAD in order to provide them with a helpful resource encouraging them to purchase and utilize self-administered CBT, similar to the way in which they would be instructed to purchase an over-the-counter medication. The practice is not affiliated with nor receiving any funds from the companies listed based on the purchase of CBT. The handout was developed by the project manager and given to the project site for use. Such handout is presented within Appendix N. Thus, the project site has adopted the practice change associated with this EBP project and plans to sustain the combination therapy protocol implemented are in place. Future plans may include the making of a self-administered CBT packet by the NP and project manager to provide to patients with GAD while at the office.
**Strengths and Limitations of the EBP Project**

Overall, successful implementation and results of this EBP project were yielded. Although there were numerous strengths of this project identified, there were also numerous limitations identified. By addressing such aspects, results of this project may be explained and future related projects can be strengthened.

**Strengths**

A strength of the project was its frequent follow up with participants every 4 weeks for a period of 12 weeks. This provided much information regarding the typical time period required for effects of self-administered CBT to become visible. It also allowed for participants to give detailed feedback regarding their unique experience multiple times throughout implementation. Another strength included measurement of a variety of outcomes, which provided much information regarding the vast effects of the combination therapy protocol. Further project strengths included the evaluation of both quantitative and incidental qualitative data. The site facilitator greatly believed in the need for this practice change, and many participants showed great interest and excitement for use of self-administered CBT. Many participants also expressed satisfaction and compliance with administration of their prescribed SSRIIs prior to the start of project implementation. Another strength is that this project provided an alternative to inaccessible, expensive treatment through a convenient, affordable method that patients could utilize essentially anytime and anywhere. Although a statistically significant difference in anxiety symptoms was not achieved from baseline to week 12, this in no way negates the positive impact of this project and combined CBT and SSRI use. A statistically significant decrease in depression symptoms was achieved from baseline to week 12, mean anxiety symptom severity steadily decreased from baseline to week 12, and participants reported satisfaction with the CBT workbook. Thus, overall results of this project were similar to those reported within high quality evidence. Many participants noted their surprise at just how effective the addition of the
CBT component was as well as their desire to continue to utilize self-administered CBT after completion of this project.

**Limitations**

The small sample size was certainly a limitation of this project, and unfortunately, it was not reflective of the high prevalence of GAD. This small sample size was limited by time constraints for recruitment as well as site facilitator decisions regarding who could be approached for participation within the project. Participants were recruited at a single-provider, rural clinic. Due to the busy nature of the practice and recent loss of a second provider, the remaining provider had limited time for project implementation. Therefore, participants were only recruited when the project manager was present in the clinic. The project manager was unable to be at the clinic more than typically two days per week during recruitment due to clinicals, class, and work. As patients with GAD were seen 5 days per week at the clinic, there was a large number of potential participants that could not be recruited. Also, the aforementioned sole provider and site facilitator, the NP whom opened and owned the clinic, knew most of her patients very well. There were some potentially eligible patients that the NP requested that the project manager not approach regarding this project for various reasons, such as time constraints or life events. This could have introduced some selection bias to the sample. The sample size was also limited by excluding children, adolescents younger than 18, and pregnant women as a result of IRB requirements and time constraints. Another limitation was the rather homogenous sample population. Of the 10 participants who completed follow up, all were Caucasian. Thus, there was a lack of racial diversity among participants, which could limit generalizability. The sample size was further limited by ineligibility based on maintenance medication use other than SSRIs as it would have been unsafe and unethical to immediately discontinue and/or change medications in many cases. Finally, mean GAD-7 and PHQ-9 scores indicated minimal anxiety and depression symptom severity at baseline. This was likely related to the majority of participants already taking an SSRI prior to project implementation. The low
scores limited the ability to see greater effects of the intervention protocol that may have been apparent provided there had been greater room for improvement.

**Implications for the Future**

This EBP project provided worthwhile information for the advanced practice nursing profession related to the effects of combination therapy of SSRIs and self-administered CBT. Future implications for practice, theory, research, and education will be explored. Such implications can be used to guide and improve future EBP projects and practice changes as well as to positively shape the way GAD is treated both nationally and globally.

**Practice**

This combination therapy utilizing SSRIs and CBT has been established as best practice in current, high quality literature. Unfortunately, it is not implemented in all primary care offices. This project allowed for this combination protocol to become standardized practice at the project site, and it is encouraged for all primary care offices to adopt this protocol. This project supported the feasibility, low cost, effectiveness, and high levels of patient satisfaction associated with combination therapy. A grant from Sigma Theta Tau Zeta Epsilon Chapter covered the costs of the CBT workbooks at no expense to the family practice office nor participants. It may not be feasible for offices to cover the expenses of the workbooks for patients. Therefore, additional planning is necessary in order to determine how patients can obtain the workbooks. This is still being discussed with the NP at the project site. Potential options that have been proposed include the NP and project manager developing their own form of self-administered CBT to pass out to patients with GAD, providing patients with a handout indicating types of self-administered CBT, cost, and where to purchase them, or having self-administered CBT available for patient purchase at the office.

