The Effect of Implementing a Generalized Anxiety Disorder Protocol for Anxiety and Depression Symptoms in the Primary Care Setting

Bailey J. Hinman

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THE EFFECT OF IMPLEMENTING A GENERALIZED ANXIETY DISORDER PROTOCOL FOR
ANXIETY AND DEPRESSION SYMPTOMS IN THE PRIMARY CARE SETTING

by

BAILEY J. HINMAN

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

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DEDICATION

This project is dedicated to my wonderful family and friends. To my wonderful parents, Todd and Robyn Hinman, thank you for raising me up to believe that I can make it up any hill I attempt to climb. Thank you for your unwavering support of all of my endeavors. You are the most selfless people that I know. Thank you for your daily sacrifices you make so that I am able to chase my dreams. All that I am is because of you. To my wonderful boyfriend, Collin Sherburne, thank you for all of your patience, understanding, and encouragement. Thank you for chasing your dreams alongside of me and mine. To my dearest friends, thank you for giving me a release from the stress of graduate school and for supporting me during this time in my life.
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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEDICATION</td>
<td>II</td>
</tr>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>IV</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>V</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>VII</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>VIII</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>IX</td>
</tr>
<tr>
<td>CHAPTERS</td>
<td></td>
</tr>
<tr>
<td>CHAPTER 1 – Introduction</td>
<td>1</td>
</tr>
<tr>
<td>CHAPTER 2 – EBP Model and Review of Literature</td>
<td>6</td>
</tr>
<tr>
<td>CHAPTER 3 – Implementation of Practice Change</td>
<td>28</td>
</tr>
<tr>
<td>CHAPTER 4 – Findings</td>
<td>35</td>
</tr>
<tr>
<td>CHAPTER 5 – Discussion</td>
<td>52</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>67</td>
</tr>
<tr>
<td>AUTOBIOGRAPHICAL STATEMENT</td>
<td>70</td>
</tr>
<tr>
<td>ACRONYM LIST</td>
<td>71</td>
</tr>
<tr>
<td>APPENDICES</td>
<td></td>
</tr>
<tr>
<td>APPENDIX A – Evidence Table</td>
<td>72</td>
</tr>
<tr>
<td>APPENDIX B – Education Provided to Patients</td>
<td>85</td>
</tr>
<tr>
<td>APPENDIX C – PowerPoint Provided to Providers</td>
<td>88</td>
</tr>
<tr>
<td>APPENDIX D – Clinical Decision Tool Provided to Providers</td>
<td>90</td>
</tr>
<tr>
<td>APPENDIX E – Demographic Form</td>
<td>91</td>
</tr>
</tbody>
</table>
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1 Demographic Characteristics</td>
<td>37</td>
</tr>
<tr>
<td>Table 2 One-Way Repeated Measures ANOVAs with Means and Standard Deviations for Primary Outcomes</td>
<td>46</td>
</tr>
<tr>
<td>Table 3 Follow Up Protected $t$-tests for Primary Outcomes</td>
<td>47</td>
</tr>
<tr>
<td>Table 4 Paired Samples $t$-tests for Secondary Outcomes</td>
<td>51</td>
</tr>
</tbody>
</table>
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>JHNEBP Model</td>
<td>7</td>
</tr>
<tr>
<td>Figure 2</td>
<td>PRISMA Flow Diagram</td>
<td>13</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Demographic Information: Sex</td>
<td>39</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Demographic Information: Education Level</td>
<td>40</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Demographic Information: Race</td>
<td>40</td>
</tr>
<tr>
<td>Figure 6</td>
<td>Demographic Information: Health Insurance</td>
<td>41</td>
</tr>
<tr>
<td>Figure 7</td>
<td>Demographic Information: Marital Status</td>
<td>41</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Demographic Information: Annual Gross Household Income</td>
<td>42</td>
</tr>
<tr>
<td>Figure 9</td>
<td>Demographic Information: Current Employment Status</td>
<td>42</td>
</tr>
</tbody>
</table>
ABSTRACT

Generalized anxiety disorder (GAD) is very prevalent in the United States with 5.7% of citizens affected (National Institute of Mental Health [NIMH], 2017). This number is expected to be even higher because individuals avoid care due to stigma of mental illness (Andrews et al., 2018). GAD can have significant implications such as decreased ability to function, decreased quality of life and increased risk of suicide (Fong, 2018; Lizarondo, 2018). The purpose of this project was to improve outcomes for adult patients with GAD in the primary care setting by improving treatment to follow best practice recommendations. The Johns Hopkins Evidence Based Practice Model was utilized as a guide throughout this project. After a thorough literature search, it was concluded that best practice for treatment of GAD is with a protocol of a combination with education provided through written and verbal transmission, cognitive behavioral therapy (CBT) via smartphone application (app) and pharmacologic therapy via a selective serotonin reuptake inhibitor (SSRI). This protocol was initiated among patients at a rural family practice office in Northeast Indiana. The patients’ anxiety and depression symptoms were measured via the Generalized Anxiety Disorder 7-item (GAD-7) scale and Patient Health Questionnaire (PHQ-9) at baseline, and at weeks 4, 6 and 12. A one-way repeated measures analysis of variance (ANOVA) was conducted to analyze scores and found statistically significant differences in anxiety ($F(3,39) = 6.992, p < .001$) and depression ($F(3, 39) = 8.867, p < .000$) symptoms from baseline ($M = 12.5714, SD = 6.51288; M = 12.4286, SD = 7.70329$) to eight weeks ($M = 5.2857, SD = 4.26846; M = 4.7143, SD = 4.51372$) and from baseline to 12 weeks ($M = 6.1429, SD = 5.88162; M = 4.6429, SD = 5.25660$). Primary care providers are encouraged to treat patients with GAD utilizing education, CBT via smartphone app, and SSRIs due to the protocol’s cost-effectiveness, accessibility, and efficacy.

Keywords: GAD, evidence-based practice, CBT, SSRI, education, protocol
CHAPTER 1

INTRODUCTION

Background

Generalized anxiety disorder (GAD) is a very common disorder that is often addressed in the primary care setting (Andrews et al., 2018). GAD can be defined as chronic, excessive worry and stress associated with clinically significant distress and functional impairment. This disorder is often accompanied by physical symptoms such as insomnia, restlessness, muscle tension and fatigue (Love & Love, 2019). The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) provides diagnostic criteria for GAD that can be used as a guideline to ensure correct diagnosis (American Psychiatric Association, 2013). The adult patient must have excessive worry with at least three other symptoms on a majority of days for at least 6 months (American Psychiatric Association, 2013). GAD may result from abnormal serotonergic and noradrenergic neurotransmitter activity and cortisol systems (DynaMed, 2018). Although, genetic and lifestyle factors can also play a role in disease formation. Of adults in the United States, GAD is more common in females (3.4%) than males (1.9%) (National Institute of Mental Health [NIMH], 2017). There is also a higher incidence in Caucasians. Patients who have family history of GAD, have history of trauma or abuse, and those with a high level of stress are more at risk of developing GAD (DynaMed, 2018). Individuals with poor family support or other comorbid psychological conditions such as substance use disorder or major depressive disorder have decreased remission rates (DynaMed, 2018). Most cases of GAD begin in early adulthood. Median age of onset is 30 years of age in adults. There is usually another upswing of cases that occurs at older adulthood that can be linked to chronic medical illnesses (DynaMed, 2018).

GAD can cause serious debilitation and impact on quality of life. Out of the results from one survey, an estimated 32.3% of adults with GAD had serious impairment (NIMH, 2017). This
impairment can come in the form of inability to perform routine tasks, decreased productivity, lack of sleep, and impairment of personal relationships. GAD can have serious consequences such as an increased risk of suicide (DynaMed, 2018). 37.6% of patients with lifetime GAD attempted suicide as compared to 4.2% of people without GAD (Fong, 2018). This disease can go beyond just psychological consequences as patients with GAD have also been shown to have increased rates of cardiovascular related mortality (DynaMed, 2018).

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

Primary care is often the place where patients first go when they decide to seek treatment for their anxiety disorder. It is estimated that 15-20% of patients in primary care settings meet the criteria for anxiety disorders (Love & Love, 2019). Often, they can present with physical symptoms that are often vague, which can make it hard for primary care providers to make a correct diagnosis (Slee et al., 2019). Patients with GAD are two times more likely than the general population to present initially with somatic complaints (Love & Love, 2019). Further, many psychiatric disorders are often somewhat similar and can occur concurrently, increasing the complexity of diagnosis (Andrews et al., 2018). Often times, anxiety goes unrecognized in the primary care setting (Andrews et al., 2018). Adults with untreated anxiety disorders miss on average 24.7 days of work per year due to the diagnosis (Love & Love, 2019). Untreated GAD can contribute extensively to health care costs. In the United States, societal costs of GAD are estimated to be 48 billion dollars per year (Love & Love, 2019). Some primary care providers may be reluctant to treat GAD as they are unfamiliar with the treatment or would feel more comfortable referring to a psychiatrist. Often, when treated in the primary care setting, GAD is not treated appropriately according to the guidelines and is often undertreated (Ministry of Health, 2015). However, the primary care setting is an appropriate setting for most cases of GAD (Andrews et al., 2018)

**National Data**
GAD is prevalent in the United States as well as other countries. Approximately 5.7% of adults in the United States have experienced generalized anxiety disorder (National Institute of Mental Health [NIMH], 2017). This number is assumed to be actually higher due to fact that approximately one third of affected patients seek treatment (Edmund & Sheppard, 2018) due to stigma or other barriers (Andrews et al., 2018). When they present to the primary care setting, providers need to be equipped with the knowledge and resources that they need in order to diagnose and treat the patient properly.

Data from the Clinical Agency Supporting Need for the Project

This evidence-based practice (EBP) project was conducted at a family practice clinic in Northeast Indiana. The clinic is part of a small healthcare system and has three providers in the office, two nurse practitioners and a physician. There are at least seven different medical assistants or nurses providing care on any particular day. All three providers and the office manager approved the EBP project. One nurse practitioner served as the site facilitator. Clinical agency data were provided by the office manager. The clinic is located in a rural town with a population of 8,732 people in 2019 (United States Census, 2019). Approximately 95.5% of those individuals are Caucasian. Most (76.5%) citizens of the town have an Internet subscription. The number of residents with a high school diploma is approximately 86.8% (United States Census, 2019). The clinic sees all ages of individuals from birth to death.

The site facilitator mentioned that the practice in general writes an abundance of benzodiazepine prescriptions for patients, and that all three providers were looking to improve the care of patients with anxiety disorder (A. Reitz, personal communication, July 8, 2020). There are a significant number of patients treated with anxiety disorder in the practice. In fact, 800 different patients were seen for GAD from January 2018 to September 2020 at this family practice clinic. There were 1,809 visits during that time frame evaluating and treating those patients for GAD. None of the charts that were reviewed mention CBT specifically, but may be
assumed when the patient is referred to psychiatry. One of the providers discussed that a big challenge is the patient’s preference to “take a pill and feel better” instead of pursuing things like psychiatric referral, counseling, or cognitive behavioral therapy (CBT) (B. German, personal communication, July 8, 2020). This Doctor of Nursing Practice (DNP) project could reduce the need for benzodiazepine usage, increase quality of life for patients, and decrease symptoms for patients.

**Purpose of the Evidence-Based Practice Project**

The purpose of this EBP project was to improve outcomes for adult patients with GAD by improving treatment to follow best practice recommendations. This was be done by providing a protocol that includes a combination of education, digital CBT and SSRI therapy to deliver evidence-based treatment to patients with GAD. The project aimed to decrease uncertainty of providers, improve consistency of care in the best practice for treatment of GAD while decreasing symptoms of GAD for patients.

**PICOT Question**

This project addressed the following PICOT question: Among adult patients presenting with generalized anxiety disorder (GAD) in the primary care setting (P), does the introduction of a protocol consisting of treatment with education via a written handout, a selective serotonin reuptake inhibitor (SSRI) and digital cognitive behavioral therapy (CBT) via smartphone application (app) (I) compared to 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 and Patient Health Questionnaire 9-item (PHQ-9) scale (O) over a 12-week period (T)?

**Significance of the EBP Project**

GAD is a very prevalent, severe disease that can often be debilitating and can cause negative health outcomes (Edmund & Sheppard, 2018). There is a stigma associated with mental illness that can cause patients to avoid receiving treatment (Edmund & Sheppard, 2018).
More education on GAD can help to decrease stigma by increasing awareness of this issue and by making patients aware that they are not alone (Ministry of Health, 2015). Patients present to the primary care setting in distress and want some relief of their symptoms. Primary care providers are more readily accessible than specialists’ offices and have been found to be an appropriate setting to diagnose and treat GAD (Andrews et al., 2018). This project aimed to implement a practice change based on current, high quality evidence-based practice recommendations in the primary care setting. This practice change involved a protocol with education, CBT via smartphone app and SSRI pharmacotherapy. Application of this protocol helped primary care providers to gain knowledge regarding diagnosis and treatment of GAD and guide treatment that is based on best evidence. Use of the protocol can decrease patient’s symptom severity, increase quality of life, and decrease the rate of suicide and cardiovascular disease (DynaMed, 2018; Fong, 2018). These improved outcomes can allow patients to return to a productive, fulfilled and healthy life.
CHAPTER 2
EBP MODEL AND REVIEW OF LITERATURE

Evidence-based Practice Model

Overview of EBP Model

The Johns Hopkins Nursing Evidence-based Practice Model (JHNEBP) was selected to act as a guide for this EBP project. The third edition of this model serves as a guide for frontline nurses who are striving to improve patient outcomes by translating research into practice.

Evidence-based practice is a way that nurses can continuously improve quality, safety and cost effectiveness of care received by patients (Dang & Dearholt, 2017).

The JHNEBP model starts with inquiry (Dang & Dearholt, 2017). An individual must want to learn and determine whether current practice and best practice are equivalent for a specific patient population or a specific problem. The next step of the model involves the practice question, evidence, translation (PET) process. There are 19 steps in this process which occurs within these three phases. The first phase involves generating an interprofessional team, defining the problem, developing and refining the EBP question, identifying stakeholders, determining responsibility for project leadership and scheduling team meetings. This could be considered the planning step. The evidence phase is next, which is comprised of steps seven-11. The team must conduct a search for evidence, appraise the level and quality of the pieces of evidence, summarize the evidence, summarize overall strength and quality of evidence, and develop recommendations for change based on evidence synthesis. In the last phase, translation (steps 12-19), the team implements and evaluates the action. More specifically, the team will determine fit, feasibility, and appropriateness of recommendations, create an action plan, secure support and resources to implement the action plan, implement the action plan, evaluate the outcomes, report the outcomes, identify the next steps and disseminate findings. This process generates best practice, which eventually leads to practice improvements. It is
important to note that at any time in the process, learning is happening and can lead to inquiry about another problem or population and the model can be implemented again with the new topic (Dang & Dearholt, 2017). Figure 1 provides a visualization of the JHNEBP model for clarity.

