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The Effect of Garlic Powder Supplementation on Appetite Control and Cardiometabolic Indices in Patients with Non-Alcoholic Fatty Liver Disease: A Double-Blind Randomized Controlled Clinical Trial

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) has become a serious health care challenge. The authors evaluated the effect of garlic powder supplementation on appetite control and cardiometabolic indices in patients with NAFLD. **Methods:** This double-blind randomized controlled clinical trial was conducted for 12 weeks in ninety patients with NAFLD. The participants were randomly assigned to receive 1600 mg/d garlic powder (treatment group) or 1600 mg/d starch (placebo group). Appetite and cardiometabolic indices such as atherogenic index of plasma (AIP), castelli risk index II (CRI-II), atherogenic coefficient (AC), and cardiometabolic index (CMI) were assessed at baseline, middle and after intervention. **Results:** A total of 88 participants completed the trial. No difference was found between groups in baseline values of appetite parameters, AIP, AC and CMI. Only CRI-II was significantly higher in the treatment group (P=0.01). After intervention, the treatment group compared to the placebo group showed significant improvements in hunger (P<0.001), fullness (P=0.001), desire to eat (P=0.002), ability to eat (P<0.001), AIP (P<0.001), CRI-II (P<0.001), AC (P<0.001), and CMI (P<0.001). **Conclusions:** Garlic improves appetite and cardiometabolic indices.

Introduction

Non-alcoholic fatty liver disease (NAFLD) is defined as a range between hepatic steatosis and non-alcoholic steatohepatitis (NASH) (Han *et al.*, 2023). Hepatic steatosis is characterized by 5% fat accumulation in the liver evidence of inflammation or significant alcohol consumption, while, in NASH, inflammation and hepatocellular damage occur along with liver fat accumulation

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(Han *et al.*, 2023). Recently, a new definition for this disease was suggested as metabolic dysfunction-associated fatty liver disease (MAFLD) (Eslam *et al.*, 2020). This disease is associated with obesity, type 2 diabetes, metabolic syndrome and insulin resistance (Eslam *et al.*, 2020, Han *et al.*, 2023). More than 25% of the global population suffers from NAFLD, and it is increasing worldwide (Younossi *et al.*, 2016). Patients with NAFLD are more likely to develop diabetes due to impaired glucose metabolism (Godoy-Matos *et al.*, 2020). Moreover, abnormal lipid metabolism, obesity, altered gut microbiota and oxidative stress are some important factors that contribute to the occurrence and progression of NAFLD (Godoy-Matos *et al.*, 2020). There is a close relationship between NAFLD and progression of cardiovascular disease (CVD) (Targher *et al.*, 2020). Some indices including atherogenic index of plasma (AIP), castelli risk index II (CRI-II), atherogenic coefficient (AC), and cardiometabolic index (CMI) are used to assess cardiometabolic risk (Fernandez-Macias *et al.*, 2019, Sujatha and Kavitha, 2017, Wakabayashi and Daimon, 2015). Unhealthy dietary patterns are associated with the development of NAFLD (Lv *et al.*, 2023). On the other hand, healthy dietary patterns such as plant-based diets can improve hepatic steatosis, obesity, and also prevent cardiovascular disorders, which is a very important approach for management of NAFLD (Lv *et al.*, 2023, Sangouni *et al.*, 2022).

Garlic (Allium sativum L.), due to its many medicinal properties, helps greatly in reducing blood pressure, improving lipid profile, and regulating glucose metabolism (Zhao *et al.*, 2024). Garlic contains organosulfur compounds such as allicin, ajoene, and diallyl disulfide, which are primarily responsible for its health benefits (De Greef *et al.*, 2021). These compounds have demonstrated a variety of positive effects, particularly on metabolic health, cardiovascular function, and immune modulation (De Greef *et al.*, 2021, El-Saadony *et al.*, 2024). In addition, garlic contains saponins, phenolic and flavonoid compounds, alliin and oil-soluble sulfur compounds (De Greef *et al.*, 2021). Allicin, one of the most studied active compounds, has been shown to reduce oxidative stress and inflammation, which are key contributors to the progression of both NAFLD and CVD (El-Saadony *et al.*, 2024). Other sulfur compounds in garlic, such as diallyl trisulfide, have also been found to improve lipid metabolism and reduce fat accumulation in the liver (El-Saadony *et al.*, 2024). Furthermore, garlic has shown promising effects on promoting weight loss (Ettehad-Marvasti *et al.*, 2022).

