Journal of Health, Population and Nutrition

RESEARCH

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Efficacy of garlic (*Allium sativum*) on metabolic syndrome components in women with polycystic ovary syndrome: randomized controlled trial

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Abstract

Background This study aimed to illustrate the effect of garlic supplementation on metabolic syndrome (MetS) components in women with polycystic ovary syndrome (PCOS).

Methods From 2020 to 2021, a randomized controlled clinical trial was conducted on 97 women with PCOS and MetS. Participants were randomly assigned to receive either garlic tablets (500 mg containing 2-3 mg allicin; $n=49$) or placebo tablets ($n=48$) twice daily for 8 weeks. The study assessed changes in MetS indices, quality of life (QoL), and sexual function before and after the intervention.

Results After 8 weeks, the garlic group showed significant reductions in fasting blood sugar (FBS) by 10.5% (from 107.2 to 95.9 mg/dL; $P<0.001$), triglycerides (TG) by 17.8% ($P=0.002$), low-density lipoprotein cholesterol (LDL-C) by 14.2% ($P<0.001$), total cholesterol (TC) by 12.6% ($P<0.001$), and C-reactive protein (CRP) by 24.7% ($P<0.001$), compared to the placebo group. A significant increase in sex hormone-binding globulin (SHBG) levels was also observed (18.3%; $P=0.005$). Systolic and diastolic blood pressure decreased significantly by 5.2% and 6.1%, respectively ($P<0.001$ and $P=0.001$), and both weight and body mass index (BMI) were significantly reduced ($P<0.01$). However, the waist-to-hip ratio (WHR) did not change significantly ($P=0.86$). Notable improvements were also observed in all six domains of the Female Sexual Function Index (FSFI)— desire, arousal, lubrication, orgasm, satisfaction, and pain ($P<0.05$ for all). Moreover, significant enhancements were recorded in all domains of the Modified Polycystic Ovary Syndrome Health-Related Quality of Life Questionnaire (MPCOSQ), including hirsutism, acne, weight, infertility, menstrual, and emotional disturbances ($P<0.001$ for all). The study's limitations include a relatively short follow-up period, lack of strict dietary control, and the omission of some relevant hormonal assays (e.g., androstenedione, DHEA, and DHEAS) due to budgetary constraints.

Conclusions The results suggest that garlic supplementation may be an effective strategy for managing MetS markers in women with PCOS.

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Trial registration IRCT20150905023897N4, Registration date: 09/11/2019 (https://irct.behdasht.gov.ir/trial/42316).

Keywords Polycystic ovary syndrome, Insulin resistance, Dyslipidemia, Inflammation, Gonadal steroid hormones, Quality of life, Sexual function

Background

Polycystic ovary syndrome (PCOS) is a common endocrine condition affecting women of reproductive age [1]. It is distinguished by hyperandrogenism, polycystic ovarian morphology, and ovulatory dysfunction, which together contribute to a variety of reproductive, metabolic, and psychological challenges. Furthermore, PCOS is associated with an increased risk of cardiovascular disease, type 2 diabetes, infertility, and endometrial cancer [2].

Metabolic syndrome (MetS) is more prevalent among women with PCOS than in the general population [3], and it is believed that the two conditions share overlapping pathogenic mechanisms [4].

Although various pharmacological treatments are available for managing PCOS and MetS, there is a growing interest in natural remedies such as garlic (*Allium sativum* L.), which is rich in organosulfur compounds and flavonoids [5]. Garlic has been shown to possess multiple health-promoting properties, including lipid-lowering, antihyperglycemic, antihypertensive, and antithrombotic effects [6]. Notably, aged garlic extract has been shown to reduce plasma homocysteine (HCy) levels by up to 30% [7]. Epidemiological studies suggest that, beyond elevated plasma low-density lipoprotein (LDL), hypertension, diabetes, smoking, genetic predisposition, and infectious agents, impaired Hcy metabolism—resulting in hyperhomocysteinemia (HHcy) —is linked to cardiovascular disease (CVD). Severe HHcy is associated with advanced CVD and premature mortality due to vascular complications [8]. In women with PCOS, hyperandrogenemia has been correlated with elevated HCy levels, particularly in the presence of obesity and insulin resistance [9]. Furthermore, studies indicate that in PCOS patients, Hcy exacerbates autophagy in granulosa cells (GCs) by modulating the mammalian target of rapamycin (mTOR) signaling pathway. This may disrupt follicular development and ovulation. Elevated HCy levels in the follicular fluid (FF) of PCOS patients have also been strongly linked to various fertility problems, including reduced oocyte and embryo quality, miscarriage, and low birth weight [10].

Despite these findings, there is a lack of comprehensive studies examining the effects of garlic supplementation on the components of MetS in women with PCOS. This gap in research highlights the need for further research into the potential role of garlic in improving metabolic health and reproductive function in this population. Therefore, this study aims to evaluate the effects of garlic supplementation on key components of MetS—including insulin resistance, lipid profile, and blood pressure in women with PCOS.

Methods

From February 2020 to January 2021, a randomized, double-blind, placebo-controlled study was conducted on women with PCOS and MetS at the Gynecology Department of Arash Hospital, Tehran, Iran. The sample size was determined based on a study by J Lord [11], which investigated the effect of metformin on fat distribution and MetS in PCOS women. Assuming an alpha level of 0.05, a statistical power of 90%, and an effect size of 0.7 (calculated based on the mean difference in systolic blood pressure between two groups divided by the standard deviation), the estimated sample size was 43 participants per group. Accounting for a 10% attrition rate, the final sample size was set at 94 participants (as shown in Fig. 1).