**Figure 1**

*JHNEBP Model*

*Note.* The JHNEBP Model was used with permission.

**Application of EBP Model to EBP Project**

The JHNEBP model was selected for this EBP project due to its detailed nature, which provides more guidance to the DNP student. The purpose of the JHNEBP model was to serve as the facilitator to motivate nurses to translate research into practice change which will benefit patients (Dang & Dearholt, 2017). This coincides with the purpose of this EBP project. The
spirit of inquiry was initiated because the DNP student was curious about evidence-based practice, had worked in the particular clinical setting, and was aware of the large number of patients with GAD. While completing clinical hours there as a student, she wondered if the current practice for GAD was evidence-based. The EBP project team was created which included one of the nurse practitioners at the office who served as the site facilitator, the office manager, and the charge nurse. Stakeholders such as the physician at the office, the other nurse practitioner, and the medical assistants and nurses were involved and notified of the project. EBP project team meetings were scheduled. The DNP student was the leader of the meetings. The purpose of the meetings was to assemble to discuss current practice, review best practice, and how to implement that at this particular office. Facilitators and barriers were discussed at these meetings along with logistics of the project. A thorough review of literature was conducted. The literature was leveled and appraised including evidence from level one to five and mostly high-quality evidence. A summary was provided of the pieces of literature the nurses and the providers in the office. The literature was synthesized. Recommendations that a protocol including education on disease, treatments, and adjunctive therapy, combined with pharmacological therapy of selective serotonin reuptake inhibitors (SSRIs) and CBT was best practice was developed based on the evidence synthesis. Finally, this protocol was implemented in accordance with the action plan. The protocol was evaluated with the site facilitator to build upon the strengths and limit the barriers of the project to ensure longevity of this project. Findings were presented to the EBP project team and other staff at the facility. Findings were also disseminated at the University of Iowa’s EBP conference.

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

Strengths of the EBP model include that it provides very detailed steps providing a guide for the DNP student, making it less overwhelming and more manageable to perform the EBP process. Using an EBP model can increase the number of nurses willing to participate in EBP
projects by reducing barriers. These detailed steps follow the nursing process steps of assessment, plan, implement, and evaluate, which can make the EBP process more understandable to nurses working in the field. Participating in EBP projects with the assistance of an EBP model can increase nurse’s involvement making them more satisfied and willing to be change agents.

Limitations of the model include its complexity with overarching phases with multiple steps implemented within each phase. In order to be able to use the model to its full capacity, a thorough review of the model has to be done. Another limitation is the lack of flexibly of this model. For example, due to the COVID-19 pandemic, the DNP student could not get into the facility during the first half of the summer in order to do the practice question step of the PET process. Being in the clinical setting while developing the practice question is ideal because a clinical problem can be identified with the EBP project team members. Thus, a modified version of the practice question step was performed and then the DNP student moved on to the evidence step in order to facilitate progress of the project. The DNP student used her prior experience at this office to establish that the clinical problem of treatment of GAD could be addressed. The DNP student cleared this with the EBP team via email due to limitations. Meetings with the EBP team needed to be postponed until the pandemic was under greater control, and the DNP student had gotten clearance from the university. Once the DNP student was allowed to return to the clinical setting, the practice question step was done more thoroughly, including implementing EBP project team meetings, and assessing current practices. Modifications to the process are not necessarily explained by Dang and Dearholt (2017), which brings about concerns that modifications may not be acceptable.

**Literature Search**

**Sources Examined for Relevant Evidence**
An exhaustive literature search was performed to find the most current, relevant evidence regarding best practice for the treatment of GAD in the family practice setting. A total of seven databases were searched, along with hand searching and citation chasing. The databases searched included Joanna Briggs Institute (JBI), Cochrane Library, Trip Database, MEDLINE with Full Text, CINAHL, PsycINFO, and PsycARTICLES. JBI and Cochrane Library were utilized because they yield high level evidence of multiple studies such as evidence summaries, and systematic reviews. CINAHL and MEDLINE with Full Text were chosen for use due to their ability to produce relevant individual studies such as randomized control trials (RCTs). Trip Database was searched in order to generate clinical practice guidelines (CPGs), which are a high level of evidence. PsycINFO and PsycARTICLES were searched to obtain high level pieces of evidence such as RCTs and because of the psychological nature of the project topic of GAD.

Inclusion and exclusion criteria were applied to ensure high level, current, relevant, and applicable evidence was arrived at. Inclusion criteria consisted of scholarly, peer reviewed sources, provided in the English language, published within the last five years, from 2015-2020, about GAD. Exclusion criteria included any evidence that pertained to children, any evidence that included interventions that were not relevant to the family practice setting and evidence that focused on comorbidities such as cancer or addiction.

The literature search began with JBI. A search using “generalized anxiety disorder*” OR “anxiety disorder*” with the limiter of 2015- current was used. This search generated 88 results six of which were accepted for inclusion in the evidence synthesis. All six pieces of evidence were JBI evidence summaries.

The next database utilized was the Cochrane Library. The keywords “generalized anxiety disorder*” OR “anxiety disorder*” with the limiter of January 1, 2015- June 1, 2020 was used. Twenty-two results were obtained. There was one relevant piece of evidence from 2016
that was found in the literature search. However, this piece of evidence was unavailable and could not be obtained, and therefore was not used.

The literature search was continued with CINAHL, a search including the key words, “generalized anxiety disorder*” OR “anxiety disorder*” AND treat* OR intervent* OR manage* AND “primary health care” OR “primary care” OR “family practice” AND adult* yielded an appropriate amount of evidence with relevant results. The limiters of scholarly (peer reviewed) journals, 2015-2020, English language, and research article were applied. Use of these search terms will be referred to as the “full search”. 78 results were arrived at, of which one RCT was accepted.

The Trip Database was used next to find CPGs on the topic of GAD. The full search yielded the best results but had to be modified to accommodate the lack of multiple fields and was as follows, (“generalized anxiety disorder*” OR “anxiety disorder*”) AND (treat* OR intervent* OR manage*) AND (“primary health care” OR “primary care” OR “family practice”) AND adult*. The limiters that were put in place were since 2015 and guidelines. When USA guidelines was implemented, there were 48 results, none of which were relevant to the EBP project. Broadening the parameters to guidelines, rather than USA guidelines, generated more relevant results. Thus, two pieces were accepted to provide supporting evidence for the EBP project.

The next database that was searched was MEDLINE with Full Text. A slight change from the full search was implemented. A major heading was utilized of (MH “anxiety disorders”) and treat* OR intervent* OR manage* AND “primary health care” OR “primary care” OR “family practice” AND adult* with the limiters of scholarly (peer reviewed) journals, English language and 2015-2020 and generated 150 results. One piece of evidence was chosen for the evidence synthesis. This piece of evidence is a preliminary report on a non-randomized control trial.
Next, the database PsycINFO was investigated. A MESH heading was utilized to limit results. The following search was conducted, MM “generalized anxiety disorder” AND treat* OR intervent* OR manage* AND “primary health care” OR “primary care” OR “family practice” AND adult* with the limiters of scholarly (peer reviewed) journals published from 2015-2020, which generated 6 results. After reviewing those, one systematic review was chosen to be included in the evidence synthesis.

Concluding the list of databases, PsycArticles was searched using the full search with the limiters of scholarly (peer reviewed) journals and 2015-2020. This search produced 7 articles, some of which were duplicates, and none were included for use in the evidence synthesis. Figure 2 is a PRISMA flow diagram that depicts the literature search and narrowing of sources.
Figure 2

PRISMA Flow Diagram

Records identified through database searching  
(n = 377)  
Additional records identified through other sources  
(n = 9)

Records after duplicates removed  
(n = 280)

Records screened  
(n = 200)  
Records excluded  
(n = 150)

Full-text articles assessed for eligibility  
(n = 65)  
Full-text articles excluded, with reasons  
(n = 54)

Studies included in review  
(n = 11)

Note. A figure describing the literature search

Citation chasing was performed in order to find more evidence from the reference lists of all six pieces of evidence from JBI. Nine current pieces of evidence were obtained from the reference list of the six JBI studies, none of which were found to be relevant for inclusion in the evidence synthesis. The JBI studies provided enough clear data and information on the individual studies, thus the individual studies were not necessary for inclusion.
A hand search of the American Journal of Psychiatry was conducted of the issues published in 2020. One relevant piece of evidence was obtained, although it was not chosen for use in the evidence synthesis because it was a low-level opinion-based editorial with no scientific base.

There was a total of 377 pieces of evidence obtained during the literature search. These pieces of evidence were narrowed down initially from a review of their titles and abstracts and excluded if they were not relevant to GAD in the primary care setting or failed to meet inclusion or exclusion criteria. Duplicate articles were also removed. After this initial tidying, 65 articles were extensively reviewed to determine which pieces of evidence were relevant to the EBP project. After thorough review and evaluation, 11 pieces of evidence were included based on their strength and applicability to the clinical setting and patient population to support the particular EBP project.

**Levels of Evidence**

Melnyk and Fineout-Overholt's (2015) Hierarchy of Evidence was used to rank the pieces of evidence by level. In the Hierarchy of Evidence, there are seven levels, with the first level being the strongest, highest level of evidence, and the seventh being the lowest based on type of study and how well it was conducted. Level I evidence includes evidence from a systematic review or meta-analysis of all relevant RCTs. Level II evidence is from well-designed RCTs. Level III evidence would be defined as obtained from well-designed controlled trials without randomization. Level IV evidence is from well-designed case-control and cohort studies. Evidence from systematic reviews of descriptive and qualitative studies is categorized as level V evidence. Level VI incorporates evidence from a single descriptive or qualitative study. Lastly, evidence from the opinion of authorities and/or reports of expert committees are considered level VII evidence (Melnyk and Fineout-Overholt, 2015).
Out of the 11 pieces of evidence that were chosen for the final literature review there was a combination of evidence summaries, systematic reviews, CPGs, RCTs, and a preliminary report on a non-randomized control trial. Six were evidence summaries from JBI, five of which are level I evidence, and one of which is considered level III evidence. One systematic review was chosen, which was considered level I evidence from Psych Info. Two CPGs from the Trip Database were selected for use, both are considered level I evidence. The RCT was found in CINAHL and is classified as level II evidence. Lastly, a level III preliminary report on a non-randomized control trial was found in Medline.

Appraisal of Relevant Evidence

After ranking the evidence by level, an appraisal of the quality of each piece of evidence was conducted. This was performed using the Johns Hopkins Research and Non-Research Evidence Appraisal Tools. Permission was requested and granted to utilize the Johns Hopkins Research and Non-Research Tools. The Johns Hopkins Research and Non-Research Evidence Tools characterize evidence into high quality, good quality, and low quality (Dang & Dearholt, 2017). There are different qualifications for the delineations of high, good and low quality depending on the type of evidence appraised. Of the 11 pieces of evidence accepted for the literature review, eight were considered high quality and three were considered good quality. A summary, leveling and appraisal of the evidence accepted in the synthesis is provided (see Appendix A).

Level I Evidence

Andrews, Bell, Boyce, Gale, Lampe, Marwat, Rapee and Wilkins (2018). A level I CPG sponsored by the Royal Australian and New Zealand College of Psychiatrists gives practitioners a guide to treatment of adults with panic disorder, social anxiety disorder, and GAD. The CPG provides parameters for diagnosis and assessment strategies.
This CPG was appraised at a high-level of evidence. There was a clear scope and purpose. The literature review was thorough. The types of evidence included were systematic reviews and meta-analyses. The inclusion and exclusion criteria were given. Limitations of the evidence were given in an honest and unbiased fashion. There was a sufficient amount of well-designed studies in the literature review. The groups to which the recommendations apply and do not apply are acknowledged. For example, there are separate sections on treatment-refractory GAD and GAD in pregnancy. Each recommendation has a leveling system associated with it and is clear. The guideline was sponsored by a professional organization and was published within the last 5 years.

Lizarondo (2019). An evidence summary was produced to discuss the evidence regarding relaxation therapy for patients with GAD. This evidence summary is from a combination of two systematic reviews and was rated high-quality. The literature search conducted was thorough and included high-level evidence and although there were not many systematic reviews, in total 66 RCTs were summarized. This summary is recent as it was published within the last 5 years and contains systematic reviews from 2018. The recommendations are clear and do not inflate the evidence from the research.

Jayasekara (2016). An evidence summary that discussed psychotherapy for patients with GAD was included in the synthesis. There were four Cochrane reviews, a meta-analysis, four RCTs and an RCT pilot study included in the evidence summary. This evidence summary was rated a high-quality level. The purpose, clinical question and intended population were clear. The recommendation was based on research. There was a large number of pieces of evidence included in the summary from a wide variety of years.

Lizarondo (2020). Another piece of level I evidence addressed exercise for patients with GAD. This JBI evidence summary was comprised of a systematic review with 12 RCTs and five meta-analyses, another systematic review of eight RCTs, and two different CPGs. This
piece of evidence was appraised as high-quality evidence. The author identifies the levels of each piece of evidence and a grade to the recommendation as well. All of the evidence summarized was of high-level. The evidence summary was clear and provided unbiased findings.

**Ministry of Health (2015).** This level I CPG is a compilation of all the best available evidence related to anxiety disorders and was appraised as good quality. The material was officially sponsored by a government agency and results and recommendations were clear with ratings and leveling provided. Groups to which the evidence applies and does not apply were clearly delineated. It is stated in the CPG that an extensive review of relevant literature, including CPGs and expert consensus, was performed, however, no more details were given in this edition of the guideline about the literature search. This limits the ability to consider this piece of evidence high quality.

**Romano (2019).** A JBI evidence summary about self-help was chosen for this literature review due to its relevance to the EBP project. The evidence summary included four systematic reviews, five meta-analyses, two RCTs and a Cochrane review. This piece was appraised as high-quality evidence. The types of evidence included are all high level. The author explicitly states what patient population the recommendations are geared toward. Each recommendation has a leveling system attached to it to delineate the strength of the recommendation. All results reviewed and recommendations are clear and are based on scientific evidence.

**Slade (2019).** Another JBI evidence summary that is based on nine systematic reviews, a CPG and a prospective trial was included in the synthesis. This evidence summary discussed pharmacotherapy for patients with GAD. This piece was appraised as high-quality evidence. This level I evidence summary included a thorough description of its purpose. The target population, evidence and recommendations were clearly stated. The sources that were used
were of high quality and from 2007-2019. There was a clear, brief summary of all results from the included evidence. The recommendation was clearly linked to a research base.

**Slee, Nazareth, Bondaronek, Liu, Cheng and Freemantle (2019).** A systematic review and network meta-analysis was performed to explore pharmacologic treatments of GAD. 89 trails were chosen for the review after a thorough literature review in multiple databases was conducted. All of these were RCTs. This level I systematic review was appraised as high quality. A thorough search was conducted using multiple databases. Inclusion and exclusion were clear. A flow diagram was used to delineate how the studies were selected and which were eliminated at what level. Limitations to this study are addressed and future recommendations are made. Specific details about each pharmacologic therapy are included in clear tables. Results are interpreted and conclusions are clear.