There are many future EBP considerations to address. Future EBP projects related to GAD with larger population sizes, greater diversity, and higher levels of anxiety and depression symptom severity would be beneficial to further explore significance and generalizability.
Additional recommendations for future projects include comparison of therapist-guided CBT versus self-administered CBT outcomes. This would aid in the ability to compare and contrast effectiveness and establish superiority regarding delivery method. It would also be beneficial for future EBP projects to explore the effect of CBT and SSRIs on children and adolescents younger than 18 years of age to further evaluate the effectiveness of this intervention across the lifespan.

Theory

Use of the Neuman Systems Model as the theoretical foundation for this EBP project aided in successful implementation of this EBP project. It allowed for a patient-centered approach that considers the unique and individualized interactions that patients encounter with the environment as well as the unique way in which they interpret and react to stressors within the environment. This project was able to consider such reactions to stressors and provide methods in which patients could become resilient and defensive against potential stressors through the use of CBT and SSRI medication. These interventions were able to restructure the way in which patients think about stressors and anxiety, leading to decreased symptoms of anxiety as well as depression. The achievement of optimal wellness was a central component of the Neuman Systems Model. Ultimately, a main goal of the EBP project was to promote quality of life and improved disease status, or put more simply, to promote wellness. The Neuman Systems Model was an excellent fit for this project, allowing for exploration and applicability of the model on a deeper level while upholding a holistic, patient-centered, wellness focus as the goal. As it assisted with successful development and implementation of this EBP project, the Neuman Systems Model is recommended for future EBP practice projects that focus on concepts of anxiety, stress, or depression. Future projects could also utilize the concepts of primary, secondary, and tertiary prevention exemplified by the Neuman Systems Model. The model describes the importance of primary prevention to strengthen the patient’s flexible line of defense, or first barrier against stressors, secondary prevention to decrease the reaction that
the patient has to the stressor within the lines of resistance, and rebuild wellness through treatment when stressors have invaded the patient’s core. As this theoretical model is so complex, future EBP projects could explore the model in even further detail and utilize as applicable for improved patient outcomes.

**Research**

Further research is needed in order to explore the effects of therapist-guided CBT in comparison to self-administered CBT. It may be that CBT guided by a therapist yields superior outcomes to those of self-administered CBT. However, self-administered CBT is useful in reducing the barriers associated with therapist-guided CBT, including lack of available therapists, lack of insurance coverage, expense, time constraints, and patient reluctance. Thus, self-administered CBT is beneficial for those who are unable or unwilling to go to CBT guided by a therapist as it provides the opportunity for the patient to participate in CBT as opposed to no CBT option. Self-administered CBT does not have to substitute therapist-guided CBT for patients willing and able to attend, but rather could be implemented during the waiting period, if one exists, between the time the patient is recommended for CBT and the patient’s established appointment.

**Education**

Patient education is a vital part of the role and responsibly of the advanced practice nurse. Educating participants about best practice treatment, side effects of medication, purpose of therapy, and additional information was incorporated into the protocol implemented through this project. Education was also a main component within the self-administered CBT workbook. Participants expressed much increased knowledge about GAD and coping skills through use of the CBT. Participants relayed that as a result of this education, their symptoms improved and they felt better overall. This also allowed participants to become well-informed consumers and take charge of their own health. Provider education is also extremely important regarding treatment for GAD. SSRIs are safer than many other medications for treatment of GAD. For
example, benzodiazepines are potentially addictive while SSRIs do not have this potential. Many providers may also not be aware of the CBT resources available within their community as well as globally. This project shines a light on the importance of familiarizing oneself with such resources, recommending them to patients, providing support to patients, and assisting them with accessing such resources.

**Conclusion**

This EBP project has allowed the NP site facilitator and project participants to see the value of the addition of CBT to their treatment regimen. The site facilitator has expressed her satisfaction with project results and her desire to continue to incorporate this combination therapy of SSRI antidepressant medication and self-administered CBT at her practice. Methods for sustainability were implemented at the project site. The site facilitator was receptive to such informative handout for patients interested in self-administered CBT and plans to continue to distribute this to eligible patients. Participants of the project also expressed their interest in continuing to utilize self-administered CBT along with taking SSRIs after experiencing the benefits first-hand. Such participants were encouraged to do so and provided with guidance regarding additional self-administered CBT resources.

In conclusion, results of this project support the effectiveness of combination therapy with self-administered CBT and SSRI medication for the treatment of adults with GAD in decreasing anxiety and depression symptoms, improving GAD status, and yielding patient acceptability and satisfaction, which is consistent with current literature. No statistical significance was achieved for evaluation of anxiety symptoms nor for evaluation of change in GAD status. However, mean GAD-7 and CGI-I scores decreased, indicating decreased anxiety symptoms and improved GAD status. Statistical significance was achieved for the evaluation of PHQ-9 scores, indicating a significant decrease in depression symptoms.

