

Evaluation of Effects of a High-Protein Hypocaloric Diet on Body Composition and Cardio-Metabolic Factors in Women with Polycystic Ovary Syndrome and Overweight or Obesity

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Background: The optimal composition of a hypocaloric diet for women with polycystic ovary syndrome (PCOS) remains uncertain. The aim of this study was to evaluate and compare the impacts of a hypocaloric high-protein diet (HPD) versus an isocaloric conventional calorie-restricted diet (CRD) with normal protein intake on the body composition and biochemical profiles of women diagnosed with PCOS combined with overweight or obesity.

Methods: This was a dietary intervention study evaluating the effects of two types of diets on women with PCOS who initiated weight loss independently at the Clinical Nutrition Clinic of Peking Union Medical College Hospital from March 2023 to March 2024 was carried out. Specifically, the records of 72 women with PCOS who were overweight or obese and underwent a 3-month weight management program were examined in a retrospective manner. The hypocaloric dietary intervention was adopted to achieve weight reduction, with either HPD or CRD. Body composition, serum lipids, glucose, insulin, and total testosterone (TT) were evaluated at baseline and post-intervention, and the differences were compared between and within groups.

Results: Both groups achieved significant weight loss, with the HPD group losing an average of -8.9 ± 4.6 kg and the CRD group losing -10.0 ± 9.4 kg, without a significant difference between them ($P > 0.05$). However, the HPD was superior in preserving fat-free mass (FFM) and fat-free mass index (FFMI), with losses of -1.5 ± 1.6 kg and -0.7 ± 1.1 kg/m², respectively, compared to the CRD group's losses of -4.4 ± 4.2 kg and -2.1 ± 1.9 kg/m² ($P < 0.01$). Additionally, the HPD group showed a more significant reduction in body fat percentage ($-5.3 \pm 3.3\%$ vs $-3.2 \pm 4.5\%$, $P < 0.05$). Biochemical indicators were comparable in both groups.

Conclusion: Compared to an isocaloric standard-protein CRD, the dietary intervention with a HPD appears to be more helpful in preserving FFM in women with PCOS during a short-term weight loss program. Further well-designed trials are needed to verify our findings.

Keywords: high-protein diet, polycystic ovary syndrome, body composition, fat-free mass, weight loss

Introduction

Polycystic Ovary Syndrome (PCOS), defined by a combination of signs and symptoms of hyperandrogenism and ovarian dysfunction in the absence of other specific diagnoses, is a complex endocrine disorder that affects 6–20% of premenopausal women.¹ Women with PCOS face a heightened risk of various complications, such as anovulation, infertility,² and a range of metabolic issues. These metabolic issues include significant insulin resistance and/or hyperinsulinemia,² impaired glucose tolerance or type 2 diabetes,³ atherogenic dyslipidemia,⁴ and hyperuricemia.⁵ Pregnant women with PCOS are also at an increased risk for gestational diabetes, pre-eclampsia, preterm delivery, and

fetal macrosomia.^{2,6} The presence of obesity, especially abdominal obesity, is common among women with PCOS and can worsen the metabolic and reproductive abnormalities, primarily by increasing insulin resistance and hyperinsulinemia.

Weight loss and improved insulin sensitivity through lifestyle modifications, including dietary interventions, are considered the primary treatment for managing PCOS symptoms and enhancing reproductive and metabolic health outcomes.⁷ Even a modest weight reduction of 5% can lead to significant improvements for individuals with PCOS, such as normalized menstrual cycles, increased medication sensitivity for ovulation induction, and better responses to fertility treatments.^{8–10} However, based on current studies regarding dietary interventions for PCOS, there is no evidence to support any 1 type of diet composition over another for anthropometric, metabolic, hormonal, reproductive, or psychological outcomes.⁷

