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A Multicomponent Tailored Intervention Program Protocol for Weight Loss in an Underserved Adult Patient Population with Obesity

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A MULTICOMPONENT TAILORED INTERVENTION PROGRAM PROTOCOL FOR WEIGHT LOSS IN AN UNDERSERVED ADULT PATIENT POPULATION WITH OBESITY

by

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DEDICATION

This project is dedicated to God and to my loving and supportive family. To my parents, who taught me the meaning of faithfulness and love, to work hard and to never give up despite obstacles. To Samuel, one of my sweetest gifts. I know that I will see you again one day. May I have made you proud.

To my wonderful husband Duane J. Arnold, thank you for your unwavering love and support throughout our marriage and this DNP program. Thank you for willingly taking on the extra work and challenges, and for never letting me give up on myself despite the many obstacles along the way. Your belief in me and encouragement have pulled me through and I will always be grateful for all the love and understanding you have shown. You have made this dream possible. To my children: Katie, Rose, Joel, Ruso, Brandon and Catherine who have supported my quest of this doctoral degree, your love and support as well as all the encouraging conversations and prayers have made this journey so much easier. To my grandchildren: Elijah, Amelia, Aaron, Christian, Simon, and Adelaide, you are the light of my life and bring so much joy to the world. May my example show that anything is possible with God and to encourage you to aim high. To Sally and Dan, thanks for providing a home, love and encouragement when I needed it. You are all my reason for reaching beyond the status quo and you have made it possible to grasp my dream.

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PREFACE

Weight management is multifactorial. It is like peeling an onion. At the core it seems it is simple math: calories in versus calories burned equals pounds lost or gained. But it is all the other layers, the factors that influence the core that are unique and make all the difference, many of which are beyond our control. May this project lead to a better understanding of the chronic disease of obesity and result in a more knowledgeable, less biased, kinder hearted and healthier provider and patient population. May it also serve as a stimulus to finding a cure for this chronic, debilitating and often life-threatening disease.

"The improvement of understanding is for two ends: first, our own increase of knowledge; secondly, to enable us to deliver that knowledge to others". -John Locke

"If you judge people you have no time to love them"- Mother Teresa

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Abstract

Obesity is a multifactorial, individualized, chronic disease that increases known risk factors for significant comorbidities and mortality. The primary purpose of this Evidence-Based practice project was to improve indicators of obesity (weight, BMI) among patients served by a free medical clinic, using a tailored multicomponent intervention. The secondary purpose was to determine if the weight loss intervention was associated with a decrease in blood pressure and depression symptoms. The intervention was guided by the Health Promotion Model by Nola Pender. The Johns Hopkins Nursing Evidence Based Practice Model (JHNEBP) guided implementation of the project. A comprehensive literature review was completed in five databases, and strong evidence supported the tailored multicomponent intervention used in this project. Eligible participants (n=26) took part in the 3-month program. Written education materials were provided in English and Spanish, and an interpreter was used when appropriate. Weight, BMI, and BP were measured weekly, then at weeks 8 and 12. The PHQ-9 was measured at baseline and at week 12. Analysis: Continuous outcome variables and dichotomous data were analyzed using the nonparametric equivalent of the paired *t*-test – the Wilcoxon signed-rank test. A weight or BMI reduction of $\geq$3% from baseline is considered clinically significant. Weight significantly decreased from baseline (228.96 lbs., SD = 57.16) to Week 4 (214.87 lbs., SD = 44.68, p = .026). Mean BMI also significantly decreased from baseline (39.87kg/m^2, SD = 6.19) to week 4 (38.27 kg/m^2, SD = 6.57, p= .028), and from baseline to week 12 (38.64 kg/m^2, SD = 6.93, p=.023). Significantly more patients in the intervention group achieved at least 3% weight loss between baseline and Week 12, compared to those who did not receive the intervention

(27% vs 16%, p = .034). Depression improved significantly from baseline to Week 12 (p = .014). There were no significant differences in SBP or DBP. Conclusions: Based on these results, a tailored multicomponent weight loss program is effective at reducing weight, BMI, and depression in the primary care setting.

Search words: obesity AND intervent* OR treat* AND “weight loss” OR BMI OR “waist circumference” OR “body fat” AND “primary care” OR “primary health care” OR “primary healthcare”

CHAPTER 1

INTRODUCTION

Background

In this chapter, the problem of obesity will be described in the global and national contexts, including its prevalence, pathophysiology, risk factors, clinical presentation, diagnostic findings, and available treatment options.

Obesity, resulting from excess adiposity and subsequent chemical imbalances create the systemic chemical effect that increases overall health risk for comorbidities and mortality, including: depression, hypertension, elevated cholesterol and triglycerides, cardiovascular disease, cerebrovascular accident, liver and gallbladder diseases, reproductive diseases, type II diabetes, osteoarthritis, certain cancers and sleep apnea. Obesity can be prevented and or treated with existing, new and or evolving discoveries (Doig & Huether, 2014; Goettler, Grosse & Sonntag, 2017; Jensen et al., 2014; Kushner & Ryan, 2014; Triplett, Repas, & Alvarez, 2014).

Prevalence

Obesity is a global health threat. In 2016, as many as 1.9 billion adults throughout the world were overweight, of which 650 million adults were obese. Moreover, 340 million children were overweight or obese, and many of these acquire lifestyle patterns in childhood that will follow them into adulthood and increase their risk for lifelong obesity (WHO, 2018).

Since 1975, the global prevalence of obesity has nearly tripled (WHO, 2018), which may be attributable to increased access to high-calorie food, less active lifestyles, more sedentary work, and automotive sources of transportation (Rolls et al.,2017). In

every global region, except for sub-Saharan Africa and Asia there are more people who are obese than underweight (WHO, 2018). Underserved and minority populations have a disproportionately higher incidence of obesity and suffer from proportional weight related comorbidities. Women of these communities are impacted at a higher degree. All women are at risk for obesity but minority and low-income women and persons living in certain rural and urban geographical regions are at a higher risk than those living in affluent regions (ACOG, 2014; Hageman et al., 2017; Katzmarzyk et al., 2018; Kozica et al., 2015) . “African American and Hispanic women are twice as likely as their white counterparts to be overweight or obese. Forty-two percent of women with incomes below 130% of the poverty level are obese” (ACOG, 2014).

Patients with obesity can be found in every clinical practice in the world, but their disease is often left unaddressed and untreated (McLaughlin, Hamilton & Kipping, 2017; Pollak et al., 2016). This may be due in part to previously experienced and anticipated poor treatment from a provider who may have a preconceived bias or stigma regarding overweight obese patients. This may cause patients to avoid seeking treatment and or poor compliance (Phelan, et al., 2015). As much as 69% of overweight or obese female patients have reported a perceived healthcare provider obesity bias (Alberga et al., 2017). This may have a significant impact on population health, because of the increased risk of obesity-related comorbidity and mortality (Doig & Huether, 2014; Guan et al., 2016; Kroes et al., 2017; Kushner & Ryan, 2014; WHO, 2018), being overweight or obese is linked to more deaths globally than being underweight or starvation.

In the United States, about two-thirds of the population is either overweight or obese, with approximately 35% of the adult population having a body mass index (BMI)

in obese range (Bomberg et al., 2017; Kroes, Osei-Assibey, Baker-Searle & Haung, 2016; Kushner & Ryan, 2014). Obesity has an enormous impact on the national, and therefore global, economy. Medical care costs are estimated to be between $200 and $220 billion in the United States and approximately $2 trillion globally (Bomberg et al., 2017). Furthermore, research shows that obesity in the workplace leads to decreased productivity and increased employee absenteeism (Bomberg et al., 2017; Goettler et al., 2017).

Obesity is preventable and treatable. Even a 5% to 10% reduction in body weight can significantly reduce the risk for obesity-related complications and improve quality of life (Bomberg et al., 2017; Kroes et al., 2016; Jensen et al., 2014; Kushner & Ryan, 2014; WHO, 2018). Because of its high prevalence, lifelong chronicity, substantial clinical and economic consequences, and high potential to be prevented and treated, obesity management is justifiably considered a high priority in the primary care setting.

Pathophysiology

Obesity is defined as a body mass index (BMI) of greater than or equal to 30kg/m^2 and develops due to an imbalance between caloric intake and caloric expenditure in persons with a genetic predisposition. The genetic component can be related to either genotype or a genetic- environment interaction. It can be associated with either single or multiple genetic defect(s) such as: GWAS or *FTO* gene, leptin or melanocortin pathway defect, the congenital deficiency of proprotein convertase subtilisin/kexin type 1 gene (PCSK1), Down or Prader-Willi syndromes. It can also be related to endocrine disorders such as: Cushing’s disease, polycystic ovary syndrome, diabetes or hypothyroidism, as well as hypothalamic injury. The intricate

pathophysiology involves a multitude of interactions between hormones, cytokines and neurotransmitters. The adipocytes are the basis for adipose tissue. Alterations in adipocytes have a systemic effect on chemical balance. Adipocytes secrete multiple hormones, and cytokines called adipokines. These help to regulate satiety, metabolism, fat storage, insulin sensitivity, vascular homeostasis, immune response, female fertility, and energy metabolism (Doig & Huether, 2014; Perreault, 2019a; Triplett, et al., 2014).

Obesity is often accompanied by frequent relapses and cyclical weight gain-weight loss (Kushner & Ryan, 2014; Rodriguez-Cristobal, 2017; McLauglin et al., 2017). Obesity often has a cyclical nature with depression and or anxiety (Kushner & Ryan, 2014; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017) and relapses often coincide with exacerbations of weight-related comorbidities, such as: worsening joint pain, hypertension, increased HbA1c or elevated cholesterol levels.

Risk factors

Because of its impact over the lifespan, obesity is considered a chronic disease with myriad risk factors (Doig & Huether, 2014; Kushner & Ryan, 2014; McLaughlin et al., 2017) that can impact every person, at every age, and nearly every system of the human body. Excess adiposity and subsequent chemical imbalances create the systemic chemical effect that increases overall health risk for comorbidities and mortality, including: depression, hypertension, elevated cholesterol and triglycerides, cardiovascular disease, cerebrovascular accident, liver and gallbladder diseases, reproductive diseases, type II diabetes, osteoarthritis, certain cancers and sleep apnea (Doig & Huether, 2014; Kroes et al., 2016; McLaughlin et al., 2017; Tapsell et al, 2017).

Since the underlying mechanism involves a metabolic imbalance between calories consumed and calories expended (usually through exercise), it seems intuitive that a high-calorie diet and sedentary lifestyle are the two most important risk factors for developing obesity (Hartman et al., 2014; Kroes et al., 2016; Kushner & Ryan, 2014; Thabault et al., 2016). However, each of these is associated with unique risk factors that ultimately determine caloric balance. Calorie consumption depends on eating patterns, the types of foods consumed, the source of calories (i.e. macronutrients), the cultural meaning of food, ability to access and prepare foods, and emotional responses to food. Since calorie consumption is the net result of a person's food choices, eating behaviors, personal beliefs and values, sociocultural context, and environmental characteristics, identifying and minimizing all risk factors for a high-calorie diet is virtually impossible.

Likewise, a sedentary lifestyle is the result of both intrapersonal and interpersonal factors that determine whether or not someone will engage in physical activity. For example, the decision to start an exercise program at a local gym may depend on a person's prior experience with that facility, their level of enjoyment engaging in a particular exercise, and the cost of gym membership. Other individual factors may include the availability of appropriate attire, transportation to the gym, and psychological comfort in a gym environment. Ultimately, these and many other factors will determine if a person starts the exercise program or not.

However, starting the program does not guarantee that the person will actually go to the gym and exercise; the person must be willing to forego other competing demands for their time, energy, and attention so they can physically follow through with their exercise plan. Still others are unable to engage in physical activity due to chronic

or acute illnesses that limit mobility or endurance. Despite a nearly limitless array of physical activities with which to engage, research shows that only 23.2% of U.S. adults meet the minimum recommendations for exercise and aerobic activity established by the CDC (2017). Clearly, calorie expenditure relies on a complex interplay between innumerable factors that are difficult for individuals (and our population) to overcome.

While it is relatively easy to think of obesity as an imbalance between calories consumed and calories expended, research suggests that genetic risk factors may also exist. Genotype and interaction of gene-environment are predisposing factors to obesity. Either single or multiple genetic defect(s) such as: leptin or melanocortin pathway defect, the congenital deficiency of proprotein convertase subtilisin/kexin type 1 gene (PCSK1), Down or Prader-Willi syndromes or endocrine disorders such as Cushing's disease, polycystic ovary syndrome, diabetes or hypothyroidism as well as hypothalamic injury may be instrumental in the development of obesity. Pathophysiology is intricate, involving delicate interactions between a multitude of hormones, cytokines and neurotransmitters producing interlocking systemic effect (Doig & Huether, 2014; Perrault, 2019a; Triplett et al., 2014).

Additionally, certain medications can be instrumental in weight gain including some: antipsychotics, antidepressants, antiepileptics, antihyperglycemics, antihistamines, alpha-blockers, beta-blockers, hormones and glucocorticoids (Perreault, 2019a; Perreault, 2019c) and are limitedly described in Table 1.1. As one intervention, a medication reconciliation and review will be completed, and whenever possible medication adjustments may be considered.

Table 1.1

Medications associated with weight gain

Medication class	Some of the drugs in class	Mechanism of action causing weight gain
Antidepressants/antianxiety: selective serotonin re-uptake inhibitors (SSRI); monoamine oxidase inhibitors (MOAI); tricyclic antidepressants (TCA)	TCA: nortriptyline, amitriptyline; SSRI: paroxetine, citalopram, escitalopram; TCA: doxepin, imipramine and mirtazapine.	SSRI:5-HT inhibition; MAO-I: increase concentrations of NE, 5-HT, and DA in neuronal synapses; TCA: Neuronal receptor sensitivity change due to down-regulation of Beta -adrenergic and 5-HT receptors
Antipsychotics	thioridazine, olanzapine, risperidone, clozapine and quetiapine	5-HT antagonism
Neurologic and mood stabilizers Antiepileptic	lithium, carbamazepine, gabapentin and valproate divalproex	Valproate component – MOA unknown Divalproex sodium/Valproate component – MOA unknown

Antihyperglycemics	insulin, sulfonylureas, thiazolidinedione, meglitinides	Plasma insulin/glucose levels related to insulin/antihyperglycemic therapy
Glucocorticoids	prednisone	Carbohydrate metabolism is increased at glucocorticoid receptor sites
Antihistamines	cyproheptadine	Nonselective 5-HT receptor antagonist and anticholinergic drug decreases ACTH secretion- and increases anticholinergic effect
Hormones	progestins, medroxyprogesterone	Alters insulin, glucose or glucagon release further altering carbohydrate metabolism
Alpha-blockers	terazosin	Slows metabolism and relaxes smooth muscles
Beta-blockers	propranolol	Beta-2 receptors are responsible for insulin

	secretion and glycogenesis

(Crismon, Argo & Buckley, 2014; Dietrich, Smith & Gums, 2014; Drayton & Pelic, 2014; Lee, 2014; Melton & Kirkwood, 2014; Perreault, 2019c; Saseen & MacLaughlin, 2014; Schrader & Ragucci, 2014; Teter, Kando & Wells, 2014; Triplitt, Repas & Alvarez, 2014)

Clinical Presentation

Patients with obesity may present to the primary care setting because they are concerned about their weight, due to a complication arising from their obesity (e.g. obstructive sleep apnea or low back pain), or for treatment of an unrelated problem (e.g. headache). They may report a recent weight gain, or they may share that they have struggled with being overweight since childhood. In any case, the patient should be weighed, and height measured so that their body mass index (BMI) can be calculated. A BMI greater than or equal to 30 kg/m^2 indicates obesity.

Beyond their BMI, the patient should be asked about their risk factors for obesity, how their weight affects their health and relationships, and if they feel motivated to lose weight. This conversation should be nonjudgmental, compassionate, and empathetic, but because of the clear health benefits of maintaining a normal BMI, it should not be avoided. The patient should also be asked about: readiness; current and previous attempts to lose weight, cultural and psychosocial barriers and motivators to weight loss, emotional health and well-being (Eaton et al., 2016; Kushner & Ryan, 2014; Samdal et al., 2017; Tapsell et al., 2017; Thabault et al., 2016).

A physical exam of a person with obesity may reveal the following: cardiovascular disease, jugular vein distention; reduced peripheral vascular circulation or varicosities; venous or lymph peripheral edema; pleural fluid retention and or dyspnea; hepatomegaly with possible ascites; Mallampati scores consistent with sleep apnea; inflammation; back or joint pain with decreased range of motion; polycystic ovaries; stress incontinence; hirsutism; rash and or cellulitis or carbuncles (Doig & Heuther, 2014). Because obesity and hypertension often occur together, a full set of vital signs including blood pressure should be evaluated. Additional clinical testing might include an evaluation of gait, cardiopulmonary fitness (e.g. 6-minute walk test), and anthropometric measurements (Kushner & Ryan, 2014; Tapsell et al, 2017).

Diagnostic Testing

Because obesity is strongly and almost universally associated with a number of chronic illnesses, it may be appropriate at their primary care visit to review fasting glucose or HbA1C and a fasting lipid panel that are consistent with current guidelines (Jensen et al., 2014; Kushner & Ryan, 2014; Tapsell et al, 2017; Uphold & Graham, 2013). Additionally, when possible, adults should have a complete blood count, liver function studies, a renal panel, and thyroid stimulating hormone, as well as an electrocardiogram based on patient risk. A referral to cardiology may be indicated if there is evidence of ischemic heart disease, which may warrant a cardiac stress test or heart catheterization. Evidence of obstructive sleep apnea should trigger a referral to a pulmonologist or sleep medicine specialist who can evaluate the patient's need for continuous positive airway pressure (CPAP). Evidence of hepatic, renal or thyroid

disease as well as any disease not routinely addressed in primary care may necessitate a referral to a specialist as well (Uphold & Graham, 2013).

Treatment Options

Traditionally, obesity treatment has relied on delivering education to the patient about calorie restricted diets and exercise. In addition, treatment may focus on preventing or managing the long-term consequences of obesity, such as hypertension and type 2 diabetes mellitus. Medications, including those presented in Table 1.2 may also be used to reduce appetite and food cravings or decrease carbohydrate absorption from the gut.

Table 1.2

Weight loss Pharmacotherapeutic Agents

Drug Class	Generic and Brand Name	Mechanism of Action
Gastrointestinal lipase inhibitor	Orlistat/ Xenical or Alli	Decreases fat absorption in the gut by inhibiting GI lipase
Serotonin 2C Receptor Agonist	Locaserin/ Belviq	Appetite suppression through activation of serotonin receptor in hypothalamus
Phentermine-Topiramate Combination	Extended release Phentermine-Topiramate/ Bontril PDM or Bontril slow release	Exact MOA unknown; May reduce appetite and increase satiety via multiple pathways

Noradrenergic Agents	Phendimetrazine/ Bontril PDM or Bontrilslow release Phentermine/ Adipex-P or Suprenza Diethylpropion/ Tenuaate or Tenuate Dospan	Exact MOA unknown; May reduce appetite and increase satiety via multiple pathways
Serotonergic Agents-Off Label (not approved for obesity management by FDA)	Fluoxetine	Increased 5-HT levels, decreases appetite and disrupts hunger satiety
Glucagon-like peptide-1 receptor/ anti-diabetic- off label	Liraglutide/ Victoza	Increases insulin and decreases glucagon release
Opiate agonist	Naltrexone/ Vivitrol or Revia	Effect not established for weight loss. Used in combination with bupropion
A noradrenergic/ dopaminergic antidepressant	Buproprion	Action in cerebral reward –dopamine centers

(Curry et al., 2018; Sheehan, Chen, Yanovski & Calis, 2014; Tek, 2016)

Finally, weight loss surgery has been an obesity management option for decades. Fairly recent improvements in surgical techniques, products, and interprofessional care coordination have resulted in dramatically beneficial outcomes for patients undergoing bariatric surgery (Jensen et al., 2014; Kushner & Ryan, 2014; Uphold & Graham, 2013; Welbourn et al., 2018).

It is clear that one treatment option does not work, or is not appropriate, for every patient with obesity. Evidence shows that tailored multicomponent interventions are an effective way to promote weight loss, but this approach can be resource-intensive, particularly in underfunded primary care settings without access to weight loss specialists, dietitians, and other team members that focus on obesity management (Eaton et al., 2016; Cheatham et al., 2018; Kushner & Ryan, 2014). The aim of this project was to help patients and providers to overcome barriers that prevent weight loss in adults with obesity through the implementation of theory-driven and Evidence-Based weight loss interventions.

Data from the Literature Supporting Need for the Project

According to the WHO (2018), obesity is a global health threat. In the United States obesity prevalence has reached 35% of the adult population (Bomberg et al., 2017; Kroes et al., 2016; Kushner & Ryan, 2014). It is a known fact that obesity related comorbidities can decrease physical well-being, functionality and quality of life, as well as lead to mortality (ADA, 2019b; American Heart Association, 2018; Kroes et al., 2016; Kushner & Ryan, 2014; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Tang et al.,

2016; Thabault et al., 2016; Welbourn et al., 2018). There is much evidence available as to how to treat obesity, however used separately there has been little impact on this growing epidemic. Obesity is a multifactorial chronic disease that is often accompanied by weight-related comorbidities, thus no one treatment will work for each person. This EBP Project combines multiple interventions into a personalized program that addresses obesity on an individual level based upon EBP and the patient's needs and preferences. The project provides a program and simply accessed tools that can be easily adopted into any primary care setting.

Data from the Clinical Agency Supporting Need for the Project

The clinical site chosen for this EBP Project is a clinic located in a low-socioeconomic urban neighborhood in North East Indiana. The clinic mission is based upon the Gospel of Matthew: 25. They provide medical, vison and dental care as well as some laboratory services to the underserved population, many of whom are minority, who are economically disadvantaged and have no insurance. The care is free and includes a limited range of free pharmaceuticals as well as refurbished glasses and hearing aids. Referrals to specialists are made based upon need and availability of service providers. The key stakeholders for this project included: physicians, nurse practitioners (NP), staff nurses (RN), administrative staff, and volunteers, as well as the patients. The medical clinic is primarily staffed six days a week by volunteers and students other than the Medical Director, two NPs, two RNs and a few administrative staff.

There is a great need for this EBP Project as currently the clinic does not have a weight management program, other than basic diet information and occasional

volunteer nutritional counseling from dieticians. Based upon available resources at the clinical site, as well as project participant resources and capabilities, some potential interventions that may produce weight loss may not be a possibility, such as: certain laboratory studies, bariatric referral or the use of some pharmacotherapies.

Comparison group: A retrospective electronic medical record (EMR) review was conducted prior to initiation of this DNP EBP Project. Patient records were accessed with the permission of administration and the Medical Director for the use in this project. Reviewed records had a baseline date of January 2019 and were included in the review if the patient had a follow up appointment between 3 to 5 months later and the patient was at least 18 years old, and had at least one BMI greater than or equal to 30 kg/m^2, had a weight and consistent height provided for each visit. Patients were excluded if they were under 18 years old, the height was incorrectly measured and varied between visits (eg.5'2" and the next visit 5'5") or in between visits time was not within then the 3 to 5 months. A total of 25 EMRs were included in this retrospective. There were seven males and 19 females. The mean age was 46.96 (13.82) years. The mean baseline weight was 235.10 (54.21) pounds (lbs.) and mean BMI was 38.61 kg/m^2 (7.18). At the 3 to 5- month follow up the group mean was 235.86 (55.36, p=.558) lbs. and mean BMI was 38.59 kg/m^2 (7.31, p=.914). There was no significant change in weight or BMI. Attainment of a 3% total body weight loss goal was achieved by only 16% of those in the comparison group.

Purpose of the Evidence-Based Practice Project

The purpose of this project was to improve selected obesity indicators, including weight, body mass index (BMI), waist circumference, and waist-to-hip ratio, through the

implementation of an Evidence-Based multicomponent intervention tailored to individual patient strengths, barriers, and resources. In addition, a secondary aim was to determine if the weight loss intervention resulted in improvement in health outcomes related to obesity, including BP, HbA1c, lipids, as well as depression and anxiety symptoms. The intervention components varied by patient, but in general, options included diet and exercise education, tracking of caloric intake and exercise, lifestyle and behavioral counseling, pharmacotherapies, and referrals for psychotherapies and or bariatric evaluation when appropriate.

PICOT Question

Specifically, this project addressed the following two-part PICOT question. Will the use of an evidenced based protocol for the assessment and treatment of obese patients assist adult patients with obesity to achieve better weight loss outcomes over a three month period compared to usual care as measured by primary outcomes of a reduction in BMI, waist circumference and waist to-hip ratio. And will the implementation improve secondary outcomes measured of BP, HbA1c, total cholesterol, HDL, LDL, triglycerides and the PHQ-9 and the GAD-7 scores.

Significance of the EBP Project

The importance of this EBP Project is represented in reduced weight-related health risk in a patient population with obesity. Obesity is a global health risk that has nearly tripled since 1975 (WHO, 2018). The risks associated with obesity and weight-related comorbidities can be life threatening and impact quality of life for the obese population. The impact of obesity is seen in poorer health, increased exacerbations of diseases, decreased mobility, decreased quality of life, and decreased productivity and

financial resources (Bomberg et al., 2017; Kroes, Osei-Assibey, Baker-Searle & Haung, 2016; Jensen et al., 2014; Kushner & Ryan, 2014; WHO, 2018).

Addressing the clinical problem

Obesity is a significant risk factor for comorbidities and mortality in the general population however it disproportionally effects those of reduced socioeconomic standing and the underserved population. Those are the people who are served by this clinical site. Currently this clinical site does not have a set protocol in place to address the problem of obesity. This project addresses this issue of obesity and weight-related risks through a multicomponent individualized tailored weight loss intervention program that is sustainable and can be simply accessed and utilized within the clinic.

How this project can improve patient outcomes

This EBP Project can improve clinical outcomes by improving overall population BMI and health risk as evidenced by improved BMI, BP, HbA1c, total cholesterol, HDL, LDL, triglycerides and PHQ-9 and GAD-7 scores. By improving BMI, BP, HbA1c, total cholesterol, HDL, LDL, triglycerides cardiovascular risk as well as those associated with elevated blood glucose and diabetes are reduced (ADA, 2019b; American Heart Association, 2018; Doig & Heuther, 2014; Kushner & Ryan, 2014; Triplett et al., 2014). Reduced PHQ-9 and GAD-& scores indicated improved mental health and wellbeing and can be directly associated with weight loss and improved BMI (Batsis et al., 2018; Bomberg et al., 2017; Kushner & Ryan, 2014; Ma et al., 2019)

CHAPTER 2

THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

Theoretical Framework

After a careful and thorough review of the health promotion and disease prevention literature, the Pender Health Promotion Model was chosen to assist with the development and implementation of an intervention that was used in this Evidence-Based practice (EBP) project. In this section, a succinct description of the Pender Health Promotion Model (Pender, 1982; Pender 2011) and an overview of how this model applies to this EBP project will be provided.

Overview of Theoretical Framework

The Pender Health Promotion Model (HPM; Pender, 1982; Pender, 2011) was developed by Nola Pender PhD, RN, FAAN, a Professor Emerita at the University of Michigan and a Distinguished Professor at Loyola University in Chicago, Illinois. The HPM was developed as a complement to existing models of health protection. In this theory, Pender states that each person has a unique set of experiences, beliefs, and attitudes that affect their willingness and ability to change detrimental health behaviors, such as consuming an unhealthy diet and exercising infrequently. This model was first presented in nursing literature in 1982 and was revised in 1996. The initial purpose of the model was to “assist nurses in understanding the major determinants of health behaviors, as a basis for behavioral counseling to promote healthy lifestyles” (Pender, 1982, p.2; Pender, 2011, p. 2). This model recognizes that a person’s context – their experiences, feelings, emotions, resources, social barriers, etc. – impacts their health behavior.

Assumptions of the HPM are that:

- People attempt to create living environments in which they can live to their personal health potential.
- People are self-aware, thoughtful and able to evaluate their own capabilities.
- People strive for positive growth and an equilibrium between change and stability.
- People desire to determine their own behavior.
- People interact with and within their environment, both changing over time through this interaction.
- Health care providers are part of the person's interpersonal environment throughout their life, impacting the person's choices.
- Behavioral change is managed through self-determined change in the person-environment interaction (Pender, 1982; Pender, 2011).

Health promotion behavior is defined as the "desired behavioral end point or outcome of health decision-making and preparation for action" (Pender, 2011, p.6). Using the HPM the healthcare provider, working in a collaborative relationship with the patient, can assess and intervene to assist with behavioral and lifestyle changes to promote health. Assessment includes prior behaviors and attempts to change behavior, personal influences, barriers and benefits, self-efficacy and enjoyment of activities, social norms and social support, role models within the social network, influences, commitment to change, and competing demands or barriers to success. Based on their

assessment findings, the nurse intervenes to support the behavior change through education, role-playing, problem-solving, and removal of perceived barriers to change.

In the model Pender theorizes that motivation is modified by specific behavioral variables and that the individuals' behavior and outcome is determined by two interrelated paradigms: Individual Characteristics and Experiences, and Behavior Specific Cognitions and Affect. Examples of Individual Characteristics and Experiences that may impact the individual's ability and desire to engage in health behavior change include whether or not they had previously attempted similar behaviors as well as biological, psychosocial or sociocultural factors supporting or preventing the intervention, such as: the individuals' perceived self-efficacy, perceived benefit and barriers, interpersonal relationships, options and demand characteristics. All of these directly influence the individual's commitment to the plan of action and health promoting behavioral changes and can be interrupted or curtailed by immediate competing demands or preferences.

This model is applicable to this project as it provides a frame from which to develop motivational strategies to encourage weight loss in project participants. This model accepts that each person is an individual in which motivation to lose weight is heavily influenced by the life experiences specific to that person and to prior weight loss behaviors. Therefore, the ideal weight loss intervention will vary from one person to another based on whether and how they have tried to lose weight in the past, their perceived facilitators and barriers to weight loss, current lifestyle patterns, and comorbidities. Therefore, the use of a multicomponent, individualized approach to treatment may theoretically promote weight loss better than a more generalized ("one-

size-fits-all") approach. For example: some patients may prefer walking over group aerobic activities or use of the My Fitness Pal phone app instead of a paper journal to track caloric intake and exercise, or face-to face counseling rather than simple written instructions. If the patient's preferences are not consistent with the recommended weight loss interventions, the HPM predicts that these interventions will not be as effective as they could be if they were more consistent with the patient's preferences.

Besides matching interventions to the patient's preferences, perceived barriers and facilitators, and immediate competing demands, the HPM promotes patient self-efficacy and autonomy. By individualizing the weight loss intervention and allowing the patient choices, consequently giving them ownership of their treatment and goals, self-efficacy and autonomy are increased. When the person feels that they have the ability within themselves to lose weight, the HPM model predicts that they are more likely to change their weight-loss behaviors.

In summary, the Pender HPM describes and explains which intrapersonal, interpersonal, and environmental factors ultimately predict a person's ability to adopt health behaviors that result in weight loss. These predictive factors, which are unique to each person, serve as opportunities for the advanced practice nurse to design a weight loss management plan that are likely to result in weight loss success.

Evidence-Based Practice Model: Purpose and Overview

The model selected to guide this EBP project was the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model. In this section, the JHNEBP Model and how it applied to this EBP project will be described.

Purpose of EBP Model

Like other models that have been used to guide EBP projects, the purpose of the JHNEBP Model is to provide direction to project leaders in integrating Evidence-Based interventions to solve real-world clinical problems (Dang & Dearholt, 2017). Using a multi-step and highly detailed approach to EBP adoption, the model supports the use of EBP as a core competency in nursing practice. Permission to use this model was obtained June 15, 2018 (Appendix B), from Johns Hopkins Medicine (2017).

Overview of EBP Model

The JHNEBP model is a three-step method that starts with Inquiry: the recognition and acknowledgement that a fixable problem exists in the health care environment. Inquiry involves critical thinking to identify the scope of the problem and to thoroughly assess the complete situation within the clinical setting, including the context, background, stakeholders and environment. Context refers to the circumstances in which the problem exists. Background refers to the events or situation that lead up to the problem. Discovering the background of a problem may lead to identification of gaps in what is known or done and what is unknown or not done. Stakeholders include all persons or entities that are affected by or have an interest in the problem. These can include: the patient, care giver, health care provider and or community. A stakeholder can also be a third party or parties such as insurance or government agencies. Environment refers to the surroundings or area in which the problem exists, such as: a clinic, hospital or the community.

After the context, background, stakeholders, and environment are explored, the EBP Project Leader begins a three-part group of activities that consists of: 1) Forming a practice question (P), 2) Discovering best available evidence (E), and 3) Translation of

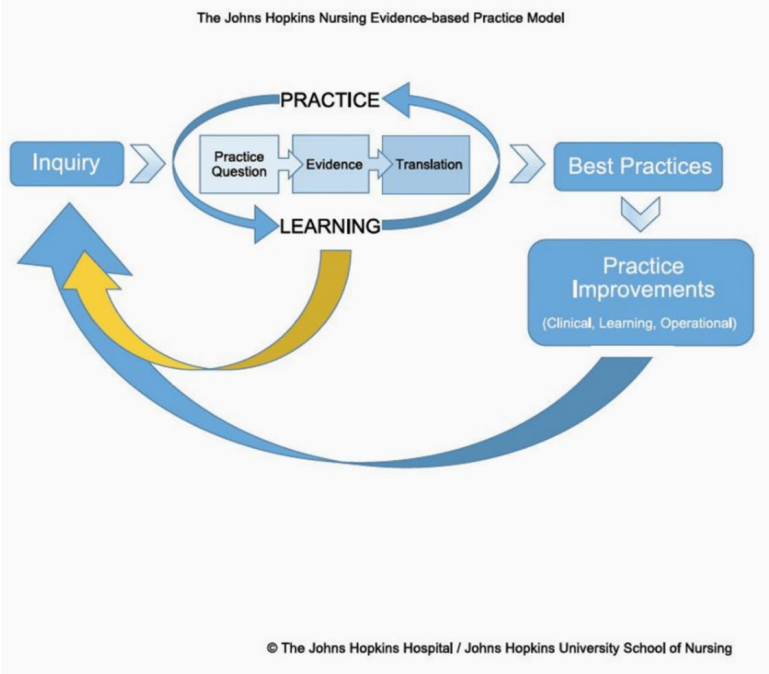
this evidence into the practice setting (T) (JHNEBP, 2017). The practice question guided the design of the EBP project and clarified which evidence to seek; therefore, it needed to be relevant, precise, accurate and provide clarity.

Based on the practice question, evidence was obtained and evaluated for: study design/level, study quality, consistency and applicability. In this project, if the evidence was level III, IV or V or of low quality it was not used as it did not offer the high level of evidentiary support needed to provide EBP.

Translation refers to converting the best available evidence into a useful and meaningful form that also incorporates professional experience and patient preferences (Dang & Deartholt, 2017). This can be difficult because even the highest level and quality of evidence may be met with translational incompatibilities with reality. Translation may require modification, education, development of a skill set, collaboration and a timeline compatible with the EBP intervention or practice improvement (Dang & Dearholt, 2017). If translation is initially unsuccessful, the EBP project team might return to the practice question or evidence steps to seek alternative approaches to use in translation. The “best practice” emerges when the translation step has been successfully completed, which then results in practice improvements that could focus on clinical, learning, or operational changes within the health care environment (Dang & Dearholt, 2017). The JHNEBP Model is pictorially depicted below (*Figure 1.1*) and demonstrates the cyclical quality that allows for change, further inquiry, evidence and translation in practice and learning.

Figure 1.1

The Johns Hopkins Nursing Evidence-Based Practice Model (2017)



(The Johns Hopkins Nursing Evidence-Based Practice Model, 2017).

Model and tools used with permission from Johns Hopkins Hospital and The Johns Hopkins University (Appendix B).

Application of EBP Model to DNP Project

This EBP project was concentrated on improving obesity-related patient outcomes at a free clinic in an underserved community in Northeast Indiana. Weight management had been identified by the practice as one of the challenges faced by the patient population at this site. Current interventions being utilized have not produced significant weight loss, improvement in comorbidities, health promotion or risk reduction. The uncertainty of how best to promote weight loss in this population served as the genesis for this project. Research shows that obesity is a multifactorial chronic disease that is exquisitely difficult to manage in the primary care setting (Bomberg et al. 2017;

Kushner & Ryan, 2014; Thabault, Burke & Ades, 2016). Moreover, the factors that cause obesity in one person may not be the same as those that cause obesity in another person; a “silver bullet” approach to obesity management is therefore unlikely to be effective.

Because this project deals with a complex clinical problem that exists within a multifaceted system consisting of the person, their primary care provider, and unique environmental nuances from one person to the next, it may take several attempts to arrive at the “best practice” for patients (Eaton et al., 2017; Hartman et al., 2014; Kushner et al., 2014). With its cyclical approach to identifying best practices, the JHNEBP Model is congruent with finding a solution to the problem of obesity. This section will describe how each of the steps of the JHNEBP Model will be used in the current EBP project.

Inquiry. The first step in the JHNEBP Model is to *inquire* about the clinical problem, gaining all pertinent information. In this project, the clinical problem is weight management among the patient population who have obesity defined as a BMI of $\geq$ 30. Many of these patients have significant health risk and weight related comorbidities including hypertension, Diabetes Mellitus type II (DMII), hyperlipidemia, depression and or anxiety.

Initial inquiry took the form of anecdotal observations made by the EBP Project Leader and a meeting with key stakeholders at the Matthew 25 Health and Dental Clinic. During the observations and meetings, it was noted that a high proportion of adult clinic patients were obese, no protocol was in place to address obesity at this clinic, the dietician services were provided by volunteers and only available a few times

a month, weight loss educational resources were very limited and staff was only able to provide limited education and coaching for weight loss. Based on these initial findings, a retrospective electronic medical record (EMR) review was conducted prior to initiation of this DNP EBP Project. With permission from the Medical Director and administration, patient records were accessed for the use in this project. Reviewed records had a baseline date of January 2019 and were included in the review if the patient had a follow up appointment between 3 to 5 months later. Inclusion criteria included patients who were at least 18 years old, had at least one BMI greater than or equal to 30 kg/m^2, and had a weight and consistent height provided for each visit. Patients were excluded if they were under 18 years old, the height was incorrectly measured or varied between visits (eg.5'2" and the next visit 5'5") or did not have recorded visits 3 to 5 months from baseline. A total of 25 EMRs were included in this retrospective. Demographics included seven males and 19 females, a mean age of 46.96 (13.82) years. The mean baseline weight was 235.10 (54.21) pounds (lbs.) and mean BMI was 38.61 kg/m^2 (7.18). The 3 to 5-month follow up group mean was 235.86 lbs. (55.36, p=.558) and mean BMI was 38.59 kg/m^2 (7.31, p=.914). There was no significant change in weight or BMI. Attainment of a 3% total body weight loss goal was achieved by only 16% of those in the comparison group.