**Level II Evidence**

**Berger, Urech, Krieger, Stolz, Vincent, Moser, Moritz, and Meyer (2017).** An RCT was conducted to investigate whether transdiagnostic, unguided internet cognitive behavioral treatment (ICBT) for anxiety disorders is more effective in primary care settings than care as usual. This piece of evidence was deemed good quality level of evidence. The purpose of the study was articulated well. The sample size was small with 139 subjects, considering the researchers aim was to obtain 176 subjects, but they were still able to have sufficient power (>0.80). A thorough literature review was performed, and recommendations are based on that as well as the researchers own results. There were no statistically significant differences between the control group and the experimental group on demographic characteristics or other variables. The researchers reported some limitations including the fact that generalizability is limited given that Velibra was a very specific intervention. The lack of generalizable results was the reason that this piece of evidence did not receive a high-quality rating. The control group was given access to the intervention at the end of the study period, increasing the studies
ethical strength.

**Level III Evidence**

Lizarondo (2018). An evidence summary written by Lizarondo (2018) discussed smartphone-based interventions as best practice to treat GAD. The subject matter that was reviewed was clearly stated. The literature review was done using a structured search and included mostly high-level evidence. The literature was relevant and within the last five years. There was a clear conclusion drawn from the evidence reviewed with rationales. The recommendation was determined to be grade B. This piece of evidence only reviewed three pieces of evidence, one of which was a systematic review of nine studies. This could limit its strength. However, smartphone-interventions are a new topic, therefore research already conducted and published may be limited. Thus, this piece of evidence was given a rating of high quality.

**Level V Evidence**

Yu, Szigethy, Wallace, Solano and Oser (2018). This piece of evidence is a preliminary report on a non-randomized control trial. This piece of evidence was appraised as good quality. The purpose of the study is clearly presented. The intervention was clearly stated. There was a high rate of loss of participants, which limits the strength of this study. Originally, 593 individuals consented to participate in the study, but only 310 actually installed the app-based intervention called Lantern. Further, only 63 of those completed both baseline and two-month GAD-7 measurements. The outcome measures were clear, the GAD-7 had a Cronbach alpha > 0.70. The results are clear and have clinical significance. Tables are used to increase clarity. A disclosure notice of potential bias is given.

**Construction of Evidence-based Practice**

**Synthesis of Critically Appraised Literature**
The literature indicated consistent results and recommendations for best practice for the treatment of GAD. The included evidence overall is strong consisting mostly of level I high-quality evidence. Common themes were generated from these consistent results. The evidence indicated that treatment of adults with GAD should include (a) education about disease etiology and lifestyle factors such as relaxation techniques and exercise, (b) CBT administered in the form of a smartphone app, and (c) SSRI pharmacotherapy.

**Population**

The literature reviewed mainly addressed adults aged 18 and over (Andrews et al., 2018; Berger et al., 2017; Ministry of Health, 2015; Romano, 2019; Slade, 2019; Slee, 2019; Yu et al., 2018). Pediatric GAD treatment is complex making the primary care setting potentially inappropriate (Andrews et al., 2018; Ministry of Health, 2015). Adult patients should be diagnosed with GAD by a provider using the DSM V criteria (Andrews et al., 2018). This criteria for diagnosis of GAD includes a) 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). Patients with suicidal ideations, psychosis, substance use disorders or personality disorders are often excluded due to the complexity, and providers are typically directed to refer these patients to psychiatry (Andrews et al., 2018; Berger et al., 2017; Ministry of Health, 2015; Yu et al., 2018). The patients were under outpatient management, rather than in inpatient settings, as again, this is something that is beyond the scope of a primary care provider.

**Interventions**

**Education.** The literature clearly states that patients with GAD should be educated about their disease process, treatments, relaxation techniques and lifestyle modifications (Andrews et al., 2018; Berger et al., 2017; Lizarondo, 2019; Lizarondo, 2020, Ministry of Health, 2015; Yu et al., 2018). Although it is not stated precisely how this education should be implemented, it is clear that it should be provided. Options for modes of education include verbal communication, written handouts, during beginning portions of CBT or in a combination of these (Andrews et al., 2018; Berger et al., 2017; Yue et al., 2018). This information should be from reliable sources and provided in a way that is understandable to the patient, including in their language of choice, and at a level the patient can understand without difficulty (Andrews et al., 2018). The CPG by Ministry of Health (2015) recommends that education include the cause of GAD, prognosis, and that GAD is a common disorder experienced by many (Ministry of Health, 2015).

Decisions about treatment should be made using shared decision making, which incorporates the provider’s expertise, the patient’s preferences and the best practice evidence (Slade, 2019). In order for patients to be able to make a decision regarding treatment of GAD, they must be informed about all options for treatment. Information that should be incorporated
includes but is not limited to, treatment description, cost, adverse effects, length of treatment and importance of consistent use (Andrews et al., 2018; Ministry of Health, 2015).

Information about relaxation techniques should be provided as part of the education (Andrews et al., 2018; Lizarondo, 2019; Ministry of Health, 2015). Primary care providers and nurses can be trained to educate patients about relaxation techniques including breathing control, meditation and progressive muscle relaxation (Ministry of Health, 2015). These therapies can be an easy, inexpensive, and effective method to reduce anxiety symptoms and improve quality of life (Andrews et al., 2018; Lizarondo, 2019). One systematic review found that relaxation techniques were as effective as CBT for treatment of GAD (Lizarondo, 2019).

Lifestyle modifications can not only improve the symptoms of anxiety but can also improve overall health and wellbeing for patients with GAD (Lizarondo, 2020). Exercise has been shown to be effective in improving anxiety symptoms, reducing physical symptoms and improving quality of life (Lizarondo, 2020; Andrews et al., 2018). While there are no specific recommendations for exercise, encouraging patients to perform aerobic, non-aerobic and/or resistance training can be of benefit (Lizarondo, 2020; Ministry of Health, 2015). Other self-care methods such as healthy eating, adequate sleep, and reduction of caffeine, tobacco, drugs and alcohol can also reduce anxiety symptoms (Ministry of Health, 2015; Andrews et al., 2018). In mild cases of GAD, education along with relaxation techniques and lifestyle factors may be enough to effectively treat symptoms, with minimal to no adverse effects, and minimal health care costs (Andrews et al., 2018).

**CBT.** There is a consensus that CBT is the most effective psychological intervention for reducing anxiety symptoms, backed by an astonishing amount of high quality, high level evidence (Andrews et al., 2018; Berger et al., 2017; Jayasekara, 2016; Lizarondo, 2018; Ministry of Health, 2015; Romano, 2019; Yu et al., 2018). Not only can CBT be used to improve symptoms, but it can help maintain remission and prevent relapse of GAD (Jayasekara, 2016).
There is much support for the effectiveness of face-to-face CBT administered by a licensed professional (Andrews et al., 2018; Jayasekara, 2016; Ministry of Health, 2015; Yu et al., 2018). However, there are many barriers to face-to-face CBT in both psychiatric and primary care settings including high cost, lack of providers, lack of experience in facilitating CBT, lack of facilities, high time commitment and lack of transportation to the facility (Lizarondo, 2018; Romano, 2019). To combat these barriers, CBT can be conducted through the use of smartphone apps or internet programs. Digital CBT has been shown in some studies to reduce anxiety symptoms, maintain symptom reduction and achieve remission more than waitlist and placebo controls and as effectively as face-to face CBT (Romano, 2019; Yu et al., 2018; Lizarondo, 2018; Andrews et al., 2018). Digital CBT has not only been shown to be effective but has also been shown to increase accessibility to CBT, increase fidelity, decrease costs for the patient and the health system, and be as safe as other methods of CBT (Andrews et al., 2018). There are various programs available that have shown success for treatment of CBT (Yu et al., 2018; Berger et al., 2017). Berger et al. (2017) examined the use of a digital CBT program called Vellibra, where 70 participants were treated with care as usual plus Vellibra and 69 participants were treated with care as usual. Vellibra is an internet intervention that consists of six modules focused on CBT. In this study, there was a significant decrease in Penn State Work Questionnaire (PSWQ) scores from 62.7 (SD = 9.3) pre-treatment to 58.4 (SD = 11.1) post-treatment ($p < 0.05$). At the completion of this study, 44.8% of patients who had GAD no longer met criteria for diagnosis (Berger et al., 2017). Another study by Yu et al. 2018, demonstrated the effectiveness of digital CBT by providing Lantern, a smartphone CBT app to the experimental group. There was a statistically significant decrease in GAD-7 scores from pre-intervention (11.5) to post intervention (9.4) ($p = 0.009$) (Yu et al., 2018). Patients should be given instructions on how to use the chosen program and they should work through the program for at least six weeks (Romano, 2019). The more patient engagement in a program, the better
the outcomes tend to be (Yu et al., 2018). For example, in one study by Yu et al. (2018), participants who completed three or more units showed a statistically significant GAD-7 reduction as compared with those who completed less than three units. There are minimal adverse effects associated with CBT, increasing its acceptability and strength (Andrews et al., 2018; Yu et al., 2018). A side effect of CBT includes emotional distress brought upon by reviewing traumatic experiences. However, CBT usually produces no serious adverse effects (Andrews et al., 2018).

Pharmacotherapy. The literature also supported use of pharmacotherapy, typically SSRIs for the treatment of GAD (Andrews et al., 2018; Ministry of Health, 2015; Slee et al., 2019; Slade, 2019). SSRIs were found to be more efficacious for treatment of anxiety symptoms compared to placebo (Slade, 2019). While the evidence is clear that SSRIs have the most evidence supporting that they are effective and tolerable for the treatment of GAD, there is conflicting evidence about which SSRI is best. Slade (2019) reported that one review indicated that fluoxetine was most effective, whereas sertraline was most tolerable. However, Slee (2019) after comparing 22 different pharmacologic therapies indicated that escitalopram was found to be the most efficacious and tolerable. According to Slee (2019), sertraline and fluoxetine were also effective and well tolerated, but recommendations were limited due to a smaller sample size. Slee (2019) found that paroxetine was effective but not well tolerated. Some side effects that can occur with SSRIs include nausea, dry mouth, constipation, and drowsiness, which occur more often than with placebos (Ministry of Health, 2015). Benzodiazepines, while effective, are not recommended as first line for the treatment of GAD due to the risk of adverse effects, tolerance, dependence and abuse (Andrews et al., 2018; Ministry of Health, 2015; Slee et al., 2019; Slade, 2019). Propranolol has not been shown to have efficacy in the treatment of GAD (Andrews et al., 2018; Ministry of Health, 2015; Slade, 2019). In review, an SSRI should be chosen with clinical judgment and patient preferences in mind (Slade, 2019).
Combination of SSRI and CBT There was support for the combination of CBT and SSRIs in all patients, but especially in patients with severe disease (Andrews et al., 2018; Slade, 2019; Slee et al., 2019). Severe disease can be defined as a score of 15-21 on the GAD-7 or patients who report extreme distress or functional impairment such as inability to perform a daily role more than seven days per month (Andrews et al., 2018). Combination therapy for a patient already on SSRI therapy can facilitate remission of anxiety and allow weaning from SSRI in order to inhibit long-term pharmacotherapy (Slade, 2019). There was reluctance from some organizations to recommend a combination of face-to-face CBT and pharmacotherapy due to cost, but with digital CBT, cost as a barrier is eliminated or reduced (Ministry of Health, 2015).

Evaluation

Evaluation is an important part of care to ensure the intervention is effective and the patient is improving. During therapy, patients should be evaluated weekly to ensure compliance, adverse effects, and to assess for deterioration of symptoms (Andrews et al., 2018). Typically, medication and CBT start to have some efficacy between 4-6 weeks after initiation, so patients should be assessed using an approved measurement tool at that time (Andrews et al., 2018; Slade, 2019). After the 4-6-week time period, depending on response to initial treatment, adjustments can be made to treatment (Andrews et al., 2018). Slade (2019) suggests that if pharmacologic therapy is not showing any efficacy at 4 weeks, it is unlikely that more time will promote further efficacy.

Outcomes

Many different outcomes measured with many different measurement tools were used among the literature in the literature review. Outcomes included reduction in anxiety symptoms, relapse rate, dropout rate, side effect, quality of life, cost-effectiveness, feasibility, remission rates, tolerability, and engagement. The most commonly used tools were the GAD-7 (Andrews et al., 2018; Ministry of Health, 2015; Yu et al., 2018), PSWQ-3 (Andrews et al., 2018; Berger et
al., 2017), HAM-A (Slee et al., 2019) and the Clinical Global Impression Scale (Ministry of Health, 2015). The GAD-7 is a 7-item screening tool for GAD that can be used to measure the severity of anxiety symptoms. The scores range from 0-21. A score of 10 or greater is suggestive of GAD (Andrews et al., 2018). It is recommended that because of the high rates of comorbidity, a patient suspected to have GAD should also be screened for depression (Andrews et al., 2018). PHQ-9 can be used to screen for depression. This is a 9-item screening tool. In terms of timing of evaluation, most studies used outcomes measurement at pre-intervention and post-intervention (Andrews et al., 2018; Berger et al., 2017; Ministry of Health, 2015; Yu et al., 2018); one study measured outcomes weekly (Andrews et al., 2018).

**Best Practice Model Recommendation**

The reviewed literature indicated the current best practice for the treatment of GAD in adults in the primary care setting includes combination therapy that includes education, CBT and pharmacotherapy. The education addressed disease etiology, disease treatments, and lifestyle factors such as relaxation techniques and exercise. This education was provided in a written handout that was reviewed verbally by the DNP student (see Appendix B). Education about pharmacotherapy was provided verbally by the provider as well. This information was also summarized in the handout given to them. CBT was administered via smartphone app. The particular app that was selected for use is called MindShift. This app is free of charge. The app is only provided in English. The user must create a username and password to log in. This app was created in Canada with support from organizations including Anxiety Disorders Association of British Columbia, Kelty Mental Health Resource Centre and Mental Health and Substance Use Services. This app is designed to help people cope with stress and anxiety and provides education about GAD and CBT as well as self-care and resources such as a thought journal, coping cards and belief experiments. The app also includes relaxation exercises that the patient can perform. Through the app, the patient can also set goals. One example of a goal is lifestyle
changes such as walking 30 minutes in the morning three times a week. MindShift was chosen after a preliminary search and review of apps for anxiety disorder. This app is free of charge and did not include in app purchases. It is backed by medical organizations, such as Mayo Clinic. It is user friendly. The app facilitates CBT rather than just meditation or mindfulness. Lastly, best practice for pharmacotherapy is initiating treatment with an SSRI. In order to promote ease of pharmacologic therapy initiation and titration, a guide was given to the providers in the office that reviewed starting, target and maximum doses for SSRIs, common adverse effects, and contraindications (see Appendix C). A clinical decision tool was given to the providers in the office to help decision making when it comes to responses at the 4-6-week mark, and when to refer patients (see Appendix D). This information aimed to increase provider confidence in prescribing these medications.

