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Applied nutritional investigation

Vegan versus traditional Mediterranean diet effects on cardiometabolic outcomes in women with fibromyalgia: FIBROVEG study

Paula Marrero-Fernández [a], Ujué Fresán [b], Siobhan Nicaudie [c], Noelia Rodrigo Huecas [a], Muthanna Abusaada [a], Gabriele Bertotti [a,d], Alberto Roldán-Ruiz [a,d], Miguel López-Moreno [a,d,*]

[a] Diet, Planetary Health and Performance, Faculty of Health Sciences, Universidad Francisco de Vitoria, Pozuelo de Alarcón, Spain
[b] IRTA - Institute of Agrifood Research and Technology, Barcelona, Spain
[c] Faculty of Experimental Sciences, Universidad Francisco de Vitoria, Pozuelo, Spain
[d] Institute of Health and Sport Sciences, Faculty of Health Science, Universidad Francisco de Vitoria, Madrid, Spain

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ABSTRACT

Objectives: Fibromyalgia (FM) is associated with adverse cardiometabolic profiles and reduced quality of life. Although plant-based dietary patterns have shown cardiovascular benefits, their effects in FM remain unclear. This randomized, parallel-arm controlled trial evaluated the effect of a vegan Mediterranean diet (VegMedDiet) compared with a traditional Mediterranean diet (MedDiet) on low-density lipoprotein cholesterol (LDL-C) and FM-related outcomes.

Methods: Twenty-two women with FM were assigned to follow either a VegMedDiet (n = 11) or a MedDiet (n = 11) for 6 weeks. Diets were isocaloric and matched for macronutrient distribution.

Results: The primary outcome was change in LDL-C; secondary outcomes included other cardiometabolic markers, body composition, and FM-related symptoms and were considered exploratory. Outcomes were analyzed using linear mixed-effects models accounting for repeated measures. Compared with the MedDiet, the VegMedDiet produced greater reductions in LDL-C (estimated mean difference −21.2 mg/dL; 95% CI: −38.3 to −4.08) and triglycerides (−27.4 mg/dL; 95% CI: −52.1 to −2.73). Additionally, a significantly greater reduction was observed in the FIQ pain item (estimated mean difference −1.88; 95% CI: −2.99 to −0.77; $P = 0.002$).

Conclusion: These findings suggest that a VegMedDiet may contribute to short-term improvements in cardiometabolic risk markers and FM-related symptoms compared with a MedDiet, supporting its potential role as a dietary strategy in individuals with FM.

Introduction

Fibromyalgia (FM) is a chronic pain disorder characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, and cognitive dysfunction involving impairments in attention, memory, and executive function [1]. These symptoms significantly impair patients' quality of life, daily functioning, and overall well-being [2]. The prevalence of this condition is estimated at 1 to 5% of the global population [3], with a female-to-male ratio of 3:1 [4]. While its etiology remains unclear, current research suggests a multifactorial origin involving genetic predisposition, environmental triggers, and neurobiological alterations related to central pain processing and neurotransmitter imbalance [1].

FM has been associated with a higher prevalence of overweight and obesity than in the general population [5]. This is often compounded by reduced physical activity levels, largely attributable to the effects of chronic pain and fatigue [6]. Both obesity and physical inactivity are recognized risk factors for the development of dyslipidemia [7]. Indeed, characteristic lipid alterations, including elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C) and triglycerides (TG), have been reported in patients with FM [8,9]. These cardiometabolic disturbances may further exacerbate the clinical burden of fibromyalgia by contributing to systemic inflammation, vascular dysfunction, and worsening symptom severity.

ADA Randomized Controlled Trial.

*Corresponding author. Miguel López-Moreno, PhD.
E-mail address: miguel.lopez@ufv.es (M. López-Moreno).

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Lifestyle factors, in particular dietary patterns, are key modifiable determinants of cardiovascular health. Different dietary factors, such as the consumption of saturated fat and cholesterol, have been associated with an increased risk of cardiovascular disease, while the intake of fiber, antioxidants, and phytochemicals has been linked to cardiovascular benefits [10]. In particular, plant-based dietary patterns that emphasize the intake of vegetables, fruits, whole grains, legumes, nuts, and seeds, while minimizing or excluding animal products, has been associated with improvements in major cardiovascular risk factors, such as high blood pressure and hypercholesterolemia [11,12]. These effects may contribute to a lower risk of cardiovascular disease [13] as well as reduced cardiovascular mortality and all-cause mortality [14]. The Mediterranean diet, characterized by its rich intake of plant-based foods, olive oil as the primary fat source, moderate consumption of fish and poultry, and limited intake of red meat and processed foods, is recognized for its health benefits, including a significantly reduced risk of cardiovascular disease [15]. Interestingly, the OMNIVEG study reported that a vegan Mediterranean diet, in which all animal-derived foods are replaced with plant-based foods, may provide even greater cardiovascular protection compared to the traditional Mediterranean pattern [16].

Given that FM is associated with an increased risk of cardiovascular disease, adopting plant-based diets may represent a promising dietary approach to manage these comorbidities and potentially improve patients´quality of life. Despite compelling evidence supporting the cardiovascular benefits of plant-based diets, the specific impact of such dietary interventions on both cardiometabolic outcomes and quality of life in patients with FM remains largely unexplored. Therefore, this study aimed to compare the effect of a vegan Mediterranean diet and traditional Mediterranean diet on LDL-C levels in patients with fibromyalgia. Secondary outcomes included other cardiovascular markers, quality of life, and factors related to dietary satisfaction, self-efficacy, and adherence to the dietary intervention.

