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Effects of a High-Phytosterol Diet on blood lipids, glucose and estimated 10-year cardiovascular disease risk among Chinese adults with dyslipidemia: a randomized controlled trial

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ABSTRACT: Background: Phytosterols are known for their cholesterol-lowering properties, yet the comparative effects of high-phytosterol diet (HPS diet) and low-phytosterol diet (LPS diet) on blood lipids, fasting blood glucose (FBG) and estimated 10-year cardiovascular disease risk (estimated 10-y CVD risk) in Chinese adults with dyslipidemia remain largely unknown.**Objective:** This trial was to investigate the effects of HPS diet on blood lipids, FBG and estimated 10-y CVD risk in Chinese adults with dyslipidemia compared with LPS diet. **Methods:** A three-month, outcome assessor-blinded, randomized controlled feeding trial was conducted in Chinese adults with dyslipidemia. 104 participants were randomly assigned to either the HPS diet group (n = 52, use HPS cooking oil) or the LPS diet group (n = 52, use LPS cooking oil) after a 2-week run-in period. The primary outcomes were serum total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), Non-high-density lipoprotein cholesterol (NON-LDL-C). Secondary outcomes included FBG and estimated 10-y CVD risk. **Results:** All participants were included in the intention-to-treat (ITT) analysis. After three months of intervention, serum TC (adjusted mean difference = -0.44 mmol/L; 95% CI: -0.67 to -0.20), TG (adjusted mean difference = -1.01 mmol/L; 95% CI: -1.67 to -0.35), LDL-C (adjusted mean difference = -0.25 mmol/L; 95% CI: -0.50 to -0.01) , Non-HDL-C (adjusted mean difference = -0.46 mmol/L; 95% CI: -0.73 to -0.19) and FBG (adjusted mean difference = -0.14 mmol/L; 95% CI: -0.28 to -0.002) were significantly lower in the HPS diet group compared to the LPS diet group (P < 0.05). Additionally, compared to the LPS diet group, the estimated 10-y CVD risk attributed to TC, BMI and all factors in the HPS diet group after intervention decreased by 0.10%, 0.13% and 0.97%, respectively. Sensitivity analysis showed that the main results from the per-protocol population were consistent with the ITT population. **Conclusions:** The HPS Chinese diet significantly lowers blood lipids, FBG and the estimated 10-y CVD risk in Chinese adults with mild dyslipidemia. These findings highlight potential cardiovascular health benefits associated with increased phytosterol intake in daily diets. Further long-term studies are warranted. **Clinicaltrials.gov ID**: NCT06060509

Keywords: Phytosterols, Dietary, Dyslipidemia, blood lipids, fasting blood glucose, Cardiovascular risk factors

1. Introduction

Cardiovascular diseases (CVD) represent the foremost cause of death, illness, and disability globally, accounting for 32% of all deaths[1]. Dietary patterns characterized by poor nutritional quality are significant modifiable risk factors for CVD, contributing to the onset of hypertension, hypercholesterolemia and

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hyperglycemia[2]. The 2021 Global Burden of Disease Study revealed that dietary risks caused 6.58 million deaths from CVD[3]. Dietary interventions targeting the reduction of CVD risk factors in individuals with dyslipidemia are essential in preventing CVD.

Phytosterols, sterol compounds naturally derived from plants and found in the unsaponifiable fractions of vegetable oils, exhibit a dose-dependent effect on low-density lipoprotein cholesterol (LDL-C) levels[4-6]. However, evidence that phytosterols directly reduce the CVD risk remains insufficient, and this relationship continues to be debated in the scientific community[7]. In our prior meta-analysis[8], we demonstrated that the consumption of dietary phytosterols may be advantageous in reducing the levels of total cholesterol (TC), triglycerides (TG), LDL-C, systolic blood pressure (SBP) and diastolic blood pressure (DBP). However, no significant effects were observed on blood glucose, glycated hemoglobin (HbA1c), interleukin-6 (IL-6), tumor necrosis factor-α (TNF-α), body mass index (BMI), waist circumference and body weight. Considering the potential advantages of phytosterols in ameliorating cardiovascular risk factors, they could influence the CVD risk. Adhering to a nutritious dietary regimen markedly reduces cardiovascular risk factors, thereby diminishing the probability of developing CVD[3, 9]. Modifying specific dietary components through daily nutritional adjustments is crucial for the management of dyslipidemia and other cardiovascular risk factors[10-12]. Although the studies have demonstrated the cholesterol-lowering effects of phytosterols, the impact of naturally dietary-sourced phytosterols and the effects of low level and high level of phytosterols on human health remain unclear and require further investigation.

Vegetable oils are one of the important and common sources of phytosterol intake among Chinese residents[13]. Modifying cooking oils to achieve diets either high or low in phytosterols represents a practical approach close to the daily diet. Wheat germ oil and corn germ oil are both considered high-quality edible oils, characterized by their substantial phytosterol content, with each oil offering distinct advantages in terms of its specific phytosterol composition[14]. The phytosterol content in peanut oil is comparatively lower than that found in wheat germ oil and corn germ oil[14-16]. Peanut oil is also one of the common daily cooking oils used by Chinese residents. By altering daily cooking oils, an intervention model can be developed that includes a high-phytosterol diet (HPS diet), utilizing high-phytosterol wheat and corn germ blended oil as cooking oil, and a low-phytosterol diet (LPS diet), employing low-phytosterol peanut oil as cooking oil. To testify the effects of high natural dietary-sourced phytosterol diet further, we designed the Phytosterols-Health Study (PHYTO-HEALTH Study). PHYTO-HEALTH Study is a human clinical dietary intervention based on the Chinese population, aiming to evaluate the effects of HPS diet and LPS diet on blood lipids, fasting blood glucose (FBG) and estimated 10-year cardiovascular disease risk (estimated 10-y CVD risk) in adults with dyslipidemia. To the best of our knowledge, few randomized controlled trials (RCTs) have been conducted to compare the effects and safety of HPS diet and LPS diet on blood lipids, FBG and estimated 10-y CVD risk among Chinese adults. Moreover, given the significant differences in dietary patterns between Western and Chinese populations, it is essential to investigate the potential health effects of HPS diet based on the characteristics of the Chinese diet.

This RCT is the first to evaluate the effects of HPS diet based on the dietary characteristics of the Chinese population compared with LPS diet on blood lipids, FBG and estimated 10-year CVD risk in Chinese adults with dyslipidemia. To improve dietary compliance, participants were provided with pre-prepared meals throughout the study.

