SPECIMEN FORMAT FOR THESES OF MONTH

Faculty	:	School of Home Science
Department	:	Food Science and Nutrition
Branch/ Area:	:	Clinical Nutrition
Sub Subject Heading:	:	Polycystic Ovarian Syndrome
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Abstract within 300 words:

PCOS is a common hormonal disorder in women of reproductive age, leading to irregular periods, obesity, acne, and fertility issues. This research explores dietary interventions to manage PCOS symptoms and assess their effectiveness among women aged 20-45years, aiming to improve their health and nutrition knowledge. The study was conducted in a tertiary care centre Central Kerala study design was Quasi experimental design . 93 participants for the study were divided into Experimental Group I (Nutrition Supplementation Education, Experimental Group II (Education only), and a Control Group (Medication). A micronutrient dense multi-seed powder was formulated and tested for acceptability and selected the most suitable variant. Participants in Experimental Group I consumed 30g of the multi seed powder daily for three months, alongside nutrition education. Before and after the intervention, their nutritional status and knowledge were evaluated through anthropometry measurements, biochemical tests, clinical exams, and dietary assessments. According to theANOVA results, significant differences were observed in weight, BMI , waist circumference , hip circumference , body fat per cent, cholesterol ($F_{2,90}=5.814$, $P=0.004$) and triglycerides ($F_{2,90}=2.97$, $P=0.05$). The cholesterol to HDL ratio also showed a significant difference ($F_{2, 90}=4.26$, $P=0.017$), as did testosterone levels ($F_{2, 90}=9.509$, $P=0.000$), which were highly significant. There was significant improvements in weight (MD=4.9), waist circumference (MD=1.41), hip circumference (MD=1.26), body fat (MD=1.27), BMI (MD=1.98) in the Experimental group I. The mean cholesterol was significantly lower in the control group compared to Experimental group I ($P=0.003$). Triglyceride levels differed significantly (MD=24.785, $P=0.044$) between Experimental group I and the control group. The cholesterol to HDL ratio also showed a significant difference (MD=0.678, $P=0.012$) between Experimental group I and the control group. Testosterone levels had the highest difference (MD=0.142, $P=0.002$) between Experimental group I and II. Participants in Experimental Group I were 4.3 times more likely to have regular menstrual cycles compared to the Control Group (OR=4.33, CI 1.385-13.552) and 9.1 times more likely compared to Experimental Group II (OR=9.1, CI 2.84- 29.146), who received only nutrition education. Overall, the Multi-seed intervention group showed significant improvements in anthropometric measurements, hormonal changes, and menstrual cycle regularity.

i) Major objectives :

- Find out the prevalence of PCOS among women in the Reproductive age (20-45 years)
- Screen and identify PCOS and collect the data related to socio economic profile, dietary and lifestyle pattern, nutritional, reproductive and health status of the selected PCOS subjects.
- Formulate and evaluate of micronutrient rich health mix and develop and validate health education modules for nutrition interventions.
- Impact of nutrition interventions on nutritional status including signs and symptoms and hormonal changes and nutritional knowledge in PCOS women in the Reproductive age group (20-45 years)

ii) Hypothesis:

- **Alternative Hypothesis (H1)**: There **is** a significant difference in Clinical signs **and symptoms** of women with PCOS between the nutrition intervention groups and control group before and after the interventions
- **Alternative Hypothesis (H2)**: There is a significant difference in th**e biochemical profile** of women with PCOS between the study groups before and after the nutritional interventions.
- **Alternative Hypothesis (H3):**There is a significant difference in menstrual cycle **regularity** among the nutrition supplementation group, nutrition education group, and control group before and after the nutritional interventions
- **Alternative Hypothesis (H4)**:Nutrition education significantly improves **nutritional knowledge** among the selected study subjects.

iii) Methodology :

Phase I

- Prevalence of PCOS among the women in the reproductive age (20-45 years)

Phase II

- Mapping of subjects having PCOS for Nutrition interventions .

Phase III

- Formulate and Evaluate of micronutrient dense Health mix and develop and validate health and nutrition education modules

Phase IV

- Impact of Nutrition Interventions on Symptoms of PCOS, nutritional status and nutrition knowledge of study participants

Phase I

- **Prevalence of PCOS among the women in the reproductive age (20-45 years)**

The present study was performed in the Gynaecology and Dietetics Outpatient Clinic of Believers Church Medical College, which is a health care institution of Believers Church located in Thiruvalla, Kerala, India. The selected Medical College is attached to 743 beds multispecialty hospital.

. The regular health check-up of the subjects was carried out between20-45 year age group and thepresence of Polycystic Ovary syndrome was screened using a validated tool Rotterdam criteria(2003). The screened positive subjects were considered for the present study.

B. Identification of Subjects having PCOS

The sample size was calculated as

$$N = \frac{Z^2 P(1-P)}{(d)^2}$$

$$= \frac{(1.96)^2 \times 0.225 \times 0.775}{(0.05)^2}$$

= 268 (Daniel, W.W.(1999)

Selection of subjects for the study based on Rotterdam 2003 criteria

To confirm PCOS, the subject should have any two of the three features
1. Clinical features of Oligomenorrhea Irregular menstrual cycle - Absence of Menstruation for more than 35 days – 182 days, Amenorrhea (Absence of menstruation for more than 182 days)
2. Ultra sound scan with at least 12 follicles of 2-9mm in diameter with a pearl like appearance arranged in the ovarian stroma, Ovarian volume >10mm^3
3. Clinical or biochemical evidence of hyperandrogenism (Hirsutism, acne, androgenic alopecia or elevated serum androgen)

Phase II

Mapping of subjects having PCOS for Nutrition interventions

- Collection of data related to socio economic profile,* medical history ,dietary and lifestyle pattern
- Assessment of Nutritional status using ABCD technique
- Assessment of mental health status
- Recording of physical activity level *
- Recording of clinical symptoms Hirsutism* , acne *.menstrual history

- The nutrient intake of the 284 subjects was assessed and gaps in their nutrient consumption were analyzed. Based on these deficiencies, the Nutritional Supplement Health Mix Powder was formulated to provide one-fifth of the Recommended Dietary Allowance (RDA) daily.

Phase III

- **Formulate and Evaluate of micronutrient dense Health mix and develop and validate health and nutrition education modules**

Finger millet and pearl millet were germinated by soaking in cold water for 24 hours. Then it was dried in a mechanical drier for 18 hours. Both the germinated ingredients were roasted for 3-6 minutes and powdered in a mixer grinder. The seeds were introduced in specified proportions after slight roasting for different variation(I to V). The ingredients were mixed in various combinations and ground into a powder for ready to consume for m . Sensory Evaluation , total microbial count , estimation of macro micro nutrient content and cost effectiveness was estimated and highest scored Variation III was Selected for the intervention

Preparation of the content validated nutrition and health education module

The Nutrition and health education modules were developed by including a brief introduction, pathophysiology, prevalence, aetiology, signs and symptoms, dietary, lifestyle and other interventions management by including pictures related to PCOS. Leaflets and PowerPoint presentation was developed on the initial stage of nutrition education

PHASE – IV Effect of Nutrition interventions on nutritional status and symptoms of Polycystic Ovarian Syndrome

The formula suggested for clinical trials by considering type one error (α) of 0.05 and type two error (β) of 0.20 (power = 80%).The sample size for the Nutritional intervention part of the study was 25 participants in each group, that is the total of 75 participants .This was calculated based on the concentration of testosterone change as per previous study (Garg et al 2015), where the standard deviation was 0.11ng/ml , difference in mean was 0.09ng/ml and was based on the formula

$N=2(Z\alpha/2+Z\beta)^2$ (Standard Deviation ÷Difference in mean $)^2$ =24

Considering a drop out of 20 % the minimum sample size was calculated as 30 per each group that is 90 participants. But we were able to recruit 32 in Experimental group I , 31 in Experimental group II and 30 in Control group. So the power of the study is not compromised for getting valid results. Those subjects who were recommended Medications (n=30) were kept as control group.

All subjects identified as PCOS and those who fit into the Inclusion and Exclusion criteria has been be enrolled in the study from the Gynecology Department. The study was a Quasi Experimental study design, because those on medications continued in the control group of the trial. The other two groups were randomly allocated . Since all the three groups did not have randomization the study was considered as quasi experimental design.Those who were advised Dietary management were divided into two Supplement group and Education group. They have been randomized either to receive supplement +Nutrition education or Nutrition education alone Randomization has been carried out using fish bowl technique or lottery method , in which 32 slips were kept as Experimental group I and 32 slips were kept as Experimental group II , all 64 slips of papers were put into a container and shuffled and each slip is randomly picked out one- by- one by the participants

1st group -Experimental group I: Multi-Seed Health mix will be given 30gram daily, along with Nutrition education ,standard calories diet plan , leaflet and module for a period of 3 months :32 participants

2nd group -Experimental group II: Participants were provided Nutrition education, standard calories diet plan , leaflet and module alone will be given for a period of 3 months : 31 participants

3rd group – Control group : On medication mainly to improve insulin sensivity , pain killers whenever they face severe pain and was not taking continuously : 30 participants

Drop out : 1 in the Experimental group II within one week

Assessment of nutritional status before and after dietary intervention

Height,Weight WC,HC ,TSF,

Body fat ,Visceral fat

Cholesterol,Hb ,RBG,HDL,LDL,VLDL,TG

Cholesterol/HDL Ratio, Testosterone

Dietary Intake *24 hour recall

Clinical Examination

Assessment of Hirsutism, Acne , Mental health status and Stress score , regularity of menstrual cycle.

Physical activity level

Evaluation of Nutrition education before and after the education programme

Statistical Analysis

- The data was analyzed using SPSS 23 version
- Descriptive statistics like percentage and mean were used to explore the demographic profile,

- Categorical variables were compared using the Mc Nemar's $\chi 2$ test and Mc Nemar's odds ratio and Inferential statistics like correlation and chi-square were applied to find the association and differences between the variables.
- Paired t- test was used to check the effect of intervention on different symptoms before and after the intervention
- Three-group comparison was performed by analysis of variance, adjusted for the baseline values. The effect size was analyzed by repeated measure analysis
- Proportion for agreement was analyzed by Kappa of agreement. The rate of change of each variable over time and rate of change was also analyzed

Findings:

- The findings of this research study highlighted that the dietary intervention with the combination of education programme ,are very **effective in improving the nutritional status including reproductive health status** of the selected participants .
- The nutrition and health **education sessions** were **instrumental to increase participant's nutrition knowledge, adapting physical activities and managing stress level** .
- These **nutrition intervention programmes serve as sustainable preventive measures** to promote reproductive health and wellness and prevent illness of the population .

Examiners

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