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**DIET, EXERCISE, SELF-MONITORING, TECHNOLOGY, AND MOTIVATIONAL INTERVIEWING
FOR WEIGHT LOSS IN ADULTS**

by

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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

2022

"I have neither given or received, nor have I tolerated others' use of unauthorized aid." Ashleigh Warburton

| | | | |
|---------------------------|----------------|-----------|----------------|
| <u>Ashleigh Warburton</u> | <u>5/11/22</u> | <u>AS</u> | <u>5/11/22</u> |
| Student | Date | Advisor | Date |



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DEDICATION

This project is dedicated to my family, my husband, and especially my children who have sacrificed so much so that I could follow my dreams. Michael and Olivia, I hope I inspire you to follow your dreams. Nothing is out of your reach. I love you both with all my heart.

Mike, thank you for always supporting me. I could not have done this without you.

Mom, I am who I am today because of you. Thank you for everything.

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I would like to acknowledge the organization, everyone at the site, and my site facilitator for allowing me to complete my project within their walls and for their patients. I would also like to acknowledge the diabetic educator for donating her time and supplies to my project, my advisor for her support, guidance, and encouragement, as well as all of the educators at Valparaiso University who I have had the pleasure of knowing. Each one of you has imprinted on me something very special that I hope to carry on to every patient I encounter as a message of hope that there are people in this world who genuinely care and want to provide patients with the absolute best health care possible. I am humbled and so grateful to have met these people, providers, educators, and every patient who I have had the pleasure of encountering.

TABLE OF CONTENTS

| <u>Chapter</u> | <u>Page</u> |
|--|--------------------|
| DEDICATION..... | iv |
| ACKNOWLEDGMENTS..... | v |
| TABLE OF CONTENTS | iv |
| LIST OF TABLES..... | 8 |
| LIST OF FIGURES | 9 |
| ABSTRACT..... | 10 |
| CHAPTERS | |
| CHAPTER 1 – Introduction | 11 |
| CHAPTER 2 – EBP Model and Review of Literature | 17 |
| CHAPTER 3 – Implementation of Practice Change | 32 |
| CHAPTER 4 – Findings..... | 39 |
| CHAPTER 5 – Discussion..... | 48 |
| REFERENCES..... | 59 |
| AUTOBIOGRAPHICAL STATEMENT..... | 64 |
| ACRONYM LIST..... | 65 |
| APPENDICES | |
| APPENDIX A – Evidence Table..... | 66 |
| APPENDIX B – Demographics Form..... | 81 |
| APPENDIX C – Self-Monitoring Templates..... | 82 |
| APPENDIX D – Program Directions..... | 83 |
| APPENDIX E – Program Timelines..... | 84 |

| | |
|---|----|
| APPENDIX F – Informed Consent Form..... | 85 |
| APPENDIX G – Implementation Calendar..... | 88 |
| APPENDIX H – Ethics Training..... | 89 |
| APPENDIX I – IRB Approval Letter..... | 90 |
| APPENDIX J – Sustainability Protocol..... | 91 |

LIST OF TABLES

| <u>Table</u> | <u>Page</u> |
|---|--------------------|
| Table 2.1 Summary of Evidence..... | 23 |
| Table 4.1 Summary of Demographics..... | 41 |
| Table 4.2 Summary of Statistics Comparison and Intervention..... | 46 |
| Table 4.3 Independent Samples test Comparison versus Intervention | 46 |
| Table 4.4 Independent Samples Test Comparison and Dropouts (Without Outliers) Versus Intervention..... | 47 |

LIST OF FIGURES

| Figure | Page |
|--|-------------|
| Figure 2.1 PRISMA Flow Chart of Literature Review..... | 20 |

ABSTRACT

Obesity, an epidemic in the United States (US), affected 42.4% of adults as of 2017-2018 (Hales, 2020). Comorbidities associated with obesity, such as cardiovascular disease, cancer, and diabetes (Orringer et al., 2020), are some of the leading causes of death in the US (Kochanek et al., 2020). The purpose of this evidence-based practice (EBP) project was to answer the following PICOT question: In adult patients aged 19 years or older who are considered overweight or obese as measured by body mass index (BMI) of $\geq 25 \text{ kg/m}^2$ (P), how effective is diet and exercise combined with self-monitoring, a phone application, motivational interviewing (MI) and feedback (I) compared to standard care (C) at lowering BMI (O) over a 12-week period (T)? Adult participants ($n = 38$) were recruited from an underserved clinic in Northwest Indiana. Participants were provided with educational materials and instructions for downloading a free phone application, following a low-fat and low sugar diet, engaging in at least 30 minutes of walking five times weekly, recording meal choices and exercise amounts, and to participate in biweekly MI phone calls over 12 weeks. An independent-samples *t*-test was calculated comparing the mean difference in weight and BMI pre and post intervention in the intervention group participants who completed the program ($n = 19$) to the mean difference in pre and post weight and BMI of participants in the comparison group ($n = 14$). No significant difference was found ($t(31) = 1.575, p > .05$) ($t(31) = .869, p > .05$). The mean difference in weight and BMI for the intervention group ($M = 3.10$; $SD = 5.92$) ($M = .32$; $SD = 1.12$) was not significantly different from the mean difference in weight and BMI for the comparison group ($M = .14$; $SD = 4.40$) ($M = 0.2$; $SD = .72$). When comparing the final weight of the intervention group to the comparison group combined with the dropout participants ($n = 30$), there was a statistically significant difference ($p = .009$). Future research may focus on evaluating the effectiveness of this program at a larger practice site and including in-person MI sessions rather than phone calls only.

Keywords: weight loss, body mass index, diet, exercise, motivational interviewing, phone application, evidence-based practice

CHAPTER 1

INTRODUCTION

Background

Obesity is considered an epidemic in the United States (US). The prevalence of obesity has increased at alarming rates in the US and globally. Healthy People 2020 and Healthy People 2030 have both set goals to combat the obesity epidemic in the US. The concern over these rising rates is based on the evidence that supports the connection between obesity to several comorbidities which are leading causes of death. Researchers have linked obesity to reduced quality of life, increased risk for developing chronic health conditions, and decreased life expectancy (Orringer et al., 2020; U.S. Department of Veteran Affairs, Department of Defense [VA/DoD], 2020). Primary care providers, including family nurse practitioners (FNPs), are often the first contact a patient has for healthcare needs when not related to an acute illness. During routine wellness visits, primary care providers are in an opportune position to provide options for weight loss. Often, a few spoken words or written materials about weight loss are ineffective. Combining diet and exercise with regular checkups, self-monitoring tools, a phone application, and accountability through motivational interviewing (MI) may enhance the effectiveness of weight loss attempts.

For screening purposes, obesity and overweight are measured using body mass index (BMI) (Centers for Disease Control and Prevention [CDC], 2021b). BMI is the calculation of weight in kilograms divided by height in meters squared. While BMI does not diagnosis the health of an individual, it is a screening tool used for categorizing weight based on height (CDC, 2021b). A higher BMI increases one's risk for developing associated comorbidities; it is not meant to reflect negatively on one's character or quality of life. According to the CDC (2021c), an individual is considered overweight if their BMI is between 25 and 30 kg/m² and an individual with a BMI of 30.0 kg/m² or higher is in the category of obesity. The category of obesity may be then

subdivided into class 1, 2, and 3 (30 to 35 kg/m², 35 to 40 kg/m², and 40 kg/m² or greater, respectively) (CDC, 2021c).

The conditions that are associated with obesity include the following: “cardiovascular disease, numerous cancers, and diabetes” (Orringer et al., 2020, p. 11). These comorbidities account for some of the highest causes of death in the US. In 2019, cardiovascular disease was reported as the leading cause of death in the US while cancer and diabetes were the second and seventh, respectively (Kochanek et al., 2020). According to Avgerinos et al. (2019) there is sufficient evidence to link obesity to cancer of the following sites: “endometrium, esophagus (adenocarcinoma), colon and rectum, liver, pancreas, postmenopausal breast and kidney (renal adenocarcinoma)” (p. 122). The pathophysiology for the development of comorbidities associated with obesity is complex. Obesity increases the propensity for plaque deposits, systemic inflammation, insulin resistance, and increased activity of the sympathetic nervous system (Gadde et al., 2018). These factors play a role in the development of cardiovascular disease and type two diabetes. While the exact relationship between the association of obesity and risk of developing cancer is not fully clear, there is convincing evidence that certain pathways play a role. Some of these pathways include the following: (a) hyperinsulinemia, (b) the synthesis of hormones, (c) oxidative stress and free fatty acids, (d) chronic inflammation, (e) deficits in dietary nutrients, and (f) altered intestinal microbiome (Avgerinos et al., 2019). The development of obesity and its comorbidities have similar beginnings: diet and exercise. Because of this, these two interventions are paramount in decreasing the risk of developing comorbidities associated with obesity.

Finally, along with detriments to health, obesity is costly. The individual patient and the healthcare system at large are impacted by the monetary cost of obesity. Annual medical costs for an individual considered obese were double (\$5,010) that of an individual with a BMI within normal limits (\$2,504) (Cawley et al., 2021). The burden of adult obesity on a healthcare system is staggering. Adult obesity cost the US healthcare system a total of \$260.6 billion in 2016

(Cawley et al., 2021). The direct cost of overweight and obesity accounts for approximately 5 to 10% of all US healthcare spending (Orringer et al., 2020). Encouraging weight loss may provide enhanced health benefits as well as financial benefits for individuals and the entire healthcare system.

Data Supporting Need for the Project

One of the objectives of Healthy People 2030 (n. d.) was developed with a goal to reduce the number of adults aged 20 years and older who fall into the obesity category by 2.6% by the year 2030. This goal is a continuation of the Health People 2020 goal. The reason for the continuation of the goal was because rates of obesity increased in the US by 4.7% rather than decreased. The percentage of adults from 2005-2008 who were considered obese rose from 33.9% to 38.6% in 2013-2016 (Healthy People 2020, 2021). These increasing rates may reflect inadequacies in current practices provided for weight loss and further emphasizes the growing need for interventions focused on obesity and weight loss. The following global, national, and state data further supports the inept current practices and the need for reform around weight loss treatment.

Global Data

The prevalence of obesity is high in the US and globally. The World Health Organization ([WHO], 2021) estimates that in 2016, 39% of all adults aged 18 years and older around the world were overweight and 13% were obese. The prevalence of obesity is high and has risen around the globe at an alarming rate, almost tripling since 1975 (WHO, 2021).

National Data

Compared to the rest of the world, the prevalence of obesity in the US is exceedingly high. As of 2017-2018, the “age-adjusted prevalence of obesity among US adults was 42.4%” (Hales, 2020, p. 1). The prevalence of obesity in the US rose by 11.9% from 1999-2000 to 2017-2018 (CDC, 2021a). Obesity in the US is present in every state. The prevalence of obesity was 30% or higher in every state except one (Colorado) (CDC, 2021d). The prevalence of obesity

was highest (35% or more) in the following states: Alabama, Arkansas, Indiana, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Oklahoma, South Carolina, Tennessee, and West Virginia (CDC, 2021d). These statistics imply that obesity treatment reform is needed throughout the nation.

State Data

The prevalence of obesity in the state of Indiana is among the highest in the US. In 2019, the prevalence of self-reported obesity among adults in Indiana was 35.3% (CDC, 2021d) making this state the 9th highest. Obesity across gender is comparable. The prevalence of obesity among men and women in Indiana was 35.7% and 34.9%, respectively (United Health Foundation, 2021). Obesity and ethnicity vary in Indiana. The prevalence of obesity among Hispanic adults was 46.2%, Black adults was 36.7%, and White adults was 34.9% (United Health Foundation, 2021). Lower income was associated with higher prevalence of obesity. Individuals making less than \$25,000 had the highest prevalence of obesity (41.7%) and individuals making \$75,000 or more had the lowest prevalence of obesity (33.5%) (United Health Foundation, 2021).

Clinical Agency Data

The clinical agency where the evidence-based practice (EBP) project was implemented is located in the Northwest part of Indiana in Lake County. While specific data about the prevalence of obesity in this clinic site, city, and county was unavailable, there is a documented association of obesity with lower socioeconomic status. This association is representative of the Indiana population as noted by the United Health Foundation (2021) statistics. This relationship may be attributed to less nutritious foods being more affordable. According to the US Census Bureau (2019), the median income for a household living in the city where the clinic site is located during 2016-2020 was \$31,315. According to the United Health Foundation (2021), the prevalence of obesity in adults was 40% among individuals living in Indiana whose income range was between \$25,001 and \$49,999.

In preparation for this EBP project, the site providers, a physician and an FNP, were interviewed regarding the need for this project within this clinical site. In summary, after talking to the providers at the clinical agency, there was a need at the clinical site for increased management of overweight and obesity due to the high numbers of individuals presenting with a BMI greater than 25 kg/m².

Purpose of the Evidence-Based Practice Project

Due to the detriments to health, and the high prevalence at this site, the purpose of the EBP project was to provide primary care providers, specifically FNPs, with a convenient, cost effective, and efficacious first line protocol for treating overweight and obesity. Particularly, the clinical question posed sought to answer what the best way for FNPs was to help adult patients (>19 years of age), who are considered overweight or obese, lose weight. Often the first point of care for patients, FNPs are in an opportune position to positively affect the obesity epidemic and help reach the Healthy People 2030 goal. Helping patients decrease their BMI will help them reach their highest potential, an important part of the holistic style of healthcare practiced by FNPs. The effectiveness of a low-fat and low sugar diet, 30 minutes of walking five times weekly, self-monitoring, a phone application, in conjunction with regular MI and feedback was evaluated in order to determine its continued use at this clinical site.

PICOT Question

This project addresses the following PICOT question: In adult patients aged 19 years or older who are considered overweight or obese as measured by BMI of ≥ 25 kg/m² (P), how effective is a low-fat and low sugar diet, 30 minutes of walking five times per week, self-monitoring, and a phone application along with regular MI and feedback (I) compared to standard care (C) at lowering BMI (O) over a 12-week period (T)?