2. Methods

2.1 Study design

The PHYTO-HEALTH Study (clinicaltrials.gov ID: NCT06060509) is a randomized, outcome assessor-blinded, parallel controlled feeding trial testing the effect of the HPS diet using high-phytosterol wheat and corn germ blended oil as cooking oil in lowering blood lipids, FBG and estimated 10-y CVD risk in Chinese adults with dyslipidemia compared with LPS diet using low-phytosterol peanut oil as cooking oil. The study was conducted in Nanjing, Jiangsu Province, China. The intervention for this study was implemented at the employee cafeteria of a corporation located in Nanjing, Jiangsu Province, China. All diets were uniformly prepared based on pre-designed recipes in this trial. The study included both the Run-In and Test phases. Eligible participants entered a three-month intervention period after following a two-week run-in phase. Participants with dyslipidemia were randomly assigned in a 1:1 ratio to either LPS diet group or HPS diet group, respectively (**Figure 1**). The first participant was enrolled on April 2, 2023. The outcomes of the study were assessed at the end of the run-in phase (baseline) and at the end of the intervention phase (endpoint). This trial was funded by the National Nutrition Research Fund Program initiated by the Chinese Nutrition Society (CNS-NNSRG2021-39). This study was approved by the Institutional Review Board of Zhongda Hospital, affiliated with Southeast University (2022ZDSYLL032-P01) and registered at clinicaltrials.gov (NCT06060509). All participants in this study signed informed consent forms.

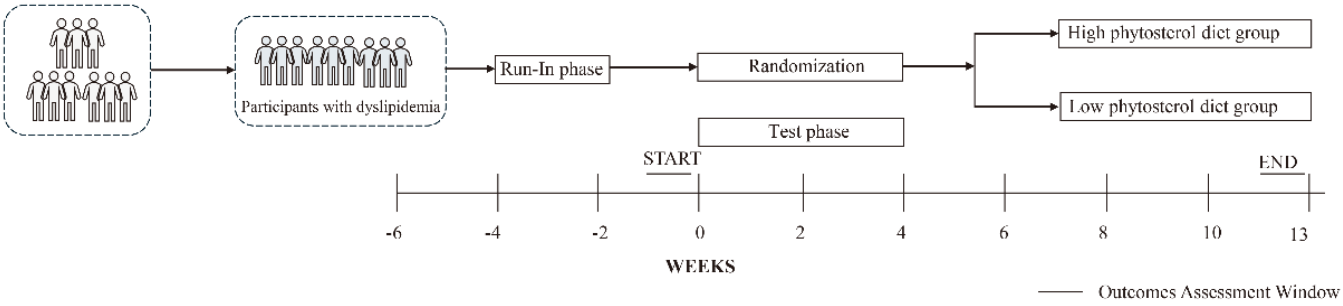

Figure 1. Study design.

2.2 Participants and recruitment

We recruited male and female participants aged 18 to 65 years diagnosed with dyslipidemia according to the 2016 Chinese Guidelines[17]. All participants were long-term residents who have lived for more than three years and regular employees of the company, with serum lipid levels meeting the specified diagnostic criteria for dyslipidemia. Women in particular circumstances, such as pregnancy or lactation, as well as participants with specific dietary habits and participants who frequently travel for work, were excluded. Detailed eligibility criteria are provided in **Supplementary Table 1**. All eligible participants entered a two-week run-in period before randomization.

2.3 Sample size

This trial estimated the theoretical sample size required for recruitment based on the sample size formula for randomized controlled trials. The specific formula is as follows: $N = (Z_\alpha+Z_\beta)^2\times2\sigma^2/\delta^2$. In formula, N represents the sample size per group. Z_α and Z_β are obtained from statistical tables. σ represents the standard deviation. δ signifies the difference between the baseline level μ1 and the expected level μ2. According to prior research[18], with a significance level of $\alpha = 0.05$ (two-tailed) and a statistical power of $1-\beta = 0.80$, the calculated sample size required for each group is $N = 43$. Assuming a dropout rate of 20%, the theoretically necessary sample size per group is approximately 52 participants, resulting in a minimum total theoretical sample size of 104 participants across both groups.

2.4 Run-in and baseline examinations

During the run-in phase, professional nutritionists assessed the participants' daily dietary preferences and collaborated with cafeteria chefs to develop and modify the weekly menus. They provided all participants with the LPS diet that reflected local dietary characteristics.

At the end of the two-week run-in period, baseline data were collected from participants via questionnaire interviews. This data encompassed general demographic characteristics, lifestyle behaviors and detailed medical and medication history. At the same time, participants underwent physical examinations, including measurements of height, weight, blood pressure, waist circumference, and hip circumference. Fasting blood samples were also collected. The collected blood samples were transported under low-temperature conditions on the same day to the laboratory of Zhongda Hospital, Southeast University, to analyze relevant indicators. The remaining blood samples were stored in a freezer at -80°C. Serum lipid levels in participants were quantified using a Roche Cobas 8000 automatic biochemistry analyzer.

2.5 Randomization and blinding

The randomization process was centrally conducted at the study coordinating center, jointly operated by the School of Public Health and Zhongda Hospital, Southeast University. The random number sequence was generated by a professional statistician not involved in data collection or analysis using SPSS 27.0 software. The randomization table was maintained in strict confidentiality by the cafeteria center manager. Due to the nature of the intervention, participant blinding was not feasible in this trial. Consequently, blinding was applied to the research personnel responsible for outcome assessment, data entry and data analysis, who remained unaware of participants' randomization prior to data unblinding. All eligible participants were randomly allocated in a 1:1 ratio to receive either HPS diet or LPS diet.

2.6 Intervention programs

After the two-week run-in period, participants assigned to the HPS diet group received the HPS diet. In contrast, Participants in the LPS diet group received the LPS diet. All diets were prepared using identical recipes. In the HPS diet group, daily cooking oils were replaced with high-phytosterol wheat and corn germ blended oil. In the LPS diet group, daily cooking oils were substituted with low-phytosterol peanut oil. Both participants were required to consume breakfast, lunch, and dinner provided for three months. The

composition of the vegetable oils used in the preparation of the dishes and Sample menus for the Test diets are presented in **Supplementary Table 2 and Supplementary Table 3**. The menus for the LPS diet and HPS diet consisted of identical Chinese dishes. These menus were developed based on the Chinese Dietary Guidelines and the Eastern dietary pattern [19]. The daily meals for both groups of participants are designed to achieve a theoretical target of 2000 kcal in total energy intake. The phytosterol content of the substituted vegetable oil in the HPS diet was 14,320 mg/kg, whereas it was 3,153 mg/kg in the LPS diet. After preparing the reference recipes, the theoretical energy of HPS diet is 2000 kcal per day, providing approximately 401 mg of phytosterols from vegetable oils daily. The LPS diet provides 88 mg of phytosterols from vegetable oils daily. In addition, the intake of phytosterols from food sources was identical between the two groups. The energy contribution ratios of macronutrients including protein, carbohydrates and fat are largely consistent between the two groups. Additional details regarding dietary interventions are provided in **Supplementary Methods**.