Based on the observations at this clinic it was clear that obesity affected a near-majority of adult clinic patients, obese patients were generally open to assistance with weight loss, and that the clinic staff could do more to facilitate and promote weight loss in this population.

Practice Question. After confirming with clinic staff that they would like to learn more about how to help patients with obesity manage their weight, an EBP project question was developed using the PICOT criteria. First, clinic staff wished to focus on weight management in the adult population, regardless of age, sex, race, ethnicity, comorbidities, or socioeconomic characteristics. Second, clinic staff were open to a variety of interventions that focused on lifestyle changes, the use of medications, and referrals to other team members (e.g. behavioral health, dietician). However, because of the type of patient population, referral to bariatric specialist could not be a consideration. They were agreeable to reasonable modifications in their workflow but hiring additional staff to support the intervention was not going to be an option. Therefore, the intervention had to be something that the current staff mix at the clinic could implement within their collective scopes of practice. Third, the comparison group would need to be a retrospective sample who received routine education and follow-up about obesity, as described above. Fourth, the outcomes for this project needed to include BMI (and therefore weight), but clinic staff were also interested in other health-related secondary outcomes such as blood pressure, glycosylated hemoglobin, and symptoms related to anxiety and depression. Finally, the time frame for the project was restricted to 6 months (September 2019 to March 2020) with targeted changes in the primary outcome expected within 3 months of starting the intervention.

These suggestions from the clinic were used to form the initial PICOT Practice Question for the JHNEBP Model: Primarily, will obese adult patients participating in a multicomponent tailored weight loss intervention achieve greater reductions in weight, BMI, and waist circumference, than those receiving the current standard of care over a

three month period? In addition, clinic staff expressed a strong desire to manage obesity-related comorbidities as part of the project. Therefore, the effect of this multicomponent tailored intervention on blood pressure, glycosylated hemoglobin, anxiety symptoms, and depression symptoms was explored over a three-month period.

Evidence. To determine which intervention(s) to implement, the literature about obesity and weight management in primary care was thoroughly reviewed using the strategy and methods described in the section entitled, “Literature Search”. Sources were appraised using the JHNEBP Appraisal System (Dang & Dearholt, 2017), which provided a tool to evaluate the quality and strength of evidence. Intervention(s) with the strongest supporting evidence, and that were also feasible within the clinical site, were implemented in this EBP project as part of a tailored multicomponent weight loss program

Evidence applicable to this EBP Project encompassed multicomponent interventions. According to the evidence, including that provided by the US Preventive Task Force (LeBlanc et al., 2018) effective weight loss intervention should consist of a multicomponent approach that addresses diet, aerobic and resistance exercise, lifestyle modifications, and behavioral counseling. General principles that should underpin all weight loss recommendations include:

- **Diet** – Lean protein, low-fat dairy, unsaturated fats, whole grains, colorful fruits and vegetables, leafy greens. Overall calorie reduction is emphasized.
- **Exercise** – Aerobic exercise (at least 150 minutes per week of moderate-intensity exercise over at least 4 or 5 days). Resistance exercise (at least

2 days per week of moderate-intensity resistance exercise using machines, free weights, or resistance bands).

- **Lifestyle Modification** - Making healthy food choices, eating at meal-time and enjoying healthy snacks, limiting alcohol consumption and empty calories, setting achievable goals and tracking progress through journaling, logs or food and activity tracking technology. Practicing healthy sleep and hygiene habits in order to promote a well-rested state to reduce food cravings.
- **Behavioral Counseling** - Assist with the patient's development of a sense of self-efficacy and autonomy through motivational counseling in which the patient makes choices, sets and achieves goals. Assessment for and treatment of depression and anxiety, with referral to psychiatry if needed. Use of antidepressant/ antianxiety medications if warranted (Batsis et al., 2016; Beeken et al., 2017; Curry et al., 2018; Eaton et al., 2016; Grossman et al., 2017; Hageman et al., 2017; Hartman et al., 2014; Kozica et al., 2015; Kroes, Osei-Assibey, Baker-Searle & Huang, 2016; Jensen et al., 2014; Kushner & Ryan, 2014; Samdal et al., 2017)
- **Additional interventions** supported in the literature include use of motivational interviewing (Rodrguez-Cristobal et al., 2017; Szczekala, Wiktor, Kanadys & Wiktor, 2018; Thabault et al., 2016; Welbourn et al., 2018), written education tools (Beeken et al., 2017; Thabault et al., 2016), phone counseling (Harrigan et al., 2016; Hartman et al., 2014), electronic media or internet based intervention (Beeken et al., 2017;

Hageman et al., 2017) and or activity tracking technology such as a FitBit ® Garmin® or AppleWatch ® or use of an app such as MyFitnessPal® (Cheatham, Stull, Fantigrassi & Motel, 2017; Tang, Abraham, Greaves & Nikolaou, 2016).

Translation. Translation of evidence can be a challenge because a given Evidence-Based practice may not be feasible within a particular clinic context or circumstance. Therefore, careful attention was paid to determining, along with input from clinic staff and patients, which EBP interventions are feasible for this project. This was completed via meetings with clinic staff and the EBP Project Leader, as well as during clinic appointments with patients, in which feasibility of the interventions was determined and an action plan was formulated. Further translation included implementation of the action plan and evaluation of outcomes as well as determining any future steps such as: modification to the individual weight loss intervention plan(s) and or modification(s) to the implementation of the weight loss intervention plan within the clinical setting (Dang & Dearholt, 2017). Additionally, results of this project will be disseminated through a published EBP Project Report and as a poster and podium presentation at a regional or national nursing conference.

Best Practice. According to Dang and Dearholt (2017), it may take several iterations of the P-E-T process to get it right. After the Practice-Evidence-Translation process successfully identified a version of the Evidence-Based intervention(s) that works best at the clinical site, this was referred to as the best practice for weight management in adult patients with obesity who seek care at this clinical site. The best practice that results intentionally included multiple potential interventions that could be

implemented for a patient, based on their unique circumstances, abilities, resources, and perceived barriers to weight management.

Practice Improvements. The most important clinical practice improvements resulting from this project included a standardized process for identifying, teaching, and supporting adult patients with obesity, which had to date been a significant challenge for clinical staff. Additional clinical practice improvements included: easily accessible standardized web-based assessment tools and better implementation of obesity assessment and treatment protocols. Improvements in learning included easily accessible standardized web-based educational materials for patients and staff. Operational improvements included the development or revision of clinic policies and procedures regarding obesity management, improved patient satisfaction with clinical care, and improvement in objective measures of care quality related to chronic disease management.

Strengths and Limitations of EBP Model for DNP Project

The JHNEBP Model has been used to guide numerous EBP projects in nursing since its inception, and it has several important strengths compared to other EBP translation models for this particular EBP project. First, the model assumes that nursing is a science and a profession. Some other models, such as the Iowa Model for Evidence-Based Practice and the Stetler Model do this as well, but many, including the Rogers' Model of the Diffusion of Innovations and the Kotter and Cohen's Model of Change do not (Dang, Melnyk & Fineout-Overholt et al., 2015; Melnyk & Fineout-Overholt, 2015). This is an important strength for this project because the JHNEBP Model focuses on collecting evidence to answer the inquiry and questions as well as

support interventions. All of the interventions that had the potential to be utilized within this EBP project had science and evidentiary support that they were effective.

The JHNEBP Model is further strengthened by the precision and usefulness of its overall structure, which consists of 19 unique steps that served as guideposts for the EBP Project Leader and team. This ensures a systematic approach to solving problems in the clinical setting, particularly for novice EBP project leaders. Moreover, clinical sites that are not experienced with the EBP project “process” can use the steps of the JHNEBP Model to increase staff engagement and anticipate process barriers so that the clinic could sustain the practice changes after the project ended.

A third major strength was the longevity of the Johns Hopkins Nursing Evidence Appraisal Tool, which has been extensively revised, used, and published over the past decade. Having a rich history of guiding EBP projects in nursing, this tool has demonstrated its utility and effectiveness at distinguishing between high-quality and low-quality evidence.

For this particular project, which focused on obesity management, being able to identify the best available evidence was paramount for two important reasons: First, weight loss is remarkably difficult, largely due to patient nonadherence to a recommended weight loss regimen (Eaton et al., 2016; McLaughlin et al., 2017; Perreault, 2019b). Therefore, clinicians who prescribe weight management interventions must be able to defend the components of their weight loss prescription using sound evidence that patients can trust. Second, primary care providers report that obesity management is extremely challenging (Eaton et al., 2016; Hageman et al., 2017, Kushner & Ryan, 2014; McLaughlin, 2017; Pollak et al., 2016). A variety of fad diets,

weight loss supplements, and other “lose weight quick” schemes are promoted through social media outlets and other sources of consumer information. These approaches to weight loss are difficult to maintain due to high cost, being over-restrictive, or being ineffective, and this can lead to patients feeling dissatisfied with the weight loss experience. Adopting Evidence-Based weight loss practices in the primary care setting may help clinicians to feel better prepared to teach patients which weight loss strategies are effective and which ones are not.

Limitations of the model

The Iowa Model of EBP to Promote Quality Care provides guidance for clinicians when making practice decisions that affect patient outcomes. This model encourages the identification of ‘triggers’ - practice questions stemming from clinical problems or new knowledge. These triggers initiate change originating at the top level and will potentiate systematic research and team forming. This model has specified decision points at which further investigation and evaluation may take place that is again potentiated from the top level down (Dang, Melnyk & Fineout-Overholt et al., 2015). The team aspect of this model would be beneficial when promoting practice change.

The Stetler Model initiated the term evidence in1976 and has since expanded the term to substantiating evidence. This model utilizes a five-step approach to acquire and utilize research to facilitate EBP. The steps consist of preparation, validation, comparative evaluation and decision making, translation and application and a final evaluation. One progresses through the steps by completing the associated tasks and moving on to the next level. The user does not return to the beginning of the process, should a change be needed but rather continues to move forward. This is unlike the

JHNEBP model in which the user may progress in a circular pattern in which further investigation and potential research may provide an alternative approach should evaluation show that a change in plan is required. This is a weakness of the Stetler Model as this model considers evidence in a use /do not use format in either informal or formal interventions or protocols in a rigid path that does not provide for alterations. This model can be utilized by the individual practitioner unlike the Iowa model (Dang, Melnyk & Fineout-Overholt et al., 2015).

In summary, the JHNEBP Model provided a cyclical step approach to EBP that included inquiry, development of a practice question, research and finding evidence, translation of evidence into practice, best practices, and finally practice improvements. This process was developed specifically for nursing and allows the novice researcher to utilize its cyclical approach and path to the EBP implementation process that can be altered as new information or questions arise, utilizing evidence obtained from scientific inquiry to promote best practice.

Literature Search

Sources Examined for Relevant Evidence

An extensive and comprehensive literature review was completed in order to support inquiry and to determine best practice for this EBP project. This included a search of five databases in addition to citation chasing. Evidence was sought out using CINAHL, MedLine via EBSCO, Joanna Briggs (JBI), PubMed and the Cochrane Library. In addition, citation chasing was utilized to discover relevant evidence from articles that were found in the online databases listed above. The CINAHL, MedLine via EBSCO, and PubMed databases were selected due to their extensive volume of health-related

research articles and rapid access to high levels of evidence. The Joanna Briggs Institute database and the Cochrane Library were selected due to the evidence summaries and systematic reviews accessible through these resources. The expertise of a health resources librarian was sought to further strengthen the literature review for this EBP project.

The literature search had several criteria for inclusion: articles published within five years, adult population, English language, human subjects, study tested an intervention to treat obesity in a primary care setting, and evidence was level I or II and of high or good quality. Articles were excluded if: study focused on weight loss for a condition other than obesity (e.g. type 2 diabetes mellitus, polycystic ovarian syndrome); the target population included children, pregnant women, or neonates; or the main intervention tested was irrelevant to the primary care setting (e.g. bariatric surgery).

Results of the literature search are summarized in Tables 2.1 and 2.2.

Table 2.1

Literature Search Summary

Database	Key search words or phrases	Limiters
CINAHL	obesity AND intervent* OR treat* AND “weight loss” OR BMI OR “waist circumference” OR “body fat” AND “primary care” OR “primary health care” OR “primary healthcare”	01/01/2016-06/30/2019; scholarly peer-reviewed; English language, human, and Adult ≥19 years Boolean phrase
Cochrane library	obesity intervent* “weight loss”	01/01/2016-06/30/2019

JBI	obesity	2016-2019
MedLine via EBSCO	obesity AND intervent* OR treat* AND “weight loss” OR BMI OR “waist circumference” OR “body fat” AND “primary care” OR “primary health care” OR “primary healthcare”	01/01/2016-06/30/2019; scholarly peer-reviewed; English language, human, and Adult ≥19years Boolean phrase
PubMed	obesity AND intervent* OR treat* AND “weight loss” OR BMI OR “waist circumference” OR “body fat” AND “primary care” OR “primary health care” OR “primary healthcare”	01/01/2016-06/30/2019; English language, human, and Adult ≥19years

Table 2.2

Evidence Search Table

Database	Yielded	Duplicates	Reviewed	Accepted
CINAHL	52	42	12	2
Cochrane	12	3	2	6
JBI	26	0	1	0
MEDLINE via EBSCO	156	139	34	5
PubMED	311	147	47	1
Citation chased	4	0	4	2
Total	561	331	100	16

Evidence Appraisal

Evidence was appraised for strength and quality using the JHNEBP Evidence Appraisal Tools (Appendix C) (Dang & Dearholt, 2017; Johns Hopkins Medicine, 2017).

Levels of Evidence

The level of evidence for a source was determined by the study design that was used in that source. For example, Level I evidence consists only of meta-analyses, systematic reviews, and randomized controlled trials. Level II evidence consists of quasi-experimental designs (e.g. cohort, case-control). Level III evidence consists of nonexperimental designs (e.g. descriptive, qualitative). Level IV evidence consists of methodically developed guidelines from nationally known experts based upon research or expert panel consensus. Finally, Level V evidence consists of a synopsis of published literature without methodically appraisal of evidence. A summary of the appraisal criteria is provided in Table 2.3. Evidence at Levels I through II were used in this EBP project.

Appraisal of Relevant Evidence

The Johns Hopkins Nursing Research Evidence Appraisal Tool (Appendix C) was also used with permission (Appendix B) to evaluate the quality of each source. Once the level of evidence was determined as level I, II or III, the quality was rated as high, good or low:

- High quality evidence was consistent, had results that were transferable, with an adequate study design, sample size, a sufficient control, and was able to provide conclusions. They contained fully inclusive literature review with references to scientific evidence and provided recommendations that were consistent with their findings.

- Good quality evidence that was consistent with results, an adequate sample size, use of a control, conclusions that were well defined and fairly decisive, recommendations based upon a relatively inclusive literature review with mention to some scientific data.

Low quality evidence had samples that were insufficient in size, provided minimal evidence with inconclusive results that provided little or no conclusions based upon the work (Dang & Dearholt, 2017; Johns Hopkins Medicine, 2017). A PDF copy of the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool is found in appendix C.

The level of chosen evidence are described in Table 2.3.

Table 2.3

Levels of Evidence

Level	Included	Quality	Design
I	11	High	SR (1) SR with MA (2) RCT (8)
I	1	Good	RCT (1)
II	3	High	SR (2) Quasi-exp. (1)
II	1	Good	SR (1)

The evaluated works were of either level I or level II and of good or high quality. There were eleven sources that were level I and high quality (3 systematic reviews, 8

randomized controlled trials), one randomized controlled trial that was level I and good quality and two systematic reviews that were level II and high quality.

Levels of Evidence

Level I evidence. A systematic review (SR) completed by Batsis and colleagues (2016) looks at obesity interventions that can be used with older adults in the clinical setting. This systematic review of 6 online databases included randomized controlled trials published between January 2005 and October 2015. Interventions focused on behavior changes that lasted at least six months. Control groups varied but included routine care from a health care practitioner/physician, usual care, no exercise, and or use of a technological device. Primary outcomes measured were quality of life, weight loss, and physical activity. Weight loss was included as a component of each RCT.

The range of weight loss was 0.5 to 10.7kg (0.1 to 9.3% of baseline body weight). The greatest weight loss was obtained from programs with both a diet intervention and an exercise intervention, rather than exercise alone. Combined diet and exercise also significantly improved quality of life and physical function. This study provides evidence that supports the use of obesity interventions, including diet and exercise, to reduce weight, improve physical function, and improve quality of life in the geriatric population.

Beeken and colleagues (2017) presented evidence from a two-arm, multi-site, randomized controlled trial (RCT) that tested the effect of a self-guided “Ten Top Tips” (10TT) leaflet about weight loss, a logbook for documenting weight loss behaviors, and an initial consultation with a nurse, on weight, BMI, total cholesterol, blood glucose, and self-reported weight loss behavior, compared to usual primary care. At three months,

patients in the intervention group lost significantly more weight than the control group (mean difference = -0.87 kg, 95% CI -1.47, -0.27, *p* = .004). This weight loss was maintained over 24 months, but it was not significantly different than the group that received usual care. Furthermore, Beeken and colleagues (2017) reported statistically significant reductions in waist circumference, BMI, and systolic blood pressure, and statistically significant increases in self-reported weight loss behavior, at 3 months after the intervention, but there was no change in total cholesterol or blood glucose.

Based on these findings, authors reported that the 10TT leaflet was effective for short term weight loss, reduction in systolic blood pressure, and increased use of weight loss habits in the primary care setting. It was found to be a low-cost option to use in primary care, with an average cost around $32 per intervention (leaflet, logbook, and nurse consultation) This report provides support for the use of written behavioral change and education materials as a weight loss intervention that could be incorporated into a multicomponent weight loss intervention and this EBP Project.

Limitations of the study included use of literature as old as 2005; some studies reviewed focused on diet only or lacked an exercise component, studies did not focus interventions in primary care; pharmacological and surgical therapy were omitted from the study. A quality rating of high was applied to this report due to clear statement of purpose, comprehensive and reproducible strategies; use of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria to reduce bias and increase transparency; use of empirical evidence; use of pilot study to provide consistency; details of studies and consistent result interpretation and generalizability.

Eaton and colleagues (2016) conducted a RCT over 24 months within a socioeconomically disadvantaged community in Rhode Island. The purpose was to test a tailored lifestyle intervention addressing obesity within the obese population in primary care with the goal of assisting weight loss and increase physical activity. Participants who were referred through primary care were randomized into one of two groups: enhanced intervention (EI) (n=106) or standard intervention (SI) (n=105). All participants received three face-to-face weight loss meetings. The EI group was also provided individualized telephone counseling and tailored printed and electronic media tools that focused on diet and exercise. The interventions were tapered after the first year of study participation. Anthropometric measurements and resting heart rate and blood pressure were obtained at baseline and at 6, 12, 18, and 24 months. The 7-day Physical Activity Recall Questionnaire and a ten-minute treadmill were used to assess participants' perception of moderate physical activity.

Results generally showed weight loss was greater in the EI group versus the SI group at 6 months (37.2% and 12.9% respectively; $p<.01$) and at 12 months (47.8% and 11.6% respectively; $p<.01$), but not at 18 months (31.4% and 26.7% respectively; $p=.64$) or at 24 months (33.3% and 24.6% respectively; $p=.39$). The EI group reported a significant increase in the number of minutes in which they engaged in physical activity at 6, 12, 18, and 24 months (95.7, 126.1, 103.6, and 101.3 respectively versus 67.9, 73.7, 63.3 and 75.0 respectively; $p = .10, .002, .02$, and $.12$ respectively).

This RCT (Eaton et al., 2016) is of high quality due to its strengths of consistency, translation and generalizable results, and definitive conclusions. Methods, study design and interventions are clearly defined and address the purpose of

evaluating a tailored intervention to promote weight loss and increase activity in the obese population. Statistical analysis was completed using ANOVA. Prior to the study, needed sample size was determined with 104 participants needed (=0.05) for each arm. This study provided results that were encouraging but it also had limitations including: only one geographic area; participants from related practice may have biased results; mainly female participants; use of self-reporting that may have skewed reliability; multiple modes of intervention delivery- DVD, printed materials and telephone; and attenuation of participants. The results provided support for the use of a tailored lifestyle intervention including face-to-face, telephone and or electronic media interventions for the treatment of obesity.

Hageman and colleagues (2017) completed a three phase, 30 month long RCT with the primary objective of comparing three weight loss interventions: web-based only (WO), web-based with peer-led discussion (WD), and web-based with professional email counseling (WE). Secondary goals included: improvements in healthy eating, activity, blood pressure and lipids. The study focused upon women living in a rural community. Phase I lasted from baseline to six months and included guided weight loss using one of the experimental treatments (WO, WD, or WE). In Phase I, all subjects had access to web-based diet and exercise recommendations, a weight loss plan, a diet and exercise log book, a pedometer, weekly goal-setting sessions, and weekly feedback. In addition, the WD group had access to a peer discussion board and the WE group had access to the peer discussion board, professional email counseling, feedback about their discussion board postings from a member of the research team, and scheduled reminders about their weight loss program. Phase II lasted from 6 to 18 months. During

this phase, all participants completed weekly weight logs, tracked diet and exercise, and received online feedback. In addition, the WD group had biweekly peer-led online discussions for the first 12 months. Phase III lasted from 18 to 30 months. During this phase, all subjects were encouraged to continue tracking diet and exercise, set goals, and receive online feedback. In addition, the WD group had access to the peer discussion board, but there was less input from the research team than before. The WE group continued to have email consultation available, but only at the participant's request.

Results showed that there was statistically significant weight loss in the WO, WD, and WE treatment groups at 6 months (5.1 kg, 4.1 kg, and 6 kg, respectively). However, this weight loss was not sustained beyond 6 months, and participants regained approximately half of the weight lost by 30 months. There were no differences in weight loss between groups, suggesting that the discussion boards and email coaching did not significantly impact weight loss more than the web resources alone. There was no significant improvement in secondary outcomes (waist circumference, daily caloric intake, minutes of moderate intensity activity, blood pressure, total cholesterol, HDL, LDL, triglycerides, and fasting glucose).

This study suggests that the use of web-based resources, with or without supplemental interventions, can facilitate short-term weight loss in women with obesity. However, this weight loss may not be sustainable beyond 6 months, and there was no clinically or statistically significant improvement in obesity-related clinical outcomes. Strengths of this study that led to the high quality rating included: design -three arm trial of web-based interventions and web-based interventions with enhancements with

adequate control; sufficient sample with a large cohort of participants-n=301; three phase time table of 30 months; use of EBP and standardized methods with established validity such as- Actigraph Accelerometer to track activity and the 1998 Block Health Habit and History Questionnaire to assess behavioral measures; conclusions based upon results that countered expected outcomes; clear, consistent and generalizable results. Though conclusions were based on results of the study and statistical data was presented, one of the limitations of the study was the absence of methods of analysis. Other limitations included: a sample of primarily female women of high socioeconomic background; unknown reason for missing data/observations; nonsignificant weight loss data for participants who did and did not complete program at 18 months; contamination and sharing data between group members living in same region; and varying level of engagement in program.

Harrigan and colleagues (2016) conducted a six month long, three-arm RCT at Yale University. The study compared the effects of in-person counseling, telephone counseling, or usual care on the following variables: BMI, body fat percentage, lean body mass, bone mineral density, waist and hip circumferences, physical activity, dietary intake, and obesity-related biomarkers (C-reactive protein, insulin, leptin, adiponetcim, interleukin-6, tumor necrosis factor alpha, and blood glucose). Subjects received individualized weight loss counseling in a graduated fashion (weekly for 1 month, then every 2 weeks for 2 months, then monthly for 3 months). Dietary counseling focused mainly on calorie reduction through reduced fat intake, a plant-based diet, and mindful eating practices. Physical activity counseling focused on home-based moderate-intensity activity for at least 150 minutes per week and reducing

sedentary activity. Usual care consisted of a brochure about nutrition and physical activity, along with a two-session weight management program if desired.

At six months, subjects in either of the experimental treatment groups had statistically significant reductions in weight, waist circumference, hip circumference, dietary intake from fat, and C-reactive protein, and statistically significant increases in physical activity, fiber intake, and servings of fruit and vegetables per day, compared to subjects in the usual care group. Weight loss was 6.4% in the in-person counseling group (p=.004), 5.4% in the telephone-counseling group (p=.009) and 2.0% in the usual care group (p=.46). There was no statistically significant change in percent body fat, lean body mass, bone mineral density, sugar intake, or concentrations in insulin, blood glucose, leptin, adiponectin, IL-6, or TNF-α in any group. These results suggest that either in-person or telephone-based counseling sessions are more effective than printed weight-loss information alone for managing obesity. This RCT's purpose was to examine the effect of in-person versus telephone counseling versus usual care for the treatment of overweight/obesity in a female population having survived breast cancer (Harrigan et al., 2016). Strengths of this study that determined the high quality rating included: use of a design phase estimated sample size of 30 to provide a 93% power to detect 3.5kg in weight change between control and intervention groups; use of Permuted block randomization; use of SAS (9.3) PROC MI for data computations - statistical significance set at p<.05 using two-sided tests; population sample and methods consistent with the purpose and clearly stated including a control group; interventions adapted from the Diabetes Prevention Program and 2010 US Dietary Guidelines using the American Cancer Society nutrition and physical activity guidelines;

and weight loss counseling performed by registered dieticians with specialty certification. Limitations of the study were: a 15% attrition rate; lower compliance rate among telephone counseling group; use of self-reporting of activity and use of a pedometer which may affect accuracy; lack of diversity in population studied may affect generalizability; possible recruitment bias.

Kozica and colleagues (2016) conducted a two-arm RCT in 42 rural and socioeconomically disadvantaged Victorian communities in Australia, between 2012 and 2013. The aim of the trial was to evaluate the Healthy Lifestyle Program for women (HeLP-her) program, which focused on making small sustainable lifestyle and behavioral changes. There were two arms of the trial: the control group consisted of 20 towns (n=301) and the intervention group consisted of 21 towns (n=348). Both groups received a face-to-face education session focused on national obesity management guidelines. The intervention group also received a program manual, telephone coaching, and text messages to strengthen program content and accountability. The primary outcomes were weight and BMI, which were measured at baseline and at the end of 1 year.

Results indicated that subjects in the HeLP-her intervention group lost 0.92 kg more than subjects in the control group (95% CI -1.67, -0.16) in 1 year. There was high participant satisfaction with the program, particularly with regards to coaching by either face-to-face or text messaging, compared to telephone coaching or use of a program manual. These results suggest that a weight loss program focused on small sustainable lifestyle changes can result in weight loss over a 1-year period.

This high quality RCT utilized a mixed methods approach in this large scale obesity prevention trial that targeted a population at risk (Kozica et al., 2015). This mixed methods approach consisted of qualitative data use and analysis as well as quantitative data collection methods including: questionnaires, tools and checklists to increase generalizability. In order to close knowledge gaps the study chose a variety of interventions and delivery modes. Limitations of the study included: lack of independent oversight of checklists that were conducted by research staff; lack of evaluation of fidelity of motivational interviewing; lack of data collection of delivery modes for lifestyle modification. Using multiple interventions such as: education, goal setting, behavioral self-management, action planning, addressing barriers, problem solving and relapse prevention skills, this report addresses the purpose and proposed interventions of this EBP Project.

Ma and colleagues (2019) completed a twelve-month long RCT in California. The purpose was to evaluate the effect of concurrent treatment for obesity and depression on weight loss. All participants of the control group and the intervention group received usual care from their physician as well as information about obesity and depression management and wireless physical activity tracking technology (i.e. a pedometer). Subjects in the intervention group also received a 12-month intervention that included a behavioral weight loss counseling intervention, problem-solving therapy, and antidepressant medications, if indicated. The primary outcomes for this study were BMI and severity of depression symptoms, which was measured using the Depression Symptom Checklist (SCL-20).

After 12 months, the BMI of subjects in the intervention group decreased by 0.7 kg/m^2, compared to no change in the control group (95% CI -1.1, -0.2; $p = .01$). In addition, depression severity improved significantly in the intervention group compared to the control group (95% CI -0.4, 0; $p = .01$). These findings suggest that a multicomponent care intervention that focuses on both obesity management and depression management may lead to improvements in both. The purpose of this high quality RCT was to test the hypothesis that integrated collaborative intervention would improve depression and obesity over a 12 month time frame as compared to usual care (Ma et al., 2019). Strengths included: closing the knowledge gap by becoming the first and largest RCT of its kind; findings were based on results of the study and were generalizable; sufficient sample size and timeframe; use of a control group; use of validated testing methods-SCL-20 depression symptom checklist; statistical analysis completed using linear mixed-effects models to a 95% CI, *p*-values obtained from general least square models adjusted for baseline value of outcome, and randomization of covariates. Limitations of the study were identified, addressed and included: omission of a formal literature review; limited geographical region in Northern California; homogeneous high socioeconomic sample; missing data (2% of weight, 9% of SCL-20 at 6 and 12 months); BMI data included from EMR or self–report; drop out data may have skewed results; continuity of care from other clinical sites would not have been captured in data. The results support the use of behavioral interventions including problem solving, and goal setting to promote modest weight loss and lends support to this EBP Project.

Rodriguez-Cristobal and colleagues (2017) conducted a 24 month long, multicenter, cluster RCT between 2008 and 2010. The purpose of which was to discover whether motivational interventions combined with current practice resulted in greater weight loss than usual care for the treatment of obesity. Both groups had visits with their primary care provider every three months, received basic weight loss advice about diet and exercise, caloric reduction (1200 to 1500 kcal per day), and an exercise plan. In addition, subjects in the intervention group received a motivation intervention consisting of graduated visits with trained nurses every 15 days during weeks 1 to 12 followed by monthly sessions during weeks 13 to 32.

Subjects in the intervention group lost 1.5 kg more than those in the control group (p = .02). Moreover, more subjects in the intervention group achieved a 5% loss in body weight than in the control group after 2 years (26% vs 18.1%, respectively; p = .04), but not after 1 year (22.6% vs 16.6%, respectively; p = .09). Authors also examined changes in cardiovascular risk factors (cholesterol, triglycerides, HDL, LDL, apolipoproteins A and B, and blood pressure). Subjects in the intervention group had significantly lower triglycerides (125.9 ± 65.1 vs 135.4 ± 65.6, respectively; p = .0001), APOA (p = .04) and APOA:APOB ratio (p = .0003) than those in the control group after 2 years. Changes in total cholesterol, HDL, LDL, APOB, and blood pressure were not statistically significant between groups after 1 year or 2 years. These results suggest that motivational counseling, in addition to lifestyle modifications, may result in greater weight loss and reduced cardiovascular risk than lifestyle modifications alone. These results are applicable to this EBP Project.

This RCT is of high quality due to its strengths consisting of: randomized design and intervention provision via primary care therapists, accustomed to the treatment of overweight and obese patients; dietetic non-pharmacological approach; consistent, generalizable results; conclusions based on results; sufficient sample size, n=864; sufficient time frame of 32 months. Limitations of the study included: no formal literature review; high attrition rate of 52.25 % completed the final visit-reasons not investigated; missing data not analyzed.

Rolls and associates (2017) tested the efficacy of a behavioral weight reduction program with the inclusion of two portion control strategies versus standard education within a RCT conducted over a twelve month period. The trial included women aged 20 to 65 years, with a BMI of $\geq$ 25 (n=186). All participants completed the Eating Attitudes Test (EAT) and the Beck Depression Inventory (BDI). Participants were placed in either the control group or one of two intervention groups. Subjects in the control group received usual care including advice to eat less and make healthy food choices. Subjects in one intervention group were instructed to choose foods based on energy density (ED) in order to promote healthy, satisfying foods while limiting portion size of high ED foods. Participants in this group were provided a food scale and food measuring tools as well as illustrated pictorial examples of healthy meal components and portions sizes. Subjects in the other intervention group were instructed to use pre-portioned foods in an effort to learn portion control and healthy eating choices. Pedometers were also provided to both intervention groups.

All three treatment arms resulted in weight loss from baseline after 3, 6, 9, and 12 months, although the pre-portioned group lost more weight within 3 months than the

standard advice group and the portion-selection group (5.1 kg vs 3.7 kg vs 3.8 kg, respectively; p <.05 for pre-portion group vs other groups). However, the pre-portioned group also regained weight faster than the other two groups (p = .0005 for pre-portion group vs other groups), and all subjects regained at least some weight from their nadir at approximately 6 months. Weight regain seemed to be attenuated by a higher level of dietary restraint (i.e. more able to control dietary intake) and adherence to self-monitoring. Regardless of treatment arm, cardiovascular risk factors improved significantly in all subjects from baseline to 12 months (blood pressure, waist circumference, glucose, insulin, insulin resistance, total cholesterol, HDL, and triglycerides), as did most indicators of reported food consumption (food weight per day, energy density, calories from beverages, calories from food, fruit intake, grain intake, protein intake, dairy intake, fats and oils intake, and pre-portioned foods intake). These results suggest that pre-portioned foods may increase the rate of weight loss over the short-term, but that weight regain after 3 months is likely.

This piece had several strengths. First, they used a sufficient sample of 186 participants determined using mixed effects model that determined 80% power would be achieved by a sample of 180. Secondly, there was random assignment of participants. Thirdly, participants met with registered dieticians and trained interventionists who used standardized instruction manuals to insure fidelity. Interventions for the control group included: following healthy dietary guidelines; limiting caloric intake; meal planning. The second intervention group were taught to choose high density energy foods and to control portion size. The third intervention group were instructed to use pre-portioned foods. Primary outcome measured was the trajectory of

weight change over time using random coefficient model and intended–to-treat model. Secondary outcomes measured included: cardiometabolic factors, dietary intake, questionnaire responses and pedometer readings. These were analyzed by linear mixed effects model with categorical fixed factors. Lack of sample diversity may limit generalizability and continued use of pre-portioned foods and food measuring tools may not be sustainable. In total the results from this good quality RCT provide support for the use of a healthy nutritional plan based upon guidelines like those from Dietary Guidelines for Americans-2010, utilize portion control along with increase physical activity and behavioral modification can assist with weight loss.

Samdal and associated (2017) performed a systematic review and meta-regression analyses on literature about behavioral change techniques for weight loss published between January 2007 and April 2013. Interventions included cognitive or behavioral change strategies (eg. motivational counseling); simple education strategies were excluded. Outcomes measured were behavioral change technique to promote goal setting, self-monitoring, problem solving, feedback, social support, for physical activity and healthy eating (Samdal et al., 2017).

The authors found that, among 35 trials reporting effect of behavior change technique related to increased physical activity, there were 30 reports of short term (ST) effect (0.36; [0.24, 0.47] 95%CI), 17 reports of long term (LT) effect (0.25 [0.13, 0.38] 95%CI), and 47 reports of both ST and LT effect (0.31[0.23, 0.40] 95%CI). The effect of behavioral change techniques on diet was found in 20 reports of ST effect (0.41 [0.20, 0.62] 95%CI),15 reports of LT (0.19 [0.07, 0.31] 95%CI), and 35 reports of ST and LT effect (0.29 [0.16, 0.42] 95%CI). BCT effect on physical activity and diet in combination

was found in 50 ST reports (0.37 [0.26, 0.48] 95%CI), 32 LT reports (0.24 [0.15, 0.33] 95%CI), 82 ST and LT reports. The pooled size effect of ST and LT studies were 0.19 to 0.41 with a 95% CI. The CI's had analogous effect for physical activity and diet, however LT (0.24) showed a lesser result than ST (0.37) despite 95% CIs that coincided (0.15 -0.33 and 0.26- 0.48, respectively). There was high heterogeneity among ST reports (I^2 =71%, p<.0001) and lesser heterogeneity among LT reports (I^2 =59%, p<.0001).

The main results determined in the ST and LT, that behavioral interventions for diet and physical activity had a small effect however, consistency among studies was high mainly for ST. LT effect was associated with interventions such as motivational interviewing, that highlight patient-centered and autonomy facilitating communication. The results champion the use of self-monitoring, goal setting, in conjunction with person-centered and autonomy enhancing behavioral counseling. This systematic review supports the use of a behavioral intervention by the NP in primary care as part of a multicomponent weight loss intervention.

Strengths of this high quality systematic review and meta-regression analysis were: the inclusion of 46 RCTs and 2 cluster RCT with a pooled sample of 11,183 providing a sufficient sample for the analysis; study bias was addressed and analyzed for each of the RCTs; most studies reported analysis of intention-to-treat using baseline carried forward or random imputation. Attrition bias was found to be higher in long term due to drop out. This analysis was limited to a 12-month time frame, ending in 2014. Some individual study characteristics were limited and lacking in refinement. The results showed that the use of BCT had positive outcomes in the domains of goal setting,

barrier identification, problem solving as well as obesity risk and biomarker reduction. Additionally, person-centered methods such as motivational interviewing that support individual autonomy provided long term effect. These results support the use of BCT, goal setting and self-monitoring for the treatment of adult obesity.

Tang and partners (2016) completed a SR of RCTs. The purpose was to determine the effectiveness of self-directed interventions for weight loss through focus on interventions that did not require ongoing professional interaction beyond an initial consultation (Tang et al., 2016). Articles published through July 2014 were reviewed. Interventions included those that: target diet and or physical activity; are self-directed with limited face-to-face professional contact to $\leq$ one 90 minute instructional session; have at least one interactive intervention; or have at least one self-regulatory element such as goal setting or diary of thoughts and or behaviors. Outcomes measured: effectiveness of self-directed internet-based interventions; effectiveness of change technique (eg. goal setting, self-monitoring, feedback, behavioral instruction, social support) inclusion on self-directed interventions; changes in weight, BMI, waist circumference.