In conclusion, a protocol consisting of a combination of education via written and oral methods, CBT via smartphone-app MindShift and pharmacology of SSRI therapy was initiated. This protocol was a combination of the best evidence found in the literature to treat patients with GAD.
CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

The evidence led the DNP student to create a protocol that included education, CBT via smartphone app and SSRI pharmacotherapy. The goal of the protocol was to improve symptoms and quality of life for patients with GAD. On a larger scale, consistent evidence-based treatment across the nation could decrease the number of patients on controlled substances such as benzodiazepines, decrease suicide rates, and standardize care for these patients. Education was provided to the patient via verbal and written modalities. This protocol also included education for the providers about prescribing SSRIs, best practice recommendations for GAD and when they should seek referral for the patient to psychiatry. CBT was conducted via smartphone app. This particular mode of implementation was an attempt to increase access and decrease costs of a specialized treatment. An SSRI prescription was given to patients if not contraindicated.

Participants and Setting

This EBP project took place at a rural family practice office in northeast Indiana that provides primary care services to patients from birth to death. There is one physician who is the collaborating physician for the two nurse practitioners in the practice. One nurse practitioner, who was also the site facilitator has been practicing as a nurse practitioner for 46 years. The other nurse practitioner has been practicing for eight years.

Patients who were eligible for the EBP project include adult patients 18 years of age or older, who have been previously or presently diagnosed with GAD as confirmed by the DSM-5 criteria. The patients had to be able to speak and understand spoken and written English. Patients who were pregnant, had current suicidal or homicidal ideations, active psychosis, and/or concurrent alcohol or drug abuse were excluded from the EBP project, as it would be more appropriate for a psychiatrist to be managing these severe cases. These patients were
referred to a psychiatrist as indicated in the clinical decision tool created for providers. Patients on other psychiatric medications such as benzodiazepines or serotonin norepinephrine reuptake inhibitors (SNRIs) were not excluded as this would have greatly reduced sample size and it would be unethical to cease current anxiety medications. If an SSRI was not contraindicated with current pharmacotherapy, such as in a patient who is prescribed a benzodiazepine, a prescription was provided to the patient. Patients on therapy such as an SNRI where adding an SSRI was not safe, were included in the project as these patients may benefit from the addition of CBT and education.

The DNP student had a list of patients in the practice who have been diagnosed with GAD. This information was provided by the office manager who ran a report on all of the patients who were diagnosed and/or treated with GAD from January 2018- September 2020. A chart review was performed by the DNP student to determine whether patients were eligible. The DNP student had access to patients’ electronic medical record and performed a search to determine which pharmacologic therapy the patients were already on and whether or not inclusion and exclusion criteria were met. This was conducted before the patients were recruited to be in the project. The patients were recruited during their usual clinic appointments, either initial or follow up.

**Pre-Intervention Group Characteristics**

All participants were aged 18 and older. Participants were asked to complete a form with demographic information on it to be used at their initial visit after agreeing to be in the EBP project (see Appendix E). This form helped to gain information about the patient. Data was collected at pre-intervention and post-intervention to determine whether any changes were made during implementation.

**Intervention**
A significant amount of time was spent to plan this EBP project with a foundation in the literature. The evidence base pointed to a combination of education, CBT and SSRI pharmacotherapy. After meeting with the stakeholders, it was decided that many patients in the practice lack access to CBT and financial resources to have the ability to enroll in face-to-face CBT. Therefore, because there was support in the literature for the effectiveness of digital CBT and smartphone app guided CBT, a decision was made to seek out digital self-guided CBT that could be used at the patient’s convenience or at times of exacerbations. An educational handout was created using suggestions from the providers and from the literature. Input for the educational handout was received from the site facilitator and the other nurse practitioner in the practice in coordination with the literature.

The intervention consisted of development of a protocol based on best practice recommendations from the evidence chosen for the synthesis. This protocol included treatment with education, CBT via smartphone app and SSRI pharmacotherapy. It was recommended that shared decision making with the provider, patient and family members should occur (Andrews et al., 2018). Each participant verbally consented to participate in the project. A clinical decision tool was provided to the providers that could be used as a guideline to direct them in their interventions and referrals (see Appendix D). The education consisted of information about CBT, SSRIs, exercise, relaxation techniques, dietary changes, essential oil use, smoking cessation and reduction of alcohol intake. The patient was given oral as well as written information in order to further facilitate learning (see Appendix B). They were also provided information about the CBT smartphone app called MindShift. There was a handout that included screenshots of the steps that the patient will take to obtain the MindShift app (see Appendix F). They were educated that they should utilize the app during exacerbations of their anxiety and at least once weekly up to as often as they would like (Andrews et al., 2018). This education was provided by the DNP student. The nurses and medical assistants were trained on how to
perform this education for the sustainability of the project and protocol after it is completed. This training for the nurses and medical assistants was about 30 minutes long and was conducted by the DNP student. They were asked to record when and for how long they used this app on a time sheet log (see Appendix G). They also were asked to record when and for how long they exercised and used relaxation techniques on the time sheet log. Participants were provided with a prescription for an SSRI, as long as it was not contraindicated. The provider was given an educational handout about SSRIs including dosing, side effects and caveats with prescribing. The patient was instructed to fill the prescription at a pharmacy of their choice and educated on how to take their medication, including dose and frequency. They were advised to take this medication as directed and contact the health care provider if they had any concerns or want to discontinue the medication. They were provided education about the SSRI such as side effects, mechanism of action, duration of use, and timing of therapeutic effect.

**Comparison**

There are many challenges when it comes to treating GAD. There is stigma associated with mental illness which can deter patients from seeking help for these problems. If they do seek help, sometimes they are focused on the somatic issues that come along with GAD, and the provider can miss the psychiatric cause behind these somatic complaints (Andrews et al., 2018). There is a lack of psychiatrists and providers that can facilitate CBT, which decreases access and can increase costs for patients. Lack of knowledge or patient preference can hinder prescribers from prescribing first line pharmacologic therapy for patients. Time can be an impediment to the amount of education is given to the patient. This EBP project aimed to decrease these challenges and improve treatment of GAD.

There were 800 patients with GAD in the practice during the implementation period of the project. Education given to patients before implementation of the EBP project varied based upon provider and patient. For example, one nurse practitioner commonly talked to patients
about relaxation techniques for patients with GAD, while the other typically did not discuss relaxation techniques.

**Outcomes**

Multiple outcomes were selected for measurement as identified in the literature. The primary outcomes measured are anxiety level based on the GAD-7 scale (see Appendix H), and depression symptoms based on the PHQ-9 (see Appendix I). The GAD-7 is a 7-item self-report scale used to measure symptom severity experienced by the patient in the last 2 weeks. Total scores on the GAD-7 of 0-4 indicate no or minimal anxiety, 5-9 indicate mild anxiety, 10-14 indicate moderate anxiety, 15-21 indicate severe anxiety. The GAD-7 has good internal consistency indicated by a Cronbach’s alpha of 0.92 (Yu et al., 2018). The PHQ-9 is a 9-item self-report scale used to measure depressive symptoms experienced by the patient in the last 2 weeks. Both scales use a Likert scale from 0-3 to rate the questions from 0 “not at all” to 1 “several days”, 2 “more than half the days” and 3 “nearly every day”. This is in accordance with the literature in that many times anxiety and depression occur concurrently, and it would be a disservice to the patient if one went undetected (Andrews et al., 2018). Secondary outcomes include time spent exercising, time spent performing CBT via app, time spent doing relaxation techniques, usage of a benzodiazepine, and number of patients prescribed an SSRI.

Before the intervention was implemented, the patients’ GAD-7 and PHQ-9 was assessed. The patients’ baseline exercise, CBT, relaxation technique habits, and benzodiazepine use were assessed using a patient questionnaire (see Appendix J). These baseline data were used to compare to the data that were collected again at 4 weeks, 8 weeks and 12 weeks. This data were collected either by phone or in person depending on timing of patient appointments. The data were compared to determine whether GAD and depressive symptoms had improved, and how much the patient utilized relaxation techniques, exercise, the CBT app and benzodiazepines to combat symptoms.
The data were analyzed using one-way repeated measures analysis of variance (ANOVA) because there was one group receiving the intervention and the level of measurement of the variables was interval/ratio. This data analysis method was also chosen because there were four points in time that the data were collected. This will also show at what point in treatment a significant change occurred. The data were broken down by all 7 questions in the GAD-7 and all 9 questions in the PHQ-9 in order to determine whether a certain aspect of the patient’s symptoms improved, as well as the total score for both scales.

**Time**

Implementation of the project took place starting in August 2020 with the beginning of the school semester, once planning and education of providers and staff had occurred. Education was conducted by the DNP student, on the first week of the semester during the staff’s morning huddle. The staff was provided copies of the educational information that were to be given out to participants, and information about their role in the project including what education they will be providing once the DNP student left. The DNP student began recruiting patients to be involved in the EBP project based on their eligibility for the project. Once the patient agreed to be involved, data collection began, and the intervention started.

**Protection of Human Subjects**

Protection of human subjects was a priority throughout the project. The DNP student completed education about protection of human subjects through the DNP curriculum and by completing an online training course through the Collaborative Institutional Training Initiative (CITI) on April 1, 2020. The DNP student applied for approval for the project by Valparaiso University’s IRB. The DNP student was granted exemption from review on July 18, 2020. Participation in the project was voluntary. The patient’s confidentiality was upheld. The patients did not receive any reward for participating in the project. Patients who chose not to participate were given the same education and information about obtaining the CBT app. Providers were
encouraged to prescribe SSRIs for the patients with GAD who chose not to participate in the project. Patients were able to withdraw from the project at any time without retribution. Data was kept in a secure, locked laptop and paper documents were kept in a locked cabinet. There were no names kept on documents as number codes were given to patients in order to uphold anonymity.
CHAPTER 4

FINDINGS

The purpose of this EBP project was to see if implementing a protocol involving combination therapy with CBT, SSRI, and education would decrease anxiety and depression symptoms for patients. Anxiety symptoms were measured via the GAD-7 scale. Depression symptoms were measured via the PHQ-9 scale. These were measured at baseline and then again at four, six and 12 weeks post intervention. Secondary outcomes that were measured included amount of time exercise was performed, amount of time spent on app performing CBT app, amount of time spent doing relaxation techniques, usage of a benzodiazepine, and number of patients prescribed an SSRI.

Participants

A total of 24 individuals agreed to participate in the EBP project. They all completed the demographic form, patient questionnaire, PHQ-9 and GAD-7 scales for baseline data and agreed to follow up for a total of 12 weeks with three additional appointments either by phone or in person. At completion of the project, 14 participants had completed follow up with a total of four encounters. This yields a final attrition rate of 41.7%.

Participants demographic characteristics were analyzed. The average age of the participants was 46.5833 ($SD = 15.33656$). There were more females (87.5%) than males (12.5%) who participated (See Figure 1). All of the participants had at least a high school diploma or GED, while 20.9% of participants obtained a college degree (Figure 2). The majority of the participants were Caucasian (91.7%). Black individuals made up 4.2% of the population (Figure 3). The majority of the participants had private insurance (54.2%) (Figure 4). Half of the participants were married (See Figure 5). The annual gross household income level that was most commonly reported was less than $20,000 (25%) (Figure 6). Half of the participants were
employed full-time outside the home (Figure 7). Descriptive statistics of the demographic data are presented in Table 1.

Participants were given a prescription for an SSRI if one was not contraindicated such as in the case of a concomitant SNRI usage, allergy or adverse reaction. Of the 24 participants, three were prescribed citalopram (Celexa), one was prescribed paroxetine (Paxil), four were prescribed escitalopram (Lexapro) and three were prescribed sertraline (Zoloft). 11 other participants were already on SSRIs at baseline. If the dose previously prescribed was not at therapeutic dose, the dose was increased to the therapeutic dose at baseline. At the start of this project 11 out of 24 (45.8%) of the participants were prescribed an SSRI. 11 more were prescribed an SSRI during this project implementation. Therefore 91.6% of participants were on SSRI therapy at the end of this project. Participants who were on an SNRI or other medication were offered CBT and education to add to their pharmacologic therapy. One participant refused to be started on an SSRI, although did not refuse CBT and education.

There were 10 participants who did not complete the project until completion. Most (80%) did not follow up after initial intervention. The average age of these participants was 45 ($SD = 16.67333$). Two-thirds of the males originally recruited did not complete the project until it's end.
Table 1

**Demographic Characteristics**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants at commencement</td>
<td>24 (100%)</td>
</tr>
<tr>
<td>Number of participants at completion</td>
<td>14 (58.3%)</td>
</tr>
<tr>
<td>Attrition</td>
<td>10 (41.7%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
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<td>46.5833/15.33656</td>
</tr>
<tr>
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<td>18-72</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3 (12.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>21 (87.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>High school/GED</td>
<td>9 (37.5%)</td>
</tr>
<tr>
<td>Some college with no degree</td>
<td>10 (41.7%)</td>
</tr>
<tr>
<td>2-year college degree (Associates)</td>
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</tr>
<tr>
<td>4-year college degree (Bachelors)</td>
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</tr>
<tr>
<td>Master's degree</td>
<td>1 (4.2%)</td>
</tr>
<tr>
<td>Doctoral degree</td>
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<td>Race</td>
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<tr>
<td>African American</td>
<td>1 (4.2%)</td>
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<tr>
<td>Category</td>
<td>Count</td>
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<td>-------</td>
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<td>Native American</td>
<td>0</td>
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<tr>
<td>Other</td>
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</tr>
<tr>
<td>Prefer not to answer</td>
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<tr>
<td>Health Insurance</td>
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<tr>
<td>No insurance</td>
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<td>Medicaid</td>
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<td>Marital Status</td>
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<td>Widowed</td>
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<td>Less than $20,000</td>
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<tr>
<td>$20,000-$34,999</td>
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<td>$35,000-$49,999</td>
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<td>$50,000- $74,999</td>
<td>4</td>
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<tr>
<td>$75,000- $99,000</td>
<td>4</td>
</tr>
<tr>
<td>$100,000 or more</td>
<td>1</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
</tr>
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</table>
Employed full time 12 (50%)
Employed part time 0 (0%)
Unemployed and currently looking for work 2 (8.3%)
Unemployed and not currently looking for work 1 (4.2%)
Student 1 (4.2%)
Retired 2 (8.3%)
Homemaker 0 (0%)
Self-employed 2 (8.3%)
Unable to work/disabled 3 (12.5%)
Prefer not to answer 1 (4.2%)

Figure 3

Demographic Information: Sex

Note. There were more females than males in the population.
**Figure 4**

*Demographic Information: Education Level*

Note. All of the participants had at least a high school diploma/GED

**Figure 5**

*Demographic Information: Race*
Note. Most participants were Caucasian.

Figure 6

Demographic Information: Health Insurance

Note. Most participants had private insurance.

Figure 7

Demographic Information: Marital Status
Note. Most participants were married.

**Figure 8**

*Demographic Information: Annual Gross Household Income*

Note. Most participants made less than $20,000 per year.

**Figure 9**

*Demographic Information: Current Employment Status*
Note. Half of the participants were employed full time.