To the best of the authors' knowledge, the effects of garlic on appetite and cardiometabolic indices have not been investigated in patients with NAFLD. This study aims to determine the effect of garlic powder supplementation on appetite control and cardiometabolic indices in patients with NAFLD. This research could provide valuable insights into the potential role of garlic supplementation as an adjunctive approach in managing appetite and cardiometabolic risk in patients with NAFLD.

Materials and Methods

Participant selection

Adult patients diagnosed with NAFLD were recruited from a clinical center in Urmia, Iran. Eligibility criteria were being ≥18 years and ultrasound-confirmed hepatic steatosis graded between 1 and 3. Exclusion criteria comprised diabetes mellitus, viral hepatitis, liver malignancies, untreated hypothyroidism, psychiatric or renal disorders, pregnancy, lactation, hypotension, garlic allergy, use of antihypertensive medications, or unwillingness to participate. Following initial screening, 90 eligible individuals were enrolled in the study.

Study design

The study design was completely reported in previous articles (Sangouni *et al.*, 2020a, b). Participants were randomly assigned to either the garlic powder supplementation group (SG) or the placebo group (PG) using a computer-generated sequence. Each garlic tablet contained 400 mg of garlic powder standardized to 1.5 mg allicin (equivalent to ~2 g fresh garlic). According to the

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optimal dose of allicin suggested by Lawson et al. (Lawson and Hunsaker, 2018) participants consumed four tablets daily-two before lunch and two before dinner. Placebo tablets were starch-based and identical in appearance and coating. All participants received general advice on weight management, although no structured dietary or behavioral intervention was implemented. Garlic and placebo tablets were given to participants every three weeks. Participants were instructed to take the tablets one hour before meals to optimize allicin absorption and minimize protein-related interference (Lawson and Hunsaker, 2018). Both types of tablets were manufactured by Amin Pharmaceuticals Co. in Isfahan, Iran. Adherence was monitored at each visit, and participants with <80% compliance were excluded from analysis.

Measurements

Body weight, height, waist circumference (WC), and body mass index (BMI) were measured at baseline, middle and after intervention using standardized equipment. Dietary intake was assessed using a 24-hour food recall questionnaire on three non-consecutive days (including one weekend day) at weeks 0, 6, and 12. Physical activity was also evaluated using the metabolic equivalent of task (MET) questionnaire at the same intervals.

Laboratory tests were performed at weeks 0, 6, and 12 to determine serum concentrations of alanine transaminase (ALT) and aspartate transaminase (AST), as well as lipid profile components including triglycerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-c), and low-density lipoprotein cholesterol (LDL-c). Blood samples were collected after a 12-hour overnight fasting and centrifuged for 10 minutes at 3600 rpm. Then, serum samples were evenly poured into microtubes and immediately stored at −80 °C. All biochemical parameters were measured using routine enzymatic assays with commercial kits (Pars Azmoon, Iran) and analyzed by an autoanalyzer (Siemens, United Kingdom). Moreover, laboratory assessments were conducted in the Nutrition Department laboratory using standard procedures, and the participants and the researchers were blinded during study.

Appetite-related parameters including hunger, fullness, desire to eat, and ability to eat were evaluated using a visual analogue scale (VAS) (Sangouni *et al.*, 2021a) at baseline, week 6, and week 12.

Cardiometabolic risk was assessed using the following indices:

AIP = log (TG/HDL−c) (Fernandez-Macias et al., 2019)

CRI-II = LDL−c/HDL−c (Sangouni et al., 2021b)

AC = (TC−HDL−c)/HDL−c (Sujatha and Kavitha, 2017)

CMI = (TG/HDL-c) × waist to height ratio (WHtR) (Wakabayashi and Daimon, 2015)

Ethical considerations

This 12-week randomized, double-blind, placebo-controlled clinical trial was approved by the Ethics Committee of Urmia University of Medical Sciences and registered at the Iranian Registry of Clinical Trials (IRCT20170206032417N4, https://irct.behdasht.gov.ir/trial/34737).

Data analysis and sample size

Sample size was calculated to be 90 based on values of HDL-c in the study of Ashraf *et al.* (Ashraf *et al.*, 2005) to ensure 95% power with α=0.05, which accounted for a 20% dropout rate. Baseline characteristics were compared using independent samples t-test for continuous variables and chi-square test for categorical variables. To assess appetite-related parameters between the two groups at weeks 0, 6, and 12, independent samples t-test was applied separately at each time point. For cardiometabolic and atherogenic indices, general linear model was used to evaluate differences. Additionally, univariate analysis of covariance (ANCOVA) was performed to compare mean changes between groups, adjusting for changes in energy intake. All statistical analyses were conducted using SPSS version 24, and P-values less than 0.05 were considered statistically significant.

