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Coimbatore - 641 043, Tamil Nadu, India

ANNEXURE I

Diagnosis of PCOS using Rotter Dam criteria

Diagnosis confirmed by 2 of the 3 criteria after exclusion of other aetiologies
1. Oligo and /or anovulation
2.Biochemical and /or clinical signs of hyperandrogenism Biochemical : Total Testosterone >70ng/dl .Androstenedione >245nd/dl , DHEA-S >248µg/dl Clinical : Acne , Hirsutism ,Acanthosis nigricans
3. Polycystic Ovaries : ≥ 12 follicles (2-9mm diameter) in each ovary or ovarian volume >10cc

ANNEXURE II

AN INTERVIEW SCHEDULE TO ELICIT INFORMATION ON NUTRITION AND HEALTH PROFILE OF WOMEN OF REPRODUCTIVE AGE (20-45 YEARS) HAVING PCOS

PART 1

I. DEMOGRAPHIC CHARACTERISTICS

1. Name :
2. UHID :
3. Age :
4. Religion :
5. Communication Address:
6 . Phone number:

II. LIFESTYLE PROFILE

7. Marital status

Single ☐ Married ☐ Separated ☐ Others

8. Place of residence (Area)

Rural ☐ Urban ☐ Semi Urban ☐ Metro ☐

9. Family type

Nuclear ☐ Joint ☐ Extended ☐ Broken ☐

10. Family Size

2-3 ☐ 4-5 ☐ >5 members ☐

11. Education

Primary ☐ Secondary ☐ Higher secondary ☐ UG ☐

PG ☐ Others

12. Occupation

Government ☐ Private ☐ Student ☐ Business ☐ Unemployed ☐

13. Your occupation ……..

14. Nature of Job

Coolie ☐ House wife ☐ Clerical ☐ Professional ☐

Scholarly ☐ Admin ☐ Not applicable ☐

15.Total monthly income of the family

Upto 5000-10,000 ☐ 10,001-20,000 ☐

20,001-30,000 ☐ >30,000 ☐

16. Your Monthly income …….

III FAMILY HISTORY

17. Family history of Amenorrhoea or menstrual irregularities

Yes ☐ No ☐

18. Family history of

Diabetes mellitus ☐ Thyroid Disorders ☐ CVD ☐

Obesity ☐ Hypertension ☐s

19. Has anyone in your family ever had ovarian cyst

Yes ☐ No ☐

20. Has anyone in your family ever had ovarian cyst?

Yes ☐ No ☐

21. Do you have female family members who have difficulty in conceiving?

Yes ☐ No ☐

22.Do you have female family members who have been diagnosed with PCOS?

Yes ☐ No ☐

23. Have any of your family members been diagnosed with ovarian cyst that have been described as follows: “small, follicular cyst or multiple ,immature ovarian cyst or ovaries a string of pearl appearance “

Yes ☐ No ☐

24. You were overweight during childhood

Yes ☐ No ☐

25. Are you over your ideal weight?

Yes ☐ No ☐

26. Are you carrying excess weight around middle?

Yes ☐ No ☐

27. Are you experiencing difficulty in losing weight?

Yes ☐ No ☐

28. Sleep Pattern

Regular ☐ Irregular ☐

29. Duration of sleep

<6 Hours ☐ 6 hours ☐ >6hours ☐

30. Do you have 8 or fewer periods within a year while taking normal birth control (like a birth control pill?)

Yes ☐ No ☐

31. Are you taking hormonal birth control (like the birth control) to bring on a period?

Yes ☐ No ☐

32. Do you have excess hair growth on your upper lip, chin, neck chest area and abdomen?

Yes ☐ No ☐

33. Is the head thinning?

Yes ☐ No ☐

34.Do you suffer from Acne?

Yes ☐ No ☐

35. Is your skin is darkened or discoloured in certain areas??

Yes ☐ No ☐

36. Do you experience depression or anxiety?

Yes ☐ No ☐

37. You have Mood swings

Yes ☐ No ☐

38.Have you ever had ovarian cyst?

Yes ☐ No ☐

39. Do you have blood sugar swings or hypoglycaemia?

Yes ☐ No ☐

40. Have you been told you have a fasting glucose level greater than 99mg/dl?

Yes ☐ No ☐

41. Applicable for married women only: Have you been trying conceive without success for six months or more

Yes ☐ No ☐ NA ☐

PART II

I. REPRODUCTIVE PROFILE

1. Age at Menarche ……..

2. Menstrual cycle

26days ☐ 28days ☐ ys ☐ egular ☐

3. Irregular periods

Yes ☐ No ☐

If YES

Once in 35days ☐ Once in 40 days ☐ Once in 60days ☐

Once in 90 days and above ☐

4. Duration of periods

3 ☐ 5 ☐ 7 ☐ >7days ☐

5. Menstruation flow

Regular ☐ irregular ☐

6. Do you ever experienced any symptoms during menstruation

Yes ☐ No ☐

If Yes, Please mention ……

7. During your menstruating years (not including during pregnancy) did you have a tendency to grow dark, coarse hair on your (circle all that apply)

a. upperlip ☐ b. chin ☐ c. breasts ☐ d. chest between breasts ☐

e.back ☐ f. belly ☐ g. Upper arms h☐r thigh ☐

8. Pregnancy

A. previously pregnant ☐ previously attempted ☐

C. Previously attempted without success for≥ 1 year ☐

9. Had acne as an adult

Yes ☐ No ☐

10 .If yes what medical treatment taken up for acne

11.Do you have continuous weight gain

Yes ☐ No ☐

12. How much of weight you have gained during the period of suffering?

13. Other Complications like

a. insulin resistance ☐ b. oily skin ☐ c. skin discolouration ☐

d. high cholesterol level ☐ e. high blood pressure ☐ f. all of the above ☐

14. Mention the haemoglobin level

15 .Are the HB levels low?

Yes ☐ No ☐

16.Do you have hypothyroidism?

Yes ☐ No ☐

17. What kind of treatment you are taking up for PCOS:

18.Any special diet taken up as cure?

19 .Physical activity which you peruse for weight management?

If yes, is what are they and is it beneficial?

20. Any other mode of treatment taken up for PCOS

a. Ayurveda ☐ b. homeopathic ☐ aturopathic ☐

d.yoga ☐ e any other ☐

21. If any of the above is taken up mention the treatment and its benefits

PART III

MEDICAL HISTORY

1. Health problem related to menstrual cycle (specify)
2. Type of problem
3. Do you intake special food or avoid
4. Do you take any mode of treatment?
5. Are you under medication?

Yes ☐ No ☐

If yes, how long? Why?

7. Are you taking any nutritional supplement?

Yes ☐ No ☐

8. If yes, how long? Why?
9. Are you interested to include nutritional supplement as part of treatment

PART IV

DIETARY HABITS

1. Dietary habits

Vegan ☐ Lacto Vegetarian ☐ Non Vegetarian ☐

Ovo vegetarian ☐

2. Skipping meals

Daily ☐ Frequently ☐ Occasionally ☐ Not at all ☐

3. Type of skipping meal

Breakfast ☐ Lunch ☐ Dinner ☐

4. Daily intake of fast foods

Daily ☐ Frequently ☐ Occasionally ☐ Not at all ☐

5. Daily intake of fried foods

Daily ☐ Frequently ☐ Occasionally ☐ Not at all ☐

6. Daily intake of coffee /tea

>5 ☐ 5-4 ☐ 2-3 ☐ 1-2 ☐ None ☐

7. Daily intake of milk and its products

350g ☐ 200-350g ☐ 100-200g ☐ <100g ☐ No intake ☐

8. Daily intake of water

<1 L ☐ 1-1.5L ☐ 1.5-2L ☐ >2L ☐

9 .Daily intake of fruits

1 fruit ☐ 2 fruits ☐ More than 2 fruits ☐ None ☐

10 You have Craving for sweets, CHO, Fats

Yes ☐ No ☐

III Anthropometric profile

Height:- Weight:- Body Mass Index(BMI):-

Triceps Skin Fold (TSF) : Waist Circumference(WC):

Hip Circumference (HC) : Waist/Hip Ratio:-

IV Body Composition Analysis

Body fat%:- Water%:- Muscle mass:- Visceral fat:-

V Biochemical profile

- Random Blood sugar
- Hb
- Lipid profile
- High Density Lipoprotein (HDL)
- Low Density Lipoprotein (LDL)
- Cholesterol /HDL Ratio
- Very Low Density Lipoprotein (VLDL)
- Triglycerides (TG)
- Total serum testosterone

VI Others:-

Ultrasound scanning report:-

VII Clinical Signs

പ്രത്യല്പാദന പ്രായത്തിലുള്ള സ്ത്രീകളിൽ പോളിസിസ്റ്റിക് ഓവേറിയൻ സിന്ഡ്രോമിന്റെ ലക്ഷണങ്ങളിൽ പോഷകാഹാരത്തിനുള്ള സ്വാധീനം

ലക്ഷ്യം

പി..സി .ഒ .എസ് ലേയ്ക്ക് നയിക്കുന്ന ഘടകങ്ങൾ പഠിയ്ക്കുകയും അവയുടെ പോഷക നില വിലയിരുത്തുകയും ചെയ്യുക.

ലക്ഷണങ്ങളും, ആന്തോപോമെട്രി, ബയോക്കെമിക്കൽ, ക്ലിനിക്കൽ ആഹാരസംബന്ധമായ ഘടകങ്ങളും തമ്മ്ിലുള്ള ബന്ധം വിലയിരുത്തുന്നതിന്

പി.സി.ഒ.എസ് രോഗികളിൽ പോഷകാഹാര സപ്ലിമെന്റുകളുടെ ഉപയോഗം പരിശോധിയ യ്ക്കുക

പി.സി.ഒ.എസ് രോഗികളുടെ ആഹാരകാര്യങ്ങളിലുള്ള അറിവ് വർദ്ധിപ്പിയ്ക്കുന്നതിനുള്ള മെഡ്യൂൾ തയ്യാറാക്കലും വിലയിരുത്തലും

പി.സി.ഒ.എസ് ലക്ഷണങ്ങളിൽ സാമൂഹിക ,സാമ്പത്തിക നില, ഭക്ഷണക്രമം, ആർത്തവ ചക്രത്തിലെ മാറ്റങ്ങൾ എന്നിവയുടെ സ്വാധീനം പഠിയ്ക്കുക.

പി.സി.ഒ.എസ് രോഗികളിൽ ധാതുലവണ സംപുഷ്ടമായ (മൈക്രോന്യൂട്രിയന്റ്) ആഹാ രരീതിയുടെ പ്രഭാവം പരിശോധിയ്ക്കുക.

അനുമതി

നൽകിയ വിവരങ്ങൾ ഞാൻ വായിയ്ക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു. പഠന ത്തെക്കുറിച്ചുള്ള ശരിയായ വിവരങ്ങൾ എനിയ്ക്ക് ലഭിച്ചിട്ടുണ്ട്. ആയതിനാൽ ഈ പഠന ത്തിൽ (റിസേർച്ച്) പങ്കെടുക്കാൻ എനിയ്ക്ക് പൂർണ്ണ സമ്മതമാണ്. ''പ്രത്യുല്പാദന പ്രായ ത്തിലുള്ള സ്ത്രീകളിൽ പോളിസിസ്റ്റിക് ഓവേറിയൻ സിന്ഡ്രോമിന്റെ ലക്ഷണങ്ങളിൽ പോഷ കാഹാരത്തിന്റെ സ്വാധീനം'' എന്ന ഗവേഷണത്തിനായി ഞാൻ നൽകുന്ന വിവരങ്ങൾ ഉപയോഗിയ്ക്കുമെന്ന് എനിയ്ക്ക് അറിവുള്ളതാകുന്നു. ഈ ഗവേഷണത്തിനായി ഞാൻ സ്വമേധയാ സമ്മതം അറിയിച്ചുകൊള്ളുന്നു.

പങ്കാളിയുടെ ഒപ്പ് .....പേര്.....ദിവസം

അഭിമുഖം (10 മിനിറ്റ്)

പഠനത്തിനുള്ള നേട്ടങ്ങൾ

വന്ധ്യത, പൊണ്ണത്തടി, മെറ്റബോളിക് തകരാറുകൾ, ഹോർമോൺ തകരാറുകൾ എന്നിവ കുറയ്ക്കാൻ പോഷകാഹാര സപ്ലിമെന്റ് സഹായിയ്ക്കുന്നു.

ഫലങ്ങൾ എങ്ങനെ ഉപയോഗിയ്ക്കും ? ഗവേഷണം പ്രസിദ്ധീകരണം

ഇന്റർവ്യൂ, ബയോളജിക് ചോദ്യങ്ങൾക്ക് ഉത്തരം നൽകുന്നതിന് നിങ്ങൾക്ക് അസ്വസ്ഥത യുണ്ടെങ്കിൽ എപ്പോൾ വേണമെങ്കിലും ഈ പഠനത്തിൽ നിന്ന് പിൻമാറാൻ നിങ്ങൾക്ക് അവകാശമുണ്ട്. ഈ അഭിമുഖത്തിനായി ഞങ്ങളോടൊപ്പം ചെലവഴിയ്ക്കുന്ന സമയത്തിന് നിങ്ങൾക്ക് യാതൊരു പ്രതിഫലവും നൽകേണ്ടതല്ലെന്നും, കർശനമായ വിശ്വസ്തതയോടെ സൂക്ഷിയ്ക്കുമെന്നു അറിയിക്കുന്നു.

ഒരു കാരണവശാലും പ്രതികരിയ്ക്കുന്നവരുടെയോ അവരുടെ കുടുംബാംഗങ്ങളുടെയോ ഐഡന്റിറ്റി ആരോടും വെളിപ്പെടുത്തുന്നതല്ല. ശേഖരിയ്ക്കുന്ന വിവരങ്ങൾ അംഗീകൃത ഗവേഷണ ആവശ്യങ്ങൾക്ക് മാത്രമെ ഉപയോഗിയ്ക്കൂ ഏതെങ്കിലും സുപ്രധാനമായ കണ്ടെത്തലുകളെക്കുറിച്ച് നിങ്ങളെ അറിയ്ക്കുന്നതായിരിക്കും.

സമ്മതം:- പഠവുമായ ബന്ധപ്പെട്ട മേൽപ്പറഞ്ഞ വിവരങ്ങൾ ഞാൻ വായിച്ചിട്ടുണ്ട് , അവരോടൊപ്പം അന്വേഷക എനിയ്ക്ക് വിശദീകരിച്ചു തന്നതുമാണ്. അത് മനസ്സിലാക്കി എന്റെ അഭിമുഖം നടത്താനും, ബയോളജിക്കൽ സാമ്പിൾ ശേഖരിയ്ക്കാനും ഞാൻ സമ്മതം നൽകുന്നു. ഈ പഠനത്തിൽ പങ്കെടുക്കാനുള്ള എന്റെ സമ്മതവും, സന്നദ്ധതയും ഞാൻ അറിയിക്കുന്നു.

പഠന ദ്യകന്റെ/നിയമപ്രതിനിധിയുടെ/ഇടത് തള്ളവിരലിന്റെ മുദ്ര

അഭിമുഖം നടത്തുന്നയാളുടെ ഒപ്പ്

പേര്/ സാക്ഷിയുടെ ഒപ്പ്

വിഷയം

പ്രത്യല്പാദന പ്രായത്തിലുള്ള സ്ത്രീകളിൽ പോളിസിസ്റ്റിക് ഓവേറിയൻ സിന്ഡ്രോമിന്റെ ലക്ഷണങ്ങളിൽ പോഷകാഹാരത്തിന്റെ സ്വാധീനം

വൈവാഹിക നില

അവിഹിത ☐ വിവഹിത ☐ വേർപിരിഞ്ഞു ☐ മറ്റുള്ളവ ☐

8. താമസ്ക്കുന്ന സ്ഥലം

ഗ്രാമം ☐ നഗരം ☐ അർദ്ധ നഗരം ☐ മെട്രോ ☐

9. കുടുംബ തരം

വിസ്തൃതമായ കുടുംബം ☐ അണുകുടുംബം ☐ കൂട്ടുകുടുംബം ☐

കുടുംബമില്ല ☐

10. കുടുംബാംഗങ്ങളുടെ എണ്ണം

2-3 ☐ 4-5 ☐ >5 ☐

11. വിദ്യാഭ്യാസം

പ്രഥമിക വിദ്യാഭ്യാസം ☐ സെക്കന്ററി വിദ്യാഭ്യാസം ☐

ഹയർസെക്കന്ററി വിദ്യാഭ്യാസം ☐ ബുരുദധാരി ☐

ബിരുദാനന്ത ബിരുദം ☐ മറ്റുള്ളവ ☐

12. തൊഴിൽ/ജോലി

സർക്കാർ ഉദ്യോഗസ്ഥ ☐ സ്വകാര്യ സ്ഥാപനത്തിൽ ജോലി ☐

വിദ്യാർത്ഥി ☐ ബിസിനസ്സ് ☐ തൊഴിൽരഹിത ☐

13.ജോലിയുടെ സ്വഭാവം

ക്ലാർക്ക് ☐ കൂലി ☐ വീട്ടമ്മ ☐ പണ്ഡിത ☐

പ്രൊഫഷണൽ ☐ ബാധകമല്ല ☐ മുതലാളി ☐

14. കുടുംബത്തിന്റെ പ്രതിമാസ വരുമാനം

5000-10,000 ☐ 10,001-20,000 ☐

20,001-30,000 ☐ > 30,000 ☐

15. നിങ്ങളുടെ പ്രതിമാസ വരുമാനം

16. നിങ്ങളുടെ കുടംബത്തിൽ ആർത്തവക്രമക്കേടുകൾ ഉള്ളവരുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

17. നിങ്ങളുടെ കുടംബത്തിൽ രോഗങ്ങളുള്ളവർ ഉണ്ടോ

പ്രമേഹം ☐ തൈറോയിഡ് രോഗങ്ങൾ ☐ ഹൃദ്രോഗം ☐

അമിതവണ്ണം ☐ മറ്റുള്ളവ ☐

18. നിങ്ങളുടെ കുടുംബത്തിൽ ആർക്കെങ്കിലും പി.സി.ഒ.എസ് ഉണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

19. നിങ്ങളുടെ കുടുംബത്തിൽ ആർക്കെങ്കിലും ഗർഭധാരണത്തിന് താമസം നേരിട്ടുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

20. പി.സി.ഒ.എസ് ഉള്ള ആരെങ്കിലും കുടുംബത്തിലുണ്ടോ?