Results of this meta-analysis showed that participants using self-directed interventions had greater weight loss than those who received minimal or no intervention (mean difference = -1.56 kg; 95% CI -2.25, -0.86). The mean individual weight loss in the intervention group (IG), who would have received any of the interventions listed above, ranged from 0.6 to 5.3 kg. Compared to no intervention, self-directed interventions produced significantly greater reduction in BMI (mean difference = -0.41kg/m2; 95% CI -0.70, 0.11) and waist circumference (mean difference= -2.37cm;

95% CI -4.12, -0.61). Self-directed interventions included with in this study were predominately internet based (18 out of 25, 72%). Studies employing change techniques interventions such as: goal setting, self-monitoring, behavior skills were not found to be significantly more helpful than those who did not (p=.48, p=.35, p=.26 respectively). However those that employed feedback and social support were found to be successful (p<.0001, p=.001 respectively). Participants in the internet-based intervention group experienced greater weight loss and BMI reduction than the control group (mean difference = -1.72 kg; 95% CI -2.60, -0.84; -0.47kg/m2; 95% CI -0.81, -0.41 respectively). The intervention group also experienced greater waist circumference loss than control group (mean difference = -2.69 cm; 95% CI -5.01, -0.37).

This study had many strengths and limitations. First it was the first to focus exclusively on self-directed weight loss measures, many of them internet based. This provided for specific intervention analysis; however, it was limited by a small sample size, thus reducing the power to determine effect on a heterogeneous sample and provide long term conclusions. There was a wide variation found for time of follow up when meta-analytic calculations were performed that may have resulted from diverse populations. Additionally, many trials utilized methods that could have biased interpretation. Targeted study outcomes included physical activity and or diet; self-direction with no more than initial professional intervention or face-to-face contact; at least one interactive component (eg. entering personal data); at least one self-regulatory element (eg. diary, goalsetting or review).

The results suggest that self-directed weight loss interventions can provide a mechanism for modest short-term weight loss, but these would need to be

supplemented with additional interventions including community resources and clinical services to achieve long-term significant weight loss. This article is applicable to this EBP project as part of a multicomponent weight loss intervention.

Tapsell and colleagues (2017) conducted a single blind controlled trial with the object of determining the effectiveness of interdisciplinary treatment versus usual care for the treatment of overweight and obese adults. Participants were randomly assigned to either the control group, an interdisciplinary intervention group, or an interdisciplinary intervention group with a supply of 30 grams of walnuts per day. Interventions included: seven clinical counseling sessions that included: diet, exercise and behavioral coaching from professional nurse and interdisciplinary team based upon the Australian Guide to Healthy Eating (AGHE); walnuts; quarterly support telephone calls, measures of blood pressure, anthropometric and biomarkers (eg. lipid panel, fasting blood glucose and HbA1c); assessment with the International Physical Activity Questionnaire (IPAQ), Physical and Mental Health 12 Item Short Form Health Survey (SF-12) and the Acceptance and Action Questionnaire for Weight loss (AAQ-W). Outcomes measured included: weight loss from baseline and at 12 months; change in blood pressure; fasting blood glucose and lipids; changes in diet and exercise; psychological measures (AAQ-W, DASS-21, QoL SF-12) (Tapsell et al., 2017). Individual outcomes measured not stated.

Primary results indicated that both intervention groups had greater weight loss than the control group at 3 months and at 6 months. Post hoc analysis indicated that at 3 months the intervention group, and the intervention plus walnut group had a greater weight loss than the control group (-1.2kg, p=.045; -1.3kg, p=.025). At six months the

intervention plus walnuts group had a greater weight loss than the control (-2.1kg, *p*=.010). The difference between control and intervention plus walnut group was -2.2kg *p*=.056 (95% CI). The 12 month adjusted weight change showed an effect significance of *p*=.056, consistent with the difference in weight between the intervention plus walnuts group and the control group of -2.2kg (95%CI -4.6 to0.1kg, *p*=.068) versus the intervention group and the control group was -1.9kg (95%CI -4.5 to 0.7kg, *p*=.228) and the intervention and the intervention plus walnuts groups -0.3kg (95% CI-2.8 to 2.2kg, *p*=1.00). Achievement of 5% weight loss at twelve months (*p*=.091) among the control group was 20%, among the intervention plus walnuts group it was 33% and among the intervention group it was 38%.

Secondary results indicated that blood pressure tended to be lower among all groups, the difference was not statistically significant (*p*=.441). Fasting blood glucose was significantly lower at 3 (*p*=.040), 6 (*p*<.001) and 12 months (*p*=.003), compared to baseline. While the intervention group plus walnuts measurement of HbA1C at twelve months remained unchanged from baseline at 5.1 (4.9-5.4; *p*=.031), it was lower than baseline for the control and intervention groups 5.2 and 5.1 (5.0-5.4, 4.9-5.4 respectively; *p*=.031). Lipid panels improved across the board at 3 months. Total cholesterol (mmol/L) for control, intervention and intervention plus walnut groups showed lower scores 5.2, 5.0, and 4.8 (4.4-5.6, 4.4-5.5, and 4.3-5.6 respectively; *p*=0.193), this trend continued for the control group at 12 months but not for the intervention or intervention plus walnut groups. Low density lipids (mmol/L) were also lower at three months (*p*<.001; $\leq$ .031) and at six months (*p*=.020, *p*=.034). At 12months HDL rose above baseline (*p*$\leq$ .021). Group effect showed better total cholesterol means

for the intervention plus walnut groups versus intervention or control groups (p=.037 and p=.001 respectively).

Self-reported caloric and total fat intake were lower than baseline for all groups at three months (p<.001) and at twelve months (p=.020). Physical activity was higher than at baseline at all time measures (p<.001). The findings indicated that interdisciplinary collaboration and intervention with an individualized approach provided greater results than usual care. The collaborative and individualized method of the intervention is applicable to the primary care setting and specifically to the multicomponent approach of this EBP Project.

This study had several strengths and limitations. Strengths included: its applicability and generalizability within primary care. Secondly, analysis was conducted using intention-to-treat instead of compliance-based method. Thirdly, possible confounding variables were controlled. This study addressed gaps in current research and is transferrable. However, the sample size was small and limited to one clinical setting in which there was a language barrier, thus limiting access to potential at risk participants. Between group reporting inaccuracies may skew dietary results. Results of the study indicated that there is benefit from looking beyond dietary restriction. Behavioral and psychological factors have a role in weight loss and attrition and regular patient-clinician interaction (eg. 4 visits within 3 months) seems to provide positive effect. Primary care is a suitable atmosphere within which obesity and weight loss as well as weight related risk prevention can be addressed.

In summary, Level I evidence supports the use of primary care interventions that focus on diet, exercise, self-monitoring of food intake and physical activity, and

concurrent management of depression as strategies to manage obesity, control depression symptoms, and reduce cardiovascular risk.

Level II: Cheatham and colleagues (2018) conducted a systematic review using Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. with the purpose of appraising current evidence related to the efficacy of wearable activity tracking technology (eg. Fitbit) as part of a comprehensive weight loss program (Cheatham et al., 2018). A search of five databases was conducted through December of 2016. Authors found 7184 citations and 25 relevant sources, of which 21 scored 6 or higher (7)/10, and 4 scored a 5/10 using the Physiotherapy Evidence Database (PEDro) scale indicating moderate to high quality evidence.

Interventions included in the review: behavioral and nutrition counseling; self-monitoring of diet and activity (eg.website or Smartphone); self-monitoring through journaling; and use of an activity tracker. Outcomes measured included: BMI, waist circumference, body composition, physical activity, dietary changes/ caloric intake, blood pressure and heart rate. Strengths of the study were use of consistent research technique using PRISMA guidelines and PEDro evidence appraisal. The study filled a gap in current research. Limitations of the study were, primarily female participants, diversity in type of studies reviewed and no consistent type of activity tracking, and the limited age groups studied. Authors found that there was evidence to support the use of activity trackers as part of a comprehensive weight loss program. These devices, which included: pedometers, websites, Fitbit, Smartphone and accelerometer, electronic arm band, activity tracker with Bluetooth, and paper journal, provided statistically significant short-term weight loss that was superior to weight loss in programs without activity

trackers. Results suggest that an activity tracker used as part of a multicomponent intervention may provide positive short term weight loss. These findings provide support for the use of activity tracking technology (eg. pedometer, Fitbit, Smartphone applications) as part of a multicomponent weight loss intervention program and this EBP Project.

Kroes, Osei-Assibey and Baker-Searle (2016) conducted a systematic review the objective of which was to evaluate evidence concerning the impact of weight/BMI change on health-related quality of life (HRQoL) in obese adults. This was done through various weight loss interventions (Kroes et al., 2016). These interventions included: lifestyle modification and behavioral counseling; dietary and exercise coaching and education; pharmacotherapies, bariatric intervention; and some measure of health-related quality of life (HRQoL) (eg. SF-36, IWQOL-Lite). Outcomes measured included changes in weight, BMI, body composition, and HRQoL. HRQoL was measured with either the Short Form Health Survey (SF-36) tool or the Impact of Weight on Quality of Life (IWQOL-Lite) tool. Results of the pharmaceutical weight loss study using pooled data, at 52 weeks indicated the mean weight loss was 2.7% from baseline; 34.9% of participants lost 0.4 % to 9% of baseline. Weight gain was seen in 26.2% of participants. Changing weight correlated with SF-36 scores (0.2 for weight loss of 0-4.9% to 2.8 for weight loss $\geq$ 10 % from baseline). Lifestyle modification included diet, exercise and behavioral interventions resulted in weight loss that ranged from 3% to 10% from baseline. Multiple studies (n=6) utilized the SF-36 tool to measure HRQoL. Results showed that regardless of lifestyle intervention, weight loss was associated with better HRQoL scores (increase of 0.64 in SF-36 for every 5kg weight loss). Weight loss

and improved physical abilities produced improvement in HRQoL scores as measured with the SF-36 (mean change 1.65).

This study had many strengths. First a comprehensive search was conducted in four databases according to PRISMA guidelines identifying 6793 citations of which 32 were included. Analysis of evidence was completed via standard methods. Conclusions drawn indicate that BMI $\geq$ 25 typically coincide with decreased HRQoL. Significant weight loss following bariatric surgery may improve HRQoL. Non-bariatric studies that provided a weight loss of $\geq$ 5 % also resulted in improved HRQoL though specific cause remains unidentified. Both SF-36 and IWQOL-Lite scores that were improved but were generally related to physical rather than mental HRQoL. Conclusions indicated that people with obesity have poorer health and thus HRQoL and even a weight loss of 5% of total baseline can reduce health risk, improve health and HRQoL.

This systematic review was given a Level II high quality rating because of the inclusion of RCT and quasi-experimental studies and consistent results. It provides support for the use of an individualized multicomponent weight loss interventions including those specific to this EBP Project (eg.lifestyle modifications, and pharmaceuticals) for weight loss to improve all aspects of HRQoL in people with obesity and within this EBP Project.

Thabault, Burke and Ades (2016) conducted a quasi-experimental study with the purpose of evaluating an intensive behavioral treatment program to manage obesity with the adult primary care population, specifically led by nurse practitioners (NPs). Multicomponent interventions included: use of the 5A’s framework (ask, assess, advise, agree, and assist); obesity screening and nutritional assessment; motivational

interviewing; and weight loss education that included a 500-1000kcal reduction with a goal of a 1-2 pound /week loss and increased physical activity; along with an introductory packet that included benefits of a healthy lifestyle and weight, dietary and activity journal, pedometer, questionnaire addressing goals and readiness to change and nutritional assessment. Outcome variables include weight loss; patient-provider satisfaction, feasibility; and acceptability.

Data were collected at baseline and at 4 and 12 weeks. Baseline means for weight, BMI, SBP and DBP were: 229, 37.4, 129 and 71 respectively. After 4 weeks, mean weight decreased by 6.6 lbs ($p < .05$), and after 12 weeks, mean weight decreased by 10.77 lbs ($p < .05$). Changes in blood pressure were not statistically significant at either time point. The authors also evaluated the extent to which patients were satisfied with components of the weight loss program. In general, patients reported that scheduling was easy, consistent appointments with a nurse practitioner increased their own accountability to adhere to the program, that providers offered adequate support, and that use of the weight loss tools was feasible.

Strengths of the study were: used of validated questionnaires, data analysis using SPSS and Excel XLSTAT Version 2013.5.3, the NP leadership, focus in primary care, and generalizability of the study. Limitations included: short duration, the study participants were referrals rather than a random sampling, and lack of further evaluation of biometric risk markers. Results indicated that a NP-led multicomponent intervention that focused on nutritional assessment, weight loss education, and motivational interviewing was satisfactory to patients and resulted in significant weight loss. This

study provided level II high quality support for this EBP project due to study design and consistent content and generalizable results.

Welbourn and colleagues (2018) completed a systematic review to appraise current evidence regarding weight loss interventions used in primary and specialty care areas, in order to create a tiered model for these interventions centered on obesity severity. Based on 50 pieces of evidence, including published guidelines, systematic reviews and RCTs published between 2011 and 2016, the authors recommended a four-tier model for weight loss. Tier I interventions focus on obesity screening using standard anthropometric measurements (e.g. weight, BMI) and counseling about diet, exercise, and lifestyle changes. Tier II interventions included those in Tier I, with the addition of pharmacotherapies to facilitate weight loss. Tier III included interventions in Tiers I and II, as well as referral to a multidisciplinary team and a weight loss specialist. Finally, Tier IV included interventions from Tiers I through III, as well as referral to a bariatric physician specialist.

Strengths of this research was the use of 50 works of evidence including recently published guidelines and policy documents, systematic reviews and RCTs obtained from six electronic databases; use of a NICE accredited process endorsed by 22 UK societies and nine Royal Colleges addressing obesity. Limitations were not addressed within the article but included: a UK rather than US specific perspective and guidance; need for translation into US insurance based medical care climate that is not National Health Service.

In summary, Level II evidence from this literature review further support the use of weight loss interventions that focus on patient education, motivational interviewing,

and self-monitoring of diet and exercise. Moreover, Level II evidence suggests that multicomponent interventions based on characteristics that are unique to patients, including their resources, barriers, and preferences, can effectively lead to weight loss and provide support for this EBP Project.

Table 2. 4

Appraisal of Evidence

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/ Findings	Level/ Quality
Batsis, J. A., Gill, L. E., Masutani, R. K., Adachi-Mejia, A. M., Blunt, H. B., Bagley, P. J., Lopez-Jimenez, F. & Bartels, S. J., (2016). Weight loss in older adults with obesity: A systematic review of randomized controlled trials since 2005. *Journal of the American Geriatrics Society, 65*(2) 257-268.	To identify obesity interventions that can direct clinical recommendations among the geriatric population.	Systematic review Interventions included: Behavioral, diet and exercise counseling including 500-1000kcal deficit; meeting with diet or exercise physiologist or specialists; group meetings; pedometer use and log or diary; vitamin supplements	The target population is community-dwelling older adults with obesity. A thorough systematic literature search was performed and found 5,741 citations published 2006 forward; 19 sources were used in the final review. Inclusion criteria:behavioral weight	Outcomes measured: Weight (kg) was measured at intervals from 6 to 18 months. Physical function was measured using physical performance testing, the 6MWT, the Western Ontario McMaster Arthritis Index, and Functional Status Questionnaire at intervals from 6 to 18 months. Quality of life was measured using the SF-36 at intervals from 6 to 18 months.	Weight loss in the intervention groups ranged from 0.5 kg to 10.7 kg (0.1%-9.3% of body weight). (p<.01) Dietary interventions produced a larger weight loss than exercise alone. (p=.52 to p=.001) Exercise increased physical function but not weight loss. (p=.02) A combination of diet and exercise interventions provided the best improvement in physical function and QoL (p=.03) (Batsis et al., 2016)	Level I Quality High

			loss not involving pharmacological or surgical intervention. Exclusion criteria: pharmacological or surgical intervention		and mitigated loss of muscle and bone mass seen in the studies with diet only interventions.	
Beeken, R. J., Leurent, B., Vickerstaff, V., Wilson, R., Croker, H., Morris, S., Omar, R. Z., Nazareth, I., & Wardle, J. (2017). A brief intervention for weight control based on habit-formation theory delivered through primary care: results from a randomized	To test the hypothesis that ten top tips (10TT) can produce significantly better weight loss than usual care over a 3 month period.	RCT Intervention group received a leaflet about weight loss, a log book, and baseline consultation with a nurse. Control group received usual care from within their primary care setting, but may have	The sample included 537 primary care patients with obesity. Inclusion criteria: obsess adults that were able to provide consent. Exclusion criteria: active psychotic illness, pregnant or terminally ill.	Weight (kg) was measured at baseline and at 3, 6, 12, and 18 months. Secondary outcomes included BMI, waist circumference, blood glucose, and blood pressure. These were measured at 3, 6, 12, and 18 months.	Weight loss in the intervention group was greater than weight loss in the control group at 3 months (1.68 kg vs 0.84 kg, respectively; p = .004). Weight loss was sustained in the intervention group for up to 24 months. Mean Glucose (HbA1c) (mmol l^{-1}) at baseline was 5.9 (SD -2.4) CG, 5.8 (SD -2.1)_ IG; 3 months the IG had a	Level I Quality High

controlled trial. International *Journal of Obesity,41*(2) 264-254.		included outside resources such as Weight Watchers ®.			mean glucose of 5.3 versus 6.0 in the CG. A change of 0.06 (SD -2.85) in the control group and 0 (SD -1.79) in the intervention group. SBP was lower in the intervention group by 2.98 mmHg (95% CI -5.73, -0.23). The 10TT leaflet intervention was effective for short-term weight loss, glucose control, and BP control.	
Cheatham, S. W., Stull, K. R., Fantigrassi, M., & Motel, I. (2018). The efficacy of wearable activity tracing technology as part of a weight loss program:	The purpose was to appraise current evidence related to the efficacy of wearable activity tracking technology as part of a comprehensive weight loss	Systematic Review Of the 25 studies, various controls and interventions were applied. Among them	N=7184; n=25 that met inclusion criteria and no exclusion criteria.Inclusion criteria included: Controlled clinical trials, peer	A systematic review conducted based upon PRISMA guidelines of databases through December of 2016. Databases included: PubMed, CINAHL, SportDiscus, Proquest and Google Scholar as well as	Results of outcomes measured among studies included (*p*-value range): Weight loss (*p*<.001-.05, *p*=.0004 to.9) BMI (*p*<.01 to.03) Decreased BP (*p*=.25, or *p*<.05)	Level II Quality High

a systematic review. *The Journal of Sports Medicine and Physical Fitness, 58*(4)534-548.	program. Three clinical questions were addressed: 1. "Are activity trackers effective as a single intervention or part of a comprehensive weight loss program? . . . 2. Does the use of activity trackers improve adherence to weight loss programs? . . . 3. Are weight loss programs using activity trackers more effective among certain age groups or sex?"(Cheatham et al., 2018)	the control groups received: Hypocaloric diet, pedometer, usual national guidelines diet and exercise advice and education, weigh in and journal use Interventions included: behavioral and nutrition counseling; self-monitoring of diet and activity (eg.website or Smartphone); self-monitoring through journaling; and use of	reviewed, and comparison of portable activity tracking devices. Exclusion criteria: non-English, no use or no measurement of activity tracking device, or special populations, or case report, series, commentaries or dissertations.	citation chasing. Relevant studies were graded using the PEDro scale. 21 studies scored $\geq$ 6 and 4 studies scored $\geq$ 5. All subjects had a BMI of $\geq$ 25kg/m^2 , the majority being female. Outcomes measured: weight, BMI, waist circumference, body composition, physical activity, dietary changes/ caloric intake, blood pressure and heart rate	Increase physical activity (p=.04 to .003, p<.001) Decreased % body fat (p=.008 to .9) Increased weight control behaviors (p=.003) Decreased kcal intake (p<.001) Decreased fat intake (p<.001) Decreased waist circumference (p<.05 to $p\leq$.0004) A total of 25 articles were reviewed and each piece of evidence was individually scrutinized and analyzed however a meta- analysis was not performed. Based upon individual works, this systematic review findings suggest that activity trackers used as part of a multi-modal intervention weight

		an activity tracker.			loss program provide short term results over standard care. Consistent research findings indicate that multi-modal interventions in general provided the best weight loss outcomes. In every article the intervention group had a significantly greater weight loss than the control group and or an increase in physical activity was found.	
Eaton, C. B., Hartman, S. J., Perzanowski, E., Pan, G., Roberts, M. B., Risica, P. M., Gans, K. m., Jakicic, J. m. & Marcus, B. H. (2016). A randomized clinical trial of a tailored lifestyle	The aim of the study was to test a tailored lifestyle intervention to improve activity and achieve weight loss in an obese primary care population.	RCT Standard care for both groups IG and CG included: 3 face-to-face meetings with lifestyle counseling, and pamphlets .	Intervention (IG) n=105, control (CG) n=106. The sample was 79% women, 16% minorities, with a mean age 48.6 years, and mean BMI 37.8 kg/m2,	Outcomes measured included: weight loss, and physical activity (walking) .	Results: Percentage of sample that had 5% loss of body weight from of baseline was greater in IG than CG (p<0.001). At 6 months the IG 37.2% and CG 12.9%; at 12 months CG 26.7%; and at 18 months IG 31.4% and CG 26.7% and at 24 months IG	Level I Quality High

intervention for obese, sedentary, primary care patients. *Annals of Family Medicine, 14*(4) 311-319.		IG also received phone call counseling , weekly mailings focused on diet, exercise and behavioral / lifestyle interventions and DVDs.	who were sedentary. Inclusion: adult18 to 80 years, BMI ≥, sedentary, English literate and able toprovide consent. Exclusion criteria: family member enrolled in the study, health condition making participation unsafe.		33.3% and CG 24.6% had a 5% reduction in weight. Activity increased significantly more among the IG than the CG (p=0.04). The mean difference in physical activity minutes among the groups: at 6 months IG 95.7 and CG 68.3; at 12 months IG 126.1 and CG 73.7; at 18 months IG 103.7 and CG 63.7 and at 24 months IG 101.3, CG 75.4 (Eaton et al., 2016). Conclusions indicate that a tailored lifestyle intervention in obese sedentary populations was an effective tool to promote weight loss and increased activity with optimal effect at 12 months.	
Hageman, P. A., Pullen, C. H., Hertzog,	“This trial compared the effectiveness of	RCT Interventions : all groups	n=301 women with BMI of 28-	Outcomes measured:	Mean body weight per group at	Level I

M., Pozehl, B., Eisenhauer, C. & Boeckner, L. S. (2017). Web-based interventions alone or supplemented with peer-led support or professional email counseling for weight loss and weight maintenance in women from rural communities: Results of a clinical trial. *Hindawi, Journal of Obesity, 2017*, 1-21. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5396444/pdf/	a web-based only (WO) intervention with web-based supplemented by peer-led discussion (WD) or professional email counseling (WE) across 3 phases to achieve weight loss and weight maintenance in women from underserved rural communities" (Hageman et al., 2017).	including the control group (WO) had web-based interventions with identical content that included diet and exercise plans, behavioral change plans, based upon 2010 Dietary Guidelines for Americans and 2008 Physical Activity Guidelines for Americans and Healthy People 2010. One intervention group also received supplemental peer led counseling	45kg/m^2 ages 40-69 years, were randomly assigned to 1 of 3 groups: Web-based only/control (WO) n=101; Web-based and peer led discussion (WD) n=100; Web-based and professional email counseling (WE) n=100 Inclusion: rural living, female, BMI 28-45kg/m^2, not on medications that affected weight, English literate, able to use telephone and	Primary: body weight and waist circumference Secondary: attainment of specified weight loss, eating and activity targets	baseline, 6, 18 and 30 months: WO: 93.6 (SD 13.7), 88.0 (14.6), 88.9 (14.8), 89.4 (14.0) respectively. WD: 94.5 (12.9), 89.4 (13.9), 89.6 (13.6), 90.4 (13.3) respectively. WE: 93.3 (12.6), 87.2 (13.5), 88.3 (15.5), 89.5 (16.7) respectively. At the 6 month mark, the mean weight loss was: WO 5.1 (SD6.0) kg WD 4.1 (5.6)kg WE 6.0 (6.3) kg with 42%, 38% and 51 % meeting the ≥ 5% total body weight loss. Body weight kg: Comparison at 6, 18 and 30 months: p[b], mean difference (SD) "WOvsWD: *p*=.138, 0.9 (-0.8 to 2.7); *p*=.360, 0.2(-1.1 to	Quality High

JOBE2017-1602627.pdf	(WD) and the second intervention group received professional email counseling (WE).	computer, internet and DVD access, able to drive. Exclusion: diabetes type I or II with insulin use, 10% or greater weight loss in past 6 months, current enrollment in weight loss program or research study, physical or mental restrictions.	1.6); *p*=.268, -0.4(-1.8 to 0.9). WO vs WE: *p*=.188, -0.8 (-2.5 to 0.9), *p*=.411, -0.2 (-1.5 to 1.2), *p*=.444, -0.19-1.4 to 1.2). WD vs WE: *p*=.047, -1.7 (-3.4 to 0.0), *p*=0.563, -0.4 (-1.7 to 1.0), *p*=.632, 0.3 (-1.0 to 1.7). Waist circumference: at 6, 18 and 30 months: p[b], mean difference (SD) WO vs WD: *p*=.070, 1.6 (-0.5 to 3.7). *p*=.497, -0.01 (-1.5 to 1.4), *p*=.479, -0.04 (-1.5 to 1.4). WO vs WE: *p*=.461, 0.1 (-2.0 to 2.2), *p*=.441, -0.1 (-1.5 to 1.3), *p*=.463, -0.1 (1.5 to 1.3). WD vs WE: *p*=.164, -1.5 (-3.5 to 0.6), *p*=.891, -0.1 (-1.6 to 1.4), *p*=.970, -0.03 (-1.5 to 1.4)”

					(Hageman et al., 2017) Results showed that the web-based intervention had short term effect for weight loss in this rural population. However at 30 months weight regain by as much as 50% was found within the population studied.	
Harrigan, M., Cartmel, B., Loftfield, E., Sanft, T., Chagpar, A. B., Zhou, Y., Playdon, M., Li, F. & Irwin, M. L. (2016). Randomized trial comparing telephone versus in-person weight loss counseling on body composition and circulating biomarkers in	The purpose was to examine the effect of in-person versus phone based weight loss counseling versus usual care on body composition, physical activity, diet and biomarkers at 6 months.	RCT Control: usual care: diet and exercise advice based upon US dietary guidelines and the LEAN book. Interventions: In-person and phone counseling included 11,	Female breast cancer survivors with BMI $\geq$25kg/m^{2,} ages 59 $\pm$ 7.5 years. n=33 in-person counseling group (IP), n=34 telephone counseling group (TC) and n=33 usual care group (UC).	Biomarkers and height and weight, waist circumference, activity and diet were measured at baseline and at 6 months.	Results indicated that at 6 months the mean weight loss was IP 6.4%,(p=0.004,) TC 5.4%(p=0.009) and UC 2.0% (p=0.46). C-reactive protein reduced 30% IP & TC; versus 1% UC (p=0.05). Both IP and TC were effective weight loss strategies that had positive effects on C-reactive protein level reduction.	Level I Quality High

women treated for breast cancer: the lifestyle, exercise and nutrition (LEAN) study. *Journal of Clinical Oncology, 34*(7)669-676.		30 minute sessions over 6 months that focused on diet and exercise advice based upon US dietary guidelines. and behavioral therapy.	Inclusion: Breast cancer survivors Dx within 5 years, stage 0-3, BMI.≥25 kg/m^2, completed chemotherapy or radiation at least 3 months prior, physically capable, English literate and agree to random assignment. Exclusion: pregnancy, CVA or MI in past 6 months, or uncontrolled mental illness.			
Kozica, S.L., Lombard, C. B., Ilic, D., Ng, S., Harrison, C. L. & Teede, H.	The aim of the study was to "conduct a process evaluation within	RCT Control: The CG received	N=649; Control group (CG) n=301; intervention	The HeLP-her Rural program took place in Australia and New Zealand beginning in	Results on Likert 1-5 ±SD indicated that face-to-face delivery methods to be the most desired by	Level I Quality High

J. (2015). Acceptability of delivery modes for lifestyle advice in a large scale randomized controlled obesity prevention trial. BMC Public Health, 15(9)699-712. doi:10.1186/s12889-015-1995-8	the context of a large-scale rural obesity prevention program measuring implementation fidelity, dose delivered, context, reach and acceptability of diverse delivery modes" (Kozica et al., 2015)	standard care-group education from National Guidelines. Intervention: low intensity lifestyle intervention that included: simple lifestyle advice via face-to-face group session, pone coaching, text messages, and an interactive manual.	group (IG) n=348; females, aged 39.6± 6 years, BMI 28.8 ±6.9kg/m^2, from low socioeconomic rural communities. The intervention group was sub divided into clusters of n=15 allowing for attrition. Inclusion: female, aged 18-50 years, living in one of 41 selected towns. No exclusion criteria stated.	2012 and lasting 12 months. At 1 year, CG n=233, IG n=259 Data collection included: interviews, checklists and questionnaires that were analyzed using chi-square and *t*-tests. Outcomes measured: Acceptability of mode for lifestyle advice: face-to-face, text messaging, telephone coaching, program manual.	participants, with at least one session being the key to success. Group education sessions was the most highly valued component of the interventions. Lifestyle advise delivered through a multicomponent program was recommended to optimize acceptability and effect. Quantitative results at 12 months (n=190): Group sessions were preferred over telephone coaching (p<.00) or program manual (p<.00). text messaging scored slightly higher than phone coaching (p<.00) and program manual (p<.000; phone coaching scores were lower than all interventions

					except program manual (*p*=.63). No statistical difference between group sessions and text messages (*p*=.13).	
Kroes, M., Osei-Assibey, G., Baker-Searle, R. & Huang, J. (2016). Impact of weight change on quality of life in adults with overweight /obesity in the United States: a systematic review. *Current Medical Research and Opinion, 32*(3)485-508.	The objective of this study was to "review published evidence on the impact of weight/BMI change on health-related quality of life (HRQoL) in adults from the US with overweight/obesity" (Kroes et al., 2016)	Systematic review (SR) Of the studies included Interventions comprised: the SF-36 or the IWQOL Lite to measure HRQoL, lifestyle approaches: diet, exercise, counseling, pharmaceutical therapies, or bariatric surgery	N=6793 titles were identified of which 32 meet inclusion criteria and did not meet one or more exclusion criteria. Upon further review n=20 provided adequate data and were included in the SR. Inclusion: Englishlanguage, published 2008	This SR was conducted using PRISMA guidelines. A comprehensive data base search of MEDLINE, Embase, Econ Lit and the Cochrane Library. Inclusion criteria included: studies in US, adults, BMI ≥25, with ≥ 1 year follow up quantified weight change and measurement of HRQoL. Studies design and outcomes were heterogeneous, with HRQoL. Outcomes measurement obtained via	Results indicated that that pharmacotherapies and lifestyle intervention, 5%-10% weight loss was achieved HRQoL also improved; lifestyle interventions coincided with SF-36 scores PCSW increased by 0.64 for every loss of 5kg (*p*<.001) .Pharmaceutical studies weight loss coincided with minor changes in SF-36 scores (0.2 to 2.8). Bariatric surgery offered the greatest weight loss, ≥ 20%, and improved	Level II Quality High

			forward, adult population, overweight/obese, follow-up 1 year or greater, change in HRQoL measure (SF-36 and or IWQOL-Lite). Exclusion: Comorbitiy focus, not obesity related.	the Short form 36 (SF-36) or the IWQOL Lite. Improved HRQoL was seen in studies in which weight-loss was obtained.	HRQoL scores. Studies reporting SF-36 post bariatric surgery: p<.008 week 92, and at 2 years p≤.02 from baseline, IWQOL-Lite scores from baseline reported significant improvements, specifically physical function and self-esteem both (p<.001). Conclusion: there was an association between overweight/obesity and lower HRQoL scores; corresponding amount of weight loss and increased HRQoL was found among evidence reviewed.	
Ma, J., Goldman-Rosas, L., Lv, N., Xiao, L.,	The objective is to “test the hypothesis that an integrated	RCT Usual care group (UC) n=205 as	N=409, adults, BMI ≥ 30 (≥27 for Asian	The study: Research Aimed at Improving Both Mood and	Findings provided statistically significant results at 12 months.	Level I Quality High

Snowden, M. B., Venditti, E. M., Lewis, M. A., Goldhaber-Fiebert, J. D. & Lavori, P. W. (2019). Effective of integrated behavioral weight loss treatment and problem-solving therapy on body mass index and depressive symptoms among patients with obesity and depression: The RAINBOW randomized clinical trial. *Journal of the American Medical Association (JAMA), 321*(9) 869-879.	collaborative care intervention would significantly improve both obesity and depression at 12 months compared with usual care" (Ma et al, 2019.)	well as intervention group (IG) n=204 received medical care from personal physicians, including information on weight management and mental health services and wellness programs routinely available in their primary care office. The UC group also received an activity tracker. The IG received the same initial information as UC but	adults), and PHQ-9 score $\geq$ 10, primary care patients in Northern California, study dates: 9/30/2014-01/12/2017, with 12-month follow up by 01/17/2018. Inclusion: adult, obese, depressive symptoms (PHQ-9 score $\geq$ 10), English literate. Exclusion: plan to relocate, serious comorbiditie s (undefined), pregnancy,	Weight (RAINBOW) integrated Behavioral weight loss treatment and problem-solving therapy with antidepressant pharmacotherapies. Outcomes measure weight loss/BMI, PHQ-9, GAD-7 and SCL-20 scores. *t*-test analysis or x^2 test analysis for unadjusted bivariables and Wald asymptomatic 95% CI for unadjusted proportions.	Intervention group (IG) versus usual care (UC): Weight loss/BMI reduction: mean baseline to 12 months: 36.7 (SD 6.9) to 35,9 (SD 7.1) between group mean -0.7 (95% CI, -1.1 to -0.2) *p*=0.01. Depressive symptoms: SCL20: IG mean score reduced from 1.5 (SD 0.5) to 1.1 (SD 1.0) IG -0.3 versus UC 1.5 (SD 0.6) to 1.4 (SD 1.3) between group scores mean difference , -0.2 (95% CI, -0.4 to 0) *p*=0.01. SCL 20 scores improved by at least 50% at 6 months (31% IG versus 16% UC) full depression remission SCL<0.50(IG 18% versus UC 6%)

		also received multimedia lifestyle and self-care materials as well as health coaching from dieticians on a weekly basis, as well as psychiatry and primary care providers routinely.			In between group GAD-7 scores: -1.2 (95% CI, -1.2 to -0.3) at 6 months; -1.5 (95% CI, -2.4 to -0.5) at 12 months. Conclusions indicate by study results: Among adults with obesity and depression a collaborative intervention approach to treatment that included behavioral weight loss treatment and problem-solving therapies, as well as antidepressant pharmacotherapies as needed provided significantly greater results in weight loss and reduction depressive symptoms than usual care.	
Rodriguez-Cristobal, J. J., Alonso-Villaveerde, C.,	The aim of the study was “to investigate whether a	RCT The intervention	N=864, overweight/obese patients	Outcomes measured: Weight, cholesterol, triglycerides, HDL, LDL, apolipoproteins	Results: Weight loss kg mean at 1 year: CG, 1.3 kg, (0.1 SE)59.3% were at	Level I Quality High

Panisello, J. M., Trave'-Mercade, P., Rodriguez-Corte's, F., Marsal, J. R. & Pena, E. (2017). Effectiveness of a motivational intervention on overweight/obese patients in primary healthcare: a cluster randomized trial. *BMC Family Practice, 18:74* (2017) 1-8. doi: 10.1186/s12875-017-0644-y	motivational intervention together with current clinical practice, was more efficient than traditional intervention in the treatment of overweight and obesity and whether this intervention reduces cardiovascular risk factors associated with overweight and obesity" (Rodriguez-Cristobal et al., 2017).	group (IG) received 32 group based sessions (every 15 days and then monthly for weeks 13 through 32) of motivational intervention along with standard 1200-1500kcal/day diet and exercise education/counseling, anthropometric measures, blood tests: triglycerides, APOA1 APOB-100, HDL and LDL cholesterol . The control group (CG)	ages 30-70 years with BMI >25, from a multicenter were randomly assigned to either the intervention group (IG) or the control group (CG) n=446, . Inclusion: Aged 30-70 years, overweight or obese, any gender, registered medical history or new diagnosis. Exclusion criteria not defined.	A and B, and blood pressure	or below baseline, and mean 50/16.6% had lost $\geq$ 5%. IG 1.8 kg,(0.4 SE) 95%CI, -0.47;1.36(*p*=.33) 61.8% were at or below baseline and mean 64/22.6% had lost $\geq$ 5%. Weight loss kg mean at 2 year: CG, 1.0 kg, (0.4SE) 55.8% were at or below baseline, and mean 36/18.1% had lost $\geq$ 5%. IG 2.5 kg, (0.5SE) 95%CI0.31; 2.74 (*p*=.01)65.5% were at or below baseline, and mean 64/26.9% had lost $\geq$ 5%. The study showed that the combination of usual care combined with professional group based motivational interventions significantly increased maintenance and

		n=446, who received standard care with visits every 3 months: standard 1200-1500kcal/day diet and exercise education/counseling based on national guidelines, anthropometric measures, blood tests: triglycerides, APOA1 APOB-100, HDL and LDL cholesterol.			weight loss. Also, a focus on psychological aspects of patient health may contribute to long term weight loss success.	
Rolls, B. J. James, B. L. & Sanchez, C. E. (2017). Does the incorporation of	The purpose of the research was to test whether the efficacy of a behavioral	RCT All three groups were given equally intensive	N=186 overweight (19%) or obese (81%) women.	Participants were randomly assigned to either the control group/standard advice (SAG); the portion selection group (PSG)	Results: weight loss for PPG was higher than other groups (P=0.021) however this group later regained more	Level I Quality Good

portion-control strategies in a behavioral program improve weight loss in a 1-year randomized controlled trial?. *International Journal of Obesity, 41*(3)434-442.	weight loss program would be improved by incorporating either one of two portion control strategies: prepackaged meals or portion selection versus standard advice	behavioral program/ counseling. The SAG/ control group were instructed to eat less food and make healthy food choices. The PSG were instructed to choose portions based on energy density and food measuremen t tools/scale. The PPG were instructed to build meals around pre-portioned foods using food vouchers for purchase.	Inclusion: Female, aged 20-65 years, BMI 28-45 kg/m^2, Exclusion: BO > 160/100mm Hg, reported weight change >4.5kg in past 3 months, medically unstable, limited physical activity tolerance, current special diet or weight loss program enrollment, pregnant or lactating, scores of >19 on Eatin	or the Pre-portioned foods group (PPG). Outcomes measures were assessed at 12 months for 151 participants (81%). Weight change/ trajectory, Secondary outcomes: dietary consumption questionnaire responses and pedometer readings. cardiometabolic factors: blood pressure, waist circumference, glucose, insulin, insulin resistance, total cholesterol, HDL, and triglycerides	weight (P=0.0005). Thus resulting in insignificant weight loss across groups at 6 months (mean $\pm$ se 5.2 $\pm$0.4kg) or 12 months (4.5 $\pm$ 0.5kg). After 1-year weight loss mean was 6% of baseline. Secondary outcomes: SBP(*p*=.0061), DBP (*p*=.0003), Waist circumference (*p*<.0001), Glucose (*p*=.0015), Insulin (*p*<.0001), insulin resistance (*p*<.0001), Total cholesterol (*p*=.0007, HDL (*p*=.0001), LDL (*p*=12), Triglycerides (*p*=.0032) Conclusions: Though early weight loss was found using pre-packaged or portion controlled/selection foods, this did not last. The use of pre-