**Changes in Outcomes**

The PICOT question that was addressed by this EBP project was: Among adult patients presenting with generalized anxiety disorder (GAD) in the primary care setting (P), does the introduction of a protocol consisting of treatment with education via a written handout, a selective serotonin reuptake inhibitor (SSRI) and digital cognitive behavioral therapy (CBT) via smartphone application (app) (I) compared to 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 and Patient Health Questionnaire 9-item (PHQ-9) scale (O) over a 12-week period (T)? Therefore, the primary outcomes were anxiety and depression symptoms measured via the GAD-7 scale and the PHQ-9 scale, respectively. Secondary outcomes included total time of exercise, relaxation techniques, and CBT via application per week, amount of benzodiazepine use, and amount of SSRI prescriptions.

**Statistical Testing and Significance**

Statistical Package for Social Sciences (SPSS) was the system utilized for data analysis. Cronk (2019) was used as a guide for data analysis and interpretation. A one-way repeated measures ANOVA was used to analyze the data from participants’ PHQ-9 and GAD-7 scores because these were measured within one group at four difference times. Exercise, relaxation and CBT times, benzodiazepine usage and SSRI prescription amounts were analyzed by performing pair-samples t-tests because these were measured at pre-intervention and at the 12-week measurement.

**Findings**

**Primary Outcomes**

**Anxiety Symptoms**. Anxiety symptoms were scored using the GAD-7, which has seven questions asked in a Likert scale format (See Appendix H). The overall prompt is “over the last
two weeks how often have you been bothered by any of the following problems?” and then the seven questions address symptoms of anxiety. The Likert scale consists of either not at all (zero), several days (one), more than half the days (two), and nearly every day (three). The score is totaled for all seven questions and can range from zero-21. Higher scores indicate higher levels of anxiety symptoms. A one-way repeated measures ANOVA was calculated comparing the total scores of participants at four different times: at baseline, week four, week eight, and week 12. A significant effect was found ($F (3,39) = 6.992, p < .001$). Follow up protected $t$ tests revealed that scores decreased significantly from baseline ($M = 12.5714, SD = 6.51288$) to week 8 ($M = 5.2857, SD = 4.26846$) and from baseline to week 12 ($M = 6.1429, SD = 5.88162$). During patient follow ups, there were anecdotal comments that were made that can provide evidence of clinical significance. One participant said on her week 4 follow up visit, “I haven’t felt this good, ever. I noticed a huge difference just since my last visit. I never want this medication [SSRI] taken away from me”. Many participants reported that they were thankful that the DNP student was there in their time of need.

**Depression Symptoms.** Depression symptoms were measured using the PHQ-9, which has 9 different questions asked in a Likert scale format (See Appendix I). The overall prompt is “over the past two weeks how often have you been bothered by any of the following problems?” and then the nine questions proceed to ask about symptoms of depression. The responses are the same as GAD-7 and are as follows: not at all (zero), several days (one), more than half the days (two), and nearly every day (three). The score is then totaled for all nine questions with higher scores indicating higher levels of depression symptoms. The scores range from 9-27. A one-way repeated measures ANOVA was calculated comparing the total scores of participants at four different times: at baseline, week four, week eight, and week 12. A significant effect was found ($F (3, 39) = 8.867, p < .000$). Follow up protected $t$ tests revealed that scores decreased significantly from baseline ($M = 12.4286, SD = 7.70329$) to week eight ($M = 4.7143, SD = $
From baseline to week 12 ($M = 4.6429$, $SD = 5.25660$) (See Table 3). To demonstrate clinical significance, one participant stated during a follow up visit, “I was never suicidal, but I would keep my leftover pills, and saved enough up that if I ever needed to or if things ever got bad enough, I would have enough ammo to do it. I recently just took all those leftover pills to the pharmacy because I know now that I will never need them.” Table 2 depicts one-way repeated measure ANOVA results with means and standard deviations for the primary outcomes of anxiety and depression symptoms.
Table 2

*One-Way Repeated Measure ANOVAs with Means and Standard Deviations for Primary Outcomes*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>F</th>
<th>p</th>
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<td>Anxiety Symptoms</td>
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<td></td>
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<tr>
<td>Baseline</td>
<td>12.5414</td>
<td>6.51288</td>
<td>6.992</td>
<td>.001*</td>
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<td>Week 4</td>
<td>9.2143</td>
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<tr>
<td>Week 8</td>
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<td>Week 12</td>
<td>6.1429</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Depression Symptoms</td>
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<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>12.4286</td>
<td>7.70329</td>
<td>8.867</td>
<td>.000*</td>
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<tr>
<td>Week 4</td>
<td>8.9286</td>
<td>6.17020</td>
<td></td>
<td></td>
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<tr>
<td>Week 8</td>
<td>4.7143</td>
<td>4.51372</td>
<td></td>
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</tr>
<tr>
<td>Week 12</td>
<td>4.6429</td>
<td>5.25660</td>
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*Note.* * signifies clinical significance
Table 3

*Follow Up Protected T-tests*

<table>
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<tr>
<th>Variable</th>
<th>Mean Difference</th>
<th>SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
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<td>Anxiety Symptoms</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to Week 4</td>
<td>3.3571</td>
<td>7.20691</td>
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<td>.105</td>
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<td>Baseline to Week 8</td>
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<td>6.89959</td>
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<td>13</td>
<td>.002</td>
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<tr>
<td>Baseline to Week 12</td>
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<td>.006</td>
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<td>Week 4 to Week 8</td>
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<td>.043</td>
</tr>
<tr>
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<td>.130</td>
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<tr>
<td>Week 8 to Week 12</td>
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<td>4.05457</td>
<td>-.791</td>
<td>13</td>
<td>.443</td>
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<tr>
<td>Depression Symptoms</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to Week 4</td>
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<td>7.57272</td>
<td>1.729</td>
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<td>.107</td>
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<tr>
<td>Baseline to Week 8</td>
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<td>7.89770</td>
<td>3.655</td>
<td>13</td>
<td>.003</td>
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<tr>
<td>Baseline to Week 12</td>
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<td>7.37124</td>
<td>3.952</td>
<td>13</td>
<td>.002</td>
</tr>
<tr>
<td>Week 4 to Week 8</td>
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<td>6.45909</td>
<td>2.411</td>
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<td>.030</td>
</tr>
<tr>
<td>Week 4 to Week 12</td>
<td>4.28571</td>
<td>6.28097</td>
<td>2.553</td>
<td>13</td>
<td>.024</td>
</tr>
<tr>
<td>Week 8 to Week 12</td>
<td>.07143</td>
<td>3.29252</td>
<td>.081</td>
<td>13</td>
<td>.937</td>
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</tbody>
</table>

*Secondary Outcome*
Exercise Usage. Participants were educated about use of exercise to improve GAD symptoms and overall health as part of the protocol. Exercise data were collected via patient report on the patient questionnaire that was administered at baseline and at week 12. They answered whether they exercised or not via a yes or no question. If they answered yes, participants were prompted to answer what type of exercise they did, how many times per week, for how many minutes, and whether the exercise was mild, moderate or strenuous. To analyze the data, the total minutes of exercise per week was calculated. Total minutes of exercise per week was compared at baseline and at week 12. A paired samples t test was calculated to compare exercise minutes per week at baseline and at week 12. The mean at baseline was 113.2 ($SD = 185.14659$) and the mean at week 12 was 195 ($SD = 238.98825$). No statistically significant difference from baseline to week 12 was found ($t(13) = -1.043, p > .05$).

Relaxation Technique Usage. The participants were educated about relaxation techniques such as a meditation, deep breathing, and progressive muscle relaxation as part of the intervention. Data were collected on relaxation usage at baseline and again at week 12 based on patient responses on the patient questionnaire. They were asked if they performed any relaxation techniques, and were given examples, with a yes or a no response. If they responded yes, they were asked how many times per week they perform relaxation techniques and for how many minutes. These data were totaled to get reported minutes per week of relaxation techniques. A paired samples t test was calculated to compare minutes utilizing relaxation techniques per week at baseline and at week 12. The mean at baseline was 7.6 ($SD = 14.22677$) and the mean at week 12 was 155.9 ($SD = 248.71159$). A significant increase from baseline to week 12 was found ($t(13) = -2.220, p = 0.45$).

CBT App Usage. The participants were educated about the importance of cognitive behavioral therapy as a treatment for GAD. They were provided access to an app with CBT techniques and given step by step instructions on how to obtain access and utilize the app. The
participants were asked whether or not they implemented CBT and if so, how many days and for how many minutes they used it at baseline and at week 12. No participants in the project utilized CBT before the protocol was initiated. A paired samples $t$ test was calculated to compare CBT usage in minutes per week at baseline and at week 12. The mean at week 12 was $21.6 \ (SD = 40.22171)$. No significant difference from baseline to week 12 was found ($t (13) = -2.013, p > .05$).

Upon inquiring about CBT app usage at follow up visits, many participants found the CBT application helpful. Many participants enjoyed the relaxation videos found in the “chill zone” tab. One patient reported, “hey, that app really does work!”.

**Benzodiazepine Usage.** Benzodiazepines have been found to be addictive and are generally reserved for use for short periods of time or with treatment refractory individuals and are not first-line treatment for GAD (Ministry of Health, 2015; Slade, 2019). Half ($n = 7$) of the participants who completed the project were prescribed and used benzodiazepines at baseline. Only three participants were using benzodiazepines by week 12. The participants reported benzodiazepine usage on the patient questionnaire at baseline and 12-week follow up. They were asked if they used benzodiazepines using a yes or no format. If they responded yes, they went on to answer what benzodiazepine they used, at what dose and how many times per week they used the medication. A paired samples $t$ test was calculated to compare mg per week used at baseline and at week 12. The mean at baseline was $0.63 \ (SD = .89916)$ and the mean at week 12 was $.17 \ (SD = .48288)$. No statistically significant difference from baseline to week 12 was found ($t (12) = 1.937, p > .05$).

**SSRI Prescriptions.** SSRIs are first-line treatment for GAD due to their efficacy and tolerability (Slade, 2019). Participants were educated on SSRI therapy including mechanism of action, side effects and directions on administration. Providers were educated about prescribing SSRIs. Prior to implementation, of the 14 patients that completed the project, 10 participants
were on no antidepressants for GAD, two (14.29%) were already on SSRI therapy, and two were on an SNRI. During implementation, nine participants (64.29%) were placed on an SSRI. One patient refused pharmacologic therapy. The two patients that were already on SSRI or SNRI therapy were kept on their regimen or the dose was increased if appropriate. After implementation, the percentage of participants prescribed an SSRI went up to 78.57%. This is a statistically significant difference ($t (13) = -4.837, p = .000$) from baseline SSRI prescriptions ($M = .1429, SD = .36314$) to post-intervention ($M = .7857, SD = .42582$). Table 4 displays the paired samples $t$-test results for the secondary outcomes.
Table 4

*Paired Samples t-tests for Secondary Outcomes*

<table>
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<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
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</tr>
</thead>
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<td><strong>Exercise Usage</strong></td>
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<td></td>
</tr>
<tr>
<td>Baseline</td>
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<td>.316</td>
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<tr>
<td>12-weeks</td>
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<td>238.98825</td>
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<tr>
<td><strong>Relaxation Technique Usage</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>7.6429</td>
<td>14.22677</td>
<td>-2.220</td>
<td>.045*</td>
</tr>
<tr>
<td>12-weeks</td>
<td>155.9286</td>
<td>248.71159</td>
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</tr>
<tr>
<td><strong>Benzodiazepine Usage</strong></td>
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<td>Baseline</td>
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<td>.105</td>
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<tr>
<td>12-weeks</td>
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<td>1.93152</td>
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<tr>
<td><strong>SSRI Prescriptions</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
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<td>.36314</td>
<td>-4.837</td>
<td>.000*</td>
</tr>
<tr>
<td>12-weeks</td>
<td>.7857</td>
<td>.42582</td>
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</tbody>
</table>

*Note.* * signifies statistical significance
CHAPTER 5
DISCUSSION

The aim of this project was to evaluate the effect of a GAD protocol with combination therapy of pharmacologic therapy with education provided through written and verbal transmission, CBT via smartphone app and SSRIs. The protocol was implemented with the desired outcomes being improved anxiety and depression symptoms, increased amount of time utilizing CBT, relaxation techniques, exercise, increased SSRI prescriptions, and decreased benzodiazepine use. This chapter will provide an explanation and interpretation of project findings, strengths and limitations of the project, and implications for the future.

Explanation of Findings

The statistically significant findings provide supporting evidence for implementation of protocols inclusive of SSRI pharmacologic therapy, CBT via smartphone app, and education in the primary care setting for treatment of adult patients with GAD. Results from this EBP project were consistent with current literature regarding treatment of patients with GAD.

Participants

Females accounted for 87.5% of the participants within this project. This correlates with the evidence that GAD is more common in women than men (DynaMed, 2018). Most (91.7%) of the sample population were Caucasian. This was an expected finding due to the fact that GAD is more common in Caucasian individuals and the population of the town in which this project was implemented is predominantly (95.5%) Caucasian (DynaMed, 2018; United States Census Bureau, 2019). A risk factor for GAD is low socioeconomic status (DynaMed, 2018). This is displayed in the demographic results of this EBP project because the most common response of participants for annual household income level was less than $20,000 (25%). This provides evidence that GAD may be linked to low socioeconomic status. Many participants (45.9%) had
either no insurance coverage or government issued insurance. Lack of employment is also a risk factor for GAD. 12.5% of participants in this project were unemployed.

**Anxiety Symptoms**

There was a statistically significant decrease in anxiety symptoms based on GAD-7 scores from baseline to eight weeks and from baseline to 12 weeks. Mean GAD-7 scores among the 14 participants who completed the 12 week follow up decreased as well. According to GAD-7 scoring, the participants went from having moderate symptom severity at baseline to having minimal symptom severity at week 12. Some (14.29%) of the participants were already taking SSRIs prior to implementation of the project, so this indicates the improvement that education and CBT via smartphone application can have on GAD-7 scores and consequently anxiety symptoms. Patients reported improvement with symptoms such as feeling nervous, worrisome anxious, restless, annoyed and irritable based on their responses to the individual GAD-7 questions. A statistically significant GAD-7 decrease indicates that there is a significant benefit to implementing a GAD protocol to lessen patients’ severity of GAD symptoms.

It has been noted in the literature that education can be effective to reduce anxiety symptoms by increasing knowledge about contributing and relieving factors of anxiety (Andrews et al., 2018; Ministry of Health, 2015). The project protocol involved education about avoiding contributing factors of anxiety such as caffeine, alcohol, nicotine, and also relieving factors of anxiety such as exercise, relaxation techniques and healthy diet. Many participants noted on patient interviews that avoiding the contributing factors and increasing the relieving factors were helpful for anxiety symptoms.