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{(X_1 - X_2)^2}$$
$$= \frac{(1.96 + 1.28)^2 \left(11.3^2 + 13.53^2\right)}{(138.40 - 122.69)^2}$$

$$Z_{1-\frac{\alpha}{2}} = 1.96 \qquad Z_{1-\beta} = 1.28$$

[X1 = 138.40 mmHg (Mean systolic blood pressure in the placebo group), X2 = 122.69 mmHg (Mean systolic blood pressure in the garlic group), S1 = 11.3 (Std. Deviation systolic blood pressure in the placebo group), S2 = 13.53 (Std. Deviation systolic blood pressure in the garlic group).

Trial design

This study was a phase II, double-blind, randomized, placebo-controlled trial conducted in gynecological clinics affiliated with Tehran University of Medical Sciences, Tehran, Iran, from February 7, 2020 to January 4, 2021. This trial conformed to the ethical guidelines of the 1975 Declaration of Helsinki, and ethical approval was obtained from the Ethics Committee prior to the commencement of the study on October 22, 2019. In addition to that, it has been registered in the Iranian Registry of Clinical Trials (IRCT20150905023897N4, Registration date: 09/11/2019).

All participants provided written informed consent after receiving detailed information about the study's objectives, potential risks, and benefits. The Rotterdam

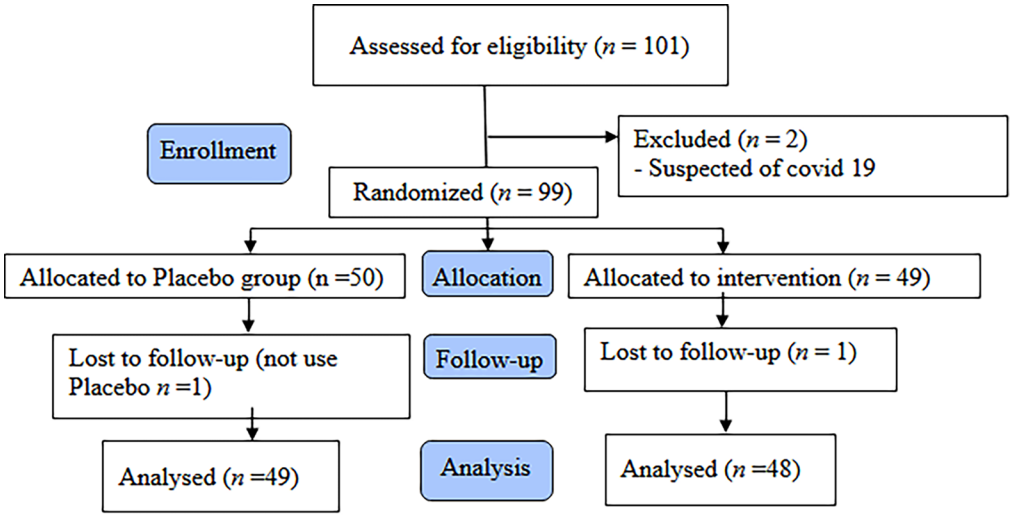

Fig. 1 The consort flowchart

criteria and the NCEP ATP III guidelines were used to diagnose PCOS and MetS, respectively [12, 13].

To be included in the study, participants had to meet the following criteria: diagnosed with both PCOS and MetS according to the Rotterdam criteria and NCEP ATP III guidelines; non-pregnant; Iranian nationality; willingness to participate; fasting blood glucose < 126 mg/dl; consumption of no more than one clove of garlic per day; no self-reported chronic diseases or coagulation disorders; and absence of other endocrine disorders (e.g., hyperprolactinemia, thyroid disease, non-classical congenital adrenal hyperplasia (CAH) according to the Rotterdam criteria. Exclusion criteria included garlic side effects, suspected or confirmed COVID-19 infection during the study period, and participation in an ovulation induction cycle (either advised by a physician or voluntarily). Participants were monitored for any side effects related to the 500 mg garlic supplementation. No serious adverse effects were reported; however, some participants experienced mild gastrointestinal symptoms such as bloating and flatulence, which are common with garlic consumption. A few participants also reported bad breath. These side effects were generally mild and resolved after the intervention period.

Although raw garlic contains allicin, which may offer similar benefits, but the garlic supplement used in this study was standardized to ensure consistent dosing and reliable bioavailability. The stability and bioavailability of allicin in raw garlic can vary, making it less reliable.

Participants were assured of their right to withdraw from the study at any time without consequences. Ultimately, a total of 97 participants were enrolled in the study (Fig. 1).

Randomization and masking

We used simple randomization based on a computer-generated list of random number groups created using the Statistical Analysis System (SAS) software, version 9.2 (SAS Institute Inc., Cary, NC, USA). All participants were randomly allocated to one of the study groups, and the investigator dispensed the medications according to the randomization list. The allocation of treatment and placebo was blinded for the participants, the investigator, and the attending physician.

Bias control

Randomization was conducted using a simple randomization method, with blinding to ensure that those administering the treatments were unaware of the group assignments. This approach helps reduce potential biases. Additionally, we employed Analysis of Covariance (ANCOVA) to control for baseline differences, ensuring that the reported outcomes are primarily attributed to the intervention rather than initial differences between the groups.

Intervention

Participants were randomly assigned to either the garlic or placebo group using block randomization. Garlic and placebo pills were manufactured by Goldaru Pharma Co., a pharmaceutical company located in Isfahan, Iran. Both types of pills were identical in shape, color, smell, and taste and were packaged in identical containers.

