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A Lifestyle Approach to Weight Loss with Women Diagnosed With Polycystic Ovarian Syndrome

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A LIFESTYLE APPROACH TO WEIGHT LOSS WITH WOMEN DIAGNOSED WITH POLYCYSTIC OVARIAN SYNDROME

by

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Abstract

Polycystic ovarian syndrome is an endocrine disorder with the highest prevalence in the United States. The purpose of this study was to determine if a whole food plant-based diet, moderate caloric restriction, and moderate-intensity exercise could reduce body mass index in overweight women diagnosed with polycystic ovarian syndrome. The study was a bound case study, five participants were recruited and two participants completed the study. Self-reported measurements on biometric data were recorded pre and post-intervention. The study also examined the effect these lifestyle changes had on menstrual regularity. Health coaches were utilized to assist participants in adherence to the lifestyle changes. The two participants experienced a reduction in their body mass index and an improvement in menstrual regularity.

Keywords: Polycystic ovarian disease, whole food plant-based diet, moderate-intensity exercise, health coach

Dedication

To my grandmothers who were the original bound case study, I watched play out throughout my life and sparked my interest in Lifestyle Medicine.

Acknowledgments

Getting to this point in my career and scholastic journey would not have occurred without the support of my husband and boys. The completion of this journey is one to be celebrated by them as they have supported me during this process.

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Chapter 1: Introduction

Many disease processes are related to the lifestyle that the individual maintains. The focus of chapter one was to look at the background of polycystic ovarian syndrome (PCOS), its disease process, diagnosis, and current treatment plans. The clinical question was developed, and concepts and terms were defined.

Background and Significance

PCOS is an endocrine disorder with a reported incidence rate of 3-10% and prevalence of 1.6-18%, depending on the criteria used for diagnosis (Wolf et al., 2018). Thus, PCOS is the most common endocrine disorder in women. Underdiagnosis of PCOS is common, with some estimates stating that as many as 75% of women with PCOS are not diagnosed (Wolf et al., 2018). PCOS is a major cause of female infertility and is linked to insulin resistance, type 2 diabetes, and dyslipidemia (El Hayek et al., 2016). In women with irregular menses, a diagnostic criterion for PCOS, Chavarro et al. (2016) noted an increased incidence of heart disease and type 2 diabetes. Dyslipidemia and type 2 diabetes have both been linked to an increase in coronary artery disease in patients less than 40 years old (Christiansen et al., 2016). In women diagnosed with PCOS, scores for depression, anxiety, and negative body image were higher than in healthy controls (Barber et al., 2019). This demonstrates that PCOS can contribute to physical ailments and mental health dysfunction.

PCOS also comes with a large price tag. In the United States alone, about 4 billion dollars are spent per year to diagnose and treat PCOS (El Hayek et al., 2016). PCOS also increases women's risk for several other diseases, such as diabetes, gestational diabetes (GDM), heart disease, high blood pressure, sleep apnea, and stroke (Centers for Disease Control and

Prevention [CDC], 2020). Each disease costs billions of dollars every year in the United States, and, while PCOS is not the only reason these diseases develop, it is a factor in some of the cases.

Diagnosis

PCOS is currently diagnosed using the Rotterdam criteria. With this criteria, two of the three following symptoms must be present: androgen excess, ovulatory dysfunction, and/or polycystic ovaries (Legro et al., 2013). Obesity and insulin resistance often accompany PCOS, yet are not used in making the diagnosis (El Hayek et al., 2016). The Rotterdam criteria further classifies PCOS according to four subgroups: frank PCOS, non-polycystic ovary PCOS, non-classic ovulatory PCOS, and non-classic PCOS. The symptoms of frank PCOS are chronic anovulation, polycystic ovaries, and hyperandrogenism. Patients with classic non-polycystic ovary PCOS have chronic anovulation and hyperandrogenism while maintaining normal ovaries. Non-classic ovulatory PCOS results in hyperandrogenism and polycystic ovaries, while patients typically preserve their regular menstruation cycles. And lastly, non-classic PCOS results in chronic anovulation, polycystic ovaries, and normal androgens (El Hayek et al., 2016).

Treatment

Current treatment for PCOS involves first screening women who meet diagnostic criteria for metabolic disease, thyroid disease, and pregnancy (Legro et al., 2013; Williams et al., 2016). Caloric restriction and exercise are the first line of treatment to manage metabolic symptoms in overweight (BMI 25 - 30 kg/m^2) and obese (BMI greater than 35 kg/m^2) women with PCOS (Legro et al., 2013; Ward et al., 2019; Williams et al., 2016; Zhou et al., 2020).). Hormonal contraception is the treatment of choice to help manage hormonal disturbance, menstrual irregularities, hirsutism, and acne (Legro et al., 2013; Williams et al., 2016). Metformin is

currently used to treat pregnancy-related complications and obesity, along with the management of acne, hirsutism, and alopecia (Legro et al., 2013).

Problem Statement

This study was designed to investigate the role of a detailed lifestyle change on symptoms of PCOS and weight loss due to the four following reasons: the incidence of PCOS, the cost of PCOS to the U.S. healthcare system, the ability of PCOS to influence long-term health, and the ability for lifestyle interventions to combat PCOS and its comorbidities.

Clinical Question

Do women between the ages of 18-45 without the onset of menopausal symptoms with a body mass index (BMI) greater than 25 have decreased WHtR, decreased BMI, and increased menses regularity after participating in a 12-week lifestyle program consisting of a WFPBD, caloric restriction, and moderate-intensity exercise?

Theoretical Framework

The study was framed by two theories. The first theory is the Adventist Nursing Theory. The Adventist Nursing Theory acknowledges that God surrounds and sustains all. The environment, individual, community, health, and family all form lines of defense around the individual (Jones et al., 2017). Connecting, caring, and empowering are needed to utilize EBP in a patient-centered model to promote health and restore the individual to wholeness (Jones et al., 2017). The outcome of this theory is to restore the connection of the individual to Christ.

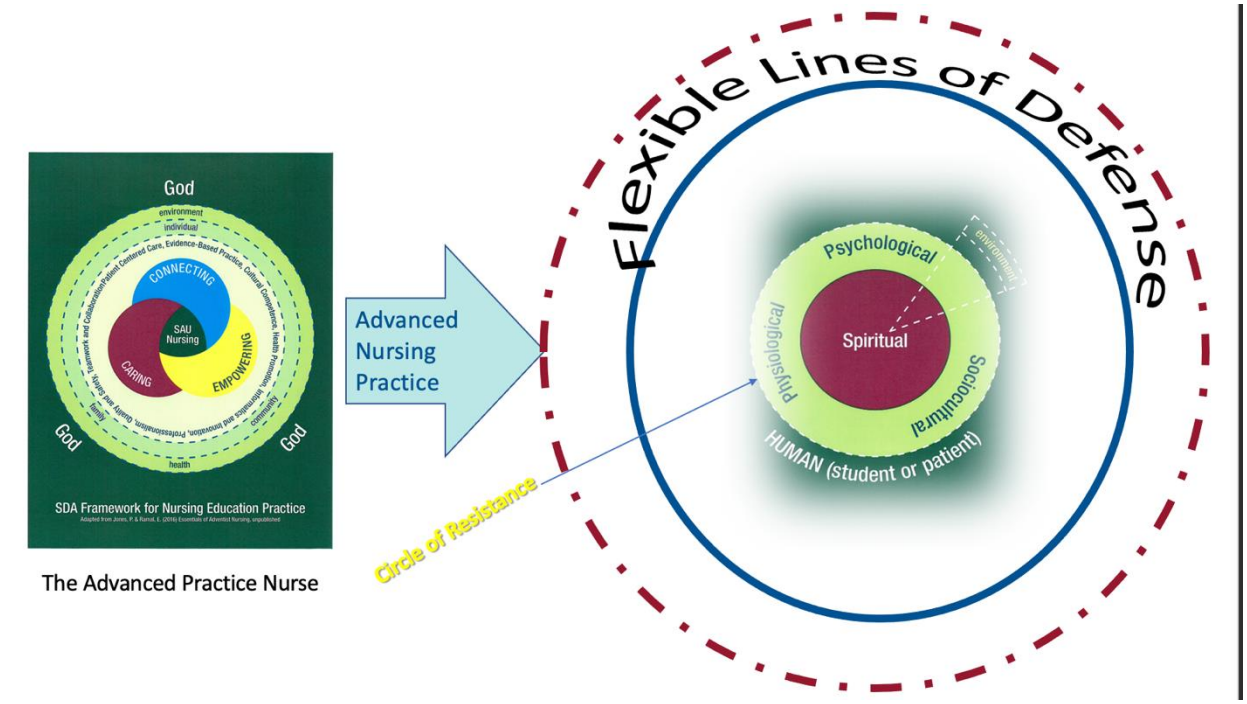
The Neuman Systems Model has a wellness focus (Fawcett & Neuman, 2011). Neuman viewed each patient as a unique system that interacts with the environment, or stressors within the environment, in a distinct way. This interaction can positively or negatively affect the flexible and normal lines of defense. The flexible line of defense is able to absorb stressors and is

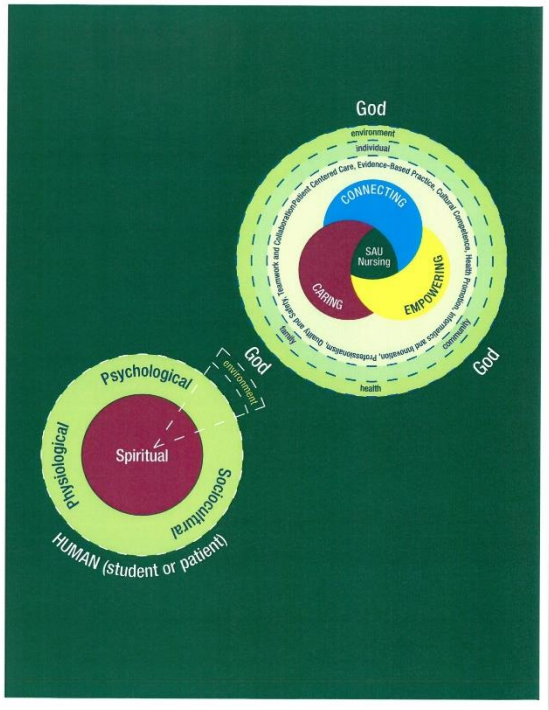
strengthened by primary prevention. A breakdown in the flexible line of defense can lead to a breakdown in the normal line of defense (Fawcett, & Neuman, 2011). A breakdown in the normal line of defense results in homeostasis being disrupted (Petiprin, 2020). Inside the individual are concentric lines of resistance that act to defend against the stressors. The nurse acts with primary, secondary, or tertiary prevention to assist the individual to maintain homeostasis and preserve energy (Petiprin, 2020). With PCOS, the normal line of defense has been compromised as hormone levels are outside of normal limits, blood pressure can rise, cholesterol and glucose levels can become elevated, and body fat stores can increase. This diseased state results from a failure of the flexible and normal line of defense. With PCOS, resistance to the stressor of disease should be combated by lifestyle measures as the first line of treatment (Williams et al., 2016).

PCOS is a diseased state that has a genetic component, which is worsened by environmental stressors, such as obesity. Lifestyle factors as addressed in the Adventist Nursing Theory can strengthen lines of resistance to protect the individual from a diseased state. Working with women, providers can strengthen the internal lines of defense and bolster the system by implementing secondary lines of defense to prevent more comorbidities from forming. This enables providers to empower women to take charge of their health and restore the flexible lines of defense.

Figure 1

Neuman's System Model Integrated with the Adventist Nursing Theory





To bolster this flexible line of defense, this study explored a WFPBD, moderate caloric restriction, and moderate-intensity exercise. The use of these factors of defense can help to bring the individual back into system stability.

The principles of wellness only result from the true God and can be shared by individuals with others to increase their state of wellness. Part of this study included connecting, caring, and empowering the study participants as they implemented the evidence-based strategies that strengthened their lines of defense. The idea that God is behind and empowers all positive changes in an individual's life cannot be overlooked. God is the source of all truth, and as providers study how to best guide patients, they study His ways.

Definition of Terms

Polycystic Ovarian Syndrome (*PCOS*)

PCOS is a condition of hyperandrogenism, (which can be diagnosed either clinically or chemically), oligomenorrhea, and polycystic ovaries (El Hayek et al., 2016).