Material and methods

The FIBROVEG study

The FIBROVEG study was a randomized, parallel-arm controlled trial carried out in Madrid (Spain) between March and April 2025. Participants were randomly assigned to follow either a vegan Mediterranean diet or a traditional Mediterranean diet for 6 weeks. Due to the nature of the dietary intervention, blinding of participants was not feasible; however, outcome assessors and data analysts were independent and blinded to group allocation to minimize detection and analytical bias. Both diets were isocaloric and tailored to individual food preferences, ensuring a comparable distribution of macronutrients across dietary interventions. The diets differed in that animal-based sources of protein and fat were substituted with plant-based alternatives matched for macronutrient content. Assessments were conducted before and after the dietary intervention to evaluate cardiometabolic outcomes, anthropometric characteristics, and quality of life using validated questionnaires (Fig. 1). In addition, questionnaires addressing factors related to dietary satisfaction, self-efficacy, and barriers to adherence were administered at weeks 3 and 6 of the intervention. Participants were asked to maintain their regular physical activity habits throughout the study. To maintain consistency, all assessments were performed in the same laboratory using identical equipment and conducted by the same research personnel.

Participants

The required sample size was determined using G*Power® software (version 3.1.9.7; Heinrich Heine University Düsseldorf, Germany), with calculations based on LDL-C as the primary outcome. The sample size calculation was based on a minimum clinically important difference (MCID) in LDL-C of 0.10 mmol/L, as reported in a previous meta-analysis [17,18]. Sample size estimation was initially based on the expected between-group difference in change in LDL-C from baseline to post-intervention. Assuming an effect size of 0.50, 80% statistical power, and a two-sided alpha level of 0.05, a total of 22 participants were estimated. To account for potential dropouts (10%), the recruitment target was increased to 24 participants. This calculation represented a conservative approach, as the primary analyses used linear mixed-effects models incorporating repeated-measures structure, which typically enhance statistical efficiency by accounting for within-subject correlations.

Participants were recruited through outreach by the Fibromyalgia Patients Association (AFIBROM, Madrid) and social media advertising. Inclusion criteria were as follows: adults aged 18 to 50 years; participants with a clinical diagnosis of fibromyalgia based on the American College of Rheumatology (ACR) criteria; nonsmokers; alcohol intake below one standard drink per day; and stable pharmacological treatment for at least 4 weeks before study commencement; and no use of medications that could affect primary outcome variables, including drugs for weight loss, lipid-lowering agents, or antihypertensive medications. Exclusion criteria included: pregnancy, lactation, or menopausal status; physical limitations preventing participation in functional capacity tests; and the presence of concomitant inflammatory conditions. Participant eligibility was determined through a tailored prescreening questionnaire and evaluation, which encompassed detailed medical history and lifestyle assessment. Prior to enrollment, all potential participants were fully informed of the possible risks and discomforts associated with the research protocol. Written informed consent was then obtained, confirming their voluntary participation in the study. The study protocol was approved by the Ethics Committee of Universidad Francisco de Vitoria (approval number 57/2024), conducted in full accordance with the Declaration of Helsinki (1964) and its subsequent amendments (most recently updated in 2013). The trial was registered at ClinicalTrials.gov (Identifier: NCT06804460).

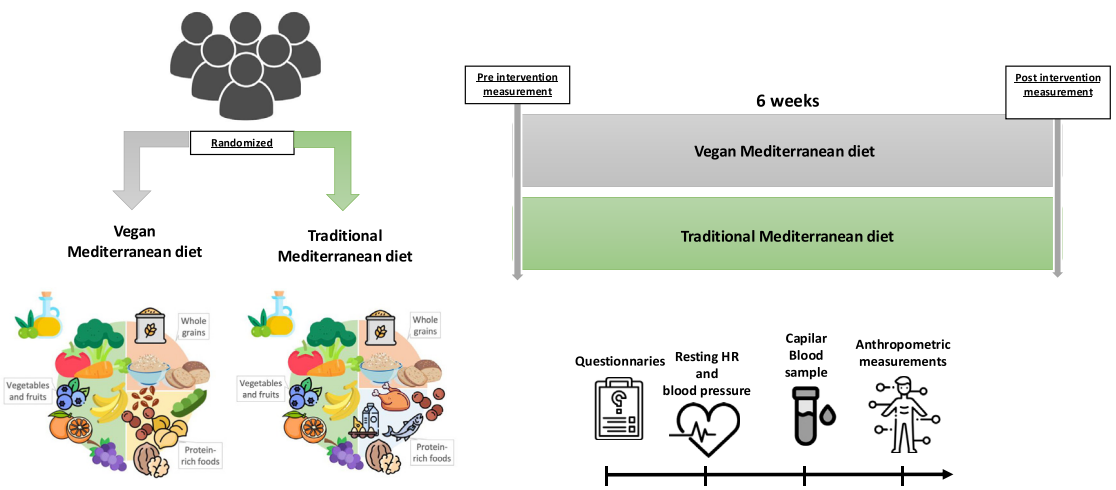

Fig. 1. Experimental design of the study.