The standard dosage of the garlic supplement was selected based on safety data related to hypertension and other cardiovascular risk factors [14, 15]. The intervention period lasted 8 weeks, a duration chosen based on previous evidence to allow for detectable metabolic and hormonal changes while maintaining participant

compliance. Each garlic tablet contained 500 mg of garlic powder (*Allium sativum*), standardized to provide 2–3 mg of allicin (Garcin 500; Goldaru Pharma Co., Isfahan-Iran, registration No. 1228030383).

Participants were instructed to take one garlic tablet one hour before lunch and another one hour before dinner for eight weeks, as garlic absorption is reduced when consumed with protein-rich meals [16]. Weekly follow-ups were conducted throughout the intervention period. The placebo group received placebo tablets (Goldaru Pharma Co., Isfahan-Iran), which were administered in the same manner.

Demographic data were collected using a questionnaire completed by the researcher at the start of the study. The questionnaire included information on age, weight, education level, marital status, and occupation.

Laboratory evaluations

Standard laboratory protocols were followed to conduct the tests. Blood samples were collected from patients after an overnight fast of 8–12 h, both at baseline and at week 8. Serum was separated by centrifugation at 3000 rpm for 15 min and then transferred into microtubes, which were immediately frozen at −70 °C until further analysis.

Fasting blood glucose (FBS) levels were measured using the glucose oxidase enzymatic process method with commercial kits from Pars Company (Tehran, Iran) and an auto-analyzer (model BT 2000, Italy). The same auto-analyzer was used to measure total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C).

Total testosterone (TT) and sex hormone-binding globulin (SHBG) levels were measured using the electrochemiluminescence method with a Cobas E411 device (Roche Instr Kit, Germany). C-reactive protein (CRP) levels were measured via photometry using kits from Pars Azmoon (Tehran, Iran).

After 8 weeks, the participants returned to the same laboratory for repeat measurements of TC, HDL-C, LDL-C, TG, FBS, CRP, TT, and SHBG.

Anthropometric evaluations

Anthropometric measurements were performed under standard conditions. Weight, height, waist circumference (WC), and hip circumference (HC) were measured by the researcher at baseline in the women's clinic. Weight was measured using a digital scale (Seca, Hamburg, Germany) with an accuracy of 0.1 kg, while participants wore minimal clothing and no shoes. Height was measured in a standing position without shoes using a stadiometer (Seca, Hamburg, Germany) with an accuracy of 0.1 cm. WC was measured at the midpoint between the iliac crest and the lower ribs using a flexible tape accurate to 0.1 cm. HC was measured along a horizontal line at the level of the greater trochanter of the femur, also with 0.1 cm precision. Body Mass Index (BMI) was calculated as weight (kg) divided by height squared (m^2). To minimize measurement error, ll measurements were performed by the same individual.

Blood pressure measurement

Blood pressure was measured from the right arm while the patient was and at rest for at least 10 min. A mercury sphygmomanometer (Yuwell, China) and the Korotkoff sound technique were used, with an accuracy of ± 2 mmHg. Subjects were instructed to avoid vigorous physical activity, eating, drinking (except water), smoking and taking medications that could affect blood pressure for at least one hour prior to the measurement. They were also asked to wear light clothing with loose sleeves, and ensure their bladder was empty during the procedure. Blood pressure was measured in a non-fasting state.

Female sexual function index (FSFI)

Female sexual function was assessed for the past four weeks using the FSFI questionnaire. This questionnaire consists of 19 items that evaluate six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. Higher scores indicate better sexual function [17]. Mohammadi et al. confirmed the reliability and validity of the Iranian version of the FSFI questionnaire [18].

Modified polycystic ovary syndrome health-related quality of life questionnaire (MPCOSQ)

The MPCOSQ assesses health-related QoL in PCOS patients. It consists of 30 Likert-scale items covering six domains: emotional disturbance, hirsutism, infertility, weight, menstrual, and acne. Higher scores indicate better QoL for these patients [19]. Bazarganipour et al. evaluated the reliability and validity of the Iranian version of the MPCOSQ [20].

Outcome

The primary endpoints were significant changes in the mean values of MetS indices, androgenic components, and CRP levels assessed after 8 weeks of treatment.

Secondary efficacy endpoints included improvements in subjects' sexual function and QoL, as evaluated by the aforementioned questionnaires.

Statistical analysis

Statistical analyses were performed using SPSS Version 22 (ver. 22.0) (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was used to assess the normality of the data. Continuous variables were presented as mean ± standard deviation (SD), and categorical variables

as frequencies with percentages. Student's t-tests (for normally distributed continuous variables) and Chi-square test (for categorical variables) were used for comparisons between the two groups.

To assess the effect of the intervention while controlling for baseline values, ANCOVA and Multivariate Analysis of Covariance (MANCOVA) were used. In these models, the term "adjusted mean" refers to the estimated group means after statistically controlling for baseline differences, thereby providing a more accurate estimate of the intervention's effect. A P-value of <0.05 was considered statistically significant for all analyses.

Results

The mean age of patients in the intervention and control groups was 32.6 ± 6.47 and 31.67 ± 6.18 years, respectively. The mean weight was 89.79 ± 9.96 kg in the intervention group and 88.05 ± 13.96 kg in the control group. The majority (%) of participants held a high School diploma, and most (%) were housewives.

There were no statistically significant differences between the garlic and placebo groups in terms of age, weight, educational level, or occupational status (all $P>0.05$). Similarly, no statistically significant differences were observed between the garlic and placebo groups at baseline in terms of WC, HC, BMI, systolic blood pressure (SBP), and levels of FBS, TG, HDL-C, LDL-C, TC, CRP, SHBG and TT (all $P>0.05$), except for a minor difference in diastolic blood pressure (DBP), which was slightly higher in the garlic group ($P=0.04$). To control for this baseline difference, ANCOVA was applied in the post-intervention analysis to adjust for initial DBP values (Table 1).