			Attitudes Test, or >25 on Becks Depression Inventory.		packaged or portion controlled/selection foods did not lead to greater long term weight loss versus standard advice.	
Samdal, G. B., Eide, G. E., Barth, T., Williams, G. & Meland, E. (2017). Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults: systematic review and meta-regression analysis. *International Journal of Behavioral Nutrition and Physical Activity, 14*(1)42-56.	The aim of the SR to "explain heterogeneity in results of interventions to promote physical activity and healthy eating for overweight and obese adults, by exploring the differential effect of behavior change techniques (BCTs) and other intervention characteristics" (Samdal et al., 2017)	SR with meta-regression analysis Interventions: Behavioral change techniques: Motivational interviewing and self-determination theory (SDT), Acceptance and commitment theory (ACT), Change theory/technique (CT), Health at Every Size (HAES),	N=6283 articles; 584 titles showed relevance after initial screening. Abstract screening for inclusion exclusion criteria produced n=48 studies that provided evidentiary support and were relevant to this project. These 48 articles contained 82 outcome reports and a pooled	SR using PRISMA of RCT ≥ 12 weeks duration; January 2007 to October 2014; adult populations-mean age 40 years; Mean BMI ≥30. Primary outcomes measured: healthy diet and physical activity.	IBM SSPS statistics were used to complete meta-analysis. Physical activity (PA) was addressed in 35 trials (30 ST,0.36 effect size (ES) 95% CI; 17 LT, 0.25 ES 95%CI; and 47 both ST and LT, 0.31 ES 95%CI). Diet was addressed in 26 trials (20 ST,0.41 ES 95%CI; 15 LT, 0.19 ES 95%CI; and 35 ST and LT, 0.29 ES 95%CI). PA and diet were both addressed in 61 trials (50 ST, 0.37 ES 95%CI;32 LT, 0.24 ES 95%CI; and 82 both ST and LT, no data).	Level I Quality High

doi: 10.1186/s12966-017-0494-y	mindfulness, other For Diet and physical activity, goal setting, self - monitoring, feedback, social support,	population of 11,183 participants. Interventions were either short-term (ST) ≤ 6 months or long-term (LT) ≥ 12 months. Inclusion: Behavioral change intervention, cognitive behavioral strategies or intervention. Exclusion: Did not include Behavioral change intervention, cognitive behavioral strategies or intervention. For physical activity and	ST Meta-regression data: Goal setting: b 0.480; 95% CI 0.257-0.705 p<0.001. Feedback behaviour: b 0.219, 95% CI -0.040, 0.479 p=0.096. Self-monitoring behavior: b 0.398, 95% CI 0.164, 0.632, p=0.001.LT meta-regression data: Goal setting: b 0.228 ; 95% CI 0.056, 0.327 p=0.057. Self-monitoring behavior: b 0.184, 95% CI 0.009, 0.360, p=0.040. Feedback: b 0.249, 95%CI 0.085, 0.412, p= 0.004 Conclusions that there are both similarities and differences in BCTs the are effective to promote healthy eating and increased activity

			healthy eating improvement		and maintenance. The results support goal setting, self-monitoring and behavioral/person-centered counseling/motivational interviewing that support autonomy.	
Tang, J. C. H., Abraham, C., Greaves, C. J. & Nikolaou, V. (2016). Self-directed interventions to promote weight loss: a systematic review and meta-analysis. *Health Psychology Review, 10*(3) 358-372.	The focus of this study was on interventions that did not involve on going professional interaction/ contact, other than an introductory face-to-face session. Research questions included: "1. How effective are self-directed interventions . . . to promote short, medium and long-term weight loss in adults? 2. Are particular	Systematic review and meta-analysis Interventions: target diet and or physical activity; self-directed with limited face-to-face professional contact to ≤ one 90-minute instructional session; had at least one interactive intervention; or had at	N= 5226 from database search and N=3 from other sources. After removal of duplications n= 3884; Of these n=27 RCTs that met inclusion and did not meet one or more exclusion criteria and were included in the	Articles included were published prior to July 2014, study data of RCTs of self-directed weight loss or weight control interventions Database search: MEDLINE, Embase, PsychINFO, CINAHL, the Cochrane Library. Outcomes measured: effectiveness of self-directed internet-based interventions; effectiveness of change technique inclusion (eg. goal setting, self-monitoring, feedback, behavioral instruction) on self-directed interventions; changes in weight,	Results: people who utilized self-directed (mostly internet based) interventions lost a greater amount of weight than those who received minimal or no intervention/ treatment; Self-monitoring: (MD= -1.56kg, CI -2.25, -0.86) (SMD = - 0.41, 95% CI – 0.60, -0.23, I^2=79% ; p=< 0.00001). The mean weight loss among the intervention group ranged between 0.6 to 5.3 kg. Change techniques: Goal setting: was not significantly	Level I Quality High

	modes of delivery of self-directed weight loss interventions more or less effective? 3. Do particular frequently employed change techniques enhance effectiveness?" (Tang et al., 2016)	least one self-regulatory element such as goal setting or diary of thoughts and or behaviors.	quantitative synthesis. Inclusion: RCTs published in English prior to August 2014, self-directed weight loss, weight control interventions. Exclusion criteria not stated.	BMI, waist circumference	difference between groups IG CG. Conclusions indicated that self-monitoring and self-directed including on-line formats could be used to assist with weight loss generating modest but significant effect.	
Tapsell, L. C., Lonergan, M., Batterham, M. J., Neale, E. P., Martin, A., Thorne, R. . . .Peoples, G. (2017). Effect of interdisciplinary care on weight loss: a randomized controlled trial. BMJ Open,	The objective was " to determine effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese volunteers" (Tapsell et al., 2017).	Single blinded RCT Participants were randomized into one of the three groups: CG, IG or IWG. The CG received the usual care. The all were provided	Initial sample: Control group/usual care (CG) n=126; Intervention group (IG) n=125 and intervention plus walnuts (IWG) n=126. Inclusion:	. Outcomes measured: weight loss from baseline and at 12 months; change in blood pressure; fasting blood glucose and lipids; changes in diet and exercise; psychological measures (AAQ-W, DASS-21, QoL SF-12)	Results: At the 3 month mark, there was a significantly greater weight loss in the IG and IWG than Cg: (-1.2 kg, p=0.045, I ; -1.3kg , *p*=0.025 IWG) and at 6 months for IWG (-2.1 kg, *p*=0.010). At 12 months the weight change adjusted for baseline weight	Level I Quality High

2017 (7) e014533. doi:10.1136/bmjopen-2016-014533		standard weight loss materials including healthy diet and exercise as well as nurse lead weight loss advice. The IG also received interdisciplinary advice from dietician, and psychologist. IWG received interdisciplinary advice and food supplement of 30g of walnuts daily	Resident of the Illawarra region, aged 25-54 years, BMI 25-40kg/$m^{2,}$ English literate. Exclusion: Not English literate, severe medical condition or terminal condition- life expectancy <1year, illegal drug use, alcoholism/regular alcohol use .50g/day, other major impediments		showed effect of p=0.056 reflective of CG- IWG difference of -2.2kg (95% CI -4.6 to 1,0kg, p=0.068) compared to CG -IG: -1.9kg (95%CI -4.5 to 0.7kg, p=0.228) and difference between IG and IWG: -0.3kg (95% CI -2.8 to 2.2 kg, p=1.00) Conclusions indicated that the intervention sample achieved significantly greater weight loss outcomes than the control/ usual care. Interdisciplinary interventions produced more clinically significant outcomes that were better sustained.	
Thabault, P. J., Burke, P., J., & Ades, p. A. (2016).	The purpose of the study was to " evaluate a nurse	Quasi-experi-mental study	Convenience sample n=38 Inclusion:	Outcomes measured: weight loss; patient-provider satisfaction,	Weight, BMI and BP were assessed at initial visit and 4 and 12 weeks. Initial	Level II Quality High

Intensive behavioral treatment weight loss program in an adult primary care practice. *Journal of the American Association of Nurse Practitioners, 28* (2016) 249-257.	practitioner lead intensive behavioral treatment (IBT) program for obesity implemented in an adult primary care practice" (Thabault et al., 2016).	No control group. Intervention: 5A's framework (ask, assess, advise, agree, and assist); obesity screening and nutritional assessment; motivational interviewing; and weight loss education (500-1000kcal reduction with a goal of a 1-2 pound /week loss and increased physical activity); introductory packet (education-benefits of a	Aged 18 years or older, primary care patients of a patient-centered medical home practice in New England, Medicare, Medicaid, or commercial insurance. Exclusion criteria not identified.	feasibility; and acceptability	mean/SD were: weight 229/36, (males: 252/35; females: 215/29) BMI 37.4/4.6 (males: 36.8/3.7; females: 37.9/5.1) ,SBP 129/14, DBP 71/13; At 4 weeks: weight 223/34, BMI 36.3/4.4, SBP 128/9, DBP 73/10; At 12 weeks: weight 219/34, BMI 36.3/ 4.4, SBP 131/15, DBP 73/12. Using paired t-test after 4 visits weight loss was significant (6.6lbs, $p<0.05$); for males (8.9lbs $p<0.05$); for females (5.2lbs $p<0.05$). At 12 weeks the mean weight loss was: males 11.73 lbs ($p<0.05$) and females 10.16lbs ($p<0.05$). Patient satisfaction was measured with a Likert scale questionnaire that

		healthy lifestyle and weight, dietary and activity journal, pedometer, questionnaire addressing goals and readiness to change and nutritional assessment) initial and 13 follow up weight loss counseling sessions, anthropometric measures,			achieved a 75% response rate that indicated favorability in all categories: appointments, weight loss counseling and tools. Conclusions indicated that NP led IBT programs were an effective means for adults in primary care to achieve weight loss and was well received by the patient population.	
Welbourn, R., Hopkins, J., Dixon, J. B., Finer, N., Hughes, C., Viner, R. & Wass, J. (2018). Commissioning guidance for	A SR of current evidence for commissioning primary/secondary weight assessment and management for patients with severe or complex	SR References included pathways, protocols and infrastructure for pediatric to adult	A total of 2,560 references were identified from 6 databases, of which n=50 were	Outcomes included: weight loss pre and post intervention, quality of life, psychological health (depression, anxiety and self-esteem), mobility, social function and diabetes.	The results provided 4 tiers of guidance for the following health domains: general practitioners/primary care actions recommended: anthropometric body measurements,	Level II Quality Good

weight assessment and management in adults and children with severe complex obesity. *Obesity Reviews: An Official Journal of The International Association for the Study of Obesity, 19*(1)14-27.	obesity. The purpose of the SR was to "produce a model for organization of multidisciplinary team clinics that could be developed in every healthcare system" (Welbourne et al., 2018)	populations with obesity. Diabetes, included: diet, exercise, bariatric, dietetics/pharmacotherapies,	included in the SR. Included in the SR: guidelines published between 2011 and 2016. Inclusion: Published guidelines, systematic reviews, RCTs published from 2011 to 2016. Exclusions: revision (bariatric) surgery.	specialist referral criteria, diabetic management and referrals for bariatric surgery; in specialist clinic/ adult weight assessment and management: interdisciplinary teams including bariatric physician, dietician, nurse specialist, psychologist/psychiatry & physical therapist and access for patients with special disabilities; Diabetic/ DMII care HbA1c <6.9, referral for bariatric specialist, assessment of CV risk; Psychological and lifestyle issues: referrals to specialist, medication history and evaluation of psychotropic drugs; Post bariatric surgical care:

interdisciplinary care.

The evidence provided guidelines for standard of treatment on a 4 level scale initiating with primary/general practice: universal interventions routine anthropometric measurements thus reducing stigma, and diet, exercise and healthy lifestyle counseling. Tier 2 multicomponent weight management that includes tier 1 components plus pharmacotherapies. Tier 3 includes tier 1 and 2 as well as a multidisciplinary team and specialist assessment. The 4th tier includes bariatric specialist assessment as well as the first 3 tiers.

- Note: Appraisal tool utilized in this evidence appraisal was the Johns Hopkins Nursing Research Evidence Appraisal Tools, ©The Johns Hopkins Hospital/ Johns Hopkins University School of Nursing (Dang & Dearholt, 2017).

Construction of Evidence-Based Practice

Synthesis of Critically Appraised Literature

According to the WHO (2018) the global incidence of obesity has nearly tripled since 1975. In 2016, approximately 13% of the global adult population was obese, and 39% were overweight (WHO, 2018). Given the overwhelming and growing prevalence of obesity, and the significant impact of obesity on morbidity and mortality, managing obesity is of paramount importance in the primary care setting. This EBP Project strove to address whether the use of an evidenced based multicomponent protocol for the assessment and treatment of obese patients assist adult patients with obesity to achieve better weight loss outcomes compared to usual care including: a reduction in BMI, waist circumference and waist to-hip ratio, as well as improve secondary outcomes measures of BP, HbA1c, total cholesterol, HDL, LDL, triglycerides and the PHQ-9 and the GAD-7 scores.

The current literature supports the use of a tailored multicomponent approach to weight loss that is unique to each patient with obesity. Furthermore, high-quality evidence demonstrates that the following interventions can effectively reduce weight, BMI, waist circumference, and other obesity indicators:

- Anthropometric measurement (eg. height, weight, BMI, waist circumference, and waist-to-hip ratio) (Tapsell et al., 2017; Welbourn et al., 2018)
- Nutritional assessment (Hageman et al., 2017; Thabault et al., 2016; Wellbourn et al., 2018)

- Individualization or tailoring of interventions (Eaton et al., 2016; Cheatham et al., 2018; Tang et al., 2016)
- Diet and exercise counseling that included: caloric reduction from between 500 -1000kcal per day and use of a healthful diet(lean protein, fresh fruits and vegetables, whole grains and low fat; portion control); increased exercise to at least 150 minutes per week, on most days that included aerobic activity (eg. brisk walking) (Batsis et al., 2016; Cheatham et al., 2018; Kozica et al., 2015; Kroes et al., 2016; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017; Thabault et al., 2016; Welbourn et al., 2018).
- Behavioral and lifestyle counseling and modification (eg. face-to-face, or telephone, printed tools; not eating in front of the television, social eating, stress, goal setting) (Batsis et al., 2016; Beeken et al., 2017; Cheatham et al., 2018; Eaton et al., 2016; Hageman et al., 2017; Harrigan et al., 2016; Kozica et al., 2015; Kroes et al., 2016; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Tang et al., 2016; Tapsell et al., 2017; Welbourn et al., 2018)
- Motivational counseling (Rodriguez-Cristobal et al., 2017; Samdal et al., 2017, Thabault et al., 2016; Welbourn et al., 2018
- The 5A’s (ask, assess, advise, agree, and assist) counseling and intervention (Thabault et al., 2016)
- Self-guided weight loss plan (eg. Ten Top Tips/10TT, online diet plans) (Beeken et al., 2017; Hageman et al., 2017; Tang et al., 2016)

- Self-monitoring of diet and activity log, goals using a diary, or tracking device (eg. Fitbit®, Smartphone application, pedometer, or online tracker) (Cheatham et al., 2018; Ma et al., 2019; Rolls et al., 2017; Tang et al., 2016)
- Peer groups, discussion boards and weekly meetings (Hageman et al., 2017)
- Psychosocial (eg. PHQ-9, GAD-7, SF-12, SF-36, SCL-20, IWQoL) (Kroes et al., 2016; Ma et al., 2019; Tapsell et al., 2017) and readiness evaluation (eg. AAQ-W) (Tapsell et al., 2017) with referral and treatment for depression and anxiety
- Specialist collaboration (eg. dietician, psychologist, bariatric) (Kroes et al., 2016; Tapsell et al., 2017; Wellbourn et al., 2018)
- Pharmacotherapies, use of weight loss medications (Kroes et al., 2016; Wellbourn et al., 2018)

In addition, the following interventions appear to significantly improve cardiovascular risk, cardiovascular and or metabolic biomarkers, quality of life, or physical function:

- Nutritional assessment (Hageman et al., 2017; Thabault et al., 2016; Wellbourn et al., 2018)
- Individualization or tailoring of interventions (Eaton et al., 2016; Cheatham et al., 2018; Tang et al., 2016)
- Diet and exercise counseling that included: caloric reduction from between 500 -1000kcal per day and use of a healthful diet (lean protein, fresh fruits

and vegetables, whole grains and low fat; portion control); increased exercise to at least 150 minutes per week, on most days that included aerobic activity (eg. brisk walking) (Batsis et al., 2016; Cheatham et al., 2018; Kozica et al., 2015; Kroes et al., 2016; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017; Thabault et al., 2016; Welbourn et al., 2018).

- Behavioral and lifestyle counseling and modification on regularly scheduled bases (eg. face-to-face, telephone, text messages, or printed tools; not eating in front of the television, social eating, stress, goal setting) (Batsis et al., 2016; Beeken et al., 2017; Cheatham et al., 2018; Eaton et al., 2016; Hageman et al., 2017; Harrigan et al., 2016; Kozica et al., 2015; Kroes et al., 2016; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Tang et al., 2016; Tapsell et al., 2017; Welbourn et al., 2018)
- Motivational counseling (Rodriguez-Cristobal et al., 2017; Samdal et al., 2017, Thabault et al., 2016; Welbourn et al., 2018
- The 5A’s (ask, assess, advise, agree, and assist) counseling and intervention (Thabault et al., 2016)
- Self-guided weight loss plan (eg. Ten Top Tips/10TT, online diet plans) (Beeken et al., 2017; Hageman et al., 2017; Tang et al., 2016)
- Self-monitoring of diet and activity log, goals using a diary, or tracking device (eg. Fitbit®, Smartphone application, pedometer, or online tracker)

(Cheatham et al., 2018; Ma et al., 2019; Rolls et al., 2017; Tang et al., 2016)

- Peer groups, discussion boards and weekly meetings (Hageman et al., 2017)
- Psychosocial (eg. PHQ-9, GAD-7, SF-12, SF-36, SCL-20, IWQoL) (Kroes et al., 2016; Ma et al., 2019; Tapsell et al., 2017) and readiness evaluation (eg. AAQ-W) (Tapsell et al., 2017) with referral and treatment for depression and anxiety
- Specialist collaboration (eg. dietician, psychologist, bariatric) (Kroes et al., 2016; Tapsell et al., 2017; Wellbourn et al., 2018)
- Pharmacotherapies, use of weight loss medications (Kroes et al., 2016; Wellbourn et al., 2018)

Evidence presented suggested that prior to initiating any form of intervention, patients should be screened for obesity. This would involve measurements of height, weight and calculating BMI. BMI $\geq$ 30 is consistent with obesity, however, this measurement can be deceiving in a patient with large muscle mass. Therefore, waist circumference and waist-to-hip ratio should also be measured. Since obesity carries known health risks, screening for comorbidities such as: hypertension, diabetes, hyperlipidemia, depression and or anxiety should also be completed when possible (Batsis et al., 2016; Beeken et al., 2017; Cheatham et al., 2018; Eaton et al., 2016; Harrigan et al., 2016; Tapsell et al., 2017; Thabault et al., 2016; Wellbourn et al., 2018).

Provider use of the 5A's (ask, assess, advise, agree, and assist) (Thabault et al., 2016) counseling and intervention technique as well as motivational interviewing or counseling techniques (Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Thabault et al., 2016; Welbourn et al., 2018) were interventions shown in Level I and Level II evidence to illicit open conversation, aid in assessment and treatment, and develop relationships that improve successful weight loss. Determining participant weight loss history, readiness to lose weight, bias(es), physical as well as psychosocial barriers and limitations can produce better outcomes (Kroes et al., 2016; Ma et al., 2019; Tapsell et al., 2017)

Obesity is a multifactorial chronic disease often accompanied by comorbidities. Therefore no one specific intervention can consistently meet each individual's needs. Multiple individualized interventions may be necessary to produce weight reduction (Cheatham et al., 2018; Eaton et al., 2016; Ma et al., 2019; Sambal et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016). These interventions may have included collaboration with one or more specialists when necessary (eg. dietician, endocrinologist, psychologist, bariatric) (Kroes et al., 2016; Tapsell et al., 2017; Wellbourn et al., 2018).

The evidence compiled for this EBP project offered a multitude of potential interventions, however at this clinical site many were unrealistic for this patient population. Those that had merit in this setting are discussed further.

On the surface, the treatment of obesity would appear to be simple, however obesity and its' treatment is complex. For these reasons evidence supports a multicomponent approach. Multiple studies (Batsis et al., 2016; Cheatham et al., 2018;

Kozica et al., 2015; Kroes et al., 2016; Kushner & Ryan,2014; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017; Thabault et al., 2016; Welbourn et al., 2018) and the Guidelines (2013) for Managing Overweight and Obesity in Adults from the NIH (Jensen et al., 2014), advocate for a reduced caloric intake with use of healthy use of a healthful diet (eg. lean protein, fresh fruits and vegetables, whole grains and low fat) as well as portion control. This diet includes: a 700kcal/day reduction or use of a 1200 to 1500kcal/day plan for adult females and 1500 to 1800kcal/day for males, along with increased physical activity. However, a standardized program may not work for all patients (eg. diabetes or a personal with physical limitations). In these cases, individualization is necessary (Batsis et al., 2016; Harrigan et al., 2016; Kroes et al., 2016; Rodriguez-Cristobal et al., 2017; Ma et al., 2019; Rolls et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016).

Increased physical activity for weight loss is supported by Level I and Level II evidence. Recommended activity consists of at least 150 minutes per week, on most days that included aerobic activity (eg. brisk walking) (Batsis et al., 2016; Cheatham et al., 2018; Kozica et al., 2015; Kroes et al., 2016; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017; Thabault et al., 2016; Welbourn et al., 2018) has been shown to increased caloric expenditure, increase physical functionality and mobility and aid in weight reduction. Again, this will need to be modified to the individual as patients have circumstances that may be prohibitive to exercise such as: physical limitations, climate, comorbidities, responsibilities, and personal desire. Motivation and enjoyment are a key to increased exercise (Batsis et al., 2016; Beeken

et al., 2017; Eaton et al., 2016; Harrigan et al., 2016; Kroes et al., 2016; Samabal et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016).

Weight loss behavioral and motivational counseling is considered to be the gold standard in weight loss (Harrigan et al., 2016) and is supported by Level I and Level II evidence. Counseling can be presented in various forms such as motivational counseling, behavioral counseling or psychotherapy. It can be implemented using various methods (eg. face-to-face, texting, or telephone) and through different media (eg. verbal, video or print materials). The best results come from frequent and continued behavioral and motivational counseling encounters, however the goal is to help the patient to be autonomous and self-monitoring (Hageman et al., 2017; Harrigan et al., 2016; Hartman et al., 2014; Kozica et al., 2015; Ma et al., 2019; Pollak et al., 2016; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016). Peer groups, online discussion boards and weekly meetings have also been supported by high level evidence to be effective interventions when used alone or as part of a multicomponent weight loss program (Hageman et al., 2017)

There are many potential barriers to weight loss. Despite these barriers, motivation can be achieved via a multitude of interventions. High levels of evidence support the use of validated tools to assess readiness to lose weight (eg. the Acceptance and Action Questionnaire for Weight/AAQ-W). Readiness has a direct correlation to successful weight loss (Tapsell et al., 2017; Thalbault et al., 2016; Welbourn et al., 2018). Therefore, a patient must be emotionally ready regardless of physical need. Additionally, weight loss success is greater in patients who have a sense of autonomy and self-efficacy, as well as those who set goals for themselves and who

hold themselves accountable for those goals (Hageman et al., 2017; Harrigan et al., 2016; Hartman et al., 2014; Kushner & Ryan, 2014; Kozica et al., 2015; Ma et al., 2019; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Tapsell et al., 2017).

Autonomy, self-efficacy and weight loss may have improved through self-guided weight loss plans (eg. Ten Top Tips/10TT, online diet plans) (Beeken et al., 2017; Hageman et al., 2017; Tang et al., 2016) as well as goal setting and self-monitoring through the use of diet and activity log, goals using a diary, or tracking device (eg. Fitbit®, Smartphone application, pedometer, or online tracker) (Cheatham et al., 2018; Ma et al., 2019; Rolls et al., 2017; Tang et al., 2016).

There is high level support for the use of tracking technology such as: FitBit® or AppleWatch® or smart phone applications such as MyFitnessPal®, along with weight loss, behavioral and motivational counseling, have been shown to increase physical activity and weight loss within the young and middle aged population (Beeken et al., 2017; Cheatham et al., 2018; Tang et al., 2016). Several studies offered group or peer led activities in an on-line format to increased autonomy, stimulate self-monitoring and provide access to those in remote or limited access communities in an effort to promote weight loss (Beeken et al., 2017; Cheatham et al., 2018; Hageman et al., 2017; Hartman et al., 2014; Kozica et al., 2015; Tang et al., 2016). In order to self-monitor and achieve set goals, various methods have been supported in the literature such as the use of a food and exercise journal (Hartman et al., 2014) or tracking technology such as: MyFitnessPal® (Tang et al., 2016) that can be used to track caloric intake, activity and search menu items and nutrition information. It also sends the user reminders to log

in. These have been shown to be effective mechanisms and enhance both short-term and long-term weight loss success.

In addition to treating comorbidities that can affect weight (eg. depression) (Ma et al., 2019) high level evidence supports the use of pharmacotherapies to enhance weight loss when accompanied by diet, exercise and lifestyle modifications (Kroes et al., 2016; Wellbourn et al., 2018). There are many drug classes that assist with weight loss, among them are: gastrointestinal lipase inhibitors (eg. Orlistat/ Xenical), serotonin 2C receptor agonists (eg. Locaserin/ Belviq), phentermine-topiramate combinations (eg. Bontril), and noradrenergic/ dopaminergic antidepressants (eg. Buproprion). Off label use of serotonic agents (eg. Fluoxetine) have not been approved by the FDA for weight loss, but have been used to treat depression, panic disorder, obsessive compulsive disorder and bulimic eating disorder (Sheehan, Chen, Yanovski & Calis, 2014; Tek, 2016)

Best Practice Model Recommendation

The clinical site for this EBP project was in an underserved community free clinic. All the patient population had limited financial resources, and had difficulty with keeping follow-up appointments, thus limiting possible weight loss interventions. This was taken into consideration when designing this EBP project.

Obesity is a multifactorial chronic disease and no one intervention will work for each individual with consistency (Cheatham et al., 2018; Eaton et al., 2016; Kushner & Ryan, 2014; Ma et al., 2019; McLaughlin et al., 2017; Sambal et al., 2017; Tapsell et al., 2017). The literature review identified an individualized multicomponent intervention as the best practice in the treatment of obesity in adults. This multicomponent intervention

should include identifying patients who are obese by measuring weight and BMI at each visit. For those with a BMI $\geq$ 30, a waist circumference measurement and waist to hip ratio should be obtained as well as an obesity history and health assessment for risks associated with obesity (Batsis et al., 2016; Beeken et al., 2017; Cheatham et al., 2018; Eaton et al., 2016; Harrigan et al., 2016; Tapsell et al., 2017). Prior to starting any intervention, and after determining the need for weight reduction, a weight loss readiness assessment should be completed as there is a direct correlation with readiness and weight loss success (Rolls et al., 2017). Because obesity is often associated with comorbidities, screening for hypertension, diabetes, hyperlipidemia, depression and or anxiety should also be completed when possible (Kroes et al., 2016; Rodriguez-Cristobal et al., 2017; Ma et al., 2019; Rolls et al., 2017; Tapsell et al., 2017). Anthropometric assessment of height, weight, BMI, was completed at baseline and at each visit. Waist circumference and waist to hip ratio should be completed at baseline and week 12. Validated and simple assessment tools, specifically the PHQ-9, as well as the GAD-7 should be incorporated to complete depression and anxiety screening at baseline and at three months. Laboratory studies should be completed at baseline and if necessary, at three months provided the patient is able to complete the studies.

Obese patients had a personalized intervention that includes weight loss with a healthy diet with caloric reduction to 1200 to 1500 kcal per day for women and 1500 to 1800 kcal per day for men, or a caloric reduction of 500 kcal to 700 kcal per day, or use of an evidence based diet. It also involves increased activity, ideally at least 150 minutes per week spanning over at least four days per week. Additionally, lifestyle and weight loss behavioral counseling should be implemented for a period of at least six

months. For this project the first three months of the weight loss counseling would take place during the intervention phase after which clinic staff would provide the remaining follow-up. This behavioral counseling may include motivational counseling, autonomy and self-efficacy building, and goal setting. Additionally, possible individualized use of internet resources such as the National Heart Lung and Blood institute (NIH) Aim for Healthy Weight page and www.choosemyplate.gov may be recommended. Printed educational tools obtained from validated web sites such as: NIH, American Diabetes Association (ADA) or the American Heart Association (AHA) may be provided (Batsis et al., 2016; Harrigan et al., 2016; Kroes et al., 2016; Rodriguez-Cristobal et al., 2017; Ma et al., 2019; Rolls et al., 2017; Tapsell et al., 2017). Medication adjustment utilizing pharmacotherapies that do not have side effects of weight gain and or use of anti-obesity medications may be helpful for some patients (Kroes et al., 2016; Ma et al., 2019). For a select group of adults with BMI $\geq$ 40 or $\geq$ 35 with obesity-related comorbidities, bariatric surgery may be beneficial and a referral would be provided in the primary care setting if the patient does not respond to multicomponent interventions (Batsis et al., 2016; Harrigan et al., 2016;; Kroes et al., 2016; Tapsell et al., 2017) .

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Evidence showed that tailored multicomponent interventions were an effective way to promote weight loss in adults with obesity. Many facilities, including the clinic used for this EBP Project do not use a standard protocol to promote weight loss. Instead, patients may receive basic education regarding the benefit of caloric reduction and increased activity to promote weight loss but lack individualized attention to the patient's resources and personal needs. At this site, obesity management is a challenge despite both staff and patients placing weight loss as a high priority for the population being served.

This project included the EBP project manager's collaboration with: a family practice physician, nurse practitioners (NP), registered nurses (RN), medical assistants (MA), dietician, as well as the office manager, all of whom appreciated the significance of the practice change for the treatment of obesity within this clinical setting. A great many barriers exist when treating obesity including: the stigma associated with obesity, propensity of providers to ignore this chronic disease and provider personal bias, lack of use of affordable and effective treatment options, lack of understanding and knowledge related to obesity and treatment, inappropriate prescribing of medications including those that contribute to weight gain or underuse of anti-obesity pharmacotherapies, all of which contribute to the aversion to provision of best practice recommendations in the management of obesity.

The aim of this project was to help patients and providers to overcome barriers that prevent weight loss in adults with obesity through the implementation of theory-

driven and Evidence-Based best practices. The purpose of this project was to improve selected obesity indicators, including weight, body mass index (BMI), waist circumference, and waist-to-hip ratio, through the implementation of an Evidence-Based multicomponent intervention tailored to individual patient strengths, barriers, and resources. In addition, a secondary aim was to determine if the weight loss intervention resulted in improvement in health outcomes related to obesity, including BP, HbA1c, lipids, as well as depression and anxiety symptoms. The intervention components varied by patient, but in general, options included diet and exercise education, tracking of caloric intake and exercise, lifestyle and behavioral counseling, pharmacotherapies, and referrals when appropriate.

Participants and Setting

This EBP project was conducted in a free family practice clinic in Northeast Indiana that provides primary care to the underserved population across the lifespan. This was the only site utilized for this practice implementation. This site was staffed by two Masters-prepared NPs and a Medical Doctor who also functions as the Medical Director, volunteers who function in various clinical and non-clinical capacities, and a small group of non-clinical and administrative staff. The Medical Doctor had been a physician since 2007 and is Board Certified in Family Medicine. He is an accomplished Family Medicine physician and an Associate Professor at Indiana University School of Medicine. The EBP project manager had never been a member of staff within this facility, thus eliminating the chance of recruiting her own patients into the project sample and, therefore, potential selection bias. Permission for the project's implementation was provided on August 29, 2019 by the Medical Director who approved the project, agreed

with the benefit of the project to the clinic and patient population, identified the project as feasible at this primary location, as well as promoted interest for the project among the clinic's staff.

Eligible participants were recruited during their appointments at the clinic and through in-house advertisement of the program from September 20 to December 10, 2019. Patients who expressed interest were initially interviewed by the project manager to evaluate eligibility. The project manager, the Medical Director and the NPs reviewed the patient charts to determine eligibility based on diagnosis and health risks. Patients who were at least 18 years of age with a BMI of at least 30kg/m2; could understand, speak, read and write in English or communicate through a translator; and were able to commit to the three-month study timeline were eligible. Patients were excluded from the project if they were pregnant or lactating, had cognitive impairment, were not ready to lose weight, or were already in an organized weight loss program. Though patients were asked to commit to the entire three-month length of the project, they were free to drop out at any time. Patients who reasonably could have been harmed by the weight loss interventions were excluded from the study.

Weight loss in the adult population is challenging due to a wide variety of personal factors, including environmental influences and demands, biological and behavioral factors, sociocultural factors, socioeconomics, prior history with weight loss programs, and self-efficacy (Bomberg et al., 2017; Ceccarini et al., 2015; Hageman et al., 2017; Kozica et al., 2015; Pender, 2011; Samdal et al., 2017; Thabault et al., 2016). Research shows that obesity is often the result of lifelong dietary and inactivity habits that are heavily ingrained within the obese individual and changing these habits can be

exquisitely difficult. Thus, it was believed that the merit of this project was to empower patients with obesity to use individualized weight loss interventions that would be most appropriate given their unique personal factors.

Outcomes

Multiple anthropometric, clinical, and laboratory outcomes were measured at baseline and monitored over time, in accordance with the literature. The primary outcome measures were weight and body mass index. Additional weight-related outcomes included waist circumference and waist-to-hip ratio. All of these additional measures are important predictors of morbidity and mortality and associated diseases of the cardiovascular system, metabolic disorders, diabetes, musculoskeletal dysfunction and various cancers (Batsis et al., 2016; Eaton et al., 2016; Hageman et al., 2017; Harrigan et al., 2016; Ma et al., 2019; Tang et al., 2016; Tran et al., 2018). Anthropometric measures of weight and BMI were collected at baseline and at follow-up visits (each week for 4 weeks, then monthly for 2 months). Waist circumference and waist-to-hip ratio were collected at baseline but not at week 12. Anthropometric measurements were collected using standardized procedures and equipment at the practice site are included in Appendix J.

Secondary outcomes included depression, anxiety, blood pressure, glycosylated hemoglobin (HbA1c), and a fasting lipid panel (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides). Each of these secondary outcomes is considered either a predictive factor or consequence of obesity, or both (Beeken et al., 2017; Grossman et al., 2017; Kushner & Ryan, 2014; Rodriguez-Cristobal et al., 2017; Tapsell et al., 2017; Thabault et al., 2016).

Obesity is often associated with chronic mental illnesses including depression and anxiety. Both of these conditions can contribute to obesity (Kushner & Ryan, 2014; Ma et al., 2019; Tapsell et al., 2017; Thabault et al., 2016) as well as predict the failure of obesity treatment (Kushner & Ryan, 2014; Ma et al., 2019; Tapsell et al., 2017; Thabault et al., 2016). Both depression and anxiety were measured at baseline and depression was measured at 3 months afterwards using the Patient Health Questionnaire -9 (PHQ-9) and Generalized Anxiety Disorder-7 Questionnaire (GAD-7). These questionnaires are included in Appendices G and H respectively.

Blood pressure, chronic hyperglycemia, and dyslipidemia are strong predictors of cardiovascular disease, and they are often present along with obesity in adults (ADA, 2019b; AHA, 2018; Curry et al., 2018; NIH, 2019). Because blood pressure is generally measured at each clinic visit as part of standard care, it was measured according to the same schedule as the anthropometric measures. Laboratory data (HbA1c and lipid panel) were obtained at baseline in patients that qualified for the test and were financially able to cover the cost if any. However, no participants completed follow up studies 3 months afterwards. Laboratory results are included in Appendix K.

Intervention

Because singular interventions are generally ineffective at managing obesity, the "intervention" for this EBP project consisted of a set of activities that were tailored to each participant's strengths, resources, and challenges. The tailored multicomponent weight loss program featured the following categories, organized along the mnemonic, "NEWER ME": **N**utrition, **E**xercise, **W**eight loss support, **E**motional support, **R**eferrals, **M**edications, and **E**xpanded accountability. This section will describe the intervention

options within each of these categories and how patients will be matched to weight loss options based on their strengths, resources, and challenges.

Choosing the "Right" Components

All patients were asked to complete a HPM questionnaire (Pender, 2011) about their individual strengths, resources, and challenges when they were enrolled into the project. In addition, the patient was screened upon enrollment for weight loss readiness, depression, and anxiety to determine the appropriateness and scope of certain program components (e.g. emotional support). Those participants who were deemed unready for the intervention based upon their answers were to be excluded at that time. No participant was excluded. In addition, participants who screened positive for either depression or anxiety at the enrollment visit were referred to a Behavioral Health Specialist. The project leader worked with the participant to select specific weight loss strategies based on the patient's responses to the questionnaire and screening tools, thus promoting autonomy, self-efficacy and accountability. Based upon how well the participant was doing at each subsequent visit, modifications to the plan were made, including addition and or subtraction of interventions.