2.7 Outcomes

The primary outcomes of this study included changes measured from baseline to the end of the trial in blood lipids including TC, TG, LDL-C, high-density lipoprotein cholesterol (HDL-C) and non-high-density lipoprotein cholesterol (Non-HDL-C). The secondary outcomes included FBG and estimated 10-y CVD risk. For the estimated 10-y CVD risk, our study utilized a 10-y CVD risk prediction model for ischemic cardiovascular disease developed from the cardiovascular epidemiological cohort collaboration studies in China and the United States[20]. This model was used to estimate the pre- and post-intervention estimated 10-y CVD risk for everyone. The risk prediction model has been externally validated. The model varies by sex, but the predictive factors included are age, SBP, BMI, TC, current smoking and diabetes status. Since age, sex and smoking status did not change, only SBP, BMI, TC, and diabetes status could be attributed to changes in the estimated 10-y CVD risk. To determine the individual contributions of these four predictive factors[21], attributable changes in each risk factor regarding the estimated 10-year CVD risk were calculated. Specifically, baseline measurements were modified to reflect values at the end of the intervention while keeping the other predictive factors constant at baseline levels. The total change in estimated 10-y CVD risk was computed by altering all four predictive factors from their baseline values to those at the end of the intervention. For the estimation, when participants' values exceeded the range provided in the scoring table, the minimum and maximum values from the scoring table were used as replacements[21]. To better investigate the effects of HPS diet, we also calculated the changes in nutrients intakes between the baseline and the end of the trial, calculated based on a 3-day 24-hour dietary recall.

2.8 Diet and nutrition data collection

During the period of the run-in and intervention of the study, professional dietitians collaborated with chefs to design the cafeteria menu for the upcoming week. Each food item was cleaned, weighed, and documented prior to cooking. Quality control researchers and project dietitians dined weekly with participants at the cafeteria, providing on-site nutritional counseling and monitoring food intake. All leftovers from participants were weighed and recorded to evaluate their actual individual food consumption.

2.9 Statistical analysis

Descriptive statistics were employed to summarize baseline demographic, clinical characteristics and dietary intake. Baseline characteristics are described using mean with standard deviation (SD), median with interquartile range (IQR), or percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Normally distributed continuous variables were summarized as mean (SD), and group comparisons were performed using t-tests or analysis of variance (ANOVA). Non-normally distributed continuous variables were summarized as median (interquartile range) and group comparisons were performed using the Kruskal-Wallis H test. Categorical variables were summarized as frequencies (percentages), and group comparisons were performed using Pearson's chi-square test. Mean changes in primary and secondary outcomes from baseline to three months were calculated across groups. Generalized estimating equations (GEE) were applied to compare changes in primary and secondary outcomes across groups at baseline and three months. The GEE model included group, time (baseline and three months), and interaction terms between group and time as independent variables; specified a linear link function, an exchangeable working correlation matrix, and a robust covariance matrix; and was adjusted for age, sex, baseline values, BMI and hypertension status. When a significant interaction between group and time was detected, pairwise comparisons were performed to assess between-group differences. Because all comparisons were specified a priori, no adjustment for multiple comparisons was performed. All participants were included in the intention-to-treat (ITT) analysis. Missing data were imputed using multiple imputations by chained equations (MICE). The per-protocol (PP) analysis included participants who adhered to the study protocol. The primary analysis was performed using the full analysis set (FAS), based on ITT analysis, for primary and secondary outcomes. Sensitivity analyses were performed using the PP analysis, with data from the per-protocol set (PPS). Daily nutrient and food intake for each participant was calculated from daily dietary menu records, recorded leftovers weight, and self-reported non-study food consumption, using the Chinese Food Composition Table (2019). Baseline consumption of various food categories and dietary nutrients was defined as the mean intake over the final three days of the run-in phase, calculated from the three-day dietary survey data. Similarly, intakes of various foods and dietary nutrients during the intervention were defined as the mean intake over the final three days of the intervention phase. A two-sided *P*-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using R software version 4.4.2 (R Foundation for Statistical Computing).

3. Results

3.1 Patient flow and Baseline characteristics

The trial flow diagram is presented in **Figure 2.** A total of 144 participants signed informed consent forms and were invited to participate in the Run-in period. After a two-week Run-in period and subsequent baseline assessments, 104 patients remained eligible and were randomly assigned to either the HPS diet group or the LPS diet group. A total of 5 participants discontinued the intervention during the trial. In the HPS diet group, 2 participants withdrew (1 due to illness and 1 for unknown reasons), while in the LPS diet group, 3

participants withdrew (1 due to illness, 1 due to lack of time or motivation to participate, and 1 for unknown reasons). 99 participants (95%) completed the outcome assessments at three months. All participants were included in the ITT analysis, while the PP analysis included 95 participants (91%). The baseline characteristics of all participants are presented in **Table 1**. In the HPS diet group, the mean age of participants was 46.33 years, with females accounting for 42.3% and a mean BMI of 24.34. In the LPS diet group, the mean age was 48.19 years, with females comprising 40.4% and a mean BMI of 25.31. The baseline parameters were comparable between the two groups. Data for the PP population are presented in **Supplementary Table 4**.