Results

Baseline characteristics of participants

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This was a randomized, controlled clinical trial conducted from August 2018 to March 2019. A total of 90 eligible participants were randomly assigned to either the SG and PG. During the follow-up period, two participants were excluded-one due to surgery and one due to loss to follow-up. Ultimately, 88 participants completed the study (45 in the SG and 43 in the PG, **Figure 1**). At baseline, demographic, anthropometric, physical activity, and dietary intake variables showed no statistically significant differences between the two groups (P>0.05, **Table 1**). No adverse effect related to the intervention was reported throughout the study.

Table 1. Baseline characteristics of patients with NAFLD.

Variable	SG	PG	P-value[c]
Sex			0.08
Male	33 (73.3)[a]	24 (55.8)	
Female	12 (26.7)	19 (44.2)	
Smoking status			0.31
Current smoker	16 (35.6)	11 (25.6)	
Nonsmoker	29 (64.4)	32 (74.4)	
Age (y)	45.2 ± 12.4[b]	44.2 ± 11.1	0.68
Weight (kg)	89.8 ± 11.9	90.0 ± 13.6	0.95
MET (h/d)	28.8 ± 3.8	27.8 ± 3.6	0.23
Energy intake (kcal/d)	2041 ± 123	2034 ± 136	0.80
ALT (iu/l)	30.9 ± 15.7	24.9 ± 15.4	0.07
AST (iu/l)	22.8 ± 11.1	21.2 ± 7.3	0.41
AIP	0.24 ± 0.21	0.20 ± 0.22	0.48
CRI-II	2.81 ± 0.67	2.46 ± 0.65	0.01
AC	3.69 ± 0.97	3.33 ± 1.19	0.12
CMI	1.29 ± 0.69	1.19 ± 0.78	0.88

*[a]: n (%); [b]: Mean± standard deviation; [c]: P-values were computed by independent t-test for continuous variables and by chi-square for categorical variables; **NAFLD**: Non-alcoholic fatty liver disease; **MET**: Metabolic equivalent task hours; **ALT**: Alanine transaminase; **AST**: Aspartate transaminase; **AIP**: Atherogenic index of plasma; **CRI**: Castelli risk index; **AC**: Atherogenic index; **CMI**: cardiometabolic index; **SG**: Supplemnetd group; **PG**: Placebo group.*

Outcome

At baseline, no significant differences were observed between the SG and PG in hunger (58.2±15.1 vs 57.9±13.7; P=0.91), fullness (48.0±12.1 vs 44.8±14.6; P=0.28), desire to eat (−48.0±10.5 vs −47.20±10.0; P=0.72), and ability to eat (55.3±11.5 vs 57.9±12.8; P=0.32, **Table 2**).

After the intervention, the SG compared to the PG showed significant improvements in hunger (mean changes: −10.9±11.6 vs +1.8±11.5; P<0.001), fullness (mean changes: 9.3±10.9 vs 0.0± 12.1; P=0.001), desire to eat (mean changes: −6.0±12.3 vs 1.9±10.0; P=0.002), and ability to eat was (mean changes: −11.5±13.4 vs −0.5±10.6; P<0.001, **Table 2**).

There was no significant difference between groups in baseline values of AIP (0.24±0.21 vs 0.20±0.22; P=0.48), AC (3.69±0.97 vs 3.33±1.19; P=0.12) and CMI (1.21±0.69 vs 1.19±0.78; P=0.01). Only CRI-II showed a significant difference between groups at baseline (2.81±0.67 vs 2.46±0.65; P=0.01, **Table 1**). The SG compared to the PG demonstrated a significant reduction in AIP (mean change: −0.13±0.13 vs 0.03±0.12; P<0.001), CRI-II (mean change: −0.47±0.34 vs 0.01±0.36; P<0.001), AC (mean change: −0.65±0.54 vs 0.14±0.51; P<0.001), and CMI (mean change: −0.32±0.37 vs 0.06±0.31; P<0.001, **Table 3**) after 12 weeks.

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Table 2. Effect of garlic on appetite control.