Table 1 Comparison of the anthropometric, metabolic and androgenic components between the 2 groups

Variables		Garlic Group *N* = 48	Control Group *N* = 49	Test statistic	*P* (95% CI)
Weight, (Kg)	Baseline* (mean ± SD)	89.79 ± 9.96	88.05 ± 13.96	t= -0.708	0.48(-6.64–3.16)
	8-week **(Adj mean for baseline) (mean ± SE)	85.39 ± 0.51	88.08 ± 0.50	F = 13.907	*P* < 0.001(1.26–4.12)
WC, [a] (Cm)	Baseline* (mean ± SD)	97.37 ± 5.23	96.1 ± 3.29	t= -1.43	0.15 (-3.03 – 4.86)
	8-week **(Adj mean for baseline) (mean ± SE)	95.08 ± 0.76	97.46 ± 0.75	F = 4.894	0.02 (0.25 – 4.52)
HC,[b] (Cm)	Baseline* (mean ± SD)	109.47 ± 6.75	107.57 ± 7.85	t= -1.281	0.2 (-4.86 – 1.04)
	8-week **(Adj mean for baseline) (mean ± SE)	106.55 ± 0.36	108.49 ± 0.35	F = 14.597	*P* < 0.001 (0.94 – 2.95)
WHR [C]	Baseline* (mean ± SD)	0.89 ± 0.04	0.89 ± 0.05	t = 0.624	0.53 (-0.01 – 0.02)
	8-week **(Adj mean for baseline) (mean ± SE)	0.89 ± 0.004	0.9 ± 0.003	F = 3.006	0.86 (-0.0008 – 0.02)
BMI,[d] (Kg/m2)	Baseline* (mean ± SD)	32.50± 3.66	31.72± 4.69	t= -0.917	0.36 (-2.48 – 0.91)
	8-week **(Adj mean for baseline) (mean ± SE)	31.04 ± 0.16	31.68 ± 0.16	F = 7.514	0.007 (0.18 – 1.11)
FBS [e] (mg/dL)	Baseline* (mean ± SD)	102.08 ± 10.12	99.71 ± 10.05	t= -1.157	0.25 (-6.43 – 1.69)
	8-week **(Adj mean for baseline) (mean ± SE)	94.35 ± 0.77	100.32 ± 0.76	F = 29.953	*P* < 0.001 (0.0.08 – 7.98)
TG [f] (mg/dL)	Baseline* (mean ± SD)	172.83 ± 47.57	180.28 ± 45.37	t = 0.790	0.43 (-11.28 – 26.18)
	8-week **(Adj mean for baseline) (mean ± SE)	153.85 ± 4.26	173.38 ± 4.21	F = 10.574	0.002 (7.37 – 41.42)
HDL-c [g](mg/dL)	Baseline* (mean ± SD)	42.79 ± 7.47	43.63 ± 7.02	t = 0.571	0.56 (-2.08 – 3.76)
	8-week **(Adj mean for baseline) (mean ± SE)	45.59 ± 0.56	43.92 ± 0.55	F = 4.435	0.38 (-3.81 – 1.84)
LDL-c [h] (mg/dL)	Baseline* (mean ± SD)	90.04 ± 21.18	89.27 ± 13.23	t= -0.213	0.83 (-7.86 – 6.33)
	8-week **(Adj mean for baseline) (mean ± SE)	83.48 ± 1.35	91.89 ± 1.33	F = 19.484	*P* < 0.001 (1.04 – 14.55)
TC [i] (mg/dL)	Baseline* (mean ± SD)	185.66 ± 29.11	175.89 ± 18.43	t= -1.97	0.05 (-19.56 – 0.03)
	8-week **(Adj mean for baseline) (mean ± SE)	163.32 ± 1.87	177.37 ± 1.89	F = 27.710	*P* < 0.001 (8.75 – 19.36)
SBP [j] (mmHg)	Baseline* (mean ± SD)	118.33 ± 1.54	113.97 ± 10.94	t= -1.982	0.05 (-8.71 – 0.007)
	8-week **(Adj mean for baseline) (mean ± SE)	110.82 ± 0.96	116.33 ± 0.95	F = 16.179	*P* < 0.001 (2.80 – 8.25)
DBP [k] (mmHg)	Baseline* (mean ± SD)	81.35 ± 6.25	78.06 ± 9.5	t= -2.019	0.04 (-6.54 – -0.4)
	8-week **(Adj mean for baseline) (mean ± SE)	75.76 ± 0.81	79.86 ± 0.72	F = 12.685	0.001 (1.82 – 6.40)
CRP [l] (mg/L)	Baseline* (mean ± SD)	6.67 ± 4.61	7.70 ± 5.24	t = 0.548	0.58 (-2.83–4.89)
	8-week **(Adj mean for baseline) (mean ± SE)	5.83 ± 0.17	7.42 ± 0.14	F = 49.084	*P* < 0.001 (1.11 – 2.03)
SHBG [m] (nmol/L)	Baseline* (mean ± SD)	31.60 ± 27.66	15.76 ± 3.64	t= -1.61	0.151 (-31.85 – 0.19)
	8-week **(Adj mean for baseline) (mean ± SE)	26.26 ± 1.18	21.27 ± 0.910	F = 10.157	0.005 (-36.61 – -4.53)
TT [n] (nmol/L)	Baseline* (mean ± SD)	0.56 ± 0.27	0.71 ± 0.56	t = 0.816	0.42 (-0.21 – 0.5)
	8-week **(Adj mean for baseline) (mean ± SE)	0.36 ± 0.17	1.003 ± 1.31	F = 1.26	0.27 (-0.14 – 1.42)