Nutrition intervention with a calorie-restricted diet (CRD) accompanied by adequate physical activity is frequently recommended to individuals with overweight or obesity as one of the treatment methods.¹¹ However, there is a risk of regaining weight after a CRD, as this can lead to increased hunger and a reduction in the feeling of satiety. Additionally, losing weight through a CRD not only reduces body fat but also fat-free mass (FFM), which can impede ongoing weight loss. In order to counteract this, it is essential to reduce calorie intake while still keeping a feeling of fullness and preserving FFM. One effective approach to achieve this is by following a high-protein CRD.^{12,13} The focus on diets with varying protein content within a caloric restriction framework is gaining prominence due to the potential benefits observed in weight management and overall health. A recent meta-analysis has indicated that HPDs, which constitute 25–35% of total energy intake, offer additional advantages in terms of weight loss when compared to isocaloric diets with standard protein content (12–18%).¹² These hypocaloric HPDs are also believed to lessen the loss of FFM and enhance satiety,^{12,14} which can contribute to maintaining resting energy expenditure¹² and improving the psychological well-being and self-esteem of those who are losing weight.¹⁵ Moreover, women with PCOS often have a lower lean body mass compared to their healthy counterparts¹⁶ and may struggle to adhere to CRDs due to various psychosocial, physiological, and appetite regulatory challenges,^{17–19} therefore they might be more likely to benefit from HPDs. Despite this, a recent meta-analysis comparing HPDs with isocaloric standard-protein diets revealed insignificant differences in anthropometric measurements, including weight, BMI, and waist circumference, but the heterogeneity of the body composition data included was too large to achieve combined results of the impacts of the two diets on body composition in women with PCOS.²⁰

HPDs may have the potential role in weight control for women with PCOS and overweight, whereas their significance has continued to be elucidated, especially the effects on body composition. Therefore the current study was initiated to directly compare the impact of calorie-restricted HPDs and isocaloric CRDs with normal protein content on the body composition and cardio-metabolic factors. This research is critical for developing targeted dietary interventions that can effectively support weight loss and improve metabolic health in women with PCOS and overweight or obese, taking into account their specific physiological and psychological needs.

Materials and Methods

This was a dietary intervention study analyzing data from women with PCOS and concurrently overweight or obesity who voluntarily lost weight at the Clinical Nutrition Clinic of Peking Union Medical College Hospital (PUMCH) between March 2023 and March 2024. Data were collected from participants' medical records. Due to the retrospective nature of the study, the need for consent to participate was waived by the Ethics Committee of PUMCH (Approved ID: No. I-24PJ066). We confirm that the participants' data were maintained with confidentiality. This study was conducted in accordance with both the Declaration of Helsinki, as revised in 1983, and the guidelines of the center's institutional review board. The inclusion criteria for this retrospective study were as follows: (1) 18–40 years; (2) BMI > 23.9 kg/m² and less than 40.0 kg/m²; (3) women who had completed a 3-month weight loss intervention, and (4) women was made a definite diagnosis of PCOS based on the Rotterdam criteria,²¹ with at least two of the following criteria: 1) menstrual irregularity (infrequent menstrual periods) and/or anovulation (heavy bleeding >7 days or short cycle <21 days or long cycle >35 days), 2) clinical and/or biochemical hyperandrogenism, 3) polycystic ovaries based on ultrasound examination (presence of ≥ 12 follicles of 2–9 mm in diameter in each ovary and/or an increase in ovarian volume of > 11cm³).

Women were excluded if they had any of the following conditions: 1) the duration of weight loss intervention was less than 12 weeks or loss of follow-up; 2) with diabetes or using any hypoglycemic or anti-obesity medication within the period of intervention; 3) with confirmed hyperthyroidism or hypothyroidism; 4) pregnancy within the period of intervention; 5) with psychological disorders or eating disorder; or 6) with incomplete data.