CBT via smartphone application is superior to in person CBT due to its greater accessibility and costs (Andrews et al., 2018; Ministry of Health, 2015; Yu et al., 2018). This project provided further evidence toward this information because before CBT via smartphone app was implemented as part of this protocol, none of the participants had access to CBT. As
shown by the demographic data, many participants were of low socioeconomic status, so the cost of in person CBT may have been too great for them to afford as well. A free CBT smart phone app gave participants a cost-effective way to access CBT. CBT is effective because it helps patients change the dysfunctional thoughts, emotions and behaviors that are involved with the GAD process (Andrews et al., 2018; Yu et al., 2018). The patients can also track their symptoms levels and know when to seek help. (Andrews et al., 2018). The results of decreased anxiety in this project are also likely due to these processes. The participants were instructed by the app to type in their maladaptive thoughts, walked them through what type of “thinking trap” this was, and helped them create a healthier thought in the thought journal section of the app.

It is assumed that the SSRI prescriptions helped with reduction of the patients’ anxiety symptoms. SSRIs are first line treatment for GAD due to their relatively low cost, efficacy evidence in various RCTs, safety and low misuse potential (Andrews et al., 2018; Ministry of Health, 2015). SSRIs help to reduce the frequency and intensity of panic attacks, reduce anticipatory anxiety and improve associated depressive mood (Ministry of Health, 2015). In this project, all participants had the financial means to obtain a prescription for an SSRI. Similar to the literature findings (Slee et al., 2019 project participants had fairly mild side effects. Subjectively during follow up visits, few patients did discuss side effects such as sexual dysfunction, gastrointestinal side effects, and unusual dreams. Often, the participants reported that the benefit they felt in their anxiety symptoms outweighed the hinderance from side effects. The protocol did not favor one particular SSRI for primary use because the literature does not indicate that any one SSRI is superior to the others (Andrews et al., 2018; Ministry of Health, 2015). This may have helped with patient satisfaction and overall result in a reduction in anxiety symptoms because participants felt some level of control over which medication they were prescribed. For example, if the medication worked for the participant’s mother, the participant
felt more comfortable taking the medication and had more faith that the medication would work for him/her as well.

**Depression Symptoms**

Depression symptoms measured by the PHQ-9 scale showed statistically significant decrease over the course of the 12-week implementation period. Mean PHQ-9 scores decreased from baseline to week four, eight and week 12. Based on the scoring of PHQ-9 this indicates that due to implementation of the protocol, participants went from moderate depression symptom severity at baseline to mild depression symptom severity at week four and then maintained that level of severity for the remainder of the duration of implementation. This demonstrates not only symptom reduction, but sustainability of symptom reduction over time. A statistically significant PHQ-9 decrease indicates a strong correlation between a decrease in severity of depression symptoms and implementation of this protocol. Andrews et al. (2018) discussed the importance of screening for depression in conjunction with screening for anxiety. This was demonstrated in this EBP project as many patients who presented with anxiety symptoms met the criteria for diagnosis of major depressive disorder as well. This protocol was able to help with both anxiety and depression symptoms as these often occur as comorbid conditions. It is likely the addition of an SSRI which is an antidepressant medication contributed to the benefit of decreased depression symptoms due to their effects on serotonin levels in the brain. Also, the education component which included information about techniques such as exercise which can increase endorphins and improve mood (Lizarondo, 2020).

**Exercise Usage**

Although a statistically significant increase in exercise usage was not achieved upon completion of this project, mean weekly exercise minutes did increase from baseline to week 12. It is anticipated that the time of year questionnaires were completed had an impact on results. Being that the project was implemented in Northeast Indiana, weather has a big impact
on the ability of individuals to safely and comfortably exercise outside. The first questionnaires were completed at the beginning of implementation, which for most participants was in the summer and fall seasons when outside exercise is more feasible. The week 12 questionnaires were distributed to most participants in the winter months when outside exercise is more challenging. Given this information, it is impressive that participants’ mean weekly exercise minutes did increase from baseline to week 12. Lack of physical activity is associated with higher levels of anxiety, and conversely physical activity has been shown to improve mood and reduce anxiety (Lizarondo, 2020). The reason for this increase in amount of exercise performed per week can be correlated with the education that was given to the patients regarding exercise and its importance and efficacy in decreasing anxiety symptoms. It is recommended that all patients with GAD receive education about lifestyle modifications that are relieving factors of anxiety symptoms (Andrews et al., 2018; Ministry of Health, 2015). Increased exercise can lead to better GAD control, as well as weight loss and prevention or improvement of other disease states such as diabetes mellitus and cardiovascular disease.

**Relaxation Technique Usage**

The literature states that nurses and general practitioners can appropriately educate patients about breathing control and relaxation techniques (Ministry of Health, 2015). The EBP protocol included education on different relaxation techniques. Relaxation techniques work because they can reduce physical symptoms of anxiety (Andrews et al., 2018; Lizarondo, 2019). Relaxation technique usage was measured in weekly minutes reported by participants on the patient questionnaire. A statistically significant increase was found from baseline to week 12. These data demonstrate that participants increased their coping abilities to stressful situations likely due to the education about relaxation techniques that was implemented in the protocol. It is suspected that because the participants were instructed to use relaxation techniques when they felt anxious or had physical symptoms, they used these positive coping mechanisms more
often from baseline to the 12 week follow up. Relaxation techniques are a self-care tactic that can have a positive impact on wellbeing (Andrews et al., 2018; Ministry of Health, 2015). Many patients indicated that they were doing meditation, yoga, progressive muscle relaxation, and praying. Some patients verbalized the positive impact that these relaxation techniques had on their stress levels and ability to fall asleep upon patient interview. Therefore, project findings support that education on relaxation techniques to increase these healthy habits in participants.

**CBT App Usage**

CBT has been found to effectively manage GAD symptoms (Andrews et al., 2018; Berger et al., 2017; Jayasekara, 2016; Ministry of Health, 2015; Yu et al., 2018) However, access, time constraints and cost are huge barriers to patients receiving CBT (Lizarondo, 2018). Smartphones can be an avenue for CBT. CBT administered via smartphone has been shown to improve mood and well-being for patients with GAD (Lizarondo, 2018). No participants in the project were implementing CBT in any form at baseline. The mean usage at week 12 was 21.6 minutes. Therefore, patients were using CBT more at the end of implementation than at baseline. The literature reported that the more frequent the use of CBT, the better results tended to be, while a patient should at least be utilizing the therapy once weekly (Andrews et al., 2018; Yu et al., 2018). While some patients reported that they really enjoyed the application, one patient reported that she was worried about cyber security when using the app. She was worried that her personal thoughts would somehow end up not being private and being shared by the app users. Another barrier to CBT via smartphone application is lack of access to a smartphone. One patient did not have access to a smartphone and so was not able to utilize the application. It is also anticipated that lack of remembering to download the app and time constraints could have affected ability to obtain significant results in this project. During the first visit, the provider can ensure that participants can download the app, introduce the app, and build rapport (Lizarondo, 2018). Some patients who did not download the application in the
office during the visit reported on their four-week visit that they forgot to get the application. Therefore, downloading of the app in the office upon baseline visit may be helpful to obtain significant results. A weekly text to the patient could be used to reinforce app use and offer encouragement (Lizarondo, 2018). This was not implemented in this protocol and if it were, may have increased compliance of usage of the app. Many of the participants went from no access or utilization of CBT to using the application at least once per week, which is what was indicated as best practice in the literature (Andrews et al., 2018)

**Benzodiazepine Usage**

Although a statistically significant decrease in benzodiazepine usage was not shown, mg per week of benzodiazepines usage did decrease from baseline to week 12. Half of participants who completed the project were using benzodiazepines at baseline, whereas at completion of the project only three (21.4%) participants were using them. Decreasing benzodiazepine usage is of benefit to patients as benzodiazepines have been linked to abuse potential and significant adverse effects such as respiratory depression and confusion in the elderly (Andrews et al., 2018). Many patients reported that they felt as though the benzodiazepines that they were prescribed just treated the symptoms, whereas the SSRI prevented the anxiety symptoms from occurring. This is congruent with the literature. It is reported that SSRIs are as effective as benzodiazepines, have a broader spectrum of action and have less of a potential for abuse (Ministry of Health, 2015). Upon patient interview at follow up visits, some patients were not satisfied with their level of anxiety control with benzodiazepines and were more satisfied with SSRIs efficacy. GAD protocols can be linked to decrease benzodiazepine use and therefore should be utilized.

**SSRI Prescriptions**

The literature displayed that SSRIs are first line treatment for GAD (Andrews et al., 2018; Ministry of Health, 2015; Slade, 2019, Slee et al., 2019). This is because SSRIs are low-
cost options that have been found to be effective in reducing anxiety symptoms while also being well tolerated (Andrews et al., 2018; Ministry of Health, 2015; Slade, 2019). SSRI prescriptions did increase as a result of implementation of this GAD protocol. Of the 14 patients that completed the project, 10 participants were on no antidepressants for GAD at baseline. Two (14.29%) were already on SSRI therapy, and two were on an SNRI medication. During implementation, nine additional participants (64.29%) were placed on an SSRI. After implementation, the percentage of participants prescribed an SSRI was 78.57%. This increase of SSRI prescriptions is a triumph. SSRIs do not have the abuse potential that benzodiazepines do, and therefore can be safer for patients (Andrews et al., 2018; Ministry of Health, 2015; Slade, 2019). The number of SSRI prescriptions went up during this project, which could inversely correlate with the decrease in anxiety symptoms. Implementation of a GAD protocol can increase prescribing of SSRIs which have been reported in the literature as being safe and effective pharmacologic therapy.

**Strengths and Limitations of the EBP Project**

**Strengths**

One strength of this project was that it offered a cost effective, easily accessible means of obtaining CBT. There is a shortage of mental health care providers and demand is far greater than supply of providers creating a gap in mental health care services such as CBT (Lizarondo, 2018). Providing access to CBT for patients that is effective, safe, secure and can be utilized in their own home at zero cost can close some of those gaps. Another strength of the project is that the clinical decision tool provided guidance to providers to refer patients who would be more appropriately treated in a psychiatric care setting than in primary care. This acceptance of the limitation of treatment in the primary care setting provides safer care for those high-risk patients. Before the project was implemented, the providers had some ambiguity about who should be referred and who could be appropriately addressed in the primary care setting. This
clinical decision tool acts a guide to make clear the patients who should be referred. Another strength of this project was the increase of prescribing practices that correlate with best practice for treatment of GAD. Less benzodiazepines were used as a result of this project and more SSRIs were prescribed, which matches the recommendations of the high-quality evidence. Using the JHNEBP model was a good resource utilized during this project. The model was a guide for all the steps of the EBP process, and it was referred to ensure that the process was being done appropriately. Another strength of the project was good buy-in from the site facilitator and the other nurse practitioner. They often would initiate the protocol with patients who they felt appropriate to initiate it for, even if the patient could not be included in the project due to meeting exclusion criteria. For example, the nurse practitioners were often initiating the protocol with teenagers. The teenagers seemed impressed with the CBT app especially, likely related to their technology expertise. The nurse practitioners would ask the DNP student to educate patients that were not diagnosed with GAD but had a procedure and seemed a bit anxious about it. It was realized throughout this project that many patients could benefit from education about self-care techniques and CBT.

Limitations

There were limitations to this project. The participant size of this project was relatively small compared to the existing evidence within the literature review. This is not reflective of the high prevalence rate of GAD. The participant size was limited by availability of the DNP student for recruitment who was the only person who recruited participants. The site facilitator saw many more patients with GAD symptoms on days when the DNP student was not present. This contributed to potential participants that were missed. This was due to lack of time in the site facilitators schedule to perform chart review to determine eligibility, collect demographic data and initial patient questionnaires. This could be mitigated in future projects by teaching support staff to provide education and CBT information. The inclusion and exclusion criteria were
another contributing factor for the small participant size. Patients who were under 18, pregnant, non-English speaking, suicidal, homicidal, having active psychosis, and/or had concurrent alcohol or drug abuse were excluded from the EBP project. There were multiple teenage individuals that were treated for GAD during the implementation period, but data were not recorded because of these criteria. The literature does recommend that children be treated with CBT adapted for their age group but recommend that psychiatric advice be sought before prescribing medication for children and adolescents (Andrews et al., 2018). In the primary care setting, a provider could implement the education and CBT portion and then refer to psychiatry if symptoms are continuing to be unmanaged. One pregnant woman was provided with a modified version of the protocol with education and CBT implemented. Again, this abbreviated protocol could be implemented, and then referral to OBGYN or psychiatry could be facilitated for pharmacologic management on these patients. These data also were not collected due to exclusion criteria. The other exclusion criteria were not hinderances on sample size during this project. Another barrier was the lack of support from the physician in the office, which limited patients who were able to be recruited for the project. He did not participate due to time constraints in his schedule and resistance to change.

Another limitation was the frequency of follow up with participants. It was recommended in the literature that treatment should be reviewed after 4-6 weeks of CBT and pharmacotherapy, so the protocol followed this recommendation (Andrews et al., 2018). This same four week interval was continued for 12 weeks. Although this provided a lot of data and gave information about when the protocol was effective and whether it remained effective over time, it was fairly time consuming for the DNP student and might not be feasible for the providers at the office to maintain such close follow up repetitively. When patients report improvement of symptoms, it then may be appropriate to extend the follow up interval. Also, follow up intervals weren’t very individualized. For example, some patients were experiencing
such great improvement on their week four follow up, that it probably would have been more appropriate to extend the interval of time out further than four weeks for their next follow up. The literature is vague on the topic of follow up intervals after achieving remission of symptoms. The literature states that follow up should occur “regularly but not too often” (Andrews et al., 2018). However, for other participants, who did not see such great results, had intolerable side effects or worsening of symptoms at their four week visit, they could have been switched to a different SSRI at a sooner date. The literature does state that patients can initially be seen weekly to monitor for adverse effects and worsening of symptoms (Andrews et al., 2018).

Another limitation of this project was the lack of standardized measurement for qualitative evidence. While participants did give verbal feedback regarding interventions during follow up visits, this information was purely random and not standardized using a tool or form. I would have created a form that asked for feedback on things such as ease of use of app, whether the participants feel as though their current level of anxiety is manageable, which self-care techniques they feel like work and if they had any negative responses to any of the components. I would have administered this form at the 12 week follow up visit.

Additionally, the COVID-19 pandemic was ongoing for the duration of this project. This impacted participants’ level of symptoms due to the stress and uncertainty surrounding the virus, employment, ability to access healthcare and other services such as exercise facilities. This could have negatively impacted results of this project.

**Implications for the Future**

This EBP project produced information for health care providers about the effects of a protocol for GAD that included combination therapy with SSRIs, CBT via smartphone app, and education. Implications for the future related to practice, theory, research and education will be discussed.