A Whole food plant-based diet (WFPBD)

WFPBD is a diet that includes a variety of vegetables, fruits, legumes, whole grains, nuts, and seeds. The diet is free of all animal products, refined grains, oils, and juices (Greger, 2020).

Moderate-intensity Exercise

Moderate-intensity aerobic exercise is set at 40-60% of max heart rate. Moderate-intensity exercise is based on individual metrics and figured by utilizing the Kasch YMCA Step Test or Rockport One-Mile Walk Test formula (Cofre-Bolados et al., 2018; Kumar & Goswami, 2019).

Moderate Caloric Deficit

A moderate caloric deficit diet is one in which caloric consumption is 25% less than the calorie level set at the resting metabolic rate (RMR), plus the calories burned during exercise (Most et al., 2018).

Insulin resistance

Insulin resistance is a state in which the peripheral cells are slow to uptake the circulating glucose in the presence of insulin (Petersen & Shulman, 2018). The pancreas produces insulin at higher rates to drive the glucose into the cell, thus resulting in elevated glucose levels.

Gestational Diabetes Mellitus (GDM)

GDM is diagnosed via a screening test in pregnant women at 24 weeks gestation. A one-hour glucose tolerance test is conducted. A glucose result greater than 140 at the one-hour mark results in a failed test. At this point, a three-hour test is completed. If the three-hour glucose is greater than 190, a diagnosis of GDM is made (Garrison, 2015).

Overweight

Overweight is defined as a BMI of 25-30 kg/ m^2n (Zhou et al., 2020).

Obesity

Moderate obesity is defined as a BMI from 30 to 35 kg/ m^2n, and severe obesity as a BMI greater than or equal to 35 kg/ m^2n (Ward et al., 2019)

Waist-to-height-ratio (WHtR)

WHtR is more recently being used as a marker for cardio-metabolic health risks. WHtR had been demonstrated to correspond to changes in visceral adiposity. This reduction of risk occurs at less than 0.5 WHtR for women (Jabłonowska-Lietz et al., 2017).

Conclusion

PCOS is a serious disease process that affects many women. Current treatment focuses on managing symptoms but does not address the root cause of the disease process. Through strengthening the various lines of defense and creating a support system for the individual to change lifestyle habits, it is theorized that an individual could reduce the physical manifestation of the disease.

Chapter 2: Literature Review

A search of available literature was completed to establish what the current body of scientific evidence demonstrated regarding the effect of lifestyle changes on body weight in women diagnosed with PCOS. Specifically, it was investigated the effect of a WFPBD, caloric restriction, and physical activity (PA).

Research Process

CINAHL an English-language database of nursing and allied health journals was utilized while searching for articles. The search terms “Whole Food Plant-Based diet” and “PCOS” or “polycystic ovarian syndrome” were entered into the search engine. This resulted in five results within the last five years. None of these studies were specific to the effect that a three-pronged lifestyle change could bring for women diagnosed with PCOS. The closest article found discussed the impact of different diets on the cardiometabolic syndrome. Articles were present that detailed the effect of diet, exercise, or caloric restriction on PCOS. Articles were thus reviewed that looked at individual factors’ effects on PCOS, and these were examined. CINAHL was also used to search for “moderate-intensity” exercise and “PCOS”. This resulted in 11 articles being found in the last five years; two were specific to exercise, PCOS, and weight loss. At the conclusion of the study, more articles were included that involved the use of health coaches. Google Scholar was used to search for the terms “health coaching” and “weight loss”, health coaching and PCOS, Health Coaching, and weight loss. Of the articles in the past five years, 3 articles were specifically reviewed that closely aligned with telehealth coaching and weight loss.

The current practice guidelines recommend lifestyle modifications as the first line of therapy to treat overweight women with PCOS (Williams et al., 2016). The practice guidelines as

set forth by the Endocrinology Society and American Academy of Family Practice recommend caloric restriction as the method to decrease weight. No recommendations have been made regarding the types of food to consume or the impact that PA could have on PCOS and weight loss (Legro et al., 2013; Williams et al., 2016). While this was a great start, as research regarding other disease states shows, adherence to a WFPBD demonstrates an opportunity to reduce insulin resistance, hyperlipidemia, and body fat. This is especially noted in metabolic diseases (Soares et al., 2016; Valachovičová et al., 2017). Given that PCOS had a large metabolic component, placing overweight and obese women diagnosed with PCOS on a caloric restricted, WFPBD and encouraging them to adhere to moderate-intensity exercise had the potential to reduce their chronic disease rate.

Kazemi et al. (2018) Investigated the effect a diet rich in plants and fiber had on women diagnosed with PCOS. Yet, these studies did not include caloric restriction. Studies have been conducted that demonstrate the role that exercise plays to help normalize weight and reduce visceral adipose tissue (VAT) stores (Jang et al., 2019). To date, no research had been done on women with PCOS looking at the combination of a WFPBD, caloric restriction, and moderate-intensity exercise to initiate weight loss and reduce waist circumference, BMI, and body fat percentages.

Weight Loss Moderate Caloric Reduction

Barber et al. (2019) examined the link between obesity and PCOS. While the researchers did note that a genetic link to PCOS exists, being overweight or obese leads to the physical manifestation of the disease. Barber et al. (2019) found a modest weight loss of even five percent had been shown to decrease the hyperandrogenic state, improve the metabolic status, and improve the reproductive status in those diagnosed with PCOS. It had been noted that as body

weight increases into the healthy range menstrual regularity increases, but as the weight goes above the overweight range, menstrual regularity increases (Chavarro et al., 2016).

In a study conducted by Fonseca et al. (2018), the methods of energy expenditure were clarified. The role of three aspects of energy expenditure are the calories needed to maintain the body at rest or the basal metabolic rate (BMR), PA, and the thermic effect of food. The BMR is the main source of calorie expenditure consisting of 60-70% of total calorie expenditure. BMR consists of the energy used for vital cellular metabolism in a neutral thermic environment. PA is the second-largest source contributing to 15-30% of the total daily expenditure. The thermic effect of food makes up approximately 10% of the daily calorie expenditure. The factors that have been noted to be modifiable were PA and, to some degree, the thermic effect of food (Fonseca et al., 2018). Setting the caloric goal at an energy deficit of 25% assisted in creating this negative energy balance (Teede et al., 2018).

Physical Activity

A habit of PA had been linked to a reduction in weight, fasting insulin, glucose level, waist circumference, fat mass, androgen excess, blood pressure, and an improvement in lipid profiles (Barber et al., 2019). The effect of PA on metabolic health is complex and multifactorial.

In a meta-analysis conducted by Bird and Hawley (2017) it was demonstrated that poor insulin sensitivity results in impaired glucose intake throughout the body. Increasing PA can have a positive impact on glucose uptake.

One of the mechanisms of interest is Apelin-12, an adipokine. Adipokines are proteins secreted by adipose tissue (Jang et al., 2019). Adipokines can have a positive effect on health influencing insulin resistance inflammation cardiovascular function energy and lipid metabolism along with lipogenesis and lipolysis in a positive manner and healthy weight individuals (Jang et

al., 2019). As the weight of an individual increases, especially into the obese range, adipokines are secreted that influence the cardiometabolic health in a negative manner (Unamuno et al., 2018). In individuals with obesity, type two diabetes, or metabolic syndrome it had been noted that these proteins play a role in lipogenesis and lipolysis affecting the absorption of glucose and fat (Jang et al., 2019). Apelin-12 is regulated by insulin and is closely related to metabolic syndrome and insulin resistance. Elevation of apelin had been linked to an increase in BMI (Polak et al., 2017).

A randomized controlled trial consisting of 24 individuals was conducted to evaluate the effect of exercise on apelin-12 serum concentrations over 8 weeks (Jung et al., 2019). The participants were equally divided into three groups of eight, with one group participating in aerobic exercise, another group participating in resistance training in the third group engaging in no exercise (Jung et al., 2019). It was noted that 8 weeks of aerobic training at 60 to 70% of max heart rate experienced a decrease in serum apelin-12 (Jung et al., 2019). Participants engaging in resistance training also experienced a reduction in serum Aplin-12 (Jung et al., 2019). It should be noted that both exercising groups experienced a decrease in overall body weight, waist circumference, BMI, and body fat (Jung et al., 2019). Thus, it can be shown that physical activity influences the way our metabolism works efficiently. Promoting healthy weight loss and improvement in glucose metabolism (Jung et al., 2019).

PA had been shown to increase the basal metabolic rate thus helping to create a negative energy balance (Fonseca et al., 2018). PA had been demonstrated to be useful in controlling the symptoms of PCOS (Barber et al., 2019; Beena & Thomas 2016; Smyka et al., 2017). Patten et al. (2020) helped to establish that PA is an important pillar in PCOS management due to exercise's ability to help stabilize weight and to improve insulin and glucose levels. PA had been

demonstrated to decrease VAT (Gepner et al., 2018). VAT fat loss was also shown to decrease triglycerides and cholesterol (Gepner et al., 2018). PA can be performed in a myriad of different ways. There is both resistance exercise and aerobic exercise. Moderate-intensity aerobic exercise is exercising at an intensity of 60-75% of maximum heart rate (American College of Sports Medicine [ACSM], 2018, p. 146). Middle-age, overweight and obese women exercising at moderate-intensity for 50 minutes four times per week for eight weeks resulted in weight loss and reductions in BMI, body fat percentages, and waist circumferences (Jang et al., 2019).

Poor insulin sensitivity results in impaired glucose uptake throughout the body (Bird & Hawley, 2017). Increasing PA can have a positive impact on glucose uptake. The meta-analysis by Bird and Hawley reviewed 53 articles. The summary of the articles demonstrated that increased glucose uptake and improvement of insulin sensitivity resulted following a single bout of physical activity and continued to improve with a habit of physical activity. These changes were noted irrespective of weight loss.

A small study of 16 participants evaluating the effect of physical activity and changes in body weight in obese women between a group with PCOS and a group without PCOS was conducted (Scott et al., 2017). Scott et al. found that physical activity was positively associated with weight loss. The women in the PCOS group lost an average of 4.16% of body weight, and the women without PCOS lost 4.85% of body weight (Scott et al., 2017). In the women diagnosed with PCOS who did not have a reduction in body weight, or experienced a smaller reduction in body weight they still experienced a significant reduction in central adiposity and improved aerobic capacity, and an increase in insulin sensitivity (Scott et al., 2017). This small study helps to contribute to the evidence supporting that exercise independent of weight loss is beneficial for cardiometabolic health (Scott et al., 2017)

PA increased the total energy expenditure (TEE) and increased the BMR for a 24-hour period (Fonseca et al., 2018). An increase in fat-free body mass has been linked to an increase in BMR (Fonseca et al., 2018). A habit of PA was shown to reduce VAT and increase fat-free body mass (Gepner et al., 2018). These factors combine to improve weight loss (Fonseca et al., 2018; Gepner et al., 2018).

Whole-Food-Plant-Based- Diet

The Adventist Health Study (AHS) and epidemiological study spanning five years examined the effect of different dietary patterns on health. One of the findings was the direct correlation between an increase in meat consumption and an increase in BMI (Turner-McGrievy et al., 2017). Moreover, the European Prospective Investigations into Cancer and Nutrition (EPIC-Oxford), another epidemiological study found that those consuming a vegan diet gain less weight as they age (Turner-McGrievy et al., 2017). These large studies both demonstrate the protective effect of a plant-based diet on weight gain.

The broad study was conducted in New Zealand over the course of a year (Wright et al., 2017). Participants were randomly assigned to the intervention or the control arm (Wright et al., 2017). Participants in the interventional arm were instructed on a low-fat plant-based diet, with approximately 7 to 15% of total energy from fat (Wright et al., 2017). The participants in the study were not given any caloric recommendations but were provided with a list of food to consume, limit, or avoid (Wright et al., 2017). Weights were measured at the three-month six month and 12-month intervals (Wright et al., 2017). At the conclusion, the intervention group lost an average of 11.5 kg and the control group had no significant reduction in weight (Wright et al., 2017).

A single-arm prospective study conducted over the course of eight weeks was completed by Campbell et al. (2019). In this study, participants were given instructions regarding a whole food plant-based diet with no animal products, no refined starches, sugars, or oils (Campbell et al., 2019). The participants were allowed to eat ad libitum (Campbell et al., 2019). At the end of the eight weeks, participants had lost an average of 6 kg (Campbell et al., 2019). Lipid levels were obtained pre and post-study with a mean reduction of -25.2 for total cholesterol (Campbell et al., 2019). LDL experienced a mean reduction of -15.3 (Campbell et al., 2019).