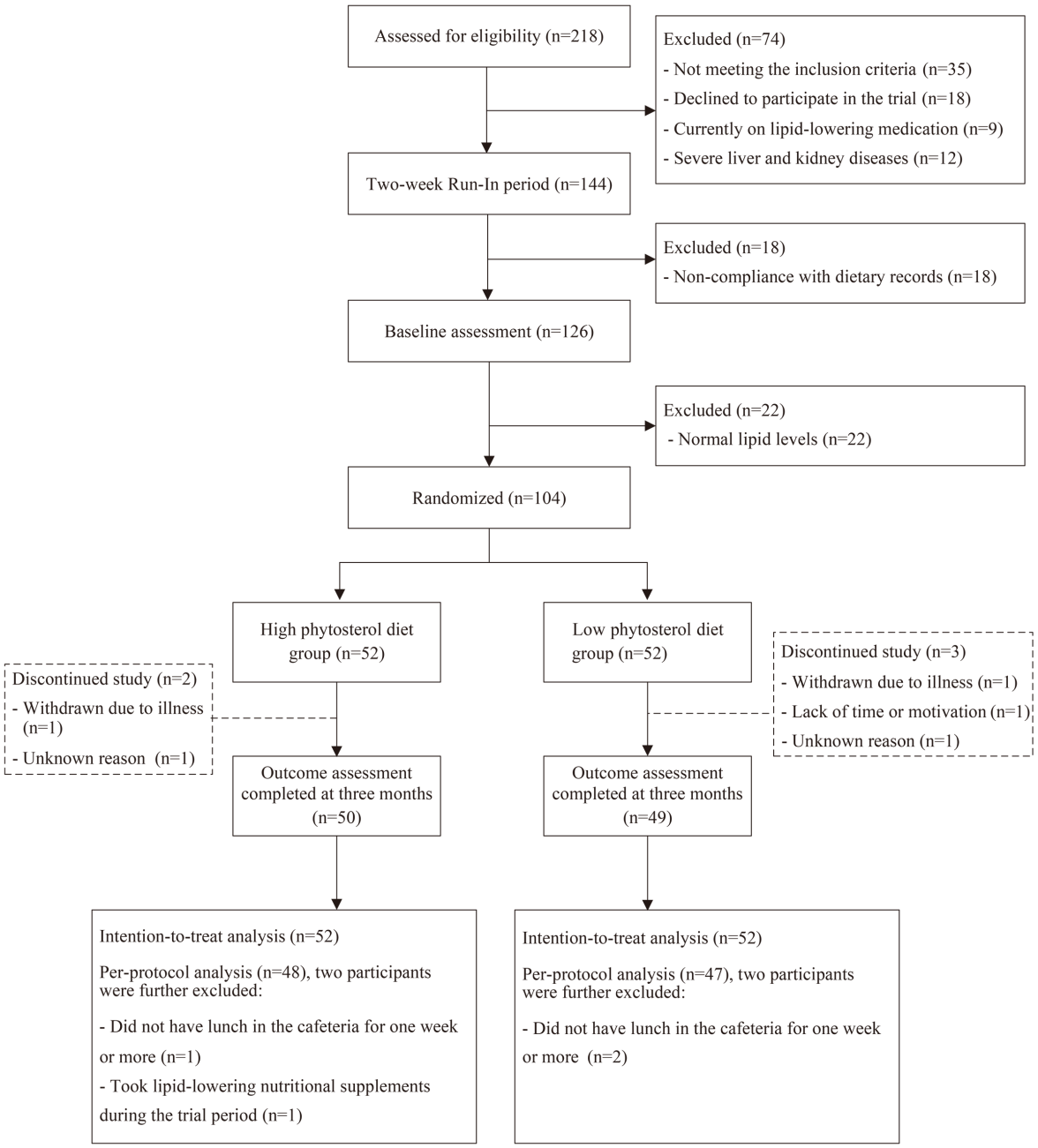

Figure 2. Participant flowchart of the study.

Table 1. Baseline characteristics of study participants

Characteristic	HPS diet group (n = 52)	LPS diet group (n = 52)	P
Age at first visit, y	46.33±6.85	48.19±7.86	0.200
Sex			

Male	22 (42.3)	21 (40.4)	0.842 [a]
Female	30 (57.7)	31 (59.6)	
BMI, kg/m^2	24.34±3.88	25.31±3.75	0.198
Blood pressure, mmHg			
Systolic	123.55±15.05	124.23±14.15	0.809
Diastolic	82.88±10.44	80.35±10.31	0.215
Blood lipids			
Total cholesterol, mmol/L	5.73±1.02	5.70±0.89	0.883
Triglycerides, mmol/L	1.48 (0.89, 2.56)	1.82 (1.17, 2.84)	0.315
LDL-C, mmol/L	3.17±0.82	3.08±0.85	0.610
HDL-C, mmol/L	1.52±0.60	1.46±0.50	0.556
Non-HDL-C, mmol/L	4.20±0.84	4.24±0.74	0.813
Fasting blood glucose, mmol/L	4.75±0.54	4.97±0.66	0.069
Level of physical activity (MET-h/week)	39.06 (30.75, 51.31)	41.44 (31.98, 51.21)	0.701
Educational Level (%)			
Bachelor's Degree or Below	49 (94.2)	52 (100.0)	0.241 [b]
Graduate Degree or Above	3 (5.8)	0 (0.0)	
Hypertension (%)			
Yes	26 (50.0)	28 (53.8)	0.695 [a]
No	26 (50.0)	24 (46.2)	
Alcohol Consumption Status (%)			
Yes	17 (32.7)	20 (38.5)	0.539 [a]
No	35 (67.3)	32 (61.5)	
Smoking (%)			
Yes	11 (21.2)	19 (36.5)	0.083 [a]
No	41 (78.8)	33 (63.5)	

BMI, Body Mass Index; LDL-C, LDL cholesterol; HDL-C, HDL cholesterol. LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group. [a] Pearson's Chi-Square Test; [b] Continuity-Corrected Pearson's Chi-Square Test.

3.2 Differences in dietary nutrients intakes and physical activity after three months of intervention

Dietary nutrient intake and physical activity did not change significantly in either group before or after the intervention. GEE analyses indicated that the interaction effects for all dietary nutrients and physical activity were not statistically significant after adjustment for age, sex, baseline values, BMI and hypertension status (P >0.05). No significant differences were observed in total energy intake, protein intake, fat intake, carbohydrate intake, percentages of energy from protein, fat and carbohydrates, dietary fiber intake, cholesterol intake or physical activity across different time points (P > 0.05) (**Table 2**). Post-hoc analyses adjusted for covariates showed that compared to the LPS diet group, the HPS diet group did not exhibit significant changes in total energy (adjusted mean difference: 4.10; 95% CI: -63.26 to 71.46; P = 0.905), protein intake (adjusted mean difference: 2.03; 95% CI: -1.03 to 5.08; P = 0.194), fat intake (adjusted mean difference: -0.91; 95% CI: -3.96 to 2.14; P = 0.559), carbohydrate intake (adjusted mean difference: 0.56; 95% CI: -9.55 to 10.67; P = 0.914), percentage of energy from protein (adjusted mean difference: 0.36; 95% CI: -0.11 to 0.84; P = 0.133), percentage of energy from fat (adjusted mean difference: -0.41; 95% CI: -1.49 to 0.67; P = 0.454), percentage of energy from carbohydrates (adjusted mean difference: 0.16; 95% CI: -0.86 to 1.18; P = 0.763), dietary fiber intake (adjusted mean difference: -0.01; 95% CI: -0.83 to 0.82; P = 0.985), cholesterol intake (adjusted mean difference: 4.79; 95% CI: -32.71 to 42.28; P = 0.802) and physical activity (adjusted mean difference: 101.17; 95% CI: -96.45 to 298.80; P = 0.316) after three months of intervention (**Table 3**). Similar results were observed in the PP analysis (**Supplementary Table 5 and Supplementary Table 6**).