**Practice**
While combination therapy utilizing SSRIs, CBT, and education is first line for treatment of GAD, not all providers treat patients in clinical practice with this evidence-based approach. This project allowed for evidence to drive the treatment of GAD at this particular clinic. It is recommended that all primary care offices adopt this protocol due to its accessibility, low cost and effectiveness. SSRIs are typically inexpensive; education does not have any additional financial costs during the visit and CBT administered via Mindshift app is free to download. Therefore, minimal budgeting is necessary for further continuation of this project. Implementing a protocol with such extensive education can be time consuming for the nurse/provider to perform. To combat this barrier, increasing appointment times for initial visits for anxiety complaints can help facilitate continuation of this protocol and the extensive education portion. The nurses and medical assistant at this particular clinical setting are going to administer the education and review the CBT information with patients who have an anxiety related chief complaint or as indicated by the provider. This could be built into the electronic health record that if the nurse types in a psychiatric chief complaint, a prompt fires that they should administer the PHQ-9 and GAD-7 assessments. Based on the results of the assessment, they would receive another prompt to facilitate the protocol.

**EBP Model**

Use of the JHNEBP model as the guide for this project allowed for a stepwise approach to successfully implementation. The model starts with inquiry, which is desire to learn about and implement best practice. Then, the PET process occurs where the planning, evidence, and translation of the change occurs. Getting started with the EBP process was daunting for the DNP student and was further compromised by the COVID-19 pandemic interrupting in person sessions. Because of this, the first phase was the most helpful for the DNP student. The first phase involves generating an interprofessional team, defining the problem, developing and refining the EBP question, identifying stakeholders, determining responsibility for project
leadership and scheduling team meetings. This could be considered the planning step. The DNP student was new to the process of EBP, and so a stepwise approach to start out was helpful. The JHNEBP model also allowed for the DNP student to realize that EBP is a fluid and continual process that is never complete. Best practice turns into practice improvements but those lead right back into inquiry to continue more EBP. The weakest part aspect of this model is that the model is designed for individual nurses to be a part of EBP processes and less about organizational changes, which was the main focus of this project.

Research

Further research is needed in specific areas of GAD treatment. Upon extensive review of the individuals results from this project, it was noted that the patients who seemed to benefit the most from this protocol were patients who were newly diagnosed with GAD or who had not been attempted on pharmacologic therapy before. These patients GAD-7 and PHQ-9 scores tended to decrease the most. Results did not seem as strong for patients who had more treatment refractory symptoms such as the patients who had tried many antidepressants inclusive of SSRIs in the past. It was also harder to choose an SSRI option that the patient had not been prescribed before. This sparked the spirit of inquiry for the DNP student. More research needs to be done about the treatment of treatment refractory GAD and how best to improve outcomes in these patients. Further research is also needed to refine whether there is a best SSRI for treatment of GAD, or whether there are certain SSRIs that should be prescribed for certain individuals. More research should be done about the effects of CBT administered via smartphone app. It is a relatively new intervention that does not yet have a large body of evidence supporting it. However, technology is becoming more popular in healthcare, so this research is necessary. Additional research should be performed about exercise in GAD including how much they should be performing and comparing the types of exercise. Similarly, more research should be conducted about education and how best that is to be provided to
patients for best absorption of information. A consensus on follow-up intervals should be arrived at to decrease the ambiguity regarding when a patient should be monitored so it is more individualized to the patient’s level of symptoms.

It is also recommended that future projects related to GAD try to enhance sample size of the project for more statistical power. It would also be beneficial to implement this protocol on a more diverse population to see what effect this diversity has on results and to improve generalizability.

Education

Education was a direct component of this EBP project. It was demonstrated that education had an impact on both providers and participants. The increased prescriptions for SSRIs and the decreased prescriptions for benzodiazepines suggest that education about SSRI prescribing had an effect on prescribing habits of the providers to more closely match high quality evidence recommendations. The fact that none of the participants were utilizing CBT at baseline, whereas some were prescribed SSRIs, provides evidence that knowledge about CBT and modalities in which it can be utilized was lacking. Education about CBT and that it can be administered via smartphone app was helpful to providers as well as participants. This is shown by the vast increase from zero patients having access to CBT at baseline to 13 of the 14 patients having access and the number of minutes per week of use increasing. The providers in the office expressed that they were unaware that CBT was available through smartphone apps. With the implementation of this protocol, more patients will have access to this first-line treatment. Increased amount of time spent exercising, using the CBT app, and doing relaxation techniques demonstrates that education about these modalities had an impact in participants’ lifestyle habits and coping skills. Statistical significance was found with relaxation techniques but was not arrived at with exercise.

Conclusion
GAD is a very prevalent disease that can cause significant symptoms and distress for affected patients. Using the JHNEBP model, the DNP student began with an extensive literature search that showed best practice for treatment of GAD is combination therapy with SSRI pharmacotherapy, CBT administered via smartphone application and education. A protocol was created inclusive of these modalities. As part of the protocol a clinical decision tool and education on SSRIs were given to providers in the office. The project demonstrated a statistically significant decrease in anxiety and depression symptoms for patients, as well as increased relaxation technique usage. These findings are consistent with current literature. Mean exercise, and weekly minutes of CBT usage increased over the course of this project, indicating an increase in positive coping strategies. This EBP project has improved symptoms for patients as well as the prescribing practice of providers at the project site. More SSRI prescriptions and less benzodiazepine prescriptions were provided to patients over the course of this project. Efforts for sustainability were necessary during the implementation period. Copies of the handouts were provided to the office for post-project use. Providers and staff were trained on how to implement the protocol after the project concluded. The providers and staff were receptive to continuing the new practice and have plans to implement the protocol now that the project is complete. Given this project’s encouraging findings, it is recommended that other primary care offices implement a GAD protocol in order to improve symptoms for patients using this cost-effective, accessible and effective method.
REFERENCES


https://www.census.gov/quickfacts/fact/table/angolacityindiana/IPE120218

AUTOBIOGRAPHICAL STATEMENT

Ms. Hinman graduated Magna Cum Laude from Valparaiso University with a Bachelor of Science in Nursing degree in 2017. She decided in 2018 to further her career by returning to Valparaiso University to pursue a Doctor of Nursing Practice (DNP) degree. She is to complete this degree in May of 2021. She has been working for four years as a registered nurse in the emergency department at Parkview Regional Medical Center in Fort Wayne, Indiana. She has precepted a number of new nurses in the emergency department helping them transition from students to novice registered nurses. She has a passion for teaching and empowering others. She is a member of Coalition of Advanced Practice Registered Nurses of Indiana. She presented her DNP project at the University of Iowa's National Evidence-Based Practice Conference in April 2021. Her decision to implement an evidence-based practice project on generalized anxiety disorder stemmed from her recognition that the unprecedented events of 2020 increased the mental health needs in her community. She is dedicated to her hometown of Angola, Indiana and serving her community members. She will strive to improve the lives of patients and families as a family nurse practitioner in honor of her friends and family.
ACRONYM LIST

ANOVA: Analysis of Variance
CBT: Cognitive Behavioral Therapy
CITI: Collaborative Institutional Training Initiative
CPG: Clinical Practice Guideline
DNP: Doctor of Nursing Practice
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EBP: Evidence-Based Practice
GAD: Generalized Anxiety Disorder
GAD-7: Generalized Anxiety Disorder 7-item Scale
ICBT: Internet Cognitive Behavioral Therapy
JBI: Joanna Briggs Institute
JHNEBP: John Hopkins Nursing Evidence-Based Practice
NIMH: National Institute of Mental Health
PET: Practice Evidence Translation
RCT: Randomized Control Trial
SNRI: Serotonin Norepinephrine Reuptake Inhibitor
SSRI: Selective Serotonin Reuptake Inhibitor
PHQ-9: Patient Health Questionnaire 9-item Scale
PSWQ: Penn State Work Questionnaire
## APPENDIX A

### Evidence Table

<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>
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<tbody>
<tr>
<td>Andrews, G., Bell, C., Boyce, P., Gale, C., Lampe, L., Marwat, O., Rapee, R., &amp; Wilkins, G. (2018). Royal Australian and New Zealand college of psychiatrists clinical practice guidelines for the treatment of panic disorder, social anxiety disorder and generalised anxiety disorder. Australian and New Zealand Journal of Psychiatry, 52(12), 1109-1172.</td>
<td>To provide guidance for health care providers on how to treat adults with panic disorder, social anxiety disorder or GAD.</td>
<td>Clinical practice guideline</td>
<td>The target population is adults aged 18-65 with mild, moderate, severe and treatment refractory panic disorder, social anxiety disorder or GAD. A thorough literature search was performed. 143 quantitative studies were included in the qualitative synthesis. Only meta-analyses or systematic reviews of RCTs were included.</td>
<td>Improvement of symptoms typically begins to occur between 4-6 weeks after starting CBT or medication treatment so treatment should be assessed then. Patients should “be seen weekly to monitor adherence, adverse effects, and to identify worsening of symptoms until there is a response and symptoms have stabilised” (p.1124). GAD-7 or PSWQ-3 is</td>
<td>Education about the nature and treatment of GAD and lifestyle factors is recommended. Select initial treatment with consideration to patient preference, cost, accessibility, tolerability and safety. Initial treatment options: CBT guided dCBT, or SSRI (or SNRI), or the combination of both.</td>
<td>Level I High quality</td>
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<thead>
<tr>
<th>Researchers</th>
<th>Trial Type</th>
<th>Participants</th>
<th>Outcome Measures</th>
<th>Results</th>
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<tr>
<td>Berger et al.</td>
<td>Randomized controlled trial</td>
<td>139 adult participants, some heard about the study from their provider, while others visited the study website and asked to be in the study. 70 were in the experimental group, 69 were in the control group</td>
<td>Depression Anxiety Stress Scales – Short Form, the Beck Anxiety Inventory, the Beck Depression Inventory-II, the Brief Symptom Inventory and the Short-Form Health Survey-12</td>
<td>44.8% of participants with a GAD diagnosis at pre-treatment no longer fulfilled diagnostic criteria at post-treatment for GAD in the experimental group, whereas 0% recovered in the control group. There were statistically significant results in post-treatment between group comparisons for most primary outcome measures ($p &lt; 0.01$).</td>
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<tr>
<td>Jayasekara, R. (2016). Evidence Summary: Anxiety disorders: Psychotherapy. <em>The Joanna Briggs Institute</em>, 1-3.</td>
<td>To determine the best evidence regarding psychotherapy for patients with GAD</td>
<td>Evidence summary Psychotherapy interventions such as CBT were utilized in the studies and summarized in the evidence summary.</td>
<td>Children, adolescents, adults, and older adults with GAD 2 Cochrane systematic reviews, 2 systematic review, 4 RCTs, 1 meta-analysis and an RCT pilot study were included in the sample.</td>
<td>The effect of CBT on anxiety levels, relapse of anxiety symptoms, and symptoms of worry and depression were measured.</td>
</tr>
<tr>
<td>Lizarondo, L. (2018). Evidence Summary: Anxiety: Smartphone-based interventions. <em>The Joanna Briggs Institute</em>, 1-3.</td>
<td>To determine the best evidence regarding the effectiveness of smartphone-based interventions for the management of anxiety</td>
<td>Evidence summary</td>
<td>Psychological interventions accessed via smartphone were discussed in the evidence that was summarized.</td>
<td>Patients with anxiety</td>
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<tr>
<td>Lizarondo, L. (2019). Evidence Summary: Anxiety disorder: Relaxation therapy. <em>The Joanna Briggs Institute</em>, 1-2.</td>
<td>To determine the best evidence regarding the effectiveness of relaxation</td>
<td>Evidence summary</td>
<td>Relaxation therapy including</td>
<td>Patients with anxiety disorders such as GAD, panic disorder, social anxiety</td>
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for the management of anxiety disorders.

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<tr>
<td>To determine the best evidence regarding the effectiveness of exercise for GAD</td>
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<tr>
<td>Evidence summary</td>
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<tr>
<td>Physical exercise including resistance exercise, non-aerobic and aerobic exercise were</td>
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<tr>
<td>Patients with GAD</td>
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<tr>
<td>2 systematic reviews, and 2 clinical practice guidelines were included in the sample.</td>
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<tr>
<td>The effect of exercise on improvement of symptoms of GAD and quality of life were measured.</td>
</tr>
<tr>
<td>Exercise can be added to usual care of patients with GAD to decrease symptoms and improve quality of life (grade B recommendation).</td>
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<td>Level I High level</td>
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| discussed in the evidence that was summarized. | Exercise can improve symptoms of anxiety.  
A significant improvement in GAD symptoms in both the aerobic and non-aerobic exercise group.  
Although, exercise has been demonstrated to have significant improvements in GAD symptoms and patients should participate, there are no specific recommendations for how long, or what type of exercise should be used in the guidelines. |
| Ministry of Health. (2015, April). Anxiety disorders. https://www.moh.gov.sg/docs/librariesprlibrar4/guidelines/cpg_anxiety-disorders-apr-2015---full-guidelines.pdf | A guide to be used by providers paired with their clinical judgment to manage adults with anxiety disorders | Clinical practice guideline | The guideline provided recommendations for patients with panic disorder, GAD, phobias, social anxiety disorder, obsessive-compulsive disorder, post-traumatic stress disorder, and anxiety disorders in pregnant women. An extensive literature review was conducted. | Drug treatment for GAD should be continued for at least 32 weeks due to high relapse rates if medications are discontinued before then. The Clinical Global Impression scales may be used to measure illness severity and treatment progress. GAD-7 scale can be used as a screening instrument for GAD and provides quantitative data of the severity of symptoms. | Diagnosis of GAD should only be considered after organic causes are ruled out. Primary care providers are appropriate for initial management of GAD, but there are certain indications for referral to psychiatry that a provider must be aware of such as when there is a serious risk of suicide, psychotic symptoms, co-occurring drug/alcohol problem, symptoms are complex, or if symptoms fail to improve on initial treatment and follow up. | Level I Good quality |
After diagnosis, patients should be educated on their disease, and about lifestyle modifications. Their family should be a part of their care.

SSRIs and venlafaxine should be used first line for pharmacologic therapy.

Benzodiazepines should not be used long-term for GAD treatment.