ഉണ്ട് ☐ ഇല്ല ☐

21. നിങ്ങളുടെ കുടുംബാംഗങ്ങളിൽ ആർക്കെങ്കിലും അണ്ഡാശയ മുഴരോഗ നിർണ്ണയം നടത്തിയിട്ടുണ്ടോ ?ഫോളിക്കുലർ സിസ്റ്റ്/ഒന്നിലധികം മുഴകൾ മുത്തുകോർത്ത ചരടുപോലെ കാണപ്പെട്ടതായിട്ടുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

22. നിങ്ങൾക്ക് കുട്ടിക്കാലത്ത് അമിതവണ്ണം ഉണ്ടായിരുന്നോ ?

ഉണ്ട് ☐ ഇല്ല ☐

23. നിങ്ങളുടെ ഭാരം വളരെ കൂടുതലായി തോന്നുന്നുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

24. നിങ്ങളുടെ വയറിന്റെ ഭാഗത്ത് വണ്ണം കൂടുതലുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

25. ശരീരഭാരം കുറയ്ക്കാൻ നിങ്ങൾ ബുദ്ധിമുട്ട് അനുഭവിയക്കുന്നുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

26.ഉറക്കം

ക്രമമായി ☐ ക്രമരഹിതമായി ☐

27. ഉറക്കത്തിന്റെ ദൈർഘ്യം

< മണിക്കൂർ ☐ 6 മണിക്കൂർ ☐ > 6 മണിക്കൂർ ☐

28. സാധാരണ ഗർഭനിരോധന മാർഗ്ഗങ്ങൾ എടുക്കുമ്പോൾ നിങ്ങൾക്ക് ഒരു വർഷത്തിനുള്ളിൽ 8 അല്ലെങ്കിൽ അതിൽകുറവ് ആർത്തവം ഉണ്ടോ ? (ഉദാ: ഗർഭനിരോധന ഗുളിക)

ഉണ്ട് ☐ ഇല്ല ☐

29. ആർത്തവം നിയന്ത്രിയ്ക്കാൻ ഗർഭനിരോധന ഗുളിക കഴിയ്ക്കാറുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

30. മുടികൊഴിച്ചിൽ ഉണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

31. നിങ്ങൾമുഖക്കുരുകൊണ്ട് കഷ്ടപ്പെടുന്നുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

32. ചിലഭാഗങ്ങളിൽ നിങ്ങളുടെ ചർമ്മം ഇരുണ്ടതോ മങ്ങിയതോ ആണോ ?

ഉണ്ട് ☐ ഇല്ല ☐

33. നിങ്ങൾക്ക് വിഷാദമോ, ഉൽഘണ്ഠയോ അനുഭവപ്പെടുന്നുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

34. നിങ്ങൾക്ക് മാനസിക അസ്വസ്ഥത ഉണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

35. നിങ്ങൾക്ക് എപ്പോഴെങ്കിലും അണ്ഡാശയ മുഴ ഉണ്ടായിട്ടുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

36. നിങ്ങളുടെ രക്തത്തിലെ പഞ്ചസാരയുടെ വ്യതിയാനമോ, ഹൈപ്പോ ഗ്ലൈസീമിയയോ അനുഭവ്പെട്ടിട്ടുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

37. നിങ്ങളുടെ ഫാസ്റ്റിംഗ് ഗ്ലൂക്കോസിന്റെ അളവ് 99 മില്ലിഗ്രാമിൽ കൂടുതലാണോ

ഉണ്ട് ☐ ഇല്ല ☐

38. വിവാഹിതയായ സ്ത്രീകൾക്ക് മാത്രം ബാധകം. 6 മാസമോ കൂടുതലോ ശ്രമിച്ചിട്ടും ഗർഭധാരണത്തിന് ബുദ്ധിമുട്ടുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

പ്രത്യുല്പാദന വിവരണം

1.ആർത്തവം തുടങ്ങിയ വയസ്സ്

2. ആർത്തവ ചക്രം

26 ദിവസം ☐ 28 ദിവസം ☐ 30 ദിവസം ☐ ക്രമരഹിതമായ ☐

3. ക്രമരഹിതമായ ആർത്തവചക്രം

ഇല്ല ☐ ഉണ്ട് ☐ ഉണ്ടെങ്കിൽ ☐ 35 ദിവസത്തിൽ ഒരിക്കൽ ☐

40 ദിവസത്തിൽ ഒരിക്കൽ ☐ 60 ദിവസത്തിൽ ഒരിക്കൽ ☐

90 ദിവസത്തിനു അതിനു മുകളിലും ☐

4. ആർത്തവത്തിന്റെ ദൈർഘ്യം

3 ☐ 5 ☐ 7 ☐ >7 ☐

5. ആർത്തവ പ്രവാഹം

ക്രമത്തിൽ ☐ ക്രമരഹിതമായി ☐

6. ആർത്തവ സമയത്ത് എന്തെങ്കിലും ലക്ഷണങ്ങൾ അനുഭവപ്പെടാറുണ്ടോ ?

ഇല്ല ☐ ഉണ്ട് ☐

7. അമിത രോമവളർച്ച കാണപ്പെടുന്നുണ്ടോ ?താഴെപ്പറയുന്ന ശരീരഭാഗങ്ങളിൽ കാണപ്പെടുന്നുണ്ടോ ?

ചുണ്ട് ☐ മാറിടം ☐ വയറ് ☐ കൈയ്യ് ☐ ഇല്ല ☐

8.ഗർഭധാരണത്തെക്കുറിച്ചുള്ള വിവരങ്ങൾ

മുൻപ് ഗർഭിണിയായിട്ടുണ്ട് ☐ ഗർഭധാരണത്തിന് ശ്രമിച്ചിരുന്നു ☐

ഗർഭാവസ്ഥയിലാണ് ☐ ഒരു വർഷത്തിലേറെയായി ഗർഭധാരണത്തിന് ശ്രമിക്കുന്നു എങ്കിലും വിജയകരമല്ല ☐

9. മുഖക്കുരു കാണപ്പെടുന്നുണ്ടോ

ഉണ്ട് ☐ ഇല്ല ☐

10. ഉണ്ടെങ്കിൽ എന്തു ചികിത്സയാണെടുത്ത് ?

11. തുടർച്ചയായി ശരീരഭാരം കുടുന്നുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

12. എത്രമാത്രം ഭാരം വർദ്ധിച്ചു ?

13. മറ്റു സങ്കീർണ്ണതകൾ

ഇൻസുലിൻ പ്രതിരോധം ☐ എണ്ണമയമുള്ള ചർമ്മം ☐

ചർമ്മത്തിന്റെ നിറവ്യത്യാസം ☐ ഉയർന്ന കൊളസ്ട്രോൾ ☐

ഉയർന്ന രക്തസമ്മർദ്ദം ☐

14. ഹീമോഗ്ലോബിന്റെ അളവ് സൂചിപ്പിക്കുക

15. ഹീമോഗ്ലോബിന്റെ അളവ് കുറവാണോ ?

ഉണ്ട് ☐ ഇല്ല ☐

16. നിങ്ങൾക്ക് ഹൈപ്പോതൈയ്റോയിഡിസം ഉണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

17. പി.സി.ഒ.എസിനായി നിങ്ങൾ ഏതു തരത്തിലുള്ള ചികിത്സയാണ് സ്വീകരിയ്ക്കുന്നത് ?

18. ഏതെങ്കിലും പ്രത്യേക ഭക്ഷണക്രം എടുക്കുന്നുണ്ടോ ?

19. ശരീരഭാരം നിയന്ത്രിയ്ക്കുന്നതിനു ചെയ്യുന്ന കാര്യങ്ങൾ എന്തൊക്കെയാണ്?

20. അവ പ്രയോജനകരമാണോ ?

21.പി.സി.ഒ.എസി നായി മറ്റേതെങ്കിലും ചികിത്സാരീതി സ്വീകരിയ്ക്കാറുണ്ടോ ?

ആയുർവ്വേദ ☐ ഹോമിയോപ്പതി ☐ യോഗ ☐ പ്രകൃതി ☐

മറ്റെന്തെങ്കിലും ☐

22. മുകളിൽ പറഞ്ഞവയിൽ എന്തെങ്കിലും എടുക്കുകയാണെങ്കിൽ ചികിത്സയും അതിന്റെ ഗുണങ്ങളും സൂചിപ്പിക്കുക.

ആരോഗ്യ ചരിത്രം

1. ആർത്തവചക്രവുമായി ബന്ധപ്പെട്ട ആരോഗ്യ ആരോഗ്യപ്രശ്നം

2. പ്രത്യേകമായി എന്തെങ്കിലും ഭക്ഷണം കഴിയ്ക്കുകയോ/ഒഴിവാക്കുകയോ ചെയ്യാറുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

3. നിങ്ങൾ എന്തെങ്കിലും മരുന്ന് കഴിയ്ക്കുന്നുണ്ടോ ? ഉണ്ടെങ്കിലും ഏത് മരുന്ന് എത്രകാല മായി കഴിയ്ക്കുന്നു

ഉണ്ട് ☐ ഇല്ല ☐

4. നിങ്ങൾ ഏതെങ്കിലും ന്യൂട്രീഷൻ സപ്ലിമെന്റ് കഴിയ്ക്കാറുണ്ടോ ? ഏത് ? എത്രകാല മായി കഴിയ്ക്കുന്നു.?

ഉണ്ട് ☐ ഇല്ല ☐

5.ചികിത്സയുടെ ഭാഗമായി ന്യൂട്രീഷൻ സപ്ലിമെന്റ് ഉൾപ്പെടുത്താൻ നിങ്ങൾക്ക് താല്പര്യ മുണ്ടോ ?

ഉണ്ട് ☐ ഇല്ല ☐

ഭക്ഷണ ശീലങ്ങൾ

1. ഭക്ഷണ ശീലങ്ങൾ

സസ്യാഹാരം ☐ ലോക്ടോ വെജിറ്റേറിയൻ ☐

മാംസാഹാരം ☐ ഓവോ വെജിറ്റേറിയൻ ☐

2. ഭക്ഷണം ഒഴിവാക്കുന്നുണ്ടോ ?

ദിവസേന ☐ പലപ്പോഴും ☐ ഇടയ്ക്കിടെ ☐

വല്ലപ്പോഴും ☐ ഒരിയക്കലും ഇല്ല ☐

3. ഭക്ഷണം ഒഴിവാക്കുന്നത് എപ്പോൾ ?

പ്രാതൽ ☐ ഉച്ചഭക്ഷണം ☐ അത്താഴം ☐ ബാധകമല്ല ☐

4.ഫാസ്റ്റ് ഫുഡുകളുടെ ദൈനംദിന ഉപയോഗം

ദിവസേന ☐ പലപ്പോഴും ☐

ഇടയ്ക്കിടെ ☐ ഒരിക്കലുമില്ല ☐

5. വറുത്ത ഭക്ഷണങ്ങളുടെ ദൈനംദിന ഉപയോഗം

ദിവസേന ☐ പലപ്പോഴും ☐

ഇടയ്ക്കിടെ ☐ ഒരിക്കലുമില്ല ☐

6. ദിവസേനയുള്ള കാപ്പി/ചായ

>5 ☐ 5-4 ☐ 2-3 ☐ 1-2 ☐ ഇല്ല ☐

7. പാലും അതിന്റെ ഉല്പന്നങ്ങളും ദിവസേന കഴിക്കുന്നത്

350 ഗ്രാം ☐ 200-350ഗ്രാം ☐ 100-200ഗ്രാം ☐

>100ഗ്രാം ☐ കഴിയ്ക്കുന്നില്ല ☐

8. ദിവസേനയുള്ള വെള്ളം

1 ലിറ്റർ ☐ 1-1.5 ലിറ്റർ ☐

1.5 –2 ലിറ്റർ ☐ 2 ലിറ്റർ ☐

9.പഴങ്ങളുടെ ദൈനദിന ഉപയോഗം

1 ഫലം 2 പഴങ്ങൾ

2 ൽ കൂടുതൽ പഴങ്ങൾ ഒന്നുമില്ല

10. നിങ്ങൾക്ക് മധുരപലഹാരങ്ങൾ കൊഴുപ്പുള്ള ഭക്ഷണങ്ങൾ എന്നിവയോട് ആസക്തി യുണ്ടോ?

ഉണ്ട് ഇല്ല

11. ഒരുദിവസത്തെ ഭക്ഷണരീതി

സമയം	ഇനങ്ങൾ	അളവ്
അതിരാവിലെ		
പ്രാതൽ		
ഇടനേരം		
ഉച്ചഭക്ഷണം		
ചായസമയം		
അത്താഴം		
ഉറക്ക സമയം		

ഭക്ഷണ ആവർത്തി

ഭക്ഷണസാധങ്ങൾ				
ഗോതമ്പ്				
പയർവർഗ്ഗങ്ങൾ				
ഇലക്കറികൾ				
കിഴങ്ങുവർഗ്ഗം				
മറ്റു പച്ചക്കറികൾ				
പഴങ്ങൾ				
കൊഴുപ്പും എണ്ണയും				

ഭക്ഷണസാധങ്ങൾ				
നട്സ് ബദാം നിലക്കടല കശുവണ്ടി				
പാലും പാൽ ഉല്പന്നങ്ങളും വെണ്ണ ചീസ് തൈര്				
ശീതളപാനീയങ്ങൾ മധുരപലഹാരങ്ങൾ ഫാസ്റ്റ് ഫുഡുകൾ പായ്ക്ക് ചെയ്തതും പ്രോസസ്ഡ് ഭക്ഷണങ്ങൾ പപ്പടം അച്ചാറുകൾ				

ആന്ത്രോപ്രോമെട്രിക് പ്രൊഫൈൽ

ഉയരം ഭാരം ബി.എം.ഐ

ടി.എസ്.എഫ് അരക്കെട്ട്/ഇടുപ്പ് അനുപാതം

ശരീരഘടന വിശകലനം

ശരീരത്തിലെ കൊഴുപ്പ് % - വെള്ളം ലീൻമാസ് വിസെറൽ കൊഴുപ്പ്

ബയോക്കെമിക്കൽ

ഹിമോഗ്ലോബിൻ - രക്തത്തിലെ പഞ്ചസാരയുടെ അളവ്
കൊളസ്ട്രോൾ എച്.ഡി.എൽ
എൽ.ഡി.എൽ
വി.എൻ.ഡി.എൽ
കൊളസ്ട്രോൾ/എച്ച്.ഡി.എൽ/അനുപാതം
ടെസ്ട്രോസ്റ്റിറോൺ
12. മറ്റുള്ളവ

The Content Validation of Questionnaire of the IEC (Approved Research Study " Impact of Nutrition Interventions on Symptoms of Polycystic Ovarian Syndrome (PCOS) among Women of Reproductive age (20-45 years) was validated by the Following Experts

slno	Subject Expert	Signature
1	Dr Patsy Varghese Professor &Head Department of Obstetrics and Gynaecology Believers Church Medical College Hospital , Thiruvalla	
2	Dr Kuruvilla P Chacko Professor Department of Obstetrics and Gynaecology Believers Church Medical College Hospital , Thiruvalla	
3	Dr Rekha G Muricken Associate Professor Department of Obstetrics and Gynaecology Believers Church Medical College Hospital , Thiruvalla	
4	Dr Sangeetha Merrin Varghese Associate Professor Department of Community Medicine Believers Church Medical College Hospital , Thiruvalla	
5	Mrs Aswathy Gopan Chief Dietician Department of Clinical Nutrition and Dietetics Medical Trust Hospital, Kulanada	

ANNEXURE III

Food frequency Questionnaire

Food groups	Daily	Weekly	Monthly	Occasionally	Rarely
1.Cereals					
Raw rice					
Parboiled rice					
Wheat (Flour)					
Maida					
Jowar					
Bajra					
Maize					
Ragi					
Oats					
Rice flakes					
Semolina / Vermicelli					
Others (Specify					
2.Pulses					
Red gram dhal					
Black gram dhal					
Soyabean					
Bengal gram (Whole)					
Green gram dhal					
Green gram (Whole)					
Horse gram (Whole)					
Green peas					
Cow pea					
Rajmah					
Others (specify)					
3.Roots and tubers					
Potato					
Carrot					
Beetroot					
Onion (big)					
Onion (small)					
Tapioca					
Sweet potato					
Yam					
Colocasia					
Others (Specify)					
4.Green leafy vegetables					
Cabbage					
Cauliflower					