[a] Waist circumference; [b] Hip circumference; [c] waist- hip ratio; [d] Body Mass Index; [e] Fasting Blood Sugar; [f] Triglyceride; [g] high density lipoprotein-cholesterol; [h] low density lipoprotein-cholesterol; [i] Total cholesterol; [j] Systolic blood pressure, [k] Diastolic blood pressure; [l] c-reactive protein; [m] sex hormone-binding globulin [n] Total Testosterone

* Independent t-test was used for comparison between the two groups at baseline

**ANCOVA (analysis of covariance) was used for comparison between the two groups at the end of the intervention after adjusting for basal values

Compared to the placebo group, the garlic group showed a significant reduction in weight ($P<0.001$), BMI ($P=0.007$), WC ($P=0.02$), HC ($P<0.001$), SBP ($P<0.001$), and DBP ($P=0.001$). However, we didn't find any significant effect on waist-hip ratio (WHR) between the garlic and control groups ($P=0.86$) (Table 1) (Charts 1 and 2).

Although the reduction in FBS ($P<0.001$), TG ($P=0.002$), LDL-C ($P<0.001$), TC ($P<0.001$), CRP ($P<0.001$), as well as the increase in SHBG levels ($P=0.005$), were statistically significant in the garlic group, the decrease in TT and the increase in HDL-C were not significant ($P=0.27$ and $P=0.38$, respectively).

At the beginning of the study, a statistically significant difference was observed between the two groups in orgasm domain ($P=0.003$) and total FSFI score ($P=0.004$) (Table 2). To determine differences in the mean scores of sexual function domains—desire, arousal, lubrication, orgasm, satisfaction, and pain—a MANCOVA test was used (Table 2). As the results demonstrate, there was a significant difference in the mean scores of the all domains following the intervention in women with PCOS ($P<0.001$ for all domains, except for satisfaction, which was significant at $P=0.02$) (Table 2). However, ANCOVA, adjusted for baseline scores of all of FSFI subdomains, showed no significant differences between the garlic and placebo groups at week eight ($P>0.05$ for all domains).

As can be seen in Table 3, at the beginning of the study, a statistically significant differences were observed between two groups in the scores of the acne, weight, infertility subdomains, and the total MPCOSQ score. However, no significant differences were found in the hirsutism, menstrual disturbance, and emotional disturbance domains ($P=0.09$, $P=0.35$, and $P=0.06$, respectively) (Table 3).

A MANCOVA test was used to determine differences in the mean scores of all MPCOSQ subdomains, including hirsutism ($P<0.001$), acne ($P<0.001$), weight ($P<0.001$), infertility ($P<0.001$), menstrual disturbance ($P<0.001$), and emotional disturbance ($P<0.001$) in women with PCOS. The results indicate a significant improvement in all six domains following garlic consumption (Table 3).

ANCOVA, controlling for baseline scores of all MPCOSQ subdomains, showed significantly higher scores in the garlic group compared to the placebo group at week eight ($P<0.05$ for all subdomains). (Table 3).