In outpatient settings, researchers provided two dietary intervention options (a hypocaloric HPD or an isocaloric conventional CRD) for women with PCOS who were aiming to lose weight. Participants voluntarily choose to follow either a hypocaloric HPD or an isocaloric conventional CRD based on their own dietary habits. (1) HPD group: Participants were given a modified hypocaloric diet where 30% of the daily energy came from protein. Notably, about 50% of this protein intake was through whey protein isolate powder, which was consumed as a meal replacement for breakfast and an afternoon snack. The remaining energy intake was provided by carbohydrates (40%) and fat (30%) as prescribed. (2) CRD group: Participants in this group were prescribed an isocaloric conventional diet with a macronutrient distribution of 55% carbohydrates, 15% protein, and 30% fat. For both groups, the daily energy intake was set to 70%–80% of the participants' total energy requirements. Additionally, all participants were advised on lifestyle modifications by trained physicians or dietitians. These recommendations included: adhering to regular meal and sleep schedules, engaging in at least 150 minutes of weekly exercise, avoiding prolonged periods of sitting, slowing down the pace of eating to promote better digestion and a sense of satiety, minimizing the frequency of dining out to control dietary intake more effectively, avoiding processed meats, which can be high in sodium and other additives, and reducing the intake of simple sugars and fried foods, which are often high in empty calories and unhealthy fats. In the course of weight reduction, participants were scheduled for a subsequent outpatient visit approximately 3 to 4 weeks post-intervention. During this appointment, researchers inquired about and assessed the participants' compliance with the prescribed diet, utilizing food models as a reference point. The level of dietary compliance was then documented in the participants' outpatient medical charts.

Anthropometric Measurements

Participants were followed up once a month, and data on weight and body compositions were measured and collected. Weight was measured in an upright position to the nearest 0.1 kg with a calibrated scale. Height was measured to the nearest 0.1 cm with a portable stadiometer. Body composition including total body fat and FFM were measured using multifrequency bioelectrical impedance analyzer (Inbody 720; 5, 50, 250, and 500 kHz; Biospace Co. Ltd., Seoul, Korea). Fat-free mass index (FFMI) was calculated as fat-free mass (kg)/(height)² (m²).

Biochemical Measurements

Blood samples were retrieved from participants (in the morning after ≥ 8 -h fasting) before and after a 3-month weight loss intervention, respectively. Concentrations of total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-c), low-density lipoprotein cholesterol (LDL-c), and fasting plasma glucose (FPG) were measured by an automatic analyzer (Beckman 5800; Beckman Coulter Inc., Brea, CA, USA) and retrieved from medical records. Total testosterone (TT) concentrations were measured using an enzymatic assay on a Beckman Coulter DX1 800 automatic chemistry analyzer (Beckman Coulter Inc., Brea, CA, USA). The calculation of homeostasis model assessment-insulin resistance (HOMA-IR) was followed by the method of Matthews et al.²²

Statistical Analysis

The sample size for the current study was determined based on data from a previous trial,²³ which reported fat mass reductions of (18.3 \pm 12.2) kg for a high protein diet and (10.5 \pm 12) kg for a normal protein diet after three months of intervention. The calculation determined that enrolling 25 participants per group would provide 90% statistical power to detect a significant difference in fat mass reduction between the two dietary interventions. For the statistical analysis, SPSS 17.0 software was utilized. Quantitative variables, such as weight, BMI, and biochemical measurements, were presented as Mean \pm Standard Deviation (SD). Categorical variables, which might include demographic factors or binary outcomes, were described in terms of frequency or percentage. To compare differences in variables between the two groups, as well as differences in the changes of these variables over time, appropriate statistical tests were applied. Chi-

square tests were used for categorical variables to assess differences in distribution, while Student's *t*-tests were employed for continuous variables to compare means between groups. The changes in variables within each group, from before to after the intervention, were assessed using paired *t* tests. A two-tailed *P*-value less than 0.05 was set as the threshold for statistical significance.

Results

Basic Characteristics of the Participants

A total of 72 women were enrolled herein. The participation flowchart is described in [Figure 1](#). No significant differences existed in participants' baseline characteristics for the two treatment groups. The mean age of the participants was 31.4 ± 4.7 years (19–40 years). The mean BMI was 30.3 ± 3.8 kg/m². Among the participants, 22 women were with overweight, and the rest were obese. Before intervention, there was no significant difference in the reported variables between the two groups (all *P* > 0.05) ([Table 1](#)).