Table 2. Analysis of Dietary intake and physical activity during three-month intervention based on GEE

	Baseline	Postintervention	Group effect		Time effect		Interaction effect	
			Wald χ^2	P [a]	Wald χ^2	P [a]	Wald χ^2	P [a]
Total Energy(kcal)								
LPS diet group (n = 52)	1769.65 (1582.70, 2090.23)	1706.40 (1529.90, 1919.73)	0.014	0.905	0.618	0.432	0.021	0.886
HPS diet group (n = 52)	1790.20 (1682.48, 2053.53)	1783.80 (1632.65, 1994.33)						
Protein Intake (g)								
LPS diet group (n = 52)	73.80 (59.15, 86.35)	76.70 (65.53, 85.03)	1.689	0.194	0.004	0.947	0.290	0.590
HPS diet group (n = 52)	78.75 (70.25, 96.50)	81.00 (70.43, 94.93)						
Fat Intake (g)								
LPS diet group (n = 52)	78.60 (72.00, 92.05)	73.00 (65.10, 84.90)	0.341	0.559	3.012	0.083	0.253	0.615
HPS diet group (n = 52)	76.25 (66.83, 88.38)	76.00 (66.33, 83.95)						
Carbohydrate Intake (g)								
LPS diet group (n = 52)	193.50 (155.38, 238.95)	189.60 (155.85, 215.60)	0.012	0.914	0.002	0.963	0.001	0.974
HPS diet group (n = 52)	194.75 (171.13, 229.62)	193.10 (173.28, 228.15)						
Percentage of Energy from Protein (%)								
LPS diet group (n = 52)	16.62 (13.83, 18.60)	17.50 (15.92, 18.31)	2.258	0.133	2.543	0.111	0.893	0.345
HPS diet group (n = 52)	17.26 (15.65, 19.00)	17.96 (15.67, 19.59)						
Percentage of Energy from Fat (%)								
LPS diet group (n = 52)	38.76 (34.83, 45.08)	38.15 (35.56, 43.57)	0.560	0.454	2.367	0.124	0.021	0.884
HPS diet group (n = 52)	38.45 (34.10, 43.11)	36.57 (33.27, 42.76)						
Percentage of Energy from Carbohydrates (%)								
LPS diet group (n = 52)	43.57 (38.19, 47.90)	44.04 (38.86, 46.64)	0.091	0.763	1.639	0.201	0.021	0.886
HPS diet group (n = 52)	43.33 (38.06, 47.59)	43.84 (39.13, 49.92)						
Dietary Fiber Intake (g)								
LPS diet group (n = 52)	10.20 (8.23, 12.90)	9.70 (6.75, 14.85)	0.000	0.985	0.509	0.476	0.513	0.474
HPS diet group (n = 52)	10.70 (9.20, 12.40)	11.35 (7.85, 13.00)						
Cholesterol Intake (g)								
LPS diet group (n = 52)	682.00 (583.25, 839.50)	686.07 (524.38, 836.00)	0.063	0.802	0.306	0.580	0.013	0.909
HPS diet group (n = 52)	705.50 (610.00, 843.75)	701.07 (537.18, 953.00)						
Physical activities, MET (min/Week)								
LPS diet group (n = 52)	2486.25 (1918.75, 3072.50)	2092.25 (1568.25, 3206.50)	1.007	0.316	0.001	0.976	0.941	0.332
HPS diet group (n = 52)	2343.75 (1845.00, 3078.75)	2434.75 (1619.00, 3311.38)						

[a] GEE were used to analyze the data, with adjustment for age, sex, baseline values, BMI and hypertension status. GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

Table 3. Post Hoc Analysis of dietary nutrients and physical activity based on GEE

	Postintervention		
	Mean adjusted change (95% CI)	SE	*P*
Total Energy (kcal)			
HPS diet Group vs. LPS diet Group	4.10 (-63.26, 71.46)	34.37	0.905
Protein Intake (g)			
HPS diet Group vs. LPS diet Group	2.03 (-1.03, 5.08)	1.56	0.194
Fat Intake (g)			
HPS diet Group vs. LPS diet Group	-0.91 (-3.96, 2.14)	1.56	0.559
Carbohydrate Intake (g)			
HPS diet Group vs. LPS diet Group	0.56 (-9.55, 10.67)	5.16	0.914
Percentage of Energy from Protein (%)			
HPS diet Group vs. LPS diet Group	0.36 (-0.11, 0.84)	0.24	0.133
Percentage of Energy from Fat (%)			
HPS diet Group vs. LPS diet Group	-0.41 (-1.49, 0.67)	0.55	0.454
Percentage of Energy from Carbohydrates (%)			
HPS diet Group vs. LPS diet Group	0.16 (-0.86, 1.18)	0.52	0.763
Dietary Fiber Intake (g)			
HPS diet Group vs. LPS diet Group	-0.01 (-0.83, 0.82)	0.42	0.985
Cholesterol Intake (g)			
HPS diet Group vs. LPS diet Group	4.79 (-32.71, 42.28)	19.13	0.802
Physical activities, MET (min/Week)			
HPS diet Group vs. LPS diet Group	101.17 (-96.45, 298.80)	100.83	0.316

The mean differences between groups before and after the intervention were used using GEE, with the LPS diet group as the reference. Changes were reported as Mean (95% CI) and adjusted for age, sex, baseline values, BMI and hypertension status. GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

3.3 Effect of the high-phytosterol diet on blood lipids

HPS diet can significantly lower blood lipid levels compared to LPS diet. GEE results indicated a statistically significant interaction effect for serum TC after adjustment for age, sex, baseline serum TC, BMI and hypertension status ($P < 0.05$). Main effects analysis revealed significant temporal changes in serum TC in both the LPS and HPS diet groups ($P < 0.05$), showing a gradual decrease over time. At baseline, between-group analysis revealed that serum TC was 0.003 mmol/L lower in the HPS diet group than in the LPS diet group, though this difference was not statistically significant ($P > 0.05$). After three months of intervention, the serum TC in the HPS diet group was 0.438 mmol/L lower than that in the LPS diet group, with a statistically significant difference ($P < 0.05$). Post-hoc analysis adjusted for covariates revealed that compared to the LPS diet group, the HPS diet group demonstrated a significant reduction in serum TC after three months of intervention (adjusted mean difference: -0.44; 95% CI: -0.67 to -0.20; $P < 0.001$).

For serum TG, GEE results indicated a statistically significant interaction effect after adjustment for age, sex, baseline serum TG, BMI and hypertension status ($P < 0.05$). Temporal main effects analysis revealed significant changes in serum TG across time points in the HPS diet group ($P < 0.05$), but not in the LPS diet group ($P > 0.05$). At baseline, between-group analysis revealed that serum TG was 0.025 mmol/L lower in the HPS diet group than in the LPS diet group, though this difference was not statistically significant ($P > 0.05$). After three months of intervention, the serum TG in the HPS diet group was 1.013 mmol/L lower than that in the LPS diet group, with a statistically significant difference ($P < 0.05$). Post-hoc analysis adjusted for covariates demonstrated that compared to the LPS diet group, the HPS diet group exhibited a significant reduction in serum TG after three months of intervention (adjusted mean difference: -1.01; 95% CI: -1.67 to -0.35; $P = 0.003$).

For serum LDL-C, GEE results indicated a statistically significant interaction effect after adjustment for age, sex, baseline serum LDL-C, BMI and hypertension status ($P < 0.05$). Temporal main effects analysis revealed significant changes in serum LDL-C across time points in the HPS diet group ($P < 0.05$), but not in the LPS diet group ($P > 0.05$). After three months of intervention, the serum LDL-C in the HPS diet group was 0.254 mmol/L lower than that in the LPS diet group, with a statistically significant difference ($P < 0.05$). Post-hoc analysis adjusted for covariates demonstrated that compared to the LPS diet group, the HPS diet group showed a significant reduction in serum LDL-C after three months of intervention (adjusted mean difference: -0.25; 95% CI: -0.50 to -0.01; $P = 0.040$).