Dietary composition of the vegan and traditional Mediterranean diet

Participants were allocated to either the vegan or the traditional Mediterranean diet arm through block randomization. The random allocation sequence was generated by an independent researcher using a web-based randomization tool (Research Randomizer), based on a unique identification code assigned to each participant. Block randomization was used to ensure balanced group sizes. The allocation sequence was concealed from the research staff involved in participant enrollment and outcome assessment until group assignment. The same independent researcher was responsible for implementing the allocation procedure. Before the start of the intervention, participants completed an initial dietary assessment performed by a registered dietitian, which included evaluation of anthropometric characteristics and habitual dietary patterns. Total daily energy expenditure was estimated by calculating basal metabolic rate using the Harris-Benedict equation and applying the corresponding physical activity factor. Based on this information, a normocaloric diet was individually designed for each participant according to their assigned group, defined as an energy intake intended to maintain stable body weight over the intervention period, and ensuring a consistent macronutrient distribution across intervention arms. The traditional Mediterranean diet was planned following established principles, characterized by an abundant intake of whole plant-based foods, moderate to low consumption of fish, poultry, low-fat dairy products, and eggs, minimal consumption of red and processed meats, and the exclusion of sweets [19]. Olive oil was the primary added fat, and animal-derived foods contributed approximately 60% of the total protein intake. The vegan Mediterranean diet was defined as a modification of the traditional Mediterranean dietary pattern in which all animal-derived foods (including meat, fish, dairy, and eggs) were excluded, while preserving its core characteristics, such as a high intake of fruits, vegetables, whole grains, legumes, nuts, and olive oil as the primary source of fat. In this approach, animal-derived foods were displaced by increasing the relative contribution of plant-based foods already inherent to the Mediterranean dietary pattern, particularly legumes and nuts, rather than introducing alternative or novel food products (Table S1). To prevent vitamin B12 deficiency associated with a vegan diet, participants received a supplement of 1000 μg of cyanocobalamin twice weekly throughout the intervention [20].

Participants followed the assigned diet for 6 weeks. Any deviations from the dietary recommendations provided by the dietitian were recorded and analyzed. To monitor dietary intake during the intervention, three 24-hour dietary recalls were completed in weeks 3 and 6 (2 on nonconsecutive weekdays and one on a weekend day). In these recalls, participants reported all foods and beverages consumed, including portion sizes (using weights or household measures), cooking methods, and timing of intake. Additionally, participants were asked to take photographs of their meals to improve the accuracy of dietary data collection. Food consumption data were analyzed using specialized software to quantify energy and nutrient intake (Dietopro, Valencia, Spain) [21]. Adherence to the dietary interventions was assessed using these dietary records, which allowed the quantification of intake across major food groups and the evaluation of participants' compliance with the predefined dietary targets established for each diet (Table S1). Deviations from the prescribed intake of key food groups were used to identify departures from the intended dietary patterns. Deviations were summarized according to under- or overconsumption relative to the predefined intake ranges for food groups within each dietary pattern (Table S1). Adequate adherence was considered when reported intake fell within the predefined intake ranges established for the major food groups of the assigned dietary pattern, as specified in Table S1.Throughout the dietary intervention, participants received continuous support from the research team through weekly individual sessions and ongoing contact to address questions, provide guidance, and promote adherence to the assigned dietary protocol.

Questionnaires

Fibromyalgia impact questionnaire (FIQ)

Perceptions of health status in patients with fibromyalgia was measured using the Spanish validated version of the FIQ, a 10-item self-administered tool [22,23]. The first item includes 10 sub-items (a–j) that evaluate functional ability through daily-life activities (e.g., shopping, driving, doing laundry), each scored on a 4-point Likert scale ranging from 0 (always) to 3 (never). The second and third items assess the number of days per week related to specific symptoms, using numeric rating scales ranging from 1 to 7 and 1 to 5, respectively. The remaining items are rated using 10-point visual analogue scales (VAS), with higher scores indicating greater symptom severity or functional limitation.

To standardize the scoring, the first 3 items were recoded as follows: the score for item one was calculated by summing the 10 sub-items, dividing by the number of completed items, and multiplying the result by 3.33; the second item was reverse-scored and multiplied by 1.43; and the third item was multiplied by 2. The total FIQ score was obtained by summing all item scores after recoding. If any item was left unanswered, the total score was calculated by averaging the completed items. The total score ranges from 0 to 100, with higher scores reflecting worse health status and greater impact of fibromyalgia.

Dietary adherence questionnaires

Diet satisfaction was assessed using the validated 28-item Diet Satisfaction Questionnaire (D-Sat28O), which evaluates participants' perceptions of their dietary experience across several dimensions [24]. This self-administered instrument includes 5 subscales: healthy lifestyle, eating out, cost, preoccupation with food, and planning and preparation. The items were rated on a 5-point Likert scale ranging from 1 ("Disagree Strongly") to 5 ("Agree Strongly"), with higher scores indicating greater diet satisfaction. Two questionnaires previously used in related studies were also administered [25]: one assessing self-efficacy in planning, shopping for, cooking, and selecting meals, and another evaluating perceived barriers to adherence to the study's dietary patterns.

Health and dietary assessment

Before testing, participants were instructed to refrain from vigorous physical activity and to maintain their usual diet and fluid intake according to the recommendations provided by the dietitians for at least 24 hours.

Cardiovascular status

On each measurement day (pre- and postintervention), they arrived at the laboratory following a minimum of 8 hours of fasting. Once compliance with all preassessment standardizations was confirmed, systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured in duplicate using a validated digital sphygmomanometer (Omron, Japan). Mean arterial pressure (MAP) for each participant was calculated using the formula: MAP = DBP + 1/3 (SBP − DBP). Subsequently, a capillary blood sample was collected from the fingertip to measure TC, LDL-C, high-density lipoprotein cholesterol (HDL-C), and TG using a POC multiparameter lux meter (Biochemical Systems International, Italy). The atherogenic index was calculated as the logarithm of the ratio between TG and HDL-C concentrations [26].