Celery					
Chekkurmanis					
Curry leaves					
Coriander leaves					
Spinach					
Mint					
Fenugreek leaves					
Drumstick leaves					
Others (Specify					
5.Other vegetables					
Ash gourd					
Cluster beans					
Beans					
Brinjal					
Kovai					
Bitter gourd					
Chow chow					
Cucumber					
Snake gourd					
Pumpkin					
Ladies finger					
Tomato					
Others (Specify)					
6.Fruits					
Dates					
Jack fruit					
Plantain					
Apple					
Lemon					
Pine apple					
Passion fruit					
Watermelon					
Banana					
Orange					
Pome granate					
Guava					
Papaya					
Others (Specify)					
7.Oils					
Gingelly oil					
Sunflower oil					
Groundnut oil					
Coconut oil					

Butter					
Ghee (Cow					
Palm oil					
Vanaspathy					
Others					
8.Nuts					
Almond					
Groundnut					
Coconut					
Cashew nut					
Others (Specify					
9.Flesh foods					
Beef					
Mutton					
Pork					
Duck					
Chicken					
Egg (Hen / Duck)					
Fish (fresh)					
Fish (Dried)					
Shell fish					
Others (specify)					
10.Milk and milk products					
Milk (Cow / buffalo / goat)					
Skimmed milk					
Curd					
Butter milk					
Whole milk powder					
Skimmed milk powder					
Others (specify					
11.Sugar and Jaggery					
Sugar					
Honey					
Jaggery					
Palm jaggery					
12.Processed/Bakery Foods					
Noodles					
Pastry					
Cutlets					
Vada					
Burger					
Biscuit					

Chips					
Bread					
Cake					
Cookies					
Puffs (Veg, Egg,					
Pizza					
Any other (Specify					
13.Sweets					
Candies					
Chocolates					
Ladoo					
Jilebi					
Jaggery					
Mysore pak					
Soan poppadi					
Peda					
Gulab jamun					
Rasagula					
14.Preserved Foods					
Squash					
Jams					
Pickles					
Papad					
Any other (Specify					
15.Beverages					
Tea					
Coffee					
Green tea					
Carbonated drinks					
Others (specify					

ANNEXURE IV

MODIFIED KUPPUSWAMY SOCIO ECONOMIC SCALE (2020)

Table 1: Occupation of the head of the family

S. No.	Occupation of the Head	Score
1	Legislators, Senior Officials & Managers	10
2	Professionals	9
3	Technicians and Associate Professionals	8
4	Clerks	7
5	Skilled Workers and Shop & Market Sales Workers	6
6	Skilled Agricultural & Fishery Workers	5
7	Craft & Related Trade Workers	4
8	Plant & Machine Operators and Assemblers	3
9	Elementary Occupation	2
10	Unemployed	1

Table 2: Education of the head of the family

S. No.	Education of the Head	Score
1	Profession or Honours	7
2	Graduate	6
3	Intermediate or diploma	5
4	High school certificate	4
5	Middle school certificate	3
6	Primary school certificate	2
7	Illiterate	1

Table 3: Total monthly income of the family

S. No.	Updated Monthly Family Income in Rupees (2012)	Updated Monthly Family Income in Rupees (2018)	Updated Monthly Family Income in Rupees (2019)	Updated Monthly Family Income in Rupees (2020)	Score
1	≥ 30,375	≥ 126,360	≥ 78,063	≥ 199,862	12
2	15,188-0,374	63,182–126,359	39,033–78,062	99,931–199,861	10
3	11,362–15,187	47,266–63,181	29,200 –39,032	74,755 –99,930	6
4	7594–11,361	31,591–47,265	19,516–29,199	49,962–74,755	4
5	4556–7593	18,953–31,590	11,708–19,515	29,973– 49,961	3
6	1521–4555	6327–18,952	3,908–11,707	10,002–29,972	2
7	≤ 1520	≤ 6326	≤ 3,907	≤ 10,001	1

Table 4: Kuppuswamy's socio-economic status scale 2020

S. No.	Score	Socioeconomic Class
1	26–29	Upper (I)
2	16–25	Upper Middle (II)
3	11–15	Lower Middle (III)
4	5–10	Upper Lower (IV)
5	< 5	Lower (V)

Source: Saleem SM. Modified Kuppuswamy socioeconomic scale updated for the year2020. Indian J Forensic Community Med. 2020;7(1):

ANNEXURE V

The modified Ferriman-Gallwey (MFG) score

1. Do you have excess hair growth in certain areas of your body Yes ☐ No ☐

If yes, please fill

Area	0 No hair	1 Mild	2 Moderate	3 Severe (More than 50%)	4 Very severe (More than 75%)
Upper Lip					
Chin					
Chest					
Upper Abdomen					
Lower Abdomen					
Thighs					
Back Arm					
Buttocks					

Hirsutism

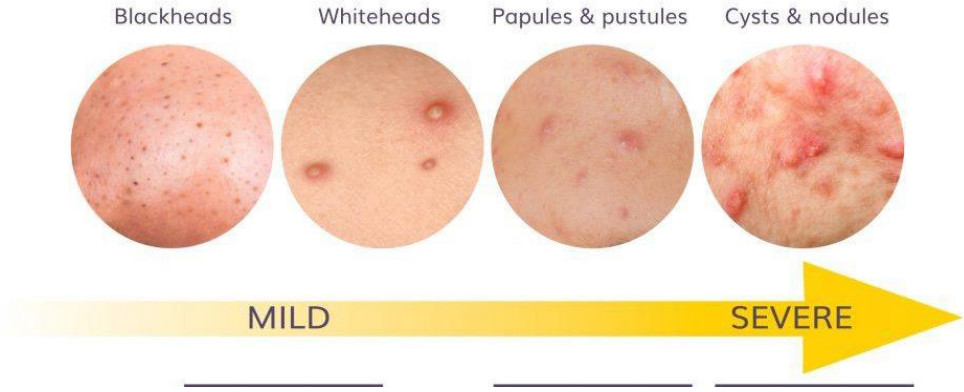
The modified Ferriman-Gallwey (mFG) score grades 9 body areas from 0 (no hair) to 4 (frankly virile), including the upper lip, chin, chest, upper abdomen, lower abdomen, thighs, back, arm, and buttocks. A total score of 8 or more is considered abnormal for an adult white woman; a score of 36 is the most severe

ANNEXURE VI

The Global Acne Grading System

Do you have Acne? Yes ☐ No ☐

If yes please select which type



Location	Yes	No
Fore head		
Right cheek		
Left cheek		
Nose		
Chin		
Chest and Upper back		

Location	Factor (*F*)	Severity (*S*)			Local score (*F*×*S*)	Acne severity	
Forehead	2	0	Nil				
Right cheek	2	1	Comedone			Mild	1–18
Left cheek	2	2	Papule			Moderate	19–30
Nose	1	3	Pustule			Severe	31–38
Chin	1	4	Nodule			Very severe	>39
Chest and upper back	3						
		Total Score					

ANNEXURE VII

Perceived Stress Scale (PSS)

Do you experience stress or anxiety Yes ☐ No ☐

0- never, 1 - almost never, 2 - sometimes, 3 - fairly often, 4 - very often

1. In the last month, how often have you been upset because of something that happened unexpectedly?

2. In the last month, how often have you felt that you were unable to control the important things in your life?

3. In the last month, how often have you felt nervous and stressed?

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

5. In the last month, how often have you felt that things were going your way?

6. In the last month, how often have you found that you could not cope with all the things that you had to do?

7. In the last month, how often have you been able to control irritations in your life?

8. In the last month, how often have you felt that you were on top of things?

9. In the last month, how often have you been angered because of things that happened that were outside of your control?

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

PSS Score

PSS score can be obtained as follows

• First, reverse scores for questions 4, 5, 7, and 8. On these 4 questions, change the scores like this:

0 = 4, 1 = 3, 2 = 2, 3 = 1, 4 = 0.

• Then add up the scores for each item to get total score.

• Individual scores on the PSS can range from 0 to 40 with higher scores indicating higher perceived stress.

► Scores ranging from 0-13 would be considered low stress.

► Scores ranging from 14-26 would be considered moderate stress.

► Scores ranging from 27-40 would be considered high perceived stress.

ANNEXURE VIII

Godin Leisure Scale (Physical activity)

Do you exercise ? Yes ☐ No ☐

	Times per week		Total
Strenuos exercise (heart beats rapidly) (e.g., running, jogging, hockey, football, basketball, judo, vigorous swimming,& long distance bicycling)		X9	
Moderate exercise (not exhausting) (e.g., fast walking, tennis, easy bicycling,volleyball, badminton, easy swimming, dancing)		X5	
Mild/light exercise (minimal effort) (e.g., yoga, fishing, easy walking)		X3	
Weekly leisure-time activity score			

Physical activity score

Weekly leisure activity score = (9 × Strenuous) + (5 × Moderate) + (3 × Light)

If the activity is

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

Total leisure activity score = (9 × 3) + (5 × 6) + (3 × 14) = 27 + 30 + 42 = 99

Adapted from: Godin, G. (2011). The Godin-Shephard leisure-time physical activity questionnaire. Health & Fitness Journal of Canada, 4(1), 18-22.

Godin Scale Score Interpretation

24 units or more Active

14 – 23 units Moderately Active

ANNEXURE - IX

SCHEDULE TO ASSESS THE SENSORY EVALUATION OF READY TO EAT FOODS

Name of the Panel Member :

Code of the food:

Criteria	Variation I	Variation 2	Variation 3	Variation 4	Variation 5
Appearance					
Taste					
Colour					
Flavour					
Texture					

Scores: 1 to 9

ANNEXURE - X

Method and Procedure for Nutrient Analysis

A. DETERMINATION OF MOISTURE CONTENT (Moisture -IS11623-2008)

Aim:

To determine the moisture content of the given food sample and calculate the percentage of moisture content.

Principle:

Estimation of moisture is done by heating at the temperature not much higher that the temperature of boiling water or by over dehydrating the agent allowing to stand overnight or by heating over vacuum.

Apparatus:

Flat bottom dish , asbestos, analytical balance, weight box, tongs, desiccators and electric oven.

Procedure:

Heated a pair of weighing bottles at 100ºc in an oven and labelled A and B. Placed on an asbestos sheet for 2 minutes and then transferred them to a desiccators where they remained for half an hour. Weighed definite amounts of supplement (2g) in each dish .An analytical balance is used to record the weights, repeated the procedure to obtain constant results.(with maximum difference of 0.0002g).Weighed indigenous supplement (2g) in each dish and placed in an electric oven thermostatically controlled at 100- 150ºc. Heated for a stipulated time (2 hours), cooled in a desiccators for half an hour and weighed. This was repeated till two consecutive weights showed no further loss.

Precautions needed:

1. Handle the bottles always sterile and not to expose to atmospheric air
2. Not to open the oven frequently, keep it closed always.
3.Lid of the desiccator should be placed appropriately
5. Do not place a dish in a desiccator for more than half an hour.
6. Carefully shut the door of the analytical balance.
7. Food sample should be free of impurities (non-edible impurities).

The loss of weight equals the moisture present in the sample. The loss of weight divided by the weight of the original sample multiplied by 100 gives the percentage of moisture.

Result:

B. DETERMINATION OF ASH CONTENT

Aim:

To determine the ash content of the given food sample.

Principle:

By continuous heating, the substance gets charred which can be used for the determination of minerals presents.

Apparatus:

Porcelain crucible, Clay pipe triangle, Muffles furnace, Desiccators, Weighing balance, Asbestos sheet.

Procedure:

About 5 g of the sample was weighed accurately into a tarred platinum or porcelain crucible (which had previously been heated to about 600ºc and cooled). The crucible was then placed on a clay pipe triangle and heated over a low flame till all the material was completely charred, followed by heated in a muffle furnace for about 3-5 hours at 600ºc. The crucible was then cooled in a desiccator and weighed. To ensure completeness of ashing heated in a muffle furnace for half an hour, cooled and weighed. This was repeated till two successive weights were the same and ash was almost white or greyish white in colour.

Result:

The ash content of food sample is ---------- g of ash contain

C.ESTIMATON OF NITROGEN (Protein - 5983(Part 1) 2005 Ra 2016)

Aim:

To determine the amount of nitrogen present in the given sample.

Principle:

Concentrated sulphuric acid in a macro kjeldahl flask is digesting the food sample by converting nitrogen to ammonium sulphate. By the action of a strong alkali in a macrokjeldahl steam distillation apparatus, Ammonia is liberated. Ammonium borate is formed by absorbing 2% boric acid is titrated against N 70 sulphuricacid. The volume of acid required to bring the test sample to the colour of the blank of the blank gives the equivalent to the ammonia. 196

Reagents:

1. N/70 Sulphuric acid
2. 40% Sodium Hydroxide
3. 2% Boric acid(in warm water)
4. Digestion mixture: A mixture of copper sulphate and potassium sulphate in the ratio of 2:98
5. Concentrated Sulphuric acid
6. Mozazaga indicator: A mixture of bromocresol green and methyl red indicator in 95% alcohol in the ratio of 4:1 (80 mg and 20 mg in 100 ml of alcohol).

PROCEDURE:

1. 0.5 g of the sample was taken into the digestion flask. To this added 15ml of concentrated sulphuric acid and a pinch of digestion as a catalyst. Kept at boiling gently over a heating mantle.
2. After digestion, the flask was cooled and the contents were transferred to a 100ml of standard flask and made upto the mark with distilled water.
3. The whole apparatus was washed with distilled water and allowed to back suck.
4. 10ml of boric acid was taken in a conical flask. A drop of indicator was added to it and kept under the condenser.
5. The tip of the condenser was well below the liquid.
6. 5ml of the digested blank was added into the distillation chamber through the funnel. Then added 10 ml of 40% of NaOH. Washed the funnel with 2-3ml of distilled water.

7. Closed the tap and the steam was generated.

8. Steam entered the distillation chamber and drove all the ammonia which is in turn absorbed by boric acid.

9. Solution was pinkish white in colour, turned blue.

10. Steam was passed for 5min and then the conical flask was lowered and the tip of the condensor washed.

11. The boric acid solution containing the liberated ammonia was titrated against N/70 H_2SO_4.

12. The end point was the appearance of pale permanent pink colour.

13. Between each estimation, the apparatus was washed.

14. The experiment was repeated to get concordant values.

RESULT:

The nitrogen content in 100g of food sample is…….. mg.

D. DETERMINATION OF FIBRE CONTENT

Aim:

To determine the fibre content of the given food sample.

Principle:

The term “crude fibre” ordinarily meant in agriculture and food analysis is the organic residue consisting largely of cellulose, that is left after other carbohydrates and proteins have been removed by successive treatment with boiling acids and alkalis. The crude fibre obtained in this way is not cellulose but contains distinct properties of hemicelluloses, and nitrogenous substances. These however are not sufficient to prevent the results from being reasonably accurate and comparable.

Apparatus:

Weighing balance, Beaker, Glass rod, Funnel, Muslin cloth, Burner and Wire gauze.

Reagents:

1. 0.255N Sulphuric acid: 0.9 ml of Sulphuric acid in 99.1ml water.
2. 0.313N Sodium hydroxide: 0.8g Sodium hydroxide in 99.2ml water.
3. Ether
4. Alcohol

Procedure:

5g of the sample was weighed into a 500ml beaker and 200ml of boiling 0.255N sulphuric acid was added. The mixture was boiled for 30 minutes keeping the volume constant

by adding water at frequent intervals (a glass rod inserted in the beaker helps smooth stirring and boiling). At the end of the period, the mixture was filtered through a muslin cloth and the residuewas washed with hot water till free from acid. The mixture was then transferred to a beaker containing 200ml of boiling 0.313N sodium hydroxide. After boiling for 30 minutes (keeping the volume constant as before) the mixture was filtered through a muslin cloth. The residue was washed with hot water till free from alkali following by washing with some alcohol and ether. It was then transferred into a crucible, dried overnight at 80-1000c and weighed. The crucible was heated in a

muffle furnace at 6000c for 2-3 hours. Cooled and weighed again. The difference in the weight represents the weight of the fibre.

Results:

100g of sample contains ---------- of fibre

E. ESTIMATION OF TOTAL CARBOHYDRATE BY ANTHRONE METHOD

Aim:

To estimate the amount of total carbohydrate present in the given food sample.

Principle:

Carbohydrates are hydrolyzed into simple sugar using dilute hydrochloric acid. In hot acidic medium glucose is dehydrated to hydroxyl methyl furfural. This compound forms with anthrone, a green colour with an absorption maximum at 630nm.

Reagents:

1. 2.5mlN HCL
2. Anthrone reagents: Dissolved 200mg anthrone in 100ml of ice cold H2SO4, prepared fresh before use.
3. Stock standard: dissolved 100mg glucose in 100ml of water.

195

4. Working standard: 10 ml of stock standard solution is diluted with 100ml distilled water. Stored refrigerated after adding a few drops of toluene.

Procedure:

1. Weigh 100mg of sample into a boiling tube.
2. Hydrolyse by keeping it in boiling water bath. Boiled for 3 hours with 5ml 2.5N HCL and cool to room temperature.
3. Neutralize it with solid sodium carbonate until effervescence cases.
4. Make up the volume to 100ml and centrifuge. Collect the supernatant and 0.5ml nad 1 ml aliquots for analysis .prepared the standard by taking 0.0 0.2,0.4,.0.6,0.8 and 1ml of the working standard ‘0’ serves as blank.
5. Make up the volume to 1ml in all the tube including the sample tubes by adding distilled water.
6. Then added 4ml of anthrone reagent and heat to 8 minutes in boiling water bath. Cool rapidly and read the green to dark green colour at 630nm.
7. Draw a standard graph by plotting concentration of the standard on the x axis verses absorbance on the y axis. From the graph calculate the amount of carbohydrates present in the sample tube.