EBP Project Description

Participants were screened within the office setting as having a BMI greater than 25 kg/m² after height and weight measurements were recorded and entered into the electronic

medical record. If agreeable to entering a weight loss program, the participant was provided a bag with educational materials on diet and exercise as well as templates for journaling daily diet and exercise over 12 weeks. The participant was instructed to download the free phone application called “Start Simple with MyPlate” and set three daily dietary goals within the application (United States Department of Agriculture [USDA], n.d.). Instructions were provided that included following a low-fat diet and walking for 30 minutes five times per week. A demographics form was also filled out by the participant through which contact information and demographic data was collected. The project leader (PL), the Valparaíso University (VU) doctoral student, then called the participant on a biweekly basis to provide MI and feedback in the form of encouragement and support. The project timeline was 12 weeks and the main data utilized for comparison comprised of the participant’s weight and BMI.

CHAPTER 2

EBP MODEL AND REVIEW OF LITERATURE

Evidence-based Practice Model

The EBP model chosen to guide this EBP project was the Iowa Model Revised: Evidence Based-Practice to Promote Excellence in Health Care (Iowa Model). The Iowa Model is a guideline for the application of EBP and the associated change process. The model was originally developed as a research model in 1994 by a team of nurses from the University of Iowa Hospitals and Clinics and College of Nursing (Titler et al., 1994). This model has changed over time since its origination. The model has seen two revisions (2001 and 2015) which simplified and clarified the process steps (Buckwalter et al., 2017). The model guides the clinician through the EBP process with seven streamlined steps and three decisions points which provide an opportunity for critical analysis and, if needed, feedback loops.

Overview of EBP Model

To summarize the model, it begins with a questioning attitude and a spirit of inquiry by identifying a need to enhance or change current practice to better serve the patient population or the organization. The process then takes the user through stating the purpose, forming a team, assembling the evidence, designing and implementing the practice change, finding ways to sustain the change, and finally disseminating the results. More specifically, step one is the identification of potential reasons for change. This is identified by the model as triggers or opportunities for promoting excellence in healthcare through the application of EBP (Dang et al., 2019). Step two simply involves stating the purpose. It is recommended that the question or purpose be stated in a Population, Intervention, Comparison, Outcome (PICO) format to provide clear goals and help the user stay focused (Dang et al., 2019). The next step is determining if the problem is a priority for those it effects. These effects may be felt by the patient population served or the organization it involves. During this assessment of prioritization, the first of three

opportunities to engage in a feedback loop is provided by a decision point. If the issue is not a priority, the model suggests considering another. If the issue is a priority, the user moves forward to step three. This step includes forming a team. This team should consist of the stakeholders involved in the practice change. The step thereafter is to assemble, appraise, and synthesize the evidence. The second decision point includes assessing if there is enough evidence. If there is not, one should conduct research and reassemble. If there is sufficient evidence, the team can move on to designing and piloting the practice change (Dang et al., 2019). This step includes developing a protocol, an implementation plan, and preparing clinicians and promoting adoption (Dang et al., 2019). The final decision point includes determining if the practice change is appropriate (Dang et al., 2019). If it is not, alternatives must be considered. If the change is appropriate, sustainability must be accomplished through engagement of stakeholders, hardwiring the change into the workflow, and reevaluating as needed (Dang et al., 2019). Finally, the results should be evaluated and provided as support for others to implement similar practice changes within other organizations.

For this EBP project, there were several rationales the Iowa Model was chosen for guidance. The model is recognized for its ease of use, and it can be applied to a wide variety of project topics. Additionally, the linear process with occasional feedback loops was appealing. Another reason this model was chosen is because it was designed by nurses. An EBP model created by nurses is most appropriate for utilization by nurses. For this EBP project, the team consists of multidisciplinary healthcare team members, but the leads of the project included a registered nurse and an FNP.

The Iowa Model supported the EBP project because utilizing the steps outlined within the model created an uncomplicated process to try and accomplish the practice change. First, the triggering issue was identified by the FNP at the primary care office where it was noted that obesity effects many of the presenting patients. Not only was it identified as a priority at the clinical site, but the need for practice change was also noted in research and supported by the

prevalence data at global, national, and state levels. The team was then formed to include the following: two clinicians in the office (a physician and an FNP), three medical assistants (MAs), and one office manager. After an exhaustive and comprehensive literature review, it was found that there was substantial, high-level evidence to endorse the project and the team was supportive of its implementation.

Literature Search

Sources Examined for Relevant Evidence

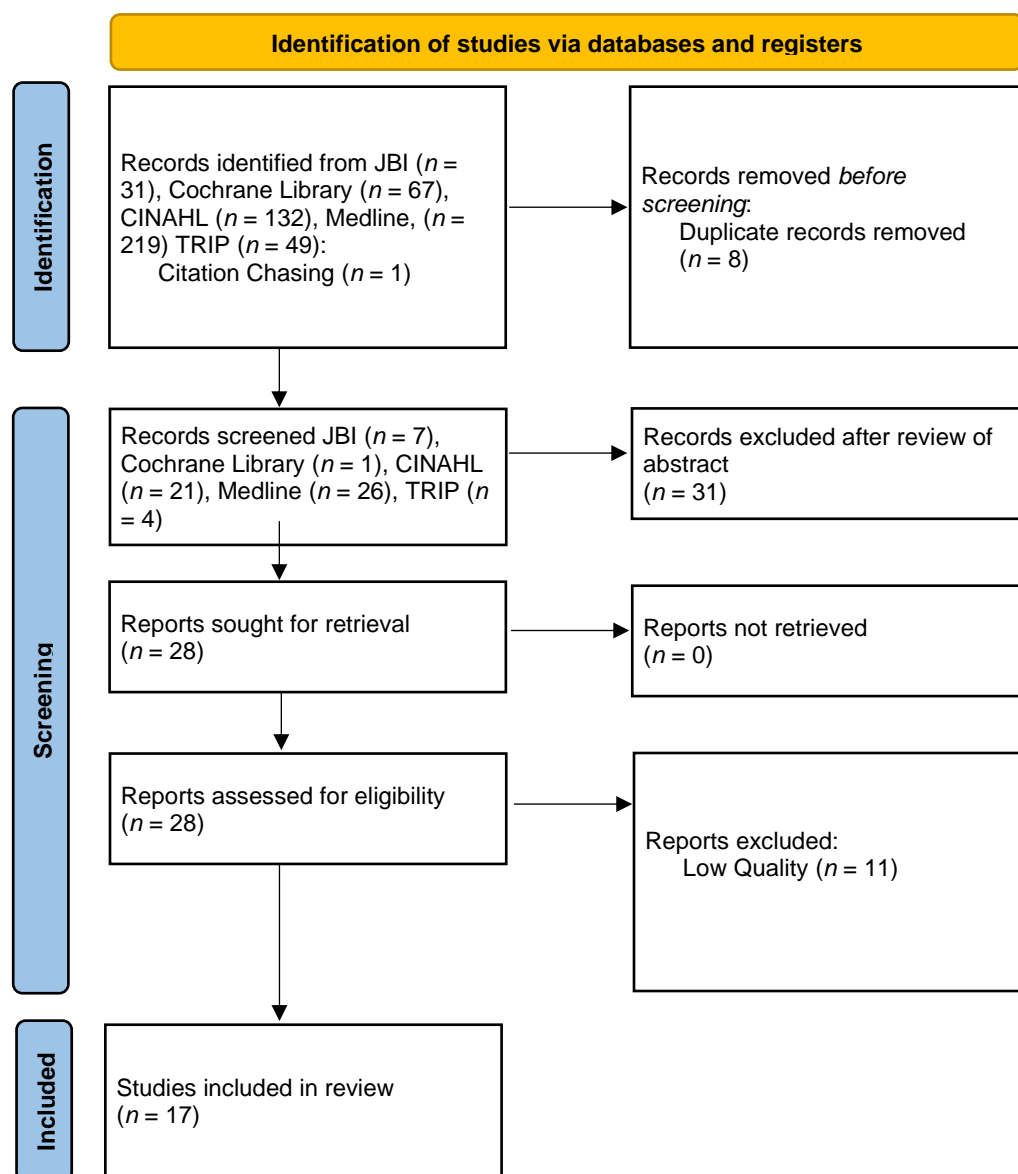
The following databases were searched for relevant evidence: (a) Joanna Briggs Institute (JBI) Evidence-based Practice Database, (b) Cochrane Library, (c) Cumulative Index to Nursing and Allied Health Literature (CINAHL), (d) Medline, and (e) Turning Evidence Into Practice (TRIP) database. Hand searching and citation chasing were also used. Within JBI and Cochrane Library, the search terms included the following: “Weight Reduc*” and “Overweight OR Obes* AND Reduc*” respectively. In all other databases, the following search words were used: “(overweight OR obes* OR BMI OR ‘Body Mass Index’) AND (interven* OR treat* OR manage* OR reduc*) AND (adult*) AND (‘primary care provider’ OR ‘primary health care’ OR ‘primary healthcare’) AND (‘best practice*’ OR ‘evidence-based practice*’ OR guideline*).” All databases that were searched included a date range limiter of articles published within the last 5 years. Due to a lack of resources available for translation, only evidence published in the English language was considered. In the CINAHL database, additional limiters included scholarly, peer-reviewed articles, whereas in the TRIP database limiters included clinical practice guidelines (CPGs). To narrow the results in Medline, articles with any variation of the following search words in the title were included in the search: (overweight OR obes* OR BMI OR ‘Body Mass Index’).

Additional inclusion criteria included evidence with the outcomes of reducing BMI or body weight for patients who were considered obese or overweight. Only studies that were already completed were considered as the results indicate applicability to practice; therefore, suggested systematic review (SR) protocols or ongoing studies were not included. Evidence about provider

perception, comorbidities, or prevention were not included because they were tangential to the purpose of this review. Patients considered pediatric, adolescent, or pregnant were excluded to maintain a topic focused on adults in the primary care setting.

During the initial search of each database, articles were selected for further screening based on the title. After selected, the abstract was reviewed and if the article appeared appropriate for inclusion, the article was read in its entirety. Next, citation chasing of the evidence cited that was written within the last five years was evaluated by its title for potential inclusion. If by the title it was determined the evidence may be included, then the abstract was read. If the topic aligned with the EBP project focus, then the entire article was read.

Within the JBI database, seven results were considered; however, due to some articles being tangential to the topic, only three were selected for inclusion. The piece of evidence that was citation chased from an article in the JBI database was also found in the Medline database. Since much of the evidence that resulted within the Cochrane Library ($n = 67$) was about comorbidities, only one article was selected for review and that article was included. The CINAHL database provided 132 results and 21 were screened for inclusion. After reading the abstract, six pieces were selected for inclusion. The Medline database resulted in 219 articles and 26 articles screened for inclusion. Of the resulted articles, a total of eight articles from this database were included with three articles being duplicates in the CINAHL database. Articles selected for screening in CINAHL and Medline were excluded for the following reasons: (a) interventions were not feasible at the primary care project site (CINAHL: five; Medline: four), (b) low levels of evidence (CINAHL: four; Medline: four), (c) insignificant results (CINAHL: three; Medline: one), and (d) tangential topic (CINAHL: 3). Finally, within the TRIP database, 49 articles resulted and four were screened. Two articles were determined to be low quality and two were kept for inclusion. Please see figure 2.1, the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow chart.

Figure 2.1*PRISMA Flow Chart of Literature Review*

Levels of Evidence

The evidence hierarchy chosen to level the evidence was the Melnyk and Fineout-Overholt's (2019) rating system. This hierarchy rates evidence for intervention questions as level I through VII. Level I is the highest and represents evidence obtained from SRs or meta-analyses that include randomized controlled trials (RCTs) (Melnyk & Fineout-Overholt, 2019). Ten pieces of evidence from the literature review fall into this category. Seven pieces of evidence fall into the Level II category which represents evidence from well-designed RCTs. Level III includes evidence obtained from RCTs without randomization (Melnyk & Fineout-Overholt, 2019). Level IV represents evidence from case-control and cohort studies (Melnyk & Fineout-Overholt, 2019). It should be confirmed that all evidence obtained from the previously named single studies be well-designed. Level V includes evidence from SRs from descriptive or qualitative studies and level VI evidence comes from single studies of the aforementioned design (Melnyk & Fineout-Overholt, 2019). Level VII is evidence from the opinions of experts. A summary of the levels of evidence is provided in Table 2.2.

Analysis and Appraisal of Relevant Evidence

To determine the quality of evidence selected from the review of literature, the evidence must be arduously appraised. The Critical Appraisal Skills Programme (CASP) checklists (2020) were used to determine the quality of evidence for the seven RCT, three SRs, and the three evidence summaries. The AGREE II tool (Brouwers et al., 2010) was used to critically appraise the four CPGs. Two tools were used because the AGREE II tool is specific for CPGs. There is not a CASP checklist available for the appraisal of CPGs. Both appraisal tools were chosen because they are validated, easy to use tools. All the evidence was appraised as moderate (3) or strong (14). Refer to table 2.1 for a summary of the quality of evidence and the appraisal tool used. A summary of the evidence can be found in Appendix A.

Table 2.1

Summary of Evidence

| Author/yr | Database(s) | Level of Evidence/Type | Quality/Tool |
|-----------------------------------|--------------------------|------------------------|-------------------|
| Marques et al. (2021) | Medline | I/SR | Moderate/CASP |
| Pamaiahgari, (2021) | JBI | I/Summary | High/CASP |
| Minooee (2021) | JBI | I/Summary | High/CASP |
| Baer et al. (2020) | CINAHL | II/RCT | High/CASP |
| Fong (2020) | JBI | I/Summary | High/CASP |
| Hooper et al. (2020) | Cochrane | I/SR | High/CASP |
| Katzmarzyk et al. (2020) | CINAHL | II/RCT | High/CASP |
| Orringer et al. (2020) | TRIP | I/CPG | High/AGREE II |
| VA/DoD (2020) | TRIP | I/CPG | High/AGREE II |
| Durrer Schutz et al. (2019) | Medline | I/CPG | Moderate/AGREE II |
| McVay et al. (2019) | CINAHL Medline | II/RCT | Moderate/CASP |
| Semlitsch et al. (2019) | Medline | I/SR | High/CASP |
| Bennett et al. (2018) | CINAHL Medline | II/RCT | High/CASP |
| USPSTF (2018) | Medline | I/CPG | High/AGREE II |
| Alghamdi (2017) | Medline | II/RCT | High/CASP |
| Rodriguez-Cristobal et al. (2017) | CINAHL Citation Chase | II/RCT | High/CASP |
| Eaton et al. (2016) | CINAHL Medline | II/RCT | High/CASP |

Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

After critical appraisal of the literature, the selected evidence was synthesized into the following themes: (a) physical examination, (b) comprehensive lifestyle intervention (CLI), (c) diet, (d) exercise, (e) behavioral interventions, and (f) technology. Other interventions were also identified in the literature such as medications and bariatric surgery; however, these were reserved for after conservative measures failed and were not applicable to the setting in which the EBP project was implemented.