Anthropometric measurements

Anthropometric measurements were obtained following standardized procedures described previously [27]. Body mass, fat mass, body fat percentage, visceral fat index, lean mass, and fat-free mass (FFM) were assessed using bioelectrical impedance analysis (Tanita BC-601, Tokyo, Japan), applying the manufacturer's predictive equations. Body mass index (BMI) was subsequently calculated as weight (kg) divided by squared height (m^2).

Statistical analysis

Continuous variables were expressed as mean and standard deviation (SD) for the total sample. The normality of each variable was assessed using the Shapiro–Wilk test. Independent samples Student's t-tests were used to compare baseline characteristics between groups, as well as to evaluate differences in diet satisfaction, self-efficacy, and macronutrient distribution during the dietary intervention. For cardiometabolic outcomes and quality of life, linear mixed-effects models were fitted using restricted maximum likelihood estimation, including fixed effects for diet group, time, and the diet × time interaction, with participant ID included as a subject-specific random intercept to account for within-subject correlation across repeated measurements. Baseline measurements were incorporated within the repeated-measures framework, with baseline defined as the reference category for time. The primary contrast of interest was the group × time interaction, representing differential change between interventions over time. Results were presented as estimated mean differences with standard errors (SE) and 95% confidence intervals (CI). Residual diagnostics were assessed using quantile–quantile plots and residual-versus-fitted plots to evaluate normality and homoscedasticity assumptions. *P* values were obtained from F tests using Satterthwaite approximation for degrees of freedom. Linear mixed-effects models use all available repeated observations and provide valid estimates under a missing-at-random assumption. As a sensitivity analysis, baseline-adjusted ANCOVA models were additionally conducted using postintervention values as outcomes and baseline values as covariates. All secondary outcomes, including cardiometabolic markers, FIQ subdomains, diet satisfaction subscales, self-efficacy items, and perceived barriers, were analyzed as exploratory endpoints.

An exploratory mediation analysis was conducted to examine whether changes in dietary fiber intake could partially explain the association between diet group and LDL-C reduction. Given the limited sample size, this analysis was considered hypothesis-generating rather than confirmatory. Change scores were calculated as postintervention minus baseline values for both LDL-C and dietary fiber intake. The mediator model included diet group as the independent variable and change in dietary fiber intake as the dependent variable. The outcome model included change in LDL-C as the dependent variable and both diet group and change in fiber intake as predictors, additionally adjusting for baseline LDL-C and baseline fiber intake. The indirect effect, quantified as the Average Causal Mediation Effect (ACME), was estimated using a nonparametric bootstrap approach with 5000 resamples. Interpretation of mediation effects assumes temporal ordering between intervention assignment, dietary fiber change, and LDL-C change, as well

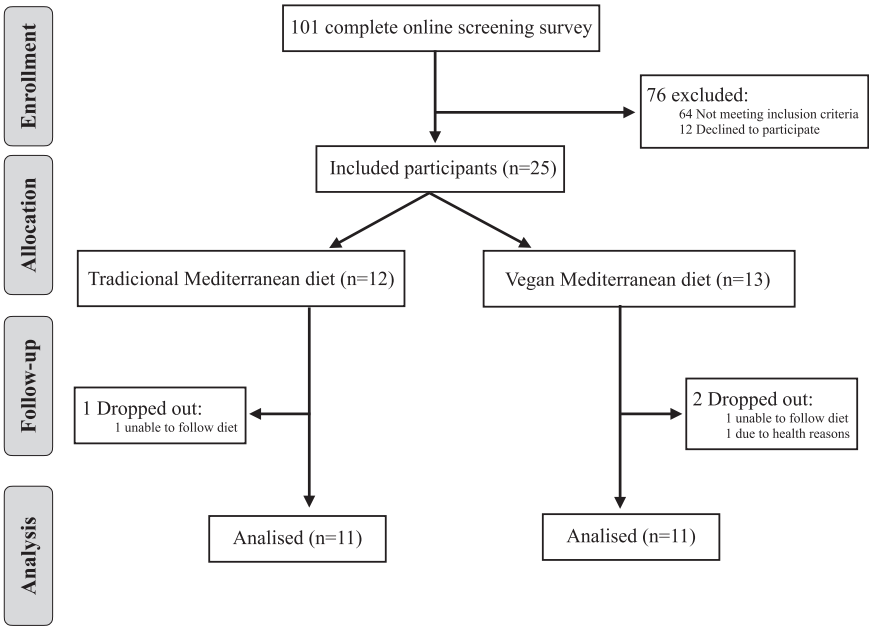

Fig. 2. Flow diagram of participants through the study.

as absence of unmeasured confounding in the mediator–outcome relationship. The significance level was set at $P < 0.05$. Statistical analyses were conducted using R statistical software (version 4.5.2) and RStudio (version 2025.09.2+418).

Results

Participants

Figure 2 depicts the participant flow diagram. One hundred one participants were initially assessed for eligibility. Sixty-four did not meet the inclusion criteria and twelve declined to participate in the study after the initial interview. Twenty-five participants were enrolled and began the intervention protocols: twelve in the Traditional Mediterranean diet group and 13 in the Vegan Mediterranean diet group. One participant withdrew during the traditional Mediterranean diet intervention and one during the vegan Mediterranean diet due to difficulties in adhering to the dietary guidelines. Moreover, one participant assigned to the vegan Mediterranean arm withdrew due to health reasons unrelated to the dietary intervention. Thus, a final sample of 22 participants, eleven per group, completed all research protocols. The mean age of participants was 43.5 years in the vegan Mediterranean diet group and 46.0 years in the traditional Mediterranean diet group. No significant between-group differences were observed in body composition or cardiovascular status at baseline ($P > 0.05$) (Table 1).