Foroozanfard et al. (2017) conducted a randomized controlled clinical trial with 60 overweight or obese patients diagnosed with PCOS. This study was conducted over a 12-week course. Patients were randomized into the control group or the DASH group (Foroozanfard et al., 2017). Both diets were calorically matched in total and macronutrients (52%-55% carbohydrates, 16%-18% proteins, and 30% total fats) (Foroozanfard et al., 2017). The DASH diet was richer in fruits, vegetables, whole grains, low-fat dairy products, and low in cholesterol and refined grains. Those in the DASH arm had a decreased BMI (-1.60+0.5), decreased insulin, and decreased free androgen. Along with other positive changes in lab values (Foroozanfard et al., 2017).

A small single-arm prospective study of 15 participants diagnosed with diabetes type two within the past year, conducted in Palestine noted a reduction of fasting glucose by 45% (Sa'ad-Aldin & Altamimi, 2018). At the commencement of the study fasting blood glucose averaged 189. At the completion of the 12-week program fasting blood sugars average 102. This also corresponded with an average weight loss of 4.6 kg (Sa'ad-Aldin & Altamimi, 2018). It was interesting to note that though the study only contained 15 participants with some of them starting at a healthy weight there was still a noted decrease in fasting blood glucose (Sa'ad-Aldin

& Altamimi, 2018). This study adds to the evidence that a whole food plant-based diet can have a profound effect on glucose levels and insulin sensitivity (Sa'ad-Aldin & Altamimi, 2018).

Another single-arm prospective 10-week study looked at the effect of a whole food plant-based diet on cardiovascular risk factors specifically LDL in 36 volunteers (Jakše et al., 2019). At the completion of the 10 weeks, participants lost an average of 2.6 kg. LDL cholesterol was reduced from 3.2 $\pm$ 1 (123 $\pm$ 38.67) to 2.6 $\pm$ 0.7 (100 $\pm$ 27) mmol/L (Jakše et al., 2019).

Kahleova et al. (2020) investigated the role of a low-fat vegan diet on several biomarkers. Kahleova et al. conducted a 16-week randomized control trial with rolling recruitment in Washington, DC. The study evaluated the effect of a low-fat vegan diet on body weight, composition, insulin resistance, hepatocellular and intramyocellular lipid levels, and the thermic effect of food in overweight and obese individuals (Kahleova et al., 2020). In total 244 participants met inclusion criteria and underwent random assignment to the intervention or control group (Kahleova et al., 2020). The intervention group was placed on a low-fat vegan diet and the control group was instructed to make no changes (Kahleova et al., 2020). Measurements were taken at zero and 16 weeks (Kahleova et al., 2020). The intervention group experienced an increase in the thermic effect of food and a weight loss of 5.9 kg (Kahleova et al., 2020). Insulin resistance decreased in the intervention group (Kahleova et al., 2020). In the intervention group, hepatocellular lipid levels decreased by 34.4%, and intramyocellular lipid levels decreased by 10.4% (Kahleova et al., 2020). The control group remained constant in the thermic effect of their food, weight, insulin resistance, hepatocellular, and intracellular lipid levels (Kahleova et al., 2020).

Valachovicova et al. (2017) completed a cross-sectional study of 548 randomly selected apparently healthy adult populations. The subjects were divided into two groups, vegetarian and

nonvegetarian, and further stratified by the age decade that they were in from 30s to 70's (Valachovicova et al. 2017). The lipid profiles were analyzed and it was found that across all age decades there was a significant reduction in total cholesterol LDL in the vegetarian population (Valachovicova et al. 2017). It was also noted among the vegetarian population homeostasis model assessment-estimated insulin resistance (HOMA-IR) was less than the non-vegetarian group 0.99 to 1.15 versus 1.15 to 1.84 respectively (Valachovicova et al., 2017).

The decrease in cholesterol had been linked to the decrease in consumption of saturated fatty acids and the increase of polyunsaturated fatty acids in the vegetarian versus non-vegetarian diet (Valachovicova et al., 2017). The higher fiber content of a vegetarian diet also had been demonstrated to reduce total plasma cholesterol, LDL cholesterol, and glycemic index (Valachovicova et al., 2017). Valachovicova et al. noted that the production of short-chain fatty acid by the fermentation of the fiber consumed on a plant predominant diet inhibits hepatic cholesterol synthesis. This demonstrates that multiple factors are at play in reducing cholesterol levels. The increase in phytonutrients and micro-nutrients that are often associated with a well-planned plant-based diet add another layer of protection in promoting cholesterol limits that are within normal limits (Manayi et al., 2020).

A WFPBD results in the high consumption of soluble and insoluble fibers. Research by Valachovičová et al. (2017) demonstrated that increasing fiber results in an increase in bile acid-binding, and thus, excretion of sterol in the feces. The fiber was also shown to cause an increase in the production of short-chain fatty acids (SCFA) in the gut, which results in a reduction of the synthesis of cholesterol in the liver (Valachovičová et al., 2017).

Legumes constitute a large part of a plant-based diet, and several components of legumes have been shown to have a positive impact on Homeostatic Model Assessment for Insulin

Resistance (HOMA-IR). In murine models, this decrease in HOMA-IR had been shown to decrease VAT stores (Clark et al., 2018). A diet high in fat had been shown to shift the gut microbiome toward pathogenic bacteria. SCFAs, produced by the microbiome after the ingestion of fiber provide the environment that promotes the proliferation of beneficial microflora (Clark et al., 2018). Dysbiosis, an overabundance of harmful gut bacteria, had been linked to insulin resistance (Clark et al., 2018).

Glycemic index (GI) is "the blood glucose increment in two hours after consuming a particular product containing 50 grams of digestible carbohydrate" (Smyka et al., 2017, p. 523). Consuming foods with a lower GI decreases the rise in glucose and thus the release of insulin, which is a growth hormone (Smyka et al., 2017). A combination of an appropriately set caloric deficiency, balanced macronutrients, and foods with a low GI is foundational to sustainable weight loss (Smyka et al., 2017).

The American Diabetes Association noted that a plant-based diet, among other diets, is acceptable for type 2 diabetes and for prediabetes (Evert et al., 2019). Due to PCOS having a large metabolic component in relation to disease states, adherence to a plant-based diet could prevent the progression of the disease.

Health Coaches

A retrospective comparison analysis was completed at a primary care center in which 271 individuals with a BMI greater than 25 were recruited and followed for two years (Sherman et al., 2017). The participants were divided into coached and not coached groups (Sherman et al., 2017). The population consisted of patients that had received health coaching for the past three months at the primary care office (Sherman et al., 2017). The patients did self-select to continue health coaching or to stop (Sherman et al., 2017). Post hoc analysis placed the weight loss at -

7.24% among the coached group at 12 months and -6.77% at 24 months (Sherman et al., 2017). There was no statistical or clinical difference seen in weight reduction in the non-coached group at the 12-month or 24-month mark (Sherman et al., 2017).

Johnson et al. (2021) conducted a large, single-arm, prospective study of 685 participants in an employee initiative for telehealth coaching, participants lost an average of 3% weight. Those with a BMI in the obese category lost an additional 1.1% body weight (Johnson et al., 2021). The telehealth appointments were conducted over six months, and the participants were required to have three health coaching visits (Johnson et al., 2021). The visits each lasted for 30 minutes and focused on goal setting (Johnson et al., 2021). Even with such few health coaching appointments, the participants in the intervention group noticed a reduction in body weight (Johnson et al., 2021).

A retrospective observational study design spanning a 12-month time frame with one-on-one health coaching sessions resulted in a weight change of -7.2% for overweight individuals and -7.6% for obese individuals (Silberman et al., 2020). For the first 24-weeks participants met with the health coach via an App (Vida) 16 times, eight weekly visits followed by eight bi-weekly visits (Silberman et al., 2020). The following seven months the participants met once per month with their health coach (Silberman et al., 2020). The majority (65%) of the weigh-ins were measured automatically with the remainder (35%) being entered manually (Silberman et al., 2020). This study helps us to see the important role that health coaches in telehealth can have on health outcomes (Silberman et al., 2020).

Synthesis

The current evidence supports that weight loss results in a positive effect on the manifestations of PCOS. A caloric deficit must be maintained to achieve weight loss. In

assessing the current literature that was available, a strong case was made for a WFPBD being beneficial in reducing weight and maintaining a healthy weight. The evidence demonstrated that metabolic disease processes have been improved with adherence to a WFPBD. A WFPBD had been shown to have a positive effect on cholesterol levels and the gut microbiome. The WFPBD being naturally high in fiber and thus having a low GI influences weight loss and metabolic health in a positive manner. PA had been shown to decrease insulin resistance, fat mass, cholesterol levels, and importantly decrease androgen excess. PA leads to an increase in energy expenditure and a habit of PA increases the lean body mass, thus resulting in an increase in the BMR.

Community, accountability, and support is an important aspect of weight loss, health coaches have been shown to have a positive impact on weight loss, and there use in telehealth had increased their availability.

Conclusion

In searching the literature, it was established that a WFPBD, moderate caloric restriction, moderate PA, and a health coach when used individually have the capability to affect a positive change in women overweight women diagnosed with PCOS.

Chapter 3: Methodology

A pre and post-intervention study can allow the participants to serve as their own controls (Thiese, 2014). The population that was chosen for this research was specific to the population affected by PCOS. The methods used for data collection and the protection of the human subjects are important details that were reviewed below.

Design

The study was designed as a pre and post-quantitative interventional study. The original design was for sixty overweight women diagnosed with PCOS, to undergo a lifestyle intervention over a 12-week course.

The dependent variables were BMI, WHtR, and menses regularity. The independent variable was time participating in the study, (pre and post). The dependent variables were classified as numerical data. The types of numerical data that were recorded were, BMI interval data, WHtR classified as ratio data, and menses regularity as ordinal data.

To maintain confidentiality, each participant was assigned a random numerical value that was entered into the Excel file.

Sample

Overweight women diagnosed with PCOS from Alabama, Kentucky, and Tennessee, were recruited via Facebook posts, advertisements in doctor's offices, and face-to-face referral. Overweight inclusion criteria were based on a BMI of greater than 25 kg/m^2. Due to the prevalence of hormonal birth control often being used to control PCOS symptoms, use or nonuse of hormonal birth control was not used as inclusion/exclusion criteria. The goal was to recruit sixty women ages 18-45. Participants were given the PA Readiness Questionnaire (PAR-Q) to assess the appropriateness for engaging in moderate-intensity PA.

Setting

The participants completed the study in the comfort of their own homes. The participants received a weekly menu with an accompanying shopping list. They conducted the grocery shopping at the store of their choice. The meals were all prepared by the participants in their homes. Participants engaged in the exercise portion of the study by utilizing trails and parks close to their homes. The health coaching occurred via a Zoom call between the participant and the assigned health coach.

Protection of Human Subjects

International Review Board (IRB) approval was obtained from Southern Adventist University prior to the commencement of the study, as risks did exist. The participants could experience pain or injury while participating in the prescribed exercise program. Risks were minimized by having all participants complete the PAR-Q survey prior to engaging in PA. In addition, participants received support from the researcher and health coaches throughout the study.

Social risks existed as well. There was a possibility that participating in research, or the revelation of the data collected by the research, could have a negative social impact. If the information obtained in this study was disclosed to individuals or entities outside of the research group, there was a risk that sharing this could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at risk of political or social reprisals.

To mitigate this risk all data was kept in an encrypted file, minimizing access to this file to the primary researcher and health coaches involved. All participants were assigned a code, and

the identifying information (name, email address, phone number) was kept separate from the data collected for the study.

Data Collection

Weight was recorded weekly with participants dressed in light clothing and no shoes. Weight was recorded pre and post-intervention in pounds and converted to kilograms. Height was self-recorded and converted to centimeters. The participants were instructed to obtain their waist circumference by measuring at the top of the iliac crest in inches and converted to centimeters (Fryar et al., 2018) and was recorded pre and post-intervention. Menstrual regularity was measured pre and post-intervention using a scale of one to five. The anchors were for one: Menstruation is very regular and comes with reoccurring frequency, and for a predictable amount of days. For anchor five the wording was: cycle is very irregular, I never know when it is coming off or how long it will last. The severity of PCOS was also rated on a scale of one to five. The anchor for one being: I hardly noticed that my period is coming, sleep, appetite, mood, and energy level remain steady. For anchor five: the cycle is very irregular, I never know when it is coming out for how long it will last. During the study, participants had a caloric restriction set at 25% less than the caloric intake needed to maintain current weight. Participants were given their caloric intake menu and submitted an estimate of the percentage of the meals for the week they maintained their weekly caloric goal. WFPBD adherence was calculated as an estimate of the percentage of meals that were in adherence. The amount of moderate-intensity exercise was recorded weekly in total minutes.