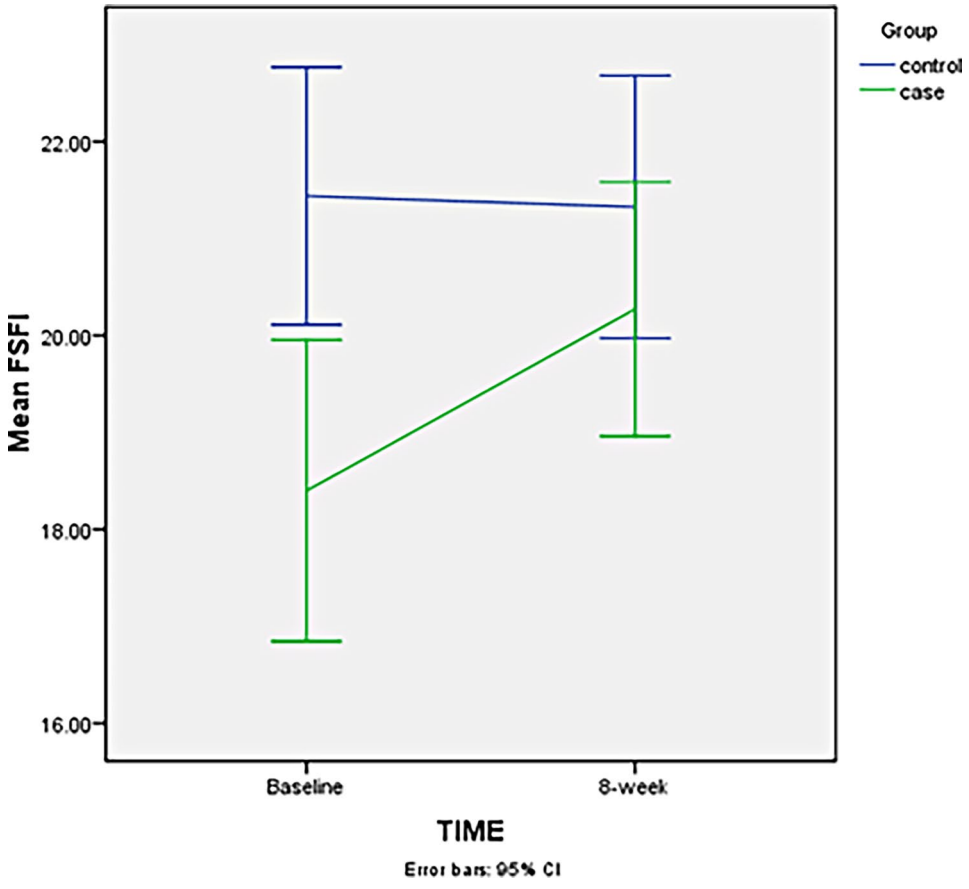

Chart 1 Changes in the Mean Scores of FSFI After 8 Weeks

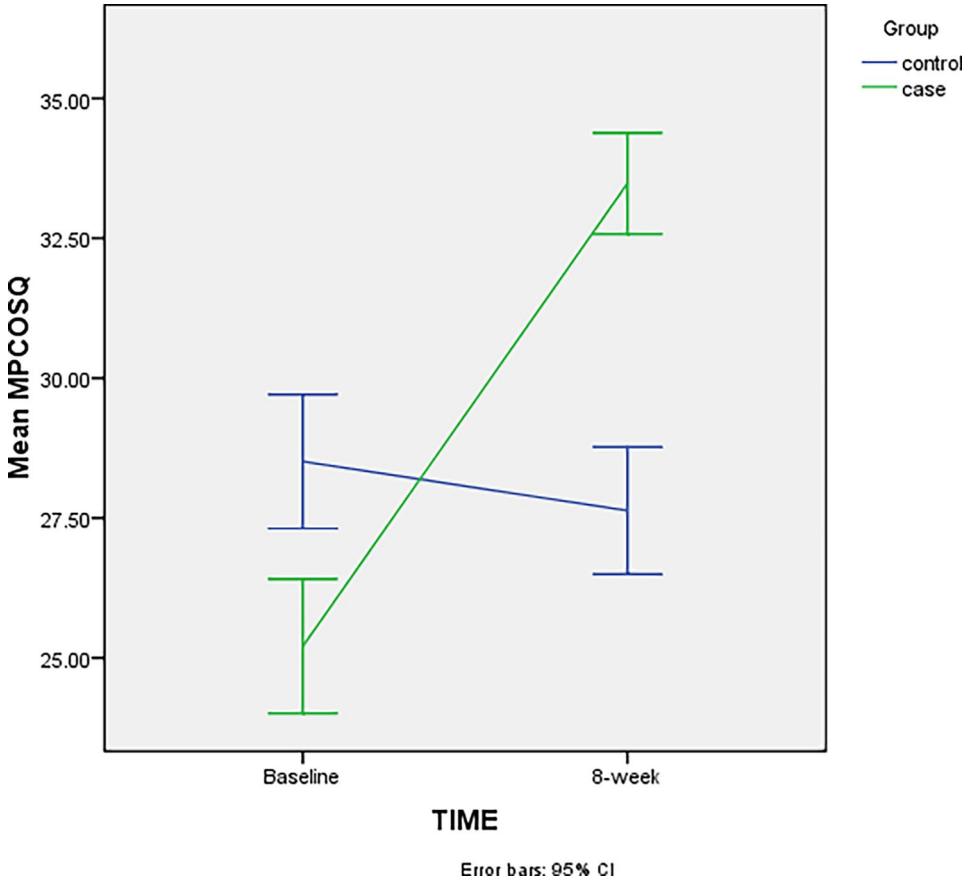

Chart 2 Changes in the Mean Scores of MPCOSQ After 8 Weeks

Table 2 Comparison of FSFI scores between the 2 groups

Domains/items		Garlic Group *N* = 48	Control Group *N* = 49	Test statistic	*P* (95% CI)
Desire	Baseline* (mean ± SD)	2.86 ± 1.25	2.99 ± 1.07	t = 0.545	0.58 (-0.34 – 0.6)
	8-week **(Adj mean for baseline) (mean ± SE)	3.22 ± 0.07	3.02 ± 0.07	F = 156.171	*P* < 0.001 (0.02 – 0.44)
Arousal	Baseline* (mean ± SD)	2.67 ± 1.23	3.14 ± 1.10	t = 1.984	0.05 (-0.0002 – 0.94)
	8-week** (Adj mean for baseline)	3.22 ± 0.07	2.85 ± 0.07	F = 34.435	*P* < 0.001 (0.03 – 0.46)
Lubrication	Baseline* (mean ± SD)	3.17 ± 1.34	3.77 ± 1.48	t = 2.123	0.36 (0.03 – 1.16)
	8-week** (Adj mean for baseline)	4.04 ± 0.13	3.47 ± 0.13	F = 34.551	*P* < 0.001 (0.03 – 0.81)
Orgasm	Baseline* (mean ± SD)	2.46± 0.92	3.07± 1.04	t = 3.057	0.003 (0.21 – 1)
	8-week **(Adj mean for baseline)	3.27 ± 0.09	2.87 ± 0.09	F = 25.296	*P* < 0.001 (0.01 – 0.61)
Satisfaction	Baseline* (mean ± SD)	2.89 ± 1	3.56 ± 1.43	t = 2.694	0.008 (0.17 – 1.17)
	8-week** (Adj mean for baseline)	3.63 ± 0.13	3.34 ± 0.13	F = 5.533	0.02 (0.25 – 0.55)
Pain	Baseline* (mean ± SD)	4.15 ± 1.91	4.79 ± 1.46	t = 1.827	0.07 (-0.05 – 1.32)
	8-week** (Adj mean for baseline)	4.25 ± 0.24	4.32 ± 0.24	F = 24.196	*P* < 0.001 (0.49–0.87)
Total score	Baseline* (mean ± SD)	18.4 ± 5.35	21.43 ± 4.62	t = 2.993	0.004 (1.02 – 5.05)
	8-week*** (Adj mean for baseline)	21.35 ± 0.44	20.26 ± 0.43	F = 2.855	0.09 (-0.8 – 2.91)

* Independent t-test

**MANCOVA (Multivariate analysis of covariance)

Discussion

The results showed that garlic supplementation administered for 8-week period improved various components of MetS, except for the waist-to-hip ratio (WHR). Although HDL-C level increased following garlic consumption, the difference between the groups was not statistically significant.