Table 1
Baseline characteristics of the study population

	Traditional Mediterranean diet (N = 11)	Vegan Mediterranean diet (N = 11)	*P* value
Age, y	46.0 (5.5)	43.5 (9.6)	0.48
Height, m	1.65 (0.6)	1.61 (0.07)	0.23
Weight, kg	68.3 (13.7)	64.9 (12.3)	0.55
BMI, kg/m^2	25.1 (4.8)	25.1 (4.9)	0.42
Fat, %	34.2 (6.3)	35.3 (4.0)	0.65
Fat mass, kg	24.1 (9.8)	23.2 (6.6)	0.80
Visceral fat	6.15 (2.3)	5.9 (2.1)	0.80
Lean mass, kg	41.9 (4.2)	39.6 (6.0)	0.31
HR, bpm	76.3 (11.9)	80.18 (9.1)	0.41
SBP, mm Hg	126.4 (9.1)	123.2 (13.9)	0.54
DBP, mm Hg	82.0 (5.2)	81.54 (10.2)	0.90
MAP, mm Hg	96.6 (5.9)	95.3 (10.9)	0.74
TG, mg/dL	119.0 (34.2)	123.5 (84.4)	0.67
TC, mg/dL	169.3 (32.1)	160.1 (43.5)	0.59
HDL-C, mg/dL	63.5 (25.6)	53.9 (19.2)	0.34
LDL-C, mg/dL	93.4 (13.7)	93.6 (18.7)	0.97
Atherogenic-index	2.36 (1.1)	2.41 (0.8)	0.90

Data are presented as means (standard deviation).
HR, heart rate; SBP, systolic blood pressure; DBP, diastolicblood pressure; MAP, mean arterial pressure; TG, triglycerides; TC, total cholesterol; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

Dietary assessments

Regarding food group intake, participants following the vegan Mediterranean diet reported significantly higher consumption of cereals, nuts, seeds, legumes, plant-based dairy alternatives, and plant-based meat alternatives ($P < 0.05$). No significant differences were observed between dietary interventions for the intake of other plant-based food groups (Table 2). Both interventions complied with the targeted dietary recommendations for total energy intake and macronutrient distribution. No differences in carbohydrate, protein, or dietary fat intakes were observed between the groups ($P > 0.05$). During the vegan Mediterranean diet, participants consumed more fiber at both week 3 ($P < 0.001$) and week 6 ($P = 0.001$) compared to the traditional Mediterranean diet (Table 2). Overall, reported intake patterns were consistent with the predefined dietary targets of each intervention, supporting adherence to the assigned dietary protocols.

Anthropometrics measurements

Table 3 presents the data on anthropometric variables after the dietary interventions. No significant changes were observed in within-group comparisons (pre- versus postintervention) for either the traditional or the vegan Mediterranean diet ($P > 0.05$).

Table 2
Macronutrient and servings intake distribution by week and diet

	Traditional Mediterranean diet		Vegan Mediterranean diet			
	Week 3	Week 6	Week 3	Week 6	Group*Week 3	Group*Week 6
Food groups						
Fruit (*s/day*)	1.5 (0.3)	1.3 (0.2)	1.6 (0.6)	1.5 (0.8)	0.63	0.40
Vegetables (*s/day*)	2.4 (0.7)	2.5 (0.5)	2.6 (0.5)	2.7 (0.6)	0.45	0.41
Cereals (*s/day*)*	1.3 (0.2)	1.1 (0.2)	2.2 (0.3)	2.5 (0.4)	<0.001	<0.001
Olive oil (*s/day*)	3.8 (0.3)	3.5 (0.5)	3.7 (0.7)	3.4 (0.4)	0.26	0.61
Olives/Nuts/Seeds (*s/day*)	1.5 (0.3)	1.2 (0.4)	1.9 (0.1)	2.2 (0.2)	<0.001	<0.001
Dairy products (*s/day*)†	1.9 (0.6)	1.6 (0.6)	-	-	<0.001	<0.001
PBMD (*s/day*)	0.3 (0.1)	0.5 (0.2)	1.6 (0.1)	1.4 (0.3)	<0.001	<0.001
Legumes (*s/week*)	2 (0.5)	1.9 (0.3)	6.7 (1.7)	6.3 (1.5)	<0.001	<0.001
Eggs (*s/week*)	2.2 (0.3)	2.5 (0.8)	-	-	<0.001	<0.001
Fish/seafood (*s/week*)	2.7 (0.4)	2.4 (0.6)	-	-	<0.001	<0.001
White meat (*s/week*)[c]	2.1 (0.7)	2.3 (0.9)	-	-	<0.001	<0.001
Red meat (*s/week*)‡	0.7 (0.2)	0.9 (0.1)	-	-	<0.001	<0.001
Processed meat (*s/week*)	0.9 (0.5)	1.1 (0.7)	-	-	<0.001	<0.001
PBMA (*s/week*)	-	-	1.0 (0.5)	1.3 (0.8)	<0.001	<0.001
Potatoes (*s/week*)	2.1 (0.2)	2.3 (0.3)	2.1 (0.3)	2.6 (0.6)	0.99	0.15
Sweets (*s/week*)§	1.0 (0.2)	1.2 (0.2)	1.0 (0.1)	1.1 (0.4)	0.99	0.47
Energy and nutrients						
Energy, kcal	1915.4 (512.9)	1987.6 (514.2)	1893.3 (214.7)	1940.1 (176)	0.91	0.81
HC, g	219.8 (95.6)	213.0 (35.5)	232.4 (34.9)	233.7 (39.5)	0.72	0.79
HC, %	48.7 (15.2)	49.9 (15.7)	49 (5.1)	48.2 (6.5)	0.97	0.34
Protein, g	74.7 (25.4)	77.4 (26.8)	68 (14.9)	69.9 (13.6)	0.50	0.45
Protein, %	20.1 (11.2)	17.4 (7.7)	14.5 (2.6)	14.5 (2.5)	0.14	0.34
Protein, g/kg/day	1.3 (0.5)	1.3 (0.5)	1.1 (0.6)	1.1 (0.3)	0.36	0.43
Fat, g	64 (8.6)	71.9 (6.8)	73.4 (14.9)	76.6 (18.9)	0.12	0.48
Fat, %	31.9 (7.1)	32.4 (7.9)	35 (5.8)	36.6 (8.8)	0.31	0.31
Fiber, g	23.8 (4.4)	26 (3.9)	42.2 (8.2)	39.8 (9.4)	<0.001	0.001