Patient education and close monitoring are also important components of such best practice protocol that should be followed to assess patient safety and response to treatment as
well as to facilitate patient understanding. Thus, this is a patient-centered protocol that upholds the best interests of patients and has a holistic focus. Providers are recommended to incorporate this combination therapy protocol including self-administered CBT and SSRI antidepressant medication for the treatment of adults with GAD as a cost-effective, accessible, effective method for improving GAD symptoms.
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Mrs. McClanahan graduated Magna Cum Laude from Valparaiso University with a Bachelor of Science in Nursing (BSN) degree in 2014. She has worked at Porter Regional Hospital for the past 7 years, beginning as a certified nursing assistant on the orthopedic unit. Since graduating with her BSN, she has worked as a registered nurse on the women and children’s unit. She decided to return to VU in 2015 to pursue a Doctor of Nursing Practice degree, which she will complete in May 2019. She is a member of several campus and professional organizations, including the American Association of Nurse Practitioners, Sigma Theta Tau Zeta Epsilon Chapter, Coalition of Advanced Practice Nurses of Indiana, Student Nurses Association, and Student Faculty Concerns Committee. She has been recommended by faculty for volunteer activities, scholarships, and presentations directed to fellow graduate students and the University Board of Directors. She enjoys mentoring students as she appreciates the support and knowledge imparted to her by faculty throughout her academic career. She was a recipient of the Indiana Organization of Nurse Executives Scholarship and CVS Health Foundation Advanced Practice Nurse Scholarship. She has received Porter Cares recognitions by patients and coworkers. In 2016, she studied abroad in Ireland and appreciated learning about diverse culture and healthcare. Her decision to implement an evidence-based practice project centered on combined pharmacological and psychological therapy for the treatment of generalized anxiety disorder stemmed from her desire to give her family, friends, and patients a way to better cope with anxiety and live more enjoyably without such burden. She was selected as a Rising Star of Research and Scholarship to present her project at the 2019 Creating Healthy Work Environments Conference in New Orleans. She also presented her project at the 2018 Northwest Indiana Research Consortium and plans to submit her work to a scholarly nursing journal. Some of her interests as a future NP include dermatology, mental health, pediatrics, and nursing education. Mrs. McClanahan will strive to make positive contributions to the nursing profession in honor of her family and hopes that doing so betters the lives of patients, nurses, fellow NPs, and more.
ACRONYM LIST

ACS: Anxiety Counselor Specialist
ADHD: Attention Deficit Hyperactivity Disorder
ADIS-P: Anxiety Disorder Interview Schedule for Children
AGREE: Appraisal of Guidelines for Research & Evaluation
ANOVA: Analysis of Variance
BAI: Beck Anxiety Inventory
CALM: Coordinated Anxiety Learning and Management
CAMELS: Child/Adolescent Anxiety Multimodal Extended Long-Term Study
CAMS: Child/Adolescent Anxiety Multimodal Study
CBT: Cognitive Behavioral Therapy
CD: Conduct Disorder
CGI-I: Clinical Global Impressions-Improvement
CGI-S: Clinical Global Impressions-Severity
COMB: Combination Therapy
DISCAP: Diagnostic Interview Schedule for Children, Adolescents, and Parents
DNP: Doctor of Nursing Practice
DoD: Department of Defense
DSM-4 (DSM-IV): The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
DSM-5 (DSM-V): The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EBP: Evidence-Based Practice
FDA: Food and Drug Administration
GAD: Generalized Anxiety Disorder
GADSS: Generalized Anxiety Disorder Severity Scale
GAD-7: Generalized Anxiety Disorder (7-item)
HAM-I: Hamilton Anxiety Rating Scale
GENERALIZED ANXIETY DISORDER PROTOCOL

ICD: International Statistical Classification of Diseases and Related Health Problems
IRB: Institutional Review Board
ISI: Insomnia Severity Index
NIH: National Institutes of Health
NP: Nurse Practitioner
OAD: Overanxious Disorder
ODD: Oppositional Defiant Disorder
PARS: Pediatric Anxiety Rating Scale
PBO: Placebo
PD: Panic Disorder
PhD: Doctor of Philosophy
PHQ-9: Patient Health Questionnaire (9-item)
PICOT: Population, Intervention, Comparison, Outcome, Time
PSQ: Patient Satisfaction Questionnaire
PSWQ: Penn State Worry Questionnaire
RCT: Randomized Controlled Trial
SAD: Separation Anxiety Disorder
SDS: Sheehan Disability Scale
SF-12: Medical Outcomes Study Short Form
SIGH-A: Structured Interview Guide for the Hamilton Anxiety Scale
SNRI: Serotonin-Norepinephrine Reuptake Inhibitor
SOP: Social Phobia
SP: Specific Phobia
SPSS: Statistical Package for the Social Sciences
SRT: Sertraline
SSRI: Selective Serotonin Reuptake Inhibitor
STAI-T: State-Trait Anxiety Inventory

TAU: Treatment as Usual

UCLA: University of California, Los Angeles

U.S.: United States

VA: Veterans Affairs

WHO: World Health Organization

5-HT: 5-hydroxytryptamine
Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that Alesha McClanahan successfully completed the NIH Web-based training course "Protecting Human Research Participants."

Date of Completion 04/05/2018

Certification Number 2628828
JOHNS HOPKINS NURSING EVIDENCE-BASED PRACTICE MODEL AND TOOLS

HERE ARE YOUR JHNEBP TOOLS (AND A SURPRISE GIFT!)

