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PCOS Lifestyle Management Change Project

Elizabeth King
EKing10@patriots.uttyler.edu

Lifestyle Modifications for PCOS

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Elizabeth King

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Contents

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Executive Summary

Polycystic ovarian syndrome (PCOS) is one of the most common endocrine disorders in reproductive age women (Nikokavoura, Johnston, Broom, Wrieden, & Rolland, 2015). This syndrome is often associated with systemic dysfunctions such as metabolic syndrome, hypertension, and dyslipidemia. Common physical manifestations include: hirsutism, obesity, acne, menstrual irregularities, and infertility (Kim et al., 2015). Other manifestations can include alopecia, deep voice, and clitoromegaly (Patel, 2018). This multisystem disorder can also be associated with depression, anxiety, and lower quality of life (Dokras et al., 2018).

Treatment often includes medications such as metformin and oral contraceptives (Patel, 2018). This condition is often treated with medications but with limited education about the condition itself and its lifelong effects. Lifestyle interventions such as low calorie/low fat diet and exercise are also considered part of the treatment plan for PCOS (Nikokavoura et al., 2015).

There is a lack of information and emphasis missing from the interactions between providers and their patients with PCOS. This lack of information stimulated the change project that focuses on education and emphasis on lifestyle interventions in patients with PCOS. This paper proposes the Lifestyle Modification Change Project to help fulfill this lack of education and emphasis on lifestyle modifications that occurs with patients diagnosed with PCOS. This change project would include a 16-week lifestyle modification program that would evaluate pre- and post- participation data including: BMI, weight, inches, testosterone levels, menstrual cycle regularity numbers, and quality of life questionnaire.

The Lifestyle Modification Change Project addresses the need for change in addressing the emphasis providers often fail to convey to PCOS patients. These lifestyle modifications provide patients with a way to gain control over their diagnosis and increase their quality of life. The following introduces the main objectives for the lifestyle modification benchmark change project.

Lifestyle Modifications for PCOS

1. Rationale for the Project

Polycystic ovarian syndrome affects an estimated 10% of reproductive age women (Domecq et al., 2013). This syndrome is often attributed as the cause of 75% of cases of infertility (Nikokavoura et al., 2015). Besides physical effects such as central obesity, hirsutism, acne, alopecia, and seborrhea, PCOS can manifest as psychological effects such as depression, low self-esteem, and reduced quality of life (Ramos et al., 2016).

Lifestyle interventions are often not emphasized enough by providers, not understood by patients on how to complete lifestyle interventions, or not understood. PCOS patients are often given medication with limited information on this syndrome. Patients often receive no education on PCOS its life-long impact, or ways to improve its' effect. This benchmark change project addresses the lack of information, impact of lack of lifestyle interventions, and associated long term effects of PCOS. Most providers recommend birth control medications with lifestyle modifications (Dokras et al., 2018). However, health care providers need to emphasize and thoroughly educate their patients on the benefits of lifestyle modifications. Patients often lack the understanding of the impact of lifestyle interventions on their condition.

Women with PCOS are often frustrated with their diagnosis and treatment process (Dokras et al., 2018). The lifestyle modification change project will educate providers and through them,

PCOS patients on the benefits of lifestyle modifications in helping manage their PCOS. Through education, exercise program and follow-up, PCOS patients will see the benefits of lifestyle modifications and gain empowerment in their treatment process. At the end of the 16-week lifestyle modification program, researchers expect to see positive results in BMI, weight, body inches, menstrual regularity, testosterone levels, and quality of life.

2. Literature Synthesis.

Lifestyle modifications, which include diet and exercise, are part of first line treatment recommendations for PCOS (Dokras et al., 2018). Several studies identify a weight loss as little as 5% can have positive effects in patients with PCOS (Marzouk & Ahmed 2015). One specific study completed by Marzouk and Ahmed (2015) explored the results of lifestyle modifications in patients with PCOS. Their results consisted of improvements in menstrual function and body inches (after using dietary modifications such as a high protein-low carbohydrate diet) (Marzouk & Ahmed, 2015). The largest improvement was in menstrual cycles versus the control group. These results demonstrate positive change after lifestyle modifications are implemented.

Another study by Zhang, Zheng, Guo, and Lai (2019) completed a meta-analysis of eight randomized controlled trials that studies the effect of a low carbohydrate diet. Their study found improvements in hormone levels, improved insulin resistance, and improved BMI after a low carbohydrate diet was introduced. Also, to be mentioned is a study completed by Nikokavoura et al. (2015) which explored lifestyle modifications using a low-calorie diet to help manage PCOS. Their study found significant weight reduction and change in BMI after changes were implemented (Nikokavoura et al., 2015). This evidence supports the intervention of diet into lifestyle modifications to improve effects of PCOS.

Exercise is another lifestyle intervention that is supported by evidence in treatment for PCOS. A study completed by Ramos et al. (2016) explored the effect of resistance training on quality of life in women with PCOS. Their study found significantly reduced testosterone levels, social aspects, vitality, and mental health after implementing their intervention for 16 weeks. In support of exercise, Costa et al. (2018) explored the effect aerobic training had on women with PCOS. Their study included twenty-seven women with PCOS and compared them with a control group. Costa et al. (2018) concluded that there is an improvement in cardiorespiratory fitness, BMI, waist circumference, and mental health. Another study, a systematic review by Pundir et al. (2019), explored the evidence found after non-pharmacological interventions, such as exercise, were implemented. Improvements were found in fasting blood glucose levels, BMI, and improved total testosterone levels (Pundir et al., 2019). This evidence suggests a significant change after a lifestyle modification of exercise is completed.

A systematic review and meta-analysis was completed by Domecq et al. (2013) that studied the effects of lifestyle modifications on patients with PCOS. Their study reviewed the results of 9 RCTs that included a total of 610 women. Diet, exercise, and a combination of both were reviewed. Improvements found included: weight reduction and insulin resistance (glucose and insulin levels) (Domecq et al., (2013). Haqq, McFarlane, Dieberg, and Smart (2015) also explored the effect of lifestyle modifications through their systematic review and meta-analysis. Their study of 12 articles found improvements in cardiorespiratory fitness and body composition such as BMI and inches (Haqq et al., 2015). Similar results were found in a randomized controlled study completed by Arentz et al. (2017). Their study found lifestyle modifications in combination with medicine provided optimum improvement compared to medicine alone.