Exercise target heart rate goals were determined at the onset of the study using the Kasch YMCA Step Test or Rockport One-Mile Walk Test formula (Cofre-Bolados et al., 2018; Kumar & Goswami, 2019; Ignaszewski et al., 2017). Calculations were completed using the heart rate

reserve (HRR) method at 60% and 70% of the maximum heart rate (ACSM, 2018, pp. 146148; Mayo Foundation for Medical Education and Research. 2021). As per guidelines, the goal was set to achieve 150 minutes of moderate-intensity exercise per week (American Heart Association [AHA], 2018).

The resting metabolic rate (RMR) was calculated using the Mifflin St. Jeor equation, as this had been demonstrated to be the most reliable in overweight and obese women (Thom et al., 2020). Weight loss should be maintained between 0.5 to 1 kg per week (Jensen et al., 2014).

Participants were given a PDF document with a menu that was set at the specific caloric requirements for them. A form was provided that allows participants to record their weekly weight, waist circumference, minutes spent exercising, and adherence to the WFPBD as a percentage.

Procedure

Participants were instructed on a WFPBD utilizing the Healthy Weight Loss Fact Sheet (*Weight Loss*, n.d.). A weekly phone call was scheduled every week with either the primary researcher or one of the health coaches to review progress and work through any difficulties. Data regarding adherence to a WFPBD was recorded by the participants every week as a percentage of adherence to the prescribed diet. The exercise was set at 150 minutes per week of moderate-intensity exercise (*AHA,* 2018). Moderate-intensity was determined utilizing the Kasch YMCA Step Test or Rockport One-Mile Walk Test formula to set a target heart rate (Cofre-Bolados et al., 2018; Kumar & Goswami, 2019; Ignaszewski et al., 2017). Participants recorded the minutes they spent exercising every day and sent the number every two weeks as minutes exercised per week to the researchers and entered into an Excel file.

Weight was recorded by the participants at the pre and post-intervention time as well as weekly. Participants received instructions to record their weight every week at the same time wearing no shoes and light clothing. BMI was auto-calculated weekly via the Excel document. This data was sent to the researcher every week and recorded in an Excel file. WHtR and abdominal circumference were recorded pre and post-intervention by the researcher and health coaches and recorded in an Excel file.

Data Analysis

Statistical analysis was to be completed using SPSS software. The Shapiro Wilk test was to be used to evaluate for normal data distribution. A value of 0.05 was used as the cut-off for the P-value. Once normal distribution had been verified, the paired samples t-test was to be utilized to examine the difference between the pre and post-test. However, data were analyzed using descriptive statistics due to the low response rate.

Opportunities and Challenges

This intervention was useful because the implementation of a WFPBD, exercise and the caloric deficit were simple to replicate. The interventions did not require medication or costly equipment. Furthermore, the subjects could be taught how to implement the changes themselves without the need for a specialist. Lastly, using a lifestyle approach for intervention was gaining acceptance among the public, which means there has been an increase in available resources. Such resources include walking paths and plant-based ready-to-eat foods in multiple grocery store chains. Apps were available on cell phones that allow for dietary and exercise tracking.

There were barriers in the proposed study that needed to be addressed. The criteria for diagnosing PCOS is varied, with a great difference in incidence and prevalence, depending on the criteria. To simplify this inclusion, criteria consisted of a diagnosis of PCOS. To power the

study correctly, it would have been ideal to have 60 test subjects. Recruitment of this many subjects was difficult, and adequate follow-up may be outside the feasibility of this study. In addition, each participant in the study group required a caloric recommendation that was specific to her. This was a time-consuming factor. Furthermore, to ensure adherence to the diet in a cost and time-efficient manner, the study participants needed to record data that was measured. Participants recorded their weight, waist circumference, minutes of exercise obtained at the prescribed heart rate, percentage of adherence to a WFPBD, and percentage of time compliant to caloric restriction.

The success of the study group was due in part to psychological factors. These factors, such as the acceptance of responsibility for one's own health and overcoming the cultural environment in which the subject resides, were unable to be controlled. Yet, screening for this would have been another variable in the study and was avoided. In future research, it could be a variable to be measured. If the study had been able to demonstrate effectiveness across a variety of population groups, it would have increased credibility and transferability to other individuals with PCOS.

Revised Methods

Due to the low recruitment of only three participants, the methodology was revised. This was submitted to IRB for approval as a case study. In a case study, an in-depth investigation is done on a specific individual or group of individuals. At the time of IRB approval, three different participants were involved, this was a multiple case design study (Polit & Beck, 2017).

This study met the requirements of a case study, as there were three women who were in their mid-30s and have been diagnosed with PCOS. The women were not on a WFPBD or engaging in regular exercise. The three women were enrolled in a very similar 12-week program

to evaluate the program's effect on weight loss and the symptoms of their PCOS disease. A pre-interventional survey was used to gather more descriptive data regarding the subjects, and the post-interventional data included descriptive data as well. Due to the low recruitment of participants hypothesis testing was not completed.

Purpose and Objectives

The purpose of this study was to examine the effect of a WFPBD, moderate-intensity exercise, and moderate caloric restriction on weight loss, BMI, WHtR, and menstrual regularity on overweight women between the ages of 18 and 45 diagnosed with PCOS.

Hypotheses

The research hypothesis was a WFPBD, moderate caloric restriction, and 150 minutes per week of moderate-intensity exercise results in weight loss among overweight women diagnosed with PCOS.

Instruments

Several instruments were used to gather data and provide measurements in regard to the progress that was made during the study.

Rockport one mile

The participants were instructed on the Rockport one-mile walk test. They were instructed to first obtain their resting heart rate (RHR) and then record it. Second, the participants warmed up with light walking or stretching. Third, they were instructed to walk briskly for one mile. The participants were given the option to walk four laps on a track or to record the distance on an exercise app. Lastly, exercise heart rate and time, was recorded at the completion of the one-mile walk (Kumar & Goswami, 2019). This information was sent to the researcher.

Max Heart Rate

Max heart rate was calculated using the heart rate reserve (HRR) method. Age was subtracted from 220 to obtain the maximum heart rate. The resting heart rate was subtracted from the maximum heart rate. This resulted in the HRR. The HRR was multiplied by 0.5 and 0.65 and the RHR was added to each number to respectively obtain an exercise heart rate at 60% and 70% of maximum heart rate.

Resting Metabolic Rate

The RMR was calculated via the Mifflin St. Jeor formula: BMR (kcal/day) = 10(kg) + 6.25 (cm) – 5(age) -161 (Thom et al., 2020).

BMI

BMI was calculated using the Adult BMI Calculator from the Centers for Disease Control (2022).

Waist-height

The WHtR was calculated by dividing the waist circumference in cm by the height in centimeters.

Intervention

The participants were instructed on a WFPBD, with a moderate caloric restriction. The participants were also instructed on a routine of PA consisting of a minimum of 150 min/week at moderate intensity. Health coaches were recruited to assist with follow-up. The health coaches were educated on the prescribed WFPBD, the set caloric restriction, and the intensity of exercise. The health coaches had completed training to be able to sit for a certifying exam but needed to complete a set number of sessions to sit for this certification. The coaches were trained on motivational interviewing and were instructed to use these techniques to assist the study

participants in making the changes in ways that work for them. The health coaches were reminded to not work in a prescriptive manner.

Conclusion

The pre and post-intervention bound case study allowed for the effect of lifestyle changes to be examined in these two participants. These two participants met the inclusion criteria of being women diagnosed with PCOS with a BMI greater than 25 kg/m^2. Simple tools and calculations were used to record and collect the data.

Chapter 4: Results

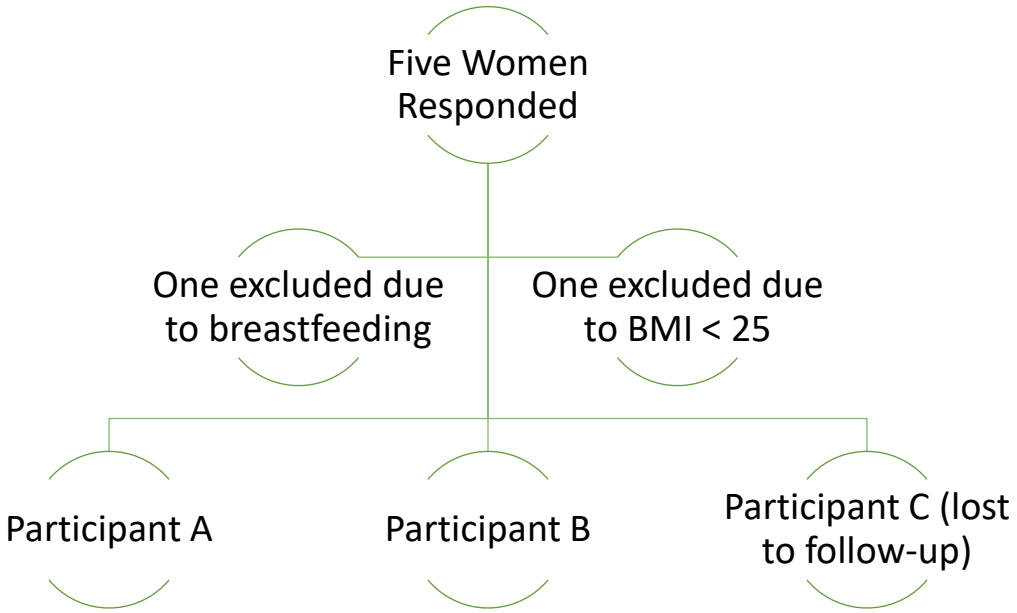
The participants had specific caloric goals and exercise recommendations. These were outlined below, along with the results of the intervention. The results of this study were examined in relation to the PICOT. The intake and completion surveys completed by the participants did not truly reflect PCOS severity. The anchor provided for PCOS severity reflected menstrual regularity.

Description of the Sample

Recruitment of a sample large enough to power the study did not occur. Five participants in total responded to the invitation. Two were excluded, one due to breastfeeding, and the other due to BMI below 25. One of the participants withdrew from the study prior to completion. The two remaining participants were women in their mid-thirties. Each participant is described in more detail below.

Figure 2

Recruitment flowchart



Participant A

Participant A was a 37-year-old Caucasian, with a BMI of 43.0, placing her in class III obesity category (Purnell, 2018). This participant did not have any other comorbidities. She had been diagnosed with PCOS between three to five years prior. Though she admits she had difficulty conceiving, she reported having two children and one miscarriage. She did not receive treatment from fertility doctors. On a scale of one to five, she rated her PCOS severity at five, with her menstrual regularity at three on the same scale. It should be noted that though the PCOS severity reflected menstrual regularity the participant ranked them at different points on a similar scale. This participant was not currently on hormonal birth control.

Over the course of the past decade Participant A had attempted Weight Watchers, human chorionic gonadotropin (HCG) diet, a low-fat diet, a vegetarian diet, a vegan diet, and a WFPBD with no oil. The participant reported that the WFPBD-no oil had worked the best when she did it for three months. She reported that she did not currently exercise but would love to have a habit of exercise. She had found, in the past, exercise helped her feel more productive and stick with her goals.

Participant A was given a caloric goal of 1,700 calories per day. This was set according to the Mifflin St. Jeor equation with an activity multiplier of 1.2 resulting in a total daily expenditure (TDEE) of 1,939 calories per day (Omni Calculator, 2021). Subtracting 25% resulted in 1,689 calories per day with a goal set at 1,700 per day to simplify planning. Menu PDFs were created based on the participant's taste preferences and according to the study design of WFPB. Frequent collaboration between the researcher and the participant was needed to adjust the menus to meet her needs.

The participant completed the Rockport One-mile Walk Test with a Vo2 Max of 9.0114 (Rockport Walk Test Calculator, 2021). Heart rate was set at 60-70 % of the max heart rate which was 138-149 beats per minute (BPM) (*Exercise intensity: How to measure it, 2021)*. The participant was encouraged to walk or use an elliptical for 150 minutes per week. The health coach worked with the participant to adjust the exercise to meet her daily demands.