Thank you for your submission. We are happy to give you permission to use the JHNEBP model and tool in adherence of our legal terms mentioned noted below:

- You may not modify the model or the tools without written approval from Johns Hopkins.
- All reference to source forms should include “©The Johns Hopkins Hospital/The Johns Hopkins University.”
- The tools may not be used for commercial purposes without special permission.
- If interested in commercial use or discussing changes to the tool, please email jhn@jmi.edu.

Click HERE to access the zipped file of the tools.

Please note: If you choose to use the Johns Hopkins Nursing Evidence-Based Practice Model and Tools in any other way, another form will need to be submitted.

Exclusive offer for users of our JHNEBP model and tools. Did you know we also offer an online course about the JHNEBP model? We’d like to give you $20 off this engaging online experience. The course follows the EBP process from beginning to end and provides guidance to the learner on how to proceed. using the tools that are part of the Johns Hopkins Nursing EBP model. Click HERE to take online course. Use coupon code JHNEBPTOOLS at check out.

Do you prefer hands-on learning? We are offering a 5-day intensive Boot Camp where you will learn and master the entire EBP process from beginning to end. Take advantage of our retreat-type setting to focus on your project, collaborate with peers, and get the expertise and assistance from our faculty. Click HERE to learn more about EBP Boot Camp. Group rates available, email jhn@jmi.edu to inquire.
Appendix C

Evidence-Based Practice Project Explanation

Anxiety is Something to Worry About: The Effects of a Cognitive Behavioral Therapy and Selective Serotonin Reuptake Inhibitor Intervention Protocol on Generalized Anxiety Disorder

Dear Patient,

My name is Alesha McClanahan. I am a registered nurse and a student in the Doctorate of Nursing Practice (DNP) program at Valparaiso University. Upon obtaining this degree and certification, I will be a nurse practitioner (NP). To fulfill this program’s curriculum, I will be implementing an evidence-based practice (EBP), or quality improvement, project at this clinic. The providers at this clinic including, L. K***, NP, support this project and will be overseeing its implementation. An evidence-based practice, or quality improvement project, aims to utilize current best practice recommendations from research and integrate them into the practice setting to improve clinical practice and patient outcomes.

My EBP project will assess the effectiveness of cognitive behavioral therapy (CBT) in combination with a selective serotonin reuptake inhibitor (SSRI) on symptoms of generalized anxiety disorder (GAD). I am serving as the project manager of this project. CBT is a noninvasive, nonpharmacologic treatment that aims to change ways of thinking to elicit more positive thoughts and develop methods for coping with anxiety. It will be delivered in the form of an established CBT workbook written by a licensed psychologist. An SSRI is an oral antidepressant medication used to treat GAD as well as depression, which is strongly linked to GAD. Current, high quality evidence supports the combined use of CBT and an SSRI as the best treatment for the management of generalized anxiety disorder in children, adolescents, adults, and older adults. Therefore, if you would like to participate in this project, you will be prescribed an SSRI and a CBT workbook.

The project will be implemented over a period of three months. Participants who agree to participate will be asked to complete a consent form, demographic information, including age and ethnicity, as well as an anxiety scale and a depression scale prior to treatment initiation and monthly over the three month period of the project. Participants will be asked to complete a satisfaction questionnaire upon project completion. For convenience, these measurements will occur via telephone calls by the project manager. These phone calls will likely be 5-10 minutes long. Participants will be asked to actively engage in the CBT workbook on their own and take their SSRI medication as directed. You are invited to participate in this project. If you choose not to participate in this project, there will be no penalty nor effect on the care provided to you today or any other time at this clinic. Participation is voluntary, and you may withdraw at any time if you wish. Patient confidentiality will be upheld, and patient information will be kept in a secure and private location.

Thank you for your consideration,

Alesha McClanahan, BSN, RN, DNP Student Valparaiso University
Appendix D

Informed Consent Form

**Project Title:** Anxiety is Something to Worry About: The Effects of a Cognitive Behavioral Therapy (CBT) and Selective Serotonin Reuptake Inhibitor (SSRI) Intervention Protocol on Symptoms of Generalized Anxiety Disorder (GAD)

**Project Manager:** Alesha McClanahan, BSN, RN, DNP Student Valparaiso University College of Nursing and Health Professions

**Purpose:** This is a consent form for evidence-based practice participation. It contains important information about the project and what to expect if I decide to participate. I understand that I am being asked to join an evidence-based practice project for patients of this clinic that will examine the effects of combined self-administered cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitor (SSRI) medication use on symptoms of anxiety.

**Voluntary participation/withdrawal:** I understand that my participation is voluntary. I am being asked to please read and consider the information carefully. I may ask questions before making my decision regarding participation and at any time during and after the project’s implementation. If I decide to participate, I will be asked to indicate my consent to participate with my signature. I understand that I may leave the project at any time. If I decide to stop participating in the project, there will be no penalty to me, and I will not lose any benefits to which I am otherwise entitled. My decision will not affect my relationship with nor the care provided to me at K*** Family Medicine today nor in the future.