Physical Examination

Recommendations for the physical examination included obtaining the following anthropometrics: height, body weight, body mass index, and waist circumference (WC) (Alghamdi, 2017; Durrer Schutz, et al., 2019; Hooper et al., 2020; Marques et al., 2021; McVay et al., 2019; Orringer et al., 2020; Rodriguez-Cristobal et al., 2017; VA/DoD, 2020). Other measurements were discussed in some of the literature such as blood pressure, heart rate and certain laboratory values; however, these recommendations did not align with the focus of this project.

Comprehensive Lifestyle Intervention

Much of the literature discussed a multifaceted lifestyle intervention or program. As described by the guidelines identified in the review of literature, a CLI should include individualized and patient-centered components related to behavior, diet, and exercise (Durrer Schutz et al., 2019; Semlitsch et al., 2019; VA/DoD, 2020). According to the guidelines by VA/DoD (2020), several concepts related to a CLI should be included: (a) weight management is a lifelong commitment, (b) practices should be sustainable, (c) an energy deficit should be achieved through reduced caloric intake and increased activity, (d) behavioral strategies (goal setting, self-monitoring) should be established, and (e) goals should be specific, measurable, and realistic. The settings for implementation varied. According to the authors of the evidence, an effective CLI

could be delivered in-person in a group or individual setting (Marques et al., 2021; Semlitsch et al., 2019) and a telephone delivered, individual or group, CLI could be used as an alternative or in conjunction with in-person interventions (VA/DoD, 2020). In other words, ongoing interaction between the participant and the provider of the CLI was a key factor. Regarding specific components of a CLI, some of the evidence included tailored caloric deficit to achieve the desired reduction in weight goal (Baer et al., 2020; Bennett et al., 2018; McVay et al., 2019; Orringer et al., 2020). All the evidence included providing some degrees of education and were at a minimum at baseline while others provided ongoing education. Furthermore, some of the literature included providing educational materials throughout the weight loss program that were at times tailored (Baer et al., 2020; Eaton et al., 2016; Katzmarzyk et al., 2020; United States Preventative Services Task Force [USPSTF], 2018). The evidence by Alghamdi (2017) provided participants with ongoing support, and if needed adjustments, at regular intervals. Overall, all of the evidence regarding a CLI provided some degree of educational materials.

Avoiding stigmatization while addressing obesity and overweight is also an important part of a CLI (Durrer Schutz et al., 2019; Orringer et al., 2020). To enhance a successful CLI it may be beneficial to provide counseling in a compassionate and empathetic manner (Durrer Schutz et al., 2019; McVay et al., 2019; Orringer et al., 2020) with a focus on the health benefits of a healthy diet, healthy weight, and increased activity rather than aesthetics.

Treatment Goals. Goals for weight loss with a CLI included a 10% (Eaton et al., 2016; Katzmarzyk et al., 2020; Orringer et al., 2020; VA/DoD, 2020) or 5 – 10% (Durrer Schutz et al., 2019; Semlitsch et al., 2019) reduction in weight over six months. Alghamdi (2017) reported a goal of $\geq 5\%$ weight reduction by the end of 12 weeks. Other weight loss goals included an initial weight loss of goal of 0.5 – 2.0 pounds per week (Orringer et al., 2020; VA/DoD, 2020) and 0.5 – 1.0 kg per week (Alghamdi, 2017; Semlitsch et al., 2019). Within the literature, initial treatment goals were reported to focus on specific dietary recommendations aimed at decreased caloric

intake, increased exercise, and support for behavioral change and self-monitoring (Durrer Schutz et al., 2019; Semlitsch et al., 2019; VA/DoD, 2020).

Diet

A significant amount of the literature identified included a dietary component. Marques et al. (2021) suggested that diet prescriptions may be more effective. In other words, a formal prescription of a diet for the participant to follow, similar to a medication prescription, was effective. Eaton et al. (2016) and Baer et al. (2020) provided a structured meal plan tailored to the participants baseline weight. Other recommendations for diet included creating a caloric deficit of 500 to 1,000 kilocalorie (kcal) per day (Eaton et al., 2016; Orringer et al., 2020; VA/DoD, 2020) or 500 to 750 kcal per day (Alghamdi, 2017; Semlitsch et al., 2019).

Individualized kcal intake should be calculated depending on height, weight, and activity level (Orringer et al., 2020). Reduction of high carbohydrate foods, low fiber foods, or high-fat foods is recommended (Durrer Schutz et al., 2019; Orringer et al., 2020; VA/DoD, 2020). Specific diet recommendations included a low-fat diet (Durrer Schutz et al., 2019; Fong, 2020; Hooper et al., 2020; VA/DoD, 2020), a Mediterranean diet (Durrer Schutz et al., 2019; VA/DoD, 2020), target carbohydrate intake of < 20 – 25 g/day (Alghamdi, 2017), and avoiding high caloric foods such as sweets, junk food, and sweetened beverages (Durrer Schutz et al., 2019; Orringer, et al., 2020). Avoidance of fast food and eating out was also indicated in the evidence (Orringer et al., 2020). Regarding a low-fat diet, energy lost should be replaced with “carbohydrates (simple or complex), protein or fruits and vegetables” (Hooper et al., 2020, p. 3). The definition of a low-fat diet according to Hooper et al. (2020) was a diet with fat intake of “≤ 30% energy from fat” (p. 7). Recommendations should also be individualized to personal preference of the participant to increase adherence (Semlitsch et al., 2019).

Other recommendations for diet included behavioral components. These included reducing portions or portion control (Katzmarzyk et al., 2020; Orringer et al., 2020; Semlitsch et al., 2019; VA/DoD, 2020) and scheduling food consumption (Orringer et al., 2020) or eating at

regular intervals (Durrer Schutz et al., 2019). Other behavioral recommendations included eating slowly, eating in response to hunger, and avoidance of snacking (Durrer Schutz et al., 2019).

Exercise

Another prominent theme within the literature and a cornerstone concept for a CLI was exercise. Recommendations for exercise included “aerobic training (e.g., cycling, supervised walking programs), resistance training (e.g., weight training), and ‘lifestyle physical activity’ (generally increasing activity during the day such as climbing extra stairs, unstructured walking activity, or getting more steps using a pedometer)” (VA/DoD, 2020, p. 41). Other examples of moderate exercise included walking briskly, moderate biking pace, light yard work, snow shoveling or actively playing with children (Orringer et al., 2020). Recommendations by the authors of the evidence were tailored to the participant for easy assimilation into daily life (VA/DoD, 2020). Walking was reported by Durrer Schutz et al. (2019) as the best exercise for participants considered overweight or obese due to convenience and ease of accomplishment. Recommendations included at least 150 minutes of moderate to intense activity per week (Durrer Schutz et al., 2019; Orringer et al., 2020; Semlitsch et al., 2019; VA/DoD, 2020) or at least 75 minutes of vigorous exercise per week (Orringer et al., 2020). In the RCT by Alghamdi (2017), the goal issued for the participants was ≥ 150 min per week of brisk walking. Eaton et al. (2016) instructed participants to engage in an additional 10 minutes of moderate to intense exercise per week to work up to 300 minutes of moderate exercise by 6 months. Likewise, Katzmarzyk et al. (2020) encouraged participants to walk up to 175 minutes per week. Walking was a recurring theme for all of the literature that addressed exercise. The minimum amount of walking suggested was 30 minutes per day five times per week.

Behavioral Interventions

According to Marques et al. (2021), behavioral interventions were successful for short- and long-term enhancement of diet and exercise. Behavioral interventions in the form of self-monitoring of diet, exercise, and thoughts related to each was recommended to enhance

awareness and address unhealthy behaviors (Durrer Schutz et al., 2019; Semlitsch et al., 2019; VA/DoD, 2020). Bennett et al. (2018) used a telephone application as a self-monitoring tool that was efficacious for weight loss. Alghamdi (2017) and Eaton et al. (2016) provided self-monitoring records to document daily food intake and exercise amounts with regular feedback.

Motivational Interviewing. It was noted in the literature that increased compliance and engagement may be influenced by encouragement, support, and MI. For this reason, it is recommended that MI be incorporated to help facilitate weight loss (Durrer Schutz, 2019; Minooee, 2021; Pamaiahgari, 2021; VA/DoD, 2020). There is also considerable evidence that MI will increase the likelihood that a participant will sustain the change long term (Durrer Schutz, 2019) and therefore MI could be applied to not only initial meetings but also subsequent ones (VA/DoD, 2020). The description of MI provided in the literature is that it is a “style of counseling that aims to facilitate behavior change by enhancing the client’s intrinsic motivation” (Minooee, 2021, para. 5). It has been suggested that fostering mutual trust through a warm, nonjudgmental, and collaborative discussion creates a conducive environmental for successful meeting of goals. It was also suggested by Rodriguez-Cristobal et al. (2017) that group MI was effective at lowering weight. Rodriguez-Cristobal et al. (2017) conducted group MI every 15 days for 12 weeks and then monthly until 32 weeks. Pamaiahgari (2021) concluded that psychological interventions such as MI are most efficacious when combined with diet and exercise interventions. The evidence supports the notion that a CLI incorporate diet and exercise but also a reciprocal relationship with a motivating individual who may hold the participant accountable for his or her choices to follow or not follow healthy diet and exercise recommendations.

Technology

While the VA/DoD (2020) reported that there is not sufficient evidence for or against the use of technology as a *primary* mode of delivery of a CLI, the guideline does recommend that individual or group telephone calls be offered either in conjunction or as an alternative to in-person interviews. Technologies (text messages, telephone calls, apps) used in conjunction or

as an alternative to on-site interventions may be effective for reinforcing goals and increasing adherence (Marques et al., 2021). The evidence demonstrates that a CLI does not necessarily have to be delivered in an in-person format and technology may be used as a supportive tool for increasing health behaviors.

Bennett et al. (2018) and Eaton et al. (2016) provided participants with telephone calls from a dietitian, student, and/or lifestyle counselor at intervals varying from weekly for a month to monthly for 6 months and bimonthly for an additional 6 months. The RCT conducted by Bennett et al. (2018) found technology in the form of a self-monitoring telephone application coupled with counseling from a dietitian and clinician was successful in reducing weight by >3% at 6 and 12 months. Likewise, Eaton et al. (2016) found that a minimally in-person intervention produced a significant amount of weight loss and an increased amount of exercise minutes when compared to the control group. Throughout the literature, the use of technology appeared in a variety of forms. McVay et al. (2019) concluded that text messages and telephone calls coupled with intervention specific counseling, in person visits, educational material, and tailored goals was most successful in reducing weight compared to comparison groups. Baer et al. (2020) concluded that an online weight loss program combined with additional support including monthly check-ins, review of progress, and encouragement of regular use of the online program was most efficacious for weight loss compared with usual care and the online program only group. Another benefit is that online weight loss programs increase accessibility and are generally less costly for the participant (Baer et al., 2020). The format of the technology based behavioral interventions outlined by the USPSTF (2018) included “computer- or web-based intervention modules, web-based self-monitoring, mobile telephone-based text messages, smartphone applications, social networking platforms, or DVD learning” (p. 1166). While the use of technology in a variety of formats is expansive and there does not appear to be a clear consensus on which is the most efficacious, it is supported by the literature that technology in some form can enhance a weight loss programs effectiveness.

Timeframe

A duration of greater than 12 months was more effective at lowering body weight and WC than interventions lasting less than 6 months (Marques et al., 2021). However, regardless of duration, a decrease in BMI was noted for all interventions evaluated by Marques et al. (2021). Weight loss measured in kilograms in the RCT by Bennett et al. (2018) was significant at 6 and 12 months. According to Semlitsch et al. (2019), any intervention duration should be at least 6 to 12 months. Alghamdi (2017) reported that a 12-week program did provide statistically significant weight loss for adults enrolled in an “intensive lifestyle intervention” (p. 837) which included interventions congruent to the CLI described previously. Eaton et al. (2016) conducted a RCT that included an active treatment phase for 12 months with a tapering phase through the next 13 to 24 months. Katzmarzyk et al. (2020) instituted a 24-month program beginning with weekly in-person and groups sessions then alternating in-person with telephone calls for the next 6 months followed finally by monthly sessions for the remaining months. In the guidelines by Orringer et al. (2020), monthly contact was recommended. In the evidence by Hooper et al. (2020), authors described multiple timeframes that analyzed a low-fat diet including “6 to < 12 months, 12 to < 24 months, 24 to < 60 months, and 60+ months” (p. 9). While the timeframes described in the literature vary, a 12-week intervention was described as producing statistically significant results. Furthermore, the general theme does appear to consist of initial more frequent contact followed by tapering.

Recommendation for Best Practice

Based on the synthesis of the evidence, the best practices identified to address the clinical problem included employing an intensive 12-week, patient-centered, CLI with dietary and exercise goals that integrated self-monitoring with technology in the form of a telephone application in conjunction with in-person visits and telephone calls to provide feedback and MI (Alghamdi, 2017; Baer et al., 2020; Bennett et al., 2018; Durrer Schutz et al. 2019; Eaton et al., 2016; Marques et al., 2021; Minooee, 2021; Pamaiahgari, 2021; Semlitsch et al, 2019; USPSTF,

2018). A baseline assessment of height and weight to calculate BMI should be obtained. While a 12-week program is not ideal, the evidence does indicate that it may still be efficacious as a baseline protocol. Diet recommendations included a low-fat diet with recommendations to avoid sweets, junk food, and sweetened beverages as well as to minimize or eliminate fast food and maximize home cooked meals. Recommendations for exercise included brisk walking for 30 minutes for 5 days per week at a minimum. Self-monitoring of diet and exercise should also be included. The incorporation of a telephone application with in-person visits should also be available to increase awareness of dietary goals and adherence of the program. While interacting with participants, a nonjudgmental and empathetic approach should be used to encourage an open exchange of realistic and patient specific goals and expectations.