CBT should be used first line for psychotherapy treatment for patients with GAD.

| Romano, M. (2019). Evidence Summary: Anxiety disorders: Self help. The Joanna Briggs Institute, 1-5. | To determine the best evidence regarding | Evidence summary | Patients with anxiety disorders such as panic | The effectiveness of self-help interventions | Self-help interventions may be used for the | Level I High quality |
| self-help interventions for patients with anxiety disorders | Psychological treatments such as CBT administered independently in books, computers, television, video or the internet were discussed in the evidence that was summarized. | disorders, social anxiety disorder, phobias, GAD, and post-traumatic stress disorder. 4 systematic reviews, 2 RCTs, 5 meta-analyses, and 1 Cochrane review were included in the sample. | with symptom reduction, cost-effectiveness and feasibility were measured. | treatment of patients with anxiety disorders in a grade A recommendation -n  
Self-help interventions are a cost-effective way to manage anxiety disorders.  
Materials should be age-appropriate and should be administered over a period of at least 6 weeks.  
Self-help interventions such as internet or computer-based therapy have shown efficacy when compared to wait-list and placebo and |
<p>| Slade, S. (2019). Evidence Summary: Generalized anxiety disorder: Pharmacotherapy. <em>The Joanna Briggs Institute</em>, 1-3. | To determine the best evidence regarding pharmacotherapy for patients with GAD. | Evidence summary Pharmacologic treatment typically combined with psychological therapy and self-care were discussed in the evidence that was summarized. | Adult patients with GAD 9 systematic reviews, 1 clinical practice guideline, 1 prospective trial | Ability to promote remission, tolerability, efficacy in reduction of symptoms and response rates were measured. | The use of antidepressants, quetiapine and pregabalin were all recommended for use, with clinical judgment and patient preferences in mind in a grade A recommendation. Fluoxetine was most strongly recommended due to obtaining response and remission. Sertraline was most strongly recommended for tolerability. “A lack of response within 4 weeks of treatment.” | Level 1 High quality |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Methodology</th>
<th>Primary Outcomes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slee, A., Nazareth, I., Bondaron, P., Liu, Y., Cheng, Z., &amp; Freemantle, N. (2019). Pharmacological treatments for generalised anxiety disorder: A systematic review and network meta-analysis. The Lancet, 393, 768-777. <a href="http://dx.doi.org/10.1016/S0140-6736(18)31793-8">http://dx.doi.org/10.1016/S0140-6736(18)31793-8</a></td>
<td>To explore pharmacological treatments for treatment of patients with GAD.</td>
<td>A systematic review and network meta-analysis. The pharmacologic treatments discussed in this review include 22</td>
<td>Primary outcomes were efficacy noted in mean difference in change in Hamilton Anxiety Scale score and acceptability measured by study. Duloxetine, pregabalin, venlafaxine, and escitalopram were more efficacious than placebo with good acceptability. Mirtazapine,</td>
<td>Level I High quality</td>
</tr>
</tbody>
</table>

Antidepressant use suggests further response is unlikely" (p.1). Benzodiazepines should only be used for treatment refractory individuals. Combining CBT with an SSRI may allow them to be weaned from the SSRI. Treatment of any anxiety disorder with propranolol is ineffective.
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>To report preliminary data on engagement and symptom improvement in adult patients with anxiety in primary care who engage in a mobile CBT program, Lantern.</td>
</tr>
<tr>
<td>different drugs including SSRIs, SNRIs and benzodiazepines</td>
</tr>
<tr>
<td>while 2 serve as control sites providing enhanced treatment as usual.</td>
</tr>
</tbody>
</table>
Appendix B

Education Provided to Patients

What is the problem? Generalized anxiety disorder. Generalized anxiety disorder is a common condition where you have excessive worry and stress for at least 6 months that causes physical distress and impairs your ability to function. This can be due to an imbalance of chemicals called neurotransmitters in your brain. Anxiety can cause physical symptoms such as trouble sleeping, restlessness, muscle aches and tiredness. Anxiety can impact your ability to function throughout the day.

What should you do? There are many things that you can do to help improve your symptoms.

1.) Cognitive Behavioral Therapy: Cognitive behavioral therapy has been shown in many different studies to decrease anxiety symptoms. This is one of the best treatments for anxiety. This therapy tries to improve your way of thinking in order to deal with your problems in a more positive way. We will be giving you information on a smart phone application that you should use. You should use this at least once per week, but the more you use it, the better. You could use the application instead of getting on Facebook, during commercial breaks of a tv show, or when you are waiting for someone or something. You can get on the application and learn about anxiety, do exercise, and perform relaxation techniques.

2.) Diet: You should try reducing your intake of caffeine. Caffeine is a stimulant which can increase your heart rate and make you jittery, which can cause you to feel anxious. You should increase your intake of fruits, vegetables, and whole grains.

3.) Essential Oils: Lavender, patchouli, clary sage has been found to calm anxiety. You can place a few drops on your skin every day, you can diffuse it in a diffuser, or put in in your bath water. You can get essential oils at Walmart, Meijer, Lakeside Farms and Nature’s Cornucopia in town, or online at places like Amazon.

4.) Exercise: You should perform 30 minutes of exercise per day most days of the week. Some examples of this could include walking, swimming, biking and/or lifting weights. It has been shown in research that exercise can decrease anxiety symptoms, help to calm you down and release tension. It can also help you lose weight and become healthier.

5.) Medications: Your provider may prescribe you a medication called a selective serotonin reuptake inhibitor. There are 5 medications in this class. Serotonin is a chemical in your brain that helps with your mood. These medications fight against the “bad guys” stealing the serotonin from your brain, so that there is more serotonin for you to have, therefore improving mood and decreasing anxiety. Your provider will tell you when and how to
take this medication, but it is important that you take it like they tell you and tell them if you want to stop it or are having side effects.

6.) Relaxation Techniques: You should try to use relaxation techniques as much as possible, but especially if you notice that your anxiety is flaring up. These techniques do not take long and could be performed 2-3 times per day. Again, do this instead of getting on social media applications, during commercial breaks, or while you’re waiting.
   a. Progressive muscle relaxation. First, you will take a deep breath and tense a muscle group for instance your clenching your hands for 4 to 10 seconds. Then, breathe out and completely relax your hands. Then, relax for 10 to 20 seconds. Then, move on to the next muscle group such as shrugging your shoulders. Continue with all of your muscles. When you are finished with all of the muscle groups, count backward from 5 to 1.
   b. Meditation: Sit or lie in a comfortable position. Close your eyes. Breathe naturally. Focus on your breath and how your body moves with each inhalation and exhalation. If your mind wanders, return your focus back to your breath.
   c. Deep breathing: Take a slow deep breath from your belly, count to 4 as you breathe in. Hold your breath, and silently count from 1 to 7. Breathe out completely as you silently count from 1 to 8. Repeat.

7.) Sleep: You should be getting 7-9 hours of sleep at night. Try going to bed at the same time every night and waking up at the same time every morning.

8.) Smoking and drinking alcohol: Smoking and drinking alcohol can increase your anxiety symptoms. If you smoke tobacco, you should quit smoking. Nicotine can cause anxiety to flare up due to its stimulating effects. Ask your provider if you need help with his such as with patches, medication or counseling. If you drink alcohol, you should attempt to cut back to 1 standard size drink per day or less for a female or 2 standard size drinks per day or less for a male. Alcohol can cause a change in the chemicals in your brain called neurostimulators and can make your anxiety worse.

Resources about Generalized Anxiety Disorder:

National Institute of Mental Health: https://www.nimh.nih.gov/health/topics/anxiety-disorders/index.shtml

Anxiety and Depression Association of America: https://adaa.org/understanding-anxiety/generalized-anxiety-disorder-gad/treatments

University of Michigan: https://www.uofmhealth.org/health-library/uz2225
National Suicide Prevention Hotline: https://suicidepreventionlifeline.org or 1800-272-8255
APPENDIX C

Power Point Provided to Providers

GENERAL INFORMATION

- First line treatment for generalized anxiety disorder
- Mechanism of action: selectively inhibits the reuptake of serotonin which enhances serotonergic activity in the CNS
- Can take several weeks to start working and several more weeks to achieve maximum benefit
- Adverse drug reactions: anxiety, insomnia, sexual dysfunction, weight gain/loss, headache, nausea.
- Interactions: other serotonergic drugs because of serotonin syndrome
  - Antidepressants: SSRIs, SNRIs, TCAs, MAOIs, trazodone
  - Analgesics: tramadol, meperidine
  - Antiemetics: ondansetron, granisetron, metoclopramide
  - Others: linezolid, dextromethorphan, St. John’s wort, triptans
- Abrupt discontinuation can lead to withdrawal symptoms: flu-like symptoms, insomnia, nausea, imbalance, sensory disturbances, hyperarousal. Can occur as soon as 1-4 days after abrupt discontinuation. Tapering over 7 to 10 days is recommended. Patients should be counseled of this.
- Fluoxetine, Sertraline, Citalopram, and Escitalopram are pregnancy category C
- Paroxetine is pregnancy category D

(Olenik, 2018)

DOSING FOR ADULTS

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Starting Dose</th>
<th>Maintenance Dose</th>
<th>Max Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxetine</td>
<td>Paxil</td>
<td>10-20 mg once daily</td>
<td>20-40 mg once daily</td>
<td>50 mg</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>Prozac</td>
<td>10-20 mg once daily</td>
<td>20-40 mg once daily</td>
<td>60 mg (can go up to 80 mg but no benefits shown and increased risk of adverse reactions)</td>
</tr>
<tr>
<td>Sertraline</td>
<td>Zoloft</td>
<td>25 mg once daily</td>
<td>50-100 mg once daily</td>
<td>200 mg</td>
</tr>
<tr>
<td>Citalopram</td>
<td>Celexa</td>
<td>10-20 mg once daily</td>
<td>20-40 mg once daily</td>
<td>60 mg</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>Lexapro</td>
<td>10 mg once daily</td>
<td>10-20 mg once daily</td>
<td>20 mg</td>
</tr>
</tbody>
</table>

(Olenik, 2018)
### ADDITIONAL INFORMATION

<table>
<thead>
<tr>
<th>Generic Name/Brand Name</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxetine/Paxil</td>
<td>Most likely to cause sedation. May be good option if patient has insomnia or if another SSRI is causing insomnia and they are disliking that side effect. Advise to take at bedtime. Avoid in pregnancy. Available in immediate release and extended release. Both dosed once daily. Controlled release associated with less GI effects but more expensive.</td>
</tr>
<tr>
<td>Fluoxetine/Prozac</td>
<td>Available as once daily immediate release or once weekly 90 mg capsule. Patient should start on immediate release then switch to weekly if necessary. May benefit patients with decreased compliance. Take in AM.</td>
</tr>
<tr>
<td>Sertraline/Zoloft</td>
<td>Most incidence of diarrhea and GI side effects, usually goes away after a week of treatment.</td>
</tr>
<tr>
<td>Citalopram/Celexa</td>
<td>Fewer drug to drug interactions than other SSRIs because less CYP450 mediated metabolism. May benefit patients on multiple other medications.</td>
</tr>
<tr>
<td>Escitalopram/Lexapro</td>
<td>Fewer drug to drug interactions than other SSRIs because less CYP450 mediated metabolism. May benefit patients on multiple other medications. (Olenik, 2018)</td>
</tr>
</tbody>
</table>
APPENDIX D

Clinical Decision Tool Provided to Providers

Diagnosis of patient with GAD after ruling out organic causes following DSM V criteria. If patient has symptoms of psychosis, drug and alcohol addiction or suicidal or homicidal ideations refer to psychiatry.

Assess patient’s level of anxiety and depression using GAD-7 and PHQ-9.

- GAD-7 results of 5-9 indicates mild severity
- GAD-7 results of 10-14 indicates moderate severity
- GAD-7 results of 15-21 indicate severe severity

Initiate education, CBT via smartphone application and SSRI pharmacotherapy.

Review response to initial treatment after 4-6 weeks.

- If at least partial response: continue treatment, monitor progress and adverse effects
- If no response or worsening of symptoms: check adherence, increase medication dose within approved range, and/or change to face to face CBT, and/or refer to psychiatry
APPENDIX E

Demographic Form

Please answer the following questions about yourself.

1. How old are you? ____________________

2. What is your sex?
   a. Male
   b. Female
   c. Other

3. What is the highest level of education that you have completed?
   a. Less than high school
   b. High school/GED
   d. Some college with no degree
   e. 2-year college degree (Associates)
   f. 4-year college degree (Bachelors)
   g. Master’s degree
   h. Doctoral degree

4. What is your race?
   a. African American
   b. Asian-Pacific Islander
   c. Caucasian
   d. Hispanic
   e. Native American
   d. Other
   f. 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
   b. Married
   c. Separated
d. Divorced
e. Widowed

7. What is your annual gross 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
   d. $100,000 or more

8. What is your current employment status?
   a. Employed full time
   b. Employed part time
   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/disabled
APPENDIX F

Handout Provided to Patients about MindShift Application

You should download the MindShift app. This app is available on Apple and Android phones. This app is free of charge and there are no in app charges.

The application looks like this.

You will then open the app and will have to create an account. Click Create Account.
This is the information you will have to fill out. This only take a minute.

You can do a daily check in.
You can set goals using the goals tab.

You can learn about anxiety and cognitive behavioral therapy (CBT) using the learn tab.
You can use the tools in the Home tab. The healthy thinking section helps you retrain your brain to think healthier thoughts. The chill zone section walks you through many different relaxation techniques. The taking action section walks you through things you can do to reduce your anxiety such as eating right, get enough sleep, be active, comfort zone challenges, and facing fears.
APPENDIX G
Patient Log Sheet

Reminders:
- Exercise 30 minutes a day. This could include walking, swimming, weight training, bike riding.
- Relaxation Techniques: Use relaxation techniques such as progressive muscle relaxation or deep breathing whenever you feel like your anxiety is flaring up.
- MindShift Smartphone App: Obtain the application and use at least once a week or whenever you notice your anxiety flaring up.

<table>
<thead>
<tr>
<th>Date</th>
<th>Exercise (Type, Intensity)</th>
<th>Relaxation Techniques (Type)</th>
<th>MindShift Application</th>
<th>Missed Dose of Medication</th>
<th>Benzodiazepine (Ativan, Xanax) Use (Dose)</th>
<th>Time Spent</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
## GAD-7 Scale

**Over the last 2 weeks, how often have you been bothered by the following problems?**

<table>
<thead>
<tr>
<th></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 is 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>

*Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.*
### PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

**Over the last 2 weeks, how often have you been bothered by any of 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**

\[ 0 + \_\_\_ + \_\_\_ + \_\_\_ = \text{Total Score: } \__ \__ \__ \__ \]

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?

<table>
<thead>
<tr>
<th>Difficulty</th>
<th>Not difficult at all</th>
<th>Somewhat difficult</th>
<th>Very difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

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APPENDIX J

Patient Questionnaire

Please answer the following questions about yourself.

1.) Do you perform any type of physical activity or exercise? Ex: swimming, running, walking, biking, weight training

   Yes       No

   **If no, skip to question 6**

2.) If so, what type of exercise?

   ______________________________________________________

3.) How many times a week do you perform this exercise?

   ______________________________________________________

4.) For how many minutes?

   ______________________________________________________

5.) Would you consider this exercise mild, moderate or strenuous?

   Mild       Moderate       Strenuous

6.) Do you perform any relaxation techniques? Ex: progressive muscle relaxation, meditation, deep breathing, yoga

   Yes       No

   **If no, skip to question 9**

7.) If so, how many times a week do you perform relaxation techniques?

   ______________________________________________________

8.) For how many minutes?

   ______________________________________________________
9.) Do you use any form of cognitive behavioral therapy? Ex: smartphone applications or face to face?

   Yes
   No

10.) If so, how many times a day do you perform cognitive behavioral therapy?

________________________________________________________________________

11.) For how many minutes?

________________________________________________________________________

12.) Do you use benzodiazepine medications such as alprazolam (Xanax) or lorazepam (Ativan) or diazepam (Valium) or clonazepam (Klonopin)?

   Yes
   No

13.) If so, what is the medication that you use and at what dose?

________________________________________________________________________

14.) How many times per week do you use this medication?

________________________________________________________________________