

A NON-WEIGHT CENTERED APPROACH TO MODIFYING EATING ATTITUDES IN
POLYCYSTIC OVARIAN SYNDROME

A Doctoral Project
Submitted to the Faculty of the
Graduate School of Arts and Sciences
of Georgetown University
in partial fulfillment of the requirements for the
degree of
Doctor of Nursing Practice

By

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Washington, D.C.
March 23, 2024

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ABSTRACT

Polycystic Ovarian Syndrome (PCOS) is an anovulatory disorder characterized by insulin resistance and endocrine dysfunction. Infertility and abnormal weight gain in women of childbearing age are often a result of PCOS, impacting quality of life and posing potential long-term health sequelae. Prescribing weight loss has been adopted by clinicians as an effective intervention to improve insulin resistance. For some patients, this practice has led to the negative effects of weight cycling and disordered eating attitudes which can result in long term adverse cardiometabolic outcomes.

A quasi-experimental pre-and-post-test study was conducted to evaluate how a non-weight centered program influences eating attitudes in patients with PCOS. Four individuals assigned female at birth (AFAB) between ages 31-40 with a known diagnosis of PCOS enrolled in a pilot program that consisted of six bi-weekly visits with a dietician, food logging, and participation in a private online support group. Participants completed the Disordered Eating Attitudes Scale (DEAS) assessment before and after completing the program. Waist circumference was measured at visits one, three, and six. The support group activity was tracked based on the participants' ability to interact three times weekly.

DEAS scores decreased for 75% of the sample with an average reduction of 13 points. All participants experienced at minimum a one-inch reduction in waist circumference with an average decrease of 2.5 inches. Fifty percent of the sample made nutrient rich (green) food choices less than 50% of the time at baseline (visit two). By visit five, 100% of the sample made

green food choices greater than 50% of the time. Majority of participants completed support group interaction only two out of ten weeks. The relationship between group support and eating attitudes remains unclear. Results suggest that a non-weight centered approach to modifying eating attitudes in clients with PCOS may be effective in helping patients achieve more sustainable lifestyle changes. Further research is indicated to explore the impact of non-weight centered approaches for the management of PCOS symptoms and reducing risk of long term sequelae.

ACKNOWLEDGEMENTS

All glory belongs to God for his grace and mercy through all of the obstacles that I've had to overcome on this journey. Thank you to my village who encouraged me along the way; especially my parents, sisters, friends and my loving husband. Thank you to my project mentor and content expert for their involvement in helping me accomplish this goal. A huge thank you to Kristin West, the smart and dedicated clinical nutritionist that saw my passion for this project and took a chance on me. I could not have done this without all of you. Last but not least, I would like to thank myself for not giving up on this dream.

We made it.

With heartfelt gratitude,
Jo Lethermon

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Chapter 1. Introduction and Review of the Evidence

Polycystic Ovarian Syndrome (PCOS) is a disorder of reproductive hormone and metabolic dysfunction that results in long term sequelae such as increased risk for cardiovascular disease, endometrial cancer, metabolic syndrome, and depression (Walters et al., 2018). Patients may present with irregular menses, weight gain, acne, and growth of facial or chest hair. Patients commonly seek care due to infertility caused by PCOS in addition to abnormal weight gain. The pathophysiology of PCOS is complex and includes genetic, environmental, transgenerational, and endocrine factors (Kim, 2021). The dysfunctional hormone cascade begins with an increased pulsatile frequency of luteinizing hormone (LH) which results in over stimulation of the ovaries, androgen excess, and suppression of sex hormone binding globulin (SHBG) (Walters et al., 2018). SHBG is responsible for binding testosterone. Without enough SHBG, testosterone levels rise and send a negative feedback signal to the hypothalamus telling it to stop producing follicle stimulating hormone (FSH) (Walters et al., 2018). Without the proper function of FSH, follicle maturation is halted and ovulation is impaired.

Follicles that are halted in maturation appear as cysts on the ovaries, which is why the term polycystic ovarian syndrome was coined. As research progresses, experts are calling PCOS a misnomer as the structures that appear on the ovaries are not actually cysts. Yet, this is a universally known characteristic of the disease. The syndrome encompasses a cycle of excess adipose tissue deposition and visceral adiposity making obesity another common characteristic (Kim, 2021). The obesity rate amongst patients with PCOS is between 50% and 80% depending on demographic factors such as age and ethnicity (Kim, 2021). A study conducted in Korea discovered that individuals ages 20-39, commonly the age range for desired conception, have had a sharp increase in obesity over the last several years (Kim, 2021). Studies have also found

that Asian women tend to accumulate more visceral fat than Caucasian women and that black women have a higher tendency for adverse cardiometabolic profiles related to obesity and insulin resistance in comparison to non-Hispanic white individuals (Kim, 2021; Wolf et al., 2018).

An increase in intra-abdominal fat mass is correlated with high circulating androgen levels in individuals with PCOS (Walters et al., 2018). Interventions that target intra-abdominal fat mass enhance insulin sensitivity which can be effective for symptom relief and can increase chances of conception (Ramírez-Manent et al., 2023). Too much insulin leads to suppression of SHBG which results in a rise of testosterone and dysfunction of FSH. Correcting hyperinsulinemia, therefore, results in more SHBG to bind testosterone which will result in appropriate follicle stimulation and finally ovulation for fertilization. Evolving knowledge on how insulin influences the ovaries is how the act of prescribing weight loss came to be the management standard.

Prescribing weight loss is the act of instructing clients to make lifestyle adjustments without providing the proper education, tools, or resources to achieve sustainable change. Many individuals left to navigate this task independently will resort to crash dieting, dietary restrictions, and self-restraint. This practice increases the likelihood that the patient will experience weight cycling, internal weight stigma, and long-term sequelae (Lee et al., 2017; Braun et al., 2022). The implementation of an intervention program that focuses on sustainable lifestyle modifications by targeting eating behaviors and food relationships in patients with PCOS may lead to sustained weight loss and a subsequent reduction in poor health outcomes. Thus, the purpose of this paper is to explore the impact of expert education from a dietitian, frequent follow ups, and group support on eating attitudes and behaviors for clients with PCOS.

Background and Significance

A publication by Ninive Sanchez (2020) suggests that women with PCOS are a part of a marginalized population in the United States. This means that the health care system both intentionally and unintentionally hinders these individuals from the rights and opportunities necessary for them to live a quality life (Sanchez, 2020). Approximately seven percent of women ages 18 to 44 in the United States are affected by PCOS (Sanchez, 2020). This number is comparable with the percent of American citizens in the same age group living with diabetes which is about nine percent (Sanchez, 2020). Clients in this population, like many other individuals affected by endocrine dysfunction, require a multidisciplinary approach for management which includes a wide range of services such as social work, behavioral health, endocrinology, women's health, and clinical nutrition (Sanchez, 2020). However, because PCOS remains both poorly understood and under-researched, important services like the use of a dietician is still severely underutilized within this population and in the healthcare system in general.

Clients can impact their own long-term health through the development of healthy lifestyle choices, such as positive eating habits. Responsibility lies with healthcare professionals to empower clients with the education needed to make these choices. The transition to long term lifestyle changes can be difficult for patients to develop and maintain if they are not given the proper guidance and if their motivation is not rooted in a cause that yields sustainable results. Clinicians are trained and qualified to give clients the tools they need to achieve long term health by walking with patients on their journeys to address the challenges that accompany PCOS and result in long term sequelae. There are many adverse effects that can occur for the client as a result of this syndrome such as the development of sleep apnea, endometrial cancer, disordered

eating, and depression (Cao et al., 2021; Lee et al., 2017; Madigan et al., 2018; Nagle et al., 2013).

As there are adverse effects for the client, PCOS has some adverse effects on the healthcare system as well which are mainly economic. Riestenberg et al. (2021) discovered that failure to diagnose PCOS in a timely fashion and treat with appropriate lifestyle and medical interventions can result in a future economic strain to the already over-burdened healthcare system. The economic strain of PCOS is related to the cost of pregnancy complications, cardiovascular complications, and endocrine complications that result from the pathophysiology of the syndrome (Riestenberg et al., 2021). These complications include diagnosis such as type 2 diabetes, gestational diabetes, elevated cholesterol, increased risk for cardiovascular disease, increased potential for pre-eclampsia development in pregnancy, and increased potential for endometrial cancer. All of these complications increase length of hospital stays and cost of treatment.

Though PCOS has become more prevalent, it is a challenging condition to manage and diagnostic guidelines can vary with age (Kim, 2021). Estimated cost related to PCOS were projected to be around eight million dollars in the year 2020. This number is predicted to climb in the years to come unless significant changes to management are made including an interdisciplinary approach to support more sustainable lifestyle changes (Riestenberg et al., 2021). Evidence shows that non-weight focused individualized life style and behavior modifications result in more favorable health outcomes (Wang et al., 2021; Nemchikova & Fontoni, 2022; Riestenberg et al., 2021). The PICOT question for this project seeks to explore aspects of this claim.

PICOT Question and Project Site

The PICOT question developed for this project is as follows: In clients with a diagnosis of PCOS (P), what is the impact of a non-weight centered dietician guided pilot wellness program (I) as compared by pre and post participation assessment scores (C) on eating attitudes (O) over a three-month period (T)? The project site is a wellness center in south Louisiana whose mission is to understand every patient's challenges and goals. The site is well known for customizing treatment plans to fit each patient's unique needs through fitness programs, nutrition therapy, education and support. Clients are referred to the center from women's health clinics in and near city limits. The lead dietician and site contact reported an estimated 15% of clients with a documented PCOS diagnosis receiving services within the practice prior to the initiation of the intervention.

Definition of Terms

This section defines components of the PICOT question.