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Throughout the planning phase the PL met at regular intervals with the office staff, the site facilitator, office physician, and the office manager to ensure thorough planning and successful implementation. Discussions and feedback from stakeholders took place over the phone and in-person at the clinic. The PL also followed the office staff during routine workdays to assess how implementation into the already established workflow would be best accomplished. Opportunities for feedback from the stakeholders regarding planning and implementation were also offered at routine intervals. All documents were provided to each stakeholder and feedback was provided to the PL. Feedback-guided document revisions took place and feedback was incorporated into the implementation phase. The PL also sought input from the assistant director at the site. Individuals within nursing leadership at the organization were also involved and included the nursing leadership student liaison, a nurse educator, and a certified diabetic educator. These individuals offered suggestions with feedback, guidance, and input on the project implementation protocol. This feedback was incorporated, if appropriate, as deemed by the PL and the site facilitator.

Participants and Setting

There were multiple participants involved in the practice change including the stakeholders within the office and patient's being recruited. The stakeholders in the office included the site facilitator who was a FNP with 12 years of experience, and the site physician with 33 years of experience. Other stakeholders were the three MAs, one of which was the office manager, with experience ranging from three months to three years at the office. Lastly, the assistant director for the office was also briefly included in the development of the project. The office setting was located in Northwest, IN where the patients were recruited. This practice served a large lower socioeconomic patient population and was part of a larger healthcare

system. The office was a primary care setting that served patients from children to adults and families.

Pre-Intervention Group Characteristics

The patient population served was predominately African American adults of both male and female gender. Patients at this office setting were frequently adults aged 18 years and older. Eligible participants for the EBP project included adults aged 19 years or older with a BMI greater than 25 kg/m². The age 19 was chosen because the organization at large considered individuals 19 years and older as adults. Pregnant and breastfeeding women were also excluded from participation. The office providers helped to determine whether any comorbidities would exclude the patient from participation. These comorbidities included current illness related to the COVID-19 virus, severe asthma, severe chronic obstructive pulmonary disease, and current chronic heart failure exacerbation. Other comorbidities that excluded patients from participation included cancer and current or previous orthopedic injury with severely limited mobility. Finally, inability to independently sign the informed consent document also excluded the participant.

A demographics form was provided to each patient to gather information about the patient population and included date of birth, gender, and phone number. Further information collected on the form with a multiple-choice answer included the following: (a) ethnicity, (b) highest level of education, (c) employment status, (d) current living situation, (e) average income per year, and (f) marital status. Each multiple-choice answer was provided with the option of “prefer not to answer” and “other.” Please see Appendix B for an example of the demographics form that was provided to participants.

Intervention

In preparation for the EBP change, educational materials were sought out by the PL. The healthcare system at large has a diabetes center and a diabetic educator who provided all the educational materials that were eventually disseminated to the patients recruited for the EBP project. These materials included the following items: (a) a pamphlet on identification of calories

in food and drinks offered at popular local restaurants, fast food establishments, baristas, and other eateries; (b) a diabetic educational handbook with guidance on portion control and calorie and carbohydrate counting; (c) a cookbook with over 100 recipes; and (d) materials on how to read food labels and choose healthy food low in fat and sugar. The marketing department within the organization supplied bags, folders, and pens which provided a place for participants to keep all materials together for ease of retrieval during phone call visits. Handouts created by the PL included the following: (a) templates for journaling daily dietary choices and exercise amounts for 12 weeks (see Appendix c); (b) a program directions overview form which included instructions on diet, exercise, downloading the smart phone app, journaling, and participation in biweekly phone calls (Appendix D); and (c) a weekly program timeline (Appendix E). Prior to receiving any of these materials, an informed consent was signed by the participant and a copy was provided (Appendix F).

During the planning phase, the PL communicated frequently with the site facilitator and the office staff to determine the best way to recruit participants and implement the project. When beginning implementation, patients were recruited by staff, the providers, or the PL. They identified patients for recruitment as having a BMI greater than 25 kg/m². If screened as a potential participant, the female patients were asked if they were pregnant or breastfeeding. If they responded “yes,” the patient failed screening and were not included in the project. If they responded “no,” the patient was offered to be a participant in a weight loss program conducted by a doctoral FNP student from VU. If the participant was agreeable, staff or the PL provided the participant with the demographics form, informed consent, and the educational bag that included the folder enclosed with directions and journaling templates. The staff or the PL then went over the directions and the educational materials with the participant. The staff or the PL reminded the participant to add the PLs phone number into their cell phone and expect a call in one week and biweekly thereafter from the PL for up to 12 weeks. During the telephone call, the PL provided MI by identifying strengths and barriers while offering the participant encouragement, support, and

feedback. The dietary choices and the exercise amounts were reviewed, and a discussion of strengths and barriers was provided.

The specific directions the participants were provided included five components (diet, exercise, technology, self-monitoring, and biweekly phone call follow-up). The dietary component included following a low-fat diet while avoiding sugary drinks and fast food and increasing the number of home-cooked meals. Participants were encouraged to use the cookbook provided. The exercise component that was recommended to the participants was to walk for at least 30 minutes 5 days per week. The participants were directed to download the free smart phone application “Start Simple with MyPlate” which allows users to choose daily dietary goals and provides reminders to complete these goals. This phone application also provided a link to the USDA website where further resources for meal recipes and dietary education could be accessed.

During the week two phone call, the PL entered the participants specific height, weight, age, and activity levels into the USDA website which provided a tailored caloric intake. The website also provided tailored intake of fruits, vegetables, starch, dairy, fat, and protein which was communicated to the participant and encouraged by the PL to integrate into their diet. The participants were also instructed to journal diet and exercise for self-monitoring and for feedback during biweekly phone calls with the PL. The biweekly phone calls provided an opportunity for feedback, further education, answering any questions, and MI. If the participant did not answer the call, they were considered terminated from participation and no other phone calls or aspects of the project were assumed to be completed thereafter. At week 12, the participant was then asked to either return to the office or self-report for the final post-intervention data collection which included height, weight, and BMI. Self-report was offered since many participants were unable to return to the office due to limitations in transportation and desire to decrease risk of being exposed to or spreading the COVID-19 virus.

Comparison

The comparison group included patients who were provided standard of care (SOC) prior to the implementation of the EBP project or who were seen in the office during implementation who were not offered participation. The SOC included verbal education about general diet and exercise recommendations during a routine office visit. The diet education that was provided often focused on reducing salt intake and eating baked or broiled foods. Comparison data was obtained during an audit of charts of patients who were seen in the clinic two times approximately 12 weeks apart and were provided the SOC. A comparison of BMI between the two visits was documented and recorded for comparison to the results of the EBP project.

Outcomes

The primary outcomes evaluated were body weight in kilograms and BMI. The participants were weighed in kilograms and measured in meters using the same office stadiometer pre intervention. The patients were encouraged to return to the office for post - intervention weight wearing similar clothes or to weigh themselves at home wearing similar clothes. Four of the participants who completed the entire 12-week intervention were weighed in the office setting for post-intervention weight during routine follow-up visits. The other 15 participant's self-reported final weight on at-home scales. The post-weight for individuals who dropped out was obtained via chart review at approximately the 12-week mark. Data regarding body weight and BMI was managed in a spreadsheet. The statistics utilized in the final analyses of data measurement collected of weight in kilograms and BMI was a paired *t* test. The data regarding body weight and BMI was interval data and was measured before and after the intervention with each participant. According to the VA/DoD (2020) guidelines for the management of overweight and obesity, BMI was a reliable tool for weighing the risks related to overweight and obesity. A measurement of height was also obtained using the stadiometer, but this measurement was only collected for use in the calculation of BMI. Weight was measured apart from BMI to determine how much weight was lost overall.

Time

The ideal start date of the EBP project for recruiting was September 7, 2021. This was in part because the organization, of which the site is affiliated, had the next available institutional review board (IRB) meeting the prior Thursday. This date was also chosen because it was after the Labor Day holiday where participants were more likely to indulge and be less inclined to participate. After submitting the initial IRB application on August 30, 2021, feedback was provided on September 2, 2021. Feedback was incorporated and the application was resubmitted on September 3, 2021. On September 8, 2021, approval was granted to begin implementing the project. Rolling recruitment began on September 9, 2021, and continued until there were at least 30 participants. Recruitment ended on October 04, 2021, to ensure that the last participant would complete the 12-week program before Christmas Day. This timeframe was chosen to allow the participant freedom from the responsibilities of compliance to the program during the holiday. The timeline for implementation is provided in Appendix G.

Protection of Human Subjects

Ethics training was completed by the PL on March 31, 2021, in preparation for the protection of human subjects. The training was provided by the Collaborative Institutional Training Initiative (CITI) and the course was titled Social Behavioral Educational Researchers. A copy of the certificate of completion can be found in Appendix H. An application to the VU IRB was also submitted and it was determined that the project did not meet requirements for review. An application for IRB approval was also submitted and approved through the site's organization at large (Appendix I). The EBP counsel, a part of the shared governance, at the site's organization was also notified and approved the project after feedback was incorporated.

Patient safety was maintained by discussing and explaining that the participant should accomplish their walking goals in a safe place which would include walking during the daylight hours or within or near one's home. The participant was told to not overexert oneself and only walk as they felt comfortable within their own limits. If the participant was not feeling well, they

were instructed to rest. The participant was instructed that if at any point they suddenly felt short of breath, chest pain, or lightheaded, they should call emergency services.

Anonymity was maintained by keeping track of patients by assigning each participant to a number on a master list generated in a spreadsheet format. This number was also used to document in a designated calendar the date and time of the scheduled follow-up phone calls. Names were not used to identify participants. The master spreadsheet also served to document completion of each biweekly phone call and manage data collected on body weight and BMI. The spreadsheet, demographics data, and calendar were saved on a password protected flash drive to which only the PL had access. The demographics form and the signed IC were kept in a locked box to which only the PL had a key.

CHAPTER 4

FINDINGS

The purpose of this EBP project was to implement a cost-effective, sustainable, and accessible way for FNP's to help support patients in weight loss beyond verbal education. The primary outcomes included lowering weight and BMI for participants in the intervention group. This was measured at baseline and again at 12 weeks.

Participants

There was a rolling recruitment of participants with a total of 38 participants consenting for participation in the intervention group. However, only a total of 19 participants completed the entire 12 weeks as measured by phone-call follow up and self-report of participation which was used in the final data analysis as the intervention group. The other 19 participants did not complete the 12 weeks and dropped out at various weeks, resulting in an attrition rate of 50%. Out of the 19 dropout participants, 12 did not answer the week two phone call. During the week four phone call, four additional participants did not answer. During the week six phone call two participants did not answer and during the week ten phone call one person did not answer. For the intervention, dropout, and comparison groups, demographics data was gathered and analyzed using descriptive statistics.

Intervention Group

The intervention group included the 19 participants that finished the full 12 weeks intervention. Of the 19 participants, there were 5 males and 14 females. The data showed 26.3% identified as male and 73.7% identified as female. The mean age was 57 ($SD = 12.77$) and the range was 32 to 77 years. Pre-intervention mean BMI was 32.73 ($SD = 6.06$) and mean weight was 207.00 pounds ($SD = 54.63$). Regarding ethnicity, 78.9% identified as African American, 15.8% Caucasian, and 5.3% Hispanic. Participants who reported having a bachelor's degree was 31.6%. Regarding employment, 47.4% reported being employed full-time, 15.8% were

unemployed, and 15.8% were retired. Most participants reported living in a house (68.4%) or living in an apartment (26.3%). Income was also reported and 21.1% of participants indicated making less than \$25,000 and between \$25,001-49,999. Only 15.8% of participants reported making \$50,000-74,999 and \$75,000 or more. The majority of participants were married (42.1%) or single (31.6%). Several participants were divorced (21.1%) and a few reported being widowed (5.3%).

Comparison Group

There was a total of 14 participants in the comparison group. Demographic data beyond age, gender, and ethnicity identified in the electronic medical record was not available since these participants were identified from chart review. The mean age for the comparison group was 55.79 ($SD = 9.82$) and the ages ranged from 40 to 70 years. Of these participants, 57.1% identified as male while 42.9% identified as female. The ethnicity of this group included 14.3% indicating being Caucasian and 85.7% indicating being African American. The initial mean BMI and weight were 34.45 ($SD = 6.52$) and 224.50 ($SD = 52.93$) respectively.

Dropout Group

The dropout group included the 19 participants who did not complete all 12 weeks of intervention. The participants in this group were similar to the intervention group with 5 males and 14 females. The mean age was 53.37 ($SD = 13.79$). Ages ranged from 26 to 71 years. Pre-intervention mean BMI was 38.08 ($SD = 10.71$) and mean weight was 237.58 ($SD = 58.78$). Pre-intervention BMI and weight ranged from 25.46 to 65.85 and 161 to 408 respectively. Regarding ethnicity, 100% identified as African American. The majority had a high school diploma (42.1%) and were employed full-time (42.1%). Just over half of the participants lived in a house (57.9%). The largest number reported earning an annual income of between \$25,001-49,999 (36.8%). The majority of participants were single (42.1%). The demographic data for the comparison group ($n = 14$), the intervention group ($n = 19$), and the dropout group ($n = 19$) with a detailed comparison of all groups are reported in table 4.1.