Result:

Amount of carbohydrate present in 100ml of the food sample is

F. DETERMINE OF FAT CONTENT

Aim:

To determine the fat content of the food stuff.

Principle:

Ether extraction of the crude fat in vegetable products is carried out in a continuous extractor that is an apparatus in which the ether, after dissolving a portion of the fat of the materials and discharging into the extraction flask, is volatized, condensed and again allowed to act on the material. The steps in the process are repeated continuously and automatically until the

extraction is complete. The soxhelt extraction used depends on the intermittent action of a glass syphon. The ether gradually condenses into the extraction tube containing the material until it rises to top when it is discharged into the extraction flask.

Reagent:

Petroleum ether (60-800 c boiling point).

Procedure:

The soxhelt flask was weighed to consecutive concordant weights. 2g of the moisture free

sample was packed into an extraction thimble and placed in an extractor which was fixed into a soxhlet flask. Poured sufficient amount (150ml) of petroleum ether so as to permit syphon action. The thimble and the contents were allowed to soak in ether for 24 hours. The entire set up was kept over an electric water bath and the extractor was connected to the condenser. The nozzle of the condensor was always plugged with moistened cotton. The temperature was maintained at 600c. A steady stream of water in the condensor was maintained. The ether evaporated rose up but owing to the condenser arrangement, it fell back into the condensor extractor. When the extractor got filled with ether, it was siphoned back into the flask. This went on till the ether that got collected in the extractor was free from any yellow colour indicating the presence of fat. The sozhelt flask was then disconnected and ether was evaporated in a water bath maintained at 600c. When the ether in the flask was evaporated, the flask was weighed again to get concordant values. From the difference in weight, the fat content was calculated.

Result:

The fat content of 100g of sample contains =

G. ESTIMATION OF CALCIUM

Aim: To estimate the amount of calcium present in the given sample.

Principle:

Calcium is determined by the precipitating it as calcium oxalate and titrating the oxalate

solution in dilute sulphuric acid against standard potassium permanganate.

Apparatus:

Beaker, Burette, Pipette flask and Standard flask.

Reagents:

1. **AMMONIUM OXALATE (4%):** Ammonium oxalate was dissolved in 200ml of distilled water till it was saturated.

2. **2.0.01 N OXALIC ACID:** 0.063g oxalic acid crystals were weighed and dissolved in 100ml

of distilled water.

3. **0.01 N KMNO4:** 0.316g of KMNO4 was dissolved in 1000ml of distilled water.

4. Strong Ammonia

5. Glacial Acetic Acid

6. **2N Sulphuric Acid :**5.5 ml of sulphuric acid was dissolved in 94.5ml of distilled water.

PROCEDURE:

Ash from the ignited sample was dissolved in hydrochloric acid and made upto the 100ml with distilled water. 10ml of the ash solution was pipette out in a conical flask and 90ml distilled water was added to it. Added 2 drops of methyl red indicator. It was made strongly alkali by adding ammonia and kept for boiling 20ml of saturated ammonium oxalate was added to the solution 10 ml each time to ensure complete precipitation directly. When it was hot, a few drops of acetic acid was added to render the medium acidic. The precipitate was allowed to settle overnight. The next morning the solution was filtered with What man No:40 filter paper. The precipitate was washed first with ammonical water and then with hot water several times until it was free from chloride. To test it 5ml of washing was collected, in a test tube and a drop of calcium chloride solution was added. The washing was continued til there was no precipitate with silver nitrate or calcium chloride solution. The filter paper was collected in a flask by making a hole in the filter paper. To this 2ml of 2N sulphuric acid was added. This solution was heated to 600 -800 C and when still hot was titrated against N/100 potassium permanganate solution. From the volume potassium permanganate solution used up the milligram of calcium present in 100g of sample was calculated.

RESULT:

100g of sample contains ---------- milligram of calcium

H. ESTIMATION OF IRON

Aim:

To estimate the amount of iron present in 100g of the given food sample.

Principle:

The food sample is oxidized with ignition or oxidation .Iron as ferric iron reacts with ammonium thiocyanate or with potassium thiocyanate to give ferric thiocyanate which is red in color .The color which is a measure of the concentration is measured colorimetrically.

Apparatus:

Volumetric flask, Test tubes, Klett, Pipettes.

Reagents:

1. Stock iron solution: Dissolved 0.0702gm (70.2mg) of reagent grade crystalline ferrous ammonium sulphate (Mohr's salt) in 100ml of water.
2. Working standard: prepared a working standard solution in a100ml volumetric flask by adding 10ml of the stock solution and diluted to the mark with distilled water.
3. Saturated potassium per sulphate solution: stcok 7 to 8g of reagent grade potassium per sulphate in 100ml of water in a glass stoppered flask. The undissolved crystals settled to the bottom and compensate the loss by decomposition.
4. 3N Potassium thiocyanate: Dissolved 146g of reagent grade potassium thiocyanate in water and diluted to 500ml with water filtered if turbid . Added 20ml of pure acetone to improve the keeping quality. Deterioration will be evident from the rapid fermentation of a yellow color in the blank. Stored in brown bottles.

Procedure:

2g of the sample was ashed by ignition. When ashing had been completed 5ml of hydrochloric acid was added and made up to 100 ml in a volumetric flask. Took different aliquots of the standard solution (1ml-5ml) to corresponding to 10-50 gamma in a series of the test tube. Added 1ml of 30% H2SO4, 1ml of potassium persulphate and 1.5ml of potassium thiocyanate to all the test tubes. This was made up to 10ml with water. A blank was prepared by adding the reagents except the standard or the unknown solution. Allowed the colour to develop for 20 minutes and the intensity was read at 530-540□□filters in the colorimeter.

Result:100g of sample contains ---------- milligram of iron.

I. ESTIMATION OF PHOSPHORUS

Aim:

To estimate the amount of phosphorous present in the given sample.

Principle:

When the ash solution is treated with ammonium molybdate, phosphomolybdic acid is formed. Phosphomolybdic acid is reduced by the addition of 1, 2,4 amino naphtholsulphonic acid reagent to produce a blue colour which is apparently a mixture of oxides of molybdenum. The intensity of the colour developed is the measure of phosphorous present.

Apparatus:

Measuring cylinder, Klett, Test tubes and Pipette.

Reagents:

1. Molybdate solution No 1:

Dissolved 25g of reagent grade ammonium Molybdate I in about 200ml of water. In one litre volumetric flask 500ml of 10N sulphuric acid was added. The molybdate solution was added and dilute with water to one litre. This solution is stable indefinitely.

2. Molybdate solution No.II:

Dissolved 25g of reagent grade ammonium Molybdate II about 200ml of water. In one litre volumetric flask, 300ml of 10N sulphuric acid was added and was dilute with water to one litre. This solution is stable indefinitely.

3. ANSA:

195ml of 15% sodium bisulphate solution was placed in a glass stoppered cylinder. 0.5g of 1, 2, 4 ANSA (amino naphtholsulphonic acid) was added followed by 5ml of 20% sodium sulphite. Put the stopper and shook until the powder was dissolved. If the solution was not complete, added more sodium sulphite, 1ml at a time with shaking but avoided excess. This solution was transferred to a brown glass bottle and stored in the refrigerator.

4. **Stock standard phosphorus solution**:

35.1mg of pure potassium dihdrogen phosphate is weighed and dissolved in water. Added 10ml of 10N sulphuric acid and made upto 100ml with water. 5ml of the solution contains 0.4mg of phosphorus. Prepared a working standard containing 8 gamma of phosphorus in 1 ml of the solution by making up 5ml of the standard solution to 50ml with water.

Procedure:

0.1ml of the ash solution was taken in two test tubes. 1ml of molybdate II and 0.4ml of 1,2,4, amino naphtholsulphonic acid were added and the volume was made upto 10ml with distilled water. To 1ml, 2ml, 3ml,4ml and 5ml of standard solution, 1ml of molybdate Isolution and 0.4ml of ANSA were added and made upto 10ml. All the tubes containing 10ml of the solution were mixed well and allowed to stand for 15 minutes. Simultaneously, a blank was prepared by mixing 8.6ml of water, 1ml of molybdate II and 0.4ml of ANSA. The colour developed was read in the colorimeter using red filter of wavelength 660 millimicrons.

Result:

100g of the foodstuff contains = of phosphorus.

J. ESTIMATION OF VITAMIN 'C' BY DYE METHOD

Aim:

To estimate the amount of vitamin c present in the given sample.

Principle:

Vitamin c is a good reducing agent and it reduces the dye 2,6dichlorophenol indophenol. In this reaction the ascorbic acid itself is oxidized to dehydro ascorbic acid. In the absence of interfering substances, the capacity of the extract of the sample to reduce a standard solution of a dye as determined by titration is directly proportional to the vitamin C content .oxalic acid is not only used to reduce the pH of the extracting medium, there by establishing the vitamin C but also form complexes with metals eg. Copper thereby preventing the catalytic oxidation of vitamin.

Apparatus:

Centrifuge, centrifuge tubes, mortar and pestle, beakers, pipette, 100ml standard flask, burette and funnel.

Reagents:

1.2,6 Dichlorophenol indophenol dye: Dissolved 42mg of bicarbonate and 52mg of 2, 6 dicholorophenol indophenol in about 50ml of water. This was diluted to 200ml, filtered, and stored in the refrigerator.

2. 4% Oxalic acid: Dissolved 4g oxalic acid in 100ml distilled water .

3. Standard ascorbic acid: Dissolved 100mg of pure ascorbic acid crystals in 100ml of 4% oxalic acid.

Standardization of the dye:

Pipette out 10 ml of the standard ascorbic acid solution into a beaker and then added 25ml of oxalic acid .From this solution pipetted out 5ml into a conical flask and placed in an ice container and the contents were titrated against the dye in the burette The end point was the appearance of pink colour which persisted for 30 seconds .the amount of dye consumed is equivalent to the amount of ascorbic acid present.

Procedure:

5g of the sample was weighed and soaked in 40% oxalic acid for 10 mts .This was then ground in a mortar and transferred to centrifuge tubes adding more oxalic acid. The solution was

centrifuged and the supernatant clear liquid was transferred to a100ml standard flask. Repeated the extraction with oxalic acid for three or four times. All the supernatants were collected in the same standard flask and this was finally made up to the mark with acid.The dye was taken in a micro burette and titrated against 5ml of the extract in a beaker .The end point was the appearance of pink color which persisted for 30 sec. The titration was repeated till concordant values were obtained.

Result:

100g of food sample contain --------- mg of ascorbic acid

100g of food stuff contain ------ □g of carotene

K.DETERMINATION OF CHROMIUM, ZINC AND MAGNESIUM

Procedure CKL/ANL/ FP/019

STOCK SOLUTION: Prepare 1 ppm stock solution by pipetting 1 ml of 9 element standard in to a 100 ml standard flask and make up to the mark using water (SIEMENS water purifier).

WORKING STANDARDS:

Working standards are prepared from stock solution by appropriate dilution so that all the standards fall within the linear range of the element of interest. Mixed standards of all elements of interest were prepared: 1ppb, 5ppb, 50ppb, 100 ppb, 200 and 250 ppb.

0.25g to 0.5 g sample is weighed accurately in to MDS digestion tube. Add 5.0 ml conc. HNO_3 (extra pure), 0.5 ml conc. HCl(extra pure), and 1.0 ml H_2O_2 (extra pure), and allow 15 min. self-digestion. Tighten the cap and keep for digestion in the MDS. After digestion quantitatively transfer the contents in to 50 ml tube and make up to 50 ml using extra pure water.

Calculation

Element (ug/L) = Concentration from calibration graph (ug/L) x dilution factor

Determination of Phosphorous (AOAC 21" Edition vol III)

- Weigh 0.5-1.5 g of sample in a crucible, to control possible contamination prepare reagent blank by an empty crucible.
- Add 0.5 g ZnO in to crucible and mix well using a glass rod
- Dry 1-2 hour at 110^0 C. Pre-ash on hot plate until residue is black
- Keep crucible in muffle furnace and 525^0 C for 4 hours
- After 4 hour take it out and let it cool at room temperature
- Add 5ml H_2O and 5 ml HCl
- Cover crucible with watch glass and boil contents for 5 minutes on hot plate
- Filter the contents in to a 100 ml standard flask and rinse crucible using hot distilled water
- Neutralize the solution by adding 50 % of KOH until the solution is slightly opalescent
- Add HCL drop wise until opalescence disappears
- Add extra drops of HCl and let it cool at room temperature and then dilute to 100 ml with H_2O
- To 1 ml sample add 20 ml of molybdate-ascorbic acid solution in a 50 ml standard flask

- ❖ Keep In water bath for 15 minutes, cool and make up to 50 ml
- ❖ Transfer the solution in to cuvettes and measure the absorbance at 523 ± 1 nm
- ❖ Construct the standard curve by plotting the absorbance s against amount P in P standard solutions(0,0.01, 0.02, 0.03, 0.04, 0.05, 0.06, mgP)

L.WATER SOLUBLE VITAMINS

Instruments

HPLC : CKL/ANL/E-027 – Agilent Technologies 1200 Infinity Series
Balance : CKL/ANL/E-001

Method

Mobile phase : Buffer : Acetonitile (99:1)

Buffer: Hexane Sulphonic acid-1.03g Hexane Sulphonic acid + 25MmDi Potassium hydrogen orthophosphate to 1000 ml (4.35g dipotassium hydrogen orthophosphate with distilled water, pH adjusted to 7.0 with orthophosphoric acid

Std preparation

Water soluble vitamin standards of different concentrations are prepared in dist.water
Sample preparation
Take 5gm sample and add 25ml Mixtrue (1.25ml acetonitrile +0.25ml glacial acetic acid make up to 25ml with dist. water). Kept in waterbath at 70o c for 45 minute. Filter and make up to50 ml with dist, water. Filter and inject to the HPLC system.

Chromatographic conditions

Column : C_{18} 4.6×150mm×5µm
Flow rate : 1.0mL/Minute
Inj.Volume : 30µL
Wave length : 220nm
Run time : 22 minute
Column temperature: 40^0

Flow:Gradient	Buffer A:	Acetonitrile C
0 minute	A-99	C 1.0
5minute	A -99	C1.0
15minute	A-70	C30
20minute	A-70	C 30
20.1minute	A-99	C 1.0

Calculation

Standard weight	:	Standard area	:
Sample Weight	:	Sample area	:
Purity of standard	:		

Reference: Determination of water soluble vitamins with the Agilent 1120 compact LC.

ANNEXURE XI

Questionnaire for Assessing Knowledge on Polycystic Ovarian Syndrome

1) Have you heard of the term PCOS?

a) Yes b) No

2. Endometrial hyperplasia is seen more often in women with PCOS.

a) True b) False

3. PCOS is aggravated by

a) Stress b) Smoking c) Alcohol d) All of the above

4. Weight reduction is an important management for all aspects in PCOS patients.

a)True b)False

5. Common measure to overcome PCOS

a) Exercise b) Dietary management c) Medication d) All

6. How does PCOS affect women while pregnant?

a) Miscarriage b) Gestational Diabetes c) Pregnancy induced hypertension d) All

7. Hormone linked to PCOS is

a) Testosterone b) TSH c) Ghrelin d)Calcitonin

8. Oligomenorrhea is defined as

a) Fewer than 8 periods in a year b) Fewer than 10 periods in a year

c) Painful periods d) absence of periods

9. Very common clinical symptom of PCOS is

a) Facial hair growth b) oedema c) headache d) skin rashes

10, Emotional symptoms in PCOS is due to

a) Serotonin b) Protein c) Leptin d) Melatonin

11. Mineral which helps to reduce the symptoms of PCOS is

a) Phosphorus b) Magnesium c) Chloride d) Sodium

12 Diet which helps to improve the symptoms f PCOS is

a) Mediterranean diet b) GM diet c) High GI diet d) Renal diet

13 .Chronic complication of PCOS is

a) NAFLD b)COPD c)Alzheimer's disease d) Hepatocellular carcinoma

14. PCOS subjects may have a chance of Obesity

a)Yes b) No

15 KD is the optimal long term dietary intervention for patients with PCOS

a) Yes b) No

16. In PCOS subjects the chance of metabolic syndrome is higher

a) True b) False

17. The exercise that relaxes mind and body among PCOS subjects are known as

a) Progressive muscle relaxation b) Aerobics c) Resistance Training

18.Which seeds are beneficial during the follicular phase?

