RESEARCH PAPER

Feasibility and Preliminary Effectiveness of Self-Practicing Strategies for the Management of Polycystic Ovary Syndrome in Adolescent College Girls: A Pilot Quasi-Experimental Study

Vahitha Sundaram[1*], Geetha Chockalingam[2], Binu Mathew[3]
[1]PhD Scholar, Lecturer/Assistant Professor, College of Nursing, All India Institute of Medical Sciences, Raipur; PhD Scholar, SBV University (Deemed to be)
Email: vahitha.s@aiimsraipur.edu.in
[2]Professor and HOD, Nursing Foundation, Associate Dean Research (former), Kasturba Gandhi Nursing College, SBV University, Puducherry (Deemed to be)
[3]Professor cum Principal, College of Nursing, All India Institute of Medical Sciences, Raipur
***Corresponding Author:** Ms. Vahitha S., Lecturer/Assistant Professor, College of Nursing, All India Institute of Medical Sciences, Raipur
Email: vahitha.s@aiimsraipur.edu.in
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ABSTRACT

Background:
Polycystic ovary syndrome (PCOS) is a heterogeneous endocrine and metabolic disorder that commonly begins during adolescence. International evidence-based guidelines recommend lifestyle modification as first-line management, while spearmint (*Mentha spicata*) has demonstrated potential anti-androgenic effects. However, the feasibility of a combined, low-cost, self-practicing strategy (SPS) among Indian college students remains uncertain.

Objectives:
To evaluate the feasibility and acceptability of a 12-week SPS package comprising spearmint tea, dietary modification, and structured physical exercise, and to generate preliminary estimates of its effects on hormonal, metabolic, clinical, and knowledge outcomes among adolescent college girls with PCOS.

Methods:
A two-arm pilot quasi-experimental study was conducted in two colleges from November 2024 to January 2025. Among 135 students screened, 20 meeting adolescent-adapted diagnostic criteria for PCOS were allocated to an intervention group (n = 10) or routine-care control group (n = 10). Feasibility outcomes included recruitment, retention, adherence, and acceptability. Preliminary efficacy outcomes included serum total testosterone, follicle-stimulating hormone (FSH), luteinising hormone (LH), fasting blood glucose, body mass index, waist–hip ratio, blood pressure, modified Ferriman–Gallwey score, Global Acne Grading System score, and PCOS knowledge.

Results:
Retention was 100% (20/20), and adherence to weekly self-monitoring diaries reached 71%. Compared with controls, the intervention group demonstrated significantly greater improvements in total testosterone ($p < 0.001$), FSH ($p < 0.001$), LH ($p < 0.001$), fasting blood glucose ($p = 0.002$), and PCOS knowledge ($p < 0.001$).

Conclusions:
The 12-week SPS package was feasible, acceptable, and achieved complete participant retention. Preliminary improvements in hormonal profile, fasting glucose, and knowledge support progression to a fully powered randomized controlled trial to establish clinical effectiveness.

Keywords: polycystic ovary syndrome; adolescents; lifestyle intervention; *Mentha spicata*; hyperandrogenism; pilot feasibility study

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1. Introduction

Poly cystic ovary syndrome (PCOS) is a heterogeneous, multi system endocrine and metabolic disorder of reproductive-aged women, characterized by a combination of ovulatory dysfunction, clinical or biochemical hyperandrogenism and, in adults, poly cystic ovarian morphology [1,2]. Although the syndrome typically becomes clinically apparent during the reproductive years, its pathophysiology begins in adolescence, and insulin resistance together with metabolic dysfunction plays a central role in its pathogenesis [3]. Diagnosis in adolescence is deliberately more conservative than in adults: because multifollicular ovaries and irregular cycles are common in the years following menarche, ultrasound morphology is not used as a diagnostic criterion, and both irregular cycles and hyperandrogenism must be present [1,4]. Adolescence is a dynamic phase of rapid physical, physiological and behavioral change. Adolescents number more than 1.2 billion worldwide, and approximately 21% of India's population falls within this age group. Puberty is governed by a sequence of neuroendocrine events in which rising luteinising hormone (LH) and follicle-stimulating hormone (FSH) stimulate ovarian sex-steroid production and drive secondary sexual maturation. Disruption of this axis, and in particular androgen excess, underlies the clinical phenotype of PCOS [5]. In an Indian epidemiological survey, predisposing factors for PCOS were common in both urban and rural populations [6], and a study conducted in Bhopal estimated a prevalence of 9.1% among those aged 15–21 years. Women with PCOS face increased risks of infertility, pre-eclampsia, early pregnancy loss and endometrial cancer, and, through their association with insulin resistance, an increased risk of type 2 diabetes, dyslipidaemia, hypertension and cardiovascular disease [3].

The 2023 International Evidence-Based Guideline recommends lifestyle modification — encompassing diet, physical activity and behavioral change — as first-line therapy for all PCOS phenotype [1]. Evidence summarized for that guideline indicates that lifestyle intervention improves anthropometry and metabolic profile, although no single dietary composition or exercise modality has proved superior [7]. Modest weight loss in women with overweight and PCOS has been associated with reduced central adiposity, lower circulating insulin and androgen concentrations, improved insulin sensitivity, restored ovulation and more regular menstrual cycles. Interest has therefore extended to complementary and integrative approaches that might be combined with conventional lifestyle advice [8].

Among these, spearmint (Mentha spicata) has the most direct supporting evidence. In women with hirsute, spearmint tea taken twice daily for five days significantly reduced free testosterone and increased LH and FSH [9]. A subsequent 30-day two-centre randomized controlled trial in women with PCOS confirmed a significant reduction in free and total testosterone accompanied by a rise in gonadotrophins, and reported a subjective improvement in hirsutism [10]. Spearmint is inexpensive, widely available in India and generally well tolerated, which makes it an attractive adjunct in resource-limited settings where the cost and adverse effects of pharmacotherapy are barriers to care.

What has not been established is whether these three components — a herbal preparation, dietary modification and structured exercise — can be combined into a single, largely self-delivered package that adolescent college students will actually adopt and sustain. Before mounting a definitive randomized trial, it is necessary to establish that participants can be recruited and retained, that adherence can be measured, and that the assessment battery is workable in a college setting. Accordingly, the primary purpose of the present study was to assess feasibility. Preliminary estimates of effect on hormonal, metabolic, clinical and knowledge outcomes were obtained as secondary, explicitly hypothesis-generating objectives, in line with guidance that pilot trials should not be used to draw conclusions about efficacy [11].