Table 4.1

Summary of Demographics

| Demographic | Intervention Group | Dropout Group | Comparison Group | Dropout and Comparison Group |
|------------------------------|--------------------|------------------|------------------|------------------------------|
| | (<i>n</i> = 19) | (<i>n</i> = 19) | (<i>n</i> = 14) | (<i>n</i> = 33) |
| | <i>n</i> (%) | <i>n</i> (%) | <i>n</i> (%) | <i>n</i> (%) |
| Age | | | | |
| Mean/ <i>SD</i> | 57 / 12.77 | 53.37 / 13.79 | 55.79 / 9.82 | 54.39 / 12.15 |
| Range | 32 – 77 | 26 - 71 | 40 – 70 | 26 - 71 |
| Gender | | | | |
| Male | 5 (26.3) | 5 (26.3) | 8 (57.1) | 13 (39.4) |
| Female | 14 (73.7) | 14 (73.7) | 6 (42.9) | 20 (60.6) |
| Pre BMI (kg/m ²) | | | | |
| Mean/ <i>SD</i> | 32.73 / 6.06 | 38.08 / 10.72 | 34.45 / 6.52 | 36.54 / 9.23 |
| Range | 26.91 – 47.23 | 25.46 – 65.85 | 27.61 – 49.73 | 25.46 – 65.85 |
| Pre Weight (lbs) | | | | |
| Mean/ <i>SD</i> | 215.94 / 54.63 | 237.58 / 58.78 | 224.50 / 52.93 | 232.03 / 55.89 |
| Range | 151 – 358 | 161 – 408 | 165 – 377 | 161 - 408 |
| Race/Ethnicity | | | | |
| Caucasian | 3 (15.8) | | 2 (14.3) | 2 (6.1) |
| African American | 15 (78.9) | 19 (100) | 12 (85.7) | 31 (93.9) |
| Hispanic | 1 (5.3) | | | |
| Education | | | | |
| Some high | 1 (5.3) | 2 (10.5) | | |

| | | |
|---------------------|----------|----------|
| High school Diploma | 4 (21.1) | 8 (42.1) |
| GED | 4 (21.1) | 3 (15.8) |
| Bachelor's degree | 6 (31.6) | 1 (5.3) |
| Master's degree | | 1 (5.3) |
| Trade School | | 1 (5.3) |
| Prefer not to say | | 2 (10.5) |
| Other | 3 (15.8) | 2 (10.5) |

Employment

| | | |
|-------------------|----------|----------|
| Full-time | 9 (47.4) | 8 (42.1) |
| Part-time | 2 (10.5) | 2 (10.5) |
| Self-employed | 1 (5.3) | |
| Unemployed | 3 (15.8) | 1 (5.3) |
| Retired | 3 (15.8) | 5 (26.3) |
| Prefer not to say | | 1 (5.3) |
| Other | 1 (5.3) | 2 (10.5) |

Living

| | | |
|-------------------|-----------|-----------|
| House | 13 (68.4) | 11 (57.9) |
| Apartment | 5 (26.3) | 7 (36.8) |
| Prefer not to say | 1 (5.3) | 1 (5.3) |

Income

| | | |
|--------------------|----------|----------|
| Less than \$25,000 | 4 (21.1) | 3 (15.8) |
|--------------------|----------|----------|

| | | |
|----------------------|----------|----------|
| \$25,001 -49,999 | 4 (21.1) | 7 (36.8) |
| \$50,000 -74,999 | 3 (15.8) | 3 (15.8) |
| \$75,000 or more | 3 (15.8) | 1 (5.3) |
| Prefer not to say | 2 (10.5) | 4 (21.1) |
| Other | 3 (15.8) | 1 (5.3) |
| Marital | | |
| Single | 6 (31.6) | 6 (31.6) |
| Married | 8 (42.1) | 8 (42.1) |
| Divorced | 4 (21.1) | 2 (10.5) |
| Widowed | 1 (5.3) | 2 (10.5) |
| Prefer not to say | | 1 (5.3) |

Changes in Outcomes

The primary outcome of this EBP project was to determine if a 12-week CLI that included diet and exercise with MI and regular feedback along with technology in the form of a mobile phone application could reduce BMI and weight to a great extent than SOC.

Statistical Testing and Significance

An independent-samples *t*-test was calculated comparing the mean difference in weight and BMI pre and post intervention in the intervention group ($n = 19$) to the mean difference in pre and post weight and BMI of participants in the comparison group ($n = 14$). The mean difference in weight and BMI for the intervention group ($M = 3.10$; $SD = 5.92$) ($M = .32$; $SD = 1.12$) was not significantly different from the mean difference in weight and BMI for the comparison group ($M = .14$; $SD = 4.40$) ($M = 0.2$; $SD = .72$). Using an independent samples *t*-test there was found to be a significant difference in the final weight of the intervention group versus the dropout group combined with the comparison group ($t(47) = 2.727$, $p = .009$).

Demographic Variables

Using a linear regression model, all the demographic variables (ethnicity, education, employment, living, income, and marital status) were compared for statistically significant impact on BMI and/or weight. There was found to be no statistically significant impact on BMI and weight for any of the variables. When analyzing the correlation between BMI and the demographics variables, the *R* value of .274 indicates a weak positive correlation between these variables and the BMI difference of the participants. When analyzing weight using the linear regression model, the *R* value of .326 indicates a weak positive correlation between the demographic variables and the weight difference of the participants.

Findings

When comparing the intervention group to the comparison group, there were no statistically significant results. However, there was found to be a statistically significant difference in pre and post weight as well as BMI reduction for the intervention group when compared to the

comparison group combined with the dropout group when outliers were removed. The participants who dropped out at later weeks did receive the educational material that the intervention group received but in analyzing the data from the weeks prior to dropout, it is clear that these individuals were not engaged. Also, the majority ($n = 12$) did not answer the week 2 phone call which was the first week of phone calls.

Primary Outcome

BMI. An independent -samples t -test was used to compare the mean difference in BMI in the intervention group pre and post intervention compared to the comparison group. The mean difference in BMI for the intervention group ($M = .32$; $SD = 1.12$) was not significantly different from the mean difference in BMI for the comparison group ($M = .02$; $SD = .72$) ($t(31) = .869$, $p = .392$) with equal variances assumed. For participants who completed the entire 12 weeks ($n = 19$) the average pre intervention BMI was 34.59 kg/m^2 . The average BMI post intervention for this group was 34.26 kg/m^2 . When comparing the intervention group ($n = 19$) against the dropout group ($n = 19$) combined with the comparison group ($n = 14$) after the outliers were removed, there was a statistically significant difference in BMI ($t(47) = 3.291$, $p = .002$). See table 4.4 for statistical data.

Weight. An independent -samples t -test was used to compare the mean difference in weight in the intervention compared pre and post intervention compared to the comparison group. The mean difference in weight for the intervention group ($M = 3.10$; $SD = 5.92$) was not significantly different from the mean difference in weight for the comparison group ($M = .14$; $SD = 4.40$) ($t(31) = 1.648$, $p = .125$) with equal variances assumed. See table 4.2 and 4.3 for the primary outcome statistical data. For participants who completed the entire 12 weeks ($n = 19$) the average pre intervention weight was 215.93 lbs. The average weight post intervention for this group 214.49 lbs. When comparing the intervention group ($n = 19$) against the dropout group ($n = 19$) combined with the comparison group ($n = 14$) after the outliers were removed, there was a

statistically significant difference in weight ($t(47) = 2.727, p = .009$). See table 4.4 for statistical data.

Table 4.2

Summary of Statistics Comparison and Intervention

| | <i>n</i> | <i>M</i> | <i>SD</i> |
|--------------|----------|----------|-----------|
| WeightDiff | | | |
| Intervention | 19 | 3.10 | 5.92 |
| Comparison | 14 | .14 | 4.40 |
| BMIDiff | | | |
| Intervention | 19 | 0.32 | 1.12 |
| Comparison | 14 | 0.02 | .72 |

Table 4.3

Independent Samples Test Comparison versus Intervention

| | <i>t</i> | <i>df</i> | <i>Sig.</i> |
|-------------------------|----------|-----------|-------------|
| WeightDiff | | | |
| Equal variances assumed | 1.575 | 31 | .125 |
| BMIDiff | | | |
| Equal variances assumed | .869 | 31 | .392 |

Table 4.4

Independent Samples Test Comparison and Dropouts (without outliers) versus Intervention

Group

| | <i>t</i> | df | Sig. |
|-------------------------|----------|----|------|
| WeightDiff | | | |
| Equal variances assumed | 2.72 | 47 | .009 |
| BMIDiff | | | |
| Equal variances assumed | 3.26 | 47 | .002 |

CHAPTER 5

DISCUSSION

The purpose of this EBP project was to implement a cost-effective, convenient, and sustainable way for primary care FNPs to help patients lower their BMI and weight. The PICOT question sought to answer the following: In adult patients aged 19 years or older who are considered overweight or obese as measured by body mass index (BMI) of $\geq 25 \text{ kg/m}^2$ (P), how effective is diet and exercise combined with self-monitoring, a phone application, MI and feedback (I) compared to standard care (C) at lowering BMI (O) over a 12-week period (T)? The following chapter will provide an explanation of the findings, strengths, limitations, an approach to sustainability, relevance of the EBP model, and recommendations for future practice.

Explanation of Findings

The statistically significant results of the outcome for this EBP project provided evidence that a weight loss program that utilized multiple components including diet, exercise, self-monitoring, technology, and MI with regular feedback and follow-up delivered in the primary care setting by FNPs can produce short-term weight loss for adults. It is unknown if the weight loss is sustainable due to the limited 12-week timeframe for this EBP project. The overall explanation of these findings is that engagement played a critical role in individual weight loss success. Using an independent *t*-test it was found that increased engagement resulted in statistically significant difference for both BMI and weight compared to those who were not engaged. It was not tested to discover if any one of the components resulted in more weight loss than the others, but rather overall engagement was measured and defined as participating in at least 50% of the intervention.

Participants

The participants recruited from the site were considered to be part of a lower socioeconomic status. The most frequently reported income brackets for the intervention and

dropout group combined were less than \$25,000 ($n = 7$) and \$25,001-49,999 ($n = 11$). This aligns with the data reported by the United Health Foundation (2021) that the prevalence of obesity in adults was 40% among individuals living in Indiana whose income range was between \$25,001 and \$49,999. Furthermore, according to DynaMed (2018) one of the risk factors for developing obesity is a lower socioeconomic status. Due to lack of resources and time to engage in the intervention, the participants recruited were affected by the lower socioeconomic status. These barriers impeded the recruited participants ability to be fully engaged in each component of the intervention. It was considered that these barriers were contributory to the results of the primary outcome that were not statistically significant.

Primary Outcome

There are several explanations for why the results for the intervention group compared to comparison group were not statistically significant. The timeframe of 12 weeks may have contributed to a result that was not statistically significant when comparing intervention ($n = 19$) and comparison group ($n = 14$). Much of the literature reviewed recommended that a CLI should last 6 to 12 months (Baer et al., 2020; Bennett et al., 2018; McVay et al., 2019; Semlitsch et al., 2019; VA/DoD, 2020) with some of the research indicating that longer timeframes are necessary such as a 24-month period (Eaton et al., 2016; Katzmarzyk et al., 2016; Rodriguez-Cristobal et al., 2017). Another factor that likely impacted the findings and results was the participants lack of access to nutritious food. As mentioned above, the patient population that the clinic served was considered part of a lower socioeconomic status and therefore it was surmised that lack of access to nutritious food played a role in the results. It was often discussed during the phone call visits that some of the participants did not have the means to purchase fruits and vegetables but rather ordered fast food, canned foods, microwavable meals, and processed foods. Furthermore, it was communicated by several participants that they did not have the necessary utensils to cook food at home including pots and pans. One participant reported that she did not cook for herself and therefore she had little to no control over her food choices.

Many of the participants also cited lack of time as a reason for dropping out or not engaging in one of more of the components of the intervention. In the intervention and dropout groups, the most reported employment status was full-time with a total of nine participants in the intervention group and eight participants in the dropout group. All the participants reported having some type of family obligations. Some were living with family members and others reported having children, spouses, and significant others who they reported impeded a full commitment to each component of the intervention.

Another explanation for the results was that initially participants did seem ready to change and then had a lack of commitment and engagement into the pursuing weeks. These two components played large factors in the findings. Most to all participants were initially very enthusiastic about weight loss and behavior changes; however, for many, this eagerness faltered in ensuing weeks. For example, at first some participants appeared committed to following all parts of the CLI, but over time stopped using the phone application or stopped journaling food choices. The majority of participants engaged in at least diet and exercise and most stopped journaling and using the phone application at 6 weeks or later. Furthermore, most participants did not engage in every element of the CLI. The majority of participants who finished the entire 12 weeks engaged in at least diet and exercise changes and the MI via phone calls with feedback.

Another consideration for why the findings were not statistically significant when intervention group ($n = 19$) was compared to the comparison group ($n = 14$) could be because of the small sample size. When the dropout group ($n = 19$) was combined with the comparison group, there was a statistically significant difference in the intervention group pre-BMI and weight compared to post-BMI and weight. While the dropout group received some of the intervention, the majority did not answer the week 2 follow-up phone call. The assumption can be made that these individuals were not engaged and did not participate in any of the CLI. Additionally, the individuals who dropped out in later weeks were considered not engaged if they did not

participate in at least 50% of the CLI components which is why the dropout group was added to the comparison group for outcome analysis. It was not known if the comparison group was utilizing any weight loss interventions.

One of the explanations considered for why several participants dropped out was that they did not fully understand what they had consented to. It was noted during the recruitment phase that some participants may have just wanted to seem interested but when they reviewed the documents further either did not feel ready or capable of completing the commitment. Several participants reported an initial desire to be recruited but upon further realization of the commitment declined a desire to continue. Many of the participants who dropped out reported lack of time as a reason for ceasing participation. Some reported lack of funds to purchase nutritious foods. One participant reported that the available food and the cookbook provided was too limiting and they declined continuation.

Interventions

In reviewing the interventions utilized, many participants engaged in diet and exercise modifications. Some participants reported that the phone application was not helpful, and they often forgot to update or review the goals that they had set in the phone application. Many participants reported lack of time regarding documenting their food choices as well as simply forgetting to do so. During the phone call conversations, all participants who completed the entire 12 weeks were accepting of feedback and did report feeling motivated to continue lifestyle changes. According to Rodriguez-Cristobal (2017), MI resulted in weight loss at 1 year, but results were not statistically significant until 24 months.