a) Sunflower seed b) sesame seeds c) flax seed d) Chia seed

19. Which type of fat is seen among young age?

a)Omega 3 fatty acid b) Omega 6 fatty acid c) Oleic acid d) None of the above

20 .Does weight loss helps in regularising menstrual cycle in PCOS

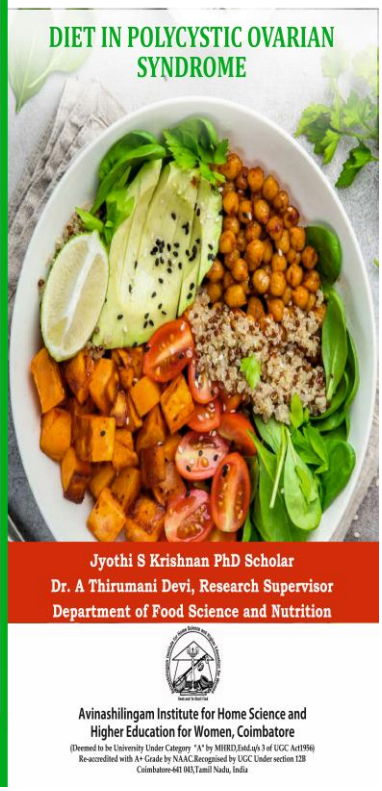
a) No b) Yes

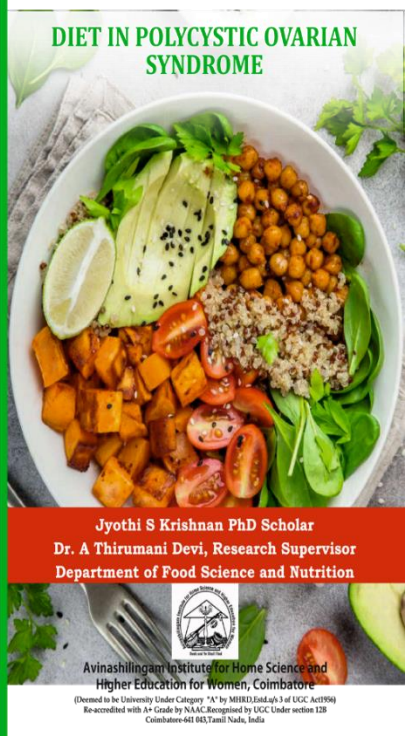
The content Validation of Health and Nutrition Education Module and KAP Questionnaire of the IEC approved study "Impact of Nutrition Interventions on Symptoms of Polycystic Ovarian Syndrome (PCOS) among Women of Reproductive age (20-45 years)" was validated by the Following Experts (IEC/20202/02/126)

Sl no	Subject Expert	Signature
1.	Dr Patsy Varghese Professor and Head Department of Obstetrics and Gynaecology BCMCH	
2	Dr Kuruvilla P Chacko Professor Department of Obstetrics and Gynaecology BCMCH	
3	Dr Rekha G Muricken Associate Professor Department of Obstetrics and Gynaecology BCMCH	
4	Dr Sangeetha Merrin Varghese Associate Professor Department of Community Medicine BCMCH	
5	Mrs Aswathy Gopan Chief Dietician Department of Clinical Nutrition and Dietetics Medical Trust Hospital Kulanada	

ANNEXURE XII

DIET EDUCATION BROCHURES





ANNEXURE XIII

ETHICAL CLEARANCE CERTIFICATE

INSTITUTIONAL HUMAN ETHICS COMMITTEE

Avinashilingam

Institute for Home Science and Higher Education for Women
(Deemed to be University under Category 'A' by MHRD, Estd. u/s 3 of UGC Act 1956) Re-accredited with 'A+' Grade by NAAC. Recognised by UGC Under Section 12 B
Coimbatore-641 043, Tamil Nadu, India

16th February 2021

To
Mrs.Jyothi S Krishnan,
Department of Food Science and Nutrition
Avinashilingam Institute for Home Science and
Higher Education for Women
Coimbatore – 641 043

Dear Jyothi S Krishnan,

Ref: Your representation of the proposal IHEC/19-20/FSN/34 entitled "Impact of Nutrition Intervention on the symptoms of Polycystic ovarian syndrome among Women of Reproductive Age (20 – 45 years)" to the IHEC on 27th January 2020.

The Institutional Human Ethics Committee of our University hereby grants approval to your research proposal IHEC/19-20/FSN/34 entitled "Impact of Nutrition Intervention on the symptoms of Polycystic ovarian syndrome among Women of Reproductive Age (20 – 45 years)" submitted and presented by you. The Approval number for the same is AUW/IHEC-19-20/ FSN/FHP- 01.

We wish you all the best in your research endeavours.

Regards,

V. Uma Mageshwari
Dr.S.Uma Mageshwari
Member Secretary

Institutional Human Ethics Committee

Believers Church
MEDICAL COLLEGE HOSPITAL

INSTITUTIONAL ETHICS COMMITTEE
Regn. No: ECR/1098/Inst/KL/2018

IEC/2020/02

Date: 25.02.2020

IEC STUDY No. IEC/2020/02/126

Ms. Jyothi Krishnan
Department of Dietary

Dear Ms. Jyothi Krishnan,

Sub: Approval of Research proposal by the I.E.C

I wish to inform you that your Research Project entitled **"Impact of nutrition intervention on the symptoms of polycystic ovarian syndrome among women of reproductive age (18- 45 years)"** has been unanimously approved by Ethical review and was approved on 25.02.2020. The approval of I.E.C is valid for a period of 2 years from the date of approval given.

You must inform the IEC of the following through the Secretary of Institutional Ethics Committee

1. The occurrence of serious Adverse Events/Drug Reactions and/or Death. While conducting this Trial in the specified format.
2. Protocol amendment in the specified format.
3. (a) Discontinuation (b) Abandonment (c) Completion of this trial, stating the reasons, if the situation of 2(a) or (b) is encountered.
4. (a) It is mandatory that a 6 monthly Interim Review Report on the status of the project be submitted to the Secretary in the specified format.
   (b) On completion of above Research Project- the Principal Investigator is responsible for submitting a brief summary of the results obtained.

With best wishes,

Dr. TOMY PHILIP MD;MRCP
Reg.No: 15918
Professor of Medicine
Pushpagiri Institute of
Medical Sciences,Tiruvalla.

Chairperson

CC: The HOD, Medical Research

Institutional Ethics Committee
Believers Church Medical College Hospital
St. Thomas Nagar, Kuttapuzha (P.O)
Thiruvalla - 689 103

INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

(Strike off items that are not applicable)

I / We (~~write name(s) of the investigator(s) here~~), Jyothi S Krishnan am / ~~are~~ carrying out a study on the topic **IMPACT OF NUTRITION INTERVENTION ON THE SYMPTOMS OF POLYCYSTIC OVARIAN SYNDROME AMONG WOMEN OF REPRODUCTIVE AGE (18- 45 YEARS)** as part of my / ~~our~~ research project being carried out under the aegis of the Department of Food Science and Nutrition

My / ~~our~~ research guide is: Dr A Thirumani Devi
(Applicable to students only)

The justification for this study is:

The objectives of this study are:

- Primary Objective(s): The main objective of the study will be to compare and examine the effect of Structured Dietary Intervention focusing on (low calorie, high protein, moderate carbohydrate, high fibre diet) on the symptoms of PCOS patients to the same along with micronutrient enriched supplement intervention in PCOS patients.

Secondary Objective(s):

- Study the etiological factors contributing to PCOS and assess the nutritional status of reproductive age women having PCOS
- To assess the association between symptoms and anthropometric , biochemical Clinical and dietary factors
- Formulation and Nutrient Analysis of the Micronutrient rich Nutraceutical.
- Preparation and evaluation of educational module to enhance the nutritional knowledge of women of reproductive age with PCOS

Sample size: 86

Study volunteers / participants are (specify population group & age group): Reproductive age Women having PCOS

Location of the study: Believers Church Medical College Hospital, Thiruvalla, Kerala

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview (specify approximate duration):15 minutes.

Data collected will be stored for a period of fifteen years. We will / will not use the data as part of another study.

Health education sessions: Number of sessions: 1

Approximate duration of each session: 20 minutes.

Clinical examination (Specify details and purpose):

Blood sample collection: Specify quantity of blood being drawn: 30ml

No. of times it will be collected: 2times

Whether blood sample collection is part of routine procedure or for research (study purpose):

[√] Routine Procedure [√] Research Purpose

Specify purpose, discomfort likely to be felt and side effects, if any: NA

Will the blood sample collected be stored after study period: [ ] Yes

[√] No, it will be destroyed

Will the blood sample collected be sold: ☐ Yes ☑ No

Will the sample collected be shared with persons from another institution: ☐ Yes ☑ No

Medication / supplementation given, if any, with duration, side effects, purpose, benefits:

Is the medication / supplementation given part of routine procedure: ☐ Yes ☑ No
(If no, state reasons for giving this medication/supplementation)

The micronutrient rich nutritional supplement helps to reduce the symptoms of PCOS

Are alternatives available for medication / supplementation given: ☐ Yes ☑ No
(If no, state reasons for giving this particular medication/supplementation)

The supplement is developed using easily available low cost food items

Final interview (specify approximate duration): 10minutes.

If photograph is taken, purpose: NA

- Benefits from this study, if any : Nutritional supplement helps to reduce reproductive health issues such as infertility , Obesity , metabolic and hormonal changes in PCOS subjects

Risks involved by participating in this study, if any : NA

How will the results be used: For research, publication

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, you have the right to withdraw from the interview / study at any time. You have the freedom to withdraw from the study at any point of time. You will NOT be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings – including adverse events, if any – whether directly or indirectly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator(s). Having understood the same, I hereby give my consent to them to interview me, and collect biological sample blood, from me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements)

Betsy BETSY ANNA KURUVILLA.

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date 29/10/19

Signature of the Witness with name: THASNEEM FATHIMA

Avinashilingam Institute for Home Science and Higher Education for Women
(Deemed to be University under Category A by MHRD, Estd. u/s 3 of UGC Act 1956)
Re-accredited with A+ Grade by NAAC. Recognised by UGC Under Section 12 B
Coimbatore - 641 043, Tamil Nadu, India

Appendix L2

(Item No 5 of Check List)
Details of Research Publications

S.No	Article	Journal	Other Details Vol/No/Page No/ Year	Published in UGC-CARE / Scopus Indexed/ Web of Science (*List of Journals in that category including the particular Journal to be attached)
1	Comparison of Clinical Findings and Nutritional Status in Women with Polycystic Ovarian Syndrome in 18-29 and 30-45 Year Age Groups	The Indian Journal of Nutrition and Dietetics 2021 ISSN:022-3174;e ISSN :2348-621X	IJND Vol.58, No3, July –September 2021 page no 350-360	UGC CARE
2	Effectiveness of micro nutrient rich supplement on the symptoms of polycystic ovarian syndrome among reproductive age women	International Journal of Health Sciences 2022 ISSN2550-6978 E-ISSN2550-696X	IJHS Vol6, No S1 7-6-2022 Pageno:14128-14144	SCOPUS INDEXED

*Proof of list of Journals from Internet to be attached along with copies of reprints.

Scholar :

Supervisor :

25/7/22
Checked By :

HoD/Dean

The Indian Journal of Nutrition and Dietetics
ISSN: 0022-3174; eISSN: 2348-621X
www.ijndonline.org

DOI:10.21048/IJND.2021.58.3.27554

Comparison of Clinical Findings and Nutritional Status in Women with Poly Cystic Ovarian Syndrome in 18-29 and 30-45 Year Age Groups

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(Received)

Abstract

Poly cystic ovarian syndrome (PCOS) is a heterogeneous disorder common among reproductive age women. The study was focused to compare the clinical findings and nutritional status of women with PCOS in 18-29 and 30-45 year age groups. Overall, 120 PCOS subjects in the age group of 18-45 years was selected for the study. Rotter Damcriteria was used for identification of the subjects for the study. Socio economic status of the subject revealed that majority of the subjects (49 %) belonged to upper lower class IV. There was a significant mean difference in BMI (p=0.007), Oligo an ovulation (p=0.02) between the two groups. The mean Scores of hirsutism and physical activity was significantly higher in the 18-29 age group (p<0.05). Nutrient intake was assessed by three day food record and food frequency questionnaire (FFQ) and calculated using Diet Cal software. The mean intake of calorie, carbohydrate and fat was remarkably higher in both age groups whereas the intake of some micronutrients such as calcium, zinc, iron and retinol was lower compared to EAR. The Vitamin D intake was very poor than the EAR in all the participants. The comparison of nutritional status of the two age groups disclosed that there was a significantly higher mean intake of calorie (p=0.045), fibre (p=0.006), iron (p=0.022), magnesium (p=0.017), chromium (p=0.016) and potassium (p=0.041) in the 30-45 year age group. Food consumption pattern affirmed that there was a remarkable difference in the intake of processed foods, soft drinks, sweets, fish, leafy vegetables, pickle between the two age groups.

Keywords: *Polycystic ovarian syndrome, mean nutrient intake dietary intake, nutritional status, micronutrients, vitamin D*

Introduction

Polycystic Ovarian syndrome is a multi factorial endocrine disorder occurs among 6% to 21% of women in the reproductive age groups and difficult to define due the heterogeneous nature of the disorder. This disorder is characterized by biochemical abnormalities, such as excess and organ levels in the blood, menstrual cycle irregularities, lack of ovulation, enlarged ovaries with numerous cysts and infertility (Moran LJ etal2013). Insulin increases the production of androgens by directly affecting the ovarian the ca cells. Intake of food of low nutritional value and high calorie is one of the leading cause to insulin resistance and obesity (Asemi, Z etal 2015). Many studies revealed high calorie, high saturated fat, high sodium consumption among PCOS population. Studies also disclosed significantly lower fibre and magnesium intake in PCO groups compared with matched control women (Douglas,C.Cetal2006). Some of the previous studies have inscribed the role of some micronutrients in improving insulin resistance including antioxidants such as β-carotene, zinc, selenium, vitamin E and vitamin C which protects against free radicals thereby preventing the adverse effects such as oxidative stress, damage of cellular membranes (RuderE.H and HartmanT.J 2009). Recent studies explained the role of supplementation of calcium and vitamin D, omega 3 fatty acid and carotenoids for reducing the testosterone and oxidative stress (Pal L et al 2018) (Oner G, andMuderris 2013). Co administration of probiotic and selenium in PCOS subjects had beneficial effects on mental health parameters and abnormal hair growth (Jamilian Metal2018). Since there is a scarcity of data on nutrient intake and its association with the development of symptoms among PCOS women in the different age group, the present study was carried out to fill their search gap. Therefore the objective of the study was to estimate the dietary profile of women with PCOS in the18-29 and 30-45 year age group to compare the clinical symptoms and nutritional status between the two age groups and to compare the mean nutrient intake with the current dietary standards.

Materials and Methods

Selection of area and required materials

The present study was conducted in the Gynaecology and Dietetics Outpatient Department of Believers Church Medical College Hospital, Thiruvalla, Kerala. Questionnaire, interview schedule, food frequency questionnaire, three day food record, 24 hour dieter call, diet cal software.

Collection of data

The study was carried out among the selected 120 women of reproductive age (18-45years) with PCOS syndrome as diagnosed using validated tool Rotter dam criteria. The participants were categorized

as having PCOS, in case of two out of the following three observations were present. Oligomennorhoea or amenorrhoea / ovulation dysfunction, biochemical hyper and rogenemia or clinical features of and rogen excess, ultrasound showing PCO morphology. PCOS women who fulfilled inclusion and exclusion criteria were included for the study. Using the tool, data on socioeconomic profile, medical profile, reproductive profile, dietary pattern and physical activity were collected. The socio economic classification of the subjects was analysed using Kuppuswamy socioeconomic scale (SaleemSM2020). Quantification of hirsutism performed using standard scoring system Modified Ferryman–Gallwey (mFG) scoring system by including nine and rogen dependent sites (FerrimanD1983). Severity of acne was assessed using Global Acne Grading System (Roshaslinie R et.al 2012), mental health status using perceived stress scale (Cohen, S 1988) and physical activity scoringusing Godin Leisure time scale (Godin G 2011). The study received ethical approval from the Institutional review board with approval number AUW/IHEC1920/ FSN/FHP-01

Assessment of anthropometric measurement and dietary pattern

Anthropometric assessment such as weight, height, BMI, WHR, body fat, was measured using standard procedures. Height was measured using a portable stadiometer (ModelHM01) to nearby 0.1 cm and weight to the nearest 10 g using digital weighing scales (SAMSO). Quantitative assessment of dietary intake was performed by analysis of 3-day food records and also using a 24 hour recall with the interview method. A dietary software DIET CAL was used to calculate the calorie, protein, fat, carbohydrate, vitamins, minerals and dietary fibre. The obtained results were compared to the standard values suggested by ICMR (2020). A Food frequency questionnaire was used to find out the consumption of different food groups. It contained 22 questions to get information on consumption pattern to categorise subjects into regular, occasional and rare consumers. Data analysis and appropriate inferential statistics was performed using SPSS23 software.

Results and Discussion

Socio-economic profile

Socioeconomic profile of the subjects was highlighted in Table I.

The above table describes the socioeconomic profile of the selected subjects. Seventy four per cent of the selected subjects were married remaining were either single or divorced. Forty five percentages of the total subjects were employed and early half ofthe total subjects were graduates in both the age groups. More than 50 per cent of the subjects were having a monthly income between 10,000

TABLE I

Socio-economic Profile of the Subjects

Religion	Number of PCOS subjects (n=120)	Percentage of PCOS subjects
Hindu	57	48
Christian	48	40
Muslim	15	12.3
Marital status		
Married	88	74
Single	30	25
Separated	1	0.8
Educational status		
Secondary	3	2.4
Higher secondary	23	20
Graduation	64	53
Post-graduation	30	25
Occupational Status		
Employed	54	45
Unemployed	66	55
Monthly income (Rs)		
99,931-199,861	3	2.4
74,755-99,930	5	4.1
49,962-74,755	6	4.9
29,973-49,961	45	37
10,002-29,972	62	51

and 29, 972. Only 6 per cent of subjects were having a monthly income above 99,931.

Socio- economic classification of the subjects

Socio-economic status was categorized by Score Kuppuswamy SEC scale 2020 and is given in Table II.

The above table depicts that majority of the subjects (49 %) belonged to upper lower class IV. Among the subjects 14 %, belonged to lower middle class, 31% belonged to upper middle class and 6% were from upper class.