2. Materials and Methods

2.1 Study design and reporting

This was a two-arm pilot quasi-experimental (non-randomized, parallel-group) study with pretest and post-test assessment. It is reported in accordance with the CONSORT 2010 extension for randomized pilot and feasibility trials [11], adapted where necessary to reflect the non-randomized allocation; a completed checklist is provided as Supplementary File 1. Feasibility was the primary objective, and all efficacy analyses are secondary and exploratory.

2.2 Setting and participants

The study was conducted in two colleges selected for their contrasting geographical location and socio-demographic profile, between November 2024 and January 2025. In an initial screening phase, a descriptive survey and clinical assessment were administered to 135 students (n = 60 and n = 75 in the two institutions).

Eligible participants were female students aged 17–19 years in whom PCOS was confirmed using adolescent-adapted criteria, requiring the presence of both (i) menstrual irregularity persisting beyond two years post-menarche and (ii) clinical or biochemical hyperandrogenism, with ovarian ultrasound morphology explicitly excluded as a diagnostic criterion in accordance with the

international guideline [1,4]. Students were excluded if they were taking combined oral contraceptives or hormone replacement therapy, or had a diagnosis of Cushing's syndrome, congenital adrenal hyperplasia, thyroid disease or hyperprolactinaemia. Twenty students met all criteria and were enrolled. Participant flow is shown in Figure 2.

2.3 Allocation

Allocation was made at the level of the individual student using a computer-generated simple random sequence, with participants from both colleges contributing to both arms. No allocation concealment mechanism was used and no blinding of participants, interventionists or outcome assessors was possible, given the overt nature of the intervention. These are acknowledged as sources of bias in Section 4.6.

2.4 Outcomes

Feasibility outcomes (primary). Recruitment rate (proportion of screened students enrolled), retention at 12 weeks, adherence to the self-monitoring diary (proportion of expected weekly entries completed), attendance at reinforcement meetings, acceptability of each intervention component, and completeness of outcome data. Progression criteria were specified a priori and are reported against in Table 3.

Preliminary efficacy outcomes (secondary). Biochemical: total testosterone, FSH, LH and fasting blood glucose. Clinical and anthropometric: BMI, waist–hip ratio, systolic and diastolic blood pressure, modified Ferriman–Gallwey (mFG) score and Global Acne Grading System (GAGS) score. Educational: PCOS knowledge score. All were measured at baseline and at week 12.

2.5 Assessment tools and measurement

- Hirsutism was graded using the modified Ferriman–Gallwey scoring system, with a score of 8 or above taken to indicate clinically significant hirsutism.
- Acne severity was graded using the Global Acne Grading System.
- PCOS knowledge was measured with a 20-item structured questionnaire developed for this study. Content validity was established by expert review (content validity index 0.85) and internal consistency was not formally assessed in this pilot sample. The instrument has not been externally validated, and scores are not comparable with those from other studies. Scores were categorised as poor (0–7), moderate (8–14) or adequate (15–20).
- Anthropometry was measured in light clothing without footwear using a calibrated stadiometer and digital scale; waist and hip circumferences were measured in duplicate with a non-stretch tape at the mid-point between the lowest rib and the iliac crest, and at the widest point of the buttocks respectively.
- Venous blood was drawn after an overnight fast of at least 8 hours. Hormonal assays were performed by enzyme-linked immunosorbent assay using [manufacturer, kit and lot number to be inserted]. Inter-assay coefficient of variation was below 8% and intra-assay coefficient of variation below 5%. All samples were analyses in a single laboratory by a technician blinded to group allocation.

Blood sampling was not standardized to a specific phase of the menstrual cycle. Because most participants were oligomenorrheic, cycle-timed sampling was not practicable; this limitation has an important bearing on the interpretation of the gonadotrophin results and is discussed in Section 4.5.

2.6 Intervention

The self-practicing strategies package comprised three components delivered over 12 weeks (Figure 1).

Educational component. A single structured session was delivered in week 1 by PowerPoint presentation, covering the definition, causes, risk factors, signs and symptoms, investigations, treatment and self-management of PCOS. Participants received a printed booklet and leaflet for reference.

Dietary component. Participants prepared spearmint tea from 2–3 g of dried Mentha spicata leaves steeped in 200 mL of boiling water for 5–10 minutes, taken twice daily on five days per week for 12 weeks. Dried leaves were supplied to participants from a single batch to limit variability. In addition, an energy intake of approximately 1800 kcal per day was recommended, comprising three principal meals with two snacks and at least 1.5 L of calorie-free fluid daily. The prescription was not individualized to estimated energy requirement.

Exercise component. Sessions comprised a warm-up, a main set of jumping jacks, squats, knee push-ups and side knee touching (15 repetitions in three sets), and a cool-down, performed on five days per week. Participants additionally walked for 20 minutes per day on five days per week and were asked to install a pedometer application with a target of 10,000 steps daily. Sessions were unsupervised after an initial demonstration.

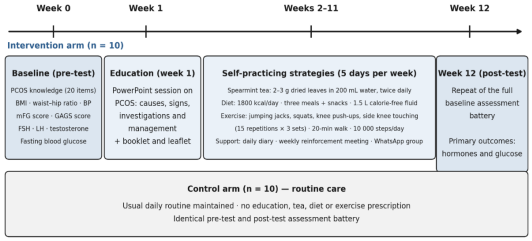


Figure 1. Study Design.

2.7 Adherence support and control condition

Intervention participants maintained a diary recording tea consumption, dietary intake and physical activity. A missing weekly entry was defined as non-adherence for that week. Weekly reinforcement meetings were held to sustain motivation, and a Whats App group facilitated reminders, queries and peer support. Control participants continued their usual routine and received no education, tea, dietary prescription or exercise programme; they underwent an identical assessment battery at baseline and week 12. Because both arms drew students from the same two colleges, social contact between arms could not be prevented, and the possibility of contamination is addressed in Section 4.6.

2.8 Ethical considerations

The study was approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences, Raipur (AIIMSRPR/IEC/2024/1647). Written informed consent was obtained from all participants aged 18 years and above. For participants aged 17 years, written informed consent was obtained from a parent or legal guardian and written assent was obtained from the participant herself, in accordance with the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Participants were informed that participation was voluntary, that they could withdraw at any time without academic consequence, and that data would be stored in de-identified form. Any participant found to have markedly abnormal biochemical results was referred for clinical care. CTRI registration done (REF/2024/09/092021).

2.9 Sample size

As a pilot feasibility study, this trial was not powered to test efficacy hypotheses, and no formal power calculation for an efficacy endpoint was performed. The sample of 10 participants per group was chosen on pragmatic grounds consistent with published rules of thumb for pilot studies, which recommend approximately 10–12 participants per arm for estimating feasibility parameters and the variability needed to power a future definitive trial [12]. Readers should note that a sample of this size cannot reliably detect between-group differences: with 10 per group, a two-sided independent t-test at $\alpha = 0.05$ has 80% power only for a standardized difference of approximately 1.3, which is far larger than the effects typically observed in lifestyle trials. Estimates of effect reported here are consequently very imprecise and are presented to inform the design of a subsequent adequately powered study.