Strengths and Limitations of the DNP Project

Strengths

One of the biggest strengths of the project was the sites willingness to accommodate and facilitate implementation of the project. The site considered overweight and obesity a concern and was receptive to implementing different, innovative ways to positively affect these patients'

outcome. Another strength of the project was ease of use and implementation. Providing over-the-phone MI and feedback was convenient for both the participant and the PL. Furthermore, frequency of contact was considered a strength. Contact every two weeks helped keep participants on track. Recent discussions were more readily recalled by and for the participant. Feedback and modifications were reinforced through discussion and repetition. It was noted that by the end of the 12-weeks, there was a clear relationship formed between the PL and the participant. Some participants looked forward to discussing their progress and were excited and proud to provide details about what they were doing to promote weight loss. Many participants anticipated questions and had changed behavior based on repetitious feedback.

Another strength related to the project was the directions were easy to follow and allowed for flexibility. The diet recommended was low fat and low sugar with specific directions to avoid eating out (Fong, 2020). The exercise directions included walking three times weekly for 30 minutes 5 days per week. This was recommended by Orringer et al. (2020). The diet and exercise regime were chosen purposefully as to not be strict and to allow for inclusion and ease of assimilation for working individuals who also had families as it was known during the planning phase that this would be the targeted demographic.

Limitations

The two major limitations to the project were the high dropout rate and the self-reporting of engagement and final weight. A high dropout rate was also discussed by Rodriguez-Cristobal et al. (2017) as a limitation. While a high attrition rate was expected due to the sensitive and time-consuming nature of weight loss, the attrition rate for this EBP project was considerably higher than expected at 50%. It was reported by the site facilitator providing incentives for completion to participants may have been beneficial. It is likely if the EBP project provided some monetary compensation to participants, it is likely the attrition rate would have been less than 50%.

Engagement was another limitation. As noted in the strengths section, ease of use and implementation of the project were cited; however, it was challenging keeping individuals engaged and motivated. A sizable portion of the participants reported not utilizing one or several components of the CLI. Reporting of engagement was also self-reported and considered a limitation as participants may have over or underestimated their participation and engagement. Participants often reported numerous reasons for not adhering to the diet and exercise recommendations or not engaging in other components. The PL was often required to suggest creative ways for overcoming these barriers. Again, one of the barriers reported by many participants was lack of access to nutritious food. Some of the participants reported that they were unable to afford many of the foods listed on the sample menu or in the cookbook provided. Two participants were referred to federal and state assistance programs by the PL as a result of engagement in the EBP project.

Lack of funding was also a limitation for the project. This limited both choice of phone application and ability to utilize incentives for participants. The phone application component chosen for the CLI was free to use and easily accessible; however, it was not interactive beyond choosing daily dietary goals. It is for this reason that many of the participants did not engage in this component. The application used by Bennett et al. (2018) was highly interactive and provided tailored feedback and tips. It also used voice activation or text messaging to facilitate self-monitoring (Bennett et al., 2018). The lack of funding impacted the attrition rate since as discussed by the site facilitator, the patient population may have responded more favorably to incentives for engagement.

Another limitation was regarding billing. One of the concerns for the director of the site was billing for follow-up visits if conducted on-site. There was a concern that charging patients would impact recruitment and because of this it was determined that the best course of action would be to implement off-site follow-up phone calls. It was suggested by the director of the site that the PL perform all the follow-up phone calls off-site so that no participants were billed for

follow-up calls. Not having a component of in person follow up could have attributed to the lack of engagement, and completion of all components with lack of face-to-face interaction.

Finally, the ongoing COVID-19 pandemic impacted the project and the ability of the participants to return to the clinic for final weight. The delta variant was prominent during the fall and winter of 2021, and this was when participants would have been offered to come to the clinic to obtain a final weight. Due to the pandemic, the participants provided self-reporting of final weight. The self-reporting of weight could have also confounded the results as uncalibrated home scales may not have been accurate.

Sustainability

If statistically significant results were found, the project would have been considered as a sustainable part of the clinics routine schedule. Without these results sustainability for this project will not be continued at this particular site for multiple reasons but changes in providers is considered the predominant cause. Sustainability was promoted at the site by development of a protocol for future use. See Appendix J. This protocol focused on frequent phone call follow-up and MI. The protocol was disseminated to the office staff for future use, the site facilitator, and the nurse educator at the organization at large. The results of the EBP project and the protocol were also provided to the student liaison and the EBP counsel at the organization. Finally, the results were presented at the organizations poster presentation during which employees and students alike disseminated findings related to EBP projects conducted and implemented at the organization.

At other clinical sites wanting to implement this project, the project could be easily integrated into the routine of any clinic. Specific recommendations for sustainability are provided in further detail based on the evidence and how the project was implemented at this site. A participant would be considered for recruitment by the MA or individual who rooms the patient and obtains the patients height and weight. The MA would alert the FNP or other providers that the BMI is greater than 25 kg/m². The FNP would then investigate the patient's readiness for

change and provide the directions for the project. An assessment of readiness should be considered for potential participants before the participant is recruited (Orringer et al., 2020). If the person was not ready to change, the efforts made by the FNP to engage the patient in MI and compliance to a weight loss program are likely to fail. If the patient is ready and willing to engage in the intervention, the follow-up visits or phone calls would then be scheduled by the front desk. For sustainability, it is recommended that the intervention consist of a longer timeframe with more frequent follow-up initially that is tapered over time. Monthly alternating phone-call and in-person visits are recommended for the first 6 months followed by every other month in-person visit for 6 additional months. Every 3 months patient's height and weight are measured in the office. Further continuation would be based on the individual goals of the patient. This scheduling of visits mirrors the schedule used by Eaton et al. (2016). Also, Orringer et al. (2020) recommended promoting self-management skills and providing education to reinforce behavior changes. For this EBP project, these self-management skills included journaling and utilization of the phone application to set daily goals. Education was provided at routine intervals during the phone calls provided throughout the project. Along with sustainability, billing for follow-up phone calls or future in-person visits must be considered. For coding for billing, the organizations informational technology department and electronic health record specialist was consulted, and it was determined that when coding for the follow-up visits a code related to dietary or exercise counseling and surveillance would be sufficient.

Relevance for EBP Model

The Iowa Model served as guidance for planning, implementation, and sustainability of the EBP project. The model was considered very useful for guiding each step. The planning phase was integral to determining which patient outcomes most needed improvement. Having a solid foundation for this step helped facilitate the following steps of developing and implementing the project. The linear step process was an essential aspect in moving the project forward and keeping the project tasks on track. Identifying opportunities and determining topic priority was

accomplished by assessing the literature and then discussed with the site facilitator. The specific recommendations provided by the model during the designing and piloting phase of the project were used and found to be very effective. For example, the model directs to user to incorporate patient preferences (Buckwalter et al., 2017). During the planning phase, several patients at the clinical site were interviewed and asked what they would like to see as part of a weight loss program. Responses were to include clear directions on what to eat and provide sample meals and menu items. This feedback from patients was incorporated into the program by providing specific recipes and a sample menu along with the educational material. For sustainability, the Iowa Model recommended hardwiring the project into the routine schedule and daily activities of the office staff and providers. For this step, a protocol was created. The final step is to disseminate the results. This was accomplished in multiple formats including at the site, the organization at large, and at local and national forums.

The Iowa Model provided a fluid, seamless, and uncomplicated transition from each step of planning, implementing, and sustaining the project. Each step in the model provided support for each process and all steps were equally integral to the overall process of moving the project from an idea contrived from the literature to a process in motion at the office for patients desiring to lose weight. The Iowa Model is an ideal model because everyone can use it including bedside nurses in the inpatient setting and outpatient primary care FNP's. The model encourages users to question the status quo and directs them to research ways to provide quality care. By using this model as a blueprint for implementing change, improved patient outcomes are possible in any practice setting.

Recommendations for the Future

Recommendations for the future included identifying other secondary outcomes that should be considered for measurement at baseline and after intervention. Some of these secondary outcomes that may be considered include the following: glycosylated hemoglobin, blood pressure, fasting lipid profile, waist circumference, and effect on depression. Areas for

improvement include in-person follow-up rather than telephone only follow-up. A second area for improvement would be instructing the participant to show the provider their diet and exercise journals in order to ensure completion. Having patients weigh themselves at the office on the same scale was also a recommendation for future use. It should also be noted that this EBP project timeframe was over 12 weeks, and it is unknown if sustainable weight loss was produced beyond that timeframe. It is recommended for future use that follow-up be conducted for a longer timeframe to assess that sustainability of weight loss.

Research

The research that is needed to build knowledge about this intervention is related to primary care providers, specifically FNPs, and the effectiveness of using regular phone call follow-up to motivate patients to stay on track with diet and exercise. There was little literature provided with results specifically on the effectiveness of routine follow-up of FNPs on weight loss. It is also suggested that further research is needed to determine the effectiveness of a phone application on weight loss and adherence to dietary changes. Further research is also needed to determine which diet is most effective for sustainable weight loss. When recommending diets to patients, it is critical that EBP be used so that sustainable weight loss is accomplished and to lessen rapidly fluctuating weight.

Education

The educational recommendations for undergraduate and graduate students would be to be aware of theories describing readiness for change. This was considered an important factor for why many participants were either not engaged or dropped out early. Another area of education that should be considered is MI and how to effectively use MI to elicit behavior changes. For the purposes of this EBP project, MI was used as a tool to incorporate patient specific goals of weight loss and to reinforce the patient's own desire to engage in the intervention and sustain the behavior changes. MI could be used in a variety of settings to engage patients in goal setting and sustaining behavior changes and using this technique

effectively should be considered as part of the education for both undergraduate and graduate students.

Conclusion

Overweight and obesity remains an epidemic in the US that must be curbed. It is clear that a few spoken words do little to promote lifestyle changes effective in supporting sustainable weight loss. Innovative ways to engage patients should be considered including utilizing FNP's as leaders in guiding weight loss. An ongoing collaborative relationship with frequent follow-up should be considered. Obesity and overweight are modifiable risk factors for numerous other diseases, illnesses, and cancers. The primary care FNP is on the front lines of this epidemic and can play a pivotal role in contributing to the Healthy People 2030 goal to reduce the proportion of obese adults. The statistically significant outcome results when comparing intervention group to comparison and dropout groups is evidence that a multi-component EBP weight loss program incorporating diet, exercise, self-monitoring, technology, and MI with regular follow-up phone calls and feedback can be effective in reducing weight for adults. This EBP project provides a framework for incorporating a multi-component weight loss program into the primary care setting. Routine follow-up phone call visits can be a convenient and cost-effective way to provide MI, encouragement, support, and opportunities for the FNP to reinforce behavior changes that can help provide weight loss over a 12-week period.

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BIOGRAPHICAL MATERIAL

Ashleigh D. Warburton graduated with honors from Purdue University in 2014 with a Bachelor of Science in Nursing degree. Ashleigh has since been working as a registered nurse in a mixed medical and cardiovascular intensive care unit (ICU). While working in the ICU, she earned two national certifications: acute/critical care nursing and cardiac medicine. She has presented three evidence-based practice (EBP) projects at the Northwest Indiana Nursing Research Consortium. In 2018 and 2019 she was the first-place award recipient for “Outstanding Clinician Poster Presentation” for the EBP poster projects titled “CLABSI Prevention at the Bedside” and “CAUTI Prevention at the Bedside”. Also during these years, Ashleigh received the “Nursing Excellence” award at the organization where she is employed as a nurse and was one of ten recipients of The Times newspaper “Heart of Healthcare” award. Ashleigh is a member of Sigma Theta Tau International Honor Society of Nursing - Zeta Epsilon Chapter, American Nurses Association, American Association of Critical-Care Nurses, Coalition of Advanced Practice Registered Nurses of Indiana, and American Association of Nurse Practitioners. Ashleigh recently presented her EBP project for which this biography was written at the University of Iowa’s Hospital and Clinics 29th National Evidence-Based Practice Conference. To satisfy her passion for primary care, patient education, EBP, and life-long learning, Ashleigh is currently attending Valparaiso University where she plans to earn her Doctor of Nursing Practice degree with a Family Nurse Practitioner specialty in May 2022.

ACRONYM LIST

CASP: Critical Appraisal Skills Programme

CDC: Centers for Disease Control

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CLI: comprehensive lifestyle intervention

CPG: clinical practice guideline

FNP: family nurse practitioner

IRB: institutional review board

Iowa Model: Iowa Model Revised: Evidence Based-Practice to Promote Excellence in Health Care

JB: Joanna Briggs Institute Evidence-based Practice Database

MA: medical assistant

MI: motivational interviewing

PL: project leader

RCT: randomized controlled trial

SOC: standard of care

SR: systematic review

TRIP: Turning Evidence Into Practice

US: United States

USDA: United States Department of Agriculture

USPSTF: United States Preventative Services Task Force

VU: Valparaiso University

VA/DoD: US Department of Veteran Affairs, Department of Defense

APPENDIX A

Evidence Table

| Lead Author/ Year/Quality | Purpose/ Design/Sample | Interventions | Measurement/ Outcomes | Results/ Findings | Strengths/ Limitations |
|---|---|----------------|--------------------------|---|--|
| Level I Evidence | | | | | |
| Durrer Schutz et al. (2019) Moderate Quality | Provide patient- centered guidelines with a focus on communication and motivational interviewing. | Not applicable | Not applicable | Approaches: Improve communication and increase motivational interviewing, avoid stigmatization, measure body weight and height and calculate BMI, measure waist circumference, treat comorbidities, use multidisciplinary teams, increase physical activity, provide nutritional and behavioral advice. | Strengths: Guidelines based on RCTs. Limitations: Moderate quality appraisal. Population focus is unknown. |

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|--------------------------------------|--|--|--|--|--|
| Fong (2020) High Quality | Evaluate the effectiveness of low-fat diets on weight loss long term/Evidence Summary/Systematic Reviews and Meta Analysis | Low fat diet, low carbohydrate, high protein diet, and very low carbohydrate ketogenic diet. | Weight loss | Diets low in fat and carbohydrates and high in protein may be effective in weight loss. | Strengths: All high level evidence. Limitations: Exact amount of fat, protein and carbohydrates is not recommended . |
| Hooper et al. (2020) High Quality | Systematic review of RCTs to evaluate the effect of cutting down dietary intake of fat on body fatness in participants not trying to loose weight. | “a low fat intake ... aimed to reduce fat intake to $\leq 30\%$ energy ... from fat, and at least partially replace the energy lost with carbohydrates (simple or complex), protein or fruit and vegetables” (p. 7). | Body fatness. Measured by BMI (kg/m^2), body weight (kg), waist circumference, and percentage of body fat. | Measurements follow-up 6-96 months after initiation. Mean weight: 1.42 kg lower; mean BMI: $0.47 \text{ kg}/\text{m}^2$ lower; mean waist circumference: 0.47 cm lower. Reduce fat intake resulted in a small reduction in body fatness in participants not trying to lose weight. | Strength: All evidence from 37 RCTs included 57,079 participants. |