The Differences Between Groups

After a 3-month intervention, the mean weight change was -8.9 ± 4.6 kg for women in HPD group and -10.0 ± 9.4 kg in CRD group (*P* > 0.05) ([Table 2](#)). Likewise, the difference in BMI changes between the two groups was comparable [-3.2 ± 1.6 kg/m²] vs [-2.8 ± 3.7 kg/m²], *P* > 0.05]. For the percentage of more than 10% weight loss, there were no significant differences between the two groups (53.8% in HPD group and 57.6% in CRD group). However, the reduction of percent body fat in HPD group was significantly more than CRD group (*P* < 0.05), and the reduction of FFM and FFMI in HPD group was significantly better preserved than those in CRD group (all *P* < 0.05) ([Table 2](#)). There was no significant difference in the changes of biochemical measurements between the two groups (all *P* > 0.05) ([Table 2](#)).

The Differences within Groups

Both CRD and HPD groups resulted in significant weight, BMI, and percent body fat loss (*P* < 0.05). For women in CRD group, the post-intervention FFM, FFMI, TG, FPG, fasting insulin, HOMA-IR, and TT, significantly decreased compared to those of pre-intervention (Paired *t* test, *P* < 0.05), but there was no significant difference in TC, LDL-c, and HDL-c

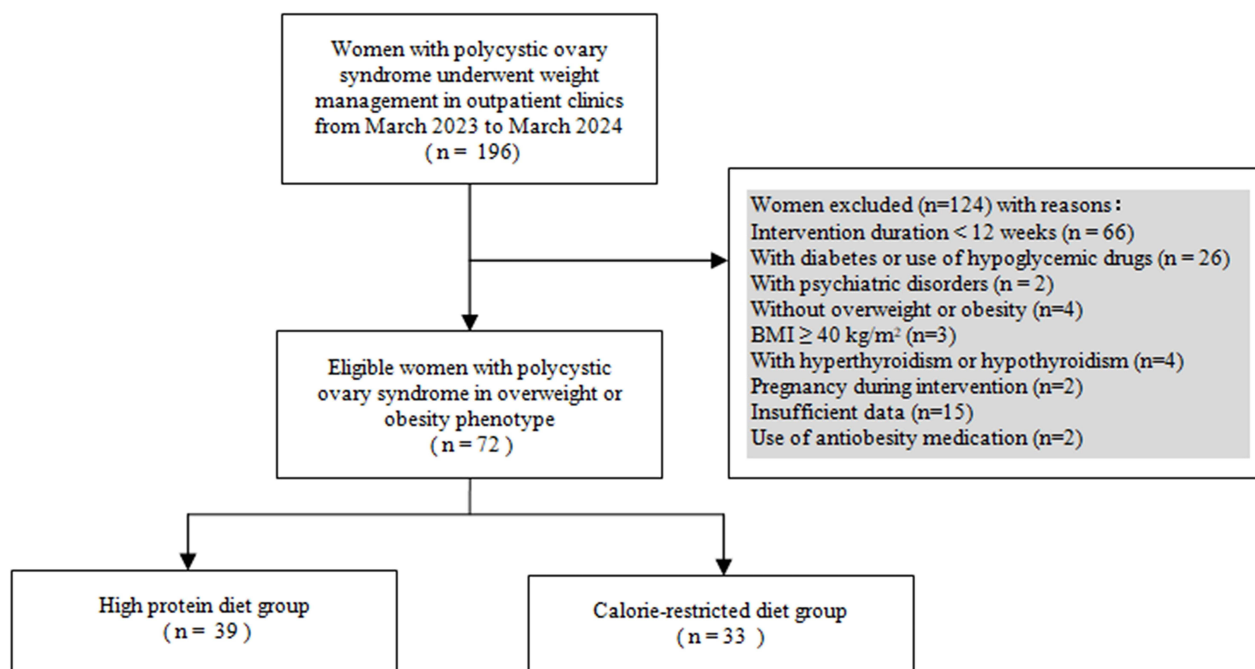


Figure 1 Participation flowchart.