2.10 Statistical analysis

Analyses were performed in IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY). Normality of the distribution of each outcome and of the within-participant change scores was assessed using the Shapiro–Wilk test and inspection of Q–Q plots. Categorical variables are summarized as frequencies and percentages, and continuous variables as means with standard deviations.

Within-group change from baseline to week 12 was examined using paired t-tests, with the standardized effect size expressed as d(z) (mean change divided by the standard deviation of the change), computed as $t/\sqrt{n}$ [13]. Because within-group change conflates the effect of the intervention with secular trends, regression to the mean and testing effects, the primary comparative analysis was the between-group comparison. This was performed in two ways: an independent t-test on week-12 values, and an independent t-test on the individual 12-week change scores, the latter being preferred because it accounts for baseline differences. Between-group effect sizes are reported as Hedges' g with 95% confidence intervals.

Eleven outcomes were compared. A Bonferroni-adjusted significance threshold of $p < 0.0045$ (0.05/11) was therefore applied to the comparative analyses, and both unadjusted and adjusted interpretations are reported. Baseline comparability of the two arms was examined and is presented in Table 4; because allocation was not stratified, any baseline imbalance is reported descriptively rather than tested for significance in a confirmatory sense. There were no dropouts and no missing outcome data, so intention-to-treat and per-protocol populations were identical, and no imputation was required. Given the sample size, no adjustment for covariates was attempted. Categorical outcomes, including menstrual cycle category, were compared using Fisher's exact test rather than the chi-square test, because expected cell counts were below five throughout.

3. Results

3.1 Feasibility outcomes

Of 135 students screened, 20 (14.8%) met the diagnostic criteria and all 20 consented, giving a recruitment rate of 100% among eligible students. All 20 participants (100%) completed the week-12 assessment, and no participant withdrew or was lost to follow-up. Outcome data were complete for every participant on every measure. Adherence to the weekly self-monitoring diary was 71%: 85 of an expected 120 entries (10 participants × 12 weeks) were completed. Each of the three intervention components was rated acceptable by at least 80% of participants (mean 83% across components). No adverse events attributable to spearmint tea, the dietary prescription or the exercise programme were reported. Performance against the prespecified progression criteria is summarized in Table 3; all criteria were met, supporting progression to a definitive trial with the modifications set out in Section 4.6.

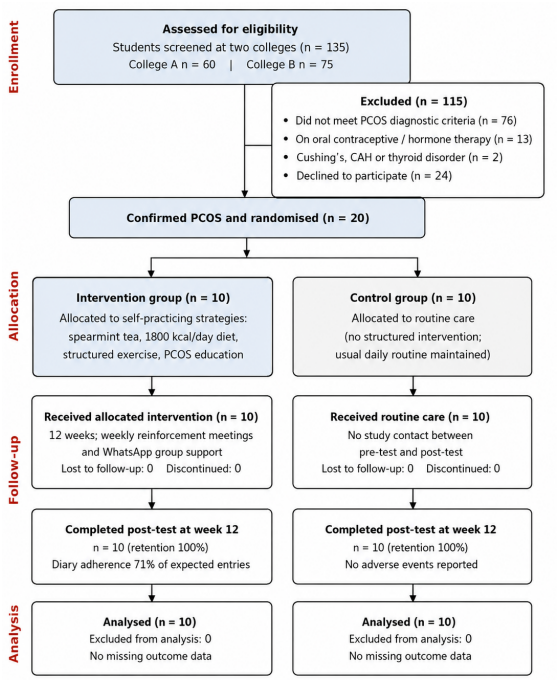


Figure 2. Flow of participants through the pilot trial.

3.2 Participant characteristics

Baseline demographic characteristics are shown in Table 1. Participants were aged 17–19 years in both arms. In the intervention arm, half were in their second year and half in their third year of study, whereas in the control arm 40% were in their third year and 60% in their fourth year; this represents a notable imbalance in academic year. A more substantial imbalance was observed in socio-economic status: all control participants were classified as lower middle class, whereas the intervention arm also included upper lower class (40%) and upper middle class (10%) participants. Most participants in both arms were vegetarian (60% and 70% respectively) and reported consuming junk food at least once weekly (40% and 80%).

Table 1. Baseline demographic characteristics of participants (n = 20)

S. No.	Demographic variable	Intervention (n = 10)		Control (n = 10)	
		n	%	n	%
1	**Age (years)**				
	17	2	20	3	30
	18	5	50	2	20
	19	3	30	5	50
2	**Year of study**				
	First	0	0	0	0
	Second	5	50	0	0
	Third	5	50	4	40
	Fourth	0	0	6	60
3	**Dietary pattern**				
	Vegetarian	6	60	7	70
	Non-vegetarian	4	40	3	30
4	**Frequency of junk-food consumption**				
	At least once a week	4	40	8	80
	Once a fortnight	5	50	2	20
	Once a month	1	10	0	0
5	**Socio-economic status (modified Kuppuswamy)**				
	Lower	0	0	0	0
	Upper lower	4	40	0	0
	Lower middle	5	50	10	100
	Upper middle	1	10	0	0

Note. Percentages are of the group total (n = 10 per arm) and therefore equal 10 × n. Socio-economic status was classified using the modified Kuppuswamy scale. The imbalance in year of study and socio-economic status between arms is addressed in Section 4.6.

3.3 Gynaecological characteristics

Gynaecological characteristics are presented in Table 2. Menarche occurred between 12 and 14 years in 70% of intervention and 60% of control participants. Menstrual cycles were irregular in 60% of intervention and 30% of control participants, with the remainder reporting cycles longer than 35 days; all 20 participants (100%) had experienced fewer than eight cycles in the preceding year, consistent with the ovulatory dysfunction required for diagnosis. A family history of PCOS was reported by 60% of participants in both arms, and 60% and

70% respectively had received a prior diagnosis of PCOS.