Improvements were seen in BMI, hormones, insulin, and mental health after lifestyle modifications were implemented (Arentz et al., 2017).

Another study of lifestyle interventions was completed by Fux Otta et al. (2010). Their study was a randomized, double blind trial that found lifestyle interventions improved effects of PCOS after interventions were implemented. Additionally, Legro et al. (2015) completed a randomized controlled trial of lifestyle interventions and their impact on 149 women. At the end of their study, improvements were found in weight, fertility, and metabolic health. Lastly, Naderpoor et al. (2015) completed a systematic review and meta-analysis of 12 randomized controlled trials that found optimum results with lifestyle modifications combined with medications versus medications alone.

Clearly, evidence demonstrates the importance of lifestyle modification in the treatment of PCOS. The Lifestyle Modification Change Project implements two modifications: diet and exercise. These modifications are supported by strong research to support their effectiveness in helping manage PCOS. Therefore, researchers anticipate positive results of the Lifestyle Modification Change Project.

3. Project Stakeholders

Stakeholders for my change project include patients, healthcare providers, and the public as there is a high population of women that are affected. Society is indirectly impacted by their relationship to women who are affected. The public is indirectly affected by an individual's health care costs. Women are directly affected by PCOS. Health care providers are directly affected in their care of their patients with PCOS. Sisters, mothers, wives, and daughters can all be affected if they are of reproductive age. This disorder affects all aspects of women's health. PCOS can cause infertility, miscarriage, obesity, insulin resistance, hyperandrogenism, anxiety,

and depression (Naderpoor et al., 2015). In other words, PCOS can affect physical health and psychological health.

Patients and health care providers are the stakeholders in changing the emphasis on lifestyle interventions as part of the treatment plan for PCOS. Because of the health impact of PCOS, early and consistent intervention are necessary to decrease this disorder's effect. Another way that PCOS can negatively affect patients is decreased quality of life (Ding, Hardiman, Peterson, & Baio, 2018). When quality of life is impacted negatively, this makes those directly affected stakeholders. Additionally, healthcare providers and the public are stakeholders because of the prevalence of PCOS in reproductive women and the healthcare costs associated with this disorder.

In the change project, patients with PCOS would receive extra education that explains the significance of lifestyle interventions in combination with medication treatment. They would also receive education that PCOS is not cured after medication administration but is a lifelong disorder that requires a lifestyle change. Thus, financial costs and health benefits would improve. Therefore, the evidence supports the need for this change project and anticipates positive results concerning stakeholder interests such as health benefits and financial cost.

4. Implementation Plan

This change project would focus on the implementation of lifestyle modifications in combination with pharmacological interventions for best care of patients diagnosed with PCOS. As this change project is a benchmark project, the implementation of the project is currently in theory only. Starting with the education of providers, office staff, and patients, researchers will educate all stakeholders. However, the most emphasis will be placed on the patient's education. The opportunity to participate in physical activity will also be given with primary care

partnerships with area gyms and physical activity facilities with pre-approved activity programs. A thorough evaluation of baseline data and comparison of data from post program participation will be completed with the patient. By providing time for data evaluation between the patient and the provider, this will allow for the patient to appreciate their efforts and the positive impact their lifestyle modification has on their disorder. The result of the project will encourage patients to continue their commitment to their lifestyle modifications. In other words, the success noted after the interventions will empower the patient to take control of their diagnosis and will assist in building a new outlook on life. The following paragraphs outline a step by step approach to plan implementation.

First, education of staff and providers on the benefits of lifestyle interventions is the initial step in completing a PCOS lifestyle intervention change program. These health care workers must understand the impact of dietary and physical modifications on the disorder of PCOS. Education will be completed in the form of verbal education and paper handouts. Education regarding proper patient appointment times (20 mins +) will also be completed. Suggestions will be made for these appointments to be scheduled at the end of the day. Appropriate follow up will be completed by the researcher to answer any questions and for office staff to verbalize their understanding of the benefits and program itself. This education time frame is estimated at 2 weeks for staff preparation for the program.

The next step is identification of patients newly diagnosed patients with PCOS or newly referred patients with PCOS. Patients who are newly diagnosed with PCOS will be flagged by the provider and office staff for potential candidates in the research project. Identification of patients with PCOS will take place from August 2020 to the end of September 2020 for inclusion

in the first rotation of the program. The expected time frame is immediately after identification of diagnosis.

Thirdly, patients will be identified as candidates in the program. Criteria for participation will be females aged 18-38 years old with a diagnosis of PCOS. The diagnosis of PCOS will be completed by providers by the Rotterdam criteria for PCOS. Exclusion from participation will be pre-existing conditions such as hypothyroidism, hyperthyroidism, cancer, cardiac history, physical impairments for physical exercise, and recent surgery. The expected time frame is within one week of identification.

An invitation to participate into the PCOS lifestyle modification program. Verbal and written invitations and education will be given to patients during office visits from August 2020 to September 2020. Patient will be given invitation and education and encouraged to think about participating in the program. Expected time frame is one week before follow up.

Next, informed consent will be obtained. Patients will have opportunity to ask questions and sign written informed consent for the research project. Patients will take education information home in the form of handouts away from the primary care office to limit perceived pressure to participate. Decision to participate from initial invitation will be completed in one week. The expected time frame is providers will schedule 20 mins for this office visit.

In the sixth step, baseline patient data will be obtained including lab work such as testosterone levels, BMI, weight, measurements in inches, menstrual frequency (dates), and quality of life questionnaire. Data will be gathered at follow up appointment after diagnosis of PCOS or initial referral visit for PCOS. Data will be gathered during the second appointment. Expected time frame is within one week of invitation which would include a 20-30 min for patient office visit.