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| Marques, et al. (2021) Moderate Quality | Study aims to synthesize interventions for primary care treatment of obesity and overweight in adults and elderly. | Individual face-to-face and/or group sessions; technology (telephone calls, website, telephone application, DVD) to enhance adherence and or monitor. Dietary prescription. Prompting lifestyle changes including food consumption and increased physical activity. | BMI, body weight, and waist circumference. | Individual and/or group onsite, face to face interventions while incorporating technology (telephone application, telephone calls, or website) may be used as an effective treatment of obesity. | Strengths: All evidence from RCTs. Eight databases searched. Multiple languages. Limitations: Studies are from low and middle-income countries are lacking. |
| Minooee (2021) High Quality | Effect of motivational interviewing on diet and exercise. | Motivational interviewing. | Weight loss | Motivational interviewing should be considered for obesity and weight loss. | Strength: High level evidence. Timeframes are provided. Limitations: Measurements are absent. |

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| Orringer et al. (2020) Moderate Quality | Clinical practice guideline for the treatment of overweight and obesity. | Lifestyle counseling (patient centered, self-management), activity (30minutes/day x 5 days per week), and diet (5 servings per day fruits and vegetables, whole grains, fat-free or low-fat milk, lean meats, decrease saturated fats). | BMI/10% weight loss in 6 months. | Not applicable. | Strengths: Clear recommendations Limitations: Literature search only included Medline database. |
| Pamaiahgari, (2021) High Quality | Evaluate the effectiveness of psychological interventions for overweight and obesity/Evidence Summary/ | Cognitive behavior therapy and behavior therapy along and in combination with diet and exercise. Motivational interviewing, mindfulness, financial incentives. | Weight loss | Cognitive behavior therapy and behavior therapy were found to be effective and when combined with diet and exercise when even more effective. Motivational interviewing resulted in significant weight loss. Mindfulness was effective for eating behaviors and anxiety. Financial incentives had no effect. | Strengths: Clinical bottom line is clear. Evidence is from high levels. Limitations: Exact interventions are vague. |

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| Semlitsch et al. (2019) High Quality | Synthesize international guidelines and provide a structured management plan for patients overweight or obese. Systematic review of evidence-based guidelines. 19 CPGs published from 2013 – 2018. Foci included, diet, bariatric surgery, pharmacotherapy, lifestyle change, and general obesity management. Date range was from 2011 to 2016. | Not applicable | Not applicable | <p>711 recommendations in 19 guidelines.</p> <p>General recommendations: Multidisciplinary team 0.25 to 1.0 kg per week 5-10% reduction in weight at 6 months and 12 months. Improvement of health to prevent or treat obesity-related complications.</p> <p>Diagnosis: BMI should be used for diagnosis. Waist circumference should not be used for diagnosis. Information should be collected including the following: possible causes, such as current weight history, personal lifestyle, psychosocial stress, other psychological issues, previous attempts to lose weight, social background, and the motivation and willingness to lose weight” (p. 1222-1223)</p> <p>Lifestyle changes: Diet and physical activity should be individualized to patient preference and ability. Behavioral interventions should be included and could come in</p> | <p>Strengths: International guidelines are provided. Limitations: Inclusion of guidelines from high-income countries. Quality of guidelines was largely of moderate quality.</p> |
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| | | | | <p>the form of individual group sessions, “motivational interviewing ... stimulus control ...cognitive restructuring” (p. 1225). Self-monitoring is recommended as “essential” (p. 1225).</p> | |
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| U.S. Department of Veteran Affairs, Department of Defense. (2020) High Quality | Guidelines for the treatment of overweight and obesity. | Recommendations for diet, activity, and counseling. | Weight loss | Recommendations provided for motivational interview. Physical activity recommendations: aerobic (biking, walking), weight training, and lifestyle modifications (parking farther away, taking the stairs). | Strengths: Thorough, clear recommendations. Limitations: Population served is veterans. |
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| <p>US Preventative Services Task Force. (2018) High Quality</p> | <p>Provide recommendation for the use of behavior counseling interventions in the treatment of obesity (BMI > 30) in adults greater than age 18.</p> | <p>Behavioral interventions “encouraged self-monitoring of weight and provided tools to support weight loss ... (eg pedometers, food scales, or exercise videos)” (p. 1165).</p> | <p>BMI, waist circumference. Behavioral counseling interventions resulted in greater weight loss and decreased waist circumference at 24 months. Moderate net benefit noted.</p> | <p>The USPSTF concludes that behavior counseling should be offered to patients with a BMI of 30 or greater.</p> | <p>Strengths: High level of evidence. Grade B recommendation, meaning that there is high certainty the benefit is moderate.</p> <p>Limitations: Moderate benefit. Minute details provided on specifics of behavior counseling.</p> |
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| Level II Evidence | | | | | |
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| Alghamdi, R. Q. (2017) High Quality | Evaluate the effectiveness of a 12-week intensive lifestyle intervention on weight loss with a goal of 5% reduction compared to education only. RCT. 140 patients (50% female). | 8 in person visits 15-20 mins each: provide support and adjustments if needed. Daily food and exercise records provided. Diet: Daily carbohydrate target: 20-25 g/day. (Energy deficit: 500-750 kcal/day) Exercise: Goal: ≥ 150 minutes per week of aerobic exercise. Behavioral techniques: Self-monitoring, taught stimulus control: change environment. | Weight (kg), BMI (kg/m^2), waist circumference. | Average weight loss of 5.58 kg in the intervention group compared to 2.8 kg weight loss in the control group. BMI: -2.14 vs -1.06 (kg/m^2) Waist circumference: -4.56 vs -2.44 (cm) | Strengths: Well-designed RCT with a sufficient sample size. Limitation: Participants are from 1 geographic location. High attrition rate. |

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| Baer et al. (2020) High Quality | Evaluate effectiveness of interventions including an online program, online program with additional support, and usual care/RCT/Participants (n=840) from 24 primary care offices aged 20-70 with a BMI of 27-40. | Online program only, usual care, and online program with additional support which included monthly check-ins, review of progress, and encouragement of regular use of online program. | Primary outcomes: change in weight at 12 months measured in kilograms from baseline weight. | At 12 months usual care group had a weight loss mean of -1.2 kg, online program only group weight loss mean was -1.9 kg, and the combined intervention group the weight loss mean -3.1 kg. | Strengths: Interventions integrated into routine care, adequate sample size. Limitations: Clinic randomization rather than participant. Single institution, largely white, well-educated participants limits generalizability. |
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| <p>Bennett et al. (2018) High Quality</p> | <p>Evaluate the effectiveness of a digital weight loss program/RCT/351 participants men and women 21-65 years of age with a BMI 30.0 - 44.9. 176 participants enrolled in the intervention group.</p> | <p>Digital weight loss intervention consisting of app-based self-monitoring with tailored feedback, a smart scale, dietitian counseling calls, and clinical counseling via electronic health record tailored by app monitoring progress.</p> | <p>Weight in kg at 6 months and primarily 12 months. Secondary outcomes: "≥ 5% weight loss, waist circumference, blood pressure, fasting lipids, glucose, and HbA1c over 12 months" (p. 778).</p> | <p>Significantly larger number of participants lost > 3% of their initial weight at 6 and 12 months than comparison group. 56% vs 15% at 6 months 55% vs 30% at 12 months.</p> | <p>Strengths: Population was considered low socioeconomic . Well-designed RCT. Limitations: Multicomponent delivery makes extent of correlation to one specific component impossible.</p> |
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| <p>Eaton et al. (2016) High Quality</p> | <p>Evaluate the effectiveness of a homebased tailored lifestyle intervention compared to the standard intervention on obese participants.</p> <p>Randomized Control Trial. Participant and researchers were all blinded.</p> <p>211 participants from 24 primary care sites in Rhode Island and southeastern Massachusetts.</p> <p>Average age of 48.6 years and average BMI of 37.8 kg/m².</p> | <p>Baseline Intervention: Meal plan and increased activity instructions. Diet and exercise journals. A baseline, 6-, and 12-month meeting with lifestyle counselor.</p> <p>Intervention group (IG) (n=105): Weekly educational materials, tailored nutritional and exercise advice, exercise videos, and feedback on journals. Monthly telephone calls for 6 months and bi-monthly for 6 months. Second year maintenance phase included diet-related educational materials and exercise feedback.</p> <p>Control Group (CG) (n=106): 5 Pamphlets provided.</p> | <p>Weight Loss: Measured in kilograms.</p> <p>Physical Activity: Measured in number of minutes participants engaged in physical activity.</p> <p>Intervention Adherence: Measured by the number of times the participant engaged in the intervention such as number of times the participant completed face-to-face visits, telephone calls, and mailed journals.</p> | <p>Significantly more (almost half) participants in the IG “lost 5 % of baseline weight” (p. 315) and more weight overall.</p> <p>The IG had significantly more weekly minutes of physical activity. Statistical significance was only reached at 12 and 18 months.</p> <p>High adherence to face-to-face meetings in both groups, IG had higher adherence of telephone visits.</p> <p>Conclusion: “Home-based individually tailored weight loss interventions with minimal face-to-face contact can be effective for helping patients reach clinically significant weight loss and increased physical activity goals” (p. 318).</p> | <p>Strength: Well-designed RCT. Inclusion of low socioeconomic participants. Limitations: Participants are from one geographic location.</p> |
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| <p>Katzmarzyk, et al. (2020) High Quality</p> | <p>Perform a RCT to evaluate the effectiveness of a “high-intensity, lifestyle-based program for obesity treatment delivered” (p. 909). 18 clinics with patients aged 20 to 75 with a BMI 30-50 (n=803) in an underserved population in Louisiana.</p> | <p>Intervention group consisted of weekly sessions with health coaches during the first 6 months (16 in person, 6 telephone visits) and then monthly for 18 months. Sessions focused on portion control, then during the second month the focus was meal prepping. An energy deficit was calculated for each patient. Patients were provided with an electronic scale for daily weights. The control group received 6 newsletters covering various health related topics.</p> | <p>Primary outcome was percent change of weight at 24 months measured at 6, 12, 18, and 24 months.</p> <p>Secondary outcomes were change in absolute weight (kg) and waist circumference (cm).</p> | <p>At 24 months, the intervention group had lost significantly more weight with a mean percent weight change of -4.99% compared to the comparison -0.48%. Mean change in absolute body weight in the intervention group was -5.43 kg compared to the comparison group, -0.91 kg. Mean change in WC was -4.42 cm and 0.71 cm respectively.</p> <p>High intensity weight loss, lifestyle-based obesity programs that use a health coach have the potential to positively effect change in weight in underserved populations.</p> | <p>Strengths: RCT, large sample size in an underserved population. Limitations: Sample was 84% female. 36 patients lost to drop out. Clinics rather than participants randomized.</p> |
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| McVay, et al. (2019) Moderate Quality | Evaluate the effectiveness of provider counseling during weight loss treatment. RCT. Participants (n=351) from central North Caroline with a BMI 30-44.9 kg/m ² . | 12-month, five aspect intervention: (1) tailored goals; (2) weekly call or text message reporting progress and providing motivation and tips; (3) educational material; (4) coaches called participants and provided further support; (5) clinic visits progress reported. | Height (baseline only) and weight (baseline and 6 and 12 months). Participant report of provider communication regarding weight measured by questionnaire. Provider documentation of weight counseling measured via chart review of the electronic health record. Provider empathy and caring measured by validated tool Consultation and Relational Empathy (CARE) measure. | Participant report of provider communication of weight counseling not associated with weight loss. Participants whose provider documented intervention specific counseling was associated with 4.0 kg more weight loss than participants who received either no or general weight loss counseling. Provider empathy was associated with weight loss. Findings indicate that provider engagement in intervention-specific counseling with patients enrolled in a digital weight loss program may be more successful. | Strengths: Study was conducted in an underserved population. Limitations: Counseling groups not randomly assigned. No objective measurement of counseling was available. |
|--|--|--|---|--|---|

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|---|---|---|----------------------|--|---|
| Rodriguez-Cristobal et al. (2017) High Quality | Evaluate the effectiveness of a motivational intervention with clinical practice compared to traditional practice to reduce weight. RCT. 846 patients 30-70 years old with a BMI greater than 25. | Control group and intervention group visited every 3 months and provided advice on lifestyle changes, diet, exercise, measurements of weight, height, and waist circumference were performed. The intervention group received an additional motivational group session every 15 days during weeks 1-12 and monthly weeks 13-32. | Weight in kilograms. | At 12 months the control group lost a mean of 1.3 kg and the intervention group lost a mean of 1.8 kg. At 24 months the mean weight lost in kg was 1 and 2.5 for the control and intervention groups respectively. In the second year, the difference in weight reduction was statistically significant ($p = 0.04$). A group motivational intervention may be effective for treatment of overweight and obesity. | Strengths: RCT design. Limitations: Many patients lost to drop-out. 52.25% of patients completed year 2. |
|---|---|---|----------------------|--|---|

APPENDIX B

Demographics Form

Weight Loss Program Demographics Form Valparaiso University

Part 1: Please fill out the form below. All information will remain confidential.

Today's Date: _____

Name: _____

Best Phone Number to be Reached at: _____

Gender: Male Female Transgender Male Transgender Female Other: _____ Prefer not to say

Date of Birth: _____

Ethnicity (Circle One):

- A. Caucasian
- B. African American
- C. Asian American
- D. Hispanic
- E. Native American
- F. Other/Unknown
- G. Prefer not to say
- H. Other

Highest Level of Education

Completed (Circle One):

- A. Some High School
- B. High School Diploma
- C. GED
- D. Bachelor's Degree
- E. Master's Degree
- F. Ph. D. or Higher
- G. Trade School
- H. Prefer not to say
- I. Other

What is your employment

status (Circle One)?