Several studies have also reported the beneficial effects on lipid profiles. For instance, Zadhoush et al. (2021) showed that garlic supplementation significantly reduced

Table 3 Comparison of MPCOSQ scores between the 2 groups

Domains/items		Garlic Group *N* = 48	Control Group *N* = 49	Test statistic	*P* (95% CI)
Hirsutism	Baseline* (mean ± SD)	4.25 ± 1.50	3.69 ± 1.74	t=-1.677	0.097 (-1.21 – 0.1)
	8-week **(Adj mean for baseline) (mean ± SE)	6.08 ± 1.08	3.61 ± 1.66	F = 255.983	< 0.001 (-3.04 – -1.90)
Acne	Baseline* (mean ± SD)	4.04 ± 1.39	5.02 ± 1.36	t = 3.493	0.001 (0.42 – 1.53)
	8-week **(Adj mean for baseline) (mean ± SE)	5.83 ± 1.22	4.89 ± 1.31	F = 94.018	< 0.001(-1.44 – -0.42)
Weight	Baseline* (mean ± SD)	4.25 ± 1.83	5.34 ± 1.18	t = 3.486	0.001 (0.47 – 1.71)
	8-week **(Adj mean for baseline) (mean ± SE)	5.87 ± 1.06	5.16 ± 1.19	F = 108.976	< 0.001 (-1.16 – -0.25)
Infertility	Baseline* (mean ± SD)	4.18 ± 1.39	5.08 ± 1.28	t = 3.282	0.001 (0.35 – 1.43)
	8-week **(Adj mean for baseline) (mean ± SE)	4.18 ± 1.39	4.73 ± 1.36	F = 398.508	< 0.001 (0.05–0.53)
Menstrual disturbance	Baseline* (mean ± SD)	4.45 ± 1.55	4.73 ± 1.39	t = 0.921	0.35 (-0.31 – 0.87)
	8-week **(Adj mean for baseline) (mean ± SE)	5.79 ± 1.07	4.61 ± 1.31	F = 63.420	< 0.001 (-1.66 – -0.69)
Emotional disturbance	Baseline* (mean ± SD)	4.02 ± 1.55	4.63 ± 1.57	t = 1.926	0.06 (-0.01 – 1.24)
	8-week **(Adj mean for baseline) (mean ± SE)	5.70 ± 1.18	4.61 ± 1.59	F = 137.019	< 0.001(-1.66 – -0.52)
Total score	Baseline* (mean ± SD)	25.20 ± 4.13	28.51 ± 4.17	t = 3.913	< 0.001 (1.62 – 4.97)
	8-week ***(Adj mean for baseline) (mean ± SE)	34.65 ± 0.30	26.48 ± 0.30	F = 334.896	< 0.001 (-7.28 – -4.41)

* Independent t-test

**MANCOVA (Multivariate analysis of covariance)

TC and LDL-C levels in 80 women with PCOS who received 800 mg of garlic supplement or placebo (starch) daily for 8 weeks. TG levels also decreased, although no significant change was observed in HDL-C levels between the groups [21].

In another study, daily consumption of 1600 mg of garlic tablets for three months led to significant improvements in TG, TC, LDL-C and HDL-C levels in patients with MetS [22]. Garlic contains bioactive compounds such as allicin, which may contribute to these effects by inhibiting cholesterol synthesis, enhancing bile acid excretion, and improving lipid metabolism. These mechanisms likely played a role in the favorable changes observed in our participants [23, 24].

However, the absence of a significant improvement in HDL-C levels is noteworthy. One possible explanation is the relatively short duration of the intervention, which may not have been sufficient for changes in HDL-C to become apparent. In the study by Sharifi et al. (2010), in which 40 adult women with MetS and 10 healthy women received 1.8 g/d of garlic for 6 weeks, no significant differences in plasma lipid levels were found between the groups [25]., 2010). The type of garlic, dosage, and duration of consumption may explain these discrepancies.

In the present study, the mean FBS level in the garlic group was significantly lower than that of the control group after eight weeks. Consistent with our findings, Faroughi et al. (2018) revealed that 400 mg/day of garlic tablets significantly reduced average FBS levels after four and eight weeks in pregnant women with borderline gestational diabetes mellitus [26]. Similarly, Soleimani et al. (2020), in a study on patients with nonalcoholic fatty liver disease, observed significant reductions in weight and serum levels of FBS, Hb A1C, TC, and TG following the administration of 800 mg of garlic for 15 weeks [27]. However, the results of our study differ from those reported by Parastouei et al. (2006), in which 50 patients with type II diabetes and hyperlipidemia received 900 mg/day of garlic (three 300-mg tablets) for six weeks, and no significant reduction in FBS level was observed [28]. One possible explanation for this discrepancy could be the presence of hypercholesterolemia (> 220 mg/dL) among participants in that study, as excessive lipid accumulation may induced insulin resistance through the formation of metabolically toxic products [29].

This study revealed that both SBP and DBP decreased following garlic supplementation. Similarly, Wlosinska et al. (2020) found that in patients with MetS, consuming 100 mg/kg of raw crushed garlic twice daily for four weeks significantly reduced both SBP and DBP [30]. It has been suggested that garlic reduces blood pressure by reducing peripheral vascular resistance through a prostaglandin-like effect. Moreover, γ-glutamyl cysteine—a bioactive compound found in garlic—may help lower blood pressure by inhibiting angiotensin-converting enzyme (ACE). Additionally, allicin can increase the elasticity of blood vessels and decrease blood viscosity, which ultimately leads to a decrease in SBP and DBP [21, 31].