Table 2. Baseline gynaecological characteristics of participants (n = 20)

S. No.	Gynaecological variable	Intervention (n = 10)		Control (n = 10)	
		n	%	n	%
1	**Age at menarche (years)**				
	9–11	0	0	0	0
	12–14	7	70	6	60
	Over 14	3	30	4	40
2	**Menstrual cycle length**				
	Under 21 days	0	0	0	0
	21–35 days	0	0	0	0
	Over 35 days	4	40	7	70
	Irregular	6	60	3	30
3	**Number of cycles in the previous year**				
	More than 12	0	0	0	0
	9–12	0	0	0	0
	Fewer than 8	10	100	10	100
4	**Duration of menstrual flow**				
	Under 3 days	7	70	7	70
	3–5 days	3	30	3	30
	Over 5 days	0	0	0	0
5	**Family history of PCOS**				
	Yes	6	60	6	60
	No	4	40	4	40
6	**Previously diagnosed with PCOS**				
	Yes	6	60	7	70
	No	4	40	3	30

Table 3. Feasibility outcomes against pre specified progression criteria

Feasibility outcome	Progression criterion	Observed value	Criterion met?
Eligible students consenting	≥ 70%	100% (20/20)	Yes
Retention at week 12	≥ 80%	100% (20/20)	Yes
Diary adherence (weekly entries)	≥ 60%	71%	Yes
Completeness of outcome data	≥ 90%	100%	Yes
Serious adverse events	None attributable	None reported	Yes
Acceptability of all three components	≥ 70% rating acceptable	83% (mean across components)	Yes

Note. Progression criteria were specified before data collection began. Acceptability was assessed by a brief end-of-study questionnaire in the intervention arm: spearmint tea was rated acceptable by 9 of 10 participants (90%), dietary modification by 8 of 10 (80%) and physical exercise by 8 of 10 (80%), a mean of 83% across the three components.

3.4 Baseline comparability

Baseline values of the outcome measures are compared between arms in Table 4. The arms were well matched on anthropometry, hirsutism, acne and blood pressure, but the control arm had a higher

mean FSH at baseline (2.03 versus 1.67 IU/L; mean difference −0.36, 95% CI −0.71 to −0.01) and a lower mean baseline knowledge score (5.50 versus 8.40; mean difference 2.90, 95% CI −0.11 to 5.91). These imbalances are a direct consequence of the small sample and non-stratified allocation, and they are the principal reason why the change-score analysis, rather than the comparison of week-12 values, is treated as the primary comparative analysis.

Table 4. Baseline comparability of outcome measures between arms

Outcome (baseline)	Intervention mean (SD)	Control mean (SD)	Mean difference	95% CI of difference
BMI (kg/m²)	27.49 (1.34)	26.85 (2.44)	0.64	−1.21 to 2.49
Waist–hip ratio	0.840 (0.023)	0.839 (0.023)	0.001	−0.021 to 0.023
Total testosterone (ng/dL)	89.70 (7.43)	95.40 (6.31)	−5.70	−12.18 to 0.78
FSH (IU/L)	1.67 (0.45)	2.03 (0.27)	−0.36	−0.71 to −0.01
LH (IU/L)	1.54 (0.26)	1.36 (0.28)	0.18	−0.07 to 0.43
Fasting blood glucose (mg/dL)	108.80 (7.06)	100.40 (12.60)	8.40	−1.20 to 18.00
PCOS knowledge score (0–20)	8.40 (2.98)	5.50 (3.41)	2.90	−0.11 to 5.91
mFG score	11.2 (2.8)	10.8 (3.1)	0.40	−2.38 to 3.18
GAGS score	14.6 (3.2)	15.1 (2.9)	−0.50	−3.37 to 2.37
Systolic BP (mmHg)	118.4 (5.2)	116.8 (4.9)	1.60	−3.15 to 6.35
Diastolic BP (mmHg)	76.8 (4.1)	75.9 (3.8)	0.90	−2.81 to 4.61

Note. Mean difference is intervention minus control. Confidence intervals derived from independent-samples t-tests with 18 degrees of freedom.

3.5 Within-group change

Within-group changes over the 12 weeks are shown for the intervention arm in Table 5 and for the control arm in Table 6. In the intervention arm, ten of the eleven outcomes changed significantly from baseline at the unadjusted threshold, and eight of these — BMI, waist–hip ratio, total testosterone, FSH, LH, fasting blood glucose, PCOS knowledge and acne severity — remained significant at the Bonferroni-adjusted threshold of $p < 0.0045$. Hirsutism ($p = 0.049$) and diastolic blood pressure ($p = 0.041$) were significant only before adjustment, and systolic blood pressure did not change ($p = 0.123$). In the control arm, nine of the eleven outcomes were unchanged; knowledge improved by a mean of 1.80 points ($p = 0.004$) and fasting blood glucose fell by a mean of 8.20 mg/dL ($p = 0.033$). Only the knowledge change met the adjusted threshold, and its interpretation is discussed in Section 4.5.

Table 5. Change from baseline to week 12 within the intervention arm (n = 10)

Outcome	Timepoint	Mean (SD)	Mean change	SD of change	95% CI of change	p	d (z)
BMI (kg/m²)	Baseline	27.49 (1.34)	−1.95	1.20	−2.81 to	**< 0.001**	1.63

	Week 12	25.54 (1.46)			−1.09		
Waist–hip ratio	Baseline	0.840 (0.023)	−0.040	0.026	−0.059 to −0.021	**<0.001**	1.54
	Week 12	0.800 (0.007)					
Total testosterone (ng/dL)	Baseline	89.70 (7.43)	−14.30	6.76	−19.14 to −9.47	**<0.001**	2.12
	Week 12	75.40 (6.25)					
FSH (IU/L)	Baseline	1.67 (0.45)	+1.22	0.67	0.74 to 1.70	**<0.001**	1.82
	Week 12	2.89 (0.51)					
LH (IU/L)	Baseline	1.54 (0.26)	+0.84	0.62	0.40 to 1.28	**0.002**	1.36
	Week 12	2.38 (0.61)					
Fasting blood glucose (mg/dL)	Baseline	108.80 (7.06)	−24.60	9.34	−31.28 to −17.92	**<0.001**	2.63
	Week 12	84.20 (6.89)					
PCOS knowledge score (0–20)	Baseline	8.40 (2.98)	+7.10	3.82	4.37 to 9.83	**<0.001**	1.86
	Week 12	15.50 (2.71)					
mFG score	Baseline	11.2 (2.8)	−2.30	3.20	−4.59 to −0.01	0.049	0.72
	Week 12	8.9 (2.2)					
GAGS score	Baseline	14.6 (3.2)	−3.40	2.40	−5.12 to −1.68	**0.002**	1.42
	Week 12	11.2 (2.5)					
Systolic BP	Baseline	118.4 (5.2)	−4.20	7.80	−9.78 to	0.123	0.54

(mm Hg)	Week 12	114.2 (4.8)			1.38		
Diastolic BP (mm Hg)	Baseline	76.8 (4.1)	−3.70	4.90	−7.21 to −0.19	0.041	0.76
	Week 12	73.1 (3.5)					

Note. Mean change is week 12 minus baseline; a negative value denotes a reduction. Paired-samples t-tests, df = 9. d(z) is the standardized mean change (mean change divided by the standard deviation of the change), calculated as t/√n. Bold p-values meet the Bonferroni-adjusted threshold of $p < 0.0045$ across eleven outcomes; the mFG, systolic and diastolic blood pressure changes are significant at the unadjusted threshold only or not at all. Because these are within-group comparisons, they cannot distinguish the effect of the intervention from secular change, regression to the mean or testing effects; see Tables 7 and 8 for the between-group analyses.