**Procedure:** If I participate in this project, I will utilize the CBT workbook for anxiety and take the prescribed SSRI medication. I understand that such CBT and SSRI use may be referred to as interventions, therapy, or treatment throughout this project. The CBT utilized for this project may be referred to as self-help or self-administered CBT as I will work on the workbook by myself, or independently, rather than with a therapist. I understand that the evidence indicates that this combined therapy yields the best outcomes for GAD. I will be asked to read and complete the CBT workbook provided to me independently and as directed throughout the 3-month study period. I will also be asked to take my SSRI medication regularly as directed throughout the 3-month period. If I participate, I will sign consent to participate and answer a demographic, anxiety, depression, and satisfaction questionnaire. The demographic questionnaire will need to be answered once at the start of the project’s implementation, and the satisfaction questionnaire will need to be answered once at the end of the project’s implementation. The anxiety and depression questionnaires will need to be answered four times, including prior to the initiation of treatment and monthly (every four weeks) for 3 months. The questionnaires will initially be answered in the office during your scheduled appointment while the other three times in which the same questionnaires will be answered will occur via telephone calls by the project manager. If I participate in this project, I understand that I give consent for the project manager to call my phone number(s) that I have provided, and I give consent for a message to be left if I am
unavailable. I will make an effort to answer the project manager’s phone calls and to call the project manager back shortly if I miss a call. The phone calls will typically last 5-10 minutes each. Phone calls will include completion of the aforementioned questionnaires. I may also ask the project manager any questions that I have during these phone calls and feel free to provide any comments about the therapy, process, etc. I am asked to be open and honest and will not receive any repercussions for my responses or comments.

**Duration:** I will tentatively participate in the study for 3 months (12 weeks). I will be regularly evaluated by the project manager and NP for my safety and to evaluate the effectiveness of the interventions. In addition to phone calls by the project manager, I may have follow up appointments with the NP per office policy to evaluate the effects of the interventions, including tolerability, side effects, and satisfaction with treatment. I will be instructed to complete certain portions of the workbook by designated times and to complete the entire workbook within 3 months. I will be asked to complete the anxiety and depression questionnaires at 1 month (4 weeks), 2 months (8 weeks), and 3 months (12 weeks) after the start of the interventions.

**Risks:** The potential risks to participating in this project are minimal but include side effects and adverse effects of SSRI medications which may include drowsiness, nausea, dry mouth, insomnia, diarrhea, nervousness, agitation, restlessness, dizziness, headache, blurred vision, sexual problems, reduced sexual desire, difficulty reaching orgasm, or inability to maintain an erection. Additional safety concerns include potential drug interactions, serotonin syndrome, and pregnancy or breastfeeding. You should inform your provider of all medications you are currently taking. Serotonin syndrome may occur when levels of serotonin are too high in the body, which typically occurs when multiple medications that raise serotonin levels are taken. Seek medical attention if you have signs and symptoms of serotonin syndrome, including anxiety, agitation, sweating, confusion, tremors, restlessness, lack of coordination, and a rapid heart rate. Speak with your provider regarding antidepressant use and pregnancy or breastfeeding if you are or plan to become pregnant or breastfeed as some antidepressants may cause harm to your baby. Do not stop taking SSRI medication abruptly as this may pose risks including withdrawal-like symptoms including uneasiness, nausea, dizziness, lethargy, and flu-like symptoms. Although most antidepressants are safe, an increase in suicidal thoughts or behavior can occur particularly upon initiation or dose change. Antidepressants are likely to reduce suicide risk long-term. However, you should be closely monitored and contact your provider or emergency services if you have suicidal thoughts. SSRIs are generally well tolerated.

The potential risks to participating in this project associated with CBT are minimal but include emotional vulnerability, emotional discomfort, frustration, crying, anger, feeling physically drained, temporary stress, and temporary anxiety as CBT aims to address negative thoughts that cause anxiety and fear and correct such maladaptive thoughts. Thus, CBT may involve the confronting of sensitive thoughts and events which may evoke unpleasant thoughts and emotions.
Benefits: The benefits of participating in this project include receiving treatment based on the recommendations of the best available evidence that aims to elicit the best outcomes and increase quality of life for patients. A CBT workbook will be administered free of charge to those who participate in this project. Researchers hope to gain valuable information regarding whether incorporating CBT and an SSRI into the treatment plan will make an impact on anxiety symptoms. The information provided may help to make advancements in nursing practice and care provided.

Confidentiality: I understand that efforts will be made to keep my project-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding my participation in this project may be disclosed if required by state law. In the event that I indicate any potential for self-harm or harm of others, it will be necessary to break confidentiality for my safety and the safety of others. Any information containing my identifying information will be kept in a locked box with access only to the project manager. My responses to questionnaires will be kept in a secure and private location with only access to the project manager and office staff. The project manager and staff will work to ensure that no one sees my questionnaire responses without my approval. A code will be used in place of my name in order to further uphold confidentiality and reduce the risk that others can view my responses. General information obtained from this project may be utilized in nursing journals, presentations, or other publications, but no one will be able to identify me from this information as no patient identifiers will be released.