Table 1 Demographic Data and Prescribed Diets of Two Groups

	Total (n=72)	HPD (n=39)	CRD (n=33)	P value
Age (years)	31.4±4.7	31.5±4.1	31.4±5.5	0.933
Weight (kg)	81.6±12.5	82.2±12.7	81.0±12.5	0.700
BMI (kg/m ²)	30.3±3.8	30.2±3.6	30.4±4.0	0.896
Overweight (%)	22 (30.6)	13 (33.3)	9 (27.3)	–
Obesity (%)	50 (69.4)	26 (66.7)	24 (72.7)	0.578
Energy (kcal)	1200~1400	1200~1400	1200~1400	–
Protein (%)	–	30%	15%	–
Carbohydrate (%)	–	40%	55%	–
Fat (%)	–	30%	30%	–

Abbreviations: BMI, body mass index; CRD, calorie-restricted diet; HPD, high protein diet.

Table 2 Body Composition and Biochemical Measurements of the Two Groups Before and After Intervention

	HPD (n=39)			CRD (n=33)		
	Baseline	Week 12	Change	Baseline	Week 12	Change
Weight (kg)	82.2±12.7	73.3±11.9 ^{###}	−8.9±4.6	81.0±12.5	71.0±11.7 ^{###}	−10.0±9.4
BMI (kg/m ²)	30.2±3.6	27.1±3.5 ^{###}	−3.2±1.6	30.4±4.0	27.5±3.3 ^{###}	−2.8±3.7
PBF (%)	40.3±4.4	35.1±5.6 ^{###}	−5.3±3.3*	40.6±4.7	37.4±4.4 ^{###}	−3.2±4.5
Fat mass (kg)	33.6±8.4	26.1±8.0 ^{###}	−7.4±4.4	33.3±8.2	27.7±6.9 ^{###}	−5.5±7.4
FFM (kg)	48.6±5.1	47.0±5.4 ^{###}	−1.5±1.6**	47.7±5.4	43.2±6.5 ^{###}	−4.4±4.2
FFMI (kg/m ²)	18.1±1.5	17.4±1.4 ^{###}	−0.7±1.1**	18.8±1.9	16.6±1.7 ^{###}	−2.1±1.9
TC (mmol/L)	5.07±1.17	5.12±1.17	0.05±1.37	5.11±0.94	4.95±0.97	−0.16±1.24
TG (mmol/L)	1.68±1.42	1.16±0.81 ^{###}	−0.52±1.73	1.75±1.35	0.88±0.45 ^{###}	−0.87±1.45
HDL-C (mmol/L)	1.34±0.36	1.34±0.34	−0.00±0.49	1.31±0.36	1.38±0.28	0.07±0.45
LDL-C (mmol/L)	3.05±0.81	2.65±0.67 [#]	−0.40±1.07	3.11±0.84	2.79±0.65	−0.32±1.08
FPG (mmol/L)	5.8±1.5	5.0±0.6 ^{###}	−0.8±1.6	5.7±0.9	5.0±0.6 ^{###}	−0.7±0.7
Fasting insulin (mIU/mL)	21.3±35.3	12.6±15.8 ^{###}	−8.7±21.4	14.0±4.8	8.8±3.3 ^{###}	−5.2±5.0
HOMA-IR	5.68±9.14	2.89±3.77 ^{###}	−2.79±6.09	3.59±1.75	2.02±1.16 ^{###}	−1.56±1.27
TT (ng/mL)	1.02±0.60	0.75±0.32 ^{###}	−0.27±0.54	0.86±0.35	0.73±0.26 [#]	−0.11±0.24

Notes: [#]*P* < 0.05 (intra-group difference); ^{###}*P* < 0.01 (intra-group difference); * *P* < 0.05 (difference in inter-group changes); ^{**}*P* < 0.01 (difference in inter-group changes).