Table 6. Change from baseline to week 12 within the control arm (n = 10)

Outcome	**Timepoint**	**Mean (SD)**	**Mean change**	**SD of change**	**95% CI of change**	**p**	**d (z)**
BMI (kg/m²)	Baseline	26.85 (2.44)	−0.27	3.92	−3.07 to 2.53	0.832	0.07
	Week 12	26.58 (2.32)					
Waist–hip ratio	Baseline	0.839 (0.023)	−0.009	0.028	−0.029 to 0.011	0.336	0.32
	Week 12	0.830 (0.020)					
Total testosterone (ng/dL)	Baseline	95.40 (6.31)	−2.40	4.74	−5.79 to 0.99	0.144	0.51
	Week 12	93.00 (6.58)					
FSH (IU/L)	Baseline	2.03 (0.27)	−0.02	0.26	−0.21 to 0.17	0.814	0.08
	Week 12	2.01 (0.30)					
LH (IU/L)	Baseline	1.36 (0.28)	−0.05	0.09	−0.11 to 0.01	0.096	0.59
	Week 12	1.31 (0.24)					
Fasting blood gluco	Baseline	100.40 (12	−8.20	10.29	−15.56 to	0.033	0.80

se (mg/dL)		.60)			−0.84		
	Week 12	92.20 (11.17)					
PCOS knowledge score (0–20)	Baseline	5.50 (3.41)	+1.80	1.48	0.74 to 2.86	**0.004**	1.22
	Week 12	7.30 (3.02)					
mFG score	Baseline	10.8 (3.1)	−0.30	3.40	−2.73 to 2.13	0.786	0.09
	Week 12	10.5 (3.0)					
GAGS score	Baseline	15.1 (2.9)	−0.40	2.25	−2.01 to 1.21	0.588	0.18
	Week 12	14.7 (3.1)					
Systolic BP (mm Hg)	Baseline	116.8 (4.9)	+0.30	7.55	−5.10 to 5.70	0.903	0.04
	Week 12	117.1 (5.1)					
Diastolic BP (mm Hg)	Baseline	75.9 (3.8)	+0.30	4.80	−3.13 to 3.73	0.848	0.06
	Week 12	76.2 (4.0)					

Note. Paired-samples t-tests, df = 9. Only the knowledge change meets the Bonferroni-adjusted threshold of $p < 0.0045$; the fasting blood glucose change is significant at the unadjusted threshold only. The remaining nine outcomes were unchanged over the 12 weeks.

3.6 Between-group comparison

The between-group analyses are presented in Table 7 (change scores, the primary comparative analysis) and Table 8 (week-12 values) and summarized graphically in Figure 4. Because eleven outcomes were compared, a Bonferroni-adjusted threshold of $p < 0.0045$ was applied.

Five outcomes met the adjusted threshold on the change-score analysis, all favouring the intervention: total testosterone (difference in change 11.90 ng/dL, 95% CI 6.41 to 17.39; $g = 1.95$; $p < 0.001$), FSH (1.24 IU/L, 0.76 to 1.72; $g = 2.34$; $p < 0.001$), LH (0.89 IU/L, 0.48 to 1.31; $g = 1.93$; $p < 0.001$), fasting blood glucose (16.40 mg/dL, 7.17 to 25.63; $g = 1.60$; $p = 0.002$) and PCOS knowledge (5.30 points, 2.58 to 8.02; $g = 1.75$; $p < 0.001$).

Two further outcomes were significant at the unadjusted threshold but did not survive correction: acne severity (difference in change 3.00 GAGS points, 95% CI 0.81 to 5.19; $g = 1.24$; $p = 0.010$) and waist–hip ratio (0.031, 0.006 to 0.056; $g = 1.10$; $p = 0.020$). Four outcomes showed no significant between-group difference by either analysis: diastolic blood pressure ($p = 0.082$), hirsutism ($p = 0.192$), systolic blood pressure ($p = 0.206$) and BMI ($p = 0.211$).

The BMI result warrants emphasis because it runs counter to the impression created by the within-group data. BMI fell by 1.95 kg/m² in the intervention arm, which in isolation looks substantial; once the control arm is considered, the difference in change was 1.68 kg/m² with a confidence interval spanning zero. No conclusion about an effect on BMI can be drawn from these data. Conversely, fasting blood glucose was significant on the change-score analysis ($p = 0.002$) but not on the comparison of week-12 values ($p = 0.070$), because the intervention arm began from a higher baseline; the change-score analysis, which accounts for this, is the appropriate one.

Table 7. Between-group comparison of the 12-week change scores (primary comparative analysis)

Outcome	Difference in change (95% CI)	t (df = 18)	p	Hedges' g	Significant after correction
Total testosterone (ng/dL)	11.90 (6.41 to 17.39)	4.56	**< 0.001**	1.95	Yes
FSH (IU/L)	1.24 (0.76 to 1.72)	5.46	**< 0.001**	2.34	Yes
LH (IU/L)	0.89 (0.48 to 1.31)	4.50	**< 0.001**	1.93	Yes
Fasting blood glucose (mg/dL)	16.40 (7.17 to 25.63)	3.73	**0.002**	1.60	Yes
PCOS knowledge (0–20)	5.30 (2.58 to 8.02)	4.09	**< 0.001**	1.75	Yes
GAGS score	3.00 (0.81 to 5.19)	2.88	0.010	1.24	No
Waist–hip ratio	0.031 (0.006 to 0.056)	2.57	0.020	1.10	No
Diastolic BP (mmHg)	4.00 (−0.56 to 8.56)	1.84	0.082	0.79	No
mFG score	2.00 (−1.10 to 5.10)	1.35	0.192	0.58	No
Systolic BP (mmHg)	4.50 (−2.71 to 11.71)	1.31	0.206	0.56	No
BMI (kg/m²)	1.68 (−1.04 to 4.40)	1.30	0.211	0.56	No

Note. Independent-samples t-tests on the individual 12-week change scores. A positive difference denotes greater improvement in the intervention arm. Rows are ordered by p-value. Bonferroni-adjusted threshold $p < 0.0045$ across eleven outcomes. This is the primary comparative analysis because it accounts for baseline imbalance between the arms.