Nutrition

Since a calorie deficit is paramount for all weight loss programs, all participants were instructed to follow a calorie-restricted diet. Depending on their weight loss goals and the participant's personal preference, the patient was prescribed one of three types of diets. The three types of diets for participants without comorbidities based upon National Guidelines (2013) for Managing Overweight and Obesity in Adults (Jensen et al., 2014; Kushner & Ryan, 2014) include eating diets that contain low unsaturated fats,

vegetables and fruits, lean proteins, whole grains and low-fat dairy, as well as increasing water and fiber intake. Caloric restriction components include one of the three following plans:

- Caloric intake of 1200-1500kcal/day for women or 1500-1800kcal/day for men
- 500kcal/day or 750kcal/day caloric deficit
- Use of an evidence–based diets that restricts certain foods such as high fat, high carbohydrate, low fiber foods to create caloric deficit such 0as www.choosemyplate.gov or Weight Watchers ® (Madigan, 2014)

In addition, participants with specific dietary needs (e.g. iron, calcium, stable vitamin K) or restrictions (e.g. sugar, sodium, saturated fat) according to their medical history were prescribed these along with their calorie restriction. Based upon the participants personal learning style, nutritional education was provided to all patients in visual, verbal and written form as well as through use of hands on examples such as product nutrition labels, plates, a deck of cards, measuring cups and spoons for participants who are kinesthetic learners. (Appendix M). Participants were asked to track their caloric intake in their food and exercise log, either via paper journal (Appendix R) or a technology-based application of their choice.

Exercise

The primary way in which calories are expended to produce a calorie deficit is through physical exercise. While there is a wide variety of exercise modalities available, the four main types this intervention will focus on are aerobic, resistance, stretching, and water based. Based on national guidelines for obesity management, all patients were prescribed a minimum exercise plan of moderate intensity exercise for 150

minutes per week, exercising on at least four days per week (Kushner & Ryan, 2014). Though walking was the most recommended and chosen form of exercise, participants could choose what type of exercise they wanted to use. This could be through a formal gym membership and use of equipment and facilities, swimming, bicycling, walking or aerobic activity as desired and tolerated. Education about physical exercise was provided to all patients in both verbal and written form or demonstrated through a professional trainer or instructor at a gym of their preference, such as an aerobics instructor at a class at their personal gym or YMCA (Appendix N). Participants were asked to track their activity in their food and exercise log.

Weight Loss Support

Participants could choose to utilize commercial weight loss programs such as Weight Watchers ® and or the use of community exercise facilities if they felt they needed the extra weight loss support. Per participant preference they may have chosen to utilize their personal gym or YMCA or work out with family or friends. The participants had a choice of how they elected to increase physical activity to meet the guidelines as tolerated and physically capable.

Emotional Support

Each participant was screened for the presence of depression and anxiety at baseline and for depression at the three-month mark using the Patient Health Questionnaire-9 (PHQ-9) as well as the Generalized Anxiety Disorder-7 (GAD-7) respectively. These screening tools were available at the clinical site in multiple languages. The PHQ-9 questions the frequency of depressed mood during the past two weeks. (Appendix E). Participants who screened positive using the PHQ-9, indicated by

a global cut-off score of 10 or more, received a referral to a behavioral health provider to determine if they should be treated for depressive disorder (American Psychology Association, 2019; Wang et al., 2015; Williams & Nieuwsma, 2019). The GAD-7 required the participant to answer seven specific questions related to anxiety-related symptoms using a Likert-type scale (Appendix F). Global scores at or above 5 would receive a referral to a behavioral health provider to determine if they should be treated for generalized anxiety disorder (Ahmad et al., 2017; Plummer et al., 2016).

Emotional support included: motivational counseling; teaching the participant to adopt positive rather than negative self-talk or placing blame; recognizing the misuse of the terminal words always and never when describing behaviors; developing problem solving strategies to manage food intake and situations; learning assertiveness and that they were allowed to say no; identifying stressors and food triggers and the techniques to reduce stressors and emotional eating; or asking for help and enlisting the assistance of family and friends in weight loss efforts. Additional emotional supportive measures included meditation and practicing mindfulness (Perreault, 2019b; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Szczekala et al., 2018; Thalbault et al., 2016; Welbourn et al., 2018).

Referrals

Referrals to a bariatric surgeon should be provided for participants with a BMI of or greater than 40kg/m2 or BMI of or greater than 35kg/m2 with comorbidities, who are highly motivated to lose weight and have not responded to non-surgical medically supervised interventions (Kroes et al., 2016; Jensen et al., 2014; Kushner & Ryan, 2014; Welbourn et al., 2018). This includes behavioral treatment with or without

pharmacotherapies and lost enough weight or maintained weight loss to meet target goals for health risk reduction. These participants should have been referred to a board certified and qualified bariatric surgeon. Unfortunately, in the current clinical setting, with this patient population, bariatric surgery was not a possibility as the participants did not have health insurance or financial resources to cover the costs. During the time frame of this EBP Project there were no *pro bono* bariatric surgery options. Therefore, patients who expressed an interest in receiving bariatric surgery for weight loss were provided with information about local physicians who could offer this service, but this referral would not be made unless patients requested information.

Referrals were also provided as needed for: mental health counseling and or psychotherapies; physical therapist and or orthopedic referral for participants with musculoskeletal dysfunction; dietitian for specific dietary needs not met by this program; and specialist providers for management of comorbidities such as cardiologist, endocrinologist or pain management (Kushner & Ryan, 2014; Ma et al., 2019; Tapsell et al., 2017; Welbourn et al., 2018) as these providers were available at or accessible through the clinic.

Medications

Medication interventions included: a review of each participant's current medications and discussion of potential drugs that could cause weight gain as well as possible alternatives to their use; starting or switching to antidepressant with the least potential for weight gain; starting weight loss medications; and medication education.

Specific drugs that are known to cause weight gain include some of the following: tricyclic anti-depressants (TCA), monoamine oxidase inhibitors (MAOI's), selective

serotonin reuptake inhibitors (SSRI's), insulin, sulfonylureas, beta blockers, contraceptives, and steroid hormones. Alternative choices include: bupropion (norepinephrine-dopamine reuptake inhibitor, NDRI), protriptyline (TCA), fluoxetine (SSRI), or sertraline (SSRI), metformin (bioguanide), liraglutide (GLP-1 receptor agonist), orlistat (lipase inhibitor), angiotensin-converting-enzyme inhibitor (ACE-I), calcium channel blockers (CCB), barrier methods of contraception, and nonsteroidal anti-inflammatory agents. Changes in medication regimens were made in collaboration with the provider, as appropriate, and within the limitations of this free clinic's formulary. Use of pharmacotherapies for weight loss for participants with a BMI of 30kg/m^2 or higher, or a BMI of 27 kg/m^2 or higher with comorbidities is indicated (Jensen et al., 2014; Kushner & Ryan, 2014). Recommended pharmacotherapies include orlistat, lorcaserin or phentermine/topiramate XR. Lorcaserin is newer and has shown positive results as it affects appetite due to its high affinity for the 5-hydroxytryptamine 2C receptor, a subtype of *5-HT receptor* that binds the endogenous serotonin (Jensen et al., 2014; Kushner & Ryan, 2014). However, due to site limitations, phentermine and topiramate are the drugs usually prescribed and are provided at no charge to the patients when pharmacotherapies are indicated. Other options may have been prescribed if the patient chose but would have needed to be obtained from an outside pharmacy and would not be free of charge. During this project no participant chose to use any weight loss specific pharmacotherapies.

Expanded Accountability

Participants tracked caloric intake and physical activity through either a paper journal or electronic technology/app (eg. FitBit®, MyFitnessPal®, SmartWatch®)

immediately after each meal and activity for weekly and monthly review with the program manager. Participants were asked to keep a daily journal and track mood and challenges, use of weight loss interventions and progression of goals and were offered simple journaling tools to use if they chose (Appendix R) or they purchased a journal or created their own document. Behavioral and lifestyle education and counseling was provided and reinforced at each appointment to enhance autonomy and accountability.

To expand autonomy and accountability, diet and exercise journals were reviewed for use and content, usually completed via verbal self-reporting. Along with reinforcement of weight loss education, observation of caloric intake and food substance was discussed with the participant. Encouragement and motivational counseling were provided, and modifications were addressed at each appointment as needed. Daily journals were reviewed with each participant via verbal interaction and self-reporting, looking for behavioral concerns and use of interventions and potential need for modifications. Additionally, review of realistic goals and progression toward successful attainment through lifestyle and behavioral modification was discussed with the participant at each visit to provide for further autonomy and self-efficacy.

Comparison

The comparison data for this project were obtained through a retrospective review of electronic medical records (EMR) prior to project implementation on September 20, 2019. The review consisted of a sample (n=25) of patients from the Matthew 25 Health and Dental Clinic who met the eligibility criteria for this project and who were seen in that clinic approximately 3 to 5 months apart. The goal of this retrospective review was to determine if standard care at the clinic resulted in

statistically significant weight loss over the period with this type of patient population. The standard care weight loss intervention at that time consisted of advice to lose weight with a healthy diet, to increase physical activity to at least 150 minutes per week with exercise on most days of the week.

Characteristics of this comparison sample (*n* =25) are provided in Table 4.2. As described in Chapter 2, this standard care intervention did not result in statistically significant weight loss. In fact, the mean baseline BMI was the same as the mean BMI 3 to 5 months after their baseline visit (38.60 kg/m^2 [SD 7.17] vs. 38.58 kg/m^2 [SD 7.31]) respectively.

Planning

A great deal of time and commitment was dedicated to the planning phase of this EBP Project in order to safeguard quality, provide evidentiary support for content, as well as increase the likelihood of a successful outcome. This project was originally planned and slated to begin at a federally qualified health clinic in Northwest Indiana. However, after a change in clinic leadership, the project was relocated to the current site. This change in clinical location and client population resulted in significant alterations in the timeline, stakeholder support, and design of the project, and delayed commencement of the project by approximately 2 months.

After discussion with key stakeholders at the current project site, as well as reflecting on prior clinical experience as a staff nurse, the need for practice change became apparent. Upon the completion of a comprehensive and exhaustive literature search for the best and current evidence practice recommendations were determined and were incorporated within this EBP Project. The project manager planned the project

with close collaboration from key stakeholders including patients, physician, NPs, RNs, MAs, volunteers, and the office manager. The intended project was reviewed and discussed. Based on stakeholder input, the EBP Project was revised to meet the needs and resources at the clinical site. Support for the project and permission for implementation was granted by the Medical Director on August 29, 2019. Project planning and modification continued with the contributions from the project manager, project faculty advisor, key stakeholders, and through additional research as well as feasibility of EBP interventions within this specific clinical setting.

Data

For this project, a combination of anthropometric, clinical, and laboratory data was to be collected using standardized procedures used by providers at the practice site.

Anthropometric Data. The anthropometric measures in this study were height, weight, BMI, waist circumference, and waist-to-hip ratio. Height in inches and centimeters and weight in pounds and kilograms were both measured using the digital scale that is normally used at the clinical site (Health-O-Meter Model 600KL). The scale was zeroed before each patient use according to the manufacturer's instructions. The BMI was automatically calculated in the clinic's EMR system when height and weight data were entered. Weight and BMI were measured at each visit. Waist and hip circumferences were measured in centimeters using a standard tape measure. The waist circumference was measured at the level of the right iliac crest, and hip circumference was measured at the level of the right greater trochanter. Waist

circumference and waist-to-hip measures were completed at baseline but due to clinical resources and protocol, it was not completed at the week 12 visit.

Clinical Data. The clinical measures used in this study were blood pressure, weight loss readiness, depression symptoms, and anxiety symptoms. Blood pressure will be measured in mmHg using the portable digital blood pressure device in the clinic (Welch Allyn Model 901058). This device had an accuracy $\pm$5 mmHg. Blood pressure was measured at each visit to screen for hypertension and to determine change with weight loss.

Weight loss readiness was measured using two tools. The Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQ-W) (Appendix G) and the Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF) Tool (Appendix H). The AAQ-W, used with permission (Appendix T), measures pragmatic avoidance and psychological rigidity that play a part in health problems including weight control. This tool targets weight control interventions (e.g. acceptance of tough or unpleasant emotions) (Lillis & Hayes, 2008). The AAQ-W tool correlates with the common levels of avoidance and rigidity as measured by the AAQ (r-0.58, p<0.001), obesity-related quality of life using ORWELL (r=0.64, p,0.001), psychological distress using GHQ (r=0.40, p<0.01) and BMI (r=0.39, p<0.001). There was also a correlation with self-reported binge eating (r=0.36, p<0.01) and exercise sessions per week (r= -0.30, p<0.01) as well as making healthy food choices while dining out (r= -0.40, p<0.01) (Palmeria, Cunha, Gouveia, Carvalho & Lillis, 2016). This tool was administered via written format and is considered an effective and validated tool to measure weight loss readiness.

Additionally, weight loss readiness was measured with the WEL-SF tool. The WEL-SF measures eating self-efficacy or one's belief in their ability to perform in a given situation. Low self-efficacy is correlated to lower weight loss success and high self-efficacy is correlated to greater weight loss success. Self-efficacy for eating is a predictor of acquired weight loss behaviors. This tool asks the participant to reflect on how confident they feel in relation to situations in which overeating may become a problem. In its original form the Weight Efficacy Lifestyle Questionnaire (WEL) is a routinely utilized measure of eating self-efficacy that comprises 20-efficacy and five circumstance related elements. The short-form WEL (WEL-SF) is a much shorter form of the tool that still addresses key aspects. There is a significant correlation between total scoring of the WEL-SF and WEL: Pearson's *r* value of 0.968 and parallel r^2 value of 0.937. The WEL-SF is a valid measure of eating self-efficacy with 94% of the variability of the WEL (Ames, Heckman, Grothe & Clark, 2012). This tool was administered via written format and is considered an effective and validated tool to measure weight loss readiness. These tools were administered to patients only upon enrollment in the project.

Because weight, depression and anxiety have a correlation (Kushner et al., 2014; Ma et al., 2019) screening of depression and anxiety was also to be completed. The Patient Health Questionnaire-9 (PHQ-9) (Appendix E) questions the frequency of depressed mood during the past two weeks. Participants who screened positive using the PHQ-9, indicated by a cut-off score of 10 or more, received further evaluation and referral to a behavioral health provider to determine if they should be treated for depressive disorder. PHQ-9 scores greater than 10 provides the most ideal balance

between sensitivity at between 0.871 to 0.88 and specificity at between 0.835 to 0.88 and a Cronbach's alpha of test-retest reliability of 0.809 and 0.882, respectively (American Psychology Association, 2019; Kroenke, Spitzer, & Williams, 2004; Wang et al., 2015). For this project, the administration of the PHQ-9 was twofold. It was administered via written format at baseline and at 12 weeks to screen for depression and to determine change in depression symptoms when accompanied by weight loss. The PHQ-9 is recognized as an effective validated tool useful when diagnosing and planning treatment for depression and providing continuity of care.

The Generalized Anxiety Disorder (GAD-7) (Appendix F) tool was used to screen for anxiety disorders, again the purpose of which was twofold. It was to be administered via written format at baseline and at week 12 to screen for anxiety and to determine change in anxiety symptoms when accompanied by weight loss. This tool involves DSM-5 criteria and requires the participant to answer seven specific questions related to anxiety-related symptoms using a Likert-type scale. A score at or below four indicates no or minimal anxiety; between five and nine indicates mild anxiety; between ten and fourteen indicates moderate anxiety; and fifteen or greater indicates severe anxiety. The GAD-7 has a Cronbach's alpha of 0.92 (Ahmad et al., 2017). Plummer and colleagues determined as a cut-off a score of eight to detect GAD during a systematic review and meta-analysis in a population of n=5223, and at this score, the GAD-7 had a pooled sensitivity of 0.83 (95% CI 0.71-0.91) and specificity of 0.83 (95% CI 0.71-0.91). Additionally, they found that scores between 7 and 10 had similar results. However, a cutoff score of 10 was identified as the optimal point for sensitivity 0.89 and specificity 0.82. At that score the GAD-7 had a test–retest reliability of p = 0.85 (Rutter & Brown,

2017). For this project, the GAD-7 was administered at baseline but after reevaluation of clinical resources and protocol, it was not completed at the week 12 visit. The GAD-7 is recognized as an effective validated tool useful when diagnosing and planning treatment and continuity of care.

Laboratory Data. Laboratory outcomes in this project included the hemoglobin A1c and a fasting lipid panel, consisting of the HDL, LDL, and total cholesterol. Blood samples were collected and analyzed using normal clinic procedures (at an off-site laboratory), and results were recorded from the electronic medical record.

At a cut-off value of 6.5%, hemoglobin A1c has a sensitivity of 0.852 and a specificity of 0.823 to detect clinically significant diabetes mellitus (Yap et al., 2017) – a potentially disastrous consequence of chronic obesity. Hemoglobin A1c will be measured upon enrollment and at the 3-month follow-up visit if clinically appropriate.

Hypercholesterolemia is associated with cardiovascular diseases such as atherosclerosis and coronary heart disease. Adipose tissue is an active endocrine and metabolic site, linked to the development of these chronic diseases. Much of the metabolism of cholesterol takes place within adipose tissue. Hypercholesterolemia has been proven toxic to smooth muscle cells, hepatocytes, and cardiomyocytes, and to induce cholesterol excess causing adipocytes hypertrophy thus leading to cardiovascular diseases (Aguilar & Fernandez, 2014). Hypercholesterolemia, specifically LDL cholesterol is associated with a 20% higher risk of cardiovascular disease and total cholesterol is associated with a 10 to 20% higher risk of premature cardiovascular morbidity and mortality (Upadhyay, 2015). For lipid panels, with a total cholesterol end point of 210, the sensitivity is 0.70 and specificity is 0.925 for detection

of LDL cholesterol greater than or equal to 130 and a sensitivity of 0.967 and specificity of 0.856 for detection of non-HDL cholesterol greater than or equal to 160. At a total end point of 230, the sensitivity is 0.749 and the specificity is 0.920 for identifying LDL cholesterol greater than or equal to 160 and a sensitivity of 0.986 and specificity of 0.898 for non-HDL cholesterol greater than or equal to190 (Aguilar & Fernandez, 2014; Kim et al., 2019; Nantsupawat et al., 2018). Obese population have a higher hazard ratio than non-obese population with BMI below 30kg/m2, specifically an all-cause mortality of 1.94 (95%CI:1.11-3.42) and those with CVD have a hazard ratio of 1.84 (95%CI:1.15-2.93) compared to non-obese population. An adjusted hazard ratio for death due to CVD at a 95% CI for obese patients with hypercholesterolemia is 1.04 (0.77-1.41; *p*=0.780). The adjusted hazard risk for death/overall mortality at a 95%CI for obese patients with hypercholesterolemia is 0.86 (0.60-1.22; *p*=0.388) (Ponce-Garcia et al., 2015).

Time

The baseline visit occurred when the participant came to the clinic for a primary care visit during the enrollment period (September 20 through December 10, 2019). Participants were to return to the clinic every seven days for the next 3 weeks to check weight and BMI, as well as to reinforce their weight loss plan. After their third weekly follow-up visit, they were to return to the clinic once per month to collect data and reinforce their weight loss plan. On their final visit (3 months after enrollment), a final set of anthropometric, clinical, and laboratory data were to be collected, and participation in the project was finished. Participants were encouraged to continue their weight loss

plan or make modifications at the recommendation of their primary care team. The EBP Project timeline can be found in Appendix I.

Collection. Data collection took place during in person face-to-face encounters with the project manager and clinical providers and staff from September 20, 2019 through March 3, 2020. This recruitment process was continuous through December 10, 2019, with starting and completion dates varying among participants, but ending at the 12-week mark after initial visit for each participant. It began at the initial baseline patient appointment when the patient was provided with the description of the EBP Project and interventions. Once the participant agreed to participate in the project, they were given the initial weight loss packet containing the PHQ-9, GAD-7, AAQ-W, and WEL-SF assessment tools. Based on these results, the patient was given individualized weight loss instructions using the NEWER-ME framework. Along with the PHQ-9, GAD-7, AAQ-W, WEL-SF, the participant's anthropometric and blood pressure measurements were completed and recorded, using the safeguards that were in place to protect health information. When indicated, secondary outcome measures data: HbA1C and lipids (total cholesterol, HDL, LDL and triglycerides), were also recorded with the identical safeguards.

All data was collected under HIPPA and CITI guidelines. To maintain anonymity participants were provided with a four-digit numeric code upon enrollment in the project that was their identifier for data collection. This code consisted of two letters and two numbers: AA01, AA02, AA03 and so on for those participants evaluated on the first day, and AB01, AB02, AB03 and so on for those participants evaluated on the second day of the first week of the project. Those participants who enter during the second week of the

project will be given a code BA01, BA02, BA03 and so on as above. A list of participants and their corresponding codes was kept in a password protected Microsoft Excel® spreadsheet as well as a paper copy kept in a locked filing cabinet. The code was recorded on all assessment tools in the upper margin including demographics, anthropometric measurements, AAQ-W, WEL-SF, PHQ-9, GAD-7 and spreadsheets. The code served as the method to identify each participant and compare comprehensive data. Data collected using paper-and-pencil forms encoded with the participant's four-digit numeric code, was then entered into a password-protected Excel spreadsheet within 8 hours of collection. All paper forms were retained in a locked filing cabinet in the EBP Project Manager's locked office. Upon completion of the project, all paper forms were shredded and only the electronic data were retained.

Management and analysis. In order to perform statistical analysis and comparisons of data, the project manager had access to the specified folder kept in the locked cabinet. Participant data and codes remained safely stored when not in use by the project manager. No identifying information was disclosed, and participants were only referenced by code during communication regarding the EBP Project. Upon project completion, all participant information including code list and all paper forms were shredded and only the electronic data were retained.

The retrospective (comparison) and the prospective (intervention) samples were described using appropriate measures of central tendency and dispersion. Continuous descriptive variables (age, weight, height, waist and hip circumference, waist-to-hip ratio, BMI, SBP, DBP, HbA1c, total cholesterol, LDL, HDL, triglycerides, PHQ-9, GAD-7) were summarized using means and standard deviations. Categorical descriptive

variables (ethnicity, sex, age) were summarized using frequencies and proportions (Figures 4.2, 4.3, 4.4). All data analyses were completed using the Statistical Package for Social Sciences (SPSS) Version 25. The reference for SPSS was Cronk (2017). The code book used in this project is included in Appendix S. Descriptive analysis included means and standard deviations for continuous variables. Due to sample size, continuous dichotomous outcome variables were analyzed using Wilcoxon signed rank tests and assigned a level of significance equal to .05. Whether continuous or categorical, descriptive variables that were significantly different between the retrospective and prospective samples were identified as potential confounders.

To determine if the NEWER-ME tailored weight loss intervention resulted in statistically significant weight loss in the prospective sample, the means for the continuous anthropometric measures (weight and BMI) along with blood pressure were compared from baseline to the final study visit using Wilcoxon signed rank tests. Differences with a *p*-value less than .05 were considered statistically significant. However, no week 12 comparison data were available for waist circumference, waist-to-hip ratio, laboratory measures (hemoglobin A1c, lipid levels) or GAD-7 global scores.

The number of patients with clinically significant weight loss (i.e. greater than 3% of their baseline BMI) was compared between the retrospective sample (comparison group) and the prospective sample (intervention group) using Wilcoxon signed rank tests. A difference with a *p*-value less than .05 was considered statistically significant.

Protection of Human Subjects

The protection of human subjects was sustained throughout this EBP Project. The project manager was educated regarding all ethical aspects via graduate ethics

coursework as well as through the completion of the NIH Protection of Human Research Participants course in April 2018 and all precautions to protect participants and preserve their anonymity were taken. The course certificate can be found in the appendices (Appendix A). The project manager applied for and ultimately gained approval and exempt status for this EBP Project from the Valparaiso University Institutional Review Board (IRB) on September 12, 2019.

Confidentiality was maintained through use of a private space when meeting with participants. Prior to beginning any interventions, all potential participants were provided with the description of the EBP Project and interventions and a list of patient rights. No patient was coerced, pressured or threatened to participate. All potential participants were informed that their involvement was voluntary, and that they could withdraw from the project at any time without retribution or penalty. They were advised that the project would not result in additional cost beyond what they would normally pay for primary care at the clinic. They were informed that this was a DNP EBP project and standard of care and were told about the need for data collection and safeguards in place to maintain privacy. All potential participant questions were answered to their satisfaction. Only pertinent demographic and clinical data were collected. All collected data remained in secure location and patient confidentiality would be maintained via safeguards, participant four-digit coding, passwords and locks. Upon completion of the project, all paper forms and participant codes were shredded and only the electronic data were retained. Because this project did not fall under the purview of “Human Subjects Research,” the requirement for informed consent was waived.

Chapter 4

FINDINGS

The purpose of this project was to implement an Evidence-Based protocol incorporating a multicomponent intervention tailored to individual patient strengths, barriers, and resources. The primary purpose of this EBP project was to improve selected obesity indicators, including anthropometric measures of weight, BMI, and the achievement of 3% weight loss from baseline. The secondary purpose was to determine if the weight loss intervention resulted in improvement in BP as well as depression symptoms measured with the PHQ-9. Analyses consisted of participant demographics and primary and secondary outcomes.

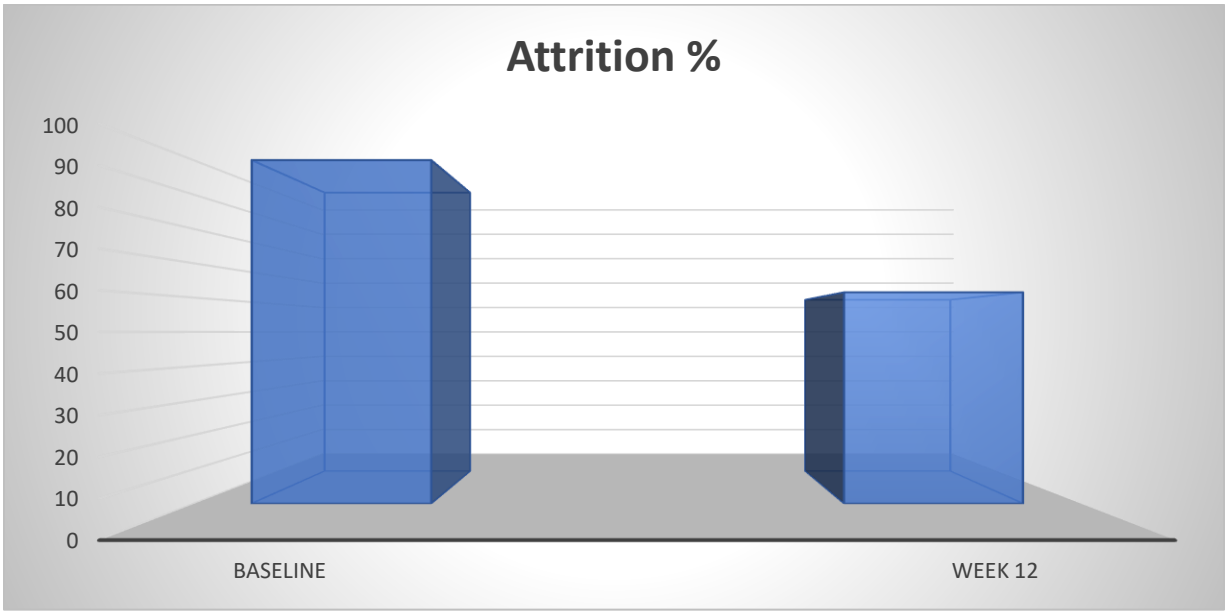
Findings. Findings indicated that participants had statistically significant weight loss in pounds from baseline to week 4. This weight loss was not sustained at week 8 but was significant among those who finished the program beyond week 8. Changes in BMI were statistically significant from baseline to weeks 4 and 12, but not from baseline to week 8. Neither SBP nor DBP were significantly improved from baseline for weeks 4, 8 or 12. Depression as measured by PHQ-9 scores decreased from baseline to week 12, and results were statistically significant.

Participants

Size. In total 26 participants started the program with staggering start dates and were followed for twelve weeks. There was moderate attrition (38.5%) with 16 participants completing at least one follow-up visit during the 12-week project period (see Figure 4.1). Participants cited one or more reasons for program discontinuation, including: outside commitments or disinterest (n=12), weather (n=2), transportation

difficulties (n=2), illness or exacerbation of disease (n=1), pregnancy (n=1), obtained insurance (n=1), and eleven participants cited ‘other’ as the reason or were unable to be contacted.

Figure 4.1. Attrition percentages of project group



Characteristics. The prospective sample is described in Table 4.1 and Figures 4.2, 4.3, 4.4 and 4.5. Most participants identified as white and Hispanic/Latino (77%), female (81%), and able to speak some English (77%). All clinic patients were at or below 200% of poverty level, and none had health insurance. The mean age of the sample was approximately 40 years.

Table 4.1. *Demographic variables for prospective group*

Variable	Frequency
Number of Participants	26
Age, mean (SD)	39.73 (11.09)
Age, min-max	18 – 57

Sex	
Female, *n* (%)	21 (80.8)
Male, *n* (%)	5 (19.2)
Race	
White, *n* (%)	26 (100)
Ethnicity	
Hispanic / Latino, *n* (%)	20 (77)
Non-Hispanic / Latino, *n* (%)	6 (23)
Able to Speak English	
Yes, *n* (%)	20 (77)
No, *n* (%)	6 (23)
Income	
Below poverty level, *n* (%)	26 (100)
Above poverty level, *n* (%)	0 (0)
Insurance Coverage	
No third-party payer, *n* (%)	26 (100)
Any third-party payer, *n* (%)	0 (0)

Figure 4.2. Race and ethnicity: prospective group

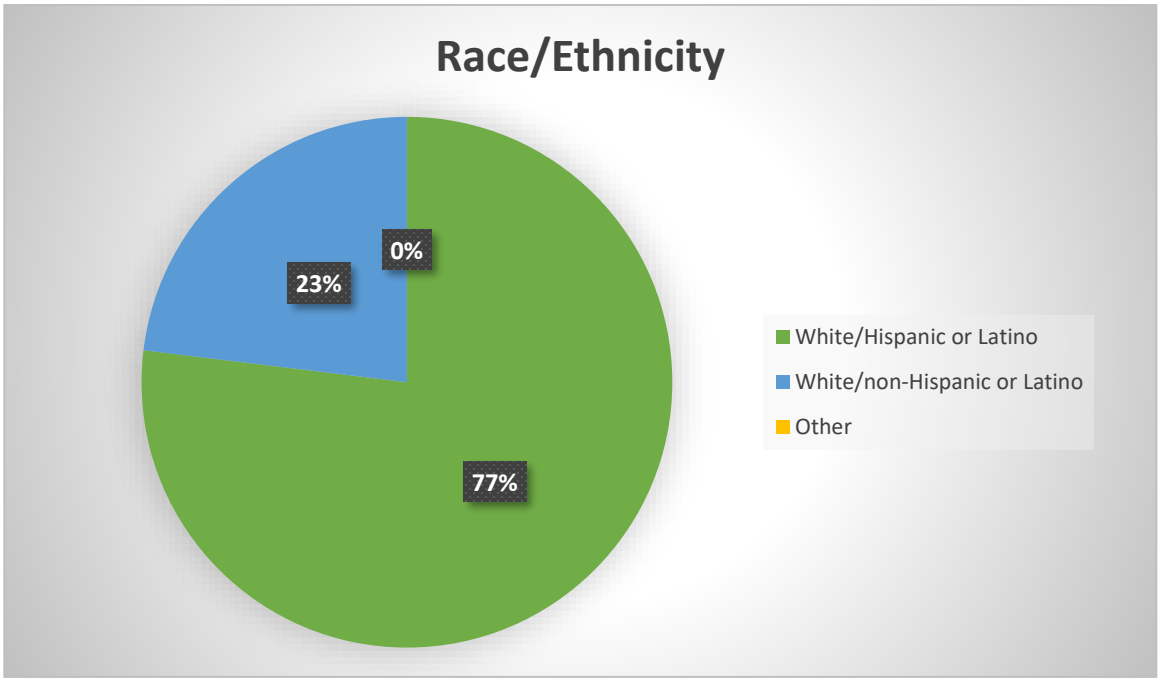


Figure 4.3. Gender

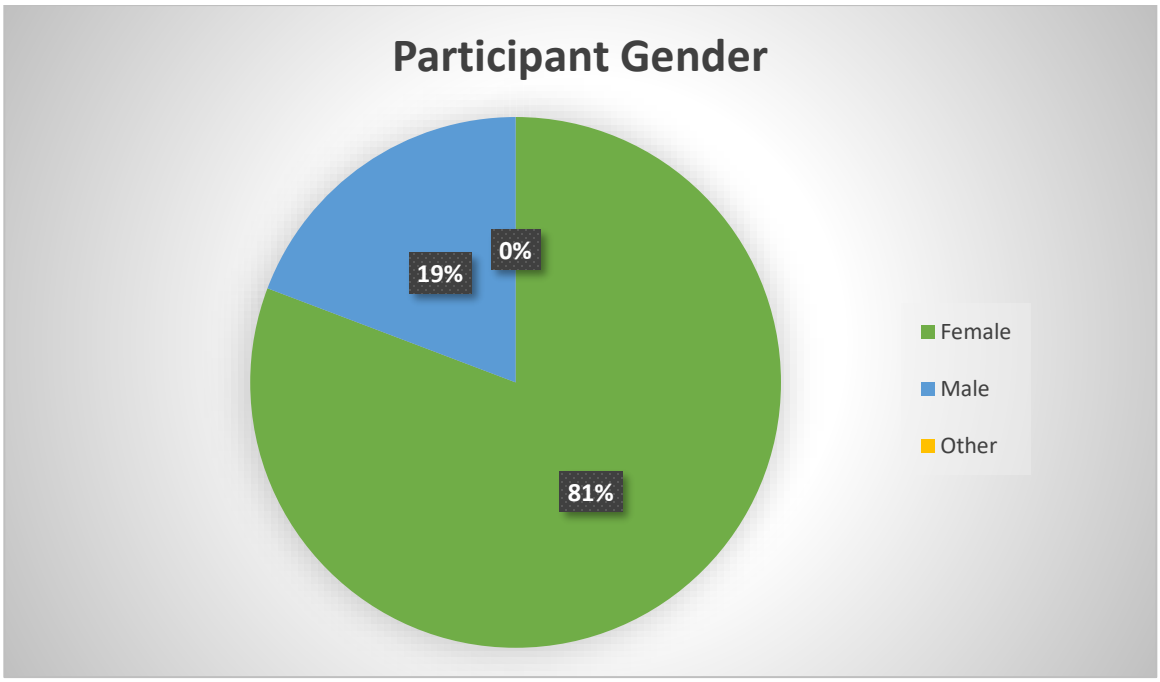


Figure 4.4. Age

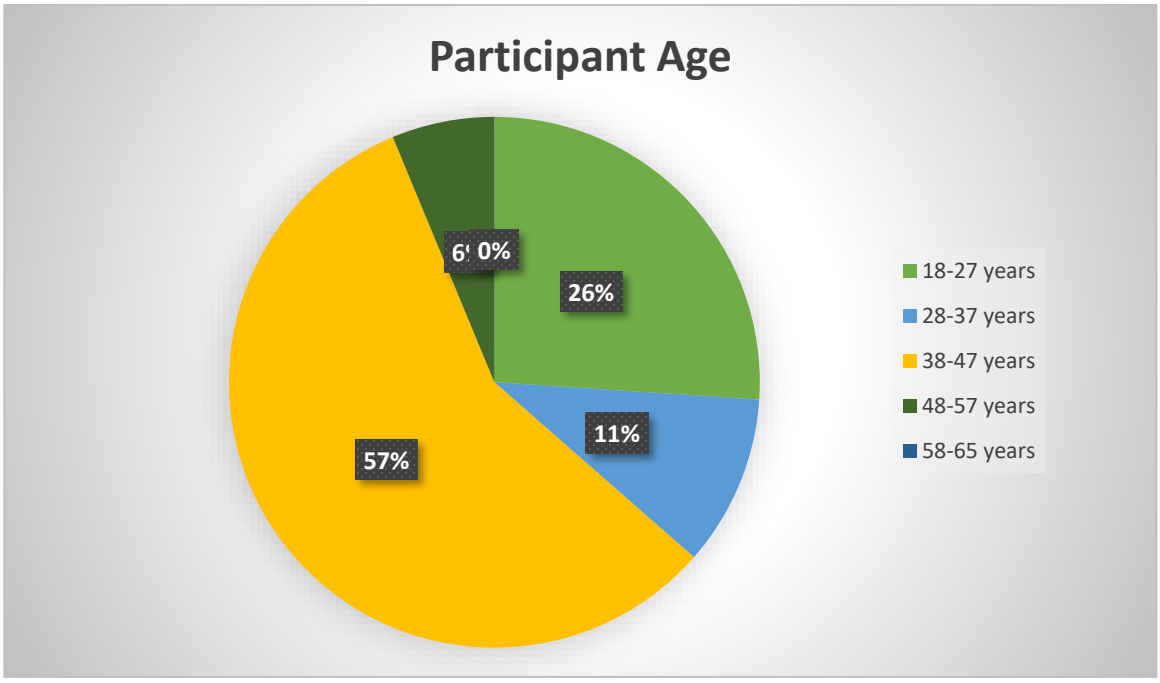
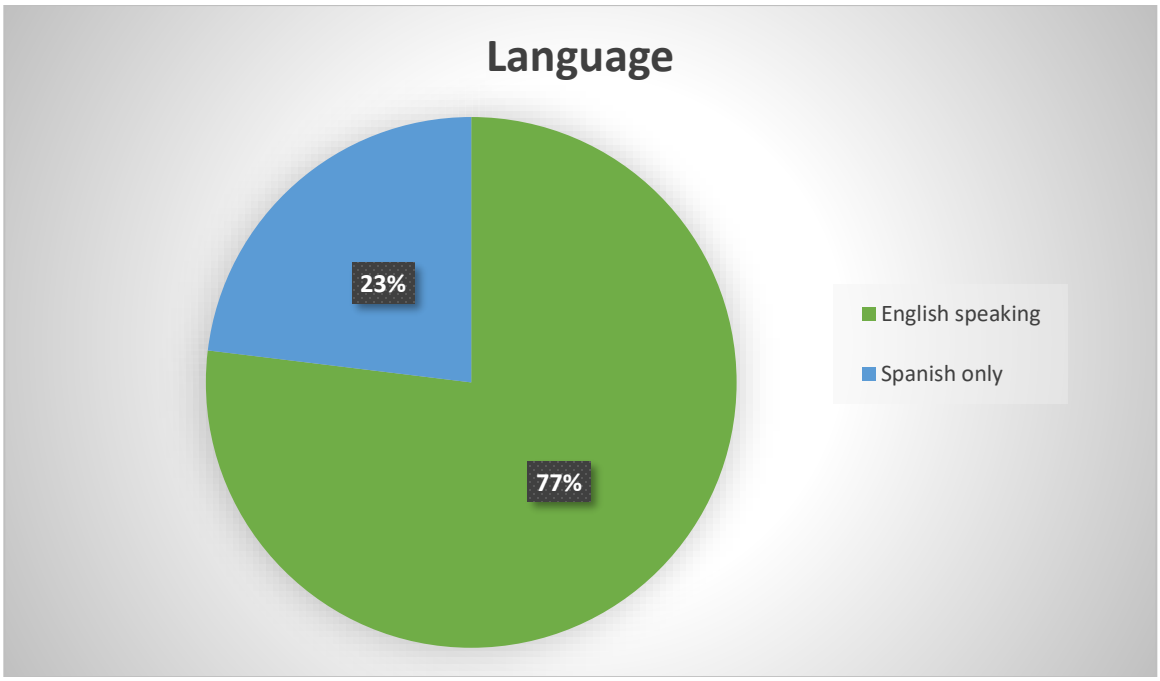


Figure 4.5. Primary Language



Changes in outcomes

Statistical testing. For most of the variables in this project, participants served as their own controls. Due to the small number of matched observations (n = 26), differences in continuous outcome variables between baseline and follow-up visits (i.e. 2 to 4 weeks after baseline and 5 to 12 weeks after baseline) were tested for statistical significance using the nonparametric equivalent of the paired t-test – the Wilcoxon signed-rank test.