For serum HDL-C, GEE results indicated a non-significant interaction effect after adjustment for age, sex, baseline serum HDL-C, BMI and hypertension status ($P > 0.05$). Additionally, between-group analysis revealed no significant difference in serum HDL-C between the HPS diet group and LPS diet group ($P > 0.05$). Post-hoc analysis adjusted for covariates revealed that compared to the LPS diet group, the HPS diet group did not show a significant difference in serum HDL-C after three months of intervention (adjusted mean difference: 0.00; 95% CI: -0.05 to 0.05; $P = 0.990$).

For serum Non-HDL-C, GEE results indicated a statistically significant interaction effect after adjustment for age, sex, baseline serum Non-HDL-C, BMI and hypertension status ($P < 0.05$). Temporal main effects analysis revealed significant changes in serum Non-HDL-C in both the HPS diet group and LPS diet group ($P < 0.05$). After three months of intervention, serum Non-HDL-C in the HPS diet group was 0.422 mmol/L lower than that in the LPS diet group, with a statistically significant difference ($P < 0.05$). Post-hoc analysis adjusted for covariates indicated that compared to the LPS diet group, the HPS diet group exhibited a significant reduction in serum Non-HDL-C after three months of intervention (adjusted mean difference: -0.46; 95% CI: -0.73 to -0.19; $P < 0.001$). Details are provided in **Tables 4** and **Table 5**.

3.4 Effect of the high-phytosterol diet on glucose

HPS diet can significantly lower FBG compared to LPS diet. GEE results indicated that a non-significant interaction effect after adjustment for age, sex, baseline serum FBG, BMI and hypertension status ($P > 0.05$). Additionally, no significant differences in FBG were observed across time points ($P > 0.05$). Post-hoc analysis adjusted for covariates indicated that compared to the LPS diet group, the HPS diet group exhibited a significant reduction in serum FBG after three months of intervention (adjusted mean difference: -0.14; 95% CI: -0.28 to -0.002; $P = 0.046$). Details are provided in **Tables 4** and **Table 5**.

Table 4. Analysis of blood lipids and glucose during three-month intervention based on GEE

	Baseline	Postintervention	Group effect		Time effect		Interaction effect	
			Wald χ^2	P [a]	Wald χ^2	P [a]	Wald χ^2	P [a]
TC (mmol/L)								
LPS diet group (n = 52)	5.70±0.89	5.10±0.88	15.339	＜0.001	129.741	＜0.001	9.262	0.002
HPS diet group (n = 52)	5.73±1.02	4.69±0.63						
TG (mmol/L)								
LPS diet group (n = 52)	1.82 (1.17, 2.84)	1.67 (1.14, 3.44)	9.708	0.002	1.867	0.172	6.251	0.012
HPS diet group (n = 52)	1.48 (0.89, 2.56)	0.99 (0.85, 2.19)						
LDL-C (mmol/L)								
LPS diet group (n = 52)	3.08±0.85	3.12±0.87	3.328	0.068	2.633	0.105	4.508	0.034
HPS diet group (n = 52)	3.17±0.82	2.91±0.70						
HDL-C (mmol/L)								
LPS diet group (n = 52)	1.46±0.50	1.37±0.43	0.000	0.990	11.026	＜0.001	0.241	0.623
HPS diet group (n = 52)	1.52±0.60	1.40±0.41						
NON-HDL-C (mmol/L)								
LPS diet group (n = 52)	4.24±0.74	3.73±0.87	15.558	＜0.001	126.766	＜0.001	10.273	0.001
HPS diet group (n = 52)	4.20±0.84	3.29±0.60						
FBG (mmol/L)								
LPS diet group (n = 52)	4.97±0.66	5.16±1.64	3.979	0.046	0.111	0.739	2.874	0.090
HPS diet group (n = 52)	4.75±0.54	4.62±0.58						

[a] GEE were used to analyze the data, with adjustment for age, sex, baseline values, BMI and hypertension status. GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

Table 5. Post Hoc Analysis of blood lipid and glucose based on GEE

	Postintervention		
	Mean adjusted change (95% CI)	SE	P
TC (mmol/L)			
HPS diet Group vs. LPS diet Group	-0.44 (-0.67, -0.20)	0.12	＜0.001
TG (mmol/L)			
HPS diet Group vs. LPS diet Group	-1.01 (-1.67, -0.35)	0.34	0.003
LDL-C (mmol/L)			
HPS diet Group vs. LPS diet Group	-0.25 (-0.50, -0.01)	0.12	0.040
HDL-C (mmol/L)			
HPS diet Group vs. LPS diet Group	0.00 (-0.05, 0.05)	0.02	0.990
NON-HDL-C (mmol/L)			
HPS diet Group vs. LPS diet Group	-0.46 (-0.73, -0.19)	0.14	＜0.001
FBG (mmol/L)			
HPS diet Group vs. LPS diet Group	-0.14 (-0.28, -0.002)	0.07	0.046

The mean differences between groups before and after the intervention were used using GEE, with the LPS diet group as the reference. Changes were reported as Mean (95% CI) and adjusted for age, sex, baseline values, BMI and hypertension status. GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

3.5 Effect of the high-phytosterol diet on estimated 10-y CVD risk

We further assessed the effects of HPS diet on estimated 10-y CVD risk and the estimated 10-y CVD risk attributable to various risk factors. For the estimated 10-y CVD risk attributable to all risk factors, the GEE indicated that after adjustment for baseline values, the interaction effect of group and time was statistically significant ($P < 0.05$). Analysis of main effects over time indicated no significant changes in the estimated 10-y CVD risk in the LPS diet group ($P > 0.05$). In contrast, the HPS diet group showed significant changes in the estimated 10-y CVD risk over time. Post-hoc analysis adjusted for covariates revealed that compared to the LPS diet group, the HPS diet group demonstrated a significant reduction in the estimated 10-y CVD risk after three months of intervention (adjusted mean difference: -0.97; 95% CI: -1.68 to -0.26; $P = 0.008$).

For the estimated 10-y CVD risk attributable to SBP, TC, FBG and BMI, the GEE indicated that a non-significant interaction effect after adjustment for baseline values ($P > 0.05$). However, significant differences in estimated 10-y CVD risk attributable to TC were observed over time ($P < 0.05$). Significant differences in estimated 10-y CVD risk attributable to TC and BMI were found between the HPS diet group and LPS diet group ($P < 0.05$). Post-hoc analysis adjusted for covariates revealed that compared to the LPS diet group, the HPS diet group demonstrated significant reductions in the estimated 10-y CVD risk attributable to TC (adjusted mean difference: -0.10; 95% CI: -0.18 to -0.02; $P = 0.014$) and BMI (adjusted mean difference: -0.13; 95% CI: -0.24 to -0.02; $P = 0.025$) after three months of intervention. Conversely, there were no statistically significant changes in the estimated 10-y CVD risk attributable to SBP (adjusted mean difference: -0.25; 95% CI: -0.53 to 0.04; $P = 0.087$) or FBG (adjusted mean difference: -0.02; 95% CI: -0.05 to 0.01; $P = 0.168$). Detailed results are shown in **Table 6** and **Table 7.**

3.6 Sensitivity analyses

After excluding four non-adherent participants, PP analysis was performed. The results in PP analysis remained robust and congruent with the main findings observed in the ITT analysis (**Supplementary Table 7, Supplementary Table 8, Supplementary Table 9** and **Supplementary Table 10**).