- A. Employed Full-Time
- B. Employed Part-Time
- C. Seeking Opportunities
- D. Self-Employed
- E. Unemployed
- F. Retired
- G. Student
- H. Prefer not to say
- I. Other

**Where do you currently live
(Circle One)?**

- A. House
- B. Apartment
- C. Shelter
- D. Homeless
- E. Prefer not to say
- F. Other

**Average Income per Year
(Circle One)?**

- A. Less than \$25,000
- B. \$25,001 - \$49,999
- C. \$50,000 - \$74,999
- D. \$75,000 or More
- E. Prefer not to say
- F. Other

Marital Status (Circle One):

- A. Single, Not Married
- B. Married
- C. Divorced
- D. Separated
- E. Widowed
- F. Prefer not to say
- G. Other

Thank you for your participation in the program. If you have any questions, feel free to contact

Ashleigh at (219) 765-1060

APPENDIX C

Self-Monitoring Templates

| | Week 1 Journal | | | | | | |
|-----------|----------------|----------|----------|-----------|----------|----------|----------|
| | Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
| | Diet | Diet | Diet | Diet | Diet | Diet | Diet |
| Breakfast | | | | | | | |
| Snack | | | | | | | |
| Lunch | | | | | | | |
| Snack | | | | | | | |
| Dinner | | | | | | | |
| Snack | | | | | | | |
| | Exercise | Exercise | Exercise | Exercise | Exercise | Exercise | Exercise |
| Time | | | | | | | |
| Type | | | | | | | |

APPENDIX D

Program Directions

Weight Loss Program

Hello and Welcome!

Thank you for taking the time to participate in this weight loss journey.

Please follow these directions:

Diet:

Follow a low-fat diet and avoid sugary drinks and fast food.

Please refer to the provided workbook for guidance.

Exercise:

Walk 5 days per week for at least 30 minutes a day.

***Walk in a safe area during day light hours or at home.

***Do not overexert yourself and do not exercise beyond your comfort or capabilities.

***Exercise slowly at first and even perhaps only five minutes at a time for a total of 30 minutes per day. Time can then slowly be built up for a total of 30 minutes per day.

***If you suddenly experience chest pain, shortness of breath, lightheadedness, or dizziness call 911. ***

Phone Application:

Download the phone application "Start Simple with My Plate" and pick at least three goals. Try to accomplish these goals.

Journaling:

Keep track of your diet and exercise with the journals provided in the folder.

Keep everything in your bag so during our biweekly phone calls we can talk about your journals.

Phone Calls:

Participate in phone call visits every other week.

Please save in your phone, the following number **219-765-1060**.

Ashleigh will contact you every other week to provide you with support, encouragement, and feedback on your journals.

APPENDIX E

Program Timeline

Weight Loss Program Timeline

Timeline:

Week 1: Initial meeting. Folder and journaling templates for 12 weeks are provided with instructions to download “Start Simple with My Plate” app. Educational materials to be provided. Instructions to journal diet and exercise daily. Participants to be encouraged to walk 30 minutes 5 times per week and to choose low-fat foods in diet.

Baseline BMI measurement to be obtained. Demographic data form to be completed. Informed Consent signed. |

Week 2: Phone call with feedback on journals and motivational interviewing.

Week 4: Phone call with feedback on journals and motivational interviewing.

Week 6: Phone call with feedback on journals and motivational interviewing.

Week 8: Phone call with feedback on journals and motivational interviewing.

Week 10: Phone call with feedback on journals and motivational interviewing.

Week 12: Patient to come into office for final weight or self-report body weight.

If you have any questions, feel free to contact

Ashleigh at (219) 765-1060

APPENDIX F

Informed Consent Form

Informed Consent Form



TITLE OF THE PROJECT:

A Weight Loss Program Using Self-Monitoring, Technology, and Motivational Interviewing

INTRODUCTION

Thank you for your interest and participation in this evidence-based practice project. I look forward to your participation and if you have any questions at any time, please do not hesitate to reach out.

RESEARCHER:

Principal Investigator:

Ashleigh Warburton, BSN, RN, CCRN-CMC, Valparaíso University Doctoral Student

Cell Phone: 219-765-1060

Email: Ashleigh.Warburton@Valpo.edu

DESCRIPTION OF THE RESEARCH STUDY

Purpose:

The purpose of this research project is to evaluate the effectiveness of self-monitoring combined with motivational interviewing and technology in the form of a free phone application on weight loss. The intervention will be primarily conducted over the telephone to motivate you to follow a low-fat diet and exercise by walking for 30 minutes five times per week. At the initial meeting, you will be provided educational material on diet and be instructed to walk for 30 minutes five times per week and follow a low-fat diet while avoiding sugary drinks and fast food and maximizing home cooked meals. You will also be instructed to download the free phone application "Start Simple with MyPlate" which allows you to choose dietary goals such as "have fruit with dinner." The phone application provides daily reminders to accomplish these goals. You will also be provided journaling templates to track your diet and exercise daily. At regular intervals (every other week for a total of 12 weeks), I will call you on the telephone and provide you with feedback on the journals and encourage you to continue to follow the program. At week 12, you will either provide your weight by either coming to the office to be weighed or use a home scale.

INCLUSION CRITERIA:

The requirement for inclusion is that you have a body mass index of greater than or equal to 25 kg/m². You must also be competent and able to consent without assistance from a guardian. The office provider will review your medical chart and history to determine if you are a candidate. You must be 19 years of age or older. There will be approximately a total of 30 to 50 participants enrolled.

EXCLUSION CRITERIA:

The exclusion criteria include women who are pregnant and/or breastfeeding. Please tell your provider and the principal investigator if you are pregnant or breastfeeding or become pregnant during the 12 weeks you are enrolled. You will also be excluded if your age is 18 years or less. You will be excluded if you cannot consent independently.

RISKS AND BENEFITS:

Potential risks may include psychological stress regarding accomplishing commitments of following the diet and exercise plan. Risk also may include injury while participating in exercise. You should walk a minimum of 30 minutes per day, 5 times per week, in safe areas, during the daytime hours, or within your home. Do not overexert yourself and do not exercise beyond your comfort or capabilities. Exercise slowly at first and even perhaps only five minutes at a time for a total of 30 minutes. Time can then slowly be built up for a total of 30 minutes per day. If you feel sudden shortness of breath, chest pain, lightheadedness, dizziness, you should stop, sit down, and call 911.

The benefit to be gained by participating in this project is increased energy and mood and better health including decreased risk for heart disease, diabetes, and cancer.

ALTERNATIVE PROCEDURES:

Alternative procedures may include medications and bariatric surgery consultation. Diet and exercise are considered the first line treatment which is the aim of this project.

COST AND PAYMENTS:

This program is completely free and there is no cost to you. There is also no monetary compensation for participants.

NEW INFORMATION:

The information that may result because of this project is that an easy and helpful way for doctors and nurse to help patients lose weight may be developed.

Initials _____ Date _____

CONFIDENTIALITY ANONYMITY:

Confidentiality and anonymity will be maintained by storing your phone number without a name on a password protected flash drive which will be stored in a locked box. This flash drive, the demographics forms, and the informed consents will not leave the office and the data will be destroyed three years after the completion of the study.

WITHDRAWAL PRIVILEGE:

Your participation in this project is completely voluntary and at any time, you are free to stop participating without reason and there will be no unpleasant effects. The office staff or the office providers will have no knowledge of your continued or discontinued enrollment in the project.

COMPENSATION FOR ILLNESS OR INJURY:

Your participation in this project is completely voluntary and the investigator does not assume any liability for illness or injury. There will be no compensation for illness or injury because of participation in this evidence-based practice project.

CONTACT INFORMATION:

At any time, please feel free to contact Ashleigh Warburton with any concerns or questions on her cell phone or at her email. You may also reach out to the office staff or providers at the office phone number without the knowledge of the principal investigator.

If you have any questions or concerns about your rights as a research participant, please contact the [REDACTED] IRB at [REDACTED]

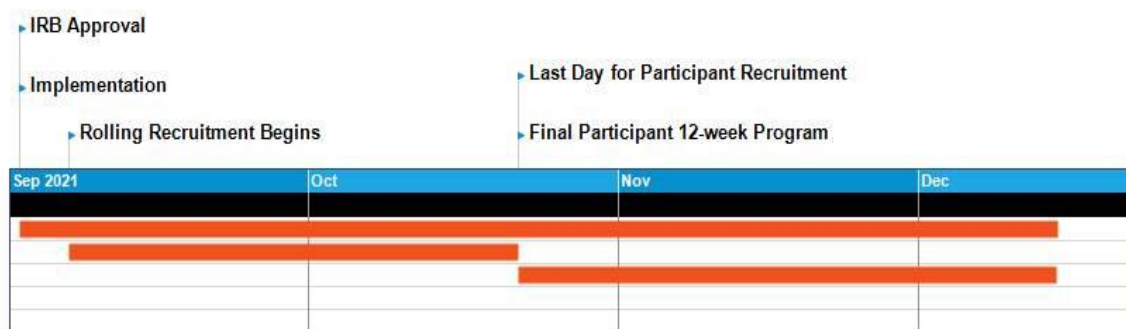
Participant Signature _____

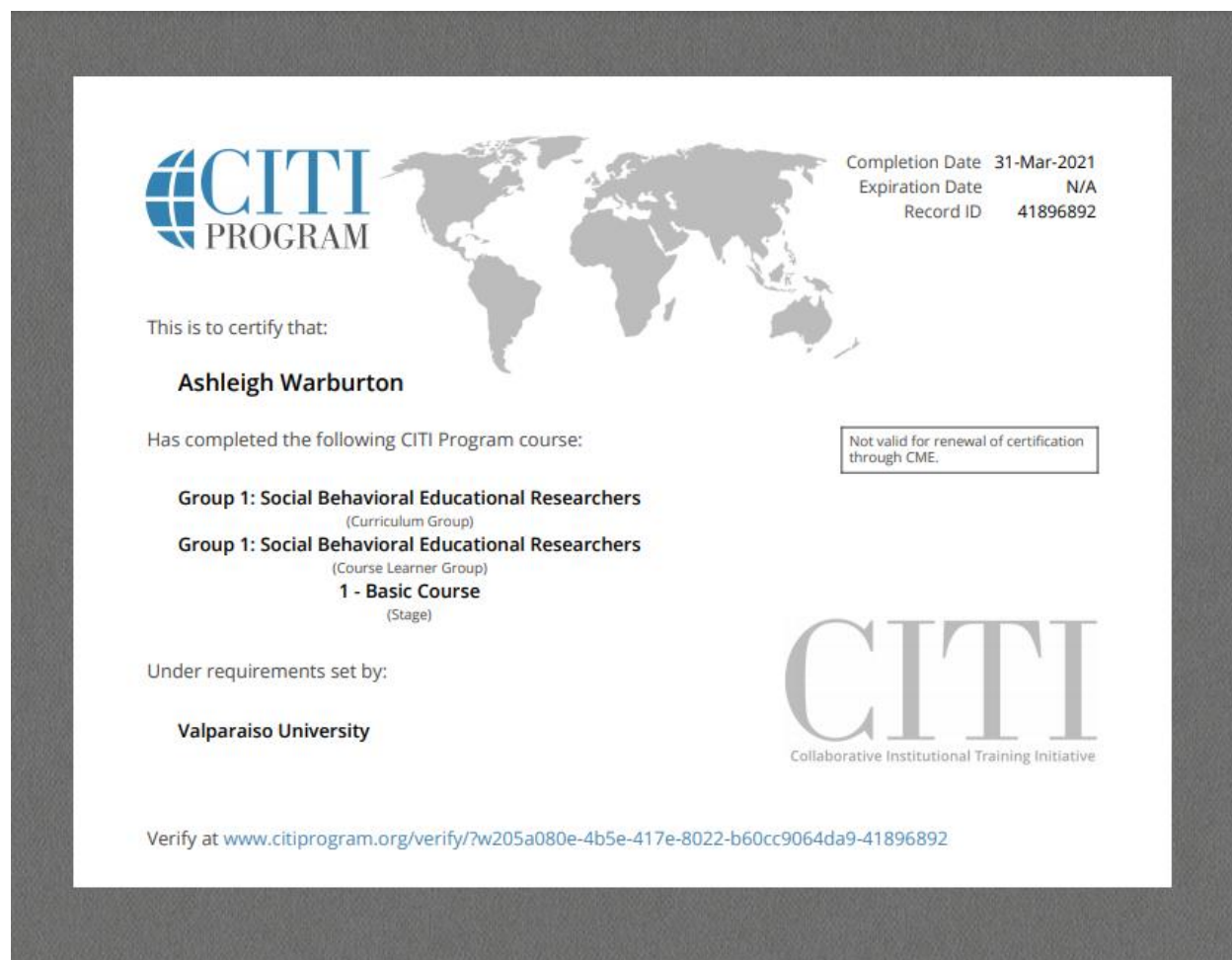
Date: | _____

Initials _____ Date _____

APPENDIX G

Implementation Calender



APPENDIX H**Ethics Training**

APPENDIX I

IRB Approval Letter



September 8, 2021

Ashleigh Warburton, BSN, RN, CCRN-CMC
5074 W. Chablis Drive
LaPorte, IN 46350

Dear Ashleigh:

This letter is in regards to your research, A Weight Loss Program Using Self-Monitoring, Technology, and Motivational Interviewing, for which you are the Principal Investigator(s).


The Subcommittee reviewed your submitted documents for your study project and concluded that the study project qualifies for Expedited Review and will be acknowledged at the Full Committee in November.

It is the responsibility of the Principal Investigator to notify the IRB of:

- modifications in the research plan that may affect the committee's initial determination of expedited status;
- personnel change that may affect the confidentiality of the data;
- changes to the study design or tools used to conduct the study;
- **when the study is concluded and submit findings.**

If there are any questions, please don't hesitate to contact 219-738-5891.

Thank you.

, Recorder
IRB Subcommittee

IRB Subcommittee: 

CC: , Chairman

APPENDIX J

Diet, Exercise, Self-Monitoring, Technology, and Motivational Interviewing for Weight Loss in Adults

Sustainability Protocol