Next, patients to participate in lifestyle interventions that include dietary recommendations and physical activity programs. The researcher will partner with area gyms and exercise centers for information of eligible exercise classes patients can participate in. Physical activity programs and information will be given during second office visit during data collection. Patients to participate in lifestyle modification recommendations for 16 weeks. During this visit, patients will set up follow up office visit for new data collection. The time frame for this step is 16 weeks.

Lastly, a 16 week follow up will be completed at the end of the program. Patients will present to the primary care office for data collection. Office visits for data collection will be scheduled for 20-30 minutes with the provider. Providers will review new data post program participation with data from pre- participation. Providers anticipate positive results in data that include: decrease in BMI, decrease in weight, decreased measurements, decrease testosterone levels, increased menstrual cycles, and improvement in quality of life questionnaire. Patients will be given the option to continue in participation in the program for another 16 weeks for another re-evaluation. Time frame for this step is 20-30 mins.

5. Timetable/Flowchart

The first step in preparation and implementation of the lifestyle modification change project is education. This will take place in the first two weeks with preparation of providers and office staff. The next time frame will extend from August 2020 to September 2020 in which eligible patients with PCOS will be identified and invited to participate in the program. Patient will be given information and education about the benefits of the program and involved lifestyle modifications. They will have one week after invitation to decide to participate. During a 20-minute office visit, patients will have opportunities to ask questions and complete informed

consent as they will have taken home the contract and education prior to this visit. Within one week of invitation to participate and after informed consent is completed, patients will complete pre-participation data collection nurse visit. This will start the beginning of the 16-week program start. After completion of the 16-week program, patients will complete a 20-minute data collection visit and another meeting with the provider to review post participation results.

6. Data Collection Methods

When data is analyzed, the researcher anticipates a noted decrease from their pre-participation state numbers. Projected decreases are anticipated in BMI, weight (kg), inches, and free testosterone levels. Projected increases are anticipated in menstrual regularity and increases in health-related quality of life questionnaire scores. Success of the program is based on three states: the patient continues to value the significance of lifestyle modifications, the provider identifies with success of the program to encourage lifestyle modifications as a treatment plan, and the patient health is positively influenced. Complete evaluation by the researcher will be completed at the end of the 16-week program with a sit-down office visit between the researcher/health care provider and the patient with PCOS. At the time of evaluation, data will be presented that includes pre-participation number and post participation numbers. Numbers will be a defining tool to evaluate the data concerning the program and both the researcher/health care provider and the patient will benefit from the evaluation. Instructions for completing the steps for evaluation and interpreting data are in the following paragraphs.

Firstly, the researcher will set up program conclusion appointments at the beginning of the program with the patient. Appointments will be completed for data collection (nurse visit) at completion of the program (16 weeks post) and for the conclusion interview (office visit) by the

provider after the data is collected. This will allow for patient and provider planning as these visits should be at the end of the clinic day.

After completion of the 16-week program, the patient will complete a nurse visit that will include collection of data including: weight, BMI, body inches, menstrual cycles (counts), testosterone level, and health questionnaire. Weight, BMI, and inches will be completed by the nurse and measured in whole numbers. Menstrual cycles will be completed by having the patient provide descriptions of the length and frequency of cycles since starting the program. The PCOS health related quality of life questionnaire will be completed during the visit and the nurse will complete the questionnaire evaluation tally. All data will be entered in the health care record for easy access by the provider.

Next, after all participants have completed their data collection nurse visits, the provider will complete data evaluation for the individual patient and the group. Group data will serve as a comparison for the patient to rate their individual progress in relation to the group. This will be completed by descriptive statistic techniques (see the following information on data collection) During the final office visit between the provider and the patient at post completion of the program the following will occur:

- The provider will present individual data to the patient. The researcher anticipates positive results since onset of the program.
- The provider will compare the patient's data with the groups data to allow for insight on the patient's success compared to the entire groups.
- The provider will allow the patient to ask questions regarding their diagnosis and disorder prognosis.

- The provider will offer the patient an opportunity to re-enlist in the program again to encourage commitment to lifestyle modification.
- The office visit will be completed at the end of the office day to allow for more time for the patient to ask questions and the provider to present a non-hurried approach for the program completion.

Descriptive statistics will be used to evaluate the patient's data as this is most appropriate to display relationships between variables (Ali & Bhaskar, 2016). The PCOS lifestyle modification program will yield individual variables for each patient. The numerical data will be obtained from the office assessment. Pre-participation variables (A) will have post-participation variables (B) subtracted from their original variable which will yield the new lifestyle modification change (C). This formula will look like: "A - B=C." This difference in variables will serve as the patient's individualized results. Group data will be completed using standard deviation. As this is a benchmark project, no data has yet been collected to demonstrate correct values.

The population of the project would serve as Ó while X will be the resulted mean, *i* is the element from the population, and *N* will be the number of my project population (Ali & Bhaskar, 2016). Mean will be found by the researcher by adding all the participants scores and dividing the sum by the number of participants. The standard deviation will serve as the comparison for the patient. This comparison will allow for the patient to appreciate their improvement or serve as motivation as to what results are possible.

Evidence will be evaluated using descriptive statistics in the form of means and standard deviation. Results will be compared from pre-participation data to post-participation data. Data to be compared will be BMI, weight, inches, testosterone level, and quality of life questionnaire. Positive results are anticipated after program participation. A follow up to discuss results and

effects of participation will be scheduled as follow up office visits. For success of the program, the researcher should see a decrease in BMI, inches, weight, testosterone level, and improved quality of life. To monitor for success of the program, the researcher will evaluate patient group data and post evaluation form regarding difficulty of modification adherence. The evaluation form will include five questions with room for comments on suggestions. The researcher will take all feedback into consideration into improving ongoing program enlistment.

7. Cost/Benefit Discussion

The Lifestyle Modification Change Project benefits include both financial and health. Concerning financial concerns, there is little financial investment or cost. The researcher, on a volunteer basis, will train providers and office staff over the two-week preparation period for an estimated 5 hours. An estimate of costs for written education is $200.00 for copies, pens, and paper for office training and patient education. Patient demographics and data will be flagged through the health care office EMR system. There will be no cost to this process as all patients identified with a PCOS diagnosis after training will be flagged through the computer EMR system once settings are set. Time will not be wasted on identifying patients from previous visits. Office visits will be scheduled as normal visits with patient covering their own visits as normal.