Variable	SG (n = 45)	PG(n = 43)	P-$_{baseline}$	P-value[b]	P-value[c]	P-value[d]
Change in hunger score						
Baseline	58.2 ± 15.1[a]	57.9 ± 13.7				
Week 6	50.2 ± 13.0	60.0 ± 12.1	0.91	< 0.001	< 0.001	< 0.001
Week 12	47.3 ± 12.8	59.7 ± 10.5				
Mean change	-10.9 ± 11.6	1.8 ± 11.5				
Change in fullness score						
Baseline	48.0 ± 12.1	44.8 ± 14.6				
Week 6	54.2 ± 13.7	44.4 ± 10.5	0.28	< 0.001	< 0.001	0.001
Week 12	57.3 ± 12.3	44.8 ± 10.9				
Mean change	9.3 ± 10.9	0.0 ± 12.1				
Change in desire to eat score						
Baseline	-48.0 ± 10.5	-47.2 ± 10.0				
Week 6	-52.6 ± 11.5	-45.8 ± 8.2	0.72	0.002	< 0.001	0.002
Week 12	-54.0 ± 10.9	-45.3 ± 9.8				
Mean change	-6.0 ± 12.3	1.9 ± 10.0				
Change in ability to eat score						
Baseline	55.3 ± 11.5	57.9 ± 12.8				
Week 6	47.1 ± 10.3	58.1 ± 9.8	0.32	< 0.001	< 0.001	< 0.001
Week 12	43.7 ± 11.7	57.4 ± 8.7				
Mean difference	-11.5 ± 13.4	-0.5 ± 10.6				

*[a]: Mean± standard deviation; [b]: Comparisons between treatment and control groups at week 6; [c]: Comparisons between treatment and control groups at week 12; [d]: Mean change comparisons between groups; **SG**: Supplemnetd group; **PG**: Placebo group.*

Table 3. Effect of garlic on cardiometabolic indices.

Variable	SG (n = 45)	PG (n = 43)	P_{Time}	P_{Group}	$P_{Time\times Group}$	P-value[b]
AIP						
Baseline	0.24 ± 0.21[a]	0.20 ± 0.22				
Week 6	0.16 ± 0.21	0.21 ± 0.21	0.001	0.31	< 0.001	< 0.001
Week 12	0.11 ± 0.20	0.23 ± 0.20				
Mean change	-0.13 ± 0.13	0.03 ± 0.12				
CRI-II						
Baseline	2.81 ± 0.67	2.46 ± 0.65				
Week 6	2.49 ± 0.64	2.45 ± 0.58	< 0.001	0.24	< 0.001	< 0.001
Week 12	2.34 ± 0.57	2.47 ± 0.63				
Mean change	-0.47 ± 0.34	0.01 ± 0.36				
AC						
Baseline	3.69 ± 0.97	3.33 ± 1.19				
Week 6	3.20 ± 0.92	3.40 ± 1.10	0.002	0.68	< 0.001	< 0.001
Week 12	3.04 ± 0.85	3.47 ± 1.12				
Mean change	-0.65 ± 0.54	0.14 ± 0.51				
CMI						
Baseline	1.21 ± 0.69	1.19 ± 0.78				
Week 6	1.03 ± 0.66	1.19 ± 0.72	< 0.001	0.24	< 0.001	< 0.001
Week 12	0.89 ± 0.50	1.25 ± 0.76				
Mean change	-0.32 ± 0.37	0.06 ± 0.31				

*[a]: Mean± standard deviation; [b]: P-values were computed by univariate analysis of covariance (ANCOVA) for parameters after controlling baseline values of indices and mean changes of energy intake; **AIP**: Atherogenic index of plasma; **CRI**: Castelli risk index; **AC**: Atherogenic index; **CMI**: cardiometabolic index; **SG**: Supplemnetd group; **PG**: Placebo group.*

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Discussion

The present study showed that garlic can be effective in management of appetite and cardiometabolic indices. Previously, a clinical trial demonstrated that garlic powder supplementation for 12 weeks improved appetite scores in individuals with metabolic syndrome (Sangouni *et al.*, 2021a). Some animal studies also support the appetite-modulating effects of garlic. In an experimental study, Masjedi (Masjedi *et al.*, 2013) found that garlic extract reduced food intake in streptozotocin-induced diabetic rats. A study conducted on mice provided a high-fat diet and induced type 2 diabetes; it showed decreased energy intake and improved cardiometabolic risk factors such as abnormal lipid metabolism after receiving garlic powder (Islam and Choi, 2008). Cardiometabolic improvement may be due to the beneficial effect of appetite control on cardiometabolic risk factors such as dyslipidemia, obesity, and insulin resistance, in addition to the direct effects of garlic bioactive compounds on metabolic risk factors (Islam and Choi, 2008). However, more studies investigating the relationship between appetite control and cardiometabolic risk are needed to reach a clear vision.