Contacts and Questions: For questions and concerns about the project, I may contact the project manager, Alesha McClanahan, at (219) 689-3369 or alesha.mcclanahan@valpo.edu. I may also contact L. K***, NP, with questions at her office (219) 956-3004. Christina Cavinder, the project’s faculty advisor, may be contacted at (219) 548-7797 or christina.cavinder@valpo.edu. I may also contact Jennifer Winquist, Chair of the Institutional Review Board at Valparaiso University at (219) 464-6841 or jennifer.winquist@valpo.edu if I have questions or concerns regarding the conduction of the evidence-based practice project.

Consent to Participate: I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in an evidence-based practice project. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this project. I understand the information that has been presented to me. By signing and submitting this form, I agree to participate in this project. I will be offered a copy of this form for my records.

The project manager may call me at this phone number(s): ______________________________

____________________________________

Participant’s Signature: ___________________________ Date: ___________________________

Printed first and last name: ________________________________
Appendix E

Demographic Form

Please answer the following questions about yourself.

1. What is your age? _____

2. Are you male or female?
   a. Male
   b. Female

3. What is the highest level of education that you have completed?
   a. Less than high school
   b. High school/GED
   c. Some college (no degree)
   d. 2-year college degree (Associates) (e.g. BA, BS)
   e. 4-year college degree (Bachelors) (e.g. BA, BS)
   f. Master’s degree (e.g. MA, MS, Med)
   g. Professional degree (e.g. MD, DDS, DVM)
   h. Doctoral degree (e.g. PhD, EdD)

4. What is your race?
   a. African American
   b. Asian-Pacific Islander
   c. Caucasian
   d. Hispanic
   e. Native American
   f. Other
   g. Prefer not to answer

5. What form of health insurance do you currently have?
   a. No insurance
   b. Medicare
   c. Medicaid
   d. Private insurance

6. What is your marital status?
   a. Single (never married)
   b. Married
   c. Separated
   d. Divorced
   e. Widowed
7. What is your annual household income?
   a. Less than $20,000
   b. $20,000 to $34,999
   c. $35,000 to $49,999
   d. $50,000 to $74,999
   e. $75,000 to $99,999
   f. Over $100,000

8. What is your current employment status?
   a. Employed full time (40 or more hours per week)
   b. Employed part time (up to 39 hours per week)
   c. Unemployed and currently looking for work
   d. Unemployed and not currently looking for work
   e. Student
   f. Retired
   g. Homemaker
   h. Self-employed
   i. Unable to work

Code Number:
## Appendix F

### Code Sheet

<table>
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<tr>
<th>Patient Name (Last, First)</th>
<th>Code Number</th>
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### Appendix G

#### Generalized Anxiety Disorder 7-item (GAD-7) Scale

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

For office coding: Add the score for each column

| + | + | + |

Total score (add column scores) =

If you checked off any problems, how difficult have these problems 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

Scores on the GAD-7 range from 0-21 with each of the 7 items scored from 0-3. Each column is added together in order to determine the total score. The total score indicates the level of severity of anxiety symptoms.

<table>
<thead>
<tr>
<th>GAD-7 Scale Score</th>
<th>Level of Anxiety Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>Minimal symptoms</td>
</tr>
<tr>
<td>5-9</td>
<td>Mild symptoms</td>
</tr>
<tr>
<td>10-14</td>
<td>Moderate symptoms</td>
</tr>
<tr>
<td>15-21</td>
<td>Severe symptoms</td>
</tr>
</tbody>
</table>
# Appendix H

Patient Health Questionnaire (PHQ-9)

Over the last 2 weeks, how often have you been bothered by the following problems? Use “√” to indicate your answer.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

For office coding: Add the score for each column

| + | + | + |

Total score (add column scores) =

If you checked off any problems, how difficult have these problems 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

Scores on the PHQ-9 range from 0-27 with each of the 9 items scored from 0-3. Each column is added together in order to determine the total score. The total score indicates the level of severity of depression symptoms.

<table>
<thead>
<tr>
<th>PHQ-9 Scale Score</th>
<th>Level of Depression Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>Minimal symptoms</td>
</tr>
<tr>
<td>5-9</td>
<td>Mild symptoms</td>
</tr>
<tr>
<td>10-14</td>
<td>Moderate symptoms</td>
</tr>
<tr>
<td>15-19</td>
<td>Moderately severe symptoms</td>
</tr>
<tr>
<td>20-27</td>
<td>Severe symptoms</td>
</tr>
</tbody>
</table>
### Appendix I

**Clinical Global Impressions-Improvement (CGI-I) Scale**

<table>
<thead>
<tr>
<th>Code Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Very Much Improved</td>
<td>Nearly all better; good level of functioning; minimal symptoms; represents a very substantial change</td>
</tr>
<tr>
<td>2 – Much Improved</td>
<td>Notably better with significant reduction of symptoms; increase in the level of functioning but some symptoms remain</td>
</tr>
<tr>
<td>3 – Minimally Improved</td>
<td>Slightly better with little or no clinically meaningful reduction of symptoms. Represents very little change in basic clinical status, level of care, or functional capacity</td>
</tr>
<tr>
<td>4 – No Change</td>
<td>Symptoms remain essentially unchanged</td>
</tr>
<tr>
<td>5 – Minimally Worse</td>
<td>Slightly worse but may not be clinically meaningful; may represent very little change in basic clinical status or functional capacity</td>
</tr>
<tr>
<td>6 – Much Worse</td>
<td>Clinically significant increase in symptoms and diminished functioning</td>
</tr>
<tr>
<td>7 – Very Much Worse</td>
<td>Severe exacerbation of symptoms and loss of functioning</td>
</tr>
</tbody>
</table>