Significant changes in anthropometric indices were observed during the study. The garlic group showed notable reductions in weight, WC, HC, and BMI. However, no significant difference was found between the two trial arms in WHR, which may be influenced by participants' lifestyle factors. In a study by Sangouni et al. (2021) garlic powder supplementation was shown to reduce appetite, and a significant decrease in average calorie intake was reported after three months of supplementation [22]. Similarly, Soleimani et al. (2016) showed that 15 weeks of garlic supplementation in patients with nonalcoholic fatty liver disease (NAFLD) significantly reduced body

weight and fat mass, without causing any significant changes in lean body mass [32].

The anti-inflammatory effects of garlic may be mediated through several potential mechanisms. Previous studies have reported that garlic consumption, or intake of specific garlic-derived compounds, is associated with improved immune function and decreased cytokine production—possibly through increased T-lymphocyte blastogenesis and phagocytic activity. Additionally, garlic compounds have been shown to suppress the NF-κB transcription factor, which plays an important role in regulating the immune responses and the expression of inflammatory cytokine genes [33]. We found that oral administration of 500 mg of garlic twice daily significantly decreased CRP levels in the garlic group over the study period. Similarly, Alami-Harandi et al. (2015) showed that nine weeks of garlic tablet supplementation reduced CRP levels in pregnant women at risk of pre-eclampsia [34].

Acne, hirsutism, obesity, infertility, and hormonal disorders associated with PCOS can lead to emotional distress, which may, in turn, negatively impact mental health, sexual function, and health-related quality of life (HRQoL) in these women [35, 36]. Female sexual performance is a multidimensional phenomenon influenced by various factors, including endocrine disorders, psychological distress, negative body images, obesity, and dermatological issues—all of which can contribute to reduced self-esteem and sexual dysfunction [37]. While sexual performance may be influenced by elevated testosterone activity, the exact role of androgens in arousal and desire remains controversial [38]. SHBG is a carrier protein that binds to androgens and estrogens, thereby regulating their biological activity [39]. Findings from the present study indicate that garlic supplementation may be effective in increasing SHBG levels.

There is limited information in the literature regarding the effectiveness of garlic on QoL and sexual performance. In a study by Shafti and Shahbazi, the QoL and sexual function of Iranian women with PCOS were evaluated. No significant differences were found in FSFI subscale scores compared to healthy women. However, with the exception of the environmental subscale, all QoL domains in the PCOS group were reported to be significantly lower than those of the control group [40].

Moosavian et al. (2020) investigated the effects of garlic supplementation on oxidative stress and QoL in women with rheumatoid arthritis and reported significant improvements in both parameters [41]. In the present study, a significant difference was observed in the MPCOSQ scores and all six domains of the FSFI between the garlic and placebo groups, as well as within the garlic group before and after the intervention. The improvement in FSFI scores may be attributed to garlic's potential to enhance blood circulation, reduce oxidative stress, and modulate inflammatory responses [24]. Moreover, the reduction in components of MetS may have indirectly contributed to improved sexual function and overall well-being.

The main limitations of this study were the short follow-up period and the absence of supplementary hormone tests—such as androstenedione, dehydroepiandrosterone (DHEA), and DHEA sulfate (DHEAS)—due to their high cost. Another limitation was the lack of strict monitoring of participants' dietary intake, physical activity, and medication use. Although participants were advised to maintain their usual diet and activity levels, no systematic tracking was implemented. Additionally, changes in medication use were not actively monitored, which may have influenced the study outcomes.

Conclusions

The findings of this study suggest that garlic supplementation may significantly improve MetS components and PCOS manifestations in PCOS patients with MetS. However, these results should be interpreted as preliminary, and further research with larger sample sizes and longer follow-up periods is warranted to confirm these findings. Moreover, incorporating garlic into daily meals may enhance its accessibility and potential benefits, offering additional health benefits as part of a balanced and nutritious diet. Future research can further explore the long-term effects and practical ways to integrate garlic into everyday routines, while also addressing potential challenges and barriers to its regular use.

Author contributions

Shahideh Jahanian Sadatmahalleh (Sh.JS) and Naiiere Gharagozloo Hesari (N.GH) contributed to the conception and design of the study; N.GH and Sh.JS did the literature search; N.GH, Parvin Mohebbi (P.M), Sh.JS, and Malihe Nasiri (M.N) performed the statistical analysis; N.GH, P.M, Ahmad Khosravi (A.Kh) and Sh.JS wrote the first draft of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

Funding

None.

Data availability

The data used and analyzed are available upon reasonable request of the corresponding author Dr. Shahideh Jahanian Sadatmahalleh (shahideh.jahanian@modares.ac.ir).

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Medical Ethics Committee of Tarbiat Modarres University (Tehran, Iran) in accordance with the Declaration of Helsinki (IR.MODARES.REC.1398.142). All procedures were in accordance with the ethical standards of the regional research committee and with the Declaration of Helsinki (1964) and its later amendments. After a thorough explanation of the study's objectives, written informed consent and verbal assent were obtained from all participants. The women were informed that their participation was voluntary, confidential, and anonymous, and that they had the right to withdraw from the research at any time. We recognize the importance of balancing open science with participant confidentiality.

Although our study obtained informed consent and ensured data anonymization, we acknowledge that enhanced protective measures are increasingly necessary in behavioral and psychiatric research. Future studies could benefit from employing structured frameworks to safeguard privacy when sharing sensitive health data.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 13 March 2025 / Accepted: 20 July 2025
Published online: 06 August 2025

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