The authors demonstrated the efficacy of 1600 mg/d garlic powder on some cardiometabolic indices. The clinical trials examining the effect of garlic on cardiometabolic indices are scarce. A clinical trial reported that garlic powder improves AIP, AC and CMI in subjects with metabolic syndrome (Sangouni *et al.*, 2023). Furthermore, cardiometabolic indices are based on body composition and lipid profile (Fernandez-Macias *et al.*, 2019, Wakabayashi and Daimon, 2015). Previous studies have suggested the beneficial effects of garlic on metabolic parameters in individuals with chronic conditions. It has been reported that garlic powder intake for 12 weeks reduced triglyceride (TG), total cholesterol (TC), LDL-c, and increased HDL-c in patients with NAFLD (Sangouni *et al.*, 2020a). Another study observed significant decreases in TG and LDL-c levels after garlic intake for 12 weeks in patients with dyslipidemia (Ashraf *et al.*, 2005). Similarly, Kojuri *et al.* (Kojuri *et al.*, 2007) showed that garlic improved lipid profile in individuals with hypercholesterolemia. In a study, a reduction in WC after 12-week garlic supplementation was reported (Sangouni *et al.*, 2020b), which aligns with the present findings. Another clinical trial that was conducted in patients with NAFLD, reported improvement of obesity after 15-week garlic powder supplementation (Soleimani *et al.*, 2016). In line with this study's findings, a systematic review and meta-analysis showed that garlic supplementation significantly improved some cardiovascular risk factors, although the magnitude of effect depended on dosage and intervention duration (Fu *et al.*, 2023).

The potential mechanisms underlying garlic's effects on cardiometabolic indices may be attributed to its bioactive compounds, particularly allicin (El-Saadony *et al.*, 2024, Melguizo-Rodriguez *et al.*, 2022). Allicin exhibits anti-inflammatory, antioxidant, and lipid-regulating properties (Melguizo-Rodriguez *et al.*, 2022). Studies have shown that it may inhibit key enzymes in lipid synthesis, reduce intestinal fat absorption, and enhance cholesterol excretion (El-Saadony *et al.*, 2024, Melguizo-Rodriguez *et al.*, 2022). Garlic reduces intestinal absorption of triglycerides, inhibits gene expressions related to the lipid production, and consequently, attenuates human preadipocyte differentiation and lipid accumulation in differentiated preadipocyte (Joo *et al.*, 2013, Keophiphath *et al.*, 2009). Garlic may also improve insulin resistance and lipid metabolism by increasing adiponectin levels and activating the AMP-activated protein kinase (AMPK) pathway (Melguizo-Rodriguez *et al.*, 2022, Padiya *et al.*, 2011).

The present study is a part of this project. In accordance with ethical principles in research, the authors declare that the effect of garlic powder supplementation on hepatic steatosis, liver enzymes, lipid profile, insulin resistance, oxidative stress, and body composition has previously been reported (Sangouni *et al.*, 2020a, b). To facilitate better understanding and interpretation, some key

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information from previous publications has been incorporated into the present article.

One limitation of this study was the lack of long-term intervention. As another important limitation, lack of mechanistic biomarkers limits causal interpretation. In addition, ultrasonography was used to detect NAFLD (Hernaez *et al.*, 2011). Fibroscan has higher accuracy than ultrasonography in detecting NAFLD (Eddowes *et al.*, 2019).

Conclusion

In conclusion, a 12-week supplementation with garlic powder led to improvements in appetite and cardiometabolic indices among individuals with NAFLD. To establish definitive conclusions, future studies should be rigorously designed to examine the effect of raw, extract, or black garlic.

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Authors' contributions

Sangouni A and Alizadeh M conceived and designed the study; Shokrani S and Nazarpour V analyzed the data; Mohammad Hosseini Azar M provided material and technical support; Shokrani S and Nazarpour V wrote the manuscript; Alizadeh M critically revised the manuscript for important intellectual content and had primary responsibility. All authors reviewed the final manuscript.

Conflict interests

The authors declared no conflict of interests.

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