Mean anthropometric measurement of the study group

BMI can be referred to as a determinant of obesity in PCOS subjects. There is a significant mean difference between the two age groups in BMI

TABLE II

Socio-economic Classification of the Subjects (n=120)

Socio Economic Status (incomers ≤ 10,001 to ≥ 199, 892)	Score Kuppuswamy SEC scale 2020	Number of subject	Per cent
Upper Lower IV	5-10	17	14
Lower Middle III	11-15	59	49
Upper Middle III	16-25	37	31
Upper	26-29	8	06

indicating higher mean BMI in the 30-45 age group (p=0.007). There was no significant difference in the mean. Height, weight, WHR and body fat percentage between the two age groups. The meananthropometric parameters of the subjects in the two age groups is represented in table III.

Symptoms of PCOS among the subjects

The PCOS subjects usually have symptoms such as oligo an ovulation, hirsutism, acne, skin colour changes, head thinning, mood swings, depression and anxiety, sleep disturbances

The table IV represents the symptoms of PCOS subjects. Among the18-29 age group 48% of subjects had head thinning and 73% had mood swings and depression, 65%had oligo an ovulation. A canthosis and acne was higher in the18-29 age group. The frequencies of all these symptoms were lower in the 30-45 age group. In the present study there was a significant association presented between menstrual regularity $(p=0.02)$ and age group.

Clinical symptoms among the subjects

Table V indicates that the two age groups were significantly different in terms

TABLE III

Mean Anthropometric Measurement of the Study Group

Parameter	18-29 age group	30-45 age group	T value	P value
Height	159.16±6.01	157.2±5.69	1.78	0.078
Weight	68.43±17.26	71.33±13.6	-1.02	0.308
BMI	24.3±9.8	28.4±6.3	-2.747	0.007
WHR	1.2±3.27	1.0±2.8	0.019	0.748
Bodyfat	29.9±16.6	29.04±13.01	-0.450	0.654

TABLE IV

Symptoms of PCOS among the Subjects

Clinical symptoms of PCOS	Age in years				Chi square	Pvalue
	18-29 (percentage)		30-45 (percentage)			
Head Thinning	Present	Not present	Present	Not Present		
	48	50	37	63	3.110a	0.211
Acne	44	56	37	60	2.043a	0.360
Acanthosis	52	48	47	51	2.275a	0.321
Depression	or					
anxiety	75	25	66	34	1.09	0.295
Moodswings	75	25	62	38	2.35	0.125
Hirsutism	67	33	38	62	9.96	0.001
Ovarian cyst	88	11.5	92	7.3	6.20	0.431
Oligo an ovulation	65	35	44	56	5.35	0.02
Sleep pattern	Regular	Irregular	Regular	Irregular	0.143	0.705

of hirsutism (p=0.007). Mean scores of stress and acne showed no significant difference between the two age groups (P>0.05).

Food consumption pattern among the PCOS subjects in the two age group

Most of the subject we consuming cereals, pulses, vegetables, fat, fish, milk regularly but fruits, nuts and green leafy vegetables were less consumed by the subjects.

The table VI clearly depicts the striking association between food consumption pattern and age of the subjects. Consumption of soft drinks was 8.2 times higher in group I compared to group II

TABLE V

Comparison of Mean Scores of Clinical Symptoms and Physical Activity among the Subjects

Parameter	Age group in years		T value	P value
	18-29	30-45		
Hirsutism	4.15±4.8	2.03±3.6	2.754	0.007
Stress	19.3±8.4	19.12±9.4	0.114	0.909
Acne	5.5±7.5	5.10±5.1	0.286	0.775

TABLE VI

Comparison of Frequency of Food Intake among Different Age Groups

Food group / food item	Intake	Age 18-29 Group 1	Age 30-45 Group II	Chi-square	P value
Cereal-Rice	Regularly	49	66	0.590	0.442
	Occasionally	3	2		
Cereal-Wheat	Regularly	45	62	0.656	0.417
	Occasionally	7	6		
Pulses	Regularly	50	66	0.074	0.784
	Occasionally	2	2		
Fruits	Regularly	28	34	0.174	0.676
	Occasionally	24	34		
Fats	Regularly	48	66	1.400	0.236
	Occasionally	4	2		
Nuts	Regularly	13	23	0.1849	0.667
	Occasionally	39	58		
Milk and milk products	Regularly	45	65	3.15	0.075
	Occasionally	7	3		
Vegetables	Regularly	51	65	0.134	0.713
	Occasionally	1	2		
Roots and tubers	Regularly	43	61	1.254	0.262
	Occasionally	9	7		
Green leafy vegetables	Regularly	18	39	6.1	0.01
	Occasionally	34	31		
Soft drinks	Regularly	18	4	15.6	0.00
	Occasionally	34	62		
Sweets	Regularly	21	14	5.589	0.018
	Occasionally	31	54		
Processed foods	Regularly	34	26	8.68	0.003
	Occasionally	18	42		
Pickle	Regularly	31	26	5.40	0.020
	Occasionally	21	42		
Fish	Regularly	47	50	5.40	0.020
	Occasionally	5	18		

(OR8.2 and 95%CI, 2.6-26.2). Sweets intake was 2.6 times higher in the age group 18-29 compared to 33-45 age group (OR 2.6 and 95% CI, 1.2-5.9). Remarkably higher proportion of subjects in the age group 18-29 consumed pickle (OR2.4 and 95% CI, 1.1-5.0) and fish (OR 3.4 and 95% CI 1.2-9.8). There was no notable difference in the consumption of cereal, pulses vegetables, milk products, root and tubers between the two age groups.

Macro micro nutrient intake of the subjects

Table VII clearly illustrate that the mean calorie intake both age groups was higher 2217.55±944.291 kcal and 2568.57±941.227 kcal respectively. There was a significant mean difference between the two groups in energy (p=0.045). The major share of carbohydrate came from simple sugars. The mean intake of protein, carbohydrate and fat was very high compared to the EAR micronutrient vitamin D (p=0.032), iron (p=0.022), magnesium (p=0.017), chromium (p=0.016), potassium (p=0.041) and fibre (p=0.006) intake was remarkably higher in the second group. Among the 18-29 age group the mean intake of vitamin C, iron was lower than the EAR whereas in the 30-45 age group retinol was lower than the EAR. Mean intake of retinol was comparatively low in the 30-45 age group showing the ratio of intake to EAR as 0.54. The mean Iron intake (17.45±7.72) was relatively higher in the second group as evidenced higher intake of protein and iron rich foods like fish, pulses, nuts and green leafy vegetables. Potassium intake was comparatively low as 50 per cent of the subjects were not consuming any fruits, green leafy vegetables, whole cereals. The mean intake of potassium was significantly higher in the 30-45 age group. Twenty two percent of subjects were having an intake above the EAR. Regarding sodium average intake was high 2310.0±465.8, 2216.10±252.35 respectively as evidenced by the junk food and processed food intake among the subjects. Considering the consumption of minerals, the mean intake of calcium was 428.10±198.75 and 464.69±192.751 respectively. The ratio of intake to EAR was 0.53 for 18-29 age group and 0.58 for 30-45age group. Mean Vitamin D intake was very poor in both the age groups.

In the present study it is evident that vitamin D was consumed in merge amount. It was clear from recent studies that vitamin D in the diet significantly contributed to higher chances of success of Intrauterine insemination. Vitamin D and calcium may positively affect the improvement of menstrual regularity and maturation of ovarian follicle (AzzizRet.al 2006). It was also observed near normal intake of folic acid. Folic acid is one of the co-enzymes taking part in homocysteine metabolism is affected with Folic acid deficiency further leading to disorders in foetus development, miscarriage and foetal death

TABLE VII

Comparison of the Nutritional Intake of the Macro and Micro-nutrients among the Subjects

Nutrient	EAR	Mean intake (18-29 age group) N=52 Group 1	Mean intake 30-45 age group N=68 Group II	T value	P value
Energy (Kcal)	1660	2217.55 ±944.291	2568.57±941.227	-2.022	0.045
Protein (g)	36.3	68.09±30.360	75.71±30.6	-1.403	0.163
Carbohydrate (g)	100-130	316.38±148.1	369.67±164.250	--1.837	0.069
Fat (g)	15-35	67.62± 42.637	80.35± 46.013	-1.550	0.124
Fibre (g)	25	38.73± 13.347	46.65±17.908	-2.775	0.006
Folicacid (µg)	180	228.83±217.513	224.77±100.388	0.136	0.892
Retinol (mcg)	390	321.57±1134.73	211.5±328.883	0.733	0.465
VitaminD (µg)	10	0.830±0.888	0.49±0.676	2.170	0.032
Calcium (mg)	800	428.10±198.75	464.69±192.751	-1.016	0.311
Iron (mg)	15	14.43±6.091	17.45±7.715	-2.319	0.022
Magnesium (mg)	310	343.17±121.323	404.74±149.213	-2.424	0.017
Selenium(µg)	40	56.6±30.5	55.6±24.9	0.377	0.707
Zinc (mg)	11	8.05±3.202	8.55±3.2	-0.8374	0.404
Vitamin C (mg)	55	48.10±40.196	59.14±44.77	-1.398	0.165
Chromium (mg)	0.05	0.07±0.034	0.08±0.036	-2.437	0.016
Potassium (mg)	3500	2421.81±945.319	2802.63±1043.272	-2.063	0.041
Sodium(mg)	2000	2310.0±465.870	2216.10±252.35	1.414	0.160

ICMR-NIN2020

(TwigtJMet,al2011). Several studies proven the effect of Zinc, Selenium and Chromiumon the insulin signalling mechanisms in PCOS patients, reducing BMI, free testosterone and fasting insulin (NargesEtal2021) (AzelianSet.al2016) (TangX, L. 2018. Some studies indicated that the dietary intake of Zinc was lower in PCOS with Metabolic syndrome (Jamilian Metal 2018) and the serum level of Zn was lower in women with PCOS (AbediniM et, al2019). Low nutritional intake vitamin E as associated with IR and proper intake can prevent metabolic syndrome (GoncalvesA 2017).

Reduced intake of these micronutrients needs to extra supplementation to reduce the consequence of PCOS.

Conclusion

The present study concluded that the mean intakeof calorie, carbohydrate and fat was remarkably higher in both age groups where as the intake of some of the micronutrients such as Calcium, Zinc, Iron and Retinol was lower compared to EAR. The Vitamin D intake was very poor than the EAR in all the participants. The comparison of Nutritional status of the 2 age groups disclosed that there was a significant difference in the mean intake of calorie (p=0.045), fibre (p=0.006), Iron (p=0.022), Magnesium (p=0.017),Chromium (p=0.016) and Potassium (p=0.041) in the 30-45 year age group. Food consumption pattern affirmed that there was a remarkable difference in the intake of processed foods, soft drinks, sweets, fish, leafy vegetables, pickle between the two age groups. Among 18-29 age group 65 % of subjects presented with oligo an ovulation and severity of hirsutism was also higher among them. It can be concluded that there was a considerable difference in the food consumption pattern and intake of calorie, fibre and some micro nutrients between the two age group of women.

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Effectiveness of micronutrient rich supplement on the symptoms of polycystic ovarian syndrome among reproductive age women

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***Abstract*---**The incidence of PCOS the most common endocrinopathy has an alarming rise the recent years. The aim of the study is to evaluate the effectiveness of Nutrition intervention on reducing the Symptoms of PCOS in comparison to Nutrition education and Medication alone. The study was an Intervention among 93 women after systematic grouping of the subjects into three groups. The supplementation group received 30g of Nutritional supplement daily for 3 months, experimental group II received nutrition Education alone for three months and Control group was received allopathic medication. The mean age of the participants was 29.31±7.1. Nutrition intervention resulted in a significant reduction in weight, BMI, TSF body fat , waist circumference and hip circumference, total cholesterol levels , cholesterol to HDL ratio and total testosterone levels ($p<0.001$). Between the groups the mean change in testosterone (M=0.145, SD=0.238) showed significant difference with education group (M=0.0023, SD=0.0646), difference was remarkable between Intervention and control group (M=-0.0147, SD=0.1167). The difference in total cholesterol, cholesterol to HDL ratio, waist circumference, and hip circumference indicated significant difference between the intervention and control group but no difference between intervention and education group. The mean change in BMI, and body fat percentage significantly differed between intervention and education group, intervention and control group. Regularity of association of intervention with menstrual cycle revealed that the Nutrition intervention had 9.1 times and Nutrition education group had 4.3 times higher chance of getting regular periods than those on nutrition education and control respectively. There was a significant considerable decrease in the mean value of Stress (p=0.000) among

all the groups .In the nutrition intervention group acne score physical activity level showed considerable increase compared to other groups

***Keywords*---**Polycystic ovarian syndrome, Nutrition Intervention, anthropometric parameters, biochemical parameters.

Introduction

Polycystic Ovarian Syndrome is a difficult to define heterogeneous disorder usually characterised by biochemical abnormality such as elevated lipid profile and androgen levels in blood, menstrual cycle irregularities, lack of ovulation, enlarged ovaries with numerous cysts and infertility. Insulin increases the production of androgens by directly affecting the ovarian theca cells (Ovalle and Aziz 2002)·Higher than normal androgen level in women can prevent the ovaries from releasing egg during each menstrual cycle, and can cause extra hair growth and acne. Sedentary lifestyle and improper dietary habits are often noticed among the women with PCO syndrome. Intake of food of low nutritional value and high calorie further leading to insulin resistance along with increasing obesity (Asemi 2015)·According to recent studies PCOS was diagnosed among 9.38% of patients consulted the gynaecologist in a hospital based in South India. Women in the age group of 13-20 years showed a greater prevalence (39.25%) followed by 21-30 years as 27.1 percent and 41-50 years as 11.2 percentage (Cheema et al, 2019).As per the studies done by Gowri and Venkata Ramana 2020 Women with high level of education under low economic status, adverse living and working conditions, stress and family life style modifications are the main associated factors for PCOS.The common features usually include excessive weight gain, oligomenorrhea/Amenorrhoea ,Increased triglyceride and insulin levels in blood, acne, hirsutism, etc. It is also associated with menstrual disorders and infertility usually occurring due to chronic anovulation. PCOS is responsible for about 75 per cent of anovulatory infertility in women during their reproductive years (Teede *et.al;*2018).Lifestyle management is followed as the first-line treatment in PCOS which helps to improve hormonal disturbances and to prevent future reproductive and metabolic complications (Moran, *et.al;* 2017).Previous studies have inscribed the role of micronutrients in reducing insulin resistance and its role in improving the symptoms (Ni Y 2015).Abdominal obesity, hypertension, impaired glucose tolerance usually observed with low serum levels of Vitamin D (Zaeemzadeh 2021). Some of the previous studies have also imposed strict restriction of calories and was found that calories alone will not significantly improve biochemical and anthropometric parameters even along with physical activity (Gann 2003). The role of a calorie restricted balanced diet and healthy lifestyle is important .Hence the present study focusing on structured dietary intervention along with a micronutrient rich formula on reducing the anthropometric, biochemical and clinical symptoms is very relevant. Antioxidant intake in the diet, including β-carotene, zinc, selenium, Vitamin E and Vitamin C protects against free radicals there by preventing the adverse effects such as oxidative stress, damage of cellular membranes (Ruder 2009). Schaefer 2019 in the recent studies have proved the role of micro nutrients in fertility and its adverse impact on female fertility if consumed in inadequate amounts.Folate, vitamins B6, B12, vitamin D, and iron all have roles in mechanisms that could

affect fertility. Folate and Vitamin A important for the quality of the oozyte ,fertilisation and implantation. The present research is undertaken to determine the role of micronutrient rich indigenous supplement and a structured diet plan in improving the metabolic, biochemical and clinical symptoms of PCOS and to compare with group who were given nutrition education and medication alone.(Szczuko 2021)

Objectives

Assess the Effectiveness of Nutrition Intervention in terms of anthropometric measurements, biochemical parameters and clinical symptoms of PCOS. Comparison of symptoms of PCOS between the Nutrition intervention, Nutrition Education and the Medication group.

Selection of Research Tools and Methods

The study was conducted in the Outpatient Department of Gynaecology and Dietetics of Believers Church Medical College Hospital, located in Thiruvalla, Kerala, India. Women of reproductive age group of 20-45 years consulted in the Gynaecology and Dietetics outpatient department between January 2019 and June 2021 were screened using the validated screening tool Rotterdam criteria (2003) .The Rotterdam criteria for selection of Subjects for the study is represented in table I.