Clinical Global Impressions-Improvement (CGI-I) Scale Scoring

<table>
<thead>
<tr>
<th>Score</th>
<th>Change in Disease Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Very much improved</td>
</tr>
<tr>
<td>2</td>
<td>Much improved</td>
</tr>
<tr>
<td>3</td>
<td>Minimally improved</td>
</tr>
<tr>
<td>4</td>
<td>No change</td>
</tr>
<tr>
<td>5</td>
<td>Minimally worse</td>
</tr>
<tr>
<td>6</td>
<td>Much worse</td>
</tr>
<tr>
<td>7</td>
<td>Very much worse</td>
</tr>
</tbody>
</table>
Appendix J

Patient Satisfaction Questionnaire (PSQ)
Self-administered Cognitive Behavioral Therapy (CBT) Workbook

Please circle your responses.

1. How convenient or inconvenient is it for you to use the CBT workbook?
   1) Extremely Inconvenient
   2) Very Inconvenient
   3) Inconvenient
   4) Somewhat Convenient
   5) Convenient
   6) Very Convenient
   7) Extremely Convenient

2. How easy or difficult is it for you to use the CBT workbook?
   1) Extremely Difficult
   2) Very Difficult
   3) Difficult
   4) Somewhat Easy
   5) Easy
   6) Very Easy
   7) Extremely Easy

3. How satisfied or dissatisfied are you with the impact that use of the CBT workbook has had on your anxiety symptoms?
   1) Extremely Dissatisfied
   2) Very Dissatisfied
   3) Dissatisfied
   4) Somewhat Satisfied
   5) Satisfied
   6) Very Satisfied
   7) Extremely Satisfied

4. How satisfied or dissatisfied are you with use of the CBT workbook overall?
   1) Extremely Dissatisfied
   2) Very Dissatisfied
   3) Dissatisfied
   4) Somewhat Satisfied
   5) Satisfied
   6) Very Satisfied
   7) Extremely Satisfied
5. How worthwhile or worthless do you find use of the CBT workbook to be?

1) Extremely Worthless
2) Very Worthless
3) Worthless
4) Somewhat Worthwhile
5) Worthwhile
6) Very Worthwhile
7) Extremely Worthwhile

Please fill in the blank.

6. How much time did you approximately spend completing the CBT workbook per week?

_______ minutes    OR    _______ hours

Patient Satisfaction Questionnaire (PSQ) Scoring

<table>
<thead>
<tr>
<th>PSQ Scale Score</th>
<th>Level of Patient Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Extremely Dissatisfied</td>
</tr>
<tr>
<td>6-10</td>
<td>Very Dissatisfied</td>
</tr>
<tr>
<td>11-15</td>
<td>Dissatisfied</td>
</tr>
<tr>
<td>16-20</td>
<td>Somewhat Satisfied</td>
</tr>
<tr>
<td>21-25</td>
<td>Satisfied</td>
</tr>
<tr>
<td>26-30</td>
<td>Very Satisfied</td>
</tr>
<tr>
<td>31-35</td>
<td>Extremely Satisfied</td>
</tr>
</tbody>
</table>

This scoring system for the PSQ was created by the project manager and is optional. Results may instead be reported per individual question via percentages as was ultimately done for this project.
Appendix K

Selective Serotonin Reuptake Inhibitor (SSRI) and Cognitive Behavioral Therapy (CBT)
Patient Instructions – Adult 18+ years

**SSRI use**
- The purpose of this medication is to help manage your anxiety by decreasing your symptoms of anxiety.
- Take your prescribed medication as directed and attend regular follow up appointments.
- Do not discontinue your medication abruptly.
- Call your provider or seek emergency attention if necessary if you experience alarming adverse effects.
- Side effects of the medication may include drowsiness, nausea, dry mouth, insomnia, diarrhea, nervousness, agitation, restlessness, dizziness, headache, or sexual problems.

**CBT use**
- The purpose of this intervention is to help manage your anxiety by teaching you coping mechanisms and changing negative and distorted thoughts into more positive and realistic thoughts.
- A CBT workbook will be provided to you at the office for you to complete independently.
- This is CBT in the form of self-help, and thus, this is not guided by a therapist. However, you are welcome to ask your provider or the project manager, Alesha, any questions.
- You will be enrolled in this project for 3 months (12 weeks), and the workbook is divided into four parts. Please complete Part 1 by 3 weeks, Part 2 by 6 weeks, Part 3 by 9 weeks, and Part 4 by 12 weeks.
- Side effects of CBT may include emotional discomfort, frustration, crying, anger, feeling drained, or temporary stress and anxiety when confronting sensitive thoughts.