All values are means (standard deviations). Weekly dietary data were based on the average of 3 unannounced 24-hour dietary recalls.
*Bread, pasta, couscous, other cereals (preferably whole grain) and pseudocereals (quinoa, amaranth or buckwheat).
†Milk, yoghurt, cheese, ice-cream (preferably low fat).
‡Chicken, turkey or rabbit [d] Pork, beef, veal, lamb, mutton or goat.
§Sugar, candies, pastries, sweetened fruit juices and soft drinks.PBMA, plant based meat alternatives; PBDA, plant based dairy alternatives; S, servings.

Likewise, no significant differences were found between the two dietary interventions ($P > 0.05$).

Cardiovascular health

Table 4 presents the cardiometabolic health variables after the traditional Mediterranean diet and the vegan Mediterranean diet. The primary outcome analysis showed that participants receiving the vegan Mediterranean diet had a greater reduction in LDL-C compared with those receiving the traditional Mediterranean diet, with an estimated mean difference of −21.2 mg/dL (95% CI, −38.3 to −4.08 mg/dL) at 6 weeks relative to baseline, as derived from the linear mixed-effects model (Fig. 3). Additionally, the vegan Mediterranean diet resulted in a greater reduction in triglycerides (estimated mean difference −27.4 mg/dL; 95% CI, −52.1 to −2.73 mg/dL) compared with the traditional Mediterranean diet. Sensitivity analyses using baseline-adjusted ANCOVA models yielded results consistent with the primary linear mixed-effects analyses. Between-group differences remained significant for LDL-C and triglycerides, with comparable effect estimates and directionality (Table S2). Exploratory mediation analysis was consistent with a possible indirect pathway of dietary fiber on LDL-C changes (ACME = −21.8 mg/dL; 95% CI: −40.6 to −1.0; $P = 0.037$).

Fibromyalgia impact questionnaire

Table 5 shows the results for the FIQ items and total score. A significantly greater reduction was observed in the pain item in the vegan Mediterranean diet compared with the traditional Mediterranean diet (estimated mean difference −1.88; 95% CI: −2.99 to −0.77; $P = 0.002$). No significant between-group differences were found for the remaining FIQ items or for the total FIQ score. Sensitivity analyses adjusted for baseline values produced similar

Table 3
Anthropometric characteristics of the participants following the dietary intervention

	Traditional Mediterranean diet			Vegan Mediterranean diet				
	Pre	Post	*P* value	Pre	Post	*P* value	Time*Group	η^2p
Weight, kg	68.3 (13.7)	67.1 (14.5)	0.06	64.9 (12.3)	64.3 (11.1)	0.43	0.52	0.02
BMI	25.1 (4.8)	24.6 (5.3)	0.07	25.1 (4.9)	24.2 (3.0)	0.26	0.34	0.05
Fat, %	34.2 (6.3)	33.3 (7.0)	0.14	35.3 (4.0)	35.6 (4.3)	0.51	0.49	0.03
Fat mass, kg	24.1 (9.8)	24.7 (10.7)	0.73	23.2 (6.6)	23.1 (6.2)	0.84	0.69	0.09
Visceral fat	6.15 (2.3)	5.8 (2.4)	0.06	5.9 (2.1)	5.5 (1.9)	0.16	0.82	0.003
Lean mass, kg	41.9 (4.2)	41.7 (4.4)	0.35	39.6 (6.0)	39.1 (5.5)	0.35	0.73	0.01
Bone tissue, kg	2.3 (0.2)	2.2 (0.2)	0.17	2.1 (0.3)	2.1 (0.1)	0.89	0.67	0.01

Data are presented as means (standard deviation).
BMI, Body Mass Index.

Table 4
Cardiometabolic health variables after traditional mediterranean diet and vegan mediterranean diet

	Vegan Mediterranean diet		Traditional Mediterranean diet			
	Pre	Post	Pre	Post	Difference estimate (SE) [95% CI]	*P* value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Primary outcome						
LDL-C, mg/dL	93.6 (18.7)	69.6 (10.4)	93.4 (13.7)	90.6 (6.7)	−21.2 (8.18) [−38.3 to −4.08]	0.018
Secondary outcome						
TC, mg/dL	160.1 (43.5)	135.7 (43.4)	169.3 (32.1)	157.2 (14.5)	−12.3 (11.7) [−36.7 to 12.1]	0.306
HDL-C, mg/dL	53.9 (19.2)	58.0 (13.5)	63.5 (25.6)	64.3 (22.1)	3.29 (10.2) [−18.1 to 24.6]	0.751
TG, mg/dL	123.5 (84.4)	100.7 (64.4)	119.0 (34.2)	107.6 (32.9)	−27.4 (11.8) [−52.1 to −2.73]	0.031
Atherogenic-index	2.41 (0.8)	1.53 (0.44)	2.36 (1.1)	2.0 (1.1)	−0.51 (0.44) [−1.44 to 0.42]	0.262
HR, bpm	80.18 (9.1)	75.18 (9.7)	76.3 (11.9)	81.1 (12.8)	−9.8 (5.02) [−20.3 to 0.71]	0.065
SBP, mm Hg	123.2 (13.9)	119.1 (6.4)	126.4 (9.1)	119.1 (9.6)	2.51 (4.82) [−7.57 to 12.6]	0.608
DBP, mm Hg	81.54 (10.2)	77.6 (5.2)	82.0 (5.2)	80.8 (7.1)	−2.71 (4.03) [−11.1 to 5.73]	0.509
MAP, mm Hg	95.3 (10.9)	91.2 (5.3)	96.6 (5.9)	93.5 (7.5)	−0.99 (3.83) [−9.01 to 7.03]	0.798

