PILOTING AN EDUCATIONAL PROGRAM TO REDUCE OBESITY AMONG POLYCYSTIC OVARY SYNDROME PATIENTS IN INDIA: A COMMUNITY SERVICE GRANT PROPOSAL

By

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Community Service Grant Proposal Framework

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EXECUTIVE SUMMARY

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder which affects up to one in five reproductive-aged females. Causes of PCOS are not known but there are some factors such as excess insulin, low grade inflammation and hereditary predisposition leading to increased androgen production which may play role in causing PCOS. Obesity, excess hair growth, acne, oligomenorrhea or amenorrhea, hirsutism, infertility, depression and anxiety are the consequences of this condition in women with PCOS. Studies have suggested that weight loss will be helpful for the obese women with PCOS by improving their health condition and preventing serious PCOS related complications. This proposal suggests piloting an educational program aimed at obesity reduction among obese women with PCOS in Chennai, Tamilnadu, India, to find out whether the educational program is effective enough to reduce Body Mass Index (BMI) among them. Random cluster sampling will be applied to select 10 gynecological clinics from the list of all gynecological clinics in Chennai, of which 5 centers will be randomly assigned to the intervention group and the remaining five to the control group. Target population will include PCOS women with BMI $\geq$ 30 in the age group of 18-44 years living in Chennai. The education program will be implemented (after the collection of baseline data) in the intervention group. The education will be provided by trained doctors working in the intervention clinics. Additionally, we will provide some educational materials to the eligible women served by the intervention clinics. Education will aim to increase women's knowledge of PCOS, and to improve their knowledge, attitude and practice (KAP) towards healthy lifestyle (diet and physical activity). All eligible women served by intervention clinics will be invited to participate in the program. This pilot educational program will be evaluated to identify its effectiveness in reducing BMI among target population. The participants for this evaluation will be chosen by simple random sampling among eligible women from each clinic of both intervention and control groups.

The evaluation will apply randomized, pre-post, experimental design to estimate and compare the mean BMI and KAP scores between the intervention and control groups. The educational program will be considered effective if in 6 months it results in relative reduction (at least 5%) of mean BMI among the target population in the intervention group when compared to the control group. Baseline and follow-up data collection will be done among a representative sample of women from intervention and control groups via height and weight measurements, and interviews using a structured questionnaire to assess their healthy lifestyle-related knowledge, attitude and practice. The surveys will be interviewer administered face to face interviews. Double data entry will be done using SPSS statistical software. Descriptive data analysis will be used to identify any important differences between intervention and control groups. Paired t-test analysis will be applied to evaluate the change in the mean BMI and the KAP score between the baseline and follow-up. The between group differences will also be examined. To control for any important differences between the groups, multiple linear regression analysis will be used to identify the adjusted associations between the education and the change in the mean BMI and the KAP score. If the evaluation proves that the educational program is effective in reducing weight among obese women with PCOS, then the program will be recommended for a statewide implementation. If the educational program proves to be ineffective in achieving its targets, the reasons for this will be identified and, accordingly, recommendations will be made to either improve educational activities or find ways to improve women's attendance to these activities.

AIM AND OBJECTIVES OF THE PROPOSED PROJECT

The proposed project aims to implement and evaluate a pilot educational program to reduce obesity among reproductive age women with PCOS and obesity residing in Chennai, Tamilnadu, India.

The specific objectives of the program include the following:

- In six months after the end of the education program there will be at least 5% relative reduction of mean BMI among the intervention group when compared to the control group.[1]
- In six months after the end of the education program there will be at least 15% relative increase in the PCOS knowledge score among the intervention group when compared to the control group.[2]
- In six months after the end of the education program there will be at least 30% relative increase in the healthy lifestyle (nutrition and exercise) related knowledge, attitude and practice (KAP) score among the intervention group when compared to the control group.[3]

Target Population: Women diagnosed with PCOS in the age group of 18-44 years (reproductive age women are a major risk group for PCOS)[4] with BMI≥30 living in Chennai, India.

INTRODUCTION

Background

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder affecting up to one in five reproductive-aged females.[5] The prevalence of PCOS varies depending on the diagnostic criteria applied. Globally, the prevalence of PCOS is found to be highly variable ranging from 2.2% to 26%.[6–9] A study conducted in Spain found the prevalence of PCOS in overweight and obese women to be 28.3%.[10] The PCOS diagnostic criteria suggested by the European Society for Human Reproduction and Embryology (ESHRE), known as the Rotterdam criteria, which yield a prevalence rate of PCOS as high as 15%-20%, globally.[11,12–15] The confirmation of PCOS diagnosis requires at least two of the following criteria: [16]

A) Clinical or biochemical hyperandrogenism

B) Anovulation (chronic or oligomenorrhea) which is defined as having less than 10 menstruations in a year (> 35 days intervals between menstruations) or evidence of the lack of ovulation despite regular menstruations

C) Polycystic ovaries on ultrasound.

Causes and consequences of PCOS

Causes of PCOS are unknown; however, there are several factors such as excess insulin, low grade inflammation and genetic leading to increased androgen (male sex hormone) production, which may play role in causing PCOS.[17] Additionally, PCOS can be caused by interaction of some environmental and genetic factors.[18] Environmental exposure to some industrial products, like Bisphenol A (BPA), may also aggravate the clinical course of PCOS.[19] Advanced Glycated End products (AGEs) and BPA may act as endocrine disruptors

involved in the pathogenesis of the syndrome.[19] Inherently predisposed individuals have insidious influence of the environment on reproductive and metabolic balance which leads to PCOS.[19] Obesity and insulin resistance often lead to increase in androgen and testosterone causing anovulation, which eventually leads to the formation of fluid filled cysts in the ovaries (observed by ultra sound examination).[20, 21] This anovulation causes excess hair growth, acne, oligomenorrhea or amenorrhea, hirsutism, infertility, depression, anxiety, and obesity.[11] Anovulation can lead to problems with periods and conception of pregnancy and it is one of the main causes of infertility.

PCOS can lead to obesity, especially abdominal obesity.[22] A study related to the size of abdominal adipocytes among PCOS women revealed that women with PCOS had higher abdominal accumulation of adipose tissue.[23] Untreated PCOS can eventually lead to serious health problems, such as diabetes and heart disease.[24] Pregnant women with PCOS have significantly higher risk of pregnancy-related complications which includes gestational diabetes, hypertensive disorders, cardiovascular problems, premature delivery, and delivery by cesarean section.[25 -26] Offspring's of women with PCOS may have increased risk of congenital abnormalities.[5] Pregnancy complications and adverse neonatal outcomes are more prevalent among female with PCOS independent of obesity.[27-28]

Situation in India

A recent study has proved that the prevalence of PCOS in Indian adolescent women is 9.13%.[29] A cross-sectional study conducted among adolescents (15-24years) in Mumbai found the prevalence of PCOS to be 22.5%.[30] The prevalence of being overweight and obese (BMI≥25kg/m2) was found to be 24.6% among general population in Tamilnadu.[31]

PCOS and obesity

According to the World Health Organization (WHO), a BMI ≥30 is considered obese. Obesity is one of the important factors resulting in PCOS and other reproductive problems.[32] The effect of obesity on PCOS is mediated through its negative impact on insulin resistance.[33,34] Weight loss can reduce both insulin and androgen levels which may restore ovulation.[35] There are various factors that can lead to obesity. These factors include over nutrition and using a diet high in AGEs.[19] Women with PCOS are found to have increased atherogenic potential due to high levels of Low Density Lipoproteins(LDL) and triglycerides and low levels of High Density Lipoprotein (HDL).[36] Thus, PCOS women have increased risk of developing diabetes and cardiovascular disease if left untreated.[37] A family history of obesity is also linked to PCOS phenotype.[38] For treatment of PCOS, metformin and clomiphene are given to regulate menstruation and ovulation.[39,40] Reducing obesity also can help preventing many complications of PCOS.[41,42] A meta-analysis reported improved levels of Follicle Stimulating Hormone (FSH), sex-hormone binding globulin, total Testosterone (T), androstenedione, Free Androgen Index (FAI), and Ferriman-Gallwey (FG) score as a result of lifestyle interventions (diet and physical activity) in women with PCOS; with improvements in metabolic indicators.[43]

Rationale for the proposal

Literature suggests that obesity is one of the main causes of PCOS and other reproductive problems among women, and it may become worse due to PCOS itself. Hence, it is important to control obesity among individuals with PCOS.[32] According to several studies, reduction of obesity can be achieved by education through the following ways:[44,45]

1. Creating awareness among women with PCOS and obesity about their health conditions and the recommended healthy lifestyle interventions (exercise and diet).

2. Creating awareness about the late complications of PCOS among physicians to diagnose PCOS at earlier stages and start a proper treatment to prevent complications.

A pilot educational project will be conducted in Chennai (the capital city and one of the districts of Tamilnadu) and the educational program's effectiveness will be evaluated. Education of women with PCOS can help them in improving their understanding of disease causes and the treatment/management of choice.[46] Structured education programs can also help empowering patients to take control of the disease-associated long term risks.[47] Currently, there are several guidelines to reduce PCOS, and reduction in obesity by proper diet and exercise is one of the most effective strategies to prevent further complications among PCOS patients.[48] Increasing knowledge, understanding of the underlying condition and interaction with peers are the main elements of a group-based structured education program.[49] According to research studies, lifestyle intervention about specific lifestyle changes such as dietary[50] or physical activity[51] or both[52,53–55] would help to improve the health condition of PCOS patients. Some of the studies noted that the intensity, duration, and type of exercise didn't have any impact in the improvements in PCOS symptoms.[56] However, the exercise that help to manage insulin and glucose levels, cardio training and strengthening exercise could help them to overcome the symptoms of PCOS, prevent cardiovascular disease and insulin resistance, increase basal metabolic rate, and lose weight.[56] According to an Australian evidence-based guidelines for assessment and management of PCOS, patients should be doing 150 minutes of exercise per week (30 minutes five times per week), with 90 minutes of that being moderate to high intensity aerobic exercise and two of those sessions being resistance or strength training.

METHODOLOGY

Appendix 1 illustrates the conceptual framework that will be applied to evaluate the proposed program.

Implementation plan

Settings of the educational program

Piloting of the educational program will be done in five randomly selected clinics in Chennai (the capital city and also a district of Tamilnadu). The education program will last for one month (April 2018). To select clinics for the intervention and its evaluation, a simple random sampling will be used from the list of all gynecological clinics located in Chennai. All women meeting the criteria for target population (women diagnosed with PCOS in the age group of 18-44 years with BMI $\geq$ 30 being served by the selected intervention clinics in Chennai, India) will be eligible to participate in the educational program. The eligibility of participants will be evaluated through their medical records in those clinics. The addresses and the phone numbers will be taken from their medical records along with patients' name, age, height and weight (to calculate BMI). The participants will be recruited by an assigned nurse in each clinic. Nurses will call eligible individuals to inform them about the educational program and invite them to participate in the program.

Two obstetrician/gynecologists (ob/gyns) from each intervention clinic will be chosen by merit and qualification to participate in training of trainers (TOT). An expert will be hired by the program coordinator to train these doctors. The TOT will focus on the methodology and content of educating this specific group of patients. In each hospital, two half-day (total of 8 hours) TOTs will be conducted. Then the trained doctors will educate the women (target population) about PCOS, its underlying conditions, and lifestyle strategies and interventions (regular exercises and dietary changes) for reducing weight. Participants will be invited

during every weekend (since the doctors could be busy during weekdays) to attend the lectures. The lectures will be about:

- The healthy lifestyle (diet and exercise) to be followed
- The late complications of PCOS.

The lectures will be held in each intervention clinic. The participants of the intervention group will be invited to attend the lectures in the clinics where they are registered. There will be four sessions in total. Each session will last for about two hours. The sessions will be held by the trained doctors.

Content of the educational program

The educational materials will be developed by an expert. All participants in the intervention group attending the lectures will be provided with educational materials. The educational materials include:

1. Brochures of about 22 pages, which will contain information on:

- Risk factors for complications of PCOS and treatment of PCOS
- Dietary recommendations to be followed (each food will be demonstrated with proper instruction including the name, pictures and the amount to be taken)
    - Hypocaloric food
    - Hypoglycemic food
    - Protein rich food
- Physical activities and exercise
    - Promotion of physical exercise of appropriate intensity and duration (each exercise will be demonstrated with proper instruction including relevant pictures and the duration of each step mentioned clearly).

2. Also a **video material** will be given which will include some information about healthy diet and instruction for doing physical exercise. The video will be particularly helpful for illiterate women, but also for literate women since it will make the learning process easier. The video will be a half an hour, and will include:

- 15 minute demonstration of exercise,
- 10 minute introduction of diet to be followed,
- Five minute explanation of the possible complications of PCOS if left untreated.

In summary, each participant will have access to:

- Eight hours (four two-hour sessions) of lectures about lifestyle changes and late complications of PCOS,
- 22-page brochure,
- Half an hour video material.

Aim of the Educational program

The main aim of the educational program is to reduce obesity among women with PCOS.

Objectives of the Educational program

- Relative reduction of mean BMI by at least 5% among the intervention group when compared to the control group.
- Relative increase in PCOS knowledge score by at least 15% among the intervention group in 6 months when compared to the control group.
- Relative increase in healthy lifestyle KAP score by at least 30% among the intervention group in 6 months when compared to the control group.

Evaluation plan

Settings/sources of evaluation program *(please refer to appendix 2 for the timeline)*

For the evaluation of the program, a total of 10 clinics in Chennai will be included. For selecting the clinics, a random cluster sampling will be used. Each clinic will serve as a cluster. Five of the 10 randomly selected clinics will be randomly assigned to the intervention group (education program implementation) and another five to the control group. Simple random sampling will be used to select the participants from each clinic based on the sample size for evaluation. The evaluation of the pilot educational program will follow a randomized pre-post experimental design *(Table 1).* As a panel study, the follow-up survey will be conducted among those who were included in the baseline survey. All those who agreed to participate in the baseline phase will be included in the follow-up phase of the evaluation. The baseline (pre-intervention) survey will be conducted in March, 2018, before the start of the educational program in the intervention clinics, and the follow-up (post-intervention) survey – 6 months after the completion of the educational program (November, 2018).

Table 1. Design of the evaluation study – Campbell & Stanley nomenclature:

Group:	**Pre-test**	**Treatment**	**Post-test**
Experimental group =	O1	X	O2
R			
Control Group =	O1		O2

Where,

O1 is the pretest conducted in both intervention and control groups.

O2 is the posttest conducted in both intervention and control groups.

X is the intervention of the structured educational program.

R is the randomization done at the cluster level. Each cluster is randomly assigned either to the control or the intervention group.

Rationale for the design: Control group helps to figure out the changes that are not related to the intervention, so that the internal validity of the study is improved. Since this is an educational program, the intervention will be implemented at the cluster (clinic) level to avoid contamination. Panel design (same individuals in both the baseline and the follow-up surveys) is suggested for this study since the results of an educational program can be more accurately compared in the same individuals between the baseline and the follow-up assessments.

Data collection

The baseline data collection will be conducted during March 2018. For this purpose participants will be chosen randomly from the medical records of those 10 clinics (both intervention and control groups). The baseline survey and assessment (March 2018) for measuring BMI, knowledge about PCOS and knowledge, attitude, practice about healthy lifestyle will be conducted among both the intervention and the control groups. After the collection of baseline data, the education program will be implemented in the intervention clinics and all the eligible participants served by these clinics will be invited to participate in the program. Then the post-test assessment will be done at the follow-up (November 2018) in both the intervention and the control group six months after the implementation of the educational program. The instruments and interviewers will be the same as at the baseline phase.

Study instrument

BMI will be calculated by measuring weight and height (BMI= weight (kg)/height^2 (m^2)). Digital weighing scale will be used to measure weight and stadiometer will be used to measure height of the participants. Standard protocols will be followed while taking the measurements. For the measurement of weight participants will be asked to put on light dresses instead of heavy clothing, the scale will be placed on a flat surface and accurate measurement will be done asking the participant to stand straight on the weighing scale. For measuring the height participants will be asked to remove high heels and accurate measurements will be taken by asking them to stand straight with their legs together and straight. Then using those measurements BMI will be calculated using calculator by the same interviewer. Then the measured BMI will be used to compare the results of pre and post assessment. Trained interviewers will conduct the measurement of height and weight during their visits for the interviews. The questionnaire will be developed in English and translated into Tamil (local language). Interviews will be conducted in the local language. Local language is preferred since many people might not understand English. The questionnaire will be pre-tested among a similar group of women and will be modified based on the feedbacks from the pre-test. The questionnaire will include five parts *(presented in Appendix 3)*:

I. Socio-demographic information
   - Anthropometric measurements

II. General questionnaire to assess the knowledge, attitude, and practice
   - Knowledge of PCOS
   - Knowledge, attitude and practice of healthy lifestyle
   - Measuring BMI of the participant

III. Women's health condition

IV. Level of exposure to the educational program (only for the follow-up intervention group)

V. Satisfaction with the program (only for the follow-up intervention group)

Alternate Hypothesis: There will be a relative (at least 5%) reduction in the mean BMI of participants in the intervention group as compared to those in the control group.

Null hypothesis: There will be no significant reduction in the mean BMI of women in the intervention group as compared to those in the control group.

Variables

Appendix 4 presents all the variables of the study

Independent variable: Presence or absence of the educational training

Dependent variables:

Primary: BMI

Secondary: Mean knowledge score of PCOS, mean KAP score on healthy lifestyle, women's satisfaction with the educational program (organization, setting, content, educational materials, manner of teaching).

Covariates:

- Presence of obesity due to other causes such as age, family lifestyle, other medical problems (insulin resistant diabetes, endometrial cancer), usage of certain medications (anti epileptics), socio-economic status, pregnancy, stress, sleep disturbances.
- Participation in other relevant educational programs.

Sample size calculation

The sample size for evaluation study is calculated using the formula used for comparison of 2 sample means.

The formula that will be used for this evaluation program depending on the outcome which is continuous will be the following:[57]

$$N = \frac{2\,(z_{\alpha} + z_{\beta})^2\,(1+(n-1)\,\rho)}{n\,[(\mu_{1} - \mu_{2})/\sigma]^2}$$

$z_{\alpha} = 1.645$

$z_{\beta} = 0.84$

$\Delta = \mu_{1} - \mu_{2} = 1$

$\sigma = 5.89$

$\rho = 0.8$

n=2 (pre & post assessment)

A design effect of 1.2 was used.

N=232.7*1.2=279.32

Further adjustment for 20% loss to follow-up was done.

N=279*1.25=349

N=349

N is the number of participants in one group (either control or intervention group). So, totally, **698** participants will be included in the evaluation. Since there are 10 clinics totally, **70** participants from each clinic will be randomly chosen.

Threats to internal validity

History may be a threat because some other program may be going on at the same time.

Maturation is a threat because people mature naturally with time since our study is a panel study which includes the same people in both baseline and the follow-up. This can also be controlled by comparing the intervention to the control group.

Testing is a threat since the same questionnaires will be used in both baseline and follow-up. Although this cannot be avoided, it can be controlled by referring to the control group.

Selection bias could be a threat since there might be a chance of getting incomparable groups. Though randomization is done, the limited number of clusters could cause selection bias.

Attrition is a threat since it is a panel design. This can't be excluded but can be reduced by comparing the characters of people dropped out to the people still in the study.

Compensatory rivalry is a threat since there is a control group.

Hawthorne effect: This can be a threat to both the control and the intervention group since it is an educational program they might become aware of the program. This would affect the knowledge of the control group which would eventually interfere with their BMI.

Threats to external validity

Testing treatment interaction is a threat to the external validity since study includes pre-post testing. This can be controlled through the control group.

Selection-treatment interaction is a threat since the characters can't be generalised for different regional people. The clinics and the patients belonging to these settings would be the same all over the world. They would vary geographically.

Reactive/Situational effects is a threat since people might become aware of the program evaluation (purposefully influence their weight) so their behaviours might be changed.

Multiple treatment effects is a threat to external validity since different program may be going

on in different regions and the same people can be subjects to different interventions at the same time.

Team members included in the evaluation program

- **Program coordinator:** The program coordinator will be an MPH graduate (the researcher) who would be involved in the processes of the program evaluation and piloting of the educational program. The coordinator will be responsible for:
    1. Selecting gynaecological centres, and also selecting participants for the study
    2. Hiring an expert who will train the doctors to educate the participants
    3. Participate (together with the expert) in developing the educational program curriculum and materials
    4. Developing study instruments
    5. Conducting training sessions for the interviewers for data collection for both interviews and anthropometric measurements
    6. Coordinating the fieldwork
    7. Coordinating the data entry
    8. Analysing data and developing a report
    9. Making recommendations
    10. Maintaining the involved materials, reports and datasets.

The following personnel will be engaged in the following activities: training, development and distribution of educational materials, data collection, and data entry.

- **Expert:** One expert for developing the educational materials.
- **Trainer:** One trainer to train doctors in intervention clinics.
- **Interviewers:** Interviewers will conduct the interviews. They will be trained by the coordinator to conduct the interviews. Two of them will be needed for this evaluation.

- **Nurses:** Nurses will recruit participants for educational program. One nurse from each intervention clinic will be involved. Totally five nurses will be involved. They will identify the eligible women, call them and invite for the educational program**.**
- **Doctors:** Doctors will educate the participants. Two doctors from each centre of the intervention group will be involved in the education program and they will be trained by the trainer. So, totally, ten doctors will be involved. At the end of the lectures, brochures and videos will be given to the participants by the doctors.
- **Data entry staff:** Two data entry staff will be trained by the coordinator for data entry. Double data entry will be done. Each of them will enter the collected data in a separate data set. Then these two datasets will be merged and the identified discrepancies eliminated. Their tasks would include the following:
    - Receive the collected data and check for the mistakes
    - Careful data entry
    - Merging the two datasets and data cleaning.

Data Entry

The data collected through interviews and the BMI variable will be entered in SPSS and analysed in STATA (statistical software package).

Data Analysis

Two variants of analysis will be done in order to control for the level of exposure to educational activities (if the program was ineffective due to insufficient exposure to it or the program content/effectiveness). So, first analysis will be done by including all the women from the intervention group irrespective of the level of their exposure to the educational program (*Intention to treat* principle). This group will be compared to the control group in order to see if the education program was effective as a whole.

The second analysis will be done by selecting women who attended at least 1 lecture (of 4) or used at least one of the educational materials provided. Within this group, those with minimal exposure to educational activities (attending one lecture and/or using one educational material) will be compared to those with more than minimal exposure (attending more than one lecture and/or using more than one educational material). This will be useful to know if the program was ineffective due to insufficient exposure of the intervention group members to the education program. The outcome variables will be continuous, since we are going to measure the reduction in the mean BMI, mean knowledge score about PCOS, and mean knowledge, attitude and practice score about healthy lifestyle. For the intervention group, women's satisfaction with educational program (organization, setting, content, educational materials, manner of teaching) will also be measured. Descriptive analysis will be used to explore the distribution of selected characteristics in the two groups. The data for continuous variables will be described using the measures of central tendency (mean, median and mode) and the measures of variability (standard deviation). The data for the categorical variables will be described using frequencies or percentages. Two sided t-test will be used for continuous variables to compare the difference in means between the intervention and the control groups. Paired t-test will be used to do pre-post comparisons. Since the outcome variables are continuous, linear regression analysis will be used to determine the relationship between the dependent and the independent variables. For the analysis comparing groups with various levels of exposure to the educational program, selected covariates (age, family lifestyle, presence of insulin resistant diabetes, endometrial cancer, usage of anti epileptics, socio-economic status, pregnancy, stress, sleep disturbances, participation in other relevant educational programs) will be controlled for to estimate the adjusted association between the dependent and independent variables *(Refer to Appendix 4 for variables: outcome, independent and covariates*). Generalized linear models such as Multiple Linear Regression

(MLR) and other relevant methods will be used to assess the change in the outcomes over time and to compare those changes across groups. All the models will have relevant random intercept/s to account for clustering (by clinic) and longitudinal nature of data. Data analysis will be done in November and December 2018. During the same period, a report on the study findings will be developed. The final report will be submitted by the end of December 2018.

BUDGET

Budget (refer to Appendix 5) is framed according to the time duration of the program, participants and work load of the personnel. It is also framed according to personnel and other direct costs for both educational and evaluation activities. The total personnel cost for educational program is $4700, the total for other direct costs for educational program is $8048, the total personnel cost for evaluation program is $16,180; the total for other direct costs for evaluation program is $23,010. The overall total amount is $51,938. The funding request will be applied to the NGO named Noble Cause Foundation which is located in Bengaluru, India, whose mission is "to identify and work alongside the economically and socially deprived, so that they become educated, skilled and aware; enable them to be self-reliant and enjoy a healthy, dignified and sustainable quality of life". If they deny accepting the proposal, we will apply to other local NGOs in Chennai.[58]

ETHICAL CONSIDERATIONS *(Refer to Appendix 6 for Consent forms)*

The evaluation plan would satisfy all the aspects of ethical considerations. Each interview will start with obtaining an informed consent form. Study participants will be informed about the study and will be given assurance that the data used for the study will not be used for any purposes other than the evaluation. Confidentiality assurance will be given. The benefits and the risks of the participation will be informed to them. They will benefit by participating in the education program since both their knowledge and health would be improved after. They

don’t have any risk in participating in this study except that they have to spend a little more time for answering the questionnaire/participating in the study. They will be informed that the participation will be completely voluntary, that they can drop out from the study whenever they feel like discontinuing. After the post-assessment interviews, educational brochures will be given by the interviewers to the control group as well. Hence, by participating in the evaluation both the intervention and the control groups will benefit by these materials.

If the evaluation program proves that the education is helpful to reduce weight among obese people with PCOS, then the program will be implemented statewide based on the study findings. If the education program proves to be ineffective due to its content and/or administration style, recommendations will be made for improving educational activities. If the educational program proves to be ineffective due to insufficient exposure of women to the educational interventions, efforts will be made to find ways to improve women’s attendance, e.g.,

1. The participants will be provided some incentives like a free check-up (ultra-sound scanning) if they complete the full educational program

2. The awareness of the program will be increased through mass media (e.g. advertisements, posters).

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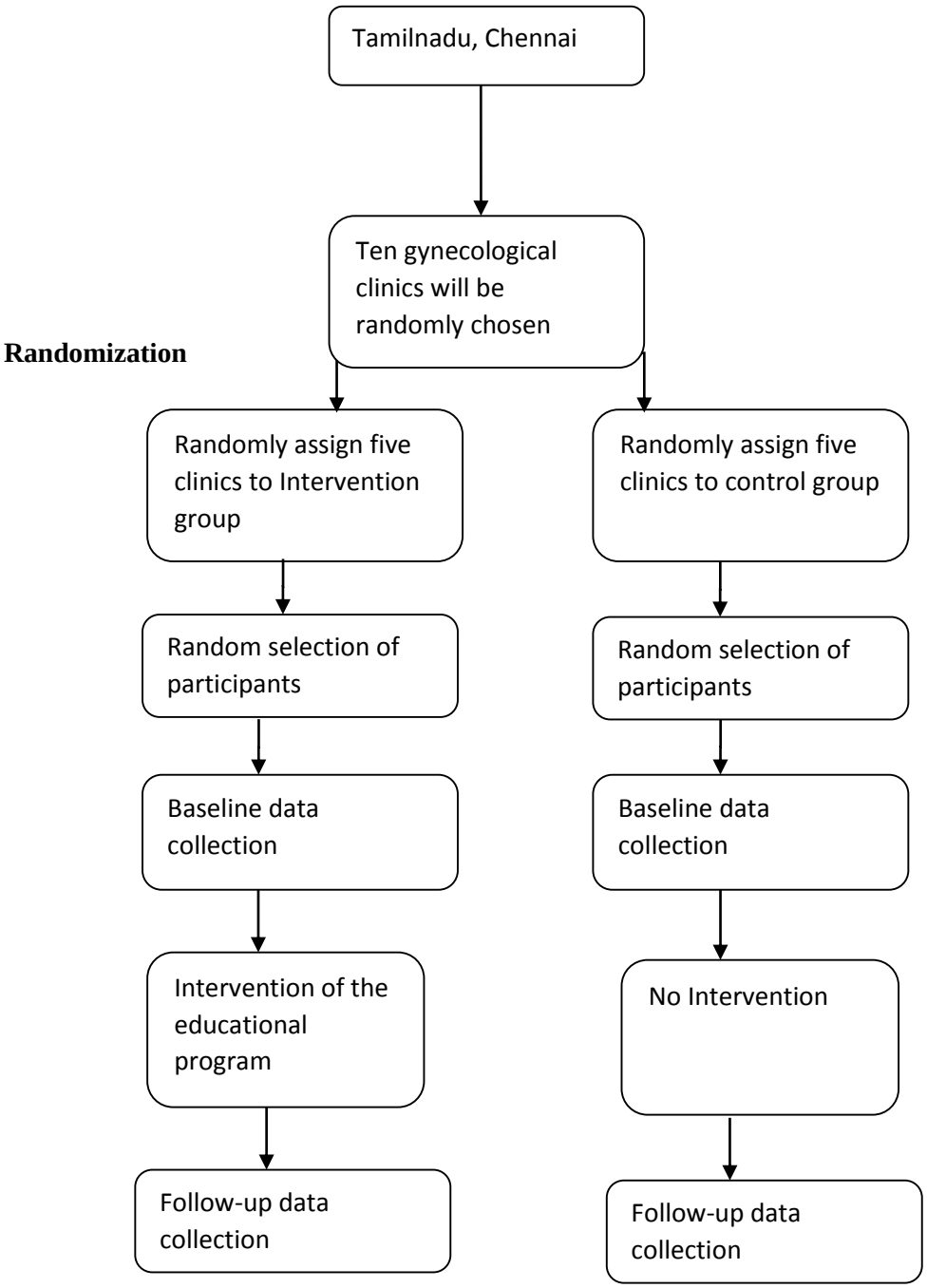
Appendix 1. Evaluation program conceptual framework



Appendix 2. Timeline for evaluation

Year 2018	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Activities	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Preparation phase (sampling and setting)	X	X										
Identifying study expert	X											
Developing the educational materials, identifying the eligible participants and inviting	X	X	X									
Developing pilot program design, including the evaluation study		X										
Developing study instruments		X	X									
Pre-testing study instruments		X	X									
Conducting pre-assessment			X									
Distributing brochures and education program implementation				X								
Conducting post-assessment											X	
Entering, cleaning and analysing the data											X	
Preparing the final report											X	X
Submitting the final report												X

Appendix 3. Questionnaire
(for both baseline and follow-up)

(99 for 'refusal' to answer any question, 100 for the option 'others', 0 for missing values)

Survey Questionnaire:

Subject ID:

DD MM YY: ___/___/___

I. Socio-demographic data:

1. Date of birth (DD MM YY): ___/___/____
2. Age of puberty attainment: _____y
3. Education:
    1. No schooling completed
    2. Nursery school to 10th grade
    3. Some high school
    4. High school graduate, diploma
    5. Bachelor's degree
    6. Master's degree
    7. Doctorate degree

5. Marital status:
    1. Single
    2. Married
    3. Divorced
    4. Widowed

6. Employment status:

1. Job involving sedentary life style
2. Job with heavy physical work
3. Not working

7. What is your family's monthly income?

1. More than $1000 2. $500-$1000 3. Less than $500

Anthropometric measurements:

8. Height in Meters (M) _____

9. Weight in Kilo Grams (KG) _____

II. General Questionnaire to assess the knowledge, attitude and practice:

Knowledge on PCOS:

1. Do you think PCOS is a severe health problem? ***(Read all the response options and mark any one of these options)***

1. Yes
2. No
3. Don't know

2. What are the causes of PCOS that you know? **(*Do not read the response categories, mark all that are stated)***

1. Hereditary
2. Obesity
3. Diabetes
4. Cholesterol and blood fat abnormalities
5. Cardiovascular diseases
6. Infection
7. Poor hygiene
8. Other _____

3. What are the signs and symptoms of PCOS that you know? **(*Do not read the response categories, mark all that are stated)***

1. Weight gain
2. Menstrual disturbance
3. Acne
4. Hirsutism
5. Anxiety
6. Depression
7. Breathing disorder
8. Weight loss
9. Anorexia
10. Fever
11. Vomiting
12. Other _____

4. What are the consequences of PCOS that you know? **(*Do not read the response categories, mark all that are stated)***

1. Diabetes
2. Heart disease
3. Pregnancy complications
4. Mental disorder
5. Kidney failure
6. Hearing disorder
7. Other _____

5. What are the aggravating factors of PCOS that you know*? **(Do not read the response categories, mark all that are stated)***

1. Physical inactivity
2. Diet
3. Obesity
4. Climate
5. Stress
6. Infection
7. Allergens (like dust)
8. Alcohol
9. Other _____

6. Do you think obesity has an influence on PCOS? ***(Read all the response options and mark any one of these options)***

1. Agree
2. Don't agree
3. Don't know

7. Do you think PCOS can be controlled with proper management? ***(Read all the response options and mark any one of these options)***

1. Agree
2. Don't agree
3. Don't know

Knowledge on healthy life style:

8. Please, state by which measures PCOS can be managed? ***(Do not read the response categories, mark all that are stated)***

1. Medicines
2. Diet
3. Physical exercise
4. Surgery
5. Physiotherapy
6. Ayurvedic treatment
7. Bed rest without any physical activity
8. Other _____
9. Cannot be managed at all once symptoms appear

9. What do you think which of the following exercises will be useful for PCOS patients? ***(Read all the response options and mark any one of these options)***

1. Aerobic for 2 days in a week (60 mins totally with mild exercise)
2. Aerobic for 5 days in a week (150 mins with 90 mins of moderate to intensity exercise)
3. Aerobic for 7 days in a week (300 mins with severe intensive exercise)
4. Heavy muscle strengthening exercise
5. None of these

10. Which diet changes would you recommend for PCOS women? ***(Do not read the response categories, mark all that are state)***

1. Hypo caloric (more fruits, vegetables)
2. Hypoglycemic (less sweetened foods like fresh fruits)
3. Protein rich (fish, milk)
4. Less fat (oil free food)
5. Other changes_____
6. No changes

Attitude: ***(Read all the response options and mark one stated option)***

11. How often do you worry about your PCOS condition?

1. Often
2. Sometimes
3. Not at all

12. How often do you discuss your condition with your doctor?

1. During every visit
2. Sometimes
3. Only if they tell something I listen, otherwise no

13. Do you think obesity reduction helps to reduce PCOS complications?

1. Definitely
2. May be
3. Not at all

14. Do you think correct diet will be helpful to manage PCOS?

1. Definitely
2. May be
3. Not at all

Practice: ***(Read all the response options and mark one stated option)***

15. Have you ever tried to reduce your weight?

1. Yes
2. No

16. How often do you exercise?

1. Regularly
2. Sometimes
3. Not at all

17. How do you follow a diet to manage PCOS?

1. Very strictly
2. Strictly
3. Liberally
4. Not at all

18. To what extent your family follows healthy lifestyle in terms of diet and physical activity?

1. Very strictly
2. Strictly
3. Liberally
4. Not concerned about healthy lifestyle

III. Woman's health condition:

19. Do you have insulin resistant diabetes?

1. Yes
2. No
3. Don't know

20. Do you have endometrial cancer?

1. Yes
2. No
3. Don’t know

21. Do you have lipid abnormalities?

1. Yes
2. No
3. Don’t know

22. Do you use antiepileptic drugs?

1. Yes
2. No
3. Don’t know

23. Do you use any weight reducing drugs like orlistat?

1. Yes
2. No
3. Don’t know

24. Do you use anti-diabetic drugs (like metformin)?

1. Yes
2. No
3. Don’t know

25. How many children do you have? ***(Read all the response options and mark as many as apply)*****:**

1. Nulliparous (no children)
2. Parous (single child)
3. Multiparous (more than one child)
4. Currently pregnant

(For the next three questions, read all the response options and mark the stated option.)

26. How much are you stressed with your work?

1. Not at all
2. A little
3. Moderately
4. Very much
5. Extremely

27. How much are you stressed with your family?

1. Not at all
2. A little
3. Moderately
4. Very much
5. Extremely

28. How much are you stressed because of your health?

1. Not at all
2. A little
3. Moderately
4. Very much
5. Extremely

29. Did you participate in any other educational program on healthy lifestyle or PCOS during the last seven months?

1. Yes
2. No

IV. Level of exposure to the educational program: **(This section is included only in the follow-up assessment of the intervention group)**

(For the next three items, read all the response options and mark the stated option.)

30. Number of lectures that you have attended in your gynecological clinic during April 2018?

1. One
2. Two
3. Three
4. Four
5. None

31. What educational materials did you receive from the clinic?

1. Video and brochure
2. Only video
3. Only brochure
4. None of them ***(Go to the next section)***

32. Of the educational materials you received, which materials you have followed?

1. Both video and brochure
2. Only video
3. Only brochure
4. None of them

V. Satisfaction with the program (*only for the follow-up intervention group*):

The following questions are about the extent you are satisfied with your gynecological clinic and the educational sessions you attended there. ***(Ask only those women with at least minimal exposure to educational sessions. Read all the response options and mark one stated option for each item).***

1. What do you think about the overall service provided by the clinic?	1. Good	2.Fair	3.Bad
2. How was the overall organization of the educational sessions?	1. Good	2.Fair	3.Bad
3. How was the setting where the lectures were provided?	1. Good	2.Fair	3.Bad
4. What do you think about the provided educational materials?	1. Good	2.Fair	3.Bad
5. How was the brochure structured?	1. Good	2.Fair	3.Bad
6. How effective was the video?	1.Very helpful	2.Helpful	3.Not so helpful
7. What do you think about the improvement of video materials?	1.Should be improved far better	2.Few corrections can be done	3.No need of any changes
8. What do you feel about the content of the educational materials?	1. Good	2.Fair	3.Bad
9. How was the manner of teaching?	1. Good	2.Fair	3.Bad
10 How informative were the lectures?	1. Good	2.Fair	3.Bad
11. How clear was the content of the lectures?	1. Good	2.Fair	3.Bad
12. How useful was it?	1. Very useful	2. Somewhat useful	3. Not useful at all
13. How useful was the program overall?	1. Very useful	2. Somewhat useful	3. Not useful at all

14. What is your overall satisfaction with the program?	1. Very satisfied	2. Somewhat satisfied	3. Not satisfied at all

Appendix 4. Variables

Variables	Type of the variable	Measurement of the variables	Sources for the variables
Dependant: ***Primary:*** Mean BMI	Continuous	Calculation of BMI	Measured
Secondary: Mean knowledge of PCOS	Continuous	Knowledge score	Questionnaire
Mean knowledge, attitude and practice about lifestyle	Continuous	KAP score (knowledge, attitude, practice score)	Questionnaire
Women's satisfaction with educational program (organization, setting, content, educational materials, manner of teaching)	Continuous	Interview	Questionnaire
Independent Presence or absence of the training	Dichotomous	Baseline measurements	Follow-up measurement
Covariates[59] Presence of obesity due to other causes such as age, family lifestyle, other medical problems (insulin resistance diabetes, endometrial cancer), usage of certain medications (anti epileptics), socio-economic status, pregnancy, stress, sleep disturbances.	Continuous	questionnaire	Interview/Medical review form
Participation in the other educational programs.	Continuous	Reply from the interview	Questionnaire

Appendix 5. Budget

a. Personnel costs for pilot educational program (only for the intervention group):

Budget Item	Type of appointment	Number of Units	Amount (INR/$)Indian Rupees/US Dollar per unit(person)	Total INR/$
Doctors	Fixed for each training session	2(number of doctors) 4(Number of lectures) 5(Number intervention clinics)	INR.5000/$75 Total amount paid to each doctor $75*4=$300 Total amount paid for doctors=5*2*4*75=$3000	INR.200000/$3000
Trainer	Fixed number of hours	1(Number of trainers) 8(number of hours in each clinic) 5(Number intervention clinics)	Amount for each hour=INR.1600/$25 Amount for each clinic=8*25 =INR.13000/$200 Total amount for trainers=5*8*1*25 =INR.65000/$1000	INR.65000/$1000
Expert	Fixed for each material developed	1(number of expert) 2(total number of educational materials-one brochure and one video)	Amount for developing one educational material=INR.6500/$100 Total amount for educational materials=1*2*100 =INR.13000/$200	INR.13000/$200
Nurses	Fixed for the entire evaluation program	5 (number of nurses)	Bonus payment for each nurse=INR.6500/$100	INR.32500/$500

Total personnel cost for education program: $4700

b. Other direct costs for pilot education plan:

Budget Item	Type of appointment	Number of Units	Amount per unit (INR)/$	Total INR/$
Paper cost and printing cost	Fixed for the each units	22(number of pages for one brochure) 185(Total number of Brochures needed for each clinic)	Amount for printing a page of color brochure =INR6.5/$0.1	INR.132275/$2035
Others(videos)	Fixed totally	1(number of video for each women) 185(Total number of videos needed for each clinic)	Amount for a DVD=INR.325/$5	INR.300625/$4625
Phone calls(To recruit the patients served by the clinic)	Fixed for each phone calls	5(total number of clinics) 185(number of patients served by each clinic)	INR.100/$1.5	INR.90188/$1388

Total administrative costs for education program: $8048

c. Personnel costs for evaluation plan:

Budget Item	**Type of appointment**	**Number of Units**	**Amount (INR)/$** **Indian Rupees/US dollar per unit(person)**	**Total INR/$**
Project Coordinator	Fixed Monthly	1(number of coordinator) 12(total number of months for entire evaluation plan)	INR.30000/$450	INR.360000/$5400
Interviewer	Fixed for number of interviews completed	1400(total number of interviews conducted-both pre & post assessment)	INR.325/$5	INR.455000/$7000
				Pretest of questionnaire =INR.6500/$100
		20 (number of interviews for the pre-test of the instrument)		Total =INR.461500/$7100
Data entry staff	Paid for per questionnaire	1400(Number of questionnaires entered-both pre & post assessment)	INR.163/$2.5	INR.227500/$3500
Office for data entry which includes all technical services needed	Paid for a month	1(number of month)	Monthly rent INR.9750/$150 Tax INR.2000/$30	INR.11750/$180

Total personnel costs for evaluation plan: $16180

d. Other direct costs for evaluation plan:

Budget Item	Type of appointment	Number of Units	Amount per unit (INR)/$	Total INR/$
Paper cost and printing cost	Fixed for the entire evaluation including pretesting of the instrument	1500(number of questionnaires including consent form) Number of pages in each questionnaire(15) 500(Number of medical review forms) 2(Number of pages for each form)	Amount for each pagesINR.4/$0.06 Total amount for each questionnaireINR.60/$0.9 Total amount for each (medical form)INR.8/$0.12	INR.91650/$1410
Translation of the questionnaire	Fixed for the entire evaluation	_	INR.3250/$50	INR.3250/$50
Transport(for interviews)	Fixed for each visit	1400(number of households-both pre &post assessment)+20 (number of households for pre-testing the questionnaire) 1.5(number of attempts per household)	Amount for one visit=INR.650/$10	INR.1366300/$21200
BMI measuring equipments (Stadiometer and weighing scale)	Fixed for each equipment used	2(number of stadiometer) 2(number of weighing machine)	Amount for one stadiometer =INR.6500/$100 Amount for one weighing machine=INR.5000/$75	INR.23000/$350

Total administrative cost for evaluation: $23010

Appendix 6. Informed Consent Form
(For both intervention and control groups)

American University of Armenia

Institutional Review Board#1

Evaluation of pilot educational program to reduce obesity among PCOS women, Chennai, India

Hello! I am_____. We are implementing and evaluating a pilot educational program to reduce obesity among PCOS women in Chennai, India. I am going to give you information and invite you to be part of this research. There may be some words that you do not understand. Please ask me to stop as I go through the information and I will take time to explain.

For the evaluation, ten gynecological clinics were randomly chosen from the list of all clinics in Chennai. Of these ten clinics, five were randomly assigned to the group where the pilot educational program will be implemented, where the remaining five of them are assigned randomly to the control group. (You can participate in the intervention program since you are served by the clinic which was randomly assigned to the intervention clinic for the implementation of the pilot program)*. (You belong to the control group since you are served by the clinic which was randomly assigned to the control group)**. You have been approached as one of the potential participant of this survey since you were randomly chosen from the list of all eligible women (woman with PCOS in the age group 18-44 years with BMI≥30, living in Chennai, Tamilnadu, India) from all those ten clinics. Totally 700 participants will be approached in the scope of evaluation. Your participation in the survey is voluntary and refusal to participate will not cause any undesired consequences. I will ask you several questions about your health, and general knowledge on healthy lifestyle just to know how much you are aware of these issues. Also, I will measure your height and weight in order to calculate your BMI (Body Mass Index).

After six months, you will be contacted again to give the interview about the same issues. (Only for baseline)

The total duration of the interview will be 30 minutes. You can skip any question if you feel discomfort or not willing to answer and you can stop the interview at any time. The information you provide for this survey will be confidential and only the summary of information from all participants will be presented in the final report. By participating in this survey, there will not be any risk to you and the information provided by you will be very helpful for us. Participation in the survey will not cause any benefit to you, but it will help to develop an effective program for women with PCOS.

If you have any doubts regarding the survey you can contact the principal investigator of the project Vahe Khachadourian (vahe.khachadourian@gmail.com). If you feel you have not been treated fairly or think you have been hurt by participating in this survey, please contact Dr. Kristina Akopyan, the Human Subject Protection Administrator of the American University of Armenia (+3754 60 612-561).

Do you agree to participate? Thank you. If yes, shall we continue?

*The interviewer will read this sentence only for the intervention group
**The interviewer will read this sentence only for the control group

Appendix 7. Journal Form

#	Eligible patients' name	Patient's address	Patient's phone number	Age	Referral Clinic name	Baseline		Follow-up	
						Attempt 1	Attempt 2	Attempt 1	Attempt 2
						Date/ Result code	Date/ Result code	Date/ Result code	Date/ Result code
001									
002									
003									
004									
005									
006									
007									
008									
009									
010									

Result Codes

1. Completed survey
2. Participant was not available at home
3. Participant was unable to participate because of severe health condition
4. Participant was unable to participate because of business
5. Postponed interview
6. Refusal to participate
7. Participant is incompetent (poor vision, illiteracy, etc.)_____
8. Incomplete interview _____
9. Other _____