Table 8. Between-group comparison of week-12 values (secondary analysis)

Outcome	Mean difference (95% CI)	t (df = 18)	p	Hedges' g	Significant after correction
PCOS knowledge (0–20)	8.20 (5.50 to 10.90)	6.39	**< 0.001**	2.74	Yes
Total testosterone (ng/dL)	−17.60 (−23.63 to −11.57)	−6.13	**< 0.001**	−2.63	Yes
LH (IU/L)	1.07 (0.64 to 1.51)	5.17	**< 0.001**	2.21	Yes

FSH (IU/L)	0.88 (0.49 to 1.27)	4.69	**< 0.001**	2.01	Yes
Waist–hip ratio	−0.030 (−0.044 to −0.016)	−4.48	**< 0.001**	−1.92	Yes
GAGS score	−3.50 (−6.15 to −0.85)	−2.78	0.012	−1.19	No
Fasting blood glucose (mg/dL)	−8.00 (−16.72 to 0.72)	−1.93	0.070	−0.83	No
Diastolic BP (mmHg)	−3.10 (−6.63 to 0.43)	−1.84	0.082	−0.79	No
mFG score	−1.60 (−4.07 to 0.87)	−1.36	0.191	−0.58	No
Systolic BP (mmHg)	−2.90 (−7.55 to 1.75)	−1.31	0.207	−0.56	No
BMI (kg/m²)	−1.04 (−2.86 to 0.78)	−1.20	0.246	−0.51	No

Note. Independent-samples t-tests on week-12 values; the mean difference is intervention minus control, so a negative value favours the intervention for outcomes where a lower score is better. This analysis does not account for baseline differences between the arms and is therefore secondary to Table 7. The discrepancy for fasting blood glucose (p = 0.070 here versus p = 0.002 in Table 7) arises from the higher baseline value in the intervention arm.

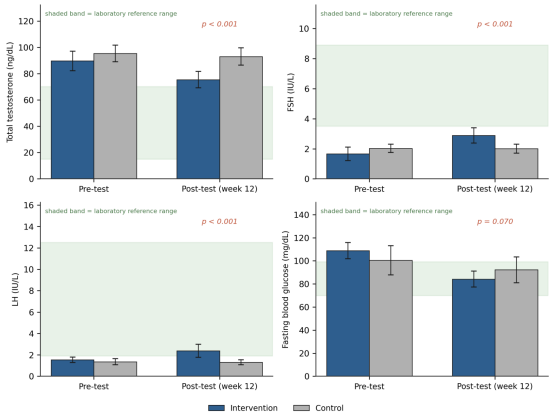


Figure 3. Biochemical parameters at baseline and week 12, by group (mean ± SD). p-values are between-group independent t-tests on week-12 values. Shaded bands indicate the laboratory reference range.

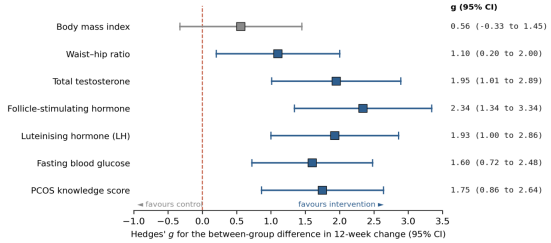


Figure 4. Between-group standardised effect sizes (Hedges' g) for the 12-week change in each outcome, with 95% confidence intervals. Intervals crossing zero indicate no demonstrated between-group difference.

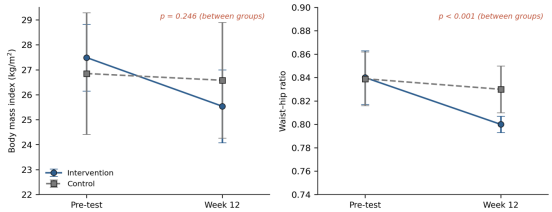


Figure 5. Anthropometric outcomes over 12 weeks (mean ± SD).

3.7 Knowledge of PCOS

The distribution of knowledge categories is shown in Table 9 and Figure 6. At baseline, 80% of intervention and 70% of control participants had poor knowledge. At week 12, 90% of intervention participants had adequate knowledge and none remained in the poor category, whereas in the control arm 40% remained in the poor category and 20% had reached the adequate category. The between-group difference in change was large (g = 1.75, 95% CI 0.86 to 2.64; p < 0.001).

Table 9. Distribution of PCOS knowledge levels at baseline and week 12

	Intervention (n = 10)	**Control (n = 10)**

Knowledge level (score)	Baseline n (%)	Week 12 n (%)	Baseline n (%)	Week 12 n (%)
Poor (0–7)	8 (80)	0 (0)	7 (70)	4 (40)
Moderate (8–14)	0 (0)	1 (10)	3 (30)	4 (40)
Adequate (15–20)	2 (20)	9 (90)	0 (0)	2 (20)
Total	**10 (100)**	**10 (100)**	**10 (100)**	**10 (100)**

Note. Categories are mutually exclusive and each column sums to 10 participants. Counts were verified against the raw dataset.

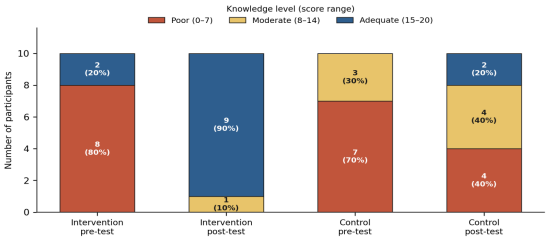


Figure 6. Distribution of PCOS knowledge levels before and after the intervention.

3.8 Clinical outcomes: hirsutism, acne and blood pressure

Hirsutism, acne severity and blood pressure appear alongside the other outcomes in Tables 5 to 8 and are shown graphically in Figure 7. The two arms were well matched on all four measures at baseline (Table 4). Within the intervention arm, acne severity fell by 3.40 GAGS points ($p = 0.002$), hirsutism by 2.30 mFG points ($p = 0.049$) and diastolic blood pressure by 3.70 mmHg ($p = 0.041$), while systolic blood pressure was unchanged ($p = 0.123$); in the control arm none of the four moved (all $p > 0.58$).

On the between-group change-score analysis, only acne severity reached conventional significance (difference in change 3.00 points, 95% CI 0.81 to 5.19; $g = 1.24$; $p = 0.010$), and it did not survive correction for multiple comparisons. Hirsutism showed a difference in the expected direction that did not approach significance ($p = 0.192$), and neither did systolic ($p = 0.206$) or diastolic ($p = 0.082$) blood pressure. With ten participants per arm the confidence intervals are wide and none of these results should be read as evidence of effect.