3.7 Safety outcome

No participants withdrew due to adverse reaction throughout the trial. Mild adverse events, such as constipation, food allergies, aversions or intolerances, gastroenteritis, and other adverse events, were reported, but these were not related to the intervention. Furthermore, no significant differences in adverse event incidence were found between the LPS diet group and HPS diet group ($P > 0.05$) (**Supplementary Table 11**).

Table 6. Analysis of estimated 10-y CVD risk during three-month intervention based on GEE

	Baseline	Postintervention	Group effect		Time effect		Interaction effect	
			Wald χ^2	P [a]	Wald χ^2	P [a]	Wald χ^2	P [a]
estimated 10-y CVD risk attributed to all factors (%)								

LPS diet group (n = 52)	2.10 (0.58, 3.90)	1.65 (0.65, 2.90)	8.382	0.004	0.029	0.865	6.037	0.014
HPS diet group (n = 52)	1.15 (0.50, 2.70)	0.80 (0.30, 2.03)						
estimated 10-y CVD risk attributed to SBP (%)								
LPS diet group (n = 52)	2.10 (0.58, 3.90)	1.80 (0.88, 3.65)	2.929	0.087	1.351	0.245	2.564	0.109
HPS diet group (n = 52)	1.15 (0.50, 2.70)	0.80 (0.50, 2.10)						
estimated 10-y CVD risk attributed to TC (%)								
LPS diet group (n = 52)	2.10 (0.58, 3.90)	1.65 (0.53, 2.90)	5.998	0.014	29.369	< 0.001	3.263	0.071
HPS diet group (n = 52)	1.15 (0.50, 2.70)	1.10 (0.30, 2.10)						
estimated 10-y CVD risk attributed to FBG (%)								
LPS diet group (n = 52)	2.10 (0.58, 3.90)	2.10 (0.58, 3.90)	1.897	0.168	1.774	0.183	1.774	0.183
HPS diet group (n = 52)	1.15 (0.50, 2.70)	1.15 (0.50, 2.70)						
estimated 10-y CVD risk attributed to BMI (%)								
LPS diet group (n = 52)	2.10 (0.58, 3.90)	2.10 (0.50, 3.90)	5.020	0.025	0.669	0.413	3.644	0.056
HPS diet group (n = 52)	1.15 (0.50, 2.70)	1.10 (0.50, 2.63)						

[a] GEE were used to analyze the data, with adjustment for baseline values. estimated 10-y CVD risk: estimated 10-year cardiovascular disease risk; GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

Table 7. Post Hoc Analysis of estimated 10-y CVD risk based on GEE

	Postintervention		
Characteristic	Mean adjusted change (95% CI)	SE	*P*
estimated 10-y CVD risk attributed to all factors (%)			
HPS diet Group vs. LPS diet Group	-0.97 (-1.68, -0.26)	0.36	0.008
estimated 10-y CVD risk attributed to SBP (%)			
HPS diet Group vs. LPS diet Group	-0.25 (-0.53, 0.04)	0.14	0.07
estimated 10-y CVD risk attributed to TC (%)			
HPS diet Group vs. LPS diet Group	-0.10 (-0.18, -0.02)	0.04	0.014
estimated 10-y CVD risk attributed to FBG (%)			
HPS diet Group vs. LPS diet Group	-0.02 (-0.05, 0.01)	0.02	0.168
estimated 10-y CVD risk attributed to BMI (%)			
HPS diet Group vs. LPS diet Group	-0.13 (-0.24, -0.02)	0.06	0.025

The mean differences between groups before and after the intervention were used using GEE, with the LPS diet group as the reference. Changes were reported as Mean (95% CI) and adjusted for baseline values. estimated 10-y CVD risk: estimated 10-year cardiovascular disease risk; GEE: Generalized estimating equations; LPS diet group: Low-Phytosterol diet group; HPS diet group: High-Phytosterol diet group.

4. Discussion

The present trial clearly indicated that HPS diet significantly improved lipid metabolism markers, glucose and reduced the estimated 10-y CVD risk in Chinese adults with dyslipidemia when compared to LPS diet. Furthermore, our sensitivity analysis reinforced the robustness of these findings. Notably, no intervention-related adverse events were reported in the HPS diet group. Our current findings emphasize the potential of HPS diet in preventing CVD in individuals with mild dyslipidemia in China. This potential is especially important considering the increasing prevalence of dyslipidemia and the significant burden of CVD in China[22], where deaths related to CVD constitute more than 45% of all fatalities[23].

The effects of HPS diet on lipid profiles were similar to those reported in several previous studies[24, 25]. Several clinical trials have confirmed that a daily intake of 1.3-2.0 grams of phytosterols can reduce LDL-C levels by 10-15% in individuals with hyperlipidemia[25, 26]. However, most studies to date have administered phytosterols through fat-based matrices (e.g., margarine, butter, spreads), low-fat matrices (e.g., yogurt, low-fat milk, low-fat spreads), non-fat matrices (e.g., beverages), and dietary supplements (e.g., capsules)[27]. In this study, wheat and corn germ blended oil and peanut oil were employed as carriers for phytosterols to implement HPS diet and LPS diet, respectively. Due to the solubility properties of phytosterols, individuals tend to prefer fat-rich foods, e.g., oils or fat-based spreads. Therefore, using vegetable oils as carriers is the most cost-effective method to incorporate phytosterols into the daily diet[28]. The primary finding demonstrates that incorporating high phytosterol vegetable oils into the daily diet effectively can reduce serum TC, LDL-C and Non-HDL-C levels compared to the low-phytosterol vegetable oils. Therefore, our findings demonstrate that incorporating the HPS diet in daily nutrition provides an effective and safe strategy for reducing cholesterol levels.