To analyze whether the intervention resulted in achievement of at least 3% body weight loss, compared to no intervention, the target weight loss for each participant was calculated by multiplying their weight in pounds at baseline by a factor of 0.03. If the difference between their final follow-up weight and their baseline weight was equal to or larger than their 3% goal, they were identified as having “Met” their 3% goal. If this difference was less than their 3% goal, they were identified as having “Not Met” their goal.

The comparison group for this analysis consisted of a retrospective convenience sample of patients who were seen at the project site prior to beginning this project. Participants were included in this retrospective sample if they were seen at the clinic within the last year, had at least 2 documented weights within 5 months apart, and otherwise met the project’s eligibility criteria. Race and ethnicity data were not available for comparison. Characteristics of this comparison group are provided in Table 4.2. Briefly, participants in the comparison group tended to be older than those in the project group, but there was a similar tendency for participants in the comparison group to be female, have no insurance, and live in poverty.

Table 4.2. *Retrospective comparison group demographic characteristics*

Variable	Frequency
Number of Participants	25
Age in years, mean (SD)	46.96 (13.81)
Age, min-max	19 – 71
Sex	
Female, *n* (%)	18 (72)
Male, *n* (%)	7 (28)
Income	
Below poverty level, *n* (%)	25 (100)
Above poverty level, *n* (%)	0 (0)
Insurance Coverage	
No third-party payer, *n* (%)	25 (100)
Any third-party payer, *n* (%)	0 (0)

The difference between achievement of at least 3% weight loss between baseline and the latest follow-up visit for the prospective group was tested for statistical significance using the chi-square test of independence. For all inferential analyses, differences were considered statistically significant if their *p*-value was below .05. All analyses were completed using the Statistical Package for Social Sciences (SPSS) Version 25.

Weight. The mean weight in pounds at baseline was compared to the mean weight at Week 4 (i.e. from any follow-up visit between weeks 2 and week 4), Week 8

(i.e. from any follow-up visit between weeks 5 and 8), and at Week 12 (i.e. from any follow-up visit between weeks 9 and 12). A decrease in mean weight was seen between week 1 and week 4 (228.96 lbs [SD 47.16] vs 214.87 lbs [SD 44.68], respectively), which was statistically significant (p = .026). However, weight loss from baseline to Week 8 (228.96 [SD 47.16] vs 221.73 [SD 37.01], respectively; p = .686) and from baseline to Week 12 (228.96 [SD 47.16] vs 221.57 [SD 52.20], respectively; p = .088) was not statistically significant (Table 4.3) (Figure 4.8).

Body mass index. The mean BMI at baseline was compared to the mean BMI at Week 4, (i.e. from any follow-up visit between weeks 2 and week 4) and at Week 12 (i.e. from any follow-up visit between weeks 9 and 12). A statistically significant decrease in mean BMI was seen from baseline to week 4 (39.87 kg/m^2 [SD 6.19] vs 38.27 kg/m^2 [SD 6.57], respectively; p = .028) and from baseline to week 12 (39.88 kg/m^2 [SD 6.19] vs 38.64 kg/m^2 [SD 6.93], respectively; p = .023), but not from baseline to week 8 (i.e. from any follow-up visit between weeks 5 and 8), (39.87kg/m^2 [SD 6.19] vs 40.58 kg/m^2 [SD 6.45], respectively; p = .180) (Table 4.3).

Met 3% weight loss goal. In the prospective group, ten participants out of 26 lost weight however, only 27% of all participants met the goal of a 3% total body weight loss at twelve weeks (Table 4.3) (Figure 4.7). In comparison with the retrospective group who had only four participants out of twenty-five, or 16%, reach the 3% total weight loss goal (p=.034) (Figure 4.6).

Figure 4.6. Retrospective group who met 3% total weight loss goal

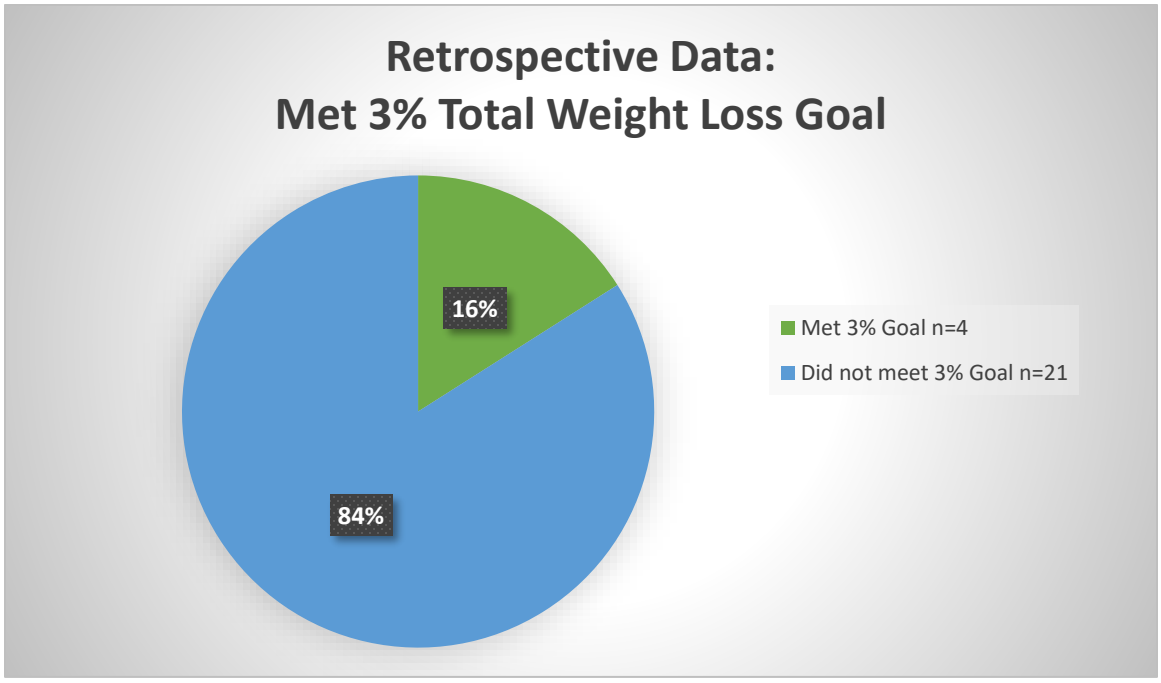
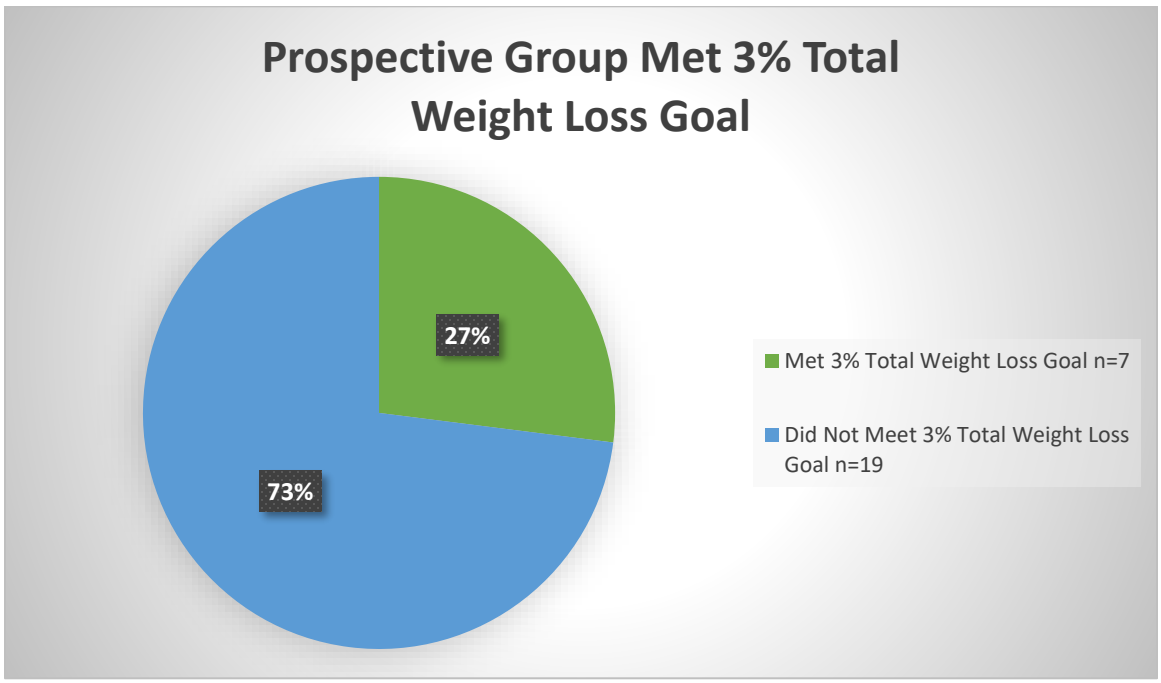


Figure 4.7. Prospective group who met 3% total weight loss goal



Waist circumference and waist-to-hip ratio. These variables were not measured at follow-up due to staff and clinical time limitations. Therefore, a comparison of neither

waist circumference nor waist-to-hip ratio between baseline and follow-up could be calculated. Baseline means were 117.26 cm (SD 12.72) and 0.96 (SD 0.10) respectively (Table 4.3).

Blood pressure. The mean SBP at baseline (127.96 mmHg) was compared to the mean SBP at weeks 4 (123.75 mmHg, SD 15.03), 8 (134.6 mmHg), and 12 (132.33 mmHg, SD 19.79). There were no statistically significant differences in mean SBP between baseline and any follow-up time frame, although there was a tendency for SBP to be higher at the week 12 follow-up visits compared to baseline (Table 4.3) (Figure 4.9). (Week 4 data includes last recorded measure weeks 2, 3 or 4 and week 12 data includes last recorded measure weeks 9, 10, 11, 12)

The mean DBP at baseline (77.96 mmHg) was similarly compared to mean DBP at weeks 4 (70.08 mmHg, SD 8.03), 8 (74.8 mmHg), and 12 (78.50 mmHg, SD 8.03). The DBP at week 4 was not significantly lower than baseline (p = .814), nor at weeks 8 (p = .273) or 12 (p = .754) (Table 4.3) (Figure 4.9). (Week 4 data includes last recorded measure weeks 2, 3 or 4 and week 12 data includes last recorded measure weeks 9, 10, 11, 12)

Depression. The mean PHQ-9 score at baseline (10.25) was compared to the mean PHQ-9 score at week 12 only (5.87). There was a statistically significant reduction in depression severity during this time frame (p = 0.14) (Table 4.3) (Figure 4.9).

Anxiety. The GAD-7 was not measured at the week 12 follow-up visit because of staffing and clinical time constraints and current clinical practice policy. Therefore, a statistical comparison of anxiety between baseline and follow-up could not be calculated. Mean score at baseline was 8.375 (SD 5.41).

Lab Data. Mean glycosylated hemoglobin, total cholesterol, LDL, HDL, and triglycerides were only measured at baseline (Table 4.3). Therefore, no statistical comparisons between baseline and follow-up could be calculated for any of these biomarkers. HbA1c and lipid tests data were only available at baseline. Mean HbA1c was 6.28 (SD 1.04), lipid test means included total cholesterol 180.14 (SD 47.15), LDL 88.83 (SD 31.37), HDL 51.57 (SD 13.35) and triglycerides 207.57 (SD 111.99).

Secondary outcome data included blood pressure, HbA1c and lipid tests, depression and anxiety screening. No data was available for HbA1c or lipid tests for week 12. PHQ-9 scores ranged from 0 to 16, with a mean score of 6.3 (SD 5.8) (Figure 4.9). One GAD-7 score was recorded for week 12, the score was 1 for this participant who scored a 3 at baseline.

Table 4.3. *Statistical analyses of outcome variables*

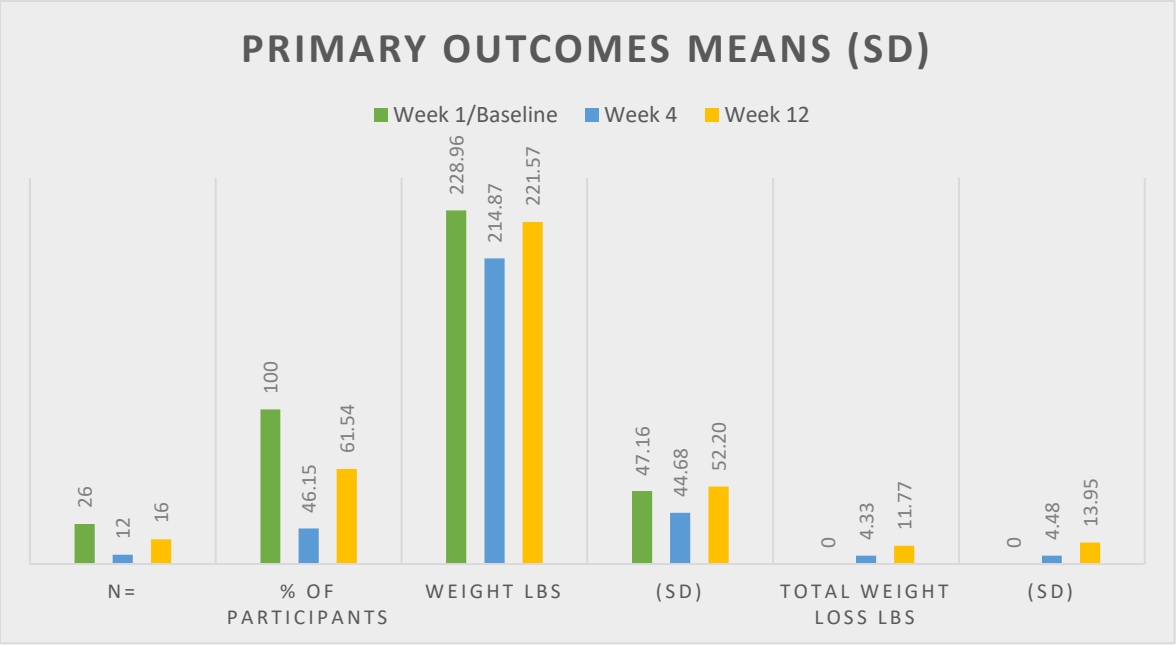
Outcome	Baseline	Follow-Up	Significance
Weight in pounds, mean (SD)	228.96 (47.16)	Wk 4 = 214.87 (44.68)	$p = .026$
		Wk 8 = 221.73 (37.01)	$p = .753$
		Wk 12 = 221.57 (52.20)	$p = .088$

BMI kg/m^2, mean (SD)	39.87 (6.19)	Wk 4 = 38.27 (6.57)	*p* = .028
		Wk 12 = 38.64 (6.93)	*p* =.023
Met 3% weight loss goal, *n* (%)	0 (0)	Wk 12 = 7 (27)	*p* =.001
Waist circumference, mean (SD)	117.26 cm (12.72)	Wk 12= 103 cm	
Waist-to-hip ratio, mean (SD)	0.96 (0.10)	Wk 12= 0.88	
SBP, mean (SD)	127.96 (15.81)	Wk 4 = 123.75 (15.03)	*p* = .814
		Wk 8 = 134.6 (16.41)	*p* = .686
		Wk 12 = 132.33 (19.79)	*p* =.754
DBP, mean (SD)	77.96 (12.30)	Wk 4 = 70.08 (8.03)	*p* = .423
		Wk 8 = 74.8 (11.69)	*p* = .273

		Wk 12 = 78.50 (9.18)	*p* =.798
Depression, mean (SD)	9.38 (5.66)	Wk 12= 5.87 (5.82)	*p* = .014
Anxiety, mean (SD)	8.0 (5.47)		
Hemoglobin A1c, mean (SD)	6.28 (1.03)		
Total cholesterol, mean (SD)	180.14 (47.15)		
LDL, mean (SD)	88.83 (31.36)		
HDL, mean (SD)	51.57 (13.35)		
Triglycerides, mean (SD)	207.57 (111.99)		

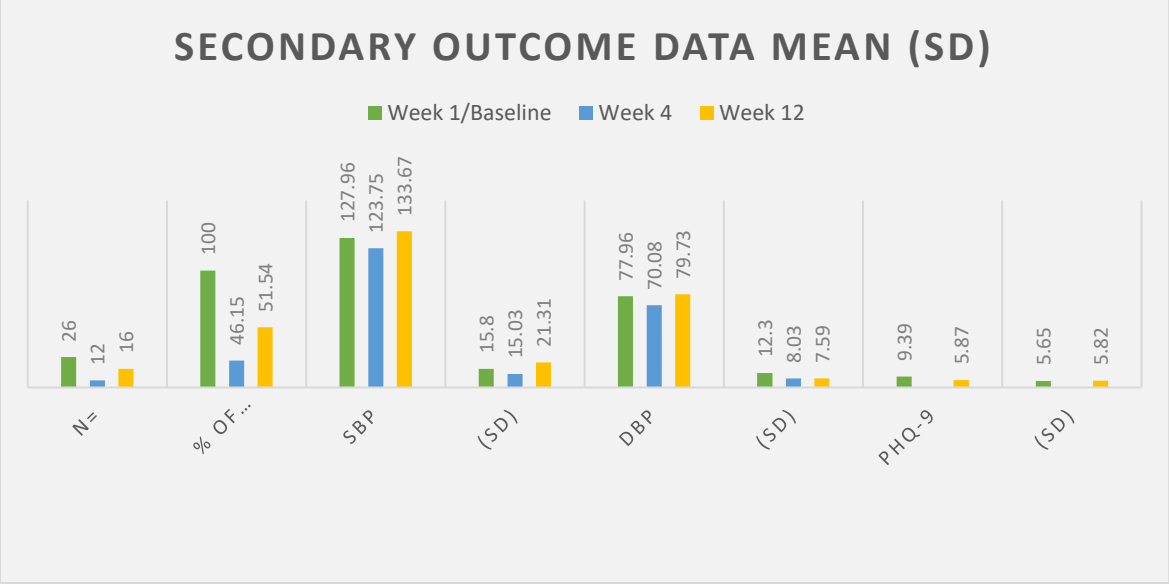
Note: Week 4 data includes last recorded measure weeks 2, 3 or 4 and week 12 data includes last recorded measure weeks 9, 10, 11, 12. Standard deviation are in parenthesis. A p-value less than or equal to .05 is statistically significant.

Figure 4.8. Primary outcomes mean (SD) weeks 1, 4 and 12



(Week 4 data includes last recorded measure weeks 2, 3 or 4 and week 12 data includes last recorded measure weeks 9, 10, 11, 12)

Figure 4.9. Secondary outcome data mean (SD)



(Week 4 data includes last recorded measure weeks 2, 3 or 4 and week 12 data includes last recorded measure weeks 9, 10, 11, 12)

Chapter 5

DISCUSSION

This EBP project attempted to answer the PICOT question, “Will the use of a tailored multicomponent intervention, compared to standard clinical care, improve indicators of obesity in a primary care adult population over a period of 3 months?” Indicators of obesity include BMI, waist circumference and waist to-hip ratio. Secondary indicators related to obesity include BP, HbA1c, total cholesterol, HDL, LDL, triglycerides, depression, and anxiety.

This project examined the impact of a tailored multicomponent intervention that combines the following care activities into the “NEWER ME” protocol: **N**utrition counseling; **E**xercise counseling; **W**eight loss support and motivation; **E**motional support and use of screening of depression and anxiety, behavioral health referrals and medication; **R**eferrals for added support and care; **M**edications; and **E**xpanded accountability and goal setting, for use within the primary care setting of a free clinic. The goal was to reduce weight by a 3% total weight loss, reduce BMI, reduce blood pressure, reduce depression and anxiety and reduce biometric markers. This chapter will describe and interpret project findings; address strengths and limitations of the project; evaluate the theoretical framework and EBP model used to guide the project; and explore implications for future practice, research and education.

Explanation of Findings

Project findings indicate that an individualized multicomponent approach was effective for reduction of weight, BMI and depression symptoms. These results are consistent with the literature. Contrary to the literature, however, SBP and DBP did not

significantly improve after the intervention. No results were obtained at week 12 for waist to hip ratio, anxiety screening, HbA1c or lipids, so the impact of the intervention on these variables is uncertain.

Participant Findings

The size of this project sample was considerably smaller (*n* = 26) than that used in most empirical studies about weight loss, although it was felt by clinic providers that this was a representative cross-section of the clinic's adult population. The small sample size was a limitation caused by various factors and will be discussed further later in this chapter. The sample was predominately white and Hispanic or Latino (77%), female (81%), and between 38 and 47 years old (57%). This distribution was expected as these groups tend to be the most common consumers of free or low-cost primary care services (Arvisais-Anhalt et al., 2018; Hunt, Adamson, Hewitt & Nazareth, 2011), and this was consistent with the demographic composition of patients at the project site. All participants were at or below 200% of the lower federal poverty limit, and no participants had health insurance. This rate of uninsured patients was not consistent with the literature study that provided rates between 43% to 94%; however, the study included clinics that accepted health insurance (Arvisais-Anhalt et al., 2018) and the clinic for this project did not accept patients with insurance. Most participants could read, write, and speak in English (77%) (Figure 4.5). This was not consistent with the literature that reported English as the primary language for 94% (Arvisais-Anhalt et al., 2018).

Weight loss and BMI. Most participants who continued with project lost a significant amount of weight initially (Appendix L) and continued to trend down at week 12. Others had fluctuations with weight loss and weight gain, re-gaining much of what

they had lost within 3 months. This finding is consistent with other weight-loss literature as adults tend to have cyclical periods of weight gain and loss (Cheatham et al. 2018; Hageman et al., 2017; Kroes et al., 2016; Rolls et al., 2017; Samdal et al., 2017). It is unknown if those participants who initially lost weight and continued to trend down maintained their weight loss past the twelve weeks.

Twelve participants completed at least one follow up visit between weeks 2 and 4. The mean weight decreased from baseline to week 4 (i.e.: the last follow up visit week 2, 3 or 4) (228.96 lbs. [47.16] vs 214.87 lbs. [44.67]) respectively, which was statistically significant (p = .026). However, the mean decrease in weight was less from baseline to Week 8, (i.e. the last follow up visit week 5-8) as weight fluctuated among participants with some gaining weight. Mean weight decreased (228.96 [47.16] vs 221.73 [37.01], respectively; p = .753). From baseline to week 12 (i.e. the last follow up visit weeks 9-12) the mean weight mean decreased (228.96 lbs. [47.16] vs 221.57 lbs. [52.20], respectively; p = .088); however, the week 12 decrease was not statistically significant (Table 4.3) (Figure 4.8). This may have been caused by attrition which may have influenced the sample mean. The varied sample size and the specific participants measured changed from week to week, thus changing the week's baseline mean and subsequently creating a potential sample or measurement bias.

At baseline the mean participant (n=26) BMI was 39.87 kg/m^2 (6.19). At the week 12 follow up the group (n=16) mean BMI mean was 38.64 kg/m^2 (6.93, p = .046) (Table 4.3). The comparison of BMI at week 12 to baseline was statistically significant. Regardless of statistical significance, most participants who experienced weight loss closely met the pound per week guidelines from the AHA (2018) and Guidelines 2013

for Managing Overweight and Obesity in Adults (Jensen et al., 2014) with a group mean loss of 11.77 (13.95) lbs. over the three months. Additionally, a total body weight reduction of 5% to 10% reduction over one year (Perreault, 2019c) is considered to lower health risk (Batsis et al., 2016; Eaton et al., 2016; Hageman et al., 2017; Jensen et al., 2014; Kroes, Osei-Assibey and Baker-Searle, 2016; Jensen et al., 2014; Kushner & Ryan, 2014; Perreault, 2019c).

Given the length of the program of twelve weeks, a 3% total body weight loss was considered significant. Nine of the participants (*n*=16) that completed the week 12 visit lost weight, and seven met the 3% total body weight reduction goal to reduce health risk. This may have been caused by attrition which may have influenced the sample mean; The varied sample size and specific participants measured changed from baseline to week 12, thus changing the mean and subsequently creating a potential sample or measurement bias. It is unknown if all original participants had completed the full program whether the results would have changed.

Waist-to-hip (W-to-H) ratio. At baseline, consenting participants (n=17) completed waist and hip measurements. W:H of greater than 0.95 in males and 0.85 in females was indicative of increased risk for cardiovascular disease and diabetes (Marshall, 2019). At baseline the mean W:H was 0.97 (SD = 0.10). Only one participant provided both baseline and week 12 data; and their W:H ratio did not change significantly (0.87 to 0.88, respectively). The lack of W:H measurements may have occurred due to a lack of clinical resources, time, staff understanding of the project protocol, language barrier or it may have been due to participant preference.

HbA1c. Participants (n=11) had a mean baseline HbA1c of 6.28% (SD = 1.04). No week 12 data were available for comparison analysis. This may have been due to the same reasons that there were no follow-up data for W:H ratio, or that the patients or clinicians did not feel that this blood test was clinically necessary. It may have also been due to a language barrier, misunderstanding about the relationship between obesity and diabetes mellitus, or a fear of having blood drawn. However, literature suggests that HbA1c should improve with weight reduction (Beeken et al., 2017; Delahanty, 2020; Rolls et al., 2017; Tapsell et al., 2017). Specifically, HbA1c reductions of 0.02 % to 0.11% could be expected depending upon the amount of weight lost as well as adherence to the dietary regimen (Bauman et al., 2019).

Lipids. Participants (n=7) had a mean total cholesterol, LDL, HDL and triglyceride count of 180.14 mg/dL (SD = 47.15), 88.83 mg/dL (SD = 31.37), 51.57 mg/dL (SD = 13.37) and 207.57 mg/dL(SD = 111.99) respectively. No week 12 data were available for comparison analysis. This was likely due to the same factors that led to missing HbA1c data at week 12. The literature suggests that lipid values should improve with weight reduction (Hageman et al., 2017; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017). Following a diet of healthy fresh vegetables and fruits, lean proteins and legumes, whole grains and unsaturated fats can result in a total cholesterol reduction (-7.4 mg/dL) and a reduction of LDL (-3.3mg/dL) and increase HDL and improve triglycerides (Tangney & Rosenson, 2019).

Depression. Depression is often linked to obesity in a cyclical nature (Kroes et al., 2016; Rodriguez-Cristobal et al., 2017; Ma et al., 2019; Rolls et al., 2017; Samdal et al., 2017; Tapsell et al., 2017). This relationship was demonstrated in this sample

between baseline and follow up results as global PHQ-9 scores improved (p=.014), often coinciding with weight loss. The direct cause of improved scores is unknown and may or may not be related to weight loss; however, when asked about improved scores, one participant stated “I just feel better since I lose the weight”. This improvement may have been impacted by improved nutrition and activity levels, environmental factors, lifestyle, or use of medication. Nine participants in the project sample were referred to their primary care provider due to PHQ-9 global scores of ten or greater as recommended in the literature (Kroes et al., 2016; Tapsell et al., 2017; Wellbourn et al., 2018). It is unknown how many of these participants received a prescription for an antidepressant or was compliant with antidepressant use, or how this may have affected weight loss outcomes.

Anxiety. Literature suggests that anxiety often accompanies depression and weight gain (Kroes et al., 2016; Rodriguez-Cristobal et al., 2017; Ma et al., 2019; Rolls et al., 2017; Tapsell et al., 2017; Welbourn et al., 2018). Although 17 participants completed the GAD-7 at baseline, only one completed it at Week 12. The participant who completed both anxiety assessments had improved anxiety symptoms from baseline to Week 12, though it is not possible to estimate the relationship between anxiety and weight loss in the overall sample. After further investigation it was found that anxiety screening was not routinely performed at this clinic. Unlike depression screening, it was only completed if the patient expressed having symptoms. Despite the obesity program protocol having been in place, this may have been a systematic error that may have been caused by a change in or limited staffing resources, lack of

knowledge or understanding of the protocol, staff may have forgotten as it was not part of the usual routine, language barrier or simply that the patient may have declined.

Blood pressure. Blood pressure was measured at each visit however sample sizes varied, and though participants obtained their medications from the clinic, participants' anti-hypertensive medication compliance is unknown. Overall, mean SBP and DBP did not change significantly from baseline to any follow-up time. This is inconsistent with most of the literature, which suggests that BP should improve with weight loss (Hageman et al., 2017; Rodriguez-Cristobal et al., 2017; Rolls et al., 2017; Tapsell et al., 2017; Thabault et al., 2016). It was expected that there would be a blood pressure decrease of 1 mm/Hg for every pound lost (Basile & Bloch, 2019).

Blood pressure may have remained unchanged in this sample for a variety of reasons, including attrition of patients with better adherence to the NEWER-ME intervention (leaving only those with poor adherence in the final sample), participant experiences and or feelings just prior to or at the time of measurement, undertreatment of hypertension in those who remained in the project, or poor adherence with antihypertensive regimens and or sodium restrictions. Clinical technique used when measuring blood pressure may have created systematic error or measurement bias. Systems were put in place to measure BP with the same Welch Allyn portable digital blood pressure device in the clinic using appropriate cuff sizes, however because different clinicians completed the measures, it is not possible to know if all followed procedures and used correct technique.

Strengths and Limitations of the DNP Project

Strengths

This EBP project had several strengths. First, there was a clear need for and interest in the project from the provider, staff, and administrative team. This translated into sustained enthusiasm about the project, an eagerness to engage patients in the intervention, and ability to initiate this new and ambitious weight loss protocol in the clinic.

Second, patients felt emotionally and financially supported in their weight loss journey. A significant portion of the time during each clinic visit was spent on promoting autonomous decision-making and self-efficacy about their weight loss, which were new territory for many of these project participants, all of whom were impoverished and disenfranchised. Participants were not paid, but were provided free health care, pharmaceuticals, laboratory studies, social services and community resources to aid them in their weight loss journey. Providing this kind of support was crucial to their sustained involvement in the project.

Third, participants were provided Evidence-Based educational guidelines about weight loss. This education was delivered using individual nutrition and behavioral counseling, a voiced Microsoft Power Point ® and written education, as well as a list of free EBP on-line resources (Appendices, M, N,O, and P). Participants in this sample had limited access to health education content on their own, so the clinic was willing to provide these educational resources at no cost so that participants could refer to them after their clinic visit. This strategy gave participants the opportunity to remain engaged with their tailored weight loss “prescription” between visits to the clinic.

Fourth, clinic staff received a thorough orientation to the project (Appendix Q) and to the various weight loss interventions before they were shared with patients. This ensured that patients would receive consistent messaging from one provider to another about the tailored interventions they would be prescribed as part of their weight loss program. The project manager created an outline of the weight loss project via a narrated Microsoft Power Point ®, (Appendix O) and this resource was then translated from English to Spanish. This content served as the topical outline for weight loss discussions with clinic patients. These tools were all available to the clinic providers and staff to ensure project continuity and continuity of the project. Furthermore, the project manager was available at the clinic most days of the week to facilitate the intervention and support the clinic staff.

Finally, this project used the JHNEBP Model (Appendix D) to provide a clear path and guidance for the management of the project. It allowed the project manager to anticipate and overcome possible barriers to implementation, which was essential for the success of this project in this complicated clinical setting.

Limitations

Though this project had many strengths there were also some barriers and limitations to this EBP project that affected data collection and patient outcomes. Most importantly, the sample size in this project was very small. While demographic characteristics of the sample were felt to accurately represent the population served by the clinic, the distribution of outcomes data from this sample may not have accurately represented how the overall clinic population might have responded to the intervention. Therefore, the results from this project, thought promising, may not apply to other

patients at the clinic. Continuing this project with a larger sample would likely produce results that could be applied to other patients seen at this clinic.

The clinic setting, which was a free clinic that provided care to patients who were uninsured, provided a unique set of challenges. Patients were required to be uninsured in order to receive care at the clinic. Without insurance, patients were unable to access some of the most effective weight loss interventions – pharmacotherapy and bariatric surgery – that patients with insurance would have been able to receive. Of the 26 participants in this project, 20 qualified for a referral to bariatric surgery based on their BMI and comorbidities (Kushner & Ryan, 2014; Jensen et al., 2014). This restriction of services required patients to fully maximize lifestyle and behavioral interventions, which is notoriously difficult for people with a fixed or unpredictable income.

This specific EBP Project addressed these issues by providing educational tools and resources as well as weight loss counseling and follow up visits free of charge. Participants could also be referred for psychological or behavioral health counseling or to the dietician when warranted free of charge. They also had access to a limited number of free weight loss medications such as phentermine and topiramate are the drugs usually prescribed and were available at the clinic pharmacy; however, no participant chose to utilized weight loss medications during this project.

A third limitation was the restricted availability of clinical resources. The included clinic's sources of revenue, staffing, and clinical resources available. Funding largely consisted of donations, grants and federal funding, thus limiting capital resources for staffing. Therefore, much of the work was completed by volunteers, clinical staff as well as physicians who may or may not have treated the participant previously. This created

bottlenecks in which project interventions could not be reliably completed from patient to patient or from visit to visit. This primarily affected the measurement of project outcomes including the GAD-7, weight loss readiness assessments, anthropometric measurements, waist and hip measurements, W:H ratio, and routine biometric measures (HbA1c and lipid panel). Additionally, with the high turnaround in staffing as well as staffing with volunteers, the clinicians needed to be frequently retrained as technique varied from person to person (e.g. collecting height and weight data in the same way with decimal). These challenges may have resulted in systematic errors in protocol adherence and data collection from one patient or visit to another.

This was mitigated through additional staff education and training, as well as re-evaluation of clinical resources by the project manager as to intervention importance in this clinical setting. This involved prioritizing interventions against available resources and trimming what was not essential to the success and sustainability of a weight loss program. Essential measures were found to include accurate weight and BMI, depression screening and when possible HbA1c and lipid panels, along with follow up care when possible.

Attrition from baseline to Week 12 was another important limitation that affected data collection and protocol adherence. Because of the attrition rates it became necessary to provide all resource materials at the baseline visit rather than over the first four visits. This amount of information may have become overwhelming, creating barriers especially with time spent providing behavioral counseling. However, it also allowed participants who would likely not have completed follow up care to have the necessary information to achieve successful weight loss on their own.

Attrition may have skewed weight loss outcomes as the sample sizes varied limiting consistency in number and specific participants being measured, thus changing the mean and subsequently creating a potential sample or measurement bias. It is unknown if all original participants had completed the full twelve weeks whether the results would have changed. Attrition in this population was slightly higher than in the traditional primary care setting and underserved primary care clinics as represented in the literature (Mallow et al., 2014). A variety of factors account for this difference in attrition between underserved settings including the distance to travel from their residence to the clinic (which was considerable for some patients in this sample); employment and financial limitations such as securing time off work, unpaid time from work, working capital; attainment of insurance resulting in the patient being refused care at the free clinic; impact of comorbidities on functional status; having an inconsistent desire to lose weight; and competing obligations such as family obligations, work schedule, legal concerns-court appointments (Arvisais-Anhalt et al.,2018; Birs et al., 2016; Mallow et al., 2014).

In effect, a free clinic may not necessarily mean totally “free” care. Because of the indirect costs of receiving care, which would affect patients in varying ways (e.g. a patient with good adherence and substantial weight loss who could not find time off work to follow up at the clinic, compared to a patient with poor adherence and weight gain who could not come to the clinic due to lack of transportation), the effectiveness of this intervention could not be fully evaluated without being able to control for these variables. The only controls available at the clinic were the safety net of the Social Services department and the free community resources. All clinic patients have access

to Social Services. Participants who were deemed in need could be referred to social service for further counseling and would be offered these resources. All participants were provided with a list of community food pantries as well as a booklet of community resources in either English or Spanish at their first visit as well as the community resources information available in the clinic lobby that they could access at any time during clinic hours Monday through Saturday.

Because the vast majority of patients who receive care at the free clinic are not citizens of the United States, fear of deportation was another possible limitation that may have differentially affected follow-up and/or intervention adherence. As a rule, providers did not ask if patients were citizens, and if the participant disclosed the information, they were reassured that they would be receiving care and that we could not divulge any patient information outside of HIPAA guidelines.

Many of these patients were also unable to speak English, and even though an interpreter was used to facilitate communication, they may not have fully understood their weight loss prescription or their plan for follow-up. To mitigate this each participant scheduled their follow up appointment and received an appointment card with their next follow up visit time and date before they left. Participants were also given a routine telephone reminder approximately 24 to 72 hours in advance by clinical staff. If possible, Spanish speaking staff members completed appointment scheduling and calls when needed.

Because of the limited clinical staff resources, both in terms of number and qualifications of staff, as well as time constraints, the project had to be altered many times to make it viable and sustainable. This limited interventions that could be used

and how they could be used. To alleviate these limitations, the project manager created an outline of the weight loss project and a narrated Microsoft Power Point ® describing the weight loss program that provided education and counseling. This resource was then to be translated from English to Spanish. This was both a limitation and a strength. It was a limitation because once it was sent to the clinic's translator it was not returned to the project manager or available for use with Spanish speaking participants. It was a strength because the English version, that was available, provided consistency and could be advanced at the participant's own pace and translated at the point of care by their on-site translator. Additionally, various tools (eg.: PHQ-9, GAD-7, educational materials) needed to be available in Spanish or needed to be translated by the participant's interpreter. To overcome these obstacles, both the PHQ-9 and GAD-7 were available in both English and Spanish as well as various other languages at the clinic. Many of the educational tools used in this project were available or could be accessed on-line in multiple languages, and all participants had access to the internet either on their mobile phone or through the library or at home. Participants were provided a list of web addresses for all referenced materials and resource tools.