Data are presented as means (standard deviation) for descriptive values. Between-group differences represent model-derived estimated mean differences with standard errors (SE) and 95% confidence intervals (CI), obtained from linear mixed-effects models including fixed effects for diet group and time (baseline as the reference level), with a diet × time interaction term and the traditional Mediterranean diet as the reference group.
HR, heart rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial pressure; TG, triglycerides; TC, total cholesterol; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

findings, with pain remaining the only FIQ domain showing a significant between-group difference (Table S3).

Dietary adherence outcomes

Diet satisfaction, as measured by the D-Sat28O, was significantly lower with the vegan Mediterranean diet than with the traditional Mediterranean diet at both week 3 ($P = 0.04$) and week 6 ($P = 0.04$) (Table S4). No differences were observed in self-efficacy to plan, shop, cook, and choose meals across diet assignments or study phases (Table S5). Regarding barriers to dietary adherence, the most frequently reported barriers during the traditional Mediterranean diet were a busy lifestyle (60% of participants) and the time required to prepare meals (40%). For the vegan Mediterranean diet, the main barriers were willpower or self-control (60%) and the price of foods required to follow the eating pattern (60%) (Table S6).

Discussion

To our knowledge, this is the first randomized controlled trial comparing a vegan Mediterranean diet with a traditional Mediterranean diet in women with fibromyalgia, providing novel evidence on both cardiometabolic and symptom-related responses to these dietary patterns. The findings suggest that the vegan Mediterranean diet led to greater improvements in LDL-C together with reductions in TG and certain FM-related symptoms, despite being associated with lower satisfaction and higher perceived barriers. These findings should be interpreted as short-term changes in cardiometabolic biomarkers rather than evidence of long-term cardiovascular risk reduction.

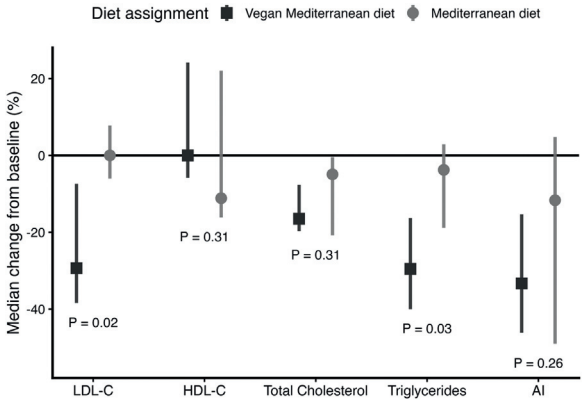

Fig. 3. Median percentage change in primary and secondary outcomes comparing vegan Mediterranean and traditional Mediterranean diets. For primary and secondary outcomes, median percent change with interquartile range and P values are presented. *P* values were obtained from F tests of the diet × time interaction using Satterthwaite's approximation. from linear mixed models. AI, Atherogenic index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

Reductions in TG and LDL-C were observed among participants following the vegan Mediterranean diet, but not in those assigned to the traditional Mediterranean diet arm. These findings are consistent with prior research highlighting the cardiovascular benefits of vegetarian diets in FM patients [28,29]. However, one of these studies lacked a control group [29], while the other was nonrandomized [28], which limits the strength of the conclusions that can be drawn regarding the effects of vegetarian diets. Previous studies have compared the effects of vegetarian diets and traditional Mediterranean diets on cardiovascular risk factors. In the OMNIVEG study, a significant reduction in TC (−22.6 mg/dL) and LDL-C (−12.8 mg/dL) was observed just 4 weeks after participants shifted from a traditional to a vegan Mediterranean diet [16]. Compared to the present study, the reduction in total cholesterol (−21.5 mg/dL) was similar; however, the decrease in LDL-C (−21 mg/dL) was greater in this study. The OMNIVEG study was conducted in healthy men with lower baseline levels of TC and LDL-C and a shorter intervention duration, which may partly explain the larger reduction observed in this study population. The benefits observed in these studies when following the vegan Mediterranean diet could be attributed to the higher consumption of legumes and nuts, which are known to positively influence lipid profile [30]. However, the OMNIVEG study did not report differences in TG levels between groups. In this sense, the CARDIVEG study, a randomized controlled clinical trial conducted in individuals at cardiovascular risk comparing a low-calorie ovo-lacto-vegetarian diet and a Mediterranean diet, reported a greater reduction in LDL-C (−9.10 mg/dL) with the vegetarian pattern. However, and in contrast to our findings, the traditional Mediterranean diet in CARDIVEG led to a greater reduction in TG levels than the ovo-lacto-vegetarian diet [31]. The discrepancy could be partly explained by the inclusion of dairy products and eggs in the vegetarian diet used in CARDIVEG, which may have resulted in a lower intake of legumes and nuts, both of which have been shown to exert beneficial effects on TG levels [32,33].