During the three-month intervention, the HPS diet group experienced a modest reduction in TC levels compared with baseline. Animal studies have demonstrated that the cholesterol-lowering effects of phytosterols are closely related to hepatic cholesterol metabolism pathways[29]. Phytosterol intervention leads to downregulation of CYP7A1 and CYP8B1, key enzymes in the classical bile acid synthesis pathway, while upregulating CYP27A1 and CYP7B1, which are involved in the alternative pathway. The cholesterol-lowering action of phytosterols is mediated by decreased hepatic expression of TGR5 and FGFR4 receptors and increased expression of FXR and SHP receptors, thereby inhibiting the classical bile acid synthesis pathway and promoting the alternative pathway[29]. Additionally, previous studies have shown that phytosterols also inhibit cholesterol absorption through multiple mechanisms, including competitive binding to intestinal sites, which ultimately reduces cholesterol uptake, as well as interference with bile acid metabolism[30, 31]. In this study, with a daily energy intake of 2000 kcal, the HPS diet provided over 401 mg of phytosterols from vegetable oil, approximately 4.5 times the amount in the LPS diet. The Chinese Nutrition Society (2023) established a recommended phytosterol intake of 800 mg per day and a tolerable upper intake level of 2400 mg per day in the Dietary Reference Intakes for Nutrients in Chinese Residents. The phytosterol intake provided by the HPS diet in this study did not reach the specific recommended intake levels, but it still provided a relatively high amount of phytosterols. However, this amount is still relatively low compared to other European countries[32]. Therefore, the observed effect changes in this study may be limited. However, prolonged adherence to the HPS diet may yield greater TC reductions over time. We also observed that the HPS diet improved certain lipid indices more markedly in females than in males, highlighting the influence of gender on the lipid-lowering effect of HPS diet. Differences in hormone levels between males and females lead to distinct responses in lipid metabolism and cholesterol absorption. In addition, differences in body fat composition between females and males may influence the body's response to phytosterols. The

gender-specific response may arise from synergistic effects and the exact mechanism requires clarification through more rigorous clinical studies.

Unexpectedly, the HPS diet group exhibited a decreasing trend in HDL-C levels in individuals with dyslipidemia. A possible explanation is that the trial was designed based on an Eastern dietary pattern, with daily fat intake controlled according to the recommendations of the Chinese Dietary Guidelines, resulting in a generally light diet with a moderate increase in carbohydrate intake. Previous studies have shown that high-carbohydrate diet or low-fat diet can reduce HDL-C levels[33-35]. Apart from epidemiological studies suggesting a negative correlation between baseline HDL-C levels and subsequent CVD risk, the health benefits of elevated HDL-C remain unclear[36, 37]. Randomized clinical trials of HDL-C-raising drugs typically demonstrate no benefit and may even have adverse effects on cardiovascular health[38]. It is an intriguing question which dietary factors have a causal relationship with HDL-C levels. The complexity of HDL-C composition and lipid profiles, however, complicates determining their cardiovascular health implications.

The observed blood glucose-lowering effect of the HPS diet had only borderline significance. This may be attributable to incomplete baseline equilibration of blood glucose levels between groups and the inclusion of baseline hyperglycemic participants whose dietary modifications during the intervention could have reduced blood glucose levels. The current findings do not fully confirm that HPS diet can improve blood glucose. HPS diet group used wheat and corn germ blended oils for their daily diet, which inevitably introduces the potential effects of linoleic acid. The potential interference from polyunsaturated fatty acids also warrants consideration. Many other potential confounding factors may influence the results, necessitating further research to validate these effects.

The estimated 10-y CVD risk comprehensively reflects the impact of major risk factors, and several studies have demonstrated an association between dietary patterns and cardiovascular disease risk[39]. Therefore, changes in the estimated 10-y CVD risk serve as a composite indicator of the overall benefits of dietary intervention. It integrates the intervention effects on multiple CVD risk factors, thereby contributing to overall risk assessment. After three months of intervention, the HPS diet group demonstrated a significant 0.97% reduction in the overall estimated 10-y CVD risk compared with the LPS diet group. This study also found that the HPS diet group demonstrated a significant 0.10% reduction in the estimated 10-y CVD risk attributable to TC compared with the LPS diet group after three months of intervention. Additionally, a significant 0.13% reduction in the estimated 10-y CVD risk attributable to BMI was observed. However, no significant changes were observed in the estimated 10-y CVD risk attributable to SBP and FBG. These findings demonstrate the beneficial effects of the HPS diet. Currently, several studies have begun to investigate the potential impacts of Chinese dietary patterns on cardiovascular health risks[40, 41]. Considering the dietary characteristics and variations across different regions of China, further research is needed in the future to explore and compare the differential effects of these dietary patterns.

Anthropometric indicators are closely associated with CVD risk through intermediary conditions such as hypertension, dyslipidemia, and insulin resistance[42-46]. Notably, after three months of intervention,

participants with dyslipidemia in the HPS diet group exhibited a slight reduction in body weight. This finding may be attributed to reduced cholesterol absorption, improved lipid metabolism and enhanced insulin sensitivity observed in participants with dyslipidemia following adherence to HPS diet. These combined effects appear to result in favorable improvements in anthropometric parameters, thereby reducing CVD risk.

This study comparatively analyzed the potential benefits of HPS diet and LPS diet implemented through daily replacement of cooking oils. The findings further support that partially or totally replacing low-phytosterol cooking oils with high-phytosterol cooking oils is an important component of a healthy daily diet for individuals at high risk of dyslipidemia or cardiovascular disease. Given the inadequate phytosterol intake in the Chinese population, it is particularly important to encourage the consumption of phytosterol-rich foods as daily dietary sources of phytosterols. From a public health policy perspective, this study can inform policies regarding phytosterol-fortified foods and provide a scientific basis for guiding consumer choices toward edible oils with high phytosterol content. Furthermore, this study provides additional evidence for non-pharmacological interventions in chronic disease management, thereby contributing to the reduction of future CVD burden.

Our current study possessed several strengths. First, the cafeteria-based provision of intervention meals and high participant adherence significantly improved the validity of the results. Second, the robustness of our findings was further confirmed through sensitivity analyses. Third, all ingredients and condiments were weighed and recorded before and after cooking. Finally, the HPS diet, based on phytosterol-fortified vegetable oil, offered high palatability and low cost, making it an appealing option for individuals with dyslipidemia in China. These strengths highlight the reliability and potential relevance of HPS diet in wider settings.

Our present trial also existed several limitations. First, considering the feasibility of implementing the intervention on-site, participants were recruited based on the availability of resources within corporate employee populations. This could have resulted in insufficient sample size, potentially limiting the ability of our study to draw definitive conclusions. Second, there remain specific covariates that could influence the stability of our conclusions. Third, dietary intervention lasted only three months due to budget constraints. The relatively short duration of the intervention may lead to the modest effects noted in the study. Additionally, direct replacement of daily cooking oils in this study resulted in differences in fatty acid composition between the HPS and LPS diets, and the potential effects of linoleic and oleic acids cannot be ignored, necessitating further rigorously designed studies to explore their impact on the results.

5. Conclusions

In conclusion, this trial demonstrated that the Chinese HPS diet may lower blood lipids, FBG and the estimated 10-y CVD risk in Chinese adults with mild dyslipidemia. These findings highlight potential cardiovascular health benefits associated with increased phytosterol intake in daily diets. Further long-term studies are warranted.

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Conflict of interest

The authors declare no conflicts of interest related to this study.

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Data Availability

All data that supports the findings of this study are available from the corresponding author upon reasonable request.

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