Implications for the Future

Practice: The need for weight loss protocols within primary care will continue to be in demand as obesity has been consistently on the rise since the 1970s (WHO, 2018). This individualized multicomponent weight loss intervention provided steady weight loss for participants at this free clinic who consistently followed the plan; however, due to the limitations described in this chapter, it is unclear if implementation at other primary care clinics will result in a similar outcome. Furthermore, resource

limitations at free clinics such as the project site may prevent patients from being referred to weight loss specialists. This is a barrier that patients in other primary care clinics may not face, which could dramatically affect weight loss outcomes in that population. Utilizing expanded resources such as pharmaceuticals and referrals, when available, may increase the participants chance for successful weight loss. The intervention tested in this project is best suited for clinics with limited resources or as a foundational step for patients in the primary care setting who are unable to safely undergo medical or surgical weight loss therapies.

This EBP project can be easily transferred into any primary care setting using the prescribed methods at a low cost, as many of the resource materials used can be found on publicly available web sites (e.g. government, professional associations, private organizations) and either viewed electronically or printed at a low cost (Appendix P). The PowerPoint ® was created at no cost by the project manager. Along with the references listed in this project report, an outline for this media can be found in Appendix O that can be used to format a presentation applicable to specific clinical settings to promote weight loss and reduce health risks.

Theory: The theory used for this project was The Health Promotion Model (Pender,1982; Pender, 2011). As discussed in chapter two, in this theory, Pender states that each person has a unique set of experiences, beliefs, and attitudes that affect their willingness and ability to change detrimental health behaviors. The initial purpose of the model was to “assist nurses in understanding the major determinants of health behaviors, as a basis for behavioral counseling to promote healthy lifestyles” (Pender, 1982, p.2; Pender, 2011, p. 2). This model recognizes that a person’s context – their

experiences, feelings, emotions, resources, social barriers, etc. – impacts their health behavior.

Evidence from this project support many assertions of the Health Promotion Model. Selection of the tailored weight loss interventions was heavily influenced by the culture, lived experiences, resources, limitations, and individual health status of each participant. Although this project did not use predictive modeling to test whether or not the amount of weight loss depended on individual demographic or cultural factors, it was clear through anecdotal evidence gathered during clinic visits that the patient's age, ethnicity, primary language, financial resources, and social support may have played a significant role in how much weight the patient was able to lose.

The model used to guide the project was the JHNEBP Model. This model was a perfect fit for this EBP project, providing a clear path through the P-E-T process and guidance for the management of the project. It allowed the project manager to anticipate and overcome possible barriers to implementation, which was essential in this complicated setting. Anticipating project needs was necessary in this environment as it had very limited resources and the time to complete this project was very brief. However, re-evaluating the project was also necessary because the clinic was in constant flux with changing providers, volunteer staff, and an inconsistent patient caseload. Therefore, it was often necessary to alter the project protocols to meet changing demands and to ensure that the project would be sustainable into the future.

Research: Further research could be completed using this program; however, the period of intervention and follow up needs to be longer than the limited time frame allowed within this EBP project. Evidence suggests a period of at least twelve months is

a minimal time frame for implementation of interventions and evaluation (Jensen et al., 2014; Kushner & Ryan, 2014; Kozica et al., 2016). A longer timeline may have produced a larger sample, larger data sets and more conclusive results. This program could also be implemented in multiple sites that provide care for the underserved population, thus further increasing the sample size and the ability to obtain and analyze data.

Further research is needed to address the genesis of the high attrition rates (Arvisais-Anhalt et al.,2018; Birs et al., 2016; Mallow et al.,2014) among this population and what can be done to resolve it. This was a significant barrier in this project and despite an exhaustive literature search, little of the research found prior to the project implementation addressed this issue. This information would have been useful for project design and may have partly eliminated necessary revisions. Many of the participants of this program did not complete the full twelve weeks but were able to lose weight on their own after the initial visit using the resources provided. This information could be translated into future research that could address the use of a dual mechanism weight loss program, initiated with their provider, who provides the initial guidance and education resources and then is completed at home, with periodic follow up.

Research is also needed to evaluate the cultural impact of obesity among the underserved and how culture drives rising obesity rates and health risk. The white and Hispanic or Latino community tend to have a diet that is higher in carbohydrate, fats and caloric content. Based upon anecdotal information, this culture tends to enjoy a great deal of family socialization in which food is largely incorporated and where eating large portions is accepted. This aspect of their culture may impact rising levels of obesity, and

health risks among this population (Drieling, Ma & Stafford, 2011). This is opportunity for research as well as education through further study.

Research is needed into the role that genetics and hormones play in obesity. Evidence suggests that as much as 21% of overweight and obesity is linked to genetics. There are many known genetic or hormone causes of overweight and obesity. Among them is a mutation that causes alterations in the gene known as GWAS or *FTO* gene and chromosome 16 that are related to fat mass and obesity. Additionally, the leptin gene may contribute to overweight and obesity in some people. Leptin signals the brain whether the amount of fat stored is enough for survival. A leptin-deficiency causes loss of signaling, leading to hyperplagia, hyperinsulinemia, insulin resistance, decreased energy, weight gain and infertility. Another known cause is the congenital deficiency of proprotein convertase subtilisin/kexin type 1 gene (PCSK1) which causes early onset obesity via a multihormonal disorder (Perreault, 2019a). Further research could be used to develop treatment and education to reduce bias associated with overweight and obesity.

Education: Providers need to be taught that weight loss is not a one size fits everyone method, but rather that each patient is unique and requires individualized attention and interventions specific to them. Interventions need to fit the person, and must also address what they have tried in the past, if anything, as well as incorporating lifestyle and abilities, culture and goals. Providers must address their own perceptions of the overweight obese patient. Weight stigma and bias are seen throughout society, even among health care professionals. Many health care providers have strong bias and stereotype patients with obesity, thus impacting their behavior, judgement and the

treatment prescribed. The stigma of overweight obesity can reduce the quality of care received despite provider intentions. People with overweight obesity may have experienced poor treatment and have come to anticipate this from a provider. This may cause them stress, fear, mistrust and complete avoidance of treatment and it may lead to poor compliance (Phelan, et al., 2015). As much as 69% of overweight or obese female patients reported that their healthcare provider was biased against them due to their weight (Alberga et al., 2017). Anecdotal information obtained during this project reiterates these statistics as participants frequently voiced concerns of being afraid of being judged by the providers. As healthcare professionals, education is a key to reducing bias and providing EBP. There are so many factors that play a role in being overweight/obese. A few are obvious such as diet and activity level, but many are not such as genetics, comorbidities, psychological barriers, individual cognition and real or perceived barriers, self-efficacy, prior life experiences and experiences with weight loss attempts, financial or cultural influences, and support systems.

Conclusion

In this EBP project report obesity has been discussed as a multifactorial, individualized, chronic disease that increases known risk factors for significant comorbidities and mortality. The primary purpose of this Evidence-Based practice project was to improve indicators of obesity (weight, BMI) among patients served by a free medical clinic, using a tailored multicomponent intervention consisting of the NEWER ME protocol that combines **N**utrition and **E**xercise with **W**eight loss and behavioral counseling, motivation, **E**motional support, **R**eferrals for added support and care, **M**edications, and **E**xpanded accountability and goal setting. The secondary

purpose was to determine if the weight loss intervention was associated with a decrease in blood pressure and depression symptoms. The intervention was guided by the Health Promotion Model by Nola Pender. The Johns Hopkins Nursing Evidence Based Practice Model (JHNEBP) guided implementation of the project. A comprehensive literature review was completed in five databases, and strong evidence supported the tailored multicomponent intervention used in this project. Eligible participants (n=26) took part in the 3-month program. To maintain consistency, a Power Point® outline of the weight loss protocol was presented at each baseline visit. Written education materials were provided in English and Spanish, and an interpreter was used when appropriate. Weight, BMI, and BP were measured weekly, then at weeks 8 and 12, and depression screening was measured at baseline and at Week 12.

Mean weight significantly decreased from 228.96 lbs. (47.16) at baseline to 214.87 lbs (44.67) at week 4 (i.e. including the last visit during weeks 2, 3 and 4). Mean BMI also significantly decreased from 39.87kg/m^2 at baseline to 38.27 kg/m^2 (6.57) at week 4 (i.e. including the last visit during weeks 2, 3 and 4) and 38.64kg/m^2 (6.93) at week 12. Significantly more patients in the intervention group achieved at least 3% weight loss between baseline and Week 12, compared to those who did not receive the intervention (27% vs 16%, p=.034). Depression improved significantly from baseline to Week 12 (p = .014). There were no significant differences in SBP or DBP.

Based on these results, a tailored multicomponent weight loss program, that focuses on individualized and limited interventions such as weight, BMI and BP measures; nutrition and exercise education; behavioral interventions and counseling, along with basic laboratory screening of lipids and HbA1c when possible, is an effective

method for reducing weight, BMI, and depression in this type of primary care setting. This type of individualized interventions could be translated and modified to fit into any primary care practice, using the JHNEBP Model (Johns Hopkins Medicine, 2017) as well as the Health Promotion Model (Pender,1982; Pender, 2011) patients can be assessed and interventions can be tailored to the patient and implemented to achieve the best weight loss outcomes. Research can lend to EBP and new information can be translated into the protocols and interventions. Education can provide knowledge informing EBP and reduce overweight obesity stigma and bias in health care. As health care providers we need to educate, support and counsel patients, while allowing them autonomy that builds self-efficacy and self-esteem. Additionally, we need to promote self-esteem and autonomy through decreased weight bias and increased provider education in order to work toward reducing health risk in an overweight and obese population.

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AUTOBIOGRAPHICAL STATEMENT

Rita R. Arnold

Ms. Arnold graduated from the Lutheran College of Health Professions with an Associate of Science in Nursing in 1990. She continued her education by completing her BS in business management at Indiana Wesleyan University in 2004. She finished her MBA at Indiana Institute of Technology in 2007. She has worked in various clinical settings, including geriatrics, surgery, obstetrics, medical-surgical, and home-health care as well as travel nursing. She also worked within the administrative and academic arena before finishing her BSN at Indiana University in 2013. She is currently expected to complete her DNP with a focus in family practice at Valparaiso University in 2020. Ms. Arnold has a keen interest in working with the underserved communities. In 2012 she was part of a medical mission team that traveled to Haiti, which was still recovering after the devastating 2010 earthquake. She and her team set up a medical clinic in the community near Port-au-Prince and traveled throughout the region attending to the medical needs of the children and staff at orphanages. Ms. Arnold often volunteers her expertise at local free clinics that serve the homeless, uninsured and disadvantaged population. Recognizing a high missed appointment rate at these clinics, she has identified a multitude of causes often associated with poverty and low-income; thus, contributing to the disparity in health care and general health risk. She plans to continue to volunteer in her new capacity as a nurse practitioner helping the underserved population, as well as to act as an educator and mentor for future nursing students.

ACRONYM LIST

AAQ-W: Acceptance and Action Questionnaire for Weight loss

ACOG: American College of Obstetricians and Gynecologists

ADA: American Diabetes Association

AGHE: Australian Guide to Healthy Eating

AHA: American Heart Association

ANA: American Nurses Association

APA: American Psychological Association

APN: Advanced Practice Nurse

APOB: Apolipoprotein B

BCT: Behavioral change technique

BMI: Body mass index

BP: Blood pressure

CDC: Centers for Disease Control

CINAHL: The Cumulative Index to Nursing and Allied Health Literature

CITI: Collaborative IRB Training Initiative

CPAP: Continuous positive airway pressure

DASS-21: Depression Anxiety Stress Scale

DBP: Diastolic blood pressure

DMII: Diabetes Mellitus type II

DNP: Doctor of Nursing Practice

EBP: Evidence-Based practice

EBSCO: Elton B. Stephens Co (MedLine via EBSCO)

FAAN: Fellows of the American Academy of Nursing

GAD-7: Generalized anxiety disorder scale

HbA1c: Glycated hemoglobin (hemoglobin A1c)

HDL: High density lipids

HIPPA: Health Insurance Portability and Accountability Act of 1996

HPM: Health Promotion Model

HRQoL: Health related quality of life

IPAQ: International Physical Activity Questionnaire

IWQOL-Lite: Impact of weight on quality of life (short-form)

JBI: Joanna Briggs Institute

JHNEBP: Johns Hopkins Nursing Evidence-Based Practice (Model)

LDL: Low density lipids

MA: Meta-analysis

NICE: The National Institute for Health and Care Excellence

NIH: National Heart Lung and Blood institute

NP: Nurse practitioner

PEDro: Physiotherapy Evidence Database

P-E-T: practice, evidence, translation

PhD: Doctor of Philosophy

PHQ-9: Patient health questionnaire

PICOT: Patient population, intervention, comparison, outcomes, time

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT: Randomized controlled trial

QoL-SF: Quality of Life-Short Form

Quasi-exp: Quasi-experimental

RN: Registered nurse

SBP: Systolic blood pressure

SF-12: Physical and Mental Health 12 Item Short Form Health Survey

SF-36: Short Form (36) Health Survey

SPSS: Statistical Package for Social Sciences

SR: Systematic review

WEL-SF: American Weight Efficacy Lifestyle Questionnaire Short Form

WHO: World Health Organization

Appendix A

Protection of Human Research Participants Certificate

Certificate of Completion

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

Date of Completion: 04/07/2018

Certification Number: 2630313

Appendix B

Johns Hopkins Nursing Evidence Based Practice Model and Tools Permission

JHNEBP MODEL AND TOOLS- PERMISSION

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

You may not modify the model or the tools without written approval from Johns Hopkins.
All reference to source forms should include “©The Johns Hopkins Hospital/The Johns Hopkins University.”
The tools may not be used for commercial purposes without special permission.

If interested in commercial use or discussing changes to the tool, please email ijhn@jhmi.edu.

Appendix C

Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool

Please note that this tool was taken from Dang & Dearholt, (2017, Appendix E, pp. 281-290) and appears as in text, content has been unaltered.

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Evidence level and quality rating:	
Article title:	Number:
Author(s):	Publication date:
Journal:	
Setting:	Sample (composition and size):
Does this evidence address my EBP question? ☐ Yes ☐ No-*Do not proceed with appraisal of this evidence*	

Is this study:

☐ **QuaNtitative** (collection, analysis, and reporting of numerical data)
Measurable data (how many; how much; or how often) used to formulate facts, uncover patterns in research, and generalize results from a larger sample population; provides observed effects of a program, problem, or condition, measured precisely, rather than through researcher interpretation of data. Common methods are surveys, face-to-face structured interviews, observations, and reviews of records or documents. Statistical tests are used in data analysis.

➡ Go to ***Section I: QuaNtitative***

☐ **QuaLitative** (collection, analysis, and reporting of narrative data)
Rich narrative documents are used for uncovering themes; describes a problem or condition from the point of view of those experiencing it. Common methods are focus groups, individual interviews (unstructured or semi structured), and participation/observations. Sample sizes are small and are determined when data saturation is achieved. Data saturation is reached when the researcher identifies that no new themes emerge and redundancy is occurring. Synthesis is used in data analysis. Often a starting point for studies when little research exists; may use results to design empirical studies. The researcher describes, analyzes, and interprets reports, descriptions, and observations from participants.

➡ Go to ***Section II: QuaLitative***

☐ **Mixed methods (**results reported both numerically and narratively)
Both quaNtitative and quaLitative methods are used in the study design. Using both approaches, in combination, provides a better understanding of research problems than using either approach alone. Sample sizes vary based on methods used. Data collection involves collecting and analyzing both quaNtitative and quaLitative data in a single study or series of studies. Interpretation is continual and can influence stages in the research process.

➡ Go to ***Section III: Mixed Methods***

1

Johns Hopkins Nursing Evidence-Based Practice

Appendix E

Research Evidence Appraisal Tool

Section I: QuaNtitative		
Level of Evidence (Study Design)		
A Is this a report of a single research study?	☐ Yes	☐No **Go to B**
1. Was there manipulation of an independent variable?	☐ Yes	☐ No
2. Was there a control group?	☐ Yes	☐ No
3. Were study participants randomly assigned to the intervention and control groups?	☐ Yes	☐ No
If **Yes to questions 1, 2, and 3,** this is a randomized controlled trial (RCT) or experimental study.		**LEVEL I**
If **Yes to questions 1 and 2 and No to question 3** or **Yes to question 1 and No to questions 2 and 3,** this is quasi-experimental. *(Some degree of investigator control, some manipulation of an independent variable, lacks random assignment to groups, and may have a control group).*		**LEVEL II**
If **No to questions 1, 2, and 3,** this is nonexperimental. *(No manipulation of independent variable; can be descriptive, comparative, or correlational; often uses secondary data).*		**LEVEL III**
Study Findings That Help Answer the EBP Question		
Skip to the **Appraisal of QuaNtitative Research Studies** section		

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Section I: QuaNtitative (continued)

B	Is this a summary of multiple sources of research evidence?	☐ Yes *Continue*	☐ No **Use Appendix F**
1.	Does it employ a comprehensive search strategy and rigorous appraisal method? *If this study includes research, nonresearch, and experiential evidence, it is an integrative review (see Appendix F).*	☐ Yes *Continue*	☐ No **Use Appendix F**

2. For systematic reviews and systematic reviews with meta-analysis (see descriptions below):

a. Are all studies included RCTs?	**LEVEL I**
b. Are the studies a combination of RCTs and quasi-experimental, or quasi-experimental only?	**LEVEL II**
c. Are the studies a combination of RCTs, quasi-experimental, and nonexperimental, or non- experimental only?	**LEVEL III**

A **systematic review** employs a search strategy and a rigorous appraisal method, but does not generate an effect size.

A **meta-analysis**, or systematic review with meta-analysis, combines and analyzes results from studies to generate a new statistic: the effect size.

Study Findings That Help Answer the EBP Question

Skip to the **Appraisal of Systematic Review** (With or Without a Meta-Analysis) section

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Appraisal of QuaNtitative Research Studies			
Does the researcher identify what is known and not known about the problem and how the study will address any gaps in knowledge?	☐ Yes	☐ No	
Was the purpose of the study clearly presented?	☐ Yes	☐ No	
Was the literature review current (most sources within the past five years or a seminal study)?	☐ Yes	☐ No	
Was sample size sufficient based on study design and rationale?	☐ Yes	☐ No	
If there is a control group: • Were the characteristics and/or demographics similar in both the control and intervention groups?	☐ Yes	☐ No	N/A
• If multiple settings were used, were the settings similar?	☐ Yes	☐ No	N/A
• Were all groups equally treated except for the intervention group(s)?	☐ Yes	☐ No	N/A
Are data collection methods described clearly?	☐ Yes	☐ No	
Were the instruments reliable (Cronbach's α[alpha] $\geq$ 0.70)?	☐ Yes	☐ No	N/A
Was instrument validity discussed?	☐ Yes	☐ No	N/A
If surveys or questionnaires were used, was the response rate $\geq$ 25%?	☐ Yes	☐ No	N/A
Were the results presented clearly?	☐ Yes	☐ No	
If tables were presented, was the narrative consistent with the table content?	☐ Yes	☐ No	N/A
Were study limitations identified and addressed?	☐ Yes	☐ No	
Were conclusions based on results?	☐ Yes	☐ No	
Complete the **Quality Rating for QuaNtitative Studies** section			

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Appraisal of Systematic Review (With or Without Meta-Analysis)		
Were the variables of interest clearly identified?	☐ Yes	☐ No
Was the search comprehensive and reproducible? • Key search terms stated	☐ Yes	☐ No
• Multiple databases searched and identified	☐ Yes	☐ No
• Inclusion and exclusion criteria stated	☐ Yes	☐ No
Was there a flow diagram that included the number of studies eliminated at each level of review?	☐ Yes	☐ No
Were details of included studies presented (design, sample, methods, results, outcomes, strengths, and limitations)?	☐ Yes	☐ No
Were methods for appraising the strength of evidence (level and quality) described?	☐ Yes	☐ No
Were conclusions based on results?	☐ Yes	☐ No
• Results were interpreted	☐ Yes	☐ No
• Conclusions flowed logically from the interpretation and systematic review question	☐ Yes	☐ No
Did the systematic review include a section addressing limitations **and** how they were addressed?	☐ Yes	☐ No
Complete the **Quality Rating for QuaNtitative Studies** section (below)		

Quality Rating for QuaNtitative Studies

Circle the appropriate quality rating below:

A High quality: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence.

B Good quality: Reasonably consistent results; sufficient sample size for the study design; some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.

C Low quality or major flaws: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn.

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Section II: QuaLitative

Level of Evidence (Study Design)		
A Is this a report of a single research study?	☐ Yes **this is Level III**	☐ No **go to II B**
Study Findings That Help Answer the EBP Question		

Complete the **Appraisal of Single QuaLitative Research Study** section (below)

Appraisal of a Single QuaLitative Research Study		
Was there a clearly identifiable and articulated: • Purpose?	❑Yes	❑No
• Research question?	❑Yes	❑No
• Justification for method(s) used?	❑Yes	❑No
• Phenomenon that is the focus of the research?	❑Yes	❑No
Were study sample participants representative?	❑Yes	❑No
Did they have knowledge of or experience with the research area?	❑Yes	❑No
Were participant characteristics described?	❑Yes	❑No
Was sampling adequate, as evidenced by achieving saturation of data?	❑Yes	❑No
Data analysis: • Was a verification process used in every step by checking and confirming with participants the trustworthiness of analysis and interpretation?	❑Yes	❑No
• Was there a description of how data were analyzed (i.e., method), by computer or manually?	❑Yes	❑No
Do findings support the narrative data (quotes)?	❑Yes	❑No
Do findings flow from research question to data collected to analysis undertaken?	❑Yes	❑No
Are conclusions clearly explained?	❑Yes	❑No

Skip to the **Quality Rating for QuaLitative Studies** section

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

B For summaries of multiple quaLitative research studies (meta-synthesis), was a comprehensive search strategy and rigorous appraisal method used?	☐Yes **Level III**	☐No go to **Appendix F**
Study Findings That Help Answer the EBP Question		
Complete the **Appraisal of Meta-Synthesis Studies** section (below)		

Appraisal of Meta-Synthesis Studies		
Were the search strategy and criteria for selecting primary studies clearly defined?	❑Yes	❑No
Were findings appropriate and convincing?	❑Yes	❑No
Was a description of methods used to: • Compare findings from each study?	❑Yes	❑No
• Interpret data?	❑Yes	❑No
Did synthesis reflect:	❑Yes	❑No
• New insights?	❑Yes	❑No
• Discovery of essential features of phenomena?	❑Yes	❑No
• A fuller understanding of the phenomena?	❑Yes	❑No
Was sufficient data presented to support the interpretations?	❑Yes	❑No
Complete the **Quality Rating for QuaLititative Studies** section (below)		

Johns Hopkins Nursing Evidence-Based Practice

Appendix E
Research Evidence Appraisal Tool

Quality Rating for QuaLitative Studies

Circle the appropriate quality rating below:

No commonly agreed-on principles exist for judging the quality of quaLitative studies. It is a subjective process based on the extent to which study data contributes to synthesis and how much information is known about the researchers' efforts to meet the appraisal criteria.

For meta-synthesis, there is preliminary agreement that quality assessments should be made before synthesis to screen out poor-quality studies[1].

A/B <u>High/Good quality</u> is used for single studies and meta-syntheses[2].

The report discusses efforts to enhance or evaluate the quality of the data and the overall inquiry in sufficient detail; and it describes the specific techniques used to enhance the quality of the inquiry.

Evidence of some or all of the following is found in the report:

- **Transparency**: Describes how information was documented to justify decisions, how data were reviewed by others, and how themes and categories were formulated.
- **Diligence**: Reads and rereads data to check interpretations; seeks opportunity to find multiple sources to corroborate evidence.
- **Verification**: The process of checking, confirming, and ensuring methodologic coherence.
- **Self-reflection and self-scrutiny**: Being continuously aware of how a researcher's experiences, background, or prejudices might shape and bias analysis and interpretations.
- **Participant-driven inquiry**: Participants shape the scope and breadth of questions; analysis and interpretation give voice to those who participated.
- **Insightful interpretation**: Data and knowledge are linked in meaningful ways to relevant literature.

C <u>Lower-quality</u> studies contribute little to the overall review of findings and have few, if any, of the features listed for High/Good quality.

1 https://www.york.ac.uk/crd/SysRev/ISSL!/WebHelp/6_4_ASSESSMENT_OF_QUALITATIVE_RESEARCH.htm
2 Adapted from Polit & Beck (2017).

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Appendix E
Research Evidence Appraisal Tool

Section III: Mixed Methods		
Level of Evidence (Study Design)		
You will need to appraise both the quaNtitative and quaLitative parts of the study independently, before appraising the study in its entirety.		
1. Evaluate the quaNitative part of the study using **Section I**.	**Level**	**Quality**
Insert here the level of evidence and overall quality for this part:		
2. Evaluate the quaLitative part of the study using **Section II**.	**Level**	**Quality**
Insert here the level of evidence and overall quality for this part:		
3. To determine the level of evidence, circle the appropriate study design:		
• **Explanatory** sequential designs collect quaNtitative data first, followed by the quaLitative data; and their purpose is to explain quaNtitative results using quaLitative findings. The level is determined based on the level of the quaNtitative part. • **Exploratory** sequential designs collect quaLitative data first, followed by the quaNtitative data; and their purpose is to explain quaLitative findings using the quaNtitative results. The level is determined based on the level of the quaLitative part, and it is always Level III. • **Convergent** parallel designs collect the quaLitative and quaNtitative data concurrently for the purpose of providing a more complete understanding of a phenomenon by merging both datasets. These designs are Level III. • **Multiphasic** designs collect quaLitative and quaNtitative data over more than one phase, with each phase informing the next phase. These designs are Level III.		
Study Findings That Help Answer the EBP Question		
Complete the **Appraisal of Mixed Methods Studies** section (below)		

Appendix E
Research Evidence Appraisal Tool

Appraisal of Mixed Methods Studies[3]			
Was the mixed-methods research design relevant to address the quaNtitative and quaLitative research questions (or objectives)?	❑Yes	❑No	❑N/A
Was the research design relevant to address the quaNtitative and quaLitative aspects of the mixed-methods question (or objective)?	❑Yes	❑No	❑N/A
For convergent parallel designs, was the integration of quaNtitative and quaLitative data (or results) relevant to address the research question or objective?	❑Yes	❑No	❑N/A
For convergent parallel designs, were the limitations associated with the integration (for example, the divergence of quaLitative and quaNtitative data or results) sufficiently addressed?	❑Yes	❑No	❑N/A
Complete the **Quality Rating for Mixed-Method Studies** section (below)			

3 National Collaborating Centre for Methods and Tools. (2015). Appraising Qualitative, Quantitative, and Mixed Methods Studies included in Mixed Studies Reviews: The MMAT. Hamilton, ON: McMaster University. (Updated 20 July, 2015) Retrieved from http://www.nccmt.ca/ resources/search/232

Quality Rating for Mixed-Methods Studies

Circle the appropriate quality rating below

A **High quality:** Contains high-quality quaNtitative and quaLitative study components; highly relevant study design; relevant integration of data or results; and careful consideration of the limitations of the chosen approach.

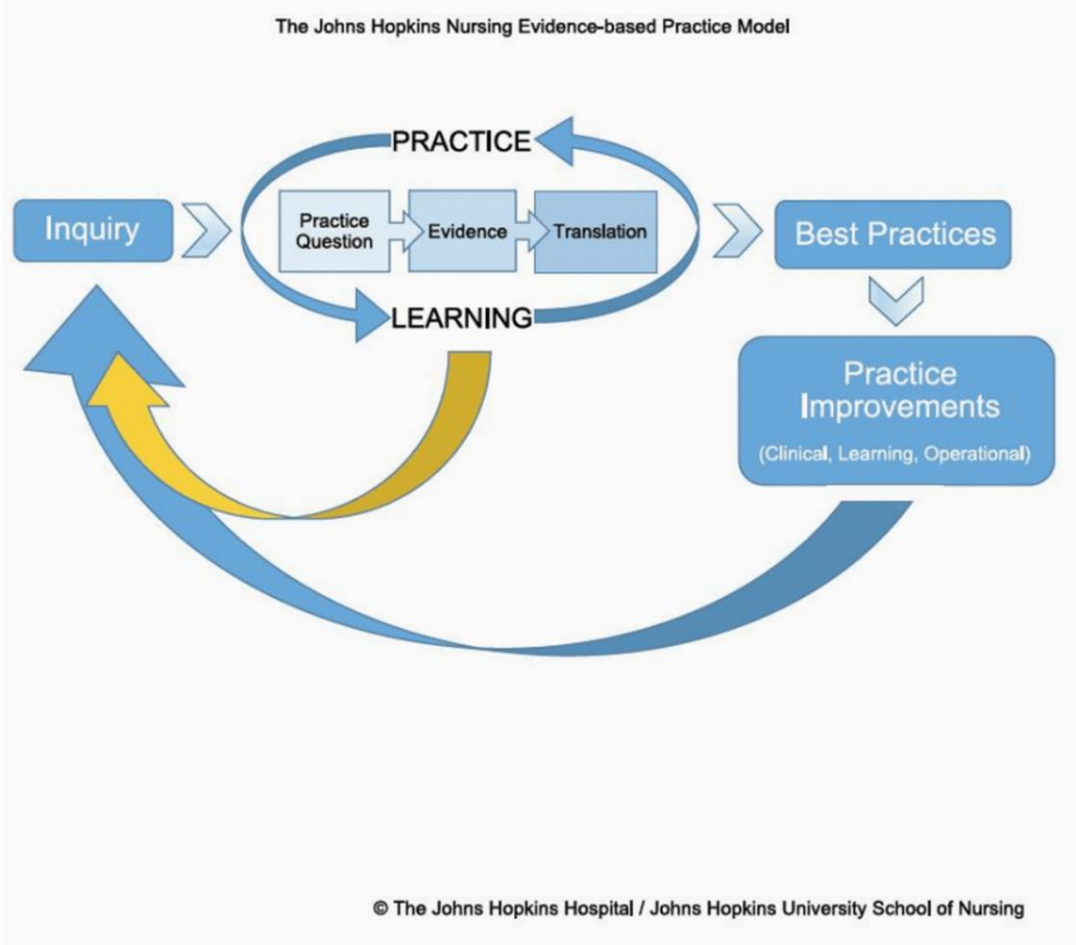
B **Good quality:** Contains good-quality quaNtitative and quaLitative study components; relevant study design; moderately relevant integration of data or results; and some discussion of limitations of integration.

C **Low quality or major flaws:** Contains low quality quaNtitative and quaLitative study components; study design not relevant to research questions or objectives; poorly integrated data or results; and no consideration of limits of integration.

Images: Dang & Dearholt, (2017, Appendix E, pp. 281-290) [Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool]

Appendix D

Johns Hopkins Nursing Evidence-Based Practice Model



(Image: The Johns Hopkins Nursing Evidence-Based Practice Model, 2017).

Appendix E

PHQ-9: English version

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

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

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

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix F

GAD-7

GAD-7

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

(For office coding: Total Score T____ = ____ + ____ + ____)

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Appendix G

AAQ-W

AAQ-W: Acceptance and Action Questionnaire- Weight

Below you will find a list of statements. ***Please rate the truth of each statement as it applies to you.***

Use the following scale to make your choice.

Never True 1 2 3 4 5 6 7 Always True

1 2 3 4 5 6 7 1. It's OK to feel fat

1 2 3 4 5 6 7 2. When I have negative feelings, I use food to make myself feel better

1 2 3 4 5 6 7 3. I try to suppress thoughts and feelings that I don't like about my body or weight by just not thinking them

1 2 3 4 5 6 7 4. I am not in control of what I eat

1 2 3 4 5 6 7 5. I try hard to avoid feeling bad about my weight or how I look

1 2 3 4 5 6 7 6. I am in control of how much physical activity I do

1 2 3 4 5 6 7 7. When I evaluate my weight or my appearance negatively, I am able to recognize that this is just a reaction, not an objective fact.

1 2 3 4 5 6 7 8. In order to eat well and do physical activity, I need to feel like it

1 2 3 4 5 6 7 9. I need to feel better about how I look in order to live the life I want to

1 2 3 4 5 6 7 10. Other people make it hard for me to accept myself

Please continue to page 2.

Imagine that the following thoughts occurred to you right now.

How valid or believable would each be?

For each question, please circle a number from 1 through 7.

Not at all believable 1 2 3 4 5 6 7 Completely believable

1 2 3 4 5 6 7 11. If I'm overweight, I can't live the life I want to

1 2 3 4 5 6 7 12. If I feel unattractive, there is no point in trying to be intimate

1 2 3 4 5 6 7 13. If I gain weight, that means I have failed

1 2 3 4 5 6 7 14. I'm in control of my eating behavior

1 2 3 4 5 6 7 15. I don't have what it takes to be healthy for life

1 2 3 4 5 6 7 16. My eating urges control me

1 2 3 4 5 6 7 17. I need to get rid of my eating urges to eat better

1 2 3 4 5 6 7 18. I am a stable person

1 2 3 4 5 6 7 19. If I eat something bad, the whole day is a waste

1 2 3 4 5 6 7 20. I should be ashamed of my body

1 2 3 4 5 6 7 21. I need to avoid social situations where people might judge me

1 2 3 4 5 6 7 22. I will always be overweight

Lillis & Hayes (2008)

Scoring:
Before a sum score is taken, items 1, 6, 7, 14, and 18 are reversed keyed: Lower scores indicate
less experiential avoidance and more psychological flexibility. The range of possible scores is 22 to 154.

Because it can be confusing to speak of a lower score reflecting “more psychological flexibility” the
scoring can be changed if the clinician or user is conceptually focused on increasing acceptance and
response flexibility. In this case, items 1, 6, 7, 14, and 18 would be scored as normally and all other items would be reverse scored.

(Note-Permission to use AAQ-W in Appendix T)

Appendix H

Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF) Tool

Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF)

Read each situation below and decide how confident (or certain) you are that you will be able to resist overeating in each of the different situations. On a scale of 0 (Not confident) to 10 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to overeat. Write that number next to each item (in the confidence number column).

0	1	2	3	4	5	6	7	8	9	10
Not at all confident										Very confident

I am confident that:	Confidence number
1. I can resist overeating when I am anxious (nervous).	
2. I can resist overeating on the weekend.	
3. I can resist overeating when I am tired.	
4. I can resist overeating when I am watching TV (or using the computer).	
5. I can resist overeating when I am depressed (feeling down).	
6. I ca resist overeating when I am in a social situation (or at a party).	
7. I can resist overeating when I am angry (or irritable).	
8. I can resist overeating when others are pressuring me to eat.	

Ames, G. E. et al., Eating self-efficacy. Development of a short-form WEL, Eating Behaviors (2012), doi: 10.1016/j.eatbeh.2012.03.013

(Ames, Heckman, Grothe & Clark, 2012)

Appendix I

EBP Project Timeline

Participation in the project involves a baseline data collection visit as part of the initial clinic visit (T0), weekly follow-up visits for the next 3 weeks (T1 – T3), and monthly follow-up visits for the next 2 months (T4 and T5). Project data will be measured according to the following timeline:

Variable	T0	T1	T2	T3	T4	T5
Weight	X	X	X	X	X	X
Body Mass Index	X	X	X	X	X	X
Waist Circumference	X					X
Waist-to-Hip Ratio	X					X
Readiness for Weight Loss	X					
Personal Strengths, Barriers, and Resources Inventory	X					
Blood Pressure	X	X	X	X	X	X

Depression	X	X
Anxiety	X	X
Lipid Panel (Total Cholesterol, LDL, HDL, Triglycerides)	X (if medically indicated)	X (if medically indicated)
Hemoglobin A1c	X (if medically indicated)	X (if medically indicated)

Appendix J

Anthropometric measures: Baseline

Pt.	Baseline Weight Lb	Baseline Weight Kg	Baseline BMI	Height inches	Height cm	Waist circum. CM	Hip circ. CM	Waist: Hip ratio (W:H)
1	190	86.2	38.4	59	149.86	120.5	123	0.979
2	295	134	52.3	63	160.02	145	153	0.947
3	195	88.4	36.8	61	154.94	109	119.5	0.912
4	259	117.7	38.2	69	175.26	120	122	0.983
5	328	148.8	51.4	67	170.18	136	152.5	0.891
6	230	104.3	42.1	62	157.48	117	125	0.936
7	180.6	81.9	34.1	61	154.94	115	122	0.942
8	207.2	93.9	35.6	64	162.56	115.5	118.5	0.974
9	225.6	102.33	38.7	64	162.56	108	125.5	0.86
10	172.8	78.38	31.6	62	157.48	114	107	1.06
11	186.6	84.64	35.3	61	154.94			
12	197.2	89.44	38.5	60	152.4	134	109	1.22
13	197.6	89.62	33.9	64	162.56	102	112.5	0.906
14	212	96.16	35.3	65	166.37	106	122	0.8688
15	269.6	122.28	41	68	172.72			
16	227.6	103.23	40.1	63.2	160.52	131.5	124	1.06
17	172	78.017	32.2	61.3	155.7	114	103	1.106
18	180.6	81.9	34.1	61	154.94	100	119.5	0.836
19	324	146.96	52.3	66	167.64			
20	293	132.9	47.3	66	167.64			
21	261.4	118.56	47.5	62.2	157.988			
22	280	127.3	42.6	68	172.72			
23	192.3	87.22	34.1	63	160.02			
24	220.6	100.06	37.9	64	162.56			
25	262	118.9	46.4	63	160.02			
26	193.2	87.63	39	59	149.86	106	121.5	0.8724
	228.9576923	**103.8741154**	**39.87307692**	**63.33461538**	**160.9183846**	**117.2647059**	**122.3235294**	**0.961952941**
	47.16288518	**21.4292008**	**6.186343521**	**2.73977259**	**6.994347021**	**12.721927**	**13.19557357**	**0.100733051**

Appendix K

Prospective Group Laboratory Results Available: Baseline

Participant	HbA1C	Total cholesterol	LDL	HDL	Triglycerides
1	9.3				
2	6.1	234		77	406
3	5.7	164	86	56	108
4					
5					
6					
7	5.6	150	70	56	119
8	6.2				
9		133	55	47	154
10	5.6				
11					
12					
13					
14	6.2	203	109	44	250
15	5.9	245	141	46	290
16					
17					
18					
19					
20	6	132	72	35	126
21					
22	6				
23					
24					
25	6.5				
26					
	MEAN: 6.281818	**180.1429**	**88.83333**	**51.57143**	**207.5714286**
	SD: 1.038093	**47.15022**	**31.36505**	**13.35237**	**111.9908585**

*No Week 12 laboratory results were available.