Patients will also have options to complete physical activity recommendations by joining a gym, recreational center, or completing physical activity at their own discretion. Patients will have a choice as to how much money they want to spend on these choices. Education will be incorporated into their visits, the difference being their visits will be scheduled at the end of the clinic day to avoid pressure to the provider to finish sessions in a rushed manner. Data will be analyzed in the providers EMR system. There is no cost as the EMR system will already be

utilized. Limited costs are estimated as the only difference clinic visits will have extra scheduled time for education at the end of the visit. This will be an opportunity to ask questions and the patient should have received written education also.

PCOS is also associated with long term comorbidities such as coronary heart disease, endometrial cancer, diabetes, and stroke (Ding et al., 2018). Since PCOS can have such detrimental short and long term effects, effective early management is important. Research has found that women with PCOS are twice as likely as women without this diagnosis to have hospital admissions (Naderpoor et al., 2015). Although the health of patients is affected by PCOS, financial burden can also be a factor. Ding et al. (2018) mention an estimated cost of treatment for women with PCOS in the U.S. to be estimated at $4.36 billion per year. Ding et al. (2018) also predict high comorbidities of PCOS and diabetes. 2.4% of PCOS patients had completed a HBA1c test within the first year after diagnosis (Ding et al., 2018). These estimates are just general estimates of the cost of PCOS. All stakeholders including society, health care providers, and PCOS patients will avoid complications of PCOS and their associated financial costs by supporting lifestyle modifications as part of PCOS treatment management.

8. Discussion of Results

The Lifestyle Modification Change Project is currently a benchmark project. There are no official results. However, the researcher anticipates positive results as there is strong evidence supporting the need for change. The evidence supports lifestyle modifications to help treat PCOS. Change can be applied to the identified problem of lack of either education or emphasis on the recommended treatment plan.

9. Conclusions/Recommendations

Lifestyle modifications are first line treatment in combination for PCOS. The Lifestyle Modification Change Project allows for patients to learn about lifestyle modifications and allows them to be held accountable while learning to incorporate these modifications in everyday life. The greatest strengths of this project are: the desire for patients to take control of their diagnosis and the desire for providers to help their patients. Once patients see the benefits that are apparent both physically and on paper, they will continue their lifestyle interventions. Providers want to help their patients and will see positive results after emphasizing and educating their patients on the benefits of lifestyle interventions in the treatment plan for PCOS. This project serves as a jump start to changing their lifestyle to help manage their PCOS. As PCOS does not have a cure, PCOS must be managed as a lifelong (reproductive life) condition. This researcher recommends initiating the Lifestyle Modification Change Project in primary care offices for improved patient outcomes.

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Appendix A

Synthesis Table

Evaluation Table Template

Caveats

1) The **only studies** you should put in these tables are the ones that **you know answer your question** after you have done rapid critical appraisal (i.e., the keeper studies)
2) Include APA reference
3) Use abbreviations & create **a legend** for readers & yourself
4) Keep your descriptions brief – there should be **NO complete sentences**
5) This evaluation is for the purpose of knowing your studies to synthesize.

Place your APA Reference here (Use correct APA reference format including the hanging indentation):

Arentz, S., Smith, C. A., Abbott, J., Fahey, P., Cheema, B. S., & Bensoussan, A. (2017). Combined lifestyle and herbal medicine in overweight women with polycystic ovary syndrome (PCOS): A randomized controlled trial. *Phytotherapy Research*, *31*(9), 1330-1340. doi:10.1002/ptr.5858

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Citation: (i.e., author(s), date of publication, & title)	**Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables Studied and Their Definitions**	**Measurement of Major Variables**	**Data Analysis**	**Study Findings**	**Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])**
Author, Year, Title	**Theoretical basis for study** **Qualit**	**Indicate design & briefly describe what was done in the study**	**Number, Characteristics, Attrition rate & why?**	**Independent variables (e.g., IV1 = IV2 =)** **Dependent variables (e.g., DV =)**	**What scales were used to measure the outcome variables (e.g., name of scale, author,**	**What stats were used to answer the clinical question**	**Statistical findings or qualitative findings (i.e., for every statistical test you have in the data analysis column, you should have a finding)**	**• Strengths and limitations of the study** **• Risk or harm if study intervention or findings implemented** **• Feasibility of use in your practice** **• Remember: level of evidence + quality of evidence = strength of evidence & confidence to act**

	ative Tradition				**reliability info [e.g., Cronbach alphas])**	**(i.e., all stats do not need to be put into the table)**		**• Use the USPSTF grading schema http://www.ahrq.gov/clinic/3rduspstf/ratings.htm**	
Arentz et al., 2017, Combined lifestyle and herbal medicine in overweight women with polycystic ovary syndro	None stated	RCT, Analysis of HM and LSI effects on women w/ PCOS.	*N* = 189, *n*= 122, Attrition = 14. Reasons in Figure 1.	IV- HM +LSI and LSI alone DV= (1) oligomenorrhoea (2) BMI, BW, WC, depression, stress, anxiety, psychological outcomes, safety (BP), LH, insulin,	No Cronbach. PCOSQ, DASS 21, B HCG, and U HCG	*CI*, *p value*, n_p^2	Most significant: reduction oligomenorrhoea combination group: 95% *CI* (-64.8,-21.1)), $p < 0.01$, $n_p^2 = 0.11$, (Comb= 63.7 days vs. LSI= 106.6 days). improvements: body weight: Comb= 90.2 kg vs LSI= 97.2 kg), BMI *SE*= -1.0, $p< 0.01$, insulin *SE* = -5.93, $p< 0.02$,	Strengths: randomized by computer, good sample size. Limitations: 3 mth follow up, future possibly longer. Non blinding, no placebo group. Risks/harm: No serious adverse events reported. Non serious adverse effects minimal/less then pharmaceutical (classic) intervention.	