Participant B

The second participant was a 35-year-old Caucasian female with a BMI of 32.4. Participant B had been diagnosed with PCOS more than 5 years prior, she reported a history of hypertension, which was treated with medication by her primary care doctor. Participant B completed the PAR-Q assessment which showed no cardiovascular risks from an exercise routine. Thus, she was able to continue in the study. On a scale of one to five, she rated her PCOS severity at three. Participant B rated her menstrual regularity at three on a scale of one to five, she did use hormonal birth control. This participant did rate both her severity and regularity of menstrual cycle the same. This is likely due to the anchors reflecting menstrual regularity.

Previously, Participant B attempted weight loss using a low-fat diet, vegetarian/vegan diet, and a general low-carb diet. The participant reported that only modest improvement had been seen with previous attempts at weight loss. Participant B reported that she loved to exercise and would go on bike rides and walks but there was little consistency to her routine. She also relayed that she enjoyed pushing herself hard on the bike and getting her heart rate up to 170 or more.

Participant B was given a caloric goal of 1,600 calories per day. This was set according to the Mifflin St. Jeor equation with an activity multiplier of 1.5 resulting in a TDEE of 2,144 calories per day (Omni Calculator, 2021). Subtracting 25% resulted in 1,608 calories per day

with a goal set at 1,600 per day to simplify planning. Menu PDFs were created based on the participant's taste preferences and according to the WFPB study design. Frequent collaboration occurred between the researcher and the participant to adjust the menus to meet her needs.

The participant completed the Rockport One-mile Walk Test with a Vo2 Max of 23.902 (Rockport Walk Test Calculator, 2021). Heart rate was set at 60- 70% of the max heart rate which was 137-149 beats per minute (BPM) (*Exercise intensity: How to measure it, 2021)*. The participant was encouraged to walk or utilize an elliptical for 150 minutes per week. The health coach worked with the participant to adjust the exercise to meet her daily demands.

Project Variables

At the end of the twelve-week period, the participants submitted their weights, waist circumference, and menses regularity, and results were used to calculate the BMI and WHtRn. For Participant A, initial weight was 100 kg and final weight was 95 kg. BMI thus decreased from 43 to 40.8 (Purnell, 2018). WHtR went from a ratio of 0.83 to 0.77. Participant A reported a change in menses regularity from three to one out of five, an increase in regularity, and predictability.

For Participant B, weight was initially 90.26 kg and ended at 83kg. BMI decreased from 33.18 to 31.36. WHtR moved from 0.61 to 0.55. Participant B had an intrauterine device (IUD) implanted, but still noted an improvement in menses regularity from a three to a two. She reported that menstrual cramps were now non-existent and premenstrual symptoms were, "not nearly as bad."

Analysis of Project Questions and Hypotheses

At the onset of this research project the question was raised, do women between the ages of 18-45 without the onset of menopausal symptoms with a BMI greater than 25 who participate

in a lifestyle program consisting of a WFPBD, caloric restriction, and moderate-intensity exercise have decreased waist-height circumference, decreased BMI, and increased menses regularity after 12 weeks? Due to the small sample size, statistical analysis of the results would have been inaccurate. Based on the results of the case study, there was a reduction in WHtR, decreased BMI, and an increase in menses regularity over a 12-week period.

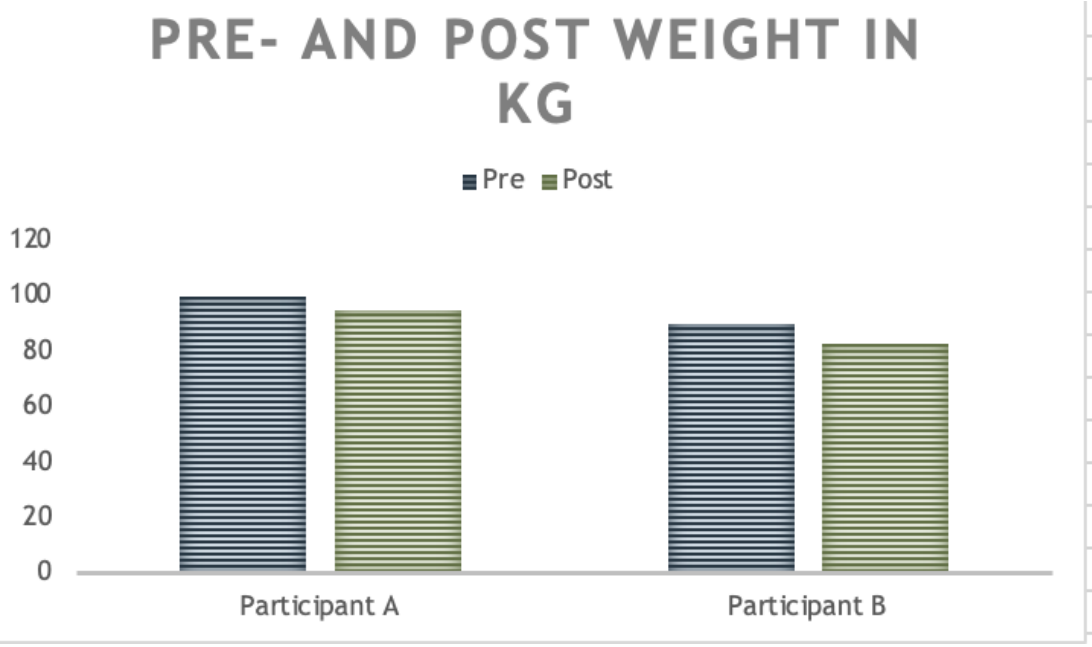
Table 1

Dependent Variable Results Pre and Post Intervention

Name	**Pre KG**	**Post-KG**	**Pre WHtR**	***Post* WHtR**	***Pre BMI***	***Post BMI***	***Menses Regularity***
Participant A	100	95	0.83	0.77	*43*	*40.8*	*Improved*
Participant B	90	83	0.61	*0.55*	*33.1*	*31.6*	*Improved*

Figure 3

Pre and Post Weight in Kg for Participants



Incidental Findings

At the conclusion of the study, an exit interview was conducted with each participant. Participant B self-reported compliance with the WFPBD 85 to 95% of the time and 90-100% compliant with the caloric recommendations. She stated, “I feel night and day difference from three months ago. There was a mental shift. I feel better both physically and emotionally and would say this is the best that I have ever felt. My anxiety has nearly resolved.” It was interesting that not only did she see an improvement in physical health but also in emotional.

Participant B shared that she was 50 to 70% compliant both with the WFPBD and the caloric restrictions. She shared that she felt a “ton better and was going to continue this path.” Participant B did have a family and was working to provide meals that were both compliant and appetizing to her children. This she found difficult.

Both participants shared that health coaching was a key to their success. They did find the switch in cooking to a WFPBD challenging but related that the support from the health coaches was a big help. They both felt the habits established during the study would help them to continue in their health journeys. One participant provided feedback that it would’ve been helpful to have more guidance regarding serving size on the recipes. A participant also suggested that it would have been helpful to reduce the overall fat content of the recipes.

Conclusion

In this bound case study, adherence to a WFPBD, caloric restriction, and a moderate exercise routine resulted in weight loss for each participant. Both participants reported feeling better overall with increased energy during the program.

Chapter 5: Discussion

The study was able to build on the available scientific evidence regarding a plant-based diet and exercise. The study examined the impact that these lifestyle changes can have on a hormonal and metabolic disease like PCOS. There were several implications for further research that can be produced from this case study.

Demographic Characteristics

The demographics of this study shared similarities to those in other studies. Yet in this case study, both participants were Caucasian. The age range was women between 30-40 years of age, in other studies the age range had been wider. The women recruited for this study were from two different states in the Southeast United States. Many studies have been done on populations from a larger geographical area. This study was limited by a small and homogenous sample.

Discussion of the Research Questions

The purpose of this study was to examine the effects of a WFPD, moderate-intensity exercise, and moderate caloric restriction on weight loss, BMI, WHtR, and menstrual regularity in overweight women diagnosed with PCOS between the ages of 18 and 45. The original intent was to have a sample size of 60 for the study to be powered correctly. And while the study had limited recruitment and was changed to a case study, both participants did lose weight. There may have been unknown extraneous variables that contributed to the positive results from both participants.

This case study was able to build on the available research and demonstrated that a shift of lifestyle habits towards ones that were more helpful can result in positive changes. Given that no laboratory testing was done on participants, inference cannot be drawn regarding the effect the changes had on insulin resistance or hyperlipidemia. Yet, given that there was a reduction in

both overall weight and on WHtR, we can deduce that body fat was reduced. This correlates with the research done by Soares et al. (2016), and Valachovičová et al. (2017) demonstrating that a WFPBD can result in a reduction of body fat. A study conducted by Foroozanfard et al. (2017) determined that an increase in fruits and vegetables led to a reduction of weight in overweight and obese women diagnosed with PCOS. This corresponds to what was seen in this case study, as increased consumption of fruits and vegetables are encouraged in a WFPBD.

PA was a separate variable that had been shown to assist with weight loss and controlling the symptoms of PCOS (Barber et al., 2019; Beena & Thomas, 2016; Smyka et al., 2017). Though it cannot be determined which intervention played the largest role in weight loss in this case study, the results indicated exercise contributed.

Limitations

Limitations to this study included the sample size. The existence of COVID and the spike of the Delta wave at the onset of recruitment likely had a negative impact on the sample size. Recruitment was conducted by placing flyers only in primary care providers' offices and in a fertility office.

Due to COVID, the assistance of an objective observer to gather data such as the Rockport One mile Walk test, participant weight, and measurements, was not available. With only two participants no inferences can be applied to the general population. Due to the voluntary nature of this study selection bias was a potential limitation of the study, as the sample was homogenous in age and ethnicity.

Furthermore, each participant self-reported measurements of weight, waist circumference, compliance with caloric recommendations, adherence to a WFPBD, and time spent exercising. Self-reporting may have impacted the accuracy of the data.

In conducting the intake and completion survey, the anchors for the question regarding the severity of PCOS refer to menstrual regularity as opposed to the severity of the PCOS. These anchors were a poor reflection of the data that was to be elicited regarding the severity of PCOS. It would have been beneficial to have severity anchors related to hirsutism, acne, male pattern baldness, and abdominal weight.

The limitations of the researcher also affected this study. Time was a limiting factor regarding data collection. This was a scholarly project and was limited to the time constraints of the academic calendar. Money was a limiting factor as no grants had been obtained.

Implications for Future Study

In future studies, it would be beneficial to have rolling recruitment to increase the sample size of the study. This would allow one to onboard participants while providing education to them at the outset. In a non-COVID environment, this could also allow the participants to have data collected by an objective observer. In this manner recruitment of a larger sample size could be obtained. In addition, with future research, it would be useful to conduct a longitudinal study to evaluate the long-term adherence of participants to lifestyle changes. Additionally, it would have been beneficial to place the flyers in endocrinology and obstetric offices.

Partnering with a meal planning service to provide pre-determined meals for a percentage of the meals would take some of the burden of meal-prep off the participants and likely increase compliance to the diet. In future research, it would be recommended to have a pantry stocking list at the commencement of the study for participants to stock their pantries with frequently used ingredients. This would reduce their weekly shopping and allow them to buy some of their food in bulk if they so desired. For participants with families, education on how to make simple

adjustments and add-ons to increase the enjoyment of a WFPBD for the rest of the family would be recommended.

It also should be noted that no lab work was collected on these participants before or after the intervention. In future research, it would be beneficial to obtain a total and free testosterone, a lipid panel, and a basal and oral glucose-stimulated glucose/insulin ratio should be conducted pre and post-intervention. This would allow for an objective measure of change in the participants. These tests would help to quantify the severity of the PCOS the participant is experiencing.

In future studies, it would be beneficial to control for extraneous variables that could impact weight loss. These variables could include diagnosis of anxiety and depression, diagnosis of a compulsion disorder, race, and socioeconomic status. Other extraneous variables could be controlled as well.

In future research it would be useful to examine the effect of lifestyle changes on mental health. Outcomes such as measures of anxiety or self-esteem could be measured pre and post-intervention. It would be helpful to examine if mental health changes are related to accomplishing a goal or the effect of the lifestyle changes.