Table 5
FIQ items and total score of the participants following the dietary intervention

	Vegan Mediterranean diet		Traditional Mediterranean diet			
	Pre Mean (SD)	Post Mean (SD)	Pre Mean (SD)	Post Mean (SD)	Difference estimate (SE) [95% CI]	*P* value
Physical functioning	5.8 (1.9)	5.5 (2.2)	4.8 (1.9)	4.0 (1.8)	−0.50 (0.81) [−2.19 to 1.2]	0.547
Absence work	4.7 (4.2)	5.5 (3.8)	4.4 (3.8)	4.5 (3.6)	−0.77 (2.38) [−5.75 to 4.2]	0.749
Days felt good	8.9 (1.3)	8.7 (1.7)	7.7 (2.3)	6.9 (2.9)	−0.57 (1.14) [−2.96 to 1.82]	0.625
Pain influencing work	8.5 (1.3)	8.1 (1.8)	7.5 (1.6)	7.3 (1.5)	0.16 (0.53) [−0.95 to 1.28]	0.762
Pain	8.5 (1.0)	7.3 (1.5)	7.0 (1.7)	7.7 (1.2)	−1.88 (0.58) [−2.99 to −0.77]	0.002
Fatigue	8.9 (1.6)	8.0 (2.5)	8.6 (1.8)	8.1 (1.7)	0.41 (0.63) [−0.91 to 1.73]	0.523
Morning tiredness	6.9 (2.7)	5.9 (3.4)	4.7 (3.5)	4.2 (3.3)	−0.46 (1.57) [−3.75 to 2.84]	0.776
Stiffness	8.1 (1.2)	8.2 (1.6)	7.9 (2.0)	8.8 (1.4)	0.81 (0.58) [−0.41 to 2.03]	0.181
Anxiety	8.0 (2.5)	7.1 (2.6)	7.8 (1.4)	6.6 (2.7)	−0.29 (0.78) [-1.92 to 1.34]	0.713
Depression	7.6 (1.7)	6.6 (2.7)	6.8 (1.8)	4.8 (3.0)	−0.97 (0.97) [−3.03 to 1.03]	0.316
Total Score	73.7 (5.9)	69.2 (11.2)	69.4 (10.9)	64.5 (10.9)	−0.36 (5.17) [−11.2 to 10.5]	0.945

Data are presented as means (standard deviation) for descriptive values. Between-group differences represent model-derived estimated mean differences with standard errors (SE) and 95% confidence intervals (CI), obtained from linear mixed-effects models including fixed effects for diet group and time (baseline as the reference level), with a diet × time interaction term and the traditional Mediterranean diet as the reference group.
FIQ, fibromyalgia impact questionnaire.

In the present study, the magnitude of LDL-C reduction observed with the vegan Mediterranean diet exceeded the previously established MCID of 0.10 mmol/L [17,18]. Although the observed pre−post changes occurred within conventional "normal" lipid ranges, evidence suggests that optimal LDL-C concentrations are substantially lower than current clinical thresholds, and that additional reductions below these levels are associated with incremental cardiovascular risk reduction [34,35]. Moreover, improvements in lipid parameters with the vegan Mediterranean diet occurred under isoenergetic conditions and without reported changes in body composition, suggesting that these benefits may extend beyond those induced by changes in body mass. Although reductions in LDL-C are generally considered favorable from a cardiovascular perspective, the present study was not designed to assess long-term cardiovascular outcomes. Therefore, these findings should be interpreted as short-term biomarker responses rather than evidence of reduced cardiovascular event risk. The study by Barnard et al. (2022) showed that a low-fat vegan diet induced a greater reduction in both LDL-C and TG compared to a Mediterranean diet [36]. However, participants in the vegan group also experienced a greater reduction in body weight. This is particularly relevant, as it is well established that even modest weight loss can lead to significant decreases in TC, LDL-C, and TG levels [37]. Therefore, the cardiometabolic benefits observed with adopting a Mediterranean or vegan diet may be more closely related to body mass loss rather than to the intrinsic effects of differences in the food composition of each diet [12]. Since no significant changes in energy intake or body composition were observed in our study, the benefits reported with the vegan Mediterranean diet may be attributable to the greater presence of whole plant-based foods characteristic of the vegan Mediterranean pattern. While LDL-C is a well-established surrogate marker of cardiovascular risk, short-term improvements in lipid concentrations do not necessarily translate into sustained reductions in cardiovascular morbidity or mortality, particularly in small trials of limited duration.

Notably, fiber intake was significantly higher during the vegan Mediterranean phase and may partially mediate the reductions in LDL-C, supporting previous evidence on the lipid-lowering effects of dietary fiber. Several mechanisms may account for this association [38]. Dietary fiber—particularly soluble fiber—increases intestinal viscosity and reduces the reabsorption of bile acids, thereby promoting their excretion [39]. Additionally, soluble fiber slows the gastric emptying rate and reduces the absorption of dietary cholesterol, which may further contribute to reductions in circulating LDL-c levels [40]. Furthermore, fermentable fibers are metabolized by gut microbiota in the colon, resulting in the production of short-chain fatty acids (SCFAs), such as acetate and propionate. These SCFAs have been shown to modulate key metabolic pathways, including hepatic cholesterol synthesis, fatty acid synthesis, and fatty acid oxidation, which may contribute to the observed improvements in the lipid profile [41,42]. Although exploratory mediation analysis suggested that dietary fiber may partially contribute to LDL-C reductions, this finding should be