Abbreviations: BMI, body mass index; CRD, calorie-restricted diet; FFM, fat-free mass; FPG, fasting plasma glucose; HDL-C, high density lipoprotein cholesterol; HPD, high protein diet; FFMI, fat-free mass index; LDL-C, low density lipoprotein cholesterol; HOMA-IR, homeostatic model assessment for insulin resistance; PBF, percent body fat; TC, total cholesterol; TG, triglyceride; TT, total testosterone.

before and after intervention (Paired *t* test, *P* > 0.05). As for women in HPD group, the post-intervention parameters significantly decreased compared to those before intervention (Paired *t* test, *P* < 0.05), except for TC, TG, and HDL-c (Paired *t* test, *P* > 0.05).

Discussion

The main findings of this study indicate that a dietary intervention with a hypocaloric high-protein diet (HPD) outperformed a conventional hypocaloric CRD diet with standard protein content in preserving FFM and reducing body fat during weight loss in women with PCOS even though both diets have comparable effects on weight loss and biochemical indicators.

Although a previous review suggested that weight loss should be the primary strategy for dealing with PCOS regardless of dietary composition,²⁴ losing weight via a calorie-restricted diet (CRD) taking no account of dietary composition is likely to result in a reduction in both fat mass and lean mass. This could impede the maintenance of a sustained caloric deficit; fairly long-term trials of 6–12 months have shown that an HPD not only aids in weight

reduction but also helps in sustaining the weight loss and preventing weight regain.¹³ In view of the characteristics of the body composition of women with PCOS,¹⁶ it is worthwhile to observe the impact of an HPD on women with PCOS undergoing weight loss. Several clinical trials have already contrasted the therapeutic impacts of an HPD with those of an isocaloric CRD featuring standard-protein content on PCOS. In our latest meta-analysis,²⁰ we aggregated the data from those trials and discovered no additional benefits of an HPD over a conventional CRD concerning weight loss and anthropometric improvements. Within those trials,^{25–32} only a subset of four^{26–29} provided reports on body composition-related indicators, which displayed significant heterogeneity and were not suitable for aggregation in the meta-analysis. Three of them specifically reported on the changes in fat-free mass (or lean mass)^{26,28} or muscle percentage.²⁷ In the study by Dou et al that compared the effects of HPDs with conventional CRDs on PCOS,²⁶ the authors noted that the mean reduction in FFM in the HPD group was less than that in the CRD group [-0.5 ($-0.57, 0.32$) kg vs -0.65 ($-1.4, 1.5$) kg, $P = 0.047$], consistent with our findings. However, in the other two studies,^{27,28} no differences were observed in changes to muscle percentage²⁷ or lean mass.²⁸ As for the changes in body fat, two studies found that HPDs produced more favorable reductions in percent body fat²⁶ or fat mass,²⁸ compared to conventional CRDs. Conversely, in studies by Elham et al and Mehrabani et al, the authors did not report the similar findings.^{27,28} Our results indicated that HPDs significantly reduced percent body fat rather than fat mass compared to isocaloric conventional CRDs.

These above results suggest some variability in the impact of HPDs on body composition among women with PCOS. One potential reason contributing to the heterogeneity could be the generally small sample size of the current trials, which might lead to the variability in body composition results. As a result, there is a need for well-designed, large-scale trials to provide more conclusive evidence.