Appendix L

Participants Weight (Lbs.) Trends

Participant	Baseline	Week 2	Week 3	Week 4	Week 8	Week 12
1	190.0					
2	295.0	295.0				286.00
3	195.0	193.2	189.0	188.6		189.00
4	295.0					
5	328.0					333.00
6	230.0					220.50
7	180.6	177.6	174.2	174.0		177.00
8	207.2					158.00
9	225.6		228.8		229.00	
10	172.8		173.2	172.6	172.40	
11	186.6		187.0			175.00
12	197.2		182.0	182.0		
13	197.6					198.00
14	212.0	211.6	210.8	210.4	205.40	200.80
15	269.6					276.00
16	227.6					232.00
17	172.0					170.00
18	180.6	172.4				165.40
19	324.0					
20	293.0	289.0				
21	261.4				267.00	263.00
22	280.0					280.40
23	192.3				197.00	
24	220.6		219.0			221.00
25	262.0	255.0		259.6	259.60	
26	193.2					286.00

Appendix M

Nutrition Education

Nutrition Plans:

There are 3 Evidence-Based diet plans that have been proven to work:

1. Total caloric reduction of between 500-750 calories per day, while also limiting dining out and use of fast foods, as well as eliminating or reducing high caloric 'empty calorie' foods such as pop and chips (Kushner & Ryan, 2014).
2. Eating a healthy diet of between 1200-1500 calories for women and 1500-1800 calories for men that includes lean protein, fresh vegetables and fruits, whole grains and legumes, low fat dairy and unsaturated fats while limiting sugars and 'empty calories' (Kushner & Ryan, 2014).
3. Use of an evidence–based diets that restricts certain foods such as high fat, high carbohydrate, low fiber foods to create caloric deficit such as www.choosemyplate.gov or Weight Watchers ® (Kushner & Ryan, 2014; Madigan, 2014).

Healthy Nutrition:

A healthy diet should include:

- Lean protein, fresh vegetables and fruits, whole grains and legumes, low fat dairy and unsaturated fats while limiting sugars and 'empty calories' (Kushner & Ryan, 2014)
- Recommended daily intake is 3 servings of lean protein per day (3-4 ounces/serving).
- Aim for 5 servings of vegetables/ fruits (DM limit fruit intake) per day
- Use of whole grains and legumes
- Carbohydrate intake should be 45-65% of daily total calories
- Low fat dairy (2-3 servings per day)
- Unsaturated fats- olive oil, avocado
- 6-8, 8-ounce glasses of zero calorie water per day unless on fluid restriction Limit empty calorie such as sweets, snack foods, processed foods and alcohol as these add to caloric intake and contain added salt, sugar and fats (ADA, 2019; AHA, 2019; Delahanty, 2020; Kushner & Ryan, 2014; Mayo Clinic, 2019; NIH, 2019; USDA-ChooseMyPlate.gov, 2019)

Cooking: bake, broil, boil, stream or grill meats and vegetables; eat fresh /raw fruits and vegetables. Limit frying or cooking with fat (ADA; AHA).

Track your caloric intake: Learning to read food labels is very important. Weigh and measure foods to maintain caloric intake control. Use a food journal such as MyFitnessPal®, spreadsheet or a paper journal (Perreault & Apovian, 2019).

Appendix N

Exercise Education

Exercise and Physical Activity

- The National Guidelines and the American Heart Association recommend increasing physical activity to at least 150 minutes per week with activity, including “moderate-intensity aerobic activity”. (AHA, 2018; Kushner & Ryan, 2014). This is about 30 minutes per day, 4-5 days per week.
- OR “75 minutes per week of vigorous aerobic activity (or a combination of both)” (AHA, 2018).
- Some aerobic activities may include: fast walking; running; use of exercise machines like the treadmill, exercise bike, or elliptical machine; swimming; bicycling; or taking a jazzercise or zumba class or what ever type of safe and healthy activity you choose that increases heart rate and breathing without causing health risk. Be realistic and safe!
- Aerobic activity should increase your heart rate; “Your heart will beat faster, and you’ll breathe harder than normal” (AHA, 2018).
- STOP immediately if you experience chest, neck, back or shoulder pain or become light-headed or feel or experience fainting or nausea with increased activity. Seek emergency medical care or call 911.
- Move More, Sit Less: “Get up and move throughout the day. Any activity is better than none. Even light-intensity activity can offset the serious health risks of being sedentary” (AHA, 2018).
- And check with your healthcare provider before starting any new physical exercise plan.
- Be safe! Try to exercise with a friend. Always carry identification and emergency contact when exercising especially outside.

Appendix O

EBP Project Power Point Outline

A Multicomponent Tailored Intervention Program Protocol for Weight Loss in an Underserved Adult Patient Population: A Power Point Outline

1. Title slide:
    a. A Personalized Weight Loss Program for an Over-weight or Obese Population (Author: Rita R. Arnold MBA, BSM, BSN, RN, DNP Student Valparaiso University 2020)
2. Part One: The Program Plan
    a. NEWER ME
3. According to the WHO (2018)
    a. Since 1975 obesity has nearly tripled worldwide
    b. As of 2016 approximately 39% of the world's adult population was over-weight and 13% were obese.
    c. Approximately 340 million children were either overweight or obese
    d. Epidemic levels
4. Health Risk of Over-weight and Obesity:
    a. Cardiovascular diseases (AHA, 2019; Jensen et al., 2014; Kushner & Ryan, 2014)
    b. Diabetes Mellitus type II (ADA, 2019; Jensen et al., 2014; Kushner & Ryan, 2014; Triplett et al., 2014)
    c. Fatty liver disease (Harvard Health, 2018; Jensen et al., 2014; Kushner & Ryan, 2014)

d. High blood pressure/ hypertension (AHA, 2019; Jensen et al., 2014; Kushner & Ryan, 2014)
e. Joint and back pain/injury (Jensen et al., 2014; Kushner & Ryan, 2014)
f. Infertility and Polycystic Ovarian Syndrome (ACOG, 2014)
g. Depression and anxiety (Jensen et al., 2014; Kushner & Ryan, 2014; Ma et al, 2019; Melton & Kirkwood, 2019)
h. Certain cancers (Jensen et al., 2014; Kushner & Ryan, 2014)
i. As well as many others . . .

5. Understanding Obesity
    a. Chronic disease (ACOG,2014; ADA, 2019; AHA, 2019; Cheatham et al., 2018; Eaton et al., 2016; Jensen et al., 2014; Kushner & Ryan, 2014; Ma et al., 2019;; Sambal et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016).
        i. ICD-10 code: E66 (.0-.9)
    b. Many factors contribute
    c. Cyclical nature where relapses are common: weight loss and regain (Kushner & Ryan, 2014; Rodriguez-Cristobal, 2017; McLauglin et al., 2017).
    d. Obesity is often associated with:
        i. depression (Ma et al, 2019; Melton & Kirkwood, 2019)
        ii. anxiety (Ma et al, 2019; Melton & Kirkwood, 2019)
        iii. loss of self-esteem (Ma et al, 2019; Melton & Kirkwood, 2019)

iv. reduced quality of life (Kroes, Osei-Assibey and Baker-Searle, 2016; Tapsell et al., 2017)

v. risk of weight related comorbidities/ health risk (Jensen et al., 2014; Kushner & Ryan, 2014)

vi. psychosocial isolation (Eaton et al., 2016; Kushner & Ryan, 2014; Samdal et al., 2017; Tapsell et al., 2017; Thabault et al., 2016).

vii. stigma and bias (Phelan, et al., 2015; Welbourn et al., 2015).

6. There are many factors that contribute to over-weight and obesity. Among them are:

   Genetic or hormonal component (21%) (Doig & Huether, 2014; Perreault, 2019a).

   a. Chemical imbalances or disease states
   b. Depression anxiety
   c. Certain medication side effects
   d. Caloric intake and types of foods
   e. Activity and aerobic exercise
   f. Sedentary lifestyle: work and leisure
   g. Fatigue: poor sleep/sleep apnea/ hours of sleep
   h. Demands and over scheduling: busy lifestyle and commitments
   i. Over working, absent minded eating/ eating alone
   j. Cultural influences
   k. Support systems

7. The good news is there is help: NEWER ME

a. Weight loss is a multicomponent process that includes:
    i. Nutrition: a healthy diet and reduced caloric intake (Jensen et al., 2014; Kushner & Ryan, 2014; Perreault & Apovian, 2019)
    ii. Exercise: increased physical activity: ≥ 150 minutes per week (AHA, 2019)
    iii. Weight loss support (Curry et al., 2018; Jensen et al., 2014; Kushner & Ryan, 2014; Perreault, 2019b;)
    iv. Emotional support: behavior and lifestyle changes (Curry et al., 2018; Ma et al., 2017; Perreault, 2019b; Samdal et al, 2017)
        1. The 5 A's: Provider use of the 5A's (ask, assess, advise, agree, and assist) (Thabault et al., 2016; Vallis et al., 2013) counseling and intervention technique as well as motivational interviewing or counseling techniques (Rodriguez-Cristobal et al., 2017; Samdal et al., 2017, Thabault et al., 2016; Welbourn et al., 2018)
    v. Referrals for added support and care or counseling
    vi. Medication: review, change, additions
    vii. Expanded accountability: motivation and goals (and)
    viii. Autonomy and decision making (and)
    ix. Belief in one's abilities-self-efficacy (Batsis et al., 2016; Beeken et al., 2017; Curry et al., 2018; Eaton et al., 2016; Grossman et al., 2017; Hageman et al., 2017; Hartman et al., 2014; Kozica et al.,

2015; Kroes, Osei-Assibey, Baker-Searle & Huang, 2016; Jensen et al., 2014; Kushner & Ryan, 2014; Samdal et al., 2017)

8. Weight change is achieved by:
    a. Choice!
    b. The balance between caloric intake and calories utilized through bodily functions and physical activity (like a two-sided scale)
    c. Each pound of body fat results from 3500 calories taken in that are not utilized and stored as fat
    d. It's simple math!
        i. Calories eaten minus calories burned = weight gain or loss
9. A Healthy Diet and Reduced caloric intake
    a. According to the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: A Report of the American College of Cardiology/American Heart Association (2019) Task Force on Practice Guidelines and The Obesity Society (Jensen et al., 2014).
    b. There are 3 Evidence-Based diet plans that have been proven to work:
        i. **Total caloric reduction of between 500-750 calories per day,** while also limiting dining out and use of fast foods, as well as eliminating or reducing high caloric 'empty calorie' foods such as pop and chips (Jensen, et al., 2014; Kushner & Ryan, 2014)
        ii. **Eating a healthy diet of between 1200-1500 calories for women and 1500-1800 calories for men** that includes lean protein, fresh vegetables and fruits, whole grains and legumes, low fat dairy and

unsaturated fats while limiting sugars and ‘empty calories’ (Jensen, et al., 2014; Kushner & Ryan, 2014)

iii. **Use of an evidence–based diets** that restricts certain foods such as high fat, high carbohydrate, low fiber foods to create caloric deficit such as **www.choosemyplate.gov** or Weight Watchers ® (Jensen, et al., 2014; Kushner & Ryan, 2014; Madigan, 2014; USDA)

10. Increased Physical Activity
    a. Check with your healthcare provider before starting any new physical exercise plan.
    b. Stop immediately if you experience chest, neck, back or shoulder pain or light-headedness/dizziness or fainting, or nausea with increased activity and seek emergency medical care or call 911.
    c. Stay hydrated, drink plenty of water!
    d. Avoid exercising in extreme conditions of heat or cold.
    e. Having a support system, family member or friend to exercise with can help keep you on track.
11. Increased Physical Activity
    a. The National Guidelines and the American Heart Association recommend increasing physical activity to at least 150 minutes per week with activity, including “moderate-intensity aerobic activity”. (AHA, 2018; Kushner & Ryan, 2014)

   b. OR “75 minutes per week of vigorous aerobic activity (or a combination of both)” (AHA, 2018).

12. Increased Physical Activity
    a. Add Intensity; “Moderate to vigorous aerobic exercise is best” (AHA, 2018).
    b. Aerobic activity should increase your heart rate; “Your heart will beat faster, and you’ll breathe harder than normal” (AHA, 2018).
    c. Some aerobic activities may include fast walking, running, use of exercise machines, swimming, bicycling, or taking a jazzercise, dancing or zumba class
13. Increased Physical Activity
    a. Move More, Sit Less!
    b. “Get up and move throughout the day. Any activity is better than none. Even light-intensity activity can offset the serious health risks of being sedentary” (AHA, 2018).
14. Choosing and making behavioral and lifestyle changes
    a. Meal planning and shopping (www.choosemyplate.gov)
    b. Making meals ahead, use your freezer
    c. Packing your lunch instead of dining out or getting take-out
    d. Taking a lunch or dinner break instead of eating at your desk, on the go or skipping meals
    e. Don’t eat and drive, watch TV or multi-task
        i. Mindfulness-be in the moment

        ii. Enjoy your food (Perreault, 2019b; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Szczekala et al., 2018

    f. Don’t use food as an emotional support
        i. Food is fuel (Perreault, 2019b; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Szczekala et al., 2018; Thalbault et al., 2016; Welbourn et al., 2018).
    g. You can say ‘No Thank You’
        i. when pressured to over-eat
        ii. or to eat unhealthy foods
    h. Look for healthy choices at social gatherings or bring your own
    i. Limit alcohol
        i. Empty calories: Low calorie to nutrition ratio
    j. Plan ahead

15. Cooking TIPS
    a. Bake, broil, grill, steam or boil.
    b. Avoid deep frying!
    c. Cooking in oil adds calories and fat to food.
    d. Use a sprayer bottle with olive oil if necessary
    e. Use a nonstick pan instead of adding oils.
    f. Eat fruits and vegetables, washed and raw!
16. Track your food and exercise

a. The best way to have weight loss success and maintain weight loss long-term is to keep a food and exercise diary of daily caloric intake and activity.
    i. Paper journal
    ii. Technology based
    iii. Phone applications (Cheatham et al., 2017; Tang et al., 2016).

17. Motivation and Goals
    a. Ask yourself:
        i. What are my personal reasons or motivation for losing weight?
        ii. What are my weight loss goals? Set daily, weekly, short and long-term goals. Keep them realistic and attainable!
        iii. Revisit and reassess them often. Why are these goals important to me?
        iv. How can I achieve weight loss? What realistic changes can I make? (Kozica et al., 2015; Rodrguez-Cristobal et al., 2017; Szczekala et al., 2018; Thabault et al., 2016; Wellbourn et al., 2018),
    b. Make your own choices and take ownership of choices made. Be accountable!
    c. Use positive self-talk.
    d. Keep a food and exercise diary/journal.
    e. Stay motivated: Each food and exercise choice bring you one step closer to your weight loss goal!

18. Autonomy and making your own decisions
    a. EBP information
    b. Making informed choices
    c. Taking ownership of choices made (Samdal et al., 2017)
19. Positive self-talk
    a. Accept that over-weight and obesity are a *chronic disease* (Cheatham et al., 2018; Eaton et al., 2016; Ma et al., 2019; Sambal et al., 2017; Tapsell et al., 2017; Thabault Burke & Ades, 2016)
    b. Autonomy allows us to make our own choices
    c. Don't get caught in the negative self-talk trap!
    d. Human's are fallible beings- we make mistakes
    e. Owning our choices
    f. Make better choices next time
    g. Patterns developing
    h. Be Realistic-Aim for a 90:10 ratio!
        i. 90% stay vigilant
        ii. 10% enjoy a treat/rest
    i. Moving forward in a positive way- You can do this!
20. Belief in yourself-self-efficacy
    a. Weight loss can be overwhelming
    b. There can be a lot of obstacles, influences or pressures
    c. Weight loss may have been hard to achieve or maintain in the past
    d. Maybe you haven't been ready

e. One of life's biggest hurdles is belief that you can do something

f. You ***can*** lose weight.

21. Part Two

    a. NEWER ME

    b. THE DIET PLANS

22. Beginning a weight loss plan

    a. Learning to read food labels

    b. Tracking calories

    c. Choosing the right plan for me

    d. A healthy diet

    e. Portion distortion

    f. Shopping for health

    g. Party time! Planning ahead

    h. When I slip, I dust myself off and start a new

    i. Specific weight loss plans

    j. Resources

23. Reviewing a food nutrition label: making calories count

    a. Is eating it worth it?

    b. Servings per container

    c. Serving size

    d. Caloric intake per serving

    e. Carbohydrates/sugar

    f. Fats/cholesterol

g. Protein
h. Sodium
i. Vitamins
j. Minerals

24. Track food and caloric intake
    a. The best way to have weight loss success and maintain weight loss long-term is to keep a food diary of daily caloric intake.
    b. Paper journal
    c. Technology based
    d. Phone applications
    e. If it goes into your mouth…**COUNT IT!**
25. A healthy diet includes
    a. Lean protein
    b. Fresh or frozen vegetables and fruits
    c. Whole grains
    d. No-fat or low-fat dairy
    e. Unsaturated fats
    f. Water
26. Incorporate Portion Control
    a. Check package labeling for serving size
    b. Use a smaller salad plate instead of dinner plate
    c. No second helpings
    d. Order small size- don’t Super-Size!

    e. Share servings

27. Shopping for health!
    a. ChooseMyPlate.gov
    b. Shop the perimeter
        i. Fresh foods
    c. Limit or eliminate processed foods
    d. Limit or eliminate empty calories/snack foods
28. Party time! Planning ahead
    a. Plan for special events
    b. Reserve some of your weekly caloric intake so that you can enjoy special meals
    c. Exercise extra throughout the week
    d. Watch out for hidden calories
    e. Bring your own treats
    f. It’s OK to say no thank you
29. When I slip, I dust myself off and start a new
    a. Weight loss is difficult for some people
    b. A misstep is not the end of your weight loss journey
    c. Take ownership of your eating and exercise
    d. Forgive yourself, use positive self-talk
        i. Avoid words like always, and never
    e. Choose to get back on track
    f. Have a positive support person

30. The three Evidence- based diet plans that have been proven to work:
    a. Total caloric reduction of between 500-750 calories per day, while also limiting dining out and use of fast foods, as well as eliminating or reducing high caloric ‘empty calorie’ foods such as pop and chips (Jensen et al., 2014; Kushner & Ryan, 2014)
    b. Eating a healthy diet of between 1200-1500 calories for women and 1500-1800 calories for men that includes lean protein, fresh vegetables and fruits, whole grains and legumes, low fat dairy and unsaturated fats while limiting sugars and ‘empty calories’ (Jensen et al., 2014; Kushner & Ryan, 2014)
    c. Use of an evidence–based diets that restricts certain foods such as high fat, high carbohydrate, low fiber foods to create caloric deficit (Jensen et al., 2014; Kushner & Ryan, 2014)
        i. Such as the USDA www.choosemyplate.gov or Weight Watchers ® (Madigan, 2014; USDA)
31. Total caloric reduction of between 500-750 calories per day
    a. Reduce portion sizes
        i. Smaller plates
        ii. No second helpings
        iii. Order small not super-size
        iv. Share

b. Incorporating healthy food choices: lean protein, fresh or frozen vegetables and fruits, whole grains, non-fat or low-fat dairy, and unsaturated fats such as olive oil.
c. Limiting dining out and use of fast foods/drive throughs
    i. Higher caloric content
    ii. Added ingredients
    iii. Mindfulness
d. Eliminating or reducing high caloric 'empty calorie' foods such as pop and chips
e. Reducing or eliminating processed foods
f. Keep a food diary to track calories
g. Weigh in weekly
h. Increase activity
i. The goal is to burn more calories in a day through bodily function and aerobic activity, then are taken in through foods consumed.

32. Eating a healthy diet of between 1200-1500 calories for women and 1500-1800 calories for men
    a. Stay within caloric daily limits
    b. Includes lean protein, fresh vegetables and fruits, whole grains and legumes, low fat dairy and unsaturated fats (Jensen et al., 2014; Kushner & Ryan, 2014)
    c. Limiting dining out and use of fast foods/drive throughs
        i. Higher caloric content

ii. Added ingredients

iii. Mindfulness (Perreault, 2019b; Rodriguez-Cristobal et al., 2017; Samdal et al., 2017; Szczekala et al., 2018

d. Eliminating or reducing high caloric 'empty calorie' foods such as pop and chips

e. Reducing or eliminating processed foods

i. Additives sugars, salts and fats

f. Keep a food diary to track calories

g. Weigh in weekly

h. Increase activity

33. Use an Evidence-Based commercial diet

a. Restrict certain foods such as: high fat, high carbohydrate, low fiber foods to create caloric deficit (Jensen et al., 2014; Kushner & Ryan, 2014)

b. www.choosemyplate.gov or Weight Watchers ® (Madigan, 2014; USDA, 20)

34. On-line Resources

a. American Heart Association

i. https://www.heart.org/en/healthy-living/healthy-eating/losing-weight?uid=1966

b. American Diabetes Association

i. https://www.diabetes.org/fitness/weight-loss

ii. And https://www.diabetes.org/nutrition

c. National Institutes of Health: Aim for a Healthy Weight

i. https://www.nhlbi.nih.gov/health/educational/lose_wt/index.htm

d. USDA: ChooseMyPlate

i. English and Spanish

ii. www.ChooseMyPlate.gov

e. Cornerstones4Care

i. Diabetes Mellitus II control resources

ii. English and Spanish

iii. Free resource booklets and tracking tools

iv. www.cornerstones4care.com

35. References

a. Provided in this DNP EBP Project report reference section

Appendix P

On-line Participant Resource Tools

Weight Loss Web Sites and Tools
Herramientas y sitios web para bajar de peso

English:

Cornerstone4Care:Nutrition and Diabetes: It's all on the label (accessed: 2019).

- https://www.cornerstones4care.com/healthy-eating/what-to-do/nutrition-and-diabetes.html

Novomedlink Resources: professional and patient (accessed: 2019)

- https://www.novomedlink.com/content/dam/novonordisk/novomedlink/resources/generaldocuments/CountingCarbandMeal_EG.pdf

ChooseMyPlate.gov: Nutrition resources (accessed: 2019)

- https://choosemyplate-prod.azureedge.net/sites/default/files/tentips/MPMW_tipsheet_14_FINAL.pdf
- https://www.choosemyplate.gov/myplate-tip-sheets

National Institutes of Health/NIH : Healthy Eating- Tips (accessed: 2019)

- https://www.nhlbi.nih.gov/health/educational/lose_wt/eat/tips.htm
- https://www.nhlbi.nih.gov/health/educational/lose_wt/eat/calories.htm
- https://www.nhlbi.nih.gov/health/educational/lose_wt/eat/fd_exch.htm

American Diabetes Association: What to eat with diabetes or pre-diabetes (accessed: 2019)

- https://diatribe.org/what-eat-diabetes-or-prediabetes-adas-new-nutrition-guidelines
- https://www.diabetes.org/nutrition
- https://www.diabetes.org/a1c

American Diabetes Association: fitness and weight loss (accessed: 2019)

- https://www.diabetes.org/fitness
- https://www.diabetes.org/fitness/weight-loss

American Heart Association: Healthy living, eating and weight loss resources (accessed 2019)

- https://www.heart.org/en/healthy-living/healthy-eating/losing-weight
- https://www.heart.org/en/healthy-living/healthy-eating/losing-weight/5-steps-to-lose-weight-and-keep-it-off

- https://www.heart.org/en/health-topics/cholesterol/cholesterol-tools-and-resources

- https://www.heart.org/en/healthy-living/healthy-eating/losing-weight

Cleveland Clinic: exercise and calories burned chart (accessed:2019)

- https://health.clevelandclinic.org/burn-off-calories-boost-heart-health-infographic/

Spanish/Espanol resources:

Novomedlink: Cornerstone4Care: weight loss, diabetic and prediabetic free printed and online resources for clinicians and patients in Espanol (accessed 2019)

- https://www.novomedlink.com/content/dam/novonordisk/novomedlink/resources/generaldocuments/CountingCarbandMeal_SP.pdf

American Heart Association: Healthy living, eating and weight loss resources (accessed 2019)

- https://www.heart.org/en/health-topics/consumer-healthcare/order-american-heart-association-educational-brochures/losing-weight-the-healthy-way-spanish-brochure

- https://www.heart.org/en/health-topics/cholesterol/cholesterol-tools-and-resources

- https://www.heart.org/-/media/files/health-topics/cholesterol/question-for-your-doctor_spanish_2-12-19_form.pdf?la=en&hash=CCCDB417A7D7BDD2ED415A49DF0C6FB1C62E261E

ChooseMyPlate.gov: Nutrition Spanish/ Espanol language resources (accessed: 2019)

- https://choosemyplate-prod.azureedge.net/sites/default/files/printablematerials/Mini-Poster_Spanish_508.pdf

Appendix Q

Matthew 25 Health and Dental Clinic Obesity Project Program Protocol

Project Protocol

A Multicomponent Tailored Intervention Program Protocol for Weight Loss in an Underserved Adult Patient Population with Obesity

Week One:

Complete the following screenings and measures as time allows:

- Weight and height in stocking feet.
  - Encourage patient to wear same type of clothing each weigh in.
  - Calculate BMI:
    - 18-24.9= normal
    - 25-29.9= overweight
    - 30.0-39.9= obese
    - > 40 = morbidly obese
    - If the EMR does not automatically calculate this or paper charts are used, the NIH @ nhlbi.nih.gov has an online calculator for BMI
      - Need height in feet and inches and weight in lbs.
- Blood pressure
  - Complete accurately with location 1" above antecubital space, correct cuff size, sitting with feet flat, after resting for 5 minutes, with measuring arm held at heart height
  - Monitor and refer for follow up assessment if BP above ACC/AHA 2018 guidelines on 2 or more visits.
    - A BP of 120-129/>80 is class I elevated according to new guidelines
      - 130-139/80-89 is Stage I HTN
      - > 140/90 is Stage II HTN
- Laboratory testing when possible: HbA1c and lipid panel; other warranted assessments may include EKG, TSH, AST, ALT

(Jensen et al., 2014; Kushner & Ryan, 2014; Perreault, 2020)

- PHQ-9 and GAD-7
  - Assess for depression and anxiety as these often accompany overweight/obesity in a reciprocal nature
  - Refer for further evaluation if PHQ-9 score is > 10 or if GAD-7 score is > 5, or if patient requests intervention.
- AAQ-W: Acceptance and action questionnaire

- The AAQ-W is used to assess weight loss readiness; it measures pragmatic avoidance and psychological rigidity that play a part in health problems including weight control (Lillis & Hayes, 2008).
- The AAQ-W tool correlates with the common levels of avoidance and rigidity, obesity-related quality of life, psychological distress and BMI. Also there is a correlation with self-reported binge eating and exercise sessions per week as well as making healthy food choices while dining out (Palmeria, Cunha, Gouveia, Carvalho & Lillis, 2016). This considered an effective and validated tool to measure weight loss readiness.
- Scoring may range from 22 to 154 with lower scores indicating "less experimental avoidance and more psychological flexibility" (Lillis & Hayes, 2008, p. 34).

- WEL-SF: Weight Efficacy Lifestyle Questionnaire Short-Form Tool
  - The WEL-SF measures eating self-efficacy or one's belief in their ability to perform in a given situation. Low self-efficacy is correlated to lower weight loss success and high self-efficacy is correlated to greater weight loss success. Self-efficacy for eating is a predictor of acquired weight loss behaviors. This tool asks the participant to reflect on how confident they feel in relation to situations in which overeating may become a problem.
  - Likert format with scores that range between 0 to 10 with higher scores representing higher confidence levels for each question. (Ames, Heckman, Grothe & Clark, 2012; Flolo, Andersen, Neilsen, & Natvig, 2014).
  - Used to measure weight-loss readiness.
- The 5 A's: ask, assess, advise, agree, and assist (Thabault et al., 2016; Vallis et al., 2013) counseling and intervention technique:
  - Ask would it be alright if we talk about your weight or how do you feel about your weight? (Do not judge-unbiased)
  - Assess health status, weight, BMI, BP etc.
  - Advise: collaborate- say now that we know your current health and risks, can we work together to help improve things/ or what can I help you with to improve your health and lose weight?
    - This is a great time for weight loss education.
  - Agree- the patient needs to understand the treatment and agree that it's a good choice creating 'buy in' to set goals.
  - Assist-identify barriers and facilitators to success with the patient, talk about ways to overcome or promote these.
  - Use motivational interviewing or counseling techniques (Rodriguez-Cristobal et al., 2017; Samdal et al., 2017, Thabault et al., 2016; Welbourn et al., 2018)

- View program instruction via: A Personalized Weight Loss Program for an Over-weight or Obese Population -Power Point presentation
    - 2-part series in 1 presentation
    - voiced over
    - lasts about 30 minutes
- Review weight loss plan
    - There are 3 plans: the first works by decreasing calories by 500-750 calories per day and works if they are already below @2500-3000 calories per day otherwise it won't work. The third plan- use of Weight Watchers ® type that costs $$ but will work.
    - Generally, allow them to choose but explain as written above. Try to put patients on the second plan either the 1200-1500 calories for women or the 1500-1800 calories for men because it provides structured limits and guidelines. Also, this one works well for diabetes (Jensen et al., 2014; Kushner & Ryan, 2014)
        - Within the 1200-1500 /1500-1800 calories they need to get:
            - Carbohydrates/ Grains: 45-65% of daily total calories (< 125-150 grams) carbohydrate from *all sources, including grains, fruit, dairy, sugars.*
            - Fruit /veg: 5 servings (limit to 2 servings fruit if DM)
                - Corn, peas, carrots, plantains, potato, yam, squash limit 1/2c per serving; all other veg generally unlimited and doesn't need to be counted in calories due to nutrition, fiber and low calories.
                - Fresh or frozen are best due to sodium, sugar and additives in canned.
            - Protein: try to get 3 servings or between 55-75 grams of lean protein per day
                - Lean beef, poultry, fish, legumes/beans, nuts, eggs, dairy
                - (limit processed meats; no pork, ground meats or sausages)
            - Fat: < 45 grams per day: Unsaturated fats such as olive oil, avocado, banana, cooking spray
                - Avoid solid fats such as white shortening (Crisco type)
                - Use banana, avocado, apple sauce for baking, or low saturated oil.

        - Dairy: 2 servings per day, or supplement calcium with green leafy veg/ mineral supplement
      - Water: 6-8, 8-ounce glasses of no calorie water per day unless restricted.
      - No food are off limits but, tell patients if it goes in their mouth they must count it and stop eating when they have reached their daily calorie limits.
    - Bake, broil, boil, grill foods with minimal sprayed oil or fats.
    - DO NOT DEEP or fat fry.
    - AVOID Processed foods and empty calories in general.
    - Shop the perimeter of the grocery where healthy choices are.
    - Read food labels for servings/size and content
    - Weight and measure foods
    - Keep a food and exercise journal after EVERY Meal
- Discuss healthy BMI and were patient is currently: Set 3% total body weight loss as initial 12-week goal; then 5% from baseline at 6-month mark and 10% from baseline by month 12. Do not overwhelm them. Let them know this is a long-term process with no quick fix, but each day they will weigh less.
- Weigh in weekly to promote accountability
    - Remind them the scale does not lie; calories in versus calories burned makes the scale go up, down or stay the same. It is their choice.
    - Unless there is a cardiac issue/edema-then refer.
- Exercise at least 150 minutes per week on most days (about 20-30 minutes per day)- moderate intensity aerobic activity of their choice: walking, bicycling, swimming or use of exercise machines
- Review S/S of CVA MI-STOP Call 911
- Provide handouts:
    - Food and exercise journal
    - Personal daily Journal Diary: Goal setting and motivation
    - *What's on your plate?* (www.choosemyplate.gov) (English and Spanish)
    - *Planning Healthy Meals (*www.Cornerstone4Care.com)
    - *5 Steps to Lose Weight and Keep It Off* (www.heart.org)
    - *Changing Habits for Better Health (*www.niddk.nih.go)v
    - *Make a Difference with Positive Self-Talk (*www.diabetes.org)
    - *Conquer Cravings with These Healthy Substitutions (*www.heart.org)
    - *Why Do I Eat When I'm Not Hungry?*

- *Websites for Healthy Recipes (*www.cookinglight.com; www.bbcgoodfood.com)
- Recipe card Healthy Stuffed Chicken Breast (www.bbcgoodfood.com)
- Weight loss websites and tools list (ADA; AHA; www.heart.org; www.choosemyplate.gov; www.cornerstone4care.com; www.nhlbi.nih.gov; www.diabetes.org; https://diatribe.org)
- Provide Cornerstone4Care diabetes education booklets in English or Spanish (www.cornerstones4care.com)
- Provide community resource booklet and food pantry list- contact Social Services

- This is a lot of information for patients, but because of the high 'no show' rate for follow up appointments at this clinical site, it provides the necessary resource tools for them should they choose to lose weight on their own.
  - Have them bring any questions to their second visit, and monitor progress.
  - Evaluate food and exercise journal- verbal discussion.
  - Evaluate and reinforce weight loss education and need for journaling and goal setting as necessary.

Follow up. Follow up weekly for at least 4- 8 weeks; then every 2-4 weeks until at goal; then monthly for 6 months; then every 6 months for 2 years; then if weight loss goal is maintained meet yearly.

- Schedule next visit while the patient in clinic and provide appointment card. Call to remind patient of appointment 24-72 hours in advance.

Each visit. Reassess Weight, BMI and BP at each visit. Reinforce education, goal setting, behavioral interventions, food and exercise tracking, accountability and autonomy. Do not allow bias to influence treatment. Provide EBP counsel and support.

Re-assess for depression and anxiety. Reassess for depression and anxiety as these often accompany overweight/obesity in a reciprocal nature

- Complete PHQ-9 and GAD-7 at baseline, week 12, 6 months, then at each visit.
- Refer for further evaluation if PHQ-9 score is > 10 or if GAD-7 score is > 5, or if patient requests intervention.

References

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USDA ChooseMyPlate.gov. Dietary guidelines for Americans. Retrieved from: https://www.choosemyplate.gov/

Appendix R

Daily Food and Exercise Journal

Daily Food and Exercise Journal/ Diario de Alimentos y Ejercicios

Meal/ Comida	Foods eaten/ Alimentos consumidos	Protein/ proteina grams	Carbohydrates /carbo-hidrato grams	Fats/ grasas grams	Total Calories / Total de calorias	Minutes of exercise/ Ejercicios
Breakfast Desayuno					=	
Lunch/ Almuerzo		+	+	+	+/=	
Dinner/ Cena		+	+	+	+/=	
Snack/ Bocadillo		+	+	+	+/=	
Snack/ Bocadillo		+	+	+	+/=	
	Add up the total caloric intake for today from the above totals / Sumar la ingesta calorica total para hoy de los totals anteriores. Review your limits /revise sus limites.	=	=	=	=	=

Appendix S

SPSS Code Book

Demographics			
	Measure	Value	Code
1	Sex	Male	1
		Female	2
		Other	3
2	Age	True age	Number
3	Race	American Indian or Alaska Native	1
		Asian	2
		Black or African American	3
		Native Hawaiian or Other Pacific Islander	4
		White	5
		More than one race	6
		Unknown or not reported	7
	Ethnicity	Hispanic or Latino	1

			Not Hispanic or Latino	2
			Unknown or not reported	3
4	English speaking		Yes	1
			No	2
		Measures		
5	(Height in Inches)		50 - 75	Number
	HtInW1			
6	(Weight in pounds)		100 - 500	Number
	WtLbs1			
	WtLbs2			
	WtLbs3			
	WtLbs4			
	WtLbs8			
	WtLbs12			
7	(Weight In Kg)		50 - 400	Number
	WtKg1			
	WtKg2			
	WtKg3			
	WtKg4			
	WtKg8			
	WtKg12			

8	(BMI)	20 - 50	Number
	BMIW1		
	BMIW2		
	BMIW3		
	BMIW4		
	BMIW5		
	BMIW6		
9	WaistCircCMW1	75-150CM	Number
	WaistCircCMW12		
10	HipCircCMW1	75-150CM	Number
	HipCircCMW12		
11	WHRW1	0.5-1.9	Number
	WHRW12		
12	(Systolic BP)	75-200	Number
	SBPW1		
	SBPW2		
	SBPW3		
	SBPW4		
	SBPW8		
	SBPW12		
13	(Diastolic BP)	50-125	Number
	DBPW1		
	DBPW2		

	DBPW3		
	DBPW8		
	DBPW12		
14	HbA1cW1	5.5-13.9	Number
	HbA1c:W12		
15	(Chol & Lipids)	100-300	Number
	TCW1		
	TCW12		
16	LDLW1	0-300	Number
	LDLW12		
17	HDLW1	0-100	Number
	HDLW12		
18	TrigW1	40-500	Number
	TrigW12		
19	GAD-7:		
	GAD7Q1W1, GAD7Q2W1, GAD7Q3W1, . . .	0 – 3 for each item	Number
	GAD7Q7W1		
	GAD7Q1W12, GAD7Q2W12, GAD7Q3W12, . . .		
	GAD7Q7W12		
20	PHQ-9:		
	PHQ9Q1W1, PHQ9Q2W1, PHQ9Q3W1 … PHQ9Q9W1	0 – 3 for each item	Number
	PHQ9Q1W12, PHQ9Q2W12 … PHQ9Q9W12		

21	AAQW: AAQWQ1, AAQWQ2, AAQWQ3, …, AAQWQ22	0-6 for each item	Number
22	<u>WELSF:</u> WELSFQ1, WELSFQ2, WELSFQ3, …, QELSFQ8	1-10 for each item	Number
23	WksComp	1, 2, 3, 4, 8, or 12	number
24	WtLoss	Yes No	1 2
25	WtLossMaint	Yes No	1 2
26	WtChange	 -100 – 100	Number Enter as plus or minus
27	MetWtLossGoal	Yes No	1 2

Appendix T

Permission to use AAQW tool as published in 2008

Via email reply Sun., July 21, 2019, 8:07PM

Yes of course, you have my permission (though it is not needed). Best of luck with your research!

Jason

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