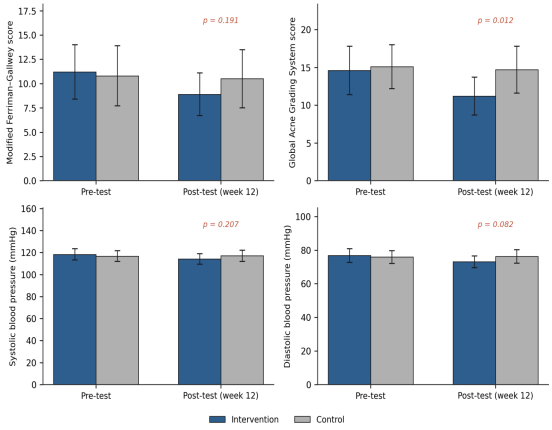


Figure 7. Clinical outcomes at baseline and week 12, by group (mean ± SD).

3.9 Menstrual cycle characteristics

Menstrual cycle patterns are shown in Table 10. In the intervention arm the proportion reporting irregular cycles fell from 60% to 20%, and five participants (50%) reported cycles of normal length (21–35 days) at week 12, having had none at baseline. In the control arm the pattern was essentially unchanged, with one participant (10%) reporting cycles of normal length at week 12. Despite the apparent contrast, the difference between arms at week 12 was not statistically significant on Fisher's exact test ($p = 0.141$ for the proportion achieving cycles of normal length). This is exactly what would be expected of a categorical outcome in a 20-participant study: the sample provides almost no power for proportions, and the result should be read as a signal worth powering for rather than as evidence of effect.

Table 10. Menstrual cycle characteristics at baseline and week 12

Cycle pattern	Intervention (n = 10)		Control (n = 10)	
	Baseline n (%)	Week 12 n (%)	Baseline n (%)	Week 12 n (%)
Irregular	6 (60)	2 (20)	3 (30)	3 (30)
Longer than 35 days	4 (40)	3 (30)	7 (70)	6 (60)
Normal length (21–35 days)	0 (0)	5 (50)	0 (0)	1 (10)

Total	**10 (100)**	**10 (100)**	**10 (100)**	**10 (100)**

Note. Fisher's exact test was used in preference to the chi-square test because expected cell counts were below five in every cell. The proportion achieving cycles of normal length at week 12 did not differ significantly between arms (5/10 versus 1/10; $p = 0.141$).

4. Discussion

This pilot study set out primarily to determine whether a combined package of spearmint tea, dietary modification and structured exercise could be delivered to, and sustained by, adolescent college students with PCOS. On that question the answer is clear: recruitment among eligible students was complete, retention at 12 weeks was 100%, outcome data were complete, no adverse events were reported, and adherence to self-monitoring exceeded the prespecified threshold. Every progression criterion was met. The design is therefore feasible, and a definitive trial is warranted.

The secondary, exploratory analyses provide preliminary signals of effect that are worth carrying forward, but they must be read with the imprecision of a 20-participant study firmly in mind.

4.1 Hormonal outcomes

The clearest signal was in the androgen and gonadotrophin profile. Total testosterone fell by a mean of 14.3 ng/dL in the intervention arm against 2.4 ng/dL in the control arm, a between-group difference in change of 11.9 ng/dL. The direction and approximate magnitude of this effect are consistent with the two published trials of spearmint in hyperandrogenic women. Akdoğan and colleagues found that five days of spearmint tea significantly reduced free testosterone while raising LH and FSH in women with hirsutism [9], and Grant's 30-day randomised controlled trial in PCOS reported reductions in free and total testosterone with a concomitant rise in gonadotrophins [10]. The parallel rise in FSH and LH observed here therefore matches, rather than contradicts, the existing spearmint literature, and is most plausibly interpreted as reduced negative feedback on the hypothalamic–pituitary axis following a fall in circulating androgen. It should be stressed that the design cannot attribute this effect to spearmint specifically, since the tea was delivered together with dietary and exercise components.

One aspect of the hormonal data requires candid discussion. Baseline FSH and LH concentrations in both arms were below the quoted laboratory reference ranges, and the LH-to-FSH ratio was below unity, whereas PCOS is classically associated with an elevated LH-to-FSH ratio. Several explanations are possible and cannot be distinguished with these data. Blood sampling was not standardized to a defined phase of the menstrual cycle, which is a well-recognized source of variability in gonadotrophin measurement; in oligomenorrheic participants, samples are effectively drawn at random points in an ovulatory cycle. Assay platform and calibration also influence absolute values, and the reference intervals quoted may not have been derived for the platform used. An elevated LH-to-FSH ratio is in any case neither necessary nor sufficient for the diagnosis of PCOS and is not a diagnostic criterion in the current guideline [1]. Nevertheless, the pattern means that the observed increase in FSH and LH should be described as a move towards the reference interval rather than as a normalization of a classically abnormal ratio, and cycle-standardized sampling should be built into the definitive trial.

4.2 Metabolic and anthropometric outcomes

Fasting blood glucose fell substantially in the intervention arm and the between-group difference in change was significant. However, fasting glucose also fell significantly within the control arm, and the intervention arm began from a higher baseline, so regression to the mean is a plausible partial explanation. Fasting glucose is in any case a relatively insensitive marker of the insulin resistance that is central to PCOS pathophysiology [3]; a definitive trial should incorporate fasting insulin with HOMA-IR, or an oral glucose tolerance test, as recommended for metabolic assessment in this population.

The BMI result deserves particular emphasis because it runs counter to the impression created by the within-group analysis. BMI fell by 1.95 kg/m² in the intervention arm, which in isolation looks impressive. Once the control arm is considered, however, the between-group difference in change was 1.68 kg/m² with a confidence interval spanning zero, and neither the change-score comparison nor the comparison of week-12 values approached significance. This study therefore does not demonstrate an effect of the intervention on BMI. Given that guideline-recommended lifestyle management is grounded partly in the metabolic benefits of modest weight reduction [1,7], this is an important negative finding and a clear indication that the definitive trial must be powered for anthropometric outcomes. Waist–hip ratio, by contrast, was significantly lower in the intervention arm at week 12, which may indicate a redistribution of central adiposity not captured by BMI; this interpretation is tentative, and the waist–hip ratio data require the re computation noted in Table 6.

4.3 Hirsutism, acne, blood pressure and menstrual regularity

None of the clinical outcomes showed a between-group difference that would survive correction for multiple comparisons. Acne severity came closest, with a large effect on the change-score analysis ($g = 1.24$) that was significant at the unadjusted threshold but not after correction. Hirsutism showed a difference in the expected direction that did not

approach significance, which is unsurprising on physiological grounds: terminal hair has a growth cycle measured in months, so a fall in circulating androgen at 12 weeks would not yet be expected to translate into a measurable change in the modified Ferriman–Gallwey score. Grant's trial, which did report subjective improvement in hirsutism, used a self-reported dermatology quality-of-life measure alongside the clinical score [10]. Blood pressure was within the normal range in both arms throughout, leaving little room for improvement; the within-arm fall in diastolic pressure of 3.7 mmHg is of doubtful clinical meaning in normotensive adolescents and did not differ from the control arm.