me (PCOS): A randomized controlled trial							LH:*SE* =-1.82, *p*= 0.04, BP *p*=0.01, PCOSQ: *SE*=-31.1, *p<0.01*, depression *SE*= -4.3, *p*< 0.01, stress *SE*= -5.0, *p*< 0.01, anxiety *SE*=-4.0, *p*< 0.01, other: oestradiol: *SE*= 68.9, *p*=0.03, WC: *SE*= -3.41, *p*< 0.01, BW: *SE*= -2.95, *p*< 0.01	Feasibility: Moderate, due to customized manufacturing of combination herbal medication. LSI teaching/followup feasible. Level 2: RCT USPSTF: Level B, level of certainty high.	
Costa et al., (2018). Aerobic training improves quality of life in women	Not stated	RCT, effects of exercise evaluated on PCOS sympt.	*N*=30, *n*= 30. No attrition was reported. Subjects female w/BMI 25-39.9 w/PCOS	IV=exercise vs inactivity DV= HRQL, cardiorespiratory fitness, cardiometabolic profile (BMI)	HRQL scores, ANOVA, Bonferroni post hoc test	M+/-SD, P, CI, ES	HRQL: (General health) ES 0.9 95% CI 0.2, 1.7, P=0.012. (Mental health) ES 1.0, 95% CI 0.0, -2.0, P=0.042. Cardioresp: VO2 peak ES 1.2 95% CI 0.6,1.8,	Strengths: randomized by computer, good sample size. Limitations: Small sample size, initially randomized then not. Generic questionnaire. Non blinding, no placebo group.	

with polycystic ovary syndrome.			. Inactive women.				P<0.001. BMI: ES -0.3, 95% CI -0.4, -0.1, P<0.001.	Risks/harm: No serious adverse events reported. Informed consent obtained. Feasibility: Worthwhile exercise programs can be implemented. May be difficult if exercise activity is supervised. Level 2: RCT USPSTF: Level B, level of certainty high.	
Domecq et al., (2013). Lifestyle modification programs in polycystic	Not stated	Systemic review and meta analysis. Eval of lifestyle mod programs & impact on PCOS pts.	*N*= 745 *N*= 19, 9 RCTs, 10 publications. Meta analysis: 610 women age 18-	IV: LSM DV: (1) FBG, (2) FBI, (3) FGM	Cochrane risk took to eval randomization performance, I^2 statistic to measure inconsiste	WMD, MD, P, CI, I^2	LSM FBG: WMD, -2.3, 95% CI -4.5 to -0.1, P= 0.04, I^2= 72% LSM FBI: WMD -2.1, 95% CI -3.3 TO -1.0, P < .001, I^2=0%. LSM FGM: WMD -0.8, 95%	Strengths: comprehensive literature research, tools to reduce error measures, protocol driven research, duplicate review. Limitations: High rates of loss of followup. Short trial duration, imprecision, heterogenity	

ovary syndrome: Systematic review and meta-analysis.			35 yrs. Attrition in 8 RCTS at 16%, no reason noted.		ncy in results.		CI, -3.5 to 1.9, P= .56	Non blinding, no placebo group. Risks/harm: No serious adverse events reported. Informed consent obtained. Feasibility: Worthwhile, lifestyle modification can be implemented by patients after education. Level 2: meta-analsysis USPSTF: Level B, level of certainty high.	

Haqq et al., (2015), The effect of lifestyle intervention on body composition, glycemic control, and cardiorespiratory fitness in polycystic ovarian syndro	None mentioned	Systematic review and meta-analysis, analysis of RCTs for LSI and impact on PCOS	*N*=233, *n*=12, searched in 3 databases (Pubmed, CINAHL, Cochrane). No language restrictions, RCTs only.	IV=LSI and usual care DV= (1)Body composition parameters (BMI, body mass, waiste circ, waste-hip ratio, body fat), (2) glycemic parameters, (3) lipid profile, (4)C-Reactive protein, (5) cardioresp fitness	Cochrange Q test, tests heterogeneity, (Higgins & Green, 2011) Egger plot, tests bias, (Egger et al., 1997) Modified PEDro score, tests quality, (Maher et al., 2003)	*M, MD, SD, CI, p*	*CI* =95% DV1: BMI: *MD*=-0.12kg.m-2, *p*= .009, *CI*=95% (-0.22,-0.03) Body mass: *MD*=-3.42, *p*<.00001, *CI*=95% (-4.86, -1.99) Waiste-cir: *MD*=-1.64cm, *p*<.0001, *CI*=95% (-2.09, -1.19) Waiste hip ratio: *MD*=-0.03, *p*=0.0002, *CI*=95% (-0.05, -0.01)	Strengths: Studies are RCTs, 12 studies, sub analysis were used. Researchers contacted study authors when data was missing. Limitations: *p* values were not available in some studies, so default values were used. Some studies used additional dietary interventions. No risk or harm noted by patient. Feasibility: -related to specialty, worthwhile to speak to patient about. Level 1- Systemic reviews

me: A systematic review and meta-analysis							Body fat: *MD =-1.71%, p*=.02, *CI=95% (-3.10, -0.32)* DV2: *MD*=-1.21pmol/L, *p*=.20, *CI*=95% (-3.06, -0.63) DV3 (Lipid profile): *MD*=-0.20 mmol/L, *p*=.89, *CI*=95% (-0.25, 0.21) DV 4 (CRP): *MD*=-0.47mmol/L, *p*=.004, *CI*=95% (-0.80, -0.15) DV5 (CARDIO): *MD*=-1.89 beats.min-1, *p*=.0002,	USPSTF: Level B rating, moderate level of certainty

							CI=95% (-2.90, -0.88)	