- A non-weight centered dietician guided pilot wellness program refers to a client-coach approach to sustainable lifestyle modifications.
- Disordered eating attitudes are abnormal beliefs, thoughts, feelings, behaviors, and relationships relative to food (Alvarenga et al., 2010). Thus, eating attitudes refers to all of the same components without an abnormality.
- Assigned female at birth (AFAB) refers to any individual with internal female reproductive organs such as a uterus, fallopian tubes, and ovaries, independent of how they may otherwise identify.
- Childbearing age is defined as 18 to 44 years (CDC, 2021).
- Patient and client may be used interchangeably and will refer to an assigned female at birth (AFAB) individual of reproductive age.

- Participant refers to a patient or client that has consented to participate in this project.
- A three-month period refers to three calendar months which in the context of this project are October, November, and December.

Rationale and Purpose for This Project

The concept of targeting weight loss to improve PCOS is not new. Lee et al. (2017) conducted a cross sectional study that revealed the increased likelihood of patients with PCOS to develop disordered eating patterns. Instructing a patient to lose weight to improve their symptoms in isolation can be a catalyst for crash dieting, yoyo dieting, and poor eating behaviors (Lee et al., 2017). The proposed intervention shifts focus from weight loss to long term health benefits by helping clients establish sustainable lifestyle modifications by targeting eating attitudes. At the project site, clients normally see the dietitian for an initial visit, a one month follow up, and then not again for three months if at all. A lifestyle modification program may run from three to six months but the first 59 days are critical for an individual forming a new habit (Keller et al., 2021; Wang et al, 2021). Clients need significant reinforcement during the initial 59-day time period to achieve sustainable outcomes. A traditional visit schedule of a one month and three month follow up may be insufficient to establish and sustain behavior change. Therefore, the intervention for this project ran over the course of three months, approximately 90 days, in an effort to reinforce teachings, provide motivation, answer questions, and assist with overcoming the areas of most resistance during and beyond the critical habit-forming time frame. One on one education from the dietitian occurred on a bi-weekly basis. The bi-weekly visit structure is a nice median between monthly visits and weekly visits. Weekly visits would have posed a strain on both the patient and the dietitian both functionally and economically. The intervention program also involved a virtual support group platform. Evidence shows that peer

support groups are effective in improving the wellbeing of women with PCOS since this population is more likely to have internalized weight stigma and a lower overall quality of life due to the psychological struggles that accompany this syndrome (Ranasinghe et al., 202; Braun et al., 2022; Turner-McGrievy et al., 2014). Therefore, having a support group may be a very important element of the proposed intervention which also contributes to positive reinforcement and habit forming in the time sensitive period.

Kapur et al. (2008), an original study on barriers to dietary changes, concluded that more frequent visits to the dietitian with education on overall methods to healthy living such as food choices and cooking methods have a positive impact on compliance and sustainability. Teaching a patient to navigate healthy eating from day to day while making long term sustainable lifestyle changes for themselves and their families is an approach that is highly likely to yield better outcomes. Dietitians are the best professionals to assist clinicians with this task and yet their services remain underutilized. Nemchikova & Frontoni (2021) published a journal article on the role of dietitians in the multidisciplinary management of PCOS. The author describes clinician use of dietitians' services as "sporadic," and also emphasizes the need to change this practice as dietitians should be considered an essential part of PCOS management.

Health Equity Considerations

Some of the obvious barriers to a multidisciplinary approach are cost, accessibility, and environment. PCOS is generally understudied and it is even more understudied in diverse groups such as non-white and Hispanic individuals (Kazemi et al., 2021). Black women with PCOS have a greater tendency for adverse cardiometabolic outcomes despite having a better triglyceride profile than their white counterparts. These disparities can be attributed to timeliness of the diagnosis and lack of standardized management practices (Kazemi et al., 2021). Absence

of a treatment protocol leaves room for implicit bias which can influence provider discretion and decision making. Lack of studies that involve black women with PCOS makes creating a treatment protocol even more of a challenge. Other social determinants play a role in the long-term outcomes of this group including environmental and socioeconomic factors (Kazemi et al., 2021). Social determinants of health (SDOH) should be taken into consideration with the implementation of any intervention. This project focused mainly on the program's cost burden for participants and how to improve access to the program by removing the financial barrier.

Specific Aims

The specific aims are: 1) to evaluate how a non-weight focused program influences eating attitudes in a group of clients with Polycystic Ovarian Syndrome, and 2) identify facilitators and barriers for clients adopting this modified approach.

Theoretical Framework

The theoretical domains framework (TDF) was chosen to help identify the barriers and facilitators associated with implementing a behavior change (Michie et al., 2005). This framework was developed by a group of behavioral scientists and implementation researchers who sought to identify the theories most relevant to implementation science (Atkins et al., 2017). The creators of TDF, Michie et al. (2005), identified 33 theories and grouped them into 14 domains (Atkins et al., 2017). Overall, the framework provides a theory informed approach to identifying determinants of behavior (Atkins et al., 2017). Some of the domains include: knowledge, skills, social/professional role and identity, beliefs about capabilities, beliefs about consequences, motivation and goals, social influences, and emotion (Atkins et al., 2017). The TDF is often illustrated as a wheel that encompasses the 14 domains married with the capability, opportunity, motivation, and behavior (COM-B) model. The COM-B model works at the core of

theoretical domains and is a key component for proper use of the framework (De Leo et al., 2021). The behavior change wheel guides the technique that will be most useful for successful implementation (Atkins et al., 2017).

The use of this framework in the project's population of interest was evaluated by Pirotta et al. (2021) in a study that aimed to identify barriers and facilitators to behavior change in a lifestyle management program for PCOS patients. The author noted successful use of the framework via the following steps (Pirotta et al., 2021):

- (1) Conduct semi structured interviews
- (2) Identify barriers and facilitators to behavior change and map them to TDF
- (3) Map the TDF domain to the COM-B model
- (4) Identify the appropriate intervention function
- (5) Then incorporate the intervention to address the barrier

The study listed the following key behavior determinants in the results: psychological and physical capability, physical and social opportunity, and reflective motivation (Pirotta et al., 2021). The results of this study were used to guide the program design.

Unlike the steps described by Pirotta et al. (2021), the initial survey did not include behavior related questions. However, behavior related questions were included in the initial visit such as: the discussion of personal, internal, and external motivators, a work and activity assessment to address social opportunities, a professional assessment of the client's level of skill with cooking or making groceries to address physical capabilities, and an assessment of the level of enjoyment of these task to determine psychologic opportunities and capabilities. These details were obtained from the client by the dietician to help inform the areas of most needed emphasis

on future diet education throughout the program. The post-study survey will include an open-ended assessment of the barriers and facilitators unique to this project specifically.

Search Criteria

A search was done using PubMed (Medline) and CINAHL databases accessed through the university library. The search terms included the following medical subject headings (MeSH headings): polycystic ovary syndrome, binge eating disorder, lifestyle modification, eating behavior, dieting, binge eating, disordered eating, and weight cycling. The following key words were used: hospital system, institution, quality of life, USA, social support, cardiometabolic, adverse outcomes, adverse effects, PCOS, waist circumference, and insulin resistance. Literature published greater than ten years ago was excluded with the exception of four seminal works. The search was also tailored to English and full text publications only.

Fourteen sources were retained for evidence and they include the following: a meta-analysis, a systematic review, three cross sectional analyses, a post hoc longitudinal analysis, a pretest/posttest control group study, a qualitative survey study using a structured questionnaire, an online based intensive longitudinal two condition randomized controlled trial (RCT), a multicenter RCT, a simple survey study, a prospective cohort study, a longitudinal study, and a randomized pilot trial. All literature was graded using the Let Evidence Guide Every Decision (LEGEND) literary appraisal system.

Literature Review

Disordered Eating and PCOS

A cross sectional analysis by Lee et al. (2017), graded 4b, sought to investigate the prevalence of disordered eating among women with PCOS. The study compared 148 women ages 18-50 with PCOS diagnosed by the Rotterdam criteria to 106 women in the same age group

without the diagnosis (Lee et al., 2017). Participants completed the Eating Disorder Examination-Questionnaire (EDE-Q) (Lee et al., 2017). An analysis of the survey data found that women with PCOS have four times the risk for disordered eating compared to women without PCOS. The strength of this study is that it addresses several gaps in current literature as it relates to information on the relationship between disordered eating and PCOS and has statistically significant results. Limitations of the study included that the data is not considered generalizable due to the sample used and it also lacks the assessment of psychological factors that may play a role in disorder eating. This piece of evidence supports the idea that assessment and intervention of eating attitudes in clients with PCOS is indicated.

The Effects of Weight Cycling

Cao et al. (2021), graded 4a, conducted a cross sectional analysis to address weight cycling and sleep patterns. A yearlong diverse community cohort with women ages 20 to 76 years was utilized as the study population with a sample size of 506 individuals (Cao et al., 2021). Participants were excluded if they were pregnant or less than six months postpartum, unable to read, unable to complete evaluations, or had any type of cognitive impairment (Cao et al., 2021). The data included participant self-reported sleep duration, quality, onset latency, insomnia severity, snoring, and sleep apnea risk score. Over the one-year time period 70% of the population reported a cyclic loss and regain of 10 pounds or more for reasons unspecified. The data showed that the percent of women that experienced episodes of weight cycling reported shorter sleep duration, poorer sleep quality, and higher obstructive sleep apnea scores (Cao et al., 2021). The community-based cohort included a racially and ethnically diverse sample which served as a strength. The study was limited in its ability to consider behavioral factors that contribute to weight cycling and sleep such as physical activity, food intake, and managing

stress. Potential recall bias also existed in self-reported surveys which is an additional limitation. In regards to how relevant the results are to the PICOT question, there is a limitation considering the study's population age range and lack of focus on PCOS specifically. However, the work does speak to the effect of weight cycling on overall health and wellbeing.

A longitudinal study written by Madigan et al. (2018), graded 4b, investigated whether weight cycling is associated with adverse mental health outcomes. The original sample consisted of 12,388 women but only 7259 women provided full data for analysis. Results revealed that 40% of women reported a history of cyclic loss and regain. These women all had statistically significant increases in depressive symptoms based on the mental health component summary scores (Madigan et al., 2018). The study was strengthened by its large sample size, study design, and long follow up period of 12 years. Yet, it was weakened by self-reported data and vague criteria for the study's definition of weight cycling.

A prospective cohort study by Nagle et al. (2013), graded 3b, was conducted to determine whether there is an association between weight cycling and risk of endometrial cancer. 2707 women were initially included in the study between ages 18-79 with newly diagnosed or historically confirmed endometrial cancer by chart review. 394 women were excluded due to inability to establish or maintain contact, mental incapacity, or severity of illness. Only 1458 participants remained in the study after accounting for consent and excluding cancer that did not originate in the endometrium. Results reported with a 95% confidence interval stated that weight cycling is associated with an increased risk of endometrial cancer. The more episodes of loss and regain of ten or more pounds, the higher the risk. Strengths of this study include statistically significant results from a large study population. Limitations include self-reported height, weight, and history data.

Economic Impact

A meta-analysis by Riestenberg et al. (2021), graded 1b, identified the economic impact of PCOS on the healthcare system. The author identified 3146 studies and then excluded 3082 based on the titles and abstracts. An additional 35 studies were excluded because they did not include the outcome of interest or match the control. One other study was excluded due to data duplication from an earlier study leaving 29 articles for this analysis (Riestenberg et al., 2021). The economic burden calculations of this meta-analysis estimated the annual burden of PCOS to be about 4 billion dollars annually as of 2020 which is an increase from two and one half billion dollars in 2004 (Riestenberg et al., 2021). Findings of this study suggest that the cost increase to eight billion dollars annually is secondary to long term complications of PCOS. The researcher believes that a growing financial strain can be prevented through rapid diagnosis and treatment of the syndrome by clinicians. Rapid diagnosis and treatment refer to the clinician's ability to adequately recognize symptoms of a hyperandrogenic disorder as they vary across the lifespan, to rule out other potentially serious endocrine and hyperandrogenic disorders, and to utilize the Rotterdam criteria appropriately (Kim, 2021). Treatment may include medication or lifestyle modifications. The author mentioned that the calculations in this analysis did not encompass all potential long term health outcomes associated with PCOS, as there are many, and therefore the estimated economic impact may be more than what was stated which is a limitation of the work published (Riestenberg et al., 2021). On the other hand, this analysis focused on the health outcomes that were quantifiable and well published in the literature which strengthened the evidence presented by this author (Riestenberg et al., 2021).

Lifestyle Modification Programs

A randomized trial by Braun et al. (2022), graded 2a, investigated the effectiveness of virtually guided lifestyle interventions. Results from a randomized sample of 28 women ages 18-65 saw improvements in internalized weight stigma, self-compassion, and intrusive eating behaviors via a virtual platform. Unfortunately, the p-values (ranging from 0.17 to 0.99) for differences between the virtual intervention group and the control group showed no statistical significance (Braun et al., 2022). However, the author does state clinical significance in the improvement of weight stigma, self-devaluation, self-compassion, dietary disinhibition, and intuitive eating. The randomized design is a strength of this study. However, the sample was insufficiently powered and the study designer had some difficulty obtaining measurements through the virtual platform. This evidence was retained to support the use of a virtual visit option for participants in this project which will be discussed in greater detail in chapter two.

A survey study conducted by Turner-McGrievy et al. (2015), graded 4b, recruited overweight and obese women with PCOS for a six-month healthy eating for reproductive health intervention. The study enrolled 18 women total with seven black, 10 white, and one person identifying as Hispanic (Turner-McGrievy et al., 2015). During this intervention surveys were used to assess dietary intake, healthy body weight, and quality of life for a score. Results demonstrated that overweight clients with PCOS scored lower in all of the above categories compared to overweight women without PCOS. The study was comprised of 39% black women in the sample which is a strength due to underrepresentation in other studies (Turner-McGrievy et al., 2015). This ratio of black women to white women is also reflective of the ratio in the United States. The study design is limiting as surveys rely heavily upon client recall and an honor system which like many studies of this design, have the potential to yield flawed results. This piece of evidence speaks to the necessity of the project intervention.

A post hoc longitudinal analysis by Wang et al. (2021), graded 4b, investigated the effects of a six-month lifestyle intervention program that consisted of diet modifications and physical activity enhancement coupled with motivational counseling and support for a group of individuals with PCOS. The intervention group consisted of 289 women. Results revealed that participants in the intervention group had improved blood pressures and better cardiometabolic profiles after three and six months with a statistically significant decrease in body mass index (BMI) (Wang et al., 2021). Cardiometabolic measurements included cholesterol and insulin/glucose labs. Analysis of the data yielded statistically significant results which is a strength of this study. However, the work was limited due to its lack of randomization and self-reported questionnaires which were found to have under reported dietary intake and overly reported physical activity. In terms of how the evidence relates to this project's intervention, the results informed the decision to implement the proposed intervention for three calendar months and supports the program's client coach approach. A major limitation of this published research is its mention of caloric restrictions considering the project's intervention does not use this method. However, the results were still included in the body of evidence due to the overall outcome of lifestyle changes and motivational support on cardiometabolic markers after a three-month time period with a recognized absence of a sustainable lifestyle modification method.

The Necessity of Frequent Visits

A qualitative survey study using a structured questionnaire was conducted by Kapur et al. (2008), graded 4b, to identify factors that enhance or reduce compliance to dietary education. A pre-tested questionnaire-based interview was given to a sample of 350 adults with type two diabetes from four large diabetic clinics in South India. The interviews were duplicated separately for at least five of the participants by two different interviewers and examined to

ensure validity. The results of the questionnaire concluded that barriers are usually related to life circumstances that are non-modifiable. The modifiable barriers were identified as lack of individualized treatment plans and self-management training (Kapur et al., 2008). Since most barriers are non-modifiable, the author placed emphasis on the elements that have a positive impact on compliance and sustainability with diet education such as frequent dietician follow ups. The author's point supports the bi-weekly visit schedule for this project. Kapur et al. (2008) also highlighted the importance of good professional advice as an important discriminator between participants who followed lifestyle modification guidance and those who did not. This finding speaks to the importance of the dietician skill set which furthermore supports the necessity of the project intervention. One pitfall of this piece of evidence is that the study was not conducted specifically for clients with PCOS. The population included patients with type two diabetes only, making these results less generalizable to the population of interest for this project. On the other hand, it is notoriously known that wellness of diabetic patients relies heavily on their ability to make sustainable changes to their eating habits, therefore making this an excellent population from which to draw the above-named conclusions. Strengths of this study lie in the large sample size, the proven validity of the questionnaire used, and the fact that the results were determined to be statistically significant.

A mixed methods RCT by Keller et al. (2021), graded 3a, was conducted to determine the time frame in which most people establish a habit using a group of 192 participants ages 18-77. Study results revealed an average of 59 days are needed to reach peak automaticity. This study evaluated within-person and between-person differences. Results were statistically significant with a p value of .003 (Keller et al., 2021). A logistic regression analysis showed that intrinsic reward, or the satisfaction of completing a task as intended, was a predictor of successful habit

forming (Keller et al., 2021). The researcher reported a powered sample which is a strength of the study. The study was limited due to the large number of younger subjects in the sample making the findings less generalizable to the project's target population and lack of discussion on other factors contributing to habit forming. The study was retained as evidence to support the timeline of the project intervention.

Peer Support Groups

The pretest/posttest control group study by Ranasinghe et al. (2021), rated 4a, evaluated the impact of support group participation on clients with PCOS looking to making lifestyle changes. A sample of 22 participants was recruited from an endocrine and subfertility clinic in Colombo, Sri Lanka. Participants ages 18-39 years attended ten support group sessions lasting 90 minutes each facilitated by a well-educated peer. Each participant was asked to complete a modified polycystic ovarian syndrome questionnaire (M-PCOSQ), a center for epidemiologic studies depression scale (CESD), and a brief COPE inventory. Results showed improved scores in the intervention group which indicated that peer support is beneficial to clients psychologically and to their overall well-being. The study used reliable and valid tools such as the modified polycystic ovary syndrome questionnaire and the center for epidemiologic studies depression scale, which is a strength. Another strength includes the ability of the study to directly correlate support group success with improvement in PCOS quality of life. Several studies have investigated the value and effectiveness of support groups and group therapy but usually not as it related to PCOS. A limitation of this study is that outcomes were assessed only after one month. Therefore, the long-term effects of this support group activity and the longevity of participation in the group could not be determined from these results. The sample size was relatively small which may prevent the findings from being generalizable. The results of this study informed the

incorporation of a support group component into the intervention though it was established via a social media platform as opposed to group meetings.

Waist Circumference and Insulin Resistance

A descriptive cross-sectional study by Ramirez-Manent et al. (2022), graded 4b, was conducted in Spain to assess the relationship between insulin resistance and metabolic syndrome. The principal investigator measured waist circumference to evaluate its relevance to the insulin resistance index. The sample consisted of 246,061 men and 172,282 women between the ages of 18 and 67. Each participant had waist circumference, blood pressure, and fasting serum labs assessed. Based on those results, the presence or absence of metabolic syndrome was determined using three different diagnostic scales. Data analysis revealed that a high waist circumference value is a central component for detecting insulin resistance and therefore can assist with early detection of metabolic syndrome (Ramirez-Manent et al., 2022). The study had a very large sample size and statistically significant results. The study included men and women that lived and worked in similar environment; therefore, the findings may not be generalizable to non-Spanish people who live in different communities and have access to different foods. There was a large enough sample of women included in the study for these findings to be applicable to the study population in this project. This evidence speaks to the relevance of the waist circumference measurements though they are not an explicit part of the project aims.