Implications for Practice, Policy, and Education

When an individual is willing to make a change, it can be recommended that a health coach be included in the care team to improve their health. In this study, participants met weekly with a health coach via Zoom. Each session lasted 30 minutes to one hour, depending on the needs of the participant. While strong statistical analysis cannot be drawn from this study both the literature and what was found demonstrate that lifestyle choices in line with a WFPBD and moderation in caloric intake combined with PA can have a positive result. In the practice setting,

it can be recommended that measurement of height, waist circumference, and calculation of WHtR be used in an educational manner. It would be recommended that education should be given to overweight and obese women diagnosed with PCOS regarding the benefits of a WFPBD, moderate caloric restriction, and moderate-intensity exercise. This education can focus on the benefit of these lifestyle changes on managing weight and a reduction of PCOS symptoms.

In the education of advanced practice providers, more information needs to be provided regarding the benefits of a WFPBD and other lifestyle factors on cardiometabolic and hormonal diseases.

Conclusion

The participants in this study were both in the obese category and diagnosed with PCOS. A WFPBD, moderate caloric restriction and moderate-intensity exercise were initiated with both participants. Both participants found the changes to be challenging, the support of health coaches was vital to their maintaining the program. Whenever one is seeking to implement drastic lifestyle changes the use of a health coach can be beneficial. These cases highlight that more research should be conducted in this field, but it was promising that a lifestyle change can provide relief to women suffering from PCOS.

References

American College of Sports Medicine. (2018). *ACSM's guidelines for exercise testing and prescription*. Lippincott Williams & Wilkins.

American Heart Association. (April 2018). *American Heart Association Recommendations for PA in Adults and Kid.* https://www.heart.org/en/healthy-living/fitness/fitness-basics/aha-recs-for-physical-activity-in-adults.

Barber, T. M., Hanson, P., Weickert, M. O., & Franks, S. (2019). Obesity and polycystic ovary syndrome: Implications for pathogenesis and novel management strategies. *Clinical Medicine Insights: Reproductive Health*, *13*. https://doi.org/1179558119874042

Bird, S. R., & Hawley, J. A. (2017). Update on the effects of PA on insulin sensitivity in humans. *BMJ open sport & exercise medicine*, *2*(1), e000143. https://doi.org/10.1136/bmjsem-2016-000143

Beena, M. R., & Thomas, K. (2016). The outcome of interventional programme on quality of life of infertile women with polycystic ovarian syndrome. *International Journal of Nursing Education*, *8*(2), 27-33. https://doi.org/10.5958/0974-9357.2016.00042.8

Campbell, E. K., Fidahusain, M., & Campbell, T. M. (2019). Evaluation of an eight-week whole-food plant-based lifestyle modification program. *Nutrients*, *11*(9), 2068. https://doi.org/10.3390/nu11092068

Centers for Disease Control and Prevention. (2020, March). *PCOS (Polycystic ovary syndrome) and diabetes.* https://www.cdc.gov/diabetes/basics/pcos.html

Centers for Disease Control and Prevention. (2022, January 21). *Adult BMI calculator*. Centers for Disease Control and Prevention. Retrieved February 13, 2022, from https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi

_calculator.html

Chavarro, J. E., Rich-Edwards, J. W., Gaskins, A. J., Farland, L. V., Terry, K. L., Zhang, C., & Missmer, S. A. (2016). Contributions of the nurses' health studies to reproductive Health Research. *American Journal of Public Health, 106*(9), 1669-1676. https://doi.org/10.2105/AJPH.2016.303350

Christiansen, M. K., Jensen, J. M., Brøndberg, A. K., Bøtker, H. E., & Jensen, H. K. (2016). Cardiovascular risk factor control is insufficient in young patients with coronary artery disease. *Vascular Health and Risk Management, 12*, 219–227. https://doi.org/10.2147/VHRM.S106436

Clark, J. L., Taylor, C. G., & Zahradka, P. (2018). Rebelling against the (Insulin) Resistance: A Review of the Proposed Insulin-Sensitizing Actions of Soybeans, Chickpeas, and Their Bioactive Compounds. *Nutrients, 10*(4), 1-28. https://doi.org/10.3390/nu10040434

Cofre-Bolados, C., Rosales, W. D., & Espinoza-Salinas, A. (2018). Validation of the ST3x1 Step Test as an estimator of peak VO2 in adults with cardiovascular risk factors. *Revista Salud Uninorte*, *34*(3), 581-588. https://doi.org/10.14482/sun.34.3.616.10

El Hayek, S., Bitar, L., Hamdar, L. H., Mirza, F. G., & Daoud, G. (2016). Polycystic ovarian syndrome: An updated overview. *Frontiers in Physiology*, *7*(4). https://doi.org/10.3389/fphys.2016.00124

Evert, A. B., Dennison, M., Gardner, C. D., Timothy Garvey, W., Karen Lau, K. H., MacLeod, J., Mitri, J., Pereira, R. F., Rawlings, K., Robinson, S., Saslow, L., Uelmen, S., Urbanski, P. B., & Yancy, W. S. (2019). Nutrition therapy for adults with diabetes or prediabetes: A consensus report. *Diabetes Care*, *42*(5), 731–754. https://doi.org/10.2337/dci19-0014

Fawcett, J., & Neuman, B. (2011). *The Neuman systems model*. Pearson Higher Ed.

Fonseca, D. C., Sala, P., Ferreira, B. D. A. M., Reis, J., Torrinhas, R. S., Bendavid, I., & Waitzberg, D. L. (2018). Body weight control and energy expenditure. *Clinical Nutrition Experimental*, *20*, 55-59. https://doi.org/10.1016/j.yclnex.2018.04.001

Foroozanfard, F., Rafiei, H., Samimi, M., Gilasi, H. R., Gorjizadeh, R., Heidar, Z., & Asemi, Z. (2017). The effects of dietary approaches to stop hypertension diet on weight loss, anti-Müllerian hormone and metabolic profiles in women with polycystic ovary syndrome: A randomized clinical trial. *Clinical Endocrinology, 87*(1), 51–58. https://doi.org/10.1111/cen.13333

Fryar, C. D., Kruszon-Moran, D., Gu, Q., & Ogden, C. L. (2018). Mean body weight, height, waist circumference, and body mass index among adults: United States, 1999-2000 through 2015-2016. *National Health Statistics Reports, 122,* 1-16

Garrison, A. (2015). Screening, diagnosis, and management of gestational diabetes mellitus. *American Family Physician, 91*(7), 1767-1773. https://www.aafp.org/afp/2015/0401/p460.html

Gepner, Y., Shelef, I., Schwarzfuchs, D., Zelicha, H., Tene, L., Meir, A. Y., Tsaban, G., Cohen, N., Bril, N., Rein, M., Serfaty, D., Kenigsbuch, S., Komy, O., Wolak, A., Chassidim, Y., Golan, R., Avni-Hassid, H., Bilitzky, A., Sarusi, B., … Shai, I. (2018). Effect of distinct lifestyle interventions on mobilization of fat storage pools central magnetic resonance imaging randomized controlled trial. *Circulation*, *137*(11), 1143–1157. https://doi.org/10.1161/CIRCULATIONAHA.117.030501

Greger, M. (2020). A whole food plant-based diet is effective for weight loss: the evidence. *American Journal of Lifestyle Medicine*, *14*(5), 500-510. https://doi.org/10.1177/1559827620912400

Ignaszewski, M., Lau, B., Wong, S., & Isserow, S. (2017). The science of exercise prescription: Martti Karvonen and his contributions. *British Columbia Medical Journal, 59*(1), 38-41. https://bcmj.org/articles/science-exercise-prescription-martti-karvonen-and-his-contributions

Jabłonowska-Lietz, B., Wrzosek, M., Włodarczyk, M., & Nowicka, G. (2017). New indexes of body fat distribution, visceral adiposity index, body adiposity index, waist-to-height ratio, and metabolic disturbances in the obese. *Kardiologia Polska (Polish Heart Journal), 75*(11), 1185-1191. https://doi.org/10.5603/KP.a2017.0149

Jakše, B., Jakše, B., Pajek, J., & Pajek, M. (2019). Effects of *ad libitum* consumed, low-fat, high-fiber plant-based diet supplemented with plant-based meal replacements on cardiovascular risk factors. *Food & Nutrition Research*, *63*, 1-10. https://doi.org/10.29219/fnr.v63.1560

Jang, S. H., Paik, I. Y., Ryu, J. H., Lee, T. H., & Kim, D. E. (2019). Effects of aerobic and resistance exercises on circulating apelin-12 and apelin-36 concentrations in obese middle-aged women: A randomized controlled trial. *BMC Women's Health*, *19*(1), 1-8. https://doi.org/10.1186/s12905-019-0722-5

Jensen, M. D., Ryan, D. H., Donato, K. A., Apovian, C. M., Ard, J. D., Comuzzie, A. G., Hu, F. B., Hubbard, V. S., Jakicic, J. M., Kushner, R. F., Loria, C. M., Millen, B. E., Nonas, C. A., Pi-Sunyer, F. X., Stevens, J., Stevens, V. J., Wadden, T. A., Wolfe, B. M., & Yanovski, S. Z. (2014). Executive summary: Guidelines (2013) for the management of overweight and obesity in adults. *Obesity, 22*(S2), 5–39. https://doi.org/10.1002/oby.20821

Johnson, K. E., Alencar, M. K., Miller, B., Gutierrez, E., & Dionicio, P. (2021). Exploring Sex Differences in the Effectiveness of Telehealth-Based Health Coaching in Weight Management in an Employee Population. *American Journal of Health Promotion*, *35*(2), 262-265. https://doi.org/10.1177/0890117120943363

Jones, P. S., James, B. R., Owino, J., Abemyil, M., Beltrán, A. P., & Ramal, E. (2017). A distinctive framework for Adventist nursing. *The Journal of Adventist Education*, 79(*5)*, 4-13. https://jae.adventist.org/2017.5.2

Kahleova, H., Petersen, K. F., Shulman, G. I., Alwarith, J., Rembert, E., Tura, A., Hill, M., Holubkov, R., & Barnard, N. D. (2020). Effect of a low-fat vegan diet on body weight, insulin sensitivity, postprandial metabolism, and intramyocellular and hepatocellular lipid levels in overweight adults: A randomized clinical trial. *JAMA Network Open*, *3*(11), e2025454-e2025454. https://do.org/10.1001/jamanetworkopen.2020.25454

Kazemi, M., McBreairty, L. E., Chizen, D. R., Pierson, R. A., Chilibeck, P. D., & Zello, G. A. (2018). A comparison of a pulse-based diet and the therapeutic lifestyle changes diet in combination with exercise and health counselling on the cardio-metabolic risk profile in women with polycystic ovary syndrome: A randomized controlled trial. *Nutrients*, *10*(10), 1-30. https://doi.org/10.3390/nu10101387

Kumar, N., & Goswami, S. (2019). Comparison of Rockport one-mile walk test and McArdle step test for the prediction of VO2max. *Saudi Journal of Sports Medicine*, *19*(3), 82-85. https://doi.org/10.4103/sjsm.sjsm_2_20

Legro, R. S., Arslanian, S. A., Ehrmann, D. A., Hoeger, K. M., Murad, M. H., Pasquali, R., & Welt, C. K. (2013). Diagnosis and treatment of polycystic ovary syndrome: An endocrine society clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism*,

98(12), 4565–4592. https://doi.org/10.1210/jc.2013-2350

Manayi, A., Vazirian, M., & Hadjiakhoondi, A. (2020). Disease modifying effects of phytonutrients at gene levels. In Mohommad, S., Suntar, I., Barreca, D., & Khan, H. (Eds.), *Food Science, Technology and Nutrition*. Woodhead Publishing. 103-116. https://doi.org/10.1016/B978-0-12-815354-3.00005-8

Mayo Foundation for Medical Education and Research. (2021, June 17). *Exercise intensity: How to measure it*. Mayo Clinic. Retrieved October 24, 2021, https://www.mayoclinic.org/healthy-lifestyle/fitness/in-depth/exercise-intensity/art-20046887

Most, J., Gilmore, L. A., Smith, S. R., Han, H., Ravussin, E., & Redman, L. M. (2018). Significant improvement in cardiometabolic health in healthy nonobese individuals during caloric restriction-induced weight loss and weight loss maintenance. *American Journal of Physiology Endocrinology and Metabolisim*, *314*(4), 396–405. https://doi.org/10.1152/ajpendo.00261.2017

Patten, R. K., Boyle, R. A., Moholdt, T., Kiel, I., Hopkins, W. G., Harrison, C. L., & Stepto, N. K. (2020). Exercise interventions in polycystic ovary syndrome: A systematic review and meta-analysis. *Frontiers in Physiology*, *11*(606), 1-17. https://doi.org/10.3389/fphys.2020.00606

Petersen, M. C., & Shulman, G. I. (2018). Mechanisms of insulin action and insulin resistance. *Physiological reviews*, *98*(4), 2133–2223. https://doi.org/10.1152/physrev.00063.2017

Petiprin, A. (2020). *Betty Neuman*. Nursing Theory. Retrieved February 11, 2022, from https://nursing-theory.org/nursing-theorists/Betty-Neuman.php

Polak, K., Czyzyk, A., Simoncini, T., & Meczekalski, B. (2017). New markers of insulin resistance in polycystic ovary syndrome. *Journal of Endocrinological Investigation*, *40*(1), 1–8. https://doi.org/10.1007/s40618-016-0523-8

Polit, D. F., & Beck, C. T. (2017). *Nursing research: Generating and assessing evidence for nursing practice* (10th ed). Wolters Kluwer.

Purnell, J. Q. (2018). Definitions, classification, and epidemiology of obesity. *Endotext [Internet]*.

Rockport Walk Test Calculator. (2021, October 23). Retrieved from https://exrx.net/Calculators/Rockport

Sa'ad-Aldin, K., & Altamimi, M. (2019). Effect of whole-grain plant-based diet on the diabetes mellitus type 2 features in newly diagnosed patients: a pilot study. *International Journal of Diabetes in Developing Countries*, *39*(3), 535-546. https://doi.org/10.1007/s13410-018-0689-z

Scott, D., Harrison, C. L., Hutchison, S., De Courten, B., & Stepto, N. K. (2017). Exploring factors related to changes in body composition, insulin sensitivity and aerobic capacity in response to a 12-week exercise intervention in overweight and obese women with and without polycystic ovary syndrome. *PloS One, 12*(8), 1-13. https://doi.org/10.1371/journal.pone.0182412

Sherman, R. P., Petersen, R., Guarino, A. J., & Crocker, J. B. (2019). Primary care–based health coaching intervention for weight loss in overweight/obese adults: A 2-year experience. *American Journal of Lifestyle Medicine, 13*(4), 405-413. https://doi.org/10.1177/1559827617715218

Silberman, J. M., Kaur, M., Sletteland, J., & Venkatesan, A. (2020). Outcomes in a digital weight management intervention with one-on-one health coaching. *PloS One*, *15*(4), https://doi.org/10.3389/fphys.2020.00606

Smyka, M., Grzechocińska, B., & Wielgoś, M. (2017). The role of lifestyle changes in the treatment of polycystic ovary syndrome. *Neuroendocrinology Letters*, *38*(8), 521–527. https://pubmed.ncbi.nlm.nih.gov/29504728/

Soares, N. P., Santos, A. C. S. Dos, Costa, E. C., Azevedo, G. D., Damasceno, D. C., Fayh, A. P. T., & Lemos, T. M. A. M. (2016). Diet-induced weight loss reduces DNA damage and cardiometabolic risk factors in overweight/obese women with polycystic ovary syndrome. *Annals of Nutrition and Metabolism*, *68*(3), 220–227. https://doi.org/10.1159/000444130

Teede, H. J., Misso, M. L., Costello, M. F., Dokras, A., Laven, J., Moran, L., Piltonen, T., & Norman, R. J. (2018). Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome. *Human Reproduction*, *33*(9), 1602–1618. https://doi.org/10.1093/humrep/dey256

Thiese M. S. (2014). Observational and interventional study design types: An overview. *Biochemia Medica*, *24*(2), 199–210. https://doi.org/10.11613/BM.2014.022

Thom, G., Gerasimidis, K., Rizou, E., Alfheeaid, H., Barwell, N., Manthou, E., Fatima, S., Gill, J. M. R., Lean, M. E. J., & Malkova, D. (2020). Validity of predictive equations to estimate RMR in females with varying BMI. *Journal of Nutritional Science*, *9*(17), 1-10. https://doi.org/10.1017/jns.2020.11

Turner-McGrievy, G., Mandes, T., & Crimarco, A. (2017). A plant-based diet for overweight and obesity prevention and treatment. *Journal of Geriatric Cardiology, 14*(5), 369. https://doi.org/10.11909/j.issn.1671-5411.2017.05.002

Unamuno, X., Gómez-Ambrosi, J., Rodríguez, A., Becerril, S., Frühbeck, G., & Catalán, V. (2018). Adipokine dysregulation and adipose tissue inflammation in human obesity. *European Journal of Clinical Investigation*, *48*(9), e12997. https://doi.org/10.1111/eci.12997

Valachovičová, M., Príbojová, J., Urbánek, V., & Bírošová, L. (2017). Selected cardiovascular risk markers in vegetarians and subjects of general population. *Central European Journal of Public Health, 25*(4), 299–302. https://doi.org/10.21101/cejph.a4529

Ward, Z. J., Bleich, S. N., Cradock, A. L., Barrett, J. L., Giles, C. M., Flax, C., Long, M.W., & Gortmaker, S. L. (2019). Projected U.S. state-level prevalence of adult obesity and severe obesity. *New England Journal of Medicine*, *381*(25), 2440-2450. https://doi.org/10.1056/NEJMsa1909301

Weight Loss. (n.d.). Physicians committee for responsible medicine. Retrieved February 4, 2021, from https://www.pcrm.org/health-topics/weight-loss

Williams, T., Mortada, R., & Porter, S. (2016). Diagnosis and treatment of polycystic ovary syndrome. *American Family Physician*, *94*(2), 106-113. https://www.aafp.org/afp/2016/0715/p106.html

Wolf, W. M., Wattick, R. A., Kinkade, O. N., & Olfert, M. D. (2018). Geographical prevalence of polycystic ovary syndrome as determined by region and race/ethnicity. *International Journal of Environmental Research and Public Health*, *15*(11), 2589. https://doi.org/10.3390/ijerph15112589

Wright, N., Wilson, L., Smith, M., Duncan, B., & McHugh, P. (2017). The BROAD study: A randomised controlled trial using a whole food plant-based diet in the community for obesity, ischaemic heart disease or diabetes. *Nutrition & Diabetes*, *7*(3), e256-e256. https://doi.org/10.1038/nutd.2017.3

Zhou, H., Zhang, D., Luo, Z., Yang, A., Cui, N., Hao, G., & Wang, W. (2020). Association between BMI and reproductive outcome in women with polycystic ovary syndrome receiving IVF/ICSI-ET. *BioMed Research International*, *2020*. https://doi.org/10.1155/2020/6434080

Appendix A: Institutional Review Board Approval

IRB approval in August due to limited recruitment.

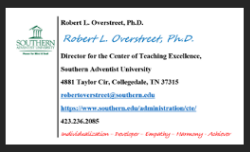
August 24, 2021

Principal Investigator: Elizabeth T. Perry
Research Project: DNP Scholarly Project
IRB Tracking Number: 2020-2021-u

Dear Elizabeth Perry,
It is a delight to inform you that your research protocol titled "Lifestyle Intervention to Achieve Weight Loss in Overweight Women Diagnosed with Polycystic Ovarian Disease" has been approved by the Southern Adventist University Institutional Research Board according to the proposal. You are now authorized to proceed with the project as outlined. This approval expires on August 24, 2022.
As a principal researcher, you have the ultimate responsibility for the conduct of the study, adherence to ethical standards, and protection of the rights and welfare of human participants. As you proceed with your research, you are expected to:

1) Conduct the study according to the approved protocol.
2) Make no changes to the approved study. If changes are necessary, proceed with one of the following:
   a) For minor changes to this protocol, please notify IRB by submitting an IRB Form B and proceed after its approval.
   b) For substantial changes, submit a new IRB Form A and proceed after its approval.
3) Use the approved procedure and forms for obtaining informed consent and data.
4) Promptly report any significant adverse events to the IRB within five working days of occurrence using an Adverse Report Form.

All forms must be submitted to irb@southern.edu.
We wish you many blessings as you move forward with this study and look forward to reading your findings when they are ready. If there is anything else we can do to assist you with this research study, please contact us.
Always in His service,



Appendix B: Informed Consent

Introduction:

My name is Elizabeth Perry. I am a doctoral nursing student (at Southern Adventist University. I am conducting a research study on the effect of a lifestyle intervention to reduce weight in overweight women diagnosed with PCOS. I am completing this research as part of my doctoral degree. Your participation is completely voluntary. I am seeking your consent to involve you and your information in this study. Reasons you might ***not*** want to participate in the study include commitment to exercise, and dietary interventions. You might want to participate in the study include specific recommendations regarding time and intensity of exercise, accountability, and guidance regarding a WFPBD, and an opportunity to talk with a trained health coach regarding lifestyle changes. An alternative to this study is simply not participating. I am here to address your questions or concerns during the informed consent process.

PRIVATE INFORMATION

Certain private information may be collected about you in this study. I will make the following effort to protect your private information, including having only your assigned number listed with your demographic and biometric data. List with names and assigned numbers were kept in an encrypted file only accessible to myself. Even with this effort, there is a chance that your private information may be accidentally released. The chance is small but does exist. You should consider this when deciding whether to participate.

Activities:

If you participate in this research, you will be asked to:

1. Complete a ten-minute intake survey.
2. Signup for an appointment to meet with researcher or research assistant. Link is provided at the end of the ten-minute survey.
3. Talk via Zoom or on a phone call with a researcher or assistant to gather data regarding weight, height, and waist circumference. Complete an exercise test to set exercise intensity.
4. Engage in a twelve-week program which will include meeting with coach 10 to 15 minutes per week, consuming a plant-based diet with caloric restrictions, and engaging in moderate-intensity exercise.
5. At the completion of week twelve you will have a conclusion meeting with a research or research assistant and conduct an exit survey via survey monkey.

Eligibility: Criteria

You are eligible to participate in this research if you:

1. Have been diagnosed with PCOS
2. Have a BMI greater than 25
3. Are between the ages of 18-45
4. Are not currently pregnant of breastfeeding
1. Answer no to the PAR-Q+ assessment. This is an assessment to help identify any risks associated with exercise.

You are not eligible to participate in this research if you:

1. Have not been diagnosed with PCOS
2. Have a BMI less than 25
3. Are currently pregnant or breastfeeding
4. Are less than 18 or greater than 45 years of age

5. Answer yes to any of the questions on the PAR-Q assessment. This study aims to enroll at list 62 participants.

Risks:

There are social risks in this study. Being overweight is often viewed as negative in our society. If information obtained in this study was disclosed to individuals or entities outside of the research group there is a risk that sharing this could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals. Risks will be minimized by storing all data in an encrypted file, minimizing access to this file to primary researcher and health coaches involved. All participants will be assigned a code and the identifying information (name, email address, phone number) will be kept separate from the data collected for the study.

Participants may experience pain and injury while participating in the prescribed exercise program. Risks will be minimized by requiring all participants to complete the PAR-Q survey prior to completion and receiving support from the researcher and health coaches throughout the study

Benefits:

If you decide to participate, there are several benefits you can experience.

You will have a personal plan to institute a habit of exercise and healthy eating. You will receive a ten-to-twenty-minute health coaching call per week. This coaching call will provide you an opportunity for accountability for maintaining healthy habits and work with you to find ways to make the lifestyle changes work for you. Following a diet high in plant foods has repeatedly demonstrated and improvement in overall health.

The potential benefits to others are an increase in the knowledge of a lifestyle intervention to achieve weight loss in overweight women diagnosed with PCOS.

Additional Costs:

There are no anticipated financial costs to you for participation in the study. You will be responsible for purchasing your own food for the study. A gym membership is not required but may be an additional cost if this option works best for you. It will be necessary to have access to a scale and tape measure to obtain the needed data.

Termination of Participation:

You have the right to withdraw this authorization if you wish to no longer participate in the study. Information gathered until this point will remain secure and no longer information will be collected. If you decide to stop participation, you may do so by contacting myself and informing me of your desire. If so, I will not use the information I gathered from you. Your removal from the study, if it does occur, may not be immediate.

New Findings:

Sometimes during a study, we learn new information. This information may come from our research or from other researchers. If new information might relate to your willingness to participate, I will give you that information as soon as possible.

Confidentiality:

The information you provide will be kept confidential to the extent allowable by law. One step I will take to keep your identity confidential is to assign you a number that will be used to track your data.

The people who will have access to your information are myself and the research team. The Institutional Review Board may also review my research and view your information.

I will secure your information with these steps: The document that has your name and assigned number will be encrypted and viewable only by myself. All other data will also be encrypted.

I will keep your data for 7 years. Then, I will delete electronic data and destroy paper data.

If any information is shared with another is shared with another entity that is not a health care plan or provider the information may no longer be protected by the federal privacy law.

Contact Information:

If you have questions for me, you can contact me at: emthomas@southern.edu

My scholarly project advisor's name is Andrew Richards, PhD. He is an associate professor at Southern Adventist University and is supervising me on this research. You can contact him at: arichards@southern.edu

If you contact us, you will be giving us information like your phone number or email address. This information will not be linked to your responses if the study is anonymous.

If you have questions about your rights in the research, or if a problem has occurred, or if you are injured during your participation, please contact the Institutional Review Board at: irb@southern.edu or 423-236-2285.

Voluntary Participation:

Your participation is voluntary. If you decide not to participate, or if you stop participation after you start, there will be no penalty to you. You will not lose any benefit to which you are otherwise entitled.

Future Research

Any information or specimens collected from you during this research may **not** be used for other research in the future, even if identifying information is removed.

Signature:

You always retain the right to refuse to sign this document. You can keep a copy of the form for your information.

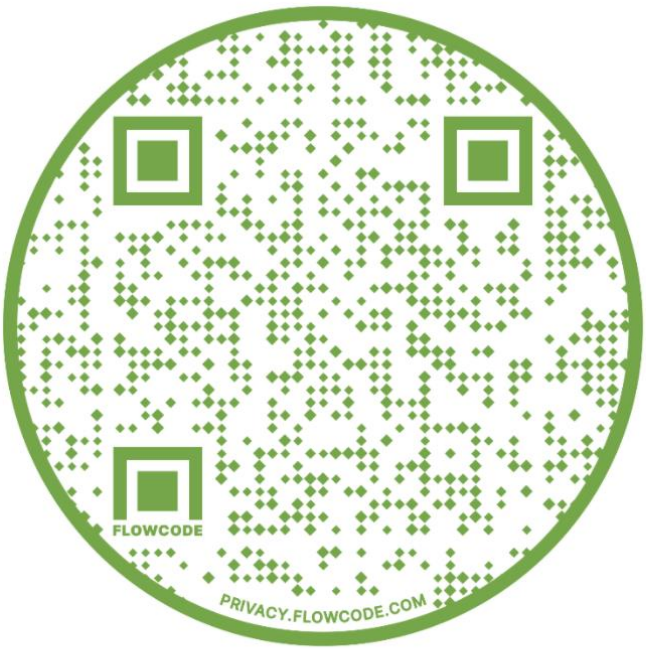
Participant Signature Printed Name Date

_____ _____ _____

Researcher Assistant Signature Research Assistant Name

Date

_____ _____ _____



Scan this code to be taken to the intake survey. Or click on link PCOS Intake Survey

Appendix C: CITI Certification

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** ELIZABETH PERRY (ID: 10008353)
- **Institution Affiliation:** Southern Adventist University (ID: 2706)
- **Institution Email:** emthomas@southern.edu
- **Institution Unit:** NICU

- **Curriculum Group:** Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in **Biomedical Research**. This course contains text, embedded case studies AND quizzes.

- **Record ID:** 41726070
- **Completion Date:** 11-Apr-2021
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 87

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Plagiarism (RCR-Basic) (ID: 15156)	10-Apr-2021	4/5 (80%)
Research Misconduct (RCR-Basic) (ID: 16604)	11-Apr-2021	5/5 (100%)
Research Involving Human Subjects (RCR-Basic) (ID: 13566)	11-Apr-2021	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kd4b9fc5a-a47b-4462-8b6d-43ed356051ab-41726070

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- Name: ELIZABETH PERRY (ID: 10008353)
- Institution Affiliation: Southern Adventist University (ID: 2706)
- Institution Email: emthomas@southern.edu
- Institution Unit: NICU

- Curriculum Group: Responsible Conduct of Research
- Course Learner Group: Same as Curriculum Group
- Stage: Stage 1 - RCR
- Description: This course is for investigators, staff and students with an interest or focus in Biomedical Research. This course contains text, embedded case studies AND quizzes.

- Record ID: 41726070
- Report Date: 11-Apr-2021
- Current Score**: 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Research Involving Human Subjects (RCR-Basic) (ID: 13566)	11-Apr-2021	5/5 (100%)
Plagiarism (RCR-Basic) (ID: 15156)	11-Apr-2021	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	11-Apr-2021	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kd4b9fc5a-a47b-4462-8b6d-43ed356051ab-41726070

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Appendix D: SurveyMonkey Intake Form

1. I have read and agree to the informed consent?
    - Yes
    - No

2. What is your height in feet and inches? For example, if are 5 feet and four inches, write 5’4”

3. What is your current weight in pounds?

4. When were you diagnosed with PCOS?
    - 1-3 years ago
    - 3-5 years ago
    - Greater than 5 years ago
    -
5. Is your menstrual cycle regular?
    1. Menstruation is very regular, comes with recurring frequency and for a predictable amount of days.
    2.
    3.
    4.
    5. Cycle is very irregular, I never know when it is coming or for how long it will last.

6. How would you rate the severity of your PCOS?
    1. I hardly notice my period is coming, sleep, appetite, mood, and energy level remain steady.
    2.
    3.
    4.
    5. Cycle is very irregular, I never know when it is coming or for how long it will last.

7. Are you currently using hormonal birth control?
    - Yes
    - No

8. How many pregnancies have you had?
    - None
    - 1
    - 2

- 3
- 4 or more

9. How many children do you have?
    - None
    - 1
    - 2
    - 3 or more

10. Have you been treated by fertility doctors in the past?
    - Yes
    - No

11. Are you currently pregnant or breastfeeding?
    - Yes
    - No

12. Have you attempted weight loss in the past?
    - Yes
    - No

13. What type of weight loss have you utilized in the past?
    - Weight Watchers
    - Low Fat
    - Ketogenic
    - Zone Diet (continued on next page)
    - Vegetarian
    - Vegan
    - Raw
    - Other: _____

14. Has your doctor ever said that you have a heart condition or high blood pressure?
    - Yes
    - No

15. Do you feel pain in your chest at rest, during your daily activities of daily living, Or when you do PA?

- Yes
- No

16. Do you lose your balance because of dizziness or have you lost consciousness in the last 12 months? (Please answer no if your dizziness was associated with over breathing, including during vigorous exercise).
    - Yes
    - No

17. Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)?
    - Yes
    - No
    - If yes, please specify_____

18. Do you currently have (or have had in the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active?
    Please answer NO if you have had a problem in the past, but it does not limit your

    current ability to be physically active.

    If yes, please specify the condition in the comment box.

    - Yes
    - No
    - Comment- _____

19. Has your doctor ever said that you should only do medically supervised PA?
    - Yes
    - No

20. Contact:
    Name: _____

    City/Town: _____

    State: _____

Email: _____

Phone number: _____

21. Thank you so much for taking the time to complete this survey. Please click on the link after submitting to schedule your initial coaching session.

Submit

Appendix E: Rockport One-Mile Walk Test

Rockport One-Mile Walk Test

Equipment:
Wearable heart rate monitor, method to record time.
A track or treadmill to walk one mile.

1. Warm up for 5 minutes with some light stretching and easy walking.
2. Walk briskly for one mile (1609 meters), with a heart rate monitor on. If no heart rate monitor available count your pulse at your wrist for 10 seconds at the completion of the walk and multiply by 6.
3. Immediately on completion of the one-mile walk record your heart rate.
4. Record the time in minutes and seconds it took to walk one mile.

Heart Rate: _____

Mile Time: _____:_____

Kumar, N., & Goswami, S. (2019). Comparison of Rockport one-mile walk test and McArdle step test for the prediction of VO2max. *Saudi Journal of Sports Medicine*, *19*(3), 82.

Appendix F: SurveyMonkey Completion Form

1. How would you describe your experience in completing the lifestyle intervention?
2. What was your experience with the health coaching session?
3. What would be your thoughts regarding recommending this program to a friend?
4. Do you feel your menstrual regularity has improved?
    - Yes
    - No
5. How would you describe your menstrual regularity?
    1. Menstruation is very regular, comes with recurring frequency and for a predictable number of days.
    2.
    3.
    4.
    5. Cycle is very irregular; I never know when it is coming or for how long it will last.
6. How would you rate the severity of your PCOS?
    1. I hardly notice my period is coming, sleep, appetite, mood, and energy level remain steady.
    2.
    3.
    4.

5. Cycle is very irregular; I never know when it is coming or for how long it will last.

2. What was your experience and adhering to the whole food plant-based diet?
3. Moving forward what will your diet and exercise look like?
4. What suggestions do you have to improve the lifestyle intervention program?
5. Thank you so much for participating in the study! Your time and dedication have been greatly appreciated please let us know if you would like us to send you the results of this study? Email address:

Appendix G: Scholarly Project EOP SLO Synthesis

Southern Adventist University
School of Nursing
DNP Scholarly Project EOP SLO Synthesis
Elizabeth T. Perry

PICO/Research question:

In overweight or obese women ages 18-50 diagnosed with PCOS will a WFPBD, caloric reduction of 500 calories per day below resting metabolic rate, and 30 minutes of moderate-intensity exercise result in weight loss, reduced weight circumference and reduction in symptoms of PCOS over a 12-week intervention?

1. Cultural Competence:
   Mentor Christian responsiveness and caring to a global culture through sensitivity and competence for patient traditions and values.

   Discuss how your proposed Scholarly Project could demonstrate Cultural Competence?

2. Evidence Based Practice:
   Translate quality research findings and outcomes to solve problems for quality personalized outcomes.

   This Scholarly Project is based on prior evidence demonstrating that a WFPBD can positively impact someone's metabolic and cardiac health status. Current research also demonstrates that weight loss through caloric restriction can help control the symptoms of PCOS. And current research demonstrates that moderate-intensity exercises can help improve metabolic health and reduce hyperinsulinemia and glucose.

3. Health Promotion:
   Propose evidence-based methods that prevent disease and promote human flourishing through the utilization of a wholistic framework to educate and empower healthy lifestyle choices.

   The Scholarly Project that is proposed demonstrates health promotion directly. The Scholarly Project will be focused on a WFPBD, moderate exercise, and caloric restriction. Obesity is a global health pandemic and

a key driver in cardiovascular disease, one of the leading causes of death. The goal of this project will be to empower individuals to take control of their health.

4. Patient Centered Care:
   Facilitate inter/intra professional healthcare to achieve personalized, compassionate, and coordinated whole person care.

   Caring for the patient involves coming near to them and assisting them to take ownership for their own health. This Scholarly Project will involve assisting the participants in understanding their own bodies and health. The project will also be personalized to the needs of the participants.

5. Quality and Safety:
   Evaluate current evidence and outcomes of practice in health care systems to ensure a just culture that minimizes the risk of harm and promotes safety and quality of care.

   The idea of first do no harm has long been talked of in the medical community, yet in our current culture is seldom practiced. Lifestyle changes that promote health do no harm to the patient. The give the patient the opportunity to experience abundance in health. Current evidence suggest lifestyle management and weight reduction to treat symptoms of PCOS yet guidelines are not established.

   The biggest safety concern that I would have would be in regard to eating disorders in women, if a women suffered from an eating disorder the focus on weight reduction could increase their urge to engage in unhealthy behaviors.

6. Informatics and Innovation:
   Analyze healthcare outcomes using knowledge of nursing, computer and information sciences to ethically and innovatively manage data, information, and technology.

   The Scholarly Project will need to rely on a computer program to store the data collected. Communication with the participants will occur over the computer either through email, zoom, or FaceTime. In addition, an App, FITR maybe utilized to track menstrual cycles and symptoms. This app allows the "coach" to have participants sign up and receive information regarding their cycles. I need to contact the app to see what other data is available to the "coach".

7. Teamwork and Collaboration:
   Organize effective inter/intra professional teams to promote quality health outcomes and reduce risk.

To complete this project, I would like to collaborate with area OBGYN's and local lifestyle medicine providers to recruit participants. If we are able it would be ideal to collaborate with the human performance lab to measure body fat percentages. Also, of interest to me would be to collaborate with graduates of the health coaching class as they are working to get 50 client visits in order to sit for the test. It would be ideal to have each participant to set up with a coach to increase accountability and adherence to the plan.

8. Professionalism:
Advocate for Christ-centered Excellence in nursing roles and professional behaviors throughout the inter/intra professional team.

This project will utilize a team approach to provide evidenced-based care in which to optimize patient outcomes. We will work to guide the participants through a complex health change. Using conceptual ideas, we will link ideas to form a more complete patient focused practice.