Legro et al., 2015, Randomized controlled trial of preconception interventions in infertile women with polycystic ovary syndrome	None stated	Randomized controlled trial, explored preconception interventions and benefits towards PCOS	*N*=216, *n*=149, AT 12% lifestyle, 8%OCP, 14% combined, reasons listed on Fig 1, two-site study, women age18-40, BMI 27-42kg/m^2, Partipants: OCP (49), LSI (50), Combined (50)	IV= OCP, LSM, Combined TX DV= weights (loss), ovulation, live births	HRQOL, oral glucose tolerance test.	*M, CI, OR*	Largest change: (combined TX) *M* -6.4%, 95% *CI*, (-7.6- -5.2), Metabolic increased in OCP *OR*, 2.47; 95% *CI*, 1.42-4.27, triglycerides Increased OCP: *p*= 0.006, weight loss: LSI -6.2%, *CI* 95%,(-7.4- -5.0), Combined: -6.4%, *CI* 95%, (-7.6- 5.2), OCP *p* < 0.001. LSI wt loss: -6.2, *CI* 95%, (-7.1- -5.3), *p* <0.0001, WC highest in LSI: -6.3, *CI* 95%, (-9.2- -3.4), *p* <0.0001, HRQOL impoved LSI (*p*=0.0001) and	Strengths: -randomized, equal 3 group assignment, control group. -good follow up, 6 mths post delivery. -TX interventions from proven studies in obesity. Limitation: -no exploration in live births between groups. - small sample size Risk/harm: steatorrhea/diarrhea, breast pain, abd pain, dysmenorrhea, AUB, HA Feasibility: interventions easily found, worthwhile to explore

							Combined (*p*= 0.008)	Level 2 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: High
Fux Otta et al., 2010, Clinical, metabolic, and endocrine parameters in response to metformin and lifestyl	Not stated	Double-blind, RCT, eval. of met., diet, exercise on endocrine and metabolic levels in PCOS	*n*=30, attrition of 1, 14 received metformin, 15 received placebo. Ages 20-34 yrs. No sig diff. in baseline charact. No economic	IV- Met w/diet/exercise DV- endocrine/metabolic values (anthropometric, gonadotropin, insulin, lipid, androgen, menstrual- Table II and Table III)	No Cronbach's alpha, no other scale to measure inernal validity. Values expressed in distributions.	*M,SD, p*	Menstrual decrease 66.35±47.09 days(*p*=0.003)w/met, 77.86±56.48 days (*p*=0.009)w/placebo. Sig decrease testosterone 93.2 ±22.02 to 76.36 ±13.59ng/dl (*p*=0.02) w/met, Waist: 98.6 (84.1-113.1) to 93.7 (77.6-109.8) *p*= 0.007, insulin: 14.2 ±	Strengths: Randomized, double-blind Limitaitons: follow up only 4 mths, no risk factors identified, small sample size. Risk/harm: none identified in article. Feasibility: -worthwhile, metformin easy to obtain/prescribe, diet and exercise also feasible.

e intervention in women with polycystic ovary syndrome: A randomized, double-blind, and placebo control trial.			demograph. Outpatients at Department of Endocriniology of Hospital Privado Centro Medico de Cordoba (Argentina)		DHEA-S, OGTT		4.03 to 9.42 ± 5.13 , *p* = 0.003, HOMA-IR 3.25 ± 1.11 to 2.05 ± 1.36, *p* = 0.01, BMI: 32.4 ± 6.7 to 31.53 ± 4.98, *p* = 0.73	Level 2 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: Moderate
Marzouk, T., & Sayed Ahmed, W. (2015). Effect of dietary weight	None stated	RCT, eval of dietary wt loss on menstrual cycles	*n*= 60, adolescent women with BMI 30+ Dx w/PCOS, no attrition	IV: calorie reduced diet. DV: (1) body wt (2) BMI (3) hirsutism score (4) menstrual regularity	No Cronbach's alpha, no other scale to measure inernal validity. Values expressed	M+/- SD, CI, P	BW: 83.7 +/- 10.3 vs 90.1 +/- 12.4, BMI: 33.2 +/- 3.8 vs 35.7 +/- 4.6, Hirsutism: 14.6 +/- 4.4 vs 18.2 +/- 6.2, Menstrual epi:	Strengths: Randomized, double-blind Limitaitons: Small number of RCTs, no risk factors identified, differences in quality of publications

loss on menstrual regularity in obese young Adult women with polycystic ovary syndrome.					in distributions.		3.1 +/- 1.2 vs 2.3 +/- 1.3	Risk/harm: none identified in article. Feasibility: -worthwhile, consistent LCD has significant impact on PCOS patients. Level 2 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: Moderate
Naderpoor et al., 2015, Metformin and lifestyle modification in polycystic	Not stated in the article	Systematic review and meta-analysis, compare L + met. and L ± placebo, and met. alone w/L ± placebo, eval.	*N*=2372 (population), *n*= 12 RCT, attrition of individual studies examined by authors. 1= no	IV= L+met. and L±plaebo DV:anthropometric para. (BMI), metabolic para. (insulin resistance), glucose	No instruments for Cronbach's alpha. QUICKI, IFG, IGT, OGTT	*MD, CI,P*	L+met. = lower BMI *MD* -0.73 kg/m^2, 95 % *CI* (-1.14, -0.32), *p*=0.0005, adipose tissue *MD* -92.49 cm ^{2}, 95% *CI* (-164.14, -20.84), *p*=0.01, Increased menstrual cycles *MD* 1.06, 95%	Strengths: Thorough investigation of studies, questioned authors when info not present. Questions of inclusion discussed/reviewed w/reviewers. Used evidence synthesis expert. Risk of bias assessment tool assessed methodological qual. Limitaitons:

ovary syndrome: Systematic review and meta-analysis		results in PCOS	reported attrition. 9 RCT w/ LSI +Met and L + P, 4 RCT Met alone W/L (± P).	intolerance (IFG/IGT) DV II- anthropometric para. (body composition) ,reproductive para. (hyperandrogenism etc), metabolic para. (lipds etc), psychological para (QOL)			*CI* (0.30, 1.82), *p*=0.006, lower test L +Met.: *MD* -4.27 *CI* 95% (-11.83, 3.29), *p*= 0.27	Studies w/small sample size, high attrition rates, poor adherence. Feasibility: Individualized, worthwhile tx. Risk or harm: side effects of metformin (N/V/D etc) Level 1- Systemic reviews USPSTF: Level B rating, Level of certainty: Moderate
Nikokavoura et al., (2015). Weight loss for women with and without	None stated	Retrospective analysis, eval. wt loss after low calorie diet in PCOS and no	*N*=102,610. Women age 18-75 yrs with BMI > 28 w/wo PCOS. Demogr	IV=VLCD DV= (1) weight loss, (2) BMI, (3) BP	No instruments for Cronbach's alpha. T test paired/unpaired, Bonferroni post hoc	*M*= +/- *SD*, *P*.	Weight loss (w/PCOS): 105.4+/- 18.9 kg vs 95.0 +/- 19.1 kg, P< 0.001 (s/PCOS): 105.3+/-19.0kg vs 94.9 +/- 19.5 kg, P < 0.001. BMI (w/PCOS):	Strengths: analysis compared PCOS and nonPCOS patients. Retrospective analysis of data, thorough investigation. Limitaitons: DX of PCOS not same criteria. Bias in financial status,