Table I Selection of subjects for the study based on Rotterdam 2003 criteria

To define 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)

Research tools were formulated on the basis of the objectives .For collection of data, interview schedule using specially designed questionnaire was used. In the interview schedule, demographic profile in terms of age, marital status, educational qualification, occupation, monthly income and dietary pattern were included. A comprehensive questionnaire consisting demographic, dietary and lifestyle pattern, reproductive, menstrual history and food frequency questionnaire, was filled during face to face interview both in paper and the "*google docs"* forms for easiness of analysis by the investigators. The questions on scoring of symptoms of Polycystic Ovary Syndrome was adapted from International evidence based guideline for assessment and management of Polycystic Ovarian Syndrome (Teede, et al,2018). Modified Ferriman-Gallwey (FG) score was used for screening and quantitative evaluation of clinical hyperandrogenism using nine parts (upper lip, chin, chest, upper and lower abdomen, thighs, upper and lower back and upper arm). Hair growth was rated

from 0 (no growth of terminal hair) to 4 (extensive hair growth) in each of the nine body areas. A score >/= 8 was indicative of androgen excess. Patients were also screened for oily skin and acne suggestive of clinical features of androgen Anthropometric measurements such as height (cm), weight (kg) were measured using standard procedures. Waist circumference in cm (at waist level minimum circumference), hip circumference in cm (maximum circumference below the level of umbilicus) was measured. Obesity was assessed according to Asian Classification of BMI, calculated as BMI=weight (Kg)/height $(m)^2$, Classified as s<18.5kg/m^2 Underweight, 18.5-22.9kg/m^2 Normal, 23.0-24.9 kg/$m,^2$ Over weight and ≥25kg/m^2 Obese. Body fat distribution was assessed by measurements of the waist to hip ratio (WHR). A WHR <0.80 was considered normal. Random blood glucose and lipid profile was done to diagnose impaired glucose tolerance, dyslipidaemia and metabolic syndrome, normal values taken were RBS<140mg/dl TC<200mg/dl, HDL >50mg/dl, LDL <130mg/dl, TG <150mg/dl an VLDL <50mg/dl. Additionally, blood pressure was measured in patients in sitting position,>/= 140/85 was considered as hypertension. Total testosterone values were analysed as a part of hormonal assay. Testosterone levels >0.59ng/mmol was considered as high. Ultrasonography results were also analysed .The study design was registered in the Clinical Trial Registry of India (CTRI), ICMR and received registration number as **CTRI/2021/09/036850.** The Research proposal to conduct the nutrition intervention was presented in the Institutional Human Ethical Committee (IHEC) of Avinashilingam Institute for Home science and Higher Education for Women, Coimbatore and obtained approval with the Registration number of **AUW/IHEC-1920/FSN/FHP-01** and also Ethical clearance from Believers Church Medical College Hospital Thiruvalla, Kerala with approval number **IEC/2020/02/126.**

Formulation and Evaluation of Nutrient dense Health mix powder and Nutrition Education for PCOS subjects

Well planned diet is always a cornerstone in treatment of any lifestyle disorders. Food supplementation is one of the reliable method to make the diet well planned to fulfil the requirement. Nutritional supplement was prepared by using the commonly available ingredients in the local market, low cost seasonal and easy to prepare ones. The micronutrient rich supplement is expected to enhance the health status in terms of improvement of biochemical and metabolic profile, mental health, ovulation, and menstrual regularity in PCOS subjects. Recent studies about PCOS focused on mineral supplementation in order to remove pathologic situations from PCOS. Micronutrients such as calcium, iron, selenium, zinc, magnesium, phosphorus chromium, fibre rich supplement was prepared using the seeds and grains available in the market.

Grains and seeds were powdered and supplement was formulated by mixing the powdered grains and seeds in the ratio 1: 5.Two top scored variations as per the sensory evaluation was selected for the intervention .The nutrition intervention group was asked to consume 30g of the supplement every day evening for a period of 90 days. Supplement I was asked to consume for the first 15 days followed by Supplement II for the remaining 15 days, they were also given a structured low calorie diet plan to be followed for 3 months. The nutrition education group was given detailed education along with structured diet plan,

they were asked to continue the plan for 3 months. The medication (control group) was asked to consume the medications alone. Microbial count of the nutritional supplement I and II was analysed. The shelf life evaluation was done after 1month and the plate count was 1.2x104 cfu/g for supplement I and 1.8x104 cfu/g supplement II respectively. The supplement was prepared without preservatives and the subjects were asked to keep the supplement in the refrigerator throughout the supplementation period .The nutrient analysis of the supplement was also done.The ingredients used in the formulation of nutritional supplement is represented in figure 1

Figure 1. Ingredients for the Micronutrient rich supplement powder

Selection of subjects for the study

Women in the age group of 20-45 years, diagnosed using Rotterdam criteria (2003) were considered for the Nutrition intervention study .The purposive sampling method was adopted for selection of participants for the intervention study. The sample size was calculated using the standard formula suggested for

clinical trials by considering type one error (α) of 0.05 and type two error (β) of 0.20 (power = 80%). Based on a previous study (Garg et.al; 2015) 0.11 ng/mL as SD and 0.09 ng/mL as the difference in mean (d) of total testosterone concentrations as used primary variable. Based on this, 25 subjects were needed in each group .Considering a dropout of five subjects in each group, a total 30 subjects per group were selected. In the present study 93 subjects were selected and 32 subjects were systematically participated in the intervention for the period of three months.

Grouping of subjects based on anthropometric, biochemical and clinical parameters

Selected subjects were further grouped based on the BMI criteria for Asians. Waist hip ratio was also checked and distributed as normal with ≤0.8 and abnormal as >0.8. Table II distributed the 93 subjects prior to intervention, 3.3 percent of subjects were in the BMI distribution 18.5-22.9 , 6.5 percent were between 23-24.9 ,43 percent were between 25-29.9 , 53.7 percent were between 30-39.9 and 4.3 percent were above 40years .Waist hip ratio was below 0.8 for sixteen percent of cases and above 0.8 for 83 percentage of cases. In the nutrition intervention group 75percent subjects were presented with PCOM morphology on USG scan and 25 percent without ovarian cyst. In the Nutrition Education group 93.5 percent and in the Medication group (Control) 90 percent of subjects were presented with PCO morphology and the remaining were not having any ovarian cyst .Forty three percent of subjects were having increased testosterone levels of >0.59ng/mmol . Menstrual cycles were irregular for 81 percent of subjects in the Intervention group and Education group and 87 percent of subjects in the control group

Table II Distribution of subjects prior to intervention based on Anthropometric and Biochemical Parameters

BMI					
	18.5-22.9	**23-24.9**	**25-29.9**	**30-39.9**	**>40**
Nutrition intervention	1	2	13	13	1
Nutrition Education	1	2	12	14	2
Control	1	2	15	13	1
WAIST HIP RATIO					
	<=0.8		**>0.81**		
Nutrition intervention	5		25		
Nutrition Education	8		23		
Control	2		30		
OVARIAN CYST					
	PRESENT		**ABSENT**		
Nutrition intervention	24		8		
Nutrition Education	29		2		
Control	27		3		
TESTOSTERONE					
	<=.59		**>0.59**		

Nutrition intervention	20	12
Nutrition Education	23	8
Control	17	13
MENSTRUAL CYCLE		
	REGULAR	**IRREGULAR**
Intervention	**6**	**26**
Experimental II	**6**	**25**
Control	**4**	**26**

Result and Discussion

Totally 93 participants with a mean age of 29.31±7 were selected for the study. Selection of subjects for the Intervention study was done using purposive sampling method. Among the selected 93 subjects 32 subjects were systematically participated in the intervention, 31 subject participated in the Nutrition Education Programme and remaining 30 subjects were given medications for the period of three months. The mean age of the Nutrition intervention group was 25.97 ± 4.78, for Control 25.00 ± 5.45 and for nutrition Education 27.84 ± 5.38.There were no significant differences between the three groups. Table III summarises the demographic profile of the participants

Demographic profile of the selected subjects

Table III represented the systematic Grouping of PCOS subjects based on demographic and socio economic profile such as the age group, religion, marital status and socio economic class. The data revealed that the 93 subjects selected for the study were between 20-45 years age groups 73 percent cases were in the age group of 20-29 , 24 percent belonged to age group 30-39 and 1 percent in the age group 40-45 years .The participants comprised of the study were 52.6 percentage Christians , 38.7 percent Hindus and 8.6 percent Muslims .Marital status of participants revealed that 54.8 percent were married and 44 percent were unmarried and 1 percent as separated .Socio Economic classification concluded that 43 percent subjects belonged to Lowe middle class family, 36.5 percent in the upper middle class, 15percent in upper lower class and 5.3 percent in the upper class

Table III Demographic profile of the selected subjects

AGE	Frequency	ExpI	Exp II	Control	Percent	Cumulative Frequency	Cumulative (%)
20-29	68	24	20	24	73.12	68	73.12
30-39	24	8	11	5	25.81	92	98.92
40-45	1	0	0	1	1.08	93	100
RELIGION							
Christian	49	17	17	15	52.69	49	52.69
Hindu	36	11	12	13	38.71	85	91.4
Muslim	8	4	2	2	8.6	93	100

MARITAL STATUS							
Married	51	16	12	23	54.84	41	44.09
Single	41	15	19	7	44.08	92	98.92
Separated	1	1	0	0	1.08	93	100
SOCIO ECONOMIC CLASS							
Upper	5	2	3	0	5.38	5	5.38
Upper middle	34	13	7	14	36.56	39	41.94
Lower middle	40	12	16	12	43.01	79	84.95
Upper lower	14	5	5	4	15.05	93	100

Impact of the Nutrition Intervention on Anthropometric parameters at baseline and following Interventions

Table IV compares the the effect of administration of micronutrient rich nutritional supplement powder, Nutrition education and allopathic medication alone on the anthropometric measurements (weight, BMI, body fat, waist circumference, hip circumference, total Skin fold Thickness, body water and visceral fat)at baseline and following 12 weeks of the study. At the starting of the study, no significant differences were observed between the three groups in terms of any of the anthropometric variables. Findings of the present study showed that after 12 weeks of intervention there was a significant reduction in anthropometric measurements in the Nutrition intervention group and Nutrition Education group.All the anthropometric variables were comparable at baseline as there were no significant difference in age, weight, BMI, TSF, WC, HC, body fat, body water and visceral fat ($P>0.05$) among the subjects. Among the Nutrition Intervention group we could see larger drop in weight, BMI, waist circumference, hip circumference, body fat and visceral fat levels ($p<001$) with a mean weight reduction in the 3 month period was 4.7kg .The reduction in BMI, TSF, waist circumference, hip circumference, and body fat was 1.9kg/m^2,1.4cm, 1.5cm, 1.08cm and 1.5% respectively. However we could not see a significant difference in waist hip ratio ($p=0.324$) and body water ($p=0.968$).A significant difference between pre and post values among the Nutrition education group for Weight, BMI ,TSF and Body fat and has shown a drop of 1.9kg, 1kg/m^2 0.54cm,0.72cm respectively($p<0.001$).Waist circumference ($p=0.640$), Hip circumference ($p=0.541$) and body water ($p=0.682$) was not significantly differed .In the Control we did not see a drop in any of the biometric variable in except for waist hip ratio ($p=0.004$), may be because the people were already taking medications before the study began. After the medication intervention there was no significant drop in weight , BMI Waist circumference , Hip circumference , body fat , body water and visceral fat ($p>0.05$).But at baseline all the biometric variables were comparable as represented in table IV.

Table IV Comparison of Anthropometric parameters between the groups at baseline and following intervention

Variable		vention (N=32)	Nutrition Education(N=31)	Control (N=30)	P*
Weight	Baseline	74.77 ± 10.50	75.65 ± 16.27	74.73 ± 12.11	0.953
	After 3m	70.05 ± 10.43	73.73 ± 16.21	74.91 ± 11.32	0.304
	Changes	-4.7188± 2.6441	-1.9226± 2.1175	0.18±3.49	0.000
	P**	<.0001	<.0001	0.78	
BMI	Baseline	29.95 ± 4.35	30.82 ± 5.82	30.43 ± 4.18	0.776
	After 3m	28.05 ± 4.27	29.82 ± 5.73	30.53 ± 4.07	0.110
	Changes	-1.9031±1.0669	-1.0035±1.2706	0.10±1.30	0.000
	P**	<.0001	0.0001	0.68	
TSF	Baseline	27.98 ± 6.69	27.55 ± 7.62	27.77 ± 7.25	0.971
	After 3m	26.49 ± 5.82	27.00 ± 7.35	27.80 ± 6.99	0.745
	Changes	-1.4969± 2.2544	-0.5452±0.8477	0.03±1.17	0.01
	P**	0.0007	0.0012	0.89	
WC	Baseline	36.73 ± 3.12	37.97 ± 4.10	36.22 ± 4.90	0.231
	After 3m	35.18 ± 3.62	37.84 ± 4.75	36.21 ± 4.34	0.049
	Changes	-1.5469±1.2051	-0.129±1.5219	-0.01±1.28	0.000
	P**	<.0001	0.6403	0.97	
HC	Baseline	41.90 ± 3.47	43.39 ± 4.04	41.81 ± 4.58	0.231
	After 3m	40.82 3.45	43.22 ± 4.19	41.99 ± 4.18	0.059
	Changes	-1.0844±1.089	-0.1677±1.5105	0.0180±1.16	0.000
	P**	<.0001	0.541	0.41	
BODY FAT	Baseline	35.85 ± 7.68	39.26 ± 6.86	35.77 ± 7.98	0.120
	After 3m	34.32 ± 7.93	38.54 ± 6.79	35.51 ± 7.84	0.079
	Changes	-1.5375±1.179	-0.7194±0.834	-0.26±1.12	
	P**	<.0001	<.0001	0.21	0.000
BODY WATER	Baseline	52.55 ± 2.53	51.55 ± 3.35	52.09 ± 2.48	0.372
	After 3m	52.56 ± 2.40	51.63 ± 3.05	52.29 ± 2.57	0.376
	Changes	0.0125±1.743	0.0871±1.1727	0.20±1.11	0.870
	P**	0.97	0.6822	0.34	
VISCERAL FAT	Baseline	9.30 ± 1.73	9.60 ± 2.66	9.39 ± 1.81	0.779
	After 3m	8.83 ± 1.96	9.44 ± 2.60	9.50 ± 1.86	0.357
	Changes	-0.4687±0.7213	-0.1645 ±0.243	0.11±0.64	.079
	P**	0.001	0.0007	0.33	

BMI body mass index, WC Waist circumference, HC Hip circumference, TSF Total skinfold thickness Data are presented as mean (SD) or geometric mean (SD). * Calculated using one-way ANOVA. . ** Calculated using paired sample t-test

Impact of interventions in terms of anthropometric parameters between the groups showed that there were significant differences in weight loss, reduction in BMI, TSF, waist circumference, and hip circumference across the three intervention groups. The ANOVA results suggests that the weight difference ($F_{2,90}$=24.215, P=0.000), BMI difference($F_{2,90}$=20.502,p=0.000. Waist circumference difference (($F_{2,90}$=12.769,P=0.000) Hip-circumference (F=8.294,P=0.000), body fat percentage difference ($F_{2,90}$=11.6,p=0.000)between

the groups differ significantly. There were no significant difference in the mean change values of body water (p=.870) and visceral fat (p=0.079) between the groups .The individual differences between groups indicated that the mean weight loss of nutrition intervention group (M=4.75 SD=2.652) was significantly different from Education group (M=1.923, SD=2.118).Weight loss in the Control groups (M=1.767, SD=3.49084) also differed significantly from the Nutrition intervention group. A significant difference between the Nutrition education and Control was also observed. The Mean difference in BMI between Nutrition intervention (M=1.88 SD=1.07) and Education (M=1.003, SD=1.270), Nutrition intervention and Control (M=-.100, SD=1.304) differed significantly. The mean difference in waist circumference in nutrition intervention (M=1.54, SD=1.205) differed significantly from Nutrition education (M=0.129, SD=1.521). No significant differences observed between Education group and Control (M=0.010, SD=1.279). Significant difference in hip circumference (M=1.084, SD=1.088) between nutrition intervention and Education group (M=0.167, SD=1.510) were observed, whereas the difference was not significant between Education and Control (M=-.176, SD=1.558). The mean difference in body fat percentage after Nutrition intervention (M=1.53, SD=1.179) differed significantly from Education group (M=0.719, SD=0.834) and Control group (M=0.264, SD=1.117).No significant difference seen between Education and Control group (p>0.05). Previous studies have proved the beneficial effects of supplementation of multiple micronutrients vitamin, E, C Selenium, chromium, magnesium and calcium on PCOS-related symptoms such as immature oocytes, hyperinsulinemia, hyperandrogenism, increased BMI, cardiovascular disorders, and mental and psychological problems. (Günalan, 2018)

Impact of the Nutrition Intervention on Biochemical parameters at baseline and following Interventions

Table V indicated that there were no differences between the interventions for haemoglobin and LDL levels. Significant difference between the treatment effects was seen in change in Total testosterone, cholesterol to HDL ratio, and change in total cholesterol levels (p<0.05).