**Progress Measurement**
- Your response to these interventions of SSRIs and CBT will be measured throughout this project by the project manager, Alesha. These measurements will occur at baseline (prior to starting these interventions) in the office and via phone calls by Alesha at 1 month, 2 months, and 3 months after starting these interventions. Phone calls will typically last 5-10 minutes or less.
- Phone calls will include completion of the Generalized Anxiety Disorder 7-item (GAD-7) Scale to assess for symptoms of anxiety and the Patient Health Questionnaire (PHQ-9) to assess for symptoms of depression. You are welcome to share any comments, concerns, or questions during these phone calls.
- These phone calls are important in order to measure these outcomes to determine the effectiveness of the interventions and to further evidence-based nursing practice.

Tentative dates of measurement include:
- Baseline –
- 1 month –
- 2 months –
- 3 months –

Alesha McClanahan, BSN, RN,
DNP Student Valparaiso University
219-689-3369
Alesha.mcclanahan@valpo.edu
Appendix L

Best Practice Intervention Protocol

<table>
<thead>
<tr>
<th>SUBJECT: Generalized Anxiety Disorder Treatment Protocol</th>
<th>REFERENCE #: 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOCATION: Primary Care Clinic</td>
<td>PAGES: 1</td>
</tr>
<tr>
<td>LAST REVISION: 9/12/18</td>
<td>EFFECTIVE: 9/21/18</td>
</tr>
<tr>
<td>APPROVED BY: Primary Care Clinic Nurse Practitioner and Office Manger</td>
<td>REVISED:</td>
</tr>
</tbody>
</table>

Purpose:
- To provide a protocol for nurse practitioners and other providers to follow in order to provide best practice treatment of patients with generalized anxiety disorder (GAD)

Protocol:
- Primary care adult patients ages 18 years old and older with a diagnosis of GAD based on DSM-5 criteria are eligible

- Combination therapy with a selective serotonin reuptake inhibitor (SSRI) plus cognitive behavioral therapy (CBT) is recommended for best outcomes
  - Age-appropriate self-help CBT bibliotherapy in the form of a workbook for anxiety
    - Adults 18+: *The Cognitive Behavioral Workbook for Anxiety: A Step-By-Step Program* (Knaus, 2014)
  AND
  - Prescribing of an SSRI
    - Sertraline with a maximum daily dose of 200 mg PO is recommended
    - Any type of SSRI will fulfill protocol requirements, and individual patient factors should be considered, such as previous medications tried, drug interactions, etc.

- Education should be provided to patients regarding safe and proper use of CBT and SSRIs and potential side effects

- Close monitoring of patients taking SSRIs is recommended

- Outcomes must be measured at baseline and monthly (every 4 weeks)
  - Anxiety symptoms, depressive symptoms, GAD status, patient satisfaction, and acceptability
  - Generalized Anxiety Disorder 7-item (GAD-7) Scale, Patient Health Questionnaire (PHQ-9), Clinical Global Impressions-Improvement (CGI-I) Scale, Patient Satisfaction Questionnaire (PSQ), and attrition rate
To: Alesha McClanahan

From: Rasha Abed
    Associate Director of Sponsored Research

RE: Anxiety is Something to Worry About: The Effects of a Cognitive Behavioral Therapy (CBT) and Selective Serotonin Reuptake Inhibitor (SSRI) Intervention Protocol on Symptoms of Generalized Anxiety Disorder (GAD)

Date: September 21, 2018

The IRB has approved the above study on September 20, 2018. The project was reviewed in accordance with all research statues and regulations pursuant to Federal regulations, 45 CFR 46.101(b).

The researcher has approval of this project until one year from the identified date.

If additional protocol changes are needed, approval must be sought from the IRB prior to implementing those changes. Please submit a new expedited request to the IRB for consideration.

When the project is completed, notify the IRB. If the research protocol needs to extend beyond one year, written approval must be sought from the IRB.

Good luck with your work. Please retain a copy of this letter for your records.
Current, high quality evidence supports the combined use of cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitor (SSRI) medication as the best treatment for generalized anxiety disorder (GAD) in children, adolescents, and adults. The purpose of both CBT and SSRIs for GAD is to help manage anxiety by decreasing symptoms of anxiety and depression. An SSRI is an oral antidepressant medication used to treat GAD as well as depression, which is strongly linked to GAD. SSRIs are typically well tolerated and safe. CBT is a noninvasive, nonpharmacologic treatment that aims to change ways of thinking to elicit more positive thoughts and teach ways to cope. Self-administered CBT via workbook is recommended as an inexpensive, convenient, and effective form of CBT. Information regarding cost, examples, and where CBT workbooks are available for purchase is listed below.

There are a multitude of other CBT workbooks available for purchase both online and in stores. Other methods of CBT to consider include mobile apps, free online resources including CBT worksheets, and counseling with a licensed therapist. Consult with your provider if you have any questions or would like more information. Combination therapy with CBT and SSRI medication should be considered for the treatment of anxiety as it has been shown to decrease anxiety and depression symptoms within current research and evidence-based practice.