polycystic ovary syndrome following a very low-calorie diet in a community-based setting with trained facilitators for 12 weeks.		PCOS pts.	aphics reported comparable. No attrition reported.		test for variance.		38.9+/-6.4 kg/m vs 35.0+/-6.6 kg/m, P< 0.001. (s/PCOS): 38.8 +/-6.4kg/m vs 35.0 +/-6.8 kg/m, P <0.001. BP (w/PCOS): -5.5+/- 6.1 mmHg vs non PCOS -0.9+/- 1 mmHg, P < 0.001.	costly commercial program. No randomization. Ethnicity not assessed. Feasibility: Individualized, worthwhile tx. for low calorie diet. Behavior change therapy difficult to initiate in PCP office. Risk or harm: no risks identified. Level 3- retrospective analsys USPSTF: Level B rating, Level of certainty: Moderate
Pundir et al., (2019). Overview of system	Not stated	Review of systematic reviews (meta-analysis)	*N*= 273, *n* = 12 systematic reivews. Only	IV: diet, physical activity, nutritional supplements (omega 3, n-	AMSTAR tool and GRADE recom. used	MD, CI, SMD, OR, pOR, RR	Inositol on menstration: RR=6.8, 95% CI 2.8, 16.6. Lifestyle inter on cycles: MD: -	Strengths: reviews with RCTs used. Limitaitons: no risk factors identified, small sample size.

atic reviews of non-pharmacologic al interventions in women with polycystic ovary syndrome.			reviews with RCTs included. No language restriction. No date restriction	acytlecysteine, vit D, inositol), alternative therapies (herbal medicine, acupuncture. DV: endocrine outcomes, fertility impact, glycemic impact.			1.19, 95% CI -2.35, -0.03. testosterone w/lifestyle:MD -1.64, 95% CI -2.94, -0.35. lifestyle intervention w/BMI: MD -1.12, 95% CI -0.22,-0.03 (MD -0.15, 95% CI 0-.24, -0.5). Lifestyle intervention w/insulin: MD -2.02, 95%CI -3.28, -0.77, WMD -2.1, 95% CI -3.3, -1.0, MD -1.10, 95% CI -2.05, -0.16.	Risk/harm: none identified in article. Feasibility: -worthwhile interventions are feasible. Level 2 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: Moderate
Ramos et al. (2016). Quality of life	Not stated	Case controlled study. Impact of restistanc	*N*=350, *n*=124, attrition 21 from pregnan	IV: RET, DV: (1)testosterone, (2) androsternedi	Linear transgressions model used for result	M+/-SD, p,	Test:88.93 +/-34.73 vs 73.24 +/-24.63, OR 16.32, 95% 7.94, 24.71, p<0.01.	Strengths: reviews with RCTs used.

in women with polycystic ovary syndrome after a program of resistance exercise training.		e exercise on PCOS pts.	cy and missed apts.	one, (3) BMI/waist circ, (4) QOL	comparison, no model for heterogeneity.	OR, CI	BMI= no change. Waist cir: 80.59 +/- 11.87 vs 79.35 +/- 10.54, OR= 0.84, 95% CI= 0.35 to 1.32, p<0.01. QOL: (functional cap) 86.86 +/- 13 vs 91.74 +/- 11.44, OR= -4.86, 95% CI= -8.89 to -0.84, p=0.02	Limitaitons: no risk factors identified, small sample size, lack of a control group. Risk/harm: none identified in article. Feasibility: -worthwhile interventions are feasible. Patients can engage in resistance training as an intervention. Level 3 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: Moderate
Zhang, X., Zheng, Y., Guo, Y., & Lai, Z. (2019).	None stated	Meta-Analysis on RCT. Impact of LCD on PCOS	*N*=340, *n*=8, no attrition mentioned.	IV=LCD DV(1)=BMI DV (2)= endorcrine	Heterogenity measuresd with tau^2, chi ^{2}, I^2. No specific	*MD*, *P*, I^2, CI, SMD	BMI= (SMD -.04, 95% CI (-1.38, -.070) P <0.00001). HOMA-IR=(SMD -.66, 95% CI (-1.01, -030)	Strengths: Randomized, double-blind

The effect of low carbohydrate diet on Ppolycystic ovary syndrome: A Meta-Analysis of Randomized Controlled Trials.			Articles LCD on attributes of PCOS: BMI, LH, endocrine, testorone.	hormones DV (3)= LH DV (4)= testosterone DV (5)= HOMA-IR	design mentioned		P = 0.0003). Endocrine Horm= (P=0.95,I^2=0%). LH= p>0.05, SMD 0.08, 95 % CI (-0.48, 0.65). testosterone= (P<0.05, I^2=86%), SMD=-1.01, 95% CI (-2.08, 0.06)P>0.05)	Limitaitons: Small number of RCTs, no risk factors identified, differences in quality of publications Risk/harm: none identified in article. Feasibility: -worthwhile, consistent LCD has significant impact on PCOS patients. Level 2 Hierarchy of evidence USPSTF: Level B rating, Level of Certainty: Moderate

Legend:

LSI=lifestyle intervention HA=headache *P*=*p* value LCD=low carb diet

M=mean, AUB=abnormal uterine bleeding *CI*= confidence interval

SD= standard deviation Abd=abdominal *I2*= I2 statistic

FGM=Ferrimen-Gallaway score

MD= mean difference

cardioresp=cardiorespiratory

Eval.= evaluate

RCTs= randomized controlled trials

met=metformin

L= lifestyle

QOL=quality of life

Comb= Combination tx

AT=attrition

OCP=oral contraceptive pills

TX=treatment

BW= body weight

HM=herbal medicaiton

N=nausea

WC= waiste circumference

BMI=body mass index

DV=dependent variable

IV=independent variable

PCOS= polycystic ovary syndrome

LSM= lifestyle modification programs

D=diarrhea

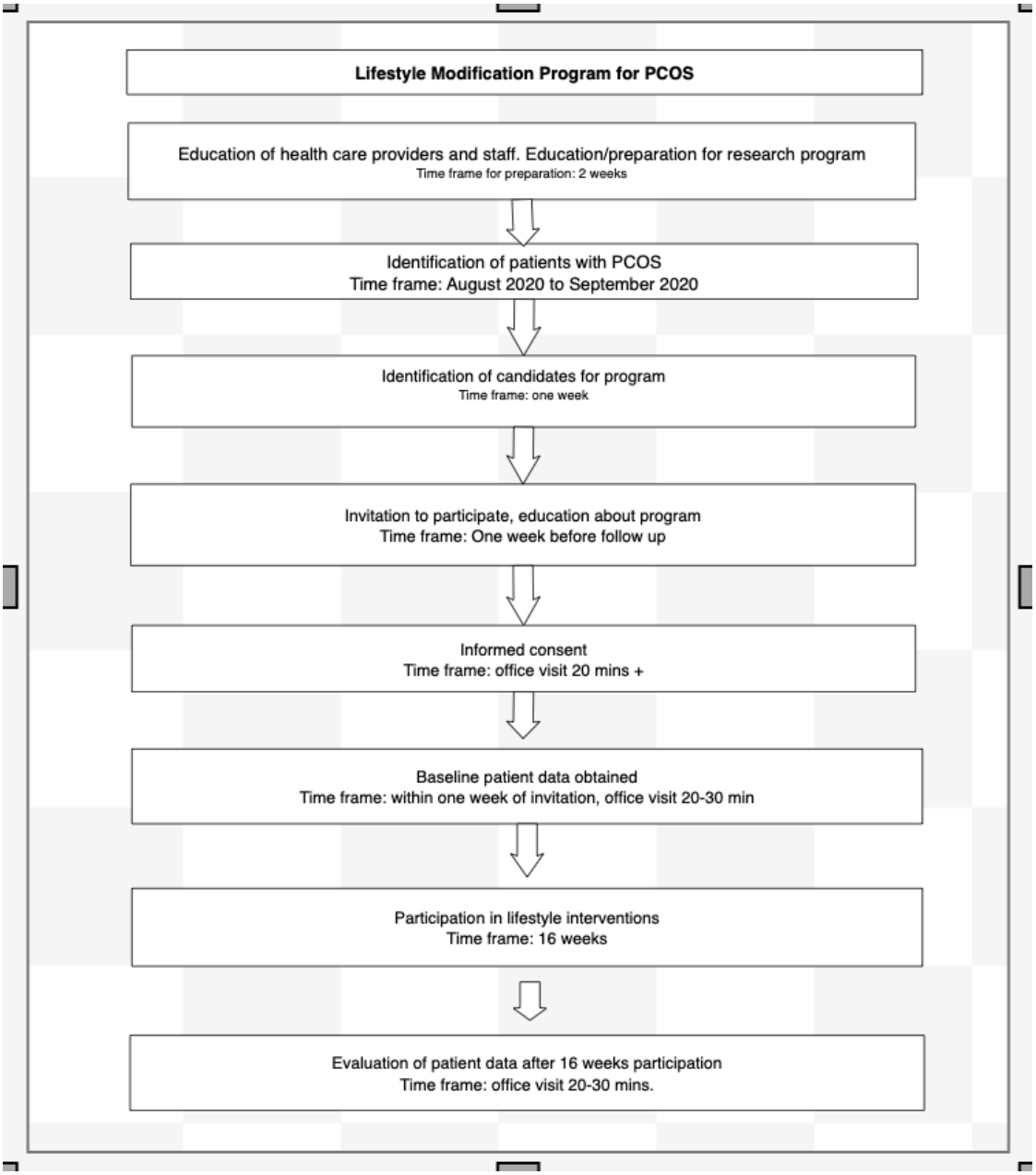
V=vomiting

P=placebo

LH= Leutinizing hormone

Appendix B

Lifestyle Modification Change Project Flowchart



Appendix C

Health-Quality of Life Questionnaire

Please fill out the following questions and submit to health care provider:

1. Over the past year have you had problems with fertility or menstrual cycle regularity?
    - Never
    - Sometimes
    - Often/Always

2. Over the past month have you felt unsexy?
    - Never
    - Sometimes
    - Often/Always

3. Over the past month have you felt unhealthy?
    - Never
    - Sometimes
    - Often/Always

4. Over the past 6 months have you had issues with body image?
    - Never
    - Sometimes
    - Often/Always

5. Over the past 6 months have you felt frustrated with your diagnosis of PCOS?
    - Never
    - Sometimes
    - Often/Always

6. Over the past 6 months have wanted to take control of your diagnosis of PCOS?
    - Never
    - Sometimes
    - Often/Always

7. Over the past month have you had issues with facial hair growth?
    - Never
    - Sometimes
    - Often/Always

8. Over the past month have you depression or anxiety?
    - Never
    - Sometimes
    - Often/Always

Appendix D

Evaluation Form

Please fill circle and answer the following questions:

1. The presentation of education material was adequate:
    - Poor
    - Good
    - Excellent

2. The office staff and provider were able to answer questions:
    - Poor
    - Good
    - Excellent

3. I was able to understand about the benefits of lifestyle interventions:
    - Poor
    - Good
    - Excellent

4. I understand about the associated co-morbidities often found with PCOS:
    - Poor
    - Good
    - Excellent

5. I am likely to complete lifestyle modifications after completing the program:
    - Not likely
    - Maybe
    - Absolutely

Please leave comments, suggestions, or complaints for the researcher to evaluate: