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A STUDY TO MEASURE THE EFFICACY OF SYNBIOTIC PRODUCT AMONG SELECTED POLYCYSTIC OVARIAN SYNDROME WOMEN IN COIMBATORE DISTRICT

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Abstract: **Aim and objectives:** To assess the efficacy of synbiotic product among selected PCOS (Polycystic ovarian syndrome) adult women from the age group of 20-40 years.

Methodology: A Quantitative Approach, the True experimental research design was adopted to assess the effficacy of synbiotic product among PCOS (Polycystic ovarian syndrome)adult women in Kavitha Fertility Hospital, Coimbatore who fulfilled the inclusion criteria. A sample of 50 adult women from the age group of 20-40 years with PCOS was selected, from which 10 women were assigned to an experimental and control group, with 5 participants in each group. Both groups had a pretest to assess the clinical manifestations of PCOS. The experimental group then received a Synbiotic product supplementation for a period of 30 days, while the control group did not receive any supplementation. Following the 30th-day supplementation period, a post-test was conducted to evaluate the clinical manifestations of PCOS in both groups. The experimental group and control group were had a pretest and post-test assessments of ovarian volume by Transvaginal ultrasound scan

Results: The study findings revealed that the post-test clinical manifestation unpaired 't' value for BMI was p=0.031, for waist-hip ratio was p=0.013, and for ovarian volume p=0.006 levels of clinical manifestations indicates a high statistical significance at $p< 0.05$ among PCOS adult women from the age group of 20-40 years.

Conclusion: The results revealed that the synbiotic Product was effective in alleviating the clinical manifestations among PCOS adult women from the age group 20-40 years.

Keywords: synbiotic product, clinical manifestations, PCOS

I. INTRODUCTION:

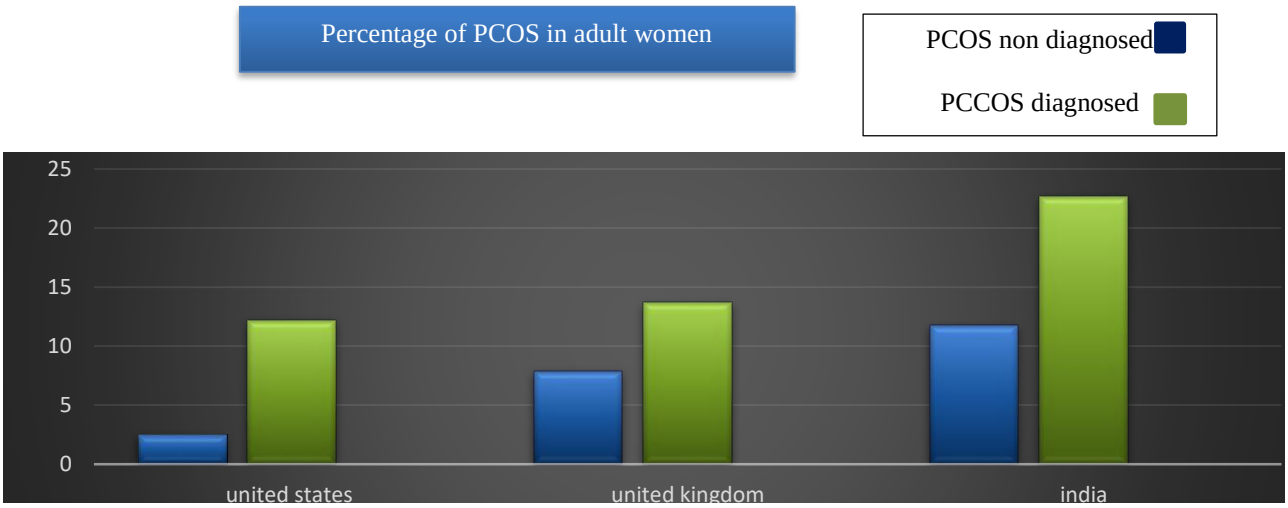
Over the past few decades, women's health has been a major area of interest and concern. It has been researched at the level of mortality, morbidity, and nutritional status as well as via effective, evidence-based interventions.[1]

PCOS is a prevalent hormonal disorder affecting fertile women. Although the symptoms may change over time, they often begin throughout adolescence. Hormonal abnormalities, irregular periods, high levels of testosterone, and ovarian cysts can all be symptoms of PCOS. It may be challenging to conceive if you have irregular periods, which are typically caused by a lack of ovulation. Roughly 8–13% of fertile women are affected by this illness, and up to 70% of cases go untreated. One of the main causes of infertility and the most frequent cause of anovulation is PCOS. .[2]

Synbiotics exert beneficial effects on immune function, dysbiosis, and bowel function and the probiotic of Lactobacillus decreased inflammatory markers in the host and the effect was increased along with prebiotics. The Synbiotic supplementation may ameliorate hormonal profiles, inflammatory indicators, and

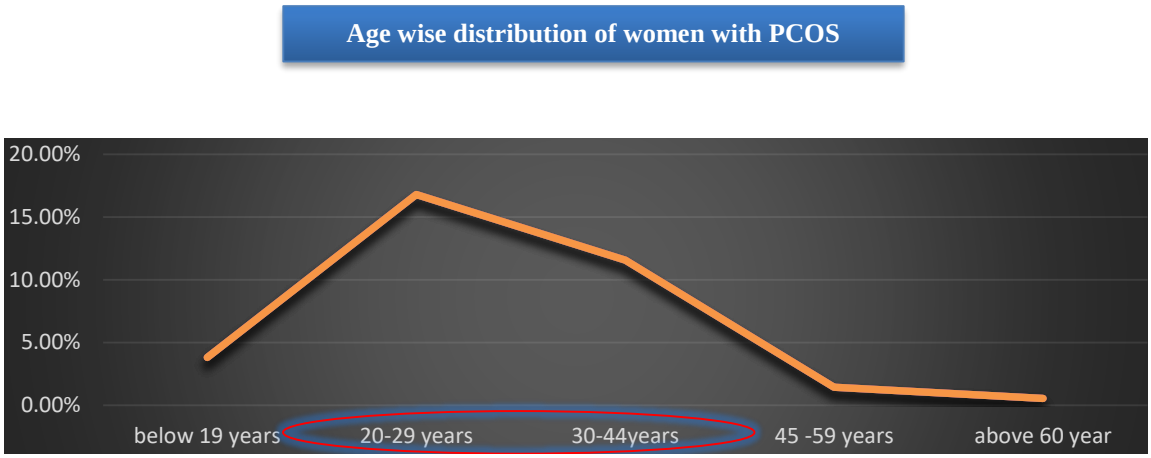
lipid metabolism disturbances associated with PCOS and it also improves weight, BMI, and insulin sensitivity indicating its potential role in protecting fertility. [3]

PCOS affects 1.55 million women of reproductive age globally, resulting in 0.43 million disability-adjusted life years. PCOS can arise at any age, beginning after menarche. Most cases are discovered between the ages of 20 and 30.PCOS describes a condition where at least one ovary has an ovarian volume greater than 10 ml and at least one ovary has an estimated ten small cysts, with diameters ranging from 2 to 9 mm. The pathophysiology of PCOS is chiefly concerned with hormonal imbalance, chronic low-grade inflammation, insulin resistance, and hyperandrogenism, which impair folliculogenesis and increase the risk of related comorbidities.[4]



Source:Tarun Jain et al., March 2021, journal of reproductive biology and endocrinology[5]

FIGURE 1



Source:Vrushali et al., October 2022, In the journal of pharmaceutical negative results[6]

FIGURE 2

1.3.STATEMENT OF THE PROBLEM

Development of the synbiotic product and assessment of the efficacy of the synbiotic product in alleviating clinical manifestation of PCOS among selected PCOS adult women from the age group of 20 - 40 years at selected hospitals in Coimbatore district.

1.4 HYPOTHESIS

Null hypothesis

NH1 – There will be no significant effectiveness in the pre and post-level in alleviating clinical manifestations of PCOS among the selected PCOS adult women from the age group of 20 - 40 years at $p<0.05$ level.

Alternative hypothesis

AH1 – There will be significant effectiveness in the pre and post-level in alleviating clinical manifestations of PCOS among the selected PCOS adult women from the age group of 20 - 40 years at $p<0.05$ level.

II. LITERATURE REVIEW:

SECTION-A

2.1Critical Review on Prevalence of Polycystic Ovarian Syndrome

According to a June 2023 report by **CSIR's National Institute of Science Communication and Policy Research**, Polycystic Ovarian Syndrome (PCOS) is the most common endocrine disorder affecting women and a primary cause of infertility cause of infertility. The global prevalence ranges from 6% to 26%, while in India, it varies between 3.7% and 22.5%.[6]

According to the **World Health Organization** in June 2023, Polycystic Ovarian Syndrome (PCOS) impacts approximately 8 to 13% of women of fertile age and as much as 70% of these women may be undiagnosed globally. PCOS is the most leading cause of anovulation and a major factor in infertility. It is also linked to various long-term health issues that can affect both physical and emotional well-being.[7]

Mintu Dewri Bharali et al., in December 2022 conducted a meta-analysis on polycystic ovarian syndrome (PCOS) prevalence in the state of India, estimating that Indian women have a pooled prevalence of PCOS. The findings indicated a high prevalence rate of PCOS among Indian women. Specifically, the pooled prevalence was approximately 10% using the Rotterdam and AES criteria, while 5.8% using the National Institute of Health criteria.[8]

Afrin Yasmin et al., in November 2022 conducted a study providing an updated overview of the Effects of ethnicities and geographic variations. Their findings revealed that Indian women had a significantly higher PCOS prevalence compared to their counterparts within the United States.[9]

SECTION- B

2.2 CRITICAL REVIEWS ON COMPLICATIONS OF POLYCYSTIC OVARIAN SYNDROME IN ADULT WOMEN

Yue che et al., in February 2023, conducted the study on Polycystic Ovarian Syndrome: Challenges and Possible Solutions emphasized that PCOS is a multifaceted syndrome that not only affects female fertility but also heightens the risk of obesity, diabetes, dyslipidemia, cardiovascular diseases, psychological issues, and various other health problems.[10]

Virginie Simon et al., in March 2023 conducted a study on the psychosocial impact of polycystic ovary syndrome (PCOS), concluding that individuals with PCOS face an elevated risk of cardiovascular disease and metabolic complications, as well as psychological issues such as depression, anxiety, eating disorders, and a reduction in self-esteem and quality of life.[11]

Chau Thien Tay et al., in April 2023 conducted an international collaborative study on PCOS to translate evidence and guide future research. This study aimed to provide recent insights into PCOS pathways from genomic studies and outline the development of rigorous guidelines. It highlighted that PCOS is associated with significant metabolic issues (including obesity, metabolic syndrome, impaired glucose tolerance, type 2 diabetes, and cardiovascular risk factors), reproductive problems (such as anovulation, subfertility, and pregnancy complications), dermatological concerns (including acne, hirsutism, and alopecia), and psychological complications (such as depression, anxiety, eating disorders, and impaired quality of life).[12]

SECTION - C

2 .3 Critical Reviews of Synbiotic Effects in Polycystic Ovarian Syndrome Women

Nur Rahman et al., 2023 April conducted experimental research to evaluate the impact of probiotic supplementation on FSH, LH, and folliculogenesis in PCOS Wistar rats. The study, which used a post-test-only controlled group design, involved 35 Wistar rats and administered the intervention over 14 days. Statistical analysis, conducted using Dunnett's post hoc test with a significance level set at $p<0.05$, revealed that supplementation with probiotics and metformin led to increased FSH levels, decreased LH levels, and enhanced folliculogenesis compared to untreated PCOS rats..[13]

Valeria Calcaterra et al., in July 2023 did a study on the management of polycystic ovarian syndrome (PCOS) with probiotics among adolescents with obesity and concluded that early probiotic intervention during adolescence can effectively reduce the incidence of PCOS in women. [14]

Arman arab et al., 2022 conducted a randomized, placebo-controlled clinical trial to assess the impact of probiotic supplementation on hormonal and clinical outcomes in women with polycystic ovarian syndrome (PCOS). The study aimed to evaluate how probiotic supplements affect the hormonal profile in PCOS. It involved 94 women aged 19 to 37, who were divided into two groups of 47 each: an intervention group and a placebo control group. The intervention included taking two probiotic capsules daily after meals for 12 weeks. Statistical analysis of the probiotic effects was performed using the Mann-Whitney U test, with a significance level set at $p < 0.05$. The study concluded that 12 weeks of probiotic supplementation significantly increased the serum levels of sex hormone-binding globulin (SHBG).[15]

SECTION -D

2.4.Critical reviews on the effect of Shatavari (Asparagus racemosus) on polycystic ovarian syndrome

Mansi. A et al., in 2023 April, conducted a study on Ayurvedic herbal medicine for women with polycystic ovary syndrome (PCOS) and reviewed the benefits of Shatavari. The herb is known to help balance hormones disrupted by PCOS, supporting the HPO axis and enhancing hormonal levels. Shatavari promotes a regular menstrual cycle, with a duration of 3 to 7 days, an interval of 28 to 35 days, and improved blood flow during menstruation. Taking 5 grams of Shatavari daily helps balance hormones, boosts antioxidant levels in the body, and improves menstrual health.[16]

Aquib Nawab et al., 2023 stated that Shatavari can help to improve fertility and support pregnancy by phytoestrogen substances and that imitates the actions of estrogen in the body, controlling estrogen levels and enhancing hormonal harmony to promote regular ovulation it concludes that Shatavari supports the reproductive organs, enhancing their performance and fostering a regular menstrual cycle.[17]

Dr. Jaspreet Sarna, in 2023 march conducted a study and stated that the estrogenic properties of Shatavari which balance the estrogen level will help to regulate the menstrual cycle, alleviate the menstrual cramps, bloating, and inflammation and it also improve the hormonal imbalance in polycystic ovarian syndrome(PCOS). [18]

III. OBJECTIVES :

1..To activate the frozen bacteria to revive and to inoculate the culture into the tea powder to form a probiotic product.

2. Formulate the synbiotic product by the incorporation of probiotic bacterial culture and prebiotic product of Shatavari in powder form and analyze the probiotic and prebiotic properties of the developed synbiotic product.

3.To evaluate the sensory characteristics of the product through sensory evaluation and analyze the shelf life of the developed synbiotic product.

4.To assess the efficacy of the synbiotic product on alleviating clinical manifestation of PCOS among the selected PCOS adult women from the age group of 20 - 40 years at selected hospitals in Coimbatore district.

IV. RESEARCH METHODOLOGY :

A **quantitative research approach** with a **True experimental research design** was adopted to assess the effficacy of synbiotic product among PCOS (Polycystic ovarian syndrome)adult women in Kavitha Fertility Hospital, Coimbatore who fulfilled the inclusion criteria. A **sample of 50 adult women with PCOS** was collected, from which 10 women were assigned to an experimental and control group, with 5 participants in each group. Both groups had a pretest to assess the clinical manifestations of PCOS. The experimental group then received a Synbiotic product supplementation for a period of **30 days**, while the control group did not receive any supplementation. Following the 30th-day supplementation period, a post-test was conducted to evaluate the **clinical manifestations** of PCOS in both groups. The experimental group and control group were had a pretest and post-test assessments of **ovarian volume** by Transvaginal ultrasound scan.

The tool consisted of two parts PART I- The data collection tool and PART II -The Intervention tool.

PART I

Data collection tools

Section A – Demographic variable assessment
Section B–Anthropometric measurements assessment
Section C–Clinical manifestations assessment
section D –Dietary assessment

Section A- Demographic variable assessment

This section includes,Name,Age,Religion,Family income,Socioeconomic status,Education level,Type of family,Lifestyle pattern,Marital status,Area of residence,Occupation,Area of residence

Section B –Anthropometric measurements assessment

This section includes,Height,Weight ,Body mass index (BMI), Waist-to-hip ratio

Section C – Clinical manifestations assessment (under the Gynecologist guidance)
This section includes,Age of the first period,Regularity of menstrual cycle,Menstrual hygiene,Duration of menstrual period,Hair loss,Hirsutism (excess hair growth on body),Fertility,Weight gain/obesity,Sleep disturbance
Abortion/miscarriage,Any type of chronic disease
Section D –Dietary assessment
This section includes,24 recall method pattern,Food frequency questionnaire
PART II
Intervention tool

- The intervention tool in this study was Synbiotic Tea
- The synbiotic product (Tea powder) was prepared by the fermentation method by the expert guidance in the laboratory
- The synbiotic tea consist of **Lactobacillus fermentum** as a Probiotic and **Shatavari(asparagus racemosus)** as a Prebiotic.
- The tea powder is initially fermented by **Probiotic lactobacillus fermentum** followed by the addition of **shatavari powder** as a prebiotic product.
- The synbiotic tea powder was given for a period of 30 days in morning and evening for the selected experimental group

4.1criteria

Table 1: Criteria

Inclusion criteria	Exclusion criteria
Adult women of age group 20-40 years with PCOS	Adult women who are having any allergic condition
Adult women of age group 20-40 years those who are free from chronic diseases and disorders	Adult women above or below the required age of 20-40 years
Adult women who were given a written consent form	Adult women who are not willing to participate in the study
Adult women Who are not taking hormonal and other medications	

4.2 Data collection procedure

The researcher worked from 9 a.m. to 2 p.m. and from 4 p.m. to 7 p.m. to complete the scheduled intervention. The study was carried out at Kavitha Fertility Hospital, Kamarajar Nagar, Sundarapuram, Coimbatore. Written consent forms were obtained from all participants before the intervention started.

PRETEST:
The Data collected from 50 PCOS adult women from the age group of 20-40 years were used to select 10 samples, who were divided into control and experimental groups. These 10 adult women then underwent a pretest assessment of clinical manifestations with the guidance of a gynecologist. A transvaginal scan was performed on the experimental group to evaluate the appearance and volume of their ovaries.

INTERVENTION
The supplement used in this study was **Synbiotic tea powder.**The Probiotic of **Lactobacillus fermentum** and the Prebiotic of **Shatavari** were used in the formulation of Synbiotic tea powder. The synbiotic Tea powder was given to the 5 selected experimental group of PCOS adult women samples. The study was conducted for a period of 30 days.
POST TEST
After 30 days of supplementation of Synbiotic tea powder, the post-test was analyzed by assessment of clinical manifestations under the guidance of a Gynecologist for the both experimental and control group. A transvaginal scan was performed on the experimental and control group to evaluate the appearance and volume of their ovaries. The obtained data were used to analyze the efficacy of the synbiotic tea powder.

4.3 Plan for data analysis

Collected data was analysed using both descriptive and inferential statistical method.

Table 2: Descriptive analysis

Methods	Remarks
Frequency and percentage distribution	Used to analyze the demographic variables, Clinical manifestations, Anthropometric measurements and Dietary assessment, food frequency, and effectiveness of synbiotic product on alleviation of PCOS clinical manifestations PCOS.
Mean and Standard deviation(S.D)	Used to analyze the effectiveness of Synbiotic product on the anthropometric measurements and ovarian volume in PCOS adult women.

Table 3:Inferential analysis

Methods	Remarks
Paired t-test	Used to analyze the effectiveness of Synbiotic product on the anthropometric measurements and ovarian volume in PCOS adult women

V. RESULTS :

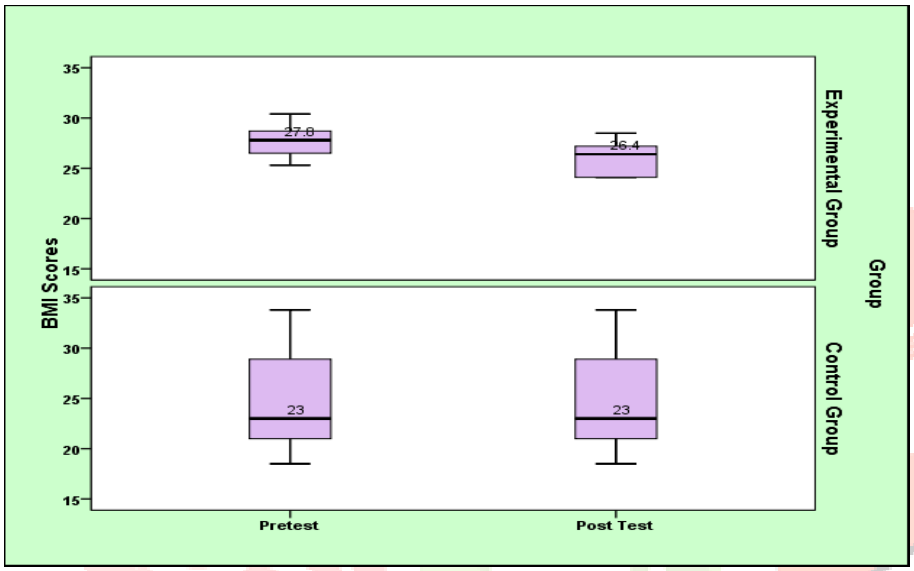
The main findings of the study revealed that

1. Descriptive statistics and inferential statistics were used to analyze the collected data. Interpretation and discussion were based on the objectives, alternative hypotheses and reviews of various literature.
2. The pre test level of weight among the PCOS adult women from the age group of 20-40 years before the supplementation of synbiotic product depicts that the mean score was 71.20 and The standard Deviation was 12.15 in the experimental group and 61.80 of the mean score and 13.88 in the control group.
3. The post-test level of weight among the PCOS adult women from the age group of 20-40 years after the supplementation of synbiotic product depicts that the mean score was 69.0 and Standard Deviation was 11.74 in the experimental group 61.80 in the mean score and 13.88 in the control group.
4. The pre and post-test level of weight among the PCOS adult women from the age group of 20-40 years, the mean difference was 2.20 % and the calculated ‘t’ value and ‘p’ value were t=3.773 and p = 0.020.
5. The pre-test level of BMI among the PCOS adult women from the age group of 20-40 years before the supplementation of synbiotic product depicts that the mean score was 27.74 and Standard Deviation was 1.96 in the experimental group 25.04 in the mean score and 6.22 in the control group.
6. The post-test level of BMI among the PCOS adult women from the age group of 20-40 years after the supplementation of synbiotic product depicts that the mean score was 26.05 and The standard Deviation was 1.94 in the experimental group 25.04 in the mean score and 6.22 in the control group.
7. The pre and post-test level of BMI among the PCOS adult women from the age group of 20-40 years, the mean difference was 1.69 % and the calculated ‘t’ value and ‘p’ value were t=3.262 and p = 0.031.
8. The pre-test level of the Waist-hip ratio among the PCOS adult women from the age group of 20-40 years before the supplementation of synbiotic product depicts that the mean score was 0.90 and Standard Deviation was 0.07 in the experimental group 0.84 of the mean score and 0.06 in the control group.
9. The post-test level of waist-hip ratio among the PCOS adult women from the age group of 20-40 years after the supplementation of synbiotic product depicts that the mean score was 0.83 and Standard Deviation was 0.06 in the experimental group 0.84 of the mean score and 0.06 in the control group.

10. The pre and post-test level of waist-hip ratio among the PCOS adult women from the age group of 20-40 years, the mean difference was 0.06 % and the calculated 't' value and 'p' value were t=4.257 and p = 0.013.

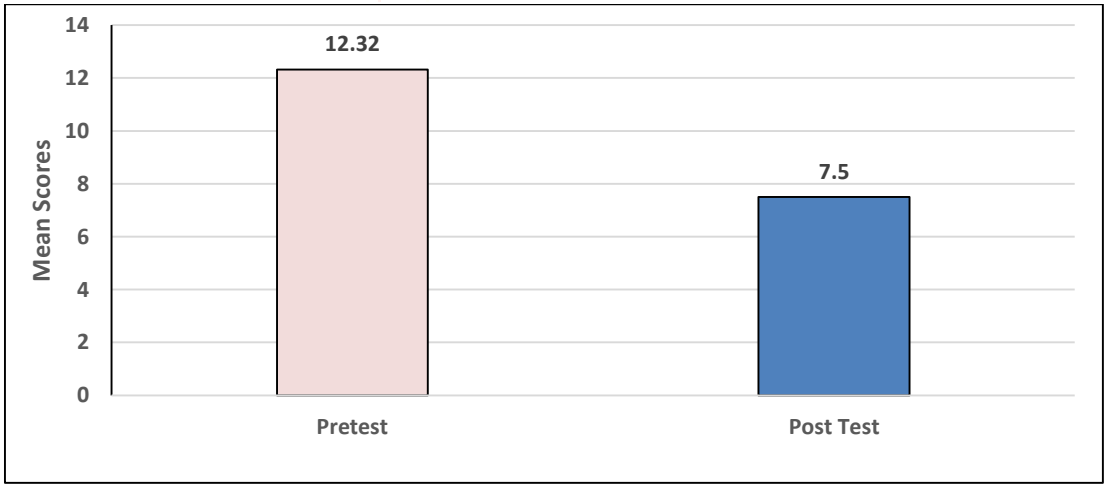
11. These results shows that the level of weight, BMI, and waist-hip ratio scores in the pre-test were found statistically not significant, and post-test level of weight, BMI, and waist-hip ratio scores show statistically significant at p<0.001. This shows that the synbiotic product was effective in reducing weight, BMI, and waist-hip ratio and alleviation of clinical manifestations of PCOS in adult women from the age group of 20-40 years.

The study aimed at developing a Synbiotic product and assessing the effectiveness of Synbiotic product to alleviate the clinical manifestation of polycystic ovarian syndrome (PCOS) among selected adult women aged 20 to 40 years at selected hospitals in Coimbatore district. The study findings revealed that there is moderate improvement in the alleviation of the clinical manifestation of polycystic ovarian syndrome (PCOS) among selected adult women from 20 to 40 years. There was a reduction in ovarian volume, along with improved alleviation of clinical manifestation scores in both pretest and post-test assessment after the administration of the synbiotic product.Thus, study findings stated that Synbiotic product was more effective in alleviation of clinical manifestation among the PCOS adult women aged 20-40 years.



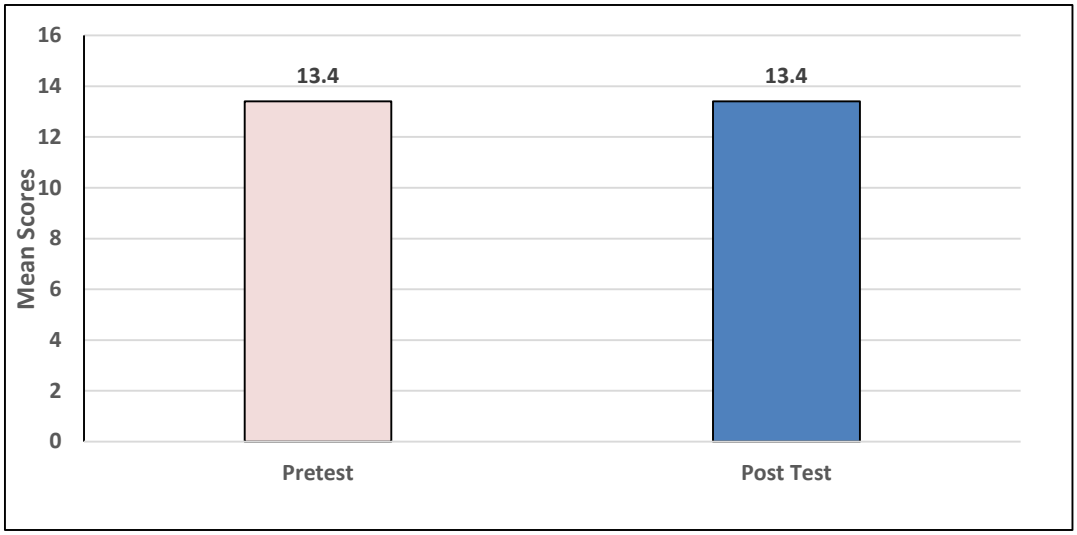
Boxplot showing the comparison of pretest and post-test scores of anthropometric measurement BMI among selected adult women with PCOS between the experimental and control group

Figure 3



Comparison of pretest and post test scores of ovarian volume scores among the women with PCOS in the experimental group

Figure 4



Comparison of pretest and post test scores of ovarian volume scores among selected adult women with PCOS in the control group

Figure 5

VI. DISCUSSION :

The finding of the study revealed that administration of synbiotic tea for 30 days will alleviating the clinical manifestation of PCOS and there was a significant difference in Pre and post-test clinical manifestations among PCOS adult women from the age group of 20-40 years at a selected hospital in Coimbatore district. The post-test mean clinical manifestation of he calculated unpaired 't' value for BMI was p=0.031, for waist-hip ratio was p=0.013, and for ovarian volume p=0.006 levels of clinical manifestations indicates a high statistical significance at $p < 0.05$ among PCOS adult women from the age group of 20-40 years. Hence, the null hypothesis, NH1 stated earlier that 'There will be no significant effectiveness of the synbiotic product on alleviation of clinical manifestations among Selected PCOS adult women from 20-40 years at $p<0.05$ level was rejected, whereas the Alternative hypothesis, AH1 stated that there will be significant effectiveness of the synbiotic product on alleviation of clinical manifestations among Selected PCOS adult women from 20-40 years at $p<0.05$ level was accepted

VII. CONCLUSION:

The study aimed at developing a Synbiotic product and assessing the effectiveness of Synbiotic Product to alleviate the clinical manifestation of polycystic ovarian syndrome (PCOS) among selected Adult women aged 20 to 40 years at selected hospitals in Coimbatore district. The study findings revealed that there is moderate improvement in the alleviation of the clinical manifestation of Polycystic ovarian syndrome (PCOS) among selected adult women from 20 to 40 years. There was a reduction in ovarian volume, along with improved alleviation of clinical manifestation scores in both Pretest and post-test assessment after the administration of the synbiotic product.Thus, study findings stated that Synbiotic product was more effective in alleviation of clinical manifestation among the PCOS adult women aged 20-40 years.The results revealed that the synbiotic Product was effective in alleviating the clinical manifestations among PCOS adult women from the age group 20-40 years.

VIII. LIMITATIONS

- The study was conducted only for a period of 30 days
- The study was conducted on PCOS adult women at selected hospital only in Coimbatore district
- The study was conducted for PCOS adult women only between 20 to 40 years

IX. RECOMMENDATIONS

- A similar study can be done with the inclusion of different bacterial species to improve the efficacy of the product.
- A similar study can be done by increasing the time duration.
- A similar study can be replicated on a large sample size.
- A similar study can be done for the adolescent age group

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