A multicenter randomized controlled trial, graded 2a, evaluated the effects of insulin resistance on fertility in women with PCOS (Zhang et al., 2019). The study involved a total of 1000 women ages 20-40 years old who had been formally diagnosed with PCOS per the Rotterdam criteria. Participants were randomized into groups and followed for four menstrual cycles. Findings revealed that insulin resistance is strongly associated with exacerbation of

PCOS phenotypes and is a positive predictor of fertility (Zhang et al., 2019). Data also showed significant positive correlations between waist circumferences and the homeostasis model assessment insulin resistance (HOMA-IR) level (Zhang et al., 2019). The author utilized a strong study design, conducted the intervention at 21 different sites for a geographically diverse sample, and yielded statistically significant results. Though the sample consisted of individuals from different communities, all participants were Chinese which makes the findings less generalizable. These results demonstrate how waist circumference reduction can achieve the goal of PCOS symptom management.

Health Disparities

A systematic review and meta-analysis, graded 1a, investigated the cardiometabolic health disparity between black and white women with PCOS in the United States (Kazemi et al., 2021). The review included 11 observational studies with a documented cardiometabolic risk profile on individuals ages 17 to 50 years old. None of the studies included reported cardiovascular events or mortality rates. Results revealed that black women exhibited increased fasting insulin, HOMA-IR levels, and systolic blood pressure (Kazemi et al., 2021). However, black women did have lower triglyceride levels compared to white women (Kazemi et al., 2021). Based on these results, the author determined that black women with PCOS are at an increased risk for long term adverse cardiometabolic outcomes in comparison to white women. A strong review method was reported by the author. However, there is a possibility that some of the studies failed to account for important confounders when exploring disparities in cardiometabolic risk factors which is a limitation. Overall, given the balance of higher and lesser quality studies the complete body of evidence is considered moderate quality according to the LEGEND system of appraisal (appendix A).

Chapter 2. Methods

A quasi-experimental pre-and-post-test design was used. The project took place over three calendar months (October, November, and December) at a small wellness center in south Louisiana. This chapter details the project design, methods, subject review, population, procedures, tools, and data analysis plan.

Human Subjects Review

The methodology and plans for this project were reviewed by the Institutional Review Board (IRB) at Georgetown University (GU) and the IRB at the project site (site-IRB). Though the project was intended to be quality improvement, it was determined to be a human subjects research project. The project protocol underwent a full IRB review. Due to the implementation of a pilot program that required active participation and real time data collection, a consent was constructed and approved by GU-IRB. The review of the initial protocol and consents took about 17 days for GU to complete. Following initial review, GU-IRB requested modifications be submitted on recruitment materials for the control group and sections of the protocol and consent addressing the risk of the study. The updated protocol was given approval seven days following modification submission contingent upon approval by the project site's IRB. All materials were submitted to the site-IRB and approval was obtained after three weeks of an expedited review. The approval letter for the site-IRB was submitted to GU, after which GU-IRB approved the study to commence. It took approximately six weeks to obtain approval from both review boards.

One week into the recruitment process, challenges occurred with recruitment of the originally proposed control group. In order to rectify the problem and move the project forward, it was decided that the control group should be eliminated and the intervention group would serve as its own control by comparing pre and post test scores within the group. A modification

was submitted explaining this change. GU-IRB and the site-IRB then approved the elimination of the original control group.

Population

The study population consisted of individuals that work within the organization. Demographic data (table 1) was obtained via the initial screening form that was used to determine eligibility of interested individuals to participate in the intervention. The participants were recruited within the organization due to the potential cost barrier that would arise for non-employees. Clients being referred to care would be responsible for approximately \$115 for the initial visit and \$55 for every subsequent follow up which can be costly for an intervention program that requires bi-weekly check ins. The participants recruited, being employees with insurance through the organization, were able to take full advantage of wellness services free of charge.

The intervention group was recruited through employee health. A GU and site IRB approved flyer was created (appendix B). The flyer was printed in poster and flyer format, posted in the employee health clinic waiting room, placed at the check in desk for distribution, sent to employee emails via internal servers, and posted to the organizations private Facebook page for employees. The flyer included a QR code that would allow potential participants to access the screening form. The screening form included questions to determine eligibility and collect demographic information. Inclusion criteria to participate included: AFAB, documented PCOS diagnosis, childbearing age per CDC definition, access to and willing use of the zoom platform, access to and willing use of the private Facebook group platform, access to and willing use of a smart device to download the Bitesnap application. Exclusion criteria included: Individuals

currently participating in a training program that provides guided workouts and a meal plan. The site initially anticipated a sample size of 10 to 20 participants total.

The form was open for two weeks and received 33 responses. Twelve interested individuals were excluded based on the eligibility criteria for the sample. The remaining 21 interested individuals were sent an IRB approved email script with instructions for scheduling a meeting with the project coordinator to discuss the project details and review the consent. Fourteen individuals scheduled a meeting via the link provided. Six individuals no-showed the consent meeting that they scheduled. Out of the eight consent meetings that were conducted, five individuals completed a consent and submit it to the dietician to proceed with the intervention program. After the second visit with the dietician, one of the participants resigned citing unforeseen life circumstances. Thus, the remaining sample included only four participants.

Table 1

Sample Demographics

	n
Anatomy and Gender Identity	
Assigned Female at Birth (AFAB)	4
Identify as Female	4
Race Identity	
American Indian	0
Asian	0
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
Hispanic or Latino	0
White	4
Age	
18-20	0
21-30	0
31-40	4
40-44	0
Job	
My job requires that I be active >50% of the time	1
My job requires that I be active exactly 50% of the time	1
My job requires that I be active <50% of the time	2

Procedures and Timeline

The process of recruiting and consenting ran concurrently over a two-week time span. After careful review of the screening form responses, a master list of eligible individuals was created via google forms through a secure Georgetown account. This master list was used to schedule informed consent meetings with each client. A Calendly link was sent to eligible participants by which they were able to self-schedule a meeting based on their availability. A time period of 30 minutes was allowed for each meeting. The informed consent meetings took place via the secure google meet platform. The share screen feature was used to display and discuss each page of the consent with the potential participant. At the end of discussion, the client was allowed time for questions and then was given directions as to what to do next if they wished to enroll in the project. Each individual that was agreeable to enrollment was asked to download and complete the consent then submit the consent to the dietitian.

Following submission, the wellness center reached out to each participant to schedule their initial visits. The dietitian redacted all patient identifiers and labeled the consents with the participant identification number (PIN) assigned to them at the time of scheduling. The redacted version of the consent was upload to an electronic data collection folder via a secure password protected and university supported file share system (GU BOX) for the project coordinator. Each participant began the intervention within seven to ten days of each other.

The participants followed the dietitian guided pilot wellness program which consisted of the following: an initial visit with an in-depth discussion of current habits, goals, and opportunities for change, in addition to laying the foundation for diet education using the red-yellow-green system. An example of this food choice system can be found in appendix C. A waist circumference measurement was also taken at the first visit. Visits continued on a bi-

weekly basis with dietician meetings alternating between virtual and in-person to reduce no show occurrences. Clients were asked to participate in a virtual support group three times weekly over the intervention course. Only the participants in the intervention program and the project designer were given access to the private support group by using a randomized password. The dietician did not have access. Though the project designer did have access, there was no interaction with the participants regarding content. The coordinator only posted notifications once the activity tracking for the weekly time period had been completed.

At each bi-weekly visit the participant and dietician discussed concerns about food choices, thoughts about food, feelings about food, and made adjustments to the goals and educational high points. Waist circumference was measured at the initial, third, and sixth visit. Food log percentages were collected prior to all visits after the initial visit. Participants kept a food photo diary via the Bitesnap app. This smart phone application served as a separate camera roll where the client and dietician kept a visual record of the participant's dietary intake in order to determine percent of red, yellow, and green foods being consumed. Participants were asked not to calculate calories or nutritional facts. They were asked to only make the food selection, capture it via photo within the app, and then put it away and think nothing else of it. The clinical nutritionist uploaded new information to the GU BOX bi-weekly. The data collection folder had a designated folder for each visit (one through six) to facilitate data organization. GU BOX also included folders for support group tracking, consents, and pre/post test scores. An additional folder was created to house the visit continuity checklist (appendix D) that assisted the dietician with maintaining a standard of care from client to client. All information shared in the GU BOX was labeled with the PIN only and no other identifying information. Information for each visit

was organized on a spread sheet and uploaded. At the end of the intervention all spread sheets were combined into one master copy and submitted to the GU statistician with a data dictionary.

All communications between the participants and the clinical nutritionist were done via a HIPPA compliant internal email server if questions or concerns did arise outside of the bi-weekly meeting. A \$30 Target gift card was issued to participants by the dietician at the conclusion of the final visit as an incentive for completing the program. The incentive budget was funded by a home care agency dedicated to supporting projects and initiatives that aim to improve the health and wellbeing of others. The participants also received a one-time meal coupon to the organization's cafeteria at the start of the intervention as incentive for participating. Furthermore, participants will be eligible for a monetary incentive through the organization's healthy living program in its designated months when they submit their improved waist circumference measurements.

Instruments, Tools, Validity and Reliability

The Disordered Eating Attitudes Scale (DEAS) was used to evaluate eating attitudes of the participants pre and post intervention. To discourage the misinterpretation of the phrase "disorder eating," a narrative was included at the top of the assessment that provided the definition of this term as described in chapter one. Convergent and known group validity was established by a sample of 196 female university students based on statistical significance (Alvarenga et al., 2010). The tool has both internal consistency and reliability (Alvarenga et al., 2010). The DEAS was determined to be an accurate predictor of success or failure of treatment geared towards changing disordered eating attitudes. The assessment tool is also useful as an aid for dieticians to evaluate reasons for food consumption, food choices, diet quality, and effectiveness of treatment plans (Alvarenga et al., 2010). Results of the convergent analysis

reported in the original publication showed that the greater the dietary restraint and disordered eating symptoms, the higher the DEAS score (Alvarenga et al., 2010).

For the purposes of this project, the short version of the DEAS was used to promote thoughtful and accurate responses. The original tool consisted of 25 questions with a minimum possible score of 37 and a maximum possible score of 190 (Alvarenga et al., 2010). The short version of the tool consisted of only 17 items with a minimum score of 17 and a maximum score of 80 (Alvarenga et al., 2010). It is not uncommon for participants to experience question fatigue when answering lengthy assessments. Thus, the DEAS short version validated in 2020, seemed to be the best option that would still yield accurate results comparable to the original tool (Alvarenga et al., 2020). Like the original tool, there is no score that indicates a positive or a negative screen. Instead, the assessment result falls on a continuum from least disordered eating attitudes to most disordered eating attitudes. As a predictor of treatment success, a decrease in the DEAS score is an indication that eating attitudes are improving and the individual is moving down the continuum towards less disordered thoughts, beliefs, attitudes towards, and relationships with food (Alvarenga et al., 2010; Alvarenga et al., 2020). Permission from the author to use this tool was obtained via university email on June 11, 2023.

The Bitesnap app is the application that was chosen to help capture each participant's food photo diary. Participants were provided a document with instruction for use at the start of the intervention. All calorie counting features were disabled as caloric restriction is not the goal of the program. Participants shared these photos with the dietician just before each bi-weekly follow up. The application is available for use on apple and android devices and free to users. Permission from the app designers to use this tool was not necessary as this is a public and free tool available to anyone for download.

Data Management and Analysis

All spreadsheets were combined into a master document and submitted to the GU statistician with the data dictionary. After initial review of findings, a virtual meeting was conducted between the project coordinator and the statistician to discuss the data analysis plan. The GU statistician concluded that due to the small sample size, statistical significance should not be expected. The data points that were analyzed include: percentage of green food choices over time, waist circumference over time, changes in assessment scores, and support group activity participation. A paired samples T-test was used to determine the means and standard deviations of the data only. A Wilcoxon signed ranks test was used to analyze the data for scores over time and waist circumference over time. Descriptive analysis was used to demonstrate the change in percentage of green foods chosen by the participants over time as well as to create an overview of the number of complete support group activity weeks next to the changes in the DEAS scores.

Chapter 3. Results

Data analysis was done using SPSS 29 (IBM, Armonk, NY) with the help of the university statistician. The measures of data included in the analysis are DEAS scores, waist circumference, percentage of participant's green food choices, and support group participation. The intervention consisted of six visits total. This chapter will present a summary of participant characteristics and project findings for the primary and secondary aims.

Analysis of Data by Project Aims

Aim 1

The first aim of this project was to evaluate how a non-weight focused program influenced eating attitudes in a group of clients with polycystic ovarian syndrome. The change in eating attitudes was evaluated by analyzing the difference between the pre intervention and post intervention assessment scores using the DEAS tool. DEAS scores (table 2) were analyzed using the Wilcoxon signed ranks test after the means and standard deviations of the data had been determined by a paired samples T-test. The DEAS scores ranged from a mean of 42.8 (SD =11.8) at visit one to 29.8 (SD = 9.0) at visit six which translates to an average decrease in DEAS scores by 13 points. Using the Wilcoxon signed ranks test, $Z= 1.46$ and $p = 0.144$. The change in mean scores from visit one to visit six was not statistically significant.

Table 2

Change in DEAS Score for Individual Participants

	Amount of DEAS Score Change
Participant 1	-23
Participant 2	-26
Participant 3	8
Participant 4	-11

Changes in eating attitudes, which includes behaviors regarding food choices, was also assessed by evaluating the food photo diary submissions. The food photo diary tracked participants' changes in red, yellow, and green (RYG) food choices over time. Red foods are foods that should be consumed in moderation. Yellow foods do not have as much nutritional value as green foods but have more value than red foods. Green foods are the foods that hold the highest nutritional value. The data from the photo diaries was analyzed by the percentage of green foods chosen over time (table 3). Participants fell into one of the following categories: chose green foods <25% of the time, chose green foods more than 25% of the time but less than 50% of the time, chose green foods exactly 50% of the time, chose green foods more than 50% of the time but less than or equal to 75% of the time, or chose green foods greater than 75% of the time.

Participants were introduced to the RYG food system at visit one (initial visit) with the dietitian. They were also given guidance on how to document all food and drinks consumed in the food photo diary using the Bite Snap app. All introductory teaching and goal setting was done at visit one and then participants gathered baseline data in their food photo diary over the following two weeks. These results were presented to the dietitian at their follow up.

Table 3

Percentage of Green Foods Chosen Based on Participant Food Photo Diaries from Visits Two Through Six

	Visit 2 <i>n</i> (%)	Visit 3 <i>n</i> (%)	Visit 4 <i>n</i> (%)	Visit 5 <i>n</i> (%)	Final Visit <i>n</i> (%)
<25%	1 (25)	0	0	0	0
25% - < 50%	1 (25)	0	0	0	0
50%	0	1 (25)	1 (25)	0	1 (25)
>50% - <=75%	2 (50)	2 (50)	3 (75)	3 (75)	3 (75)
>75%	0	1 (25)	0	1 (25)	0
Mean	2.25	1.00	1.25	0.75	1.25

At visit two (two weeks post initial visit) two participants chose green foods less than 50% of the time with one participant choosing green foods less than 25% of the time. The remaining two participants chose green foods more than 50% of the time but less than or equal to 75% of the time. By visit three (four weeks post initial visit) two participants remained in the less than 50% of the time but greater than or equal to 75% of the time category. One participant chose green foods exactly 50% of the time. The remaining participant made green food choices greater than 75% of the time. By visit four (six weeks post initial visit) three participants chose green foods greater than 50% of the time but less than or equal to 75% of the time and only one participant chose green foods exactly 50% of the time. At visit five (eight weeks post initial visit) three participants chose green foods greater than 50% of the time but less than or equal to 75% of the time with one participant choosing green foods greater than 75% of the time. Visit six (final visit) mimicked the results of visit four which was a set back from the progress demonstrated visit five. Means for the above data were calculated according to the values assigned to each percentage category in the data dictionary (table 4). Therefore, a decrease in the mean indicates an increase in the percentage of green foods chosen over a two-week time period between each visit with the dietitian. The mean declined from 2.25 at visit two to 1.00 at visit three. There was an increase in the mean at visit 4 up to 1.25. The mean reached its nadir of 0.75 at visit five, and increased to 1.25 again at visit six.

Table 4

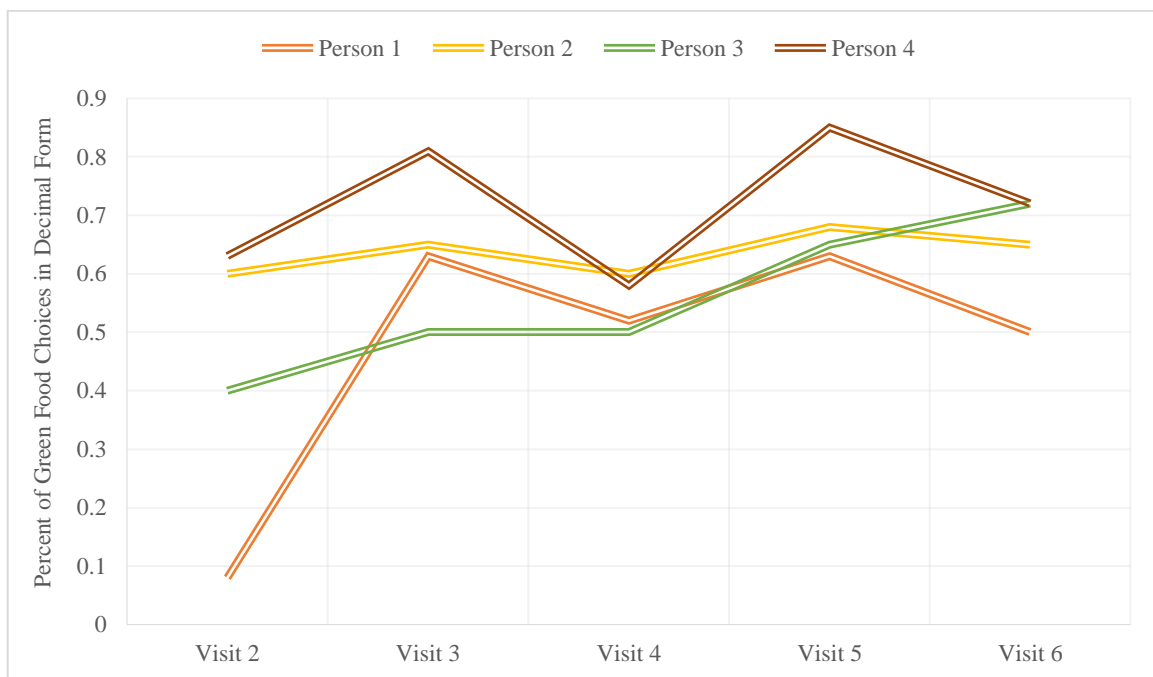
Data Dictionary for Green Food Choices

	Value
<25 %	4
25% - <50%	3
50%	2
>50% - <= 75%	1
>75%	0

The trend demonstrated by the mean is consistent with the choices made by each individual from visit one to visit six. Figure 1 demonstrates the progression of green food choices over the course of the intervention by each participant.

Figure 1

Progression of Green Foods Choices Based on Food Photo Diaries from Visits Two through Six by Individual Participant



Aim 2

The second project aim was to identify facilitators and barriers for clients adopting this modified approach. As previously explained, a question regarding barriers and facilitators was included on the post assessment to inform future projects and influence dissemination and sustainability efforts. Below are the responses to the questions from each participant:

1. Can you describe one major barrier to implementing the lifestyle changes that you learned?

Participant one: None.

Participant two: I don't like drinking water.

Participant three: I have always loved sweets more than food. I've always eaten poorly even in high school due to sports and getting home late.

Participant four: Consistency. I also need to keep a supply of healthier snack options so I am not tempted to eat something worse for me.

2. Can you describe one major facilitator that helped you implement the lifestyle changes that you learned?

Participant one: Peer motivation.

Participant two: Not looking at this as a diet. It's a comfortable change in my lifestyle.

Participant three: My significant other.

Participant four: Accountability.

Other Contributing Data

The changes in waist circumference (table 4) were also analyzed using Wilcoxon signed ranks test. Waist circumference went from a mean of 45.8 inches (SD = 7.3) at visit one to 43.3 inches (SD = 6.2) at visit six which is an average drop of 2.5 inches over the course of three months. Using Wilcoxon signs ranks, $Z = 1.83$ and $p = 0.068$. The change in waist circumference was not statistically significant.

Table 4

Waist Circumference Over Time

	Visit 1 <i>Weight in Inches</i>	Visit 3 <i>Weight in Inches</i>	Final Visit <i>Weight in Inches</i>
Participant 1	51	49	47
Participant 2	53	52	50
Participant 3	39	38	37
Participant 4	40	39	39

Lastly, participants were asked to enroll in a Facebook support group as the final component of tracked data. Participants must have interacted in the support group at least three times each week for the week to be considered complete. The numbers displayed in the table indicate the number of weeks out of ten that each individual met minimum participation. All persons except for participant three completed two out of ten weeks. Participant three had the highest participation with nine out of ten complete weeks. However, in comparison to the changes in DEAS scores (table 5), the participant with the most support group participation had the worst outcome in change of score. Participant three's DEAS score increased by eight points which is opposite of the desired outcome for the intervention. A decrease in a DEAS score indicates an improvement in eating attitudes and an increase in the score indicates the latter.

Table 5

Number of Complete Support Group Activity Weeks by Change in DEAS Score

	Number of Complete Support Group Activity Weeks	Amount of DEAS Score Change
Participant 1	2	-23
Participant 2	2	-26
Participant 3	9	8
Participant 4	2	-11

Summary of Findings

The DEAS scores decreased for 75% of participants by an average of 13 points. One participant scored eight points higher on the post intervention assessment compared to her pre intervention assessment. All participants experienced a minimum of a 1-inch reduction in waist circumference with participant number one experiencing the biggest reduction of 4 inches. There was a downward trend in the mean of green food choices from week to week with an uptick noted at weeks four and six. The mean at visit two (two weeks post initial visit), 2.25,

decreased to a mean of 0.75 by visit 5 (eight weeks post initial visit). There was no perfect participation in the support group by any of the participants. The individual with the highest participation score, nine complete weeks out of ten, had the least satisfying change in DEAS score. The remaining three participants had an equal amount of support group interaction and varying score changes ranging from an 11-point to a 25-point decrease.

Chapter 4. Discussion and Conclusion

This chapter will discuss the significance of the project results, project limitations, practice implications, and recommendations for future studies. Discussion will also include the influence of social determinants on implementing aspects of this intervention and suggestions on how to avoid these barriers when replicating this pilot.

Discussion

DEAS Scores

The mean 13-point decrease in DEAS scores from pre to post intervention indicates that the program was effective in helping improve eating attitudes among this group of participants. As previously stated, the tool is an excellent predictor of the success of treatments that target eating attitudes. A decrease in score indicates progression down the continuum towards less disordered feelings, thoughts, and behaviors related to food (Alvarenga et al., 2010; Alvarenga et al., 2020). The results demonstrate that 75% of the participants made progress towards less disordered eating attitudes over three calendar months. However, the data does not speak to the effectiveness of the pilot program in ensuring sustainability as the participants were not followed past the final visit.

The rationale behind the eight-point increase in score from pre to post intervention for one of the participants is unclear. It is possible that the participant decided to pick what might be considered correct answers on the pre assessment and true answers on the post assessment. It is possible that the intervention was a shock of reality which resulted in true self reflection on the post assessment or that the participant misread some of the questions on either assessment. Alternatively, it is also possible that the participant truly did have a rising score which translates to worsening eating attitudes. There is no evidence to support any of these theories. Regardless

of the scenario that resulted in the score increase, the clinical nutritionist ultimately decided to refer this participant to a food psychiatrist for regular visits and a more intense therapeutic program.

Though the findings are not considered statistically significant due to the small sample, the change in DEAS scores from pre to post intervention can be considered clinically significant. There is no standardized criteria for determining clinical significance. The clinical significance of a treatment is based on external standards set by the principal investigator or clinician and is generally considered a change towards normal functioning as a result of an intervention (Kraemer et al., 2003). An average decrease of 13 points from pre to post intervention scores is a change in the direction of healthy thoughts, behaviors, and attitudes towards food. This change occurred for majority of the sample and therefore is clinically significant.

Waist Circumference

Though waist circumference was not explicit in the project aims and was only collected for the organization's incentive program, it is valuable data to share with stakeholders. PCOS is an anovulatory disorder and one of the number one causes of infertility (Walters et al., 2018). Therefore, while many clients will have the long-term goal of optimizing their health, their short-term goals may include pregnancy. Waist circumference is an accurate predictor of insulin resistance and insulin resistance can predict fertility outcomes in PCOS patients (Ramirez-Manent et al., 2023; Zhang et al., 2019). A reduction in waist circumference, which indicates improved insulin sensitivity, will increase the amount of SHBG, reduce testosterone, and allow FSH to function appropriately to achieve ovulation (Walters et al., 2018; Ramirez-Manent et al., 2023; Zhang et al., 2019). An average reduction of 2.5-inches in waist circumference over three

months is progress in the direction of better cardiometabolic health and therefore is clinically significant (Ramirez-Manent et al., 2023; Kraemer et al., 2003)

The data demonstrates that reduction in waist circumference can occur during a non-weight focused program which can be beneficial in improving PCOS symptoms. It is unclear whether or not improvements in eating attitudes results in reduction of waist circumference as the correlation between these two variables was not investigated. However, it is a fact, as evidenced by the study results that the two variables can co-exist. This means that a patient can participate in a program that is non-weight centered and still experience changes to waist circumference and insulin sensitivity. These results are most likely to persuade new stakeholders to see the value in a multidisciplinary approach that will render positive outcomes in optimizing physical and mental health while also achieving short term conception goals as new locations and facilities are recruited during the process of dissemination and sustainability.

Green Food Choices

Participants improved in their ability to choose more nutrient rich food options as the intervention progressed. This was evidenced by a decrease in the mean from visit two (2.25) to visit six (1.25). Week five demonstrated the strongest improvement with a mean of 0.75. As previously described, the intervention took place over a three-month time period which was October, November, and December. It should be noted that visit 4 (six weeks post initial visit) and the visit 6 (final visit) occurred around Thanksgiving and Christmas which could explain the decrease in green food choices and slight uptick in the mean. The program was successful in modifying eating attitudes that enabled participants to choose green foods more than 50% of the time. These results are clinically significant as evidenced by identical trends of improved food choices over the course of the intervention in 100% of the sample (Figure 1).

Support Group Participation

Support group participation was measured by the participants ability to meet the three times weekly requirement for the intervention. 100% participation was not achieved. 75% of participants had only two complete weeks out of ten. It should be noted that almost all participants interacted in the support group at least once weekly but this was not counted as it is below the required minimum and therefore considered incomplete. Is it possible that external factors influenced the participants' abilities to complete the three times weekly interaction requirement such as home and work life demands? Perhaps. Nevertheless, a relationship between support group participation and changes in DEAS scores was not demonstrated by the data. There is no clear indication as to why individuals with the lowest participation scores had the most improvement in disordered eating attitudes. There is also no clear indication as to why vice versa occurred for the single individual with the highest support group participation score.

The pretest/posttest control group study that supports the use of a support group utilized an in-person meeting approach (Ranasinghe et al., 2021). An in-person meeting approach was not implemented in this project due to the already high demand of bi-weekly meetings with the dietician. Even considering a virtual synchronous meeting option may have been strenuous on participants. The social media platform created a safe space where the education being learned during meetings with the dietician could be rehearsed and reinforced and it allowed individuals to participate at a time that was most convenient for them. The responses to the barrier and facilitator questions posed on the post assessment tool speak to the need of a support group component, but it may have been far more beneficial in a different format.

Reflecting on the Project Aims

The results successfully addressed the primary and secondary aims. A majority decrease in DEAS scores and overall decrease in the mean of green foods chosen over time demonstrates that a non-weight focused program can positively influence eating attitudes in a group of clients with polycystic ovarian syndrome. The barriers and facilitators identified through the participants' responses on the post assessment tool fall into the following COM-B and theoretical domains categories: motivation, physical and psychological capability, and social opportunity/influences (Atkins et al., 2017; Pirotta et al., 2021). Though these responses helped to somewhat identify barriers and facilitators to adopting the modified approach, in retrospect the questions could have been worded differently to encourage more detailed and thoughtful responses.

Limitations

There were some significant challenges with recruitment which contributed to one of the biggest limitations of this project, the sample size. Results of the data analysis were enlightening. However, statistical significance was not an outcome of any of the metrics evaluated due to the small sample size making statistical testing of questionable reliability.

The recruitment period occurred over two weeks in an effort to keep the timing of the project on track with enough time to perform the three-month intervention. Recruitment was limited to one organization and was conducted with the help of the employee health clinic as previously described. The project originally consisted of a control group and an intervention group. Both groups were going to complete a pre and post intervention assessment. The differences within each group were going to be compared to the differences between the two groups to see if the non-weight centered approach had a significant influence on eating attitudes in comparison to the traditional weight centered approach. The control group was to come from

the referrals that the wellness center received from surrounding offices with women's health services. However, most patients being referred were not willing to pay the fees required to see the dietitian with or without insurance coverage. Therefore, it was very difficult to obtain a separate control group which resulted in the control group being completely eliminated. It was then decided that the intervention group would serve as its own control.

There were 33 responses to the initial intake form. However, there was notable lack of potential participants showing up for their scheduled consent meetings. Furthermore, there were several identified eligible participants who were contacted via email but never set up a time to meet. After the intervention began, at least two individuals responded to the notice of eligibility email but the intervention was already well underway. The project may have benefited from a longer recruitment period to potentially yielded a larger sample.

As a result of the recruitment challenges, the sample was homogenous and did not reflect the community that is served by the wellness clinic. This is partially due to the fact that the sample was composed of only the organization's employees in an effort to relieve the financial demand that bi-weekly visits might place on participants. Employees with insurance through the organization receive services from the wellness center free of charge. Out of the 33 initial responses to the intake form, 15 of those individuals identified as African American. Out of the 15 interested African American individuals, four were excluded based on the sample criteria, of the remaining 11 only two scheduled a consent meeting and though both of them showed up for the consent meeting neither decided to continue.

According to the United States Census Bureau (2023), the city of Baton Rouge's population is majority female and majority black. African Americans make up 52.5% of the population in comparison to European Americans who make up 37.2% of the population. The

sample for this project consisted of individuals that all identify as cis gender white women between ages 31 to 40 with a known diagnosis of PCOS. Though Wolf et al. (2018) reports that there is a similar prevalence of PCOS in women of childbearing age in both white and black groups, the sample is still not representative of the city in which the project took place. Therefore, the findings may be considered less generalizable. Lack of a diverse sample also eliminates the opportunity to speak to the use of this intervention in groups outside of the age and ethnic group that participated in this project, which is disappointing.

There is evidence that the DEAS tool is both valid and reliable (Alvarenga et al., 2010). However, its use has only been studied in adolescents, college students, and individuals with a known diagnosis of anorexia or bulimia. The tool has not yet been studied for use in patients with PCOS or in cis gender women in the same age group as those who participated in this project. Therefore, there is no evidence to speak to the ability of the tool to reliably assess eating attitudes in this population.

Though there were many efforts to overcome the financial barrier that participation posed, social determinants of health could have still played a very significant role in the implementation of this intervention. Participants had the assistance of the organization's insurance to offload the cost of the program. However, accessibility of and proximity to grocery stores, ownership of cooking appliances, access to transportation, ownership of a smart device, and money to purchase the above-named necessities are remaining factors that could potentially impact participant adoption and sustainability of the recommended behaviors. Success of the intervention was anticipated under the assumption that participants had adequate transportation to get to all of their appointments and to get to the grocery store; adequate financial resources to purchase groceries and appliances that would allow them to prepare their food in a healthy way;

and access to a smart device that would allow them to participate in the support group and virtual follow ups with the dietician without difficulty. These things should not be assumed.

Practice Implications

The multidisciplinary approach to treating PCOS has been underrated and underutilized for far too long. By achieving the aims of this project, the hope is that a light will be shown on the necessity of dieticians and other professionals in helping clients with PCOS optimize their health. If clinicians want to see their patients with PCOS thrive, there needs to be an end to the practices that encourage crash dieting, weight bias, stigma, and weight cycling. A culture of shared responsibility in achieving sustainable lifestyle changes should be the new goal. Using this pilot as a blueprint to a new approach and learning from its limitations in an effort to strengthen the program could be a path forward.

Unfortunately, as health disparities continue to ravage a broken system, barriers to this new practice are inevitable. Most insurance plans only cover dietician services for individuals diagnoses with type 1 or type 2 diabetes. Insurance does not currently offer coverage for these services for a person with any other endocrine disorder though it would be to their benefit. Social determinants that influence access to healthcare and proper nutrition will continue to pose a barrier. For this reason, clinicians should begin to strengthen their relationships with social workers who can help clients find community resources for food and financial assistance when necessary. In areas of high prevalence such as the southern and north-central regions of the United States, it may not be farfetched to construct a committee within each healthcare organization that is committed to fostering a partnership across all disciplines to appropriately treat clients with PCOS (Wolf et al., 2018).

Recommendations for Future Study

Investigators seeking to replicate this pilot and strengthen its findings should do so on a larger scale and with a more diverse sample. Extending the recruitment period over several months and at several locations will increase the probability that the sample will be more representative of the population and this will also increase the possibility of achieving statistical significance with the results. Having more participants will mean that more clinical nutritionist will need to be involved in helping to carry out the intervention. Having multiple dieticians from multiple locations can pose a challenge in regards to consistency of the teaching methods. Thus, the investigator would need to be certain to properly train each dietician to follow the project protocol and provide a checklist for each visit that will encourage continuity from patient to patient.

With a more diverse sample, investigators may also consider comparing pre and post score changes within different demographic groups and across demographic groups. A replicator of this pilot might also consider having the support group component in the form of an in-person meeting or a synchronous virtual session to encourage more meaningful participation. It may be useful to consider the psychology of the population being studied. It could be possible that some personalities may benefit from social support more than others. It could also be possible that certain age groups benefit from social support more than others. The psychology behind social support is worth exploring in greater detail to determine if this part of the program should be kept or eliminated altogether.

The barriers and facilitators questions evaluated at the end of the post assessment tool were phrased as follows: Can you describe one major barrier to implementing the lifestyle changes that you learned? Can you describe one major facilitator to implementing the lifestyle changes that you learned? Based on the phrasing, these questions could have been responded to

with a “yes” or “no.” An investigator interested in replicating this pilot may want to re-word these questions in an open-ended fashion in order to encourage more thoughtful responses. It may also be of some benefit to evaluate both the referring and receiving clinicians’ perspectives on barriers and facilitators to the multidisciplinary approach. Future studies may even consider exploring participant perspective on quality-of-life pre and post intervention. Better responses could be informative to dissemination and sustainability efforts.

Having financial assistance would be powerful in retaining a good sample. Investigators seeking to replicate this pilot may want to consider obtaining grant funding that may pay for all six visits of the program for each client enrolled. This may also be an opportunity to build social service relationships and identify some community resources that could mitigate some of the barriers with access to healthy food choices and transportation. Building these relationships during the implementation of the intervention may benefit the organizations involved when the intervention is complete as they continue to serve clients with PCOS in their areas. Having access to resources that help with retention could create an opportunity for a longer intervention. Based on the literature, the time needed to form a new habit is only 59 days (Keller et al., 2021). However, it may be beneficial for future studies to extend the course of the intervention over several months in order to accurately address the sustainability of the lifestyle changes adopted. Replicators may want to consider avoiding implementation around the height of the holiday season as well, considering this has the potential to skew results.

There was a lack of a physical activity component in the pilot. For the amount of time allowed for this project, it was of best interest to narrow the scope and focus on one outcome to minimize the amount of data being collected. Future investigators may consider adding physical activity but should keep in mind that this component can pose new barriers and will require

strategies to overcome them. Overcoming the barriers posed by social determinants of health will be the greatest challenge of replicating this pilot in any form.

Conclusion

PCOS is one of the top causes of infertility for women of childbearing age and its prevalence is comparable to diabetes. Prescribing weight loss as a means of symptom relief has created a culture of weight cycling which has long term adverse cardiometabolic effects. The pilot wellness program created for this project set out to shift the focus from weight loss to sustainability by targeting attitudes, thoughts, and behaviors regarding food in a group of individuals with polycystic ovarian syndrome. Seventy-five percent of the sample demonstrated an improvement in eating attitudes as evidenced by their pre and post intervention assessment scores. One hundred percent of the sample progressed to choosing green foods more than 50% of the time and 100% of the sample saw a clinically significant reduction in their waist circumference by the end of the intervention. Challenges with recruitment in the execution of this project eliminated the possibility for statistical significance due to a smaller sample size.

The old wives tale says: If you give a person a fish, you will feed them for a day, but if you teach a person to fish, you will feed them for a lifetime. That sentiment applies here. Prescribing weight loss to a client without the proper education, tools, or guidance only encourages methods that yield unsustainable results and create a metabolic catastrophe that will cost the patient and healthcare system in the years to come (Riestenberg et al., 2021). If clinicians truly commit to providing patients with the tools they need to make sustainable lifestyle changes for themselves and their families, their quality of life, mental, and physical health will benefit for a lifetime (Sanchez, 2020). The results of this pilot support the idea that a non-weight focused approach to modifying eat attitudes in client withs PCOS is necessary and

effective. May this pilot encourage other researchers to carry on this work as PCOS remains severely under researched and the skills of dieticians remain severely underutilized. The bright future of our healthcare system lies in all disciplines working together to help our patients with PCOS achieve optimal health and live their best lives.

Appendix A. LEGEND System of Appraisal



LEGEND
Let Evidence Guide Every New Decision
Table of Evidence Levels

TABLE OF EVIDENCE LEVELS: Levels of Individual Studies by Domain, Study Design, & Quality

DOMAIN OF CLINICAL QUESTION		TYPE OF STUDY / STUDY DESIGN																			
		Systematic Review Meta-Analysis	Meta-Synthesis	RCT ⁺	CCT ⁺	Psychometric Study	Qualitative Study	Cohort – Prospective	Cohort – Retrospective	Case – Control	Longitudinal (Before/After, Time Series)	Cross – Sectional	Descriptive Study Epidemiology Case Series	Quality Improvement (PDSA)	Mixed Methods Study	Decision Analysis Economic Analysis Computer Simulation	Guidelines	Case Reports N-of-1 Study	Bench Study	Published Expert Opinion	Local Consensus Published Abstracts
Intervention	Treatment, Therapy, Prevention, Harm, Quality Improvement	1a* 1b*		2a 2b	3a 3b		4a 4b	3a 3b	4a 4b	4a 4b	4a 4b	4a 4b	4a 4b	4a 4b	2a/2b 3a/3b 4a/4b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5
Diagnosis / Assessment		1a 1b			2a 2b	2a 2b			3a 3b	4a 4b			4a 4b	4a 4b		2a/2b 3a/3b 4a/4b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b
Prognosis		1a 1b						2a 2b	3a 3b	4a 4b		4a 4b	4a 4b		2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5
Etiology / Risk Factors		1a 1b		2a 2b	3a 3b			3a 3b	4a 4b	4a 4b		4a 4b	4a 4b		2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5
Incidence		1a 1b						2a 2b	3a 3b				4a 4b				5a 5b	5a 5b	5a 5b	5a 5b	5
Prevalence		1a 1b								2a 2b		3a 3b	4a 4b				5a 5b	5a 5b	5a 5b	5a 5b	5
Meaning / KAB [†]			1a 1b				2a 2b								2/3/4 a/b		5a 5b	5a 5b	5a 5b	5a 5b	5

* a = good quality study b = lesser quality study

† CCT = Controlled Clinical Trial KAB = Knowledge, Attitudes, and Beliefs RCT = Randomized Controlled Trial

Shaded boxes indicate study design may not be appropriate or commonly used for the domain of the clinical question.

Development for this table is based on:

1. Phillips, et al: Oxford Centre for Evidence-based Medicine Levels of Evidence, 2001. Last accessed Nov 14, 2007 from <http://www.cebm.net/index.aspx?o=1025>.
2. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs*, 2(3): 157-60, 2005.

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March 26, 2012

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Evidence-Based Decision Making – www.cincinnatichildrens.org/evidence

Page 1 of 1

DO YOU WANT TO CHANGE YOUR RELATIONSHIP WITH FOOD?

A NEW **QUALITY IMPROVEMENT PROJECT** IS LOOKING FOR
EMPLOYEES WITH **POLYCYSTIC OVARIAN SYNDROME (PCOS)**
TO PARTICIPATE IN THE INTERVENTION GROUP

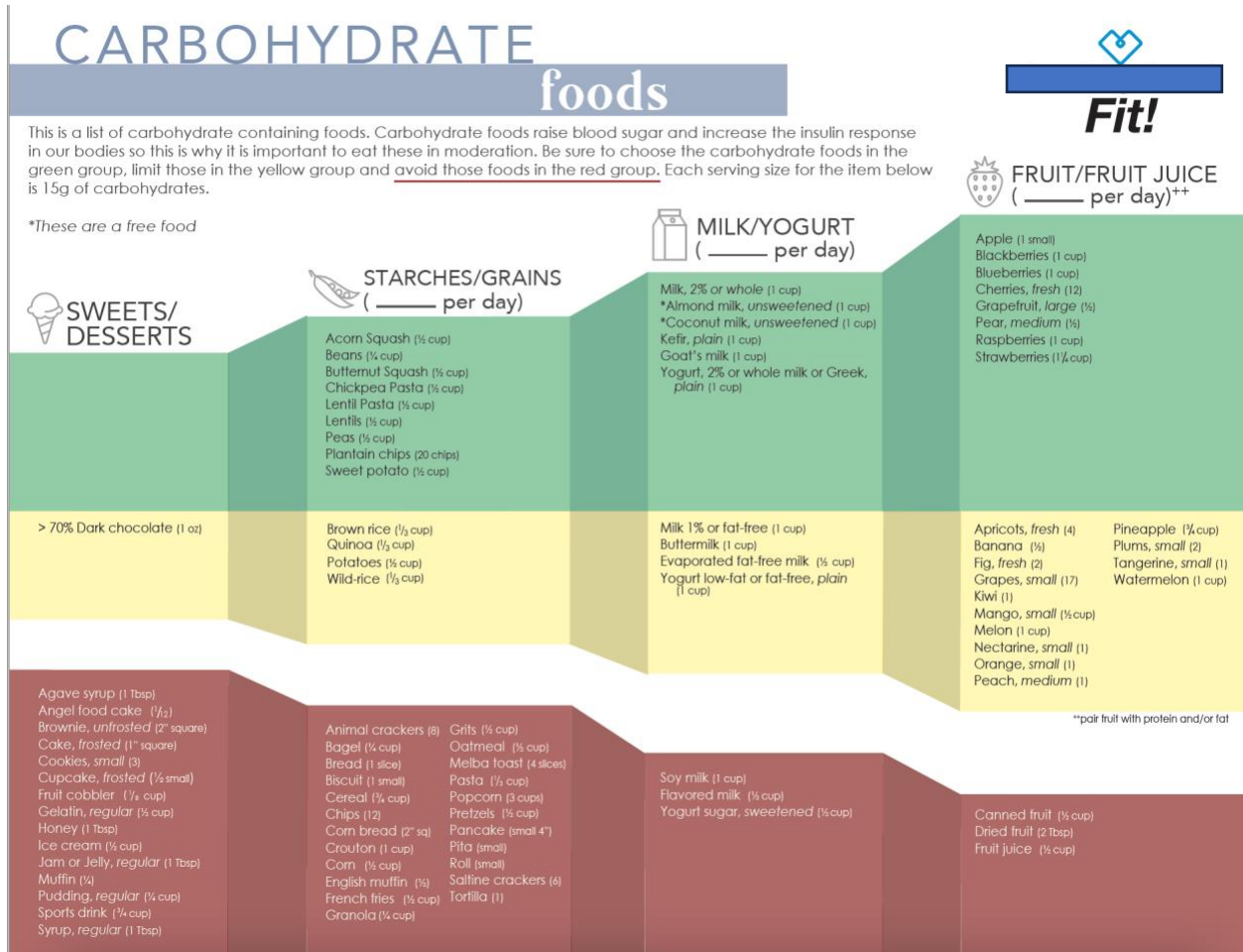


GET A MEAL COUPON CARD FOR ELIGIBLE ENROLLMENT!

This is a Georgetown University Doctor of Nursing Practice Project entitled:
A non-weight centered approach to modifying eating attitudes in polycystic ovarian syndrome

Ready to make a change? Scan the QR code above

Appendix C. Red-Yellow-Green System Example



Appendix D. Visit Continuity Checklist

Intervention Group Visit Continuity Checklist

All visits conducted by the clinical nutritionist/dietician

All education materials seen in appendices are from the organization and do not originate from the principal investigator

24 to 48 hours Prior to Initial Visit

- ☐ Client will complete pre assessment
- ☐ Results will be uploaded to box folder for the clinical nutritionist to access which she will use to guide client education
- ☐ Client will download the bite snap app and practice use

Initial visit (In Person) – 1 hour

Please give them their meal card incentive at this visit

- ☐ Dietician introduction
- ☐ Client interview
 - Foods that they enjoy
 - What do they do for work
 - What kind of activities do they enjoy
 - Food allergies
 - Food aversions
 - Normal food routine (how many meals per day, do they normally juice in the morning, etc.)
 - Do they enjoy cooking
 - Are they responsible for feeding more than just themselves
 - Additional questions suggested by nutritionist:
 - How many meals do you eat out for during the week (take out/fast food)?
 - Have you followed a specific meal plan in the past and what has been successful for you?
 - Are you currently exercising?
 - Which beverages do you drink on a daily basis?
 - Typical breakfast, lunch, dinner, snacks?
- ☐ Discuss pertinent items on pretest WITHOUT disclosing the score
- ☐ Goal setting
- ☐ Introduction to the red, yellow, green food choice system (Appendix A)
 - Emphasis on insulin friendly/PCOS friendly choices
- ☐ Grocery shopping strategies
 - My plate education (Appendix B)
 - Healthy Eating Tips (Appendix C)
- ☐ Discuss food photo diary
 - Ensure the client knows how to use bite snap app (all calorie counting features should be disabled) (Appendix D)
- ☐ Obtain waist circumference measurement (undisclosed)
- ☐ Review “what to expect”: discuss what will be done next visit
- ☐ Questions
- ☐ Schedule next appointment

24 to 48 hours Prior to follow up visit

This checklist applies to follow up visits **two through five**

- ☐ Client will submit food photo diary to clinical nutritionist via secure email
- ☐ The nutritionist will use this information to guide the follow up visit and will input the following information onto the data collection spreadsheet in BOX:
 - % of red foods
 - % of yellow foods
 - % of green foods

Follow up- 30 minutes

This checklist applies to visits **two through four**

Visits TWO AND FOUR will be virtually conducted by the clinical nutritionist via the secure virtual appointment platform approved and utilized by the organization

- ☐ Client interview
 - How has your appetite control been?
 - What is working well?
 - What are you struggling with?
- ☐ Review food photo diary with share screen feature
- ☐ Discuss substitutions
- ☐ Strategies for sustainability
- ☐ Revise goals
- ☐ Revise grocery shopping techniques
- ☐ Questions
- ☐ Schedule next appointment

Final Visit (In Person) – 30 minutes

- ☐ Client interview
 - Did they feel like they gained anything from this three-month intervention?
 - Do you feel like you can successfully distinguish between cravings and hunger?
 - Have you been able to implement mindful eating as a daily practice?
 - Do you feel in control of your food choices?
 - Do you feel confident that you can maintain a healthy diet over the long run and what area do you suspect you might struggle to be consistent with?
- ☐ Review food photo diary
- ☐ Discuss overall comparison (initial food choices to today's food choices)
- ☐ Strategies for sustainability
- ☐ Final waist circumference measurement (okay to disclose here is the client desires)
- ☐ Complete the post assessment

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