Table V Comparison of Biochemical parameters between the groups at baseline and following intervention

Variable		Nutrition Intervention (N=32)	Nutrition Education (N=31)	Medicine (Control) (N=30)	P*	
haemoglobin	Baseline	12.65±1.141	12.19±1.380	12.626±1.270	.278	
	After 3m	12.80±.97 9	12.28 ± 1.00	12.54±.82	.090	
	Changes	-.1531±.99709	-.0871±.69366	.0833±.90785	.554	
Cholesterol	Baseline	206.87±37.47	195.16±39.72	197.86±40.86	.467	
	After 3m	195.59±23.66	193.3871±38.51	207.1667±41.20	.264	
	Changes	11.28±28.439	1.774±16.169	-9.30±24.833	.004	
	P**	0.032	0.545	0.049		
Triglycerides	Baseline	126.06±65.10	139.22±92.13	133.60±77.64	.802	

	After 3m	108.84±39.813	132.61±76.58	141.16±78.042	.146
	Changes	17.218±46.87	6.6129±23.408	-7.56±45.37	0.05
	P**	0.046	0.126	0.368	
Cholesterol to HDL ratio	Baseline	4.826±1.27	4.529±1.362	4.569±1.12	.599
	After 3m	4.27 ±.98	4.28 ±1.07	4.69 ±1.14	.221
	Changes	.5563±.905	.2484±.948	-.1223±.88	.017
	P**	0.0015	0.155	0.457	
LDL	Baseline	134.12±34.46	126.35±30.33	128.70±30.05	.609
	After 3m	128.71±25.50	121.35±30.5	132.06±28.76	.322
	Changes	5.4063±25.218	6.4516±11.70	-2.8333±15.24	.1040
	P**	0.234	0.062	0.242	
Testosterone	Baseline	.587±.39	.442±.286	.52±.27	.214
	After 3m	.442± .236	.440 ±.290	.538 ±.261	.263
	Changes	.1450±.238	.0023±.064	-.0147±.116	.000
	P**	0.0017	0.847	0.496	

The test indicated that the mean Cholesterol difference of Nutrition intervention group (M=11.28 SD=28.439) was significantly differed from Control groups (M=-9.30, SD=24.833), but no difference was observed between Nutrition intervention and Education group. Studies by Romualdi 2008 reported 36 mg/d soy isoflavone genistein treatment in women with PCOS for three months provided a significantly improved lipid profile. The difference in TG values showed significant difference between Nutrition intervention (M=17.218, SD=46.873) and Control (M=-7.56, SD=45.37), but was not significantly differed from Nutrition education group (M=6.612, SD=23.408). The difference in in cholesterol to HDL ratio indicated significant difference between the intervention (M=0.556,SD=0.905) and Control (M= -.1233, SD =0.948) but no significant difference between intervention and Education group (M= 0.248,SD=0.948).In terms of testosterone changes intervention group (M=0.145, SD 0.238) showed significant difference with education group (M=0.0023,SD=0.0646), difference was remarkable between Intervention and control group (M=-0.0147,SD=0.1167).Nutrition Intervention group had significant reduction in total cholesterol levels (M= 11.28, SD=28.439), Triglycerides (M=17.218, SD=46.87), Cholesterol ton HDL ratio and total testosterone levels. Haemoglobin levels had a significant increase (M=.1531, SD=.997) within the group as evidenced by paired sample t test.In the control group the only significant difference between the treatment effects was seen in cholesterol levels. In the nutrition education group any of the variable has shown significant difference within the group. Vitamin D and Myoinositol supplementation contribute to overcome complications of PCOS including hyperandrogenism (Jakimiuk 2014).Very long chain polyunsaturated fatty acids, including omega-3 and omega-6 fats have a hypotriglyceridaemia effect and may ameliorate inflammation in metabolic syndrome (Lopez 2012)

Table VI Comparison of Anthropometric and Biochemical parameters between the groups following intervention

Variables	Nutrition intervention (N=32)	Nutrition education (Experimental II (N=31)		Medicine Control (N=30)	
	Mean ± SD	Mean ± SD	Pr > |t|	Mean ± SD	Pr > |t|
Weight	70.05 ± 10.43	73.73 ± 16.21	0.2908	74.91 ± 11.32	0.0838
BMI	28.05 ± 4.27	29.82 ± 5.73	0.169	30.53 ± 4.07	0.0228
TSF	26.49 ± 5.82	27.00 ± 7.35	0.7582	27.80 ± 6.99	0.425
WC	35.18 ± 3.62	37.84 ± 4.75	0.015	36.21 ± 4.34	0.3137
HC	40.82 ± 3.45	43.22 ± 4.19	0.0154	41.99 ± 4.18	0.2324
Body fat	34.32 ± 7.93	38.54 ± 6.79	0.0268	35.51 ± 7.84	0.5538
Body water	52.56 ± 2.40	51.63 ± 3.05	0.1839	52.29 ± 2.57	0.671
Visceral fat	8.83 ± 1.96	9.44 ± 2.60	0.2985	9.50 ± 1.86	0.1707
HB	12.80 ± 0.97	12.28 ± 1.00	0.0388	12.54 ± 0.83	0.2634
Cholesterol	195.60 ± 23.67	193.40 ± 38.52	0.786	207.20 ± 41.21	0.1855
TG	108.80 ± 39.81	132.60 ± 76.58	0.131	141.20 ± 78.04	0.0482
HDL	48.86 ± 10.72	45.72 ± 6.07	0.1565	44.86 ± 7.42	0.0917
LDL	128.70 ± 25.51	121.40 ± 30.56	0.3026	132.10 ± 28.76	0.629
Cholesterol /HDL Ratio	4.27 ± 0.99	4.28 ± 1.07	0.9654	4.69 ± 1.15	0.1255
Testosterone	0.44 ± 0.24	0.44 ± 0.29	0.9742	0.54 ± 0.26	0.1378

Effectiveness of Interventions between group following interventions

Table IV demonstrated comparison of Anthropometric and biochemical parameters between the groups following intervention. BMI (p=0.0228) and TG (p= 0.0482) was significantly differed between the Nutrition intervention and Control group. There was a significant decrease in the waist circumference (P=0.015), hip circumference (0.0154), body fat percentage (p=0.0268), haemoglobin levels (p=0.0388) between the Nutrition Intervention and Nutrition education group

Regularity of association of Intervention with Menstrual cycle

Level of regularisation of menstrual cycle post intervention is represented in figure 3.At base line there was no significant association of menstrual cycle regularity between groups. Those subjects who took Nutrition intervention had

9.1 times higher chance of getting regular periods than those on nutrition education alone (OR: 9.1,CI 2.84-29.146) and 4.3 times higher chance of getting regular periods compared to medication group (Control) (OR:4.33 CI 1.385-13.552). As per studies by Ramanand et al 2013 Irregular menstrual cycles is the consequence of the pathogenic feature anovulation in PCOS .Therefore, persistent menstrual irregularities due to anovulation can be considered as a better predictors of PCOS compared to biochemical parameters It is clear that nutrition-associated signalling pathways play a central role in the regulation of ovarian follicle growth and ovulation rates .Jakimiuk 2014 demonstrated the role of s Inositol and omega 3 supplementation in improving the metabolic and reproductive parameters associated with PCOS **.**Studies have demonstrated restoration of menstrual function with calorie controlled diets , even if there were mild or a moderate weight loss of < 5 percentage (Lefebvre, 1997)

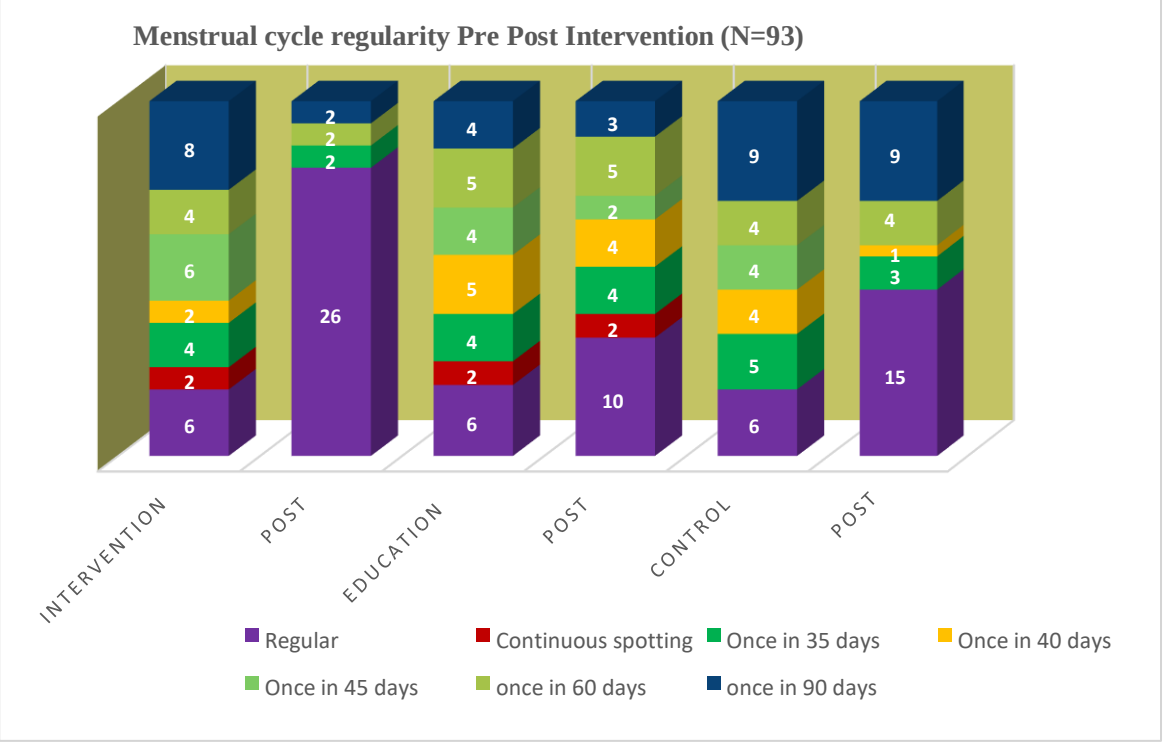

Figure 2 Menstrual cycle regularity pre post intervention

Effectiveness of intervention on Clinical parameters

Table VII depicted the significant difference in the Nutrition intervention group in terms of clinical symptoms of Acne and Stress level .Physical activity also showed a significant difference(p<0.001) with a mean increase of (5.03± 8.26) from the previous score. No significant difference seen in the hirsutism level between pre and post interventions .There was a significant considerable decrease in the mean value of Stress (M=-4.22 ± 5.68) (p=0.000) .Acne score showed significant increase(M=5.56 ,SD =13.4) (p=0.026), Physical activity level also showed considerable increase (M=5.03, SD=8.27) =0.0017).In the Education group and

control group a significant decrease in the mean values of stress ($p<0.05$) was observed .Hirsutism, acne and physical activity levels were not significantly differed among the subjects in the Education and Control group.

Table VII Effectiveness of intervention on Clinical parameters among group

Variable	Nutrition intervention (N=32)			Nutrition Education (N=31)			Control(N=30)		
	Mean ± SD	t	Pr > |t|	Mean ± SD	t	Pr > |t|	Mean ± SD	t	Pr > |t|
Hirsutism	-0.47 ± 3.39	.783	0.439	0.16 ± 2.08	-.431	0.669	-0.63 ± 3.41	1.018	0.317
Acne	5.56 ± 13.45	-2.34	0.0259	0.65 ± 13.90	-.258	0.798	1.97 ± 16.18	-.666	0.511
Stress	-4.22 ± 5.68	4.20	0.0002	-6.35 ± 7.32	4.834	<.000	-3.10 ± 5.54	3.064	0.005
Physical activity Score	5.03 ± 8.27	-3.44	0.0017	2.39 ± 10.89	-1.221	0.232	2.83 ± 8.00	-1.941	0.062

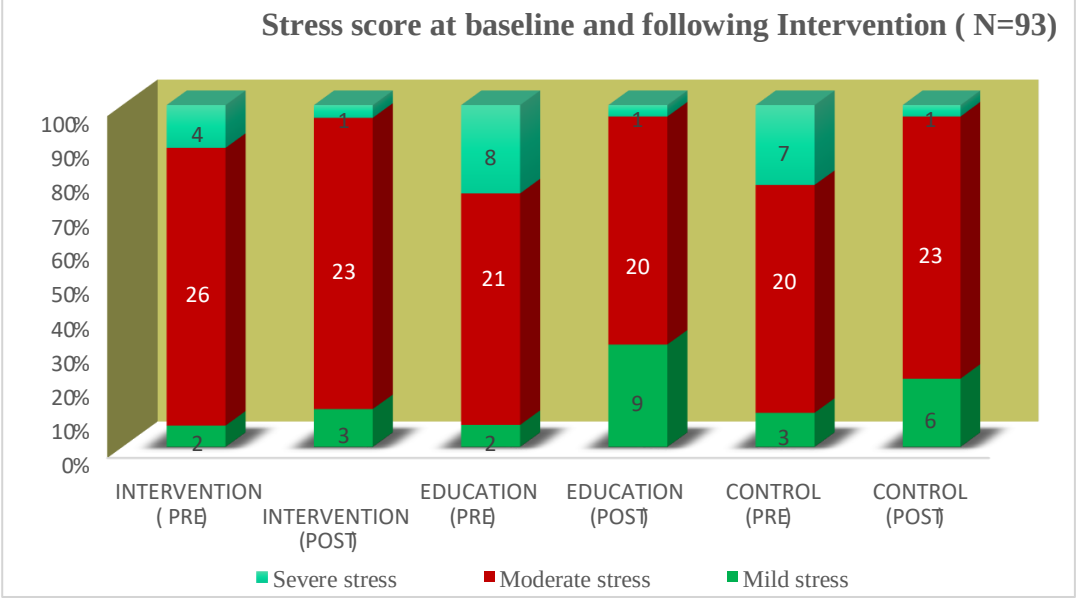

Figure 3 Stress level among the subjects at baseline and following intervention

Comparison of Stress at baseline and following interventions and the effectiveness between groups

Figure 3 revealed that the stress score was significantly reduced with a mean decrease of (M±SD 4.2188±56), (M±SD 6.35±7.3191), (M±SD 3.1 ± 5.54) among the Nutrition Intervention group, education group , medication group respectively ($p<0.001$).No significant difference in stress levels was seen between the groups following interventions .Recent studies by Sathyanarayana and Manjunatha 2019 confirmed that common mental disorders was as high as 33.5 percentage among the women of reproductive age group

Conclusion

Nutrition intervention includes introduction of a micronutrient rich formula, which has shown significant reduction in Anthropometric parameters Weight, BMI, TSF, Waist circumference, Hip circumference, body fat and visceral fat levels. Among the Nutrition Intervention group we could see larger drop in weight, BMI, Waist circumference, Hip circumference, body fat and Visceral fat levels ($p<001$) with a mean weight reduction in the 3 month period was 4.7kg .The reduction in BMI, TSF, Waist circumference, Hip circumference, and Body fat was 1.9kg/m^2,1.4cm, 1.5cm, 1.08cm and 1.5% respectively. Regarding the biochemical parameters, Haemoglobin, Total cholesterol, Triglycerides, Cholesterol to HDL ratio and total testosterone levels showed significant difference between the pre and post intervention. Acne and stress score has reduced significantly and physical activity score has increased considerably in the nutrition intervention group. Between the group comparison results showed significant weight loss ($p=0.00$), reduction in BMI($p=0.00$),reduction in TSF($p=0.01$),Waist circumference($p=0.00$) , Hip circumference($p=0.00$), but no difference in Body fat , body water and visceral fat .Cholesterol($p=0.004$),Cholesterol to HDL ratio ($p=0.0017$) and Testosterone($p=0.00$) levels has shown significant difference between the groups . Comparison of effectiveness of the interventions was checked using t test following interventions showed a significant difference between Nutrition intervention and education in terms of waist circumference ($p=0.015$)Hip circumference ($p=0.0154$), body fat ($p=0.026$) and Haemoglobin levels ($p=0.038$) .There was considerable difference in the BMI values between nutrition Intervention and education. Regularity of association of intervention with menstrual cycle revealed that the Nutrition intervention had 9.1 times higher chance of getting regular periods than those on nutrition education alone(OR : 9.1,CI 2.84-29.146) and 4.3 times higher chance of getting regular periods compared to medication group (Control) (OR:4.33 CI 1.385-13.552). There was a significant considerable decrease in the mean value of Stress in the Intervention, Education and control group ($p<0.05$). Acne and Physical activity score considerably increased in the Nutrition intervention group. Hirsutism, acne and physical activity levels were not significantly differed among the subjects in the Education and Control group

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Conflict Of Interest

'The author(s) declare(s) that there is no conflict of interest

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INTRODUCTION

Current era has witnessed increased reproductive health issues among adolescent girls, reproductive age and post-menopausal women.Female infertility posed the main threat among the young reproductive age women. Polycystic Ovarian Syndrome (PCOS) is a top ranked heterogeneous condition, encompassing alterations in metabolism, compromised reproductive health, imbalance and dysfunctions of several hormones and has higher interrelation to pregnancy complications. The prevalence is intensifying in developing countries like India and the root causes are rapid nutritional transitions due to westernized dietary and lifestyle pattern. Dietary habits are most probably handed down from mother to daughter, and also from ancestors and food habits are very closely linked to socio economic status and geographic area. Nutrition and health are intimately connected throughout the lifecycle. Maintaining optimal nutrient intake is crucial to the health of women, especially in their young years. Very few studies have come up appreciating the aspect of micronutrients in the nutritional care and support of PCOS. In this context, the present research has focused to search new alternative medical nutrition therapy options for management of symptoms of Polycystic ovarian syndrome.

Polycystic ovarian syndrome (PCOS) is a disorder involving endocrine system, presenting with combined signs and symptoms which include metabolic derangements, hormonal changes and a range of phenotypes, including reproductive issues, very frequently associated with psychological impairments including stress , mood disorders, anxiety and depression (Lujan,2013). There are several accepted definition of PCOS, the Rotterdam criteria is the most relevant, most widely recognized criteria followed in Asia for the diagnosis of PCOS (Wołczyński ,2012). The existence of hyperandrogenism, chronic anovulation, and polycystic ovaries on ultrasound findings, and among these at least two if present in a person confirms the diagnosis as per Rotterdam criteria (Rotterdam, 2004) .The definition by Androgen Excess for diagnosing PCOS is excessive androgen levels in blood and ovarian dysfunction. (Azziz,2009).Rotterdam criteria classifies the PCOS into different phenotypes, Classic PCOS exhibits symptoms such as ovulatory dysfunction and anovulation, ovarian cyst and increased androgen levels in blood. The second type is Classic noncystic type is seen with hyperandrogenaemia and anovulation but without ovarian cyst. The third type is Non-classic ovulatory type with regular menstrual cycles, cyst in the ovaries and hyperandrogenism. The fourth type is Non-classic mild or normo-androgenic anovulation, ovarian cyst and normal testosterone levels in the blood (Gaine,2019).

1

Impact of Nutrition Interventions on Symptoms of Polycystic Ovarian Syndrome (PCOS) among Women of Reproductive Age (20-45 Years)

by Jyothi S Krishnan

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