We observed a decrease in insulin resistance (HOMA-IR and fasting insulin) and concentrations of TT in both groups of women, irrespective of their dietary protein percentage. These results align with a prior trial suggesting that even a slight reduction in weight by 5–10% within a brief period of 4 weeks could result in improvements of PCOS symptoms.³¹ In Dou et al's study, alongside the expected improvements in HOMA-IR and TT, they found that an 8-week HPD resulted in a greater decrease in fasting insulin levels and a greater increase in sex hormone-binding globulin when compared to a CRD.²⁶ In line with Mehrabani et al,²⁹ our previous meta-analysis indicated that a HPD is superior to a conventional CRD in improving fasting insulin levels and HOMA-IR. However, its impact on TT and sex hormone-binding globulin is comparable to that of a CRD in women with PCOS.²⁰ The discrepancies in the results regarding insulin or TT across studies cannot be solely attributed to variations in the degree of weight loss induced by the diets. Further high-quality clinical trials are necessary to confirm whether an HPD offers superior benefits in enhancing insulin resistance and sex hormone profiles compared to an isocaloric CRD with a standard protein intake.

In our current study, we also examined the impact HPDs on FPG and serum lipid profiles. Contrary to two previous Chinese studies^{25,26} where HPDs led to more favorable reductions in FPG compared to conventional CRDs, our study only noted intra-group changes in FPG levels within each dietary group before and after the intervention, without any significant inter-group differences in FPG changes. In the study conducted by Toscani et al,³² the researchers did not find any significant differences in the changes of FPG levels either within each group when comparing pre- and post-intervention measurements or between the two groups that were following different dietary interventions. Regarding serum lipids, our results were consistent with those of our previous meta-analysis,²⁰ showing no significant differences in the changes of serum lipid indicators between the HPD and CRD groups. This suggests that the effects of both diets on lipid profiles are primarily mediated through weight loss induced by caloric restriction, rather than the specific macronutrient composition of the diets.

Our study has four primary limitations. First, it was a retrospective analysis of a non-randomized dietary intervention study, meaning that the group assignments were not randomized, despite the groups having comparable baseline characteristics. Future research would benefit from prospective, randomized clinical trials. Second, the study's relatively short duration might not fully capture the long-term effects of HPDs. This is significant because long-term trials on obesity have shown that an HPD is effective not only for weight loss but also for weight maintenance after the initial reduction.¹³ In addition, by excluding women with intervention periods shorter than 12 weeks or those with incomplete data, there is a potential for introducing bias into the study. Third, women in this study were with overweight or obesity, thus we are unable to extend the benefits of a HPD to women with PCOS

who are not overweight or obese. Furthermore, the study's sample size was drawn from women without PCOS, which might potentially impact the statistical power for some measurements, and further studies with larger sample size are needed to verify the findings of this study. Lastly, although we provided participants with education on dietary and exercise intervention, we could not accurately quantify their energy intake and exercise regimen, which might introduce some heterogeneity between the groups or contributed to inconsistencies with the results of other studies.

Conclusion

In accordance with the latest guidelines,⁷ our study indicates that, for women with PCOS, a high-protein hypocaloric diet does not outperform an isocaloric conventional calorie-restricted diet when it comes to weight loss and biochemical markers. However, we found hypocaloric HPD is more effective in preserving fat-free mass in women with PCOS and overweight or obese during a 3-month weight loss program compared to a standard-protein CRD. These findings suggest that the macronutrient composition of diets could play a crucial role in maintaining muscle mass during weight loss, which is particularly important for women with PCOS. However, further well-designed trials are needed to confirm these results and explore the long-term effects of different dietary interventions on body composition and metabolic health in women with PCOS.

Abbreviations

HPD, high-protein diet; PCOS, polycystic ovary syndrome; CRD, calorie-restricted diet; FFM, fat-free mass; FFMI, fat-free mass index; TT, total testosterone; HOMA-IR, homeostasis model assessment-insulin resistance; TC, total cholesterol; TG, triglycerides; HDL-c, high-density lipoprotein cholesterol; LDL-c, low-density lipoprotein cholesterol.

Data Sharing Statement

All relevant data is contained within the article.

Ethical Approval

This study was approved by the Ethics Committee of PUMCH (No. I-24PJ066).

Consent to Publication

This manuscript is approved by all authors for publication.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no conflicts of interest to declare.

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