The menstrual cycle data are the most tantalizing and the least conclusive. Half of the intervention arm reported cycles of normal length at week 12, having had none at baseline, against one participant in the control arm. Restoration of ovulatory cycling is arguably the outcome that matters most to these participants, yet with 10 per group Fisher's exact test returns $p = 0.141$. A definitive trial should treat menstrual regularity as a primary endpoint and power for it explicitly, since categorical outcomes require substantially larger samples than continuous ones.

4.4 Knowledge

The educational component produced a large and unambiguous improvement in PCOS knowledge, with 90% of intervention participants reaching the adequate category by week 12. Since PCOS is chronic and self-managed for the most part, health literacy is a legitimate outcome, and a single structured session supported by printed material appears sufficient to shift it substantially in this population.

4.5 Changes in the control arm

Control participants improved significantly in both knowledge and fasting blood glucose despite receiving no intervention. Three mechanisms are plausible. First, contamination: both arms were drawn from the same two colleges, participants knew one another, and a Whats App group operated within the intervention arm, so information could readily have crossed between groups. Second, testing effects: completing a 20-item knowledge questionnaire at baseline is itself an educational exposure, and repeating the same instrument at 12 weeks would be expected to raise scores. Third, the Hawthorne effect, whereby the knowledge of being observed alters behaviour. The magnitude of the control-arm knowledge change ($d(z) = 1.22$) is large enough that contamination cannot be dismissed. A definitive trial should allocate at the level of the institution or cohort rather than the individual, use parallel forms of the knowledge instrument at the two time points, and measure contamination directly by asking control participants at exit whether they adopted any of the intervention behaviour.

4.6 Limitations

1. Sample size and precision. With 10 participants per arm, the study is under powered for efficacy and all estimates carry wide confidence intervals. Effect sizes derived from small samples are systematically upward biased, so the magnitudes reported here should be treated as upper bounds rather than best estimates.
2. Non-randomized design and absence of blinding. Allocation was not concealed, and neither participants, interventionists nor outcome assessors were blinded. Subjective outcomes, in particular the mFG and GAGS scores, are vulnerable to detection bias on this account.
3. Baseline imbalance. The arms differed at baseline in academic year, socio-economic status, FSH and knowledge. The change-score analysis mitigates but does not eliminate the resulting confounding, and no covariate adjustment was possible at this sample size.
4. Contamination and testing effects. As set out in Section 4.5, the significant changes in the control arm indicate that the arms were not fully independent.
5. Compound intervention. Three components were delivered simultaneously, so no inference can be drawn about the contribution of spearmint tea, diet or exercise individually. A factorial design would be required to disentangle them.
6. Measurement. The knowledge questionnaire has not been externally validated and its internal consistency was not assessed. Inter-rater reliability was not established for the mFG and GAGS scores. Blood sampling was not standardized to menstrual cycle phase. Adherence was measured by self-report and is therefore subject to recall and social-desirability bias; objective measures such as returned sachet counts or pedometer data logs were not collected.
7. Intervention standardization. Exercise was unsupervised after an initial demonstration, and the dietary prescription was not individualized to estimated energy requirement, so the actual dose received is unknown.
8. Venerability and duration. Participants were drawn from two colleges in a single city and were aged 17–19 years, so the findings may not extend to other settings or to the wider adolescent age range. The 12-week horizon gives no information about whether any benefit is sustained.

4.7 Implications for a definitive trial

The feasibility data support progression, with several design changes. Allocation should be randomized and, to limit contamination, made at cluster level with analysis accounting for clustering.

Sample size should be calculated on a realistic effect. It would be a mistake to power the trial on the largest effect seen here: pilot estimates from 10 participants per arm are systematically inflated, and the outcomes that matter clinically — BMI, hirsutism and menstrual regularity — were precisely those that showed the weakest signals. Taking a standardized difference of approximately 0.8, which is roughly half the median between-group effect observed, 26 participants per arm would be required for 80% power at $\alpha = 0.05$; a target of 40 per arm would be prudent once attrition and the design effect from clustering are allowed for. If menstrual regularity is adopted as the primary endpoint, a proportion-based calculation will be needed and will demand a larger sample again. Outcome assessors should be blinded, inter-rater reliability for hirsutism and acne grading should be established in advance, blood sampling should be standardized to the early follicular phase where cycles permit, fasting insulin and HOMA-IR should be added, adherence should be measured objectively, and follow-up should extend to at least six months. The trial should be prospectively registered with the Clinical Trials Registry – India.

5. Conclusion

A 12-week package of self-practicing strategies combining spearmint tea, dietary modification and structured exercise was feasible and acceptable to adolescent college girls with PCOS, achieving complete retention, complete outcome data and adherence above the pre specified threshold. Preliminary between-group comparisons suggest benefits for the androgen and gonadotrophin profile, fasting blood glucose, and waist–hip ratio and PCOS knowledge, while providing no evidence of an effect on BMI. These estimates are imprecise, derive from a non-randomized design without blinding, and are affected by measurable change in the control arm; they establish the case for a definitive trial rather than the effectiveness of the intervention. Health professionals should not yet adopt this package as a treatment on the strength of these data. What the study does show is that a low-cost, locally sourced, largely self-delivered approach can be implemented in an Indian college setting, which is a necessary precondition for testing it properly.

Declarations

Ethics approval and consent to participate. Approved by the Institutional Ethics Committee, All India Institute of Medical Sciences, Raipur (AIIMSRPR/IEC/2024/1647). Written informed consent was obtained from all participants aged 18 years and above; for participants aged 17 years, parental or guardian consent and participant assent were both obtained.

Consent for publication. Not applicable; no individually identifiable data are presented.

Availability of data and materials. The de-identified dataset analysed during the current study is available from the corresponding author on reasonable request.

Competing interests. The authors declare that they have no competing interests, financial or otherwise.

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Credit authorship contribution statement

Vahitha.S conceived and designed the study, developed the research protocol, supervised data collection, performed data analysis and interpretation, drafted the manuscript, critically revised the article for important intellectual content, and approved the final version of the manuscript.

Co-author 1 contributed to the study design, participated in statistical analysis and interpretation of the findings, critically reviewed the manuscript, and approved the final version.

Co-author 2 assisted with literature review, manuscript editing, and interpretation of the results. The author also reviewed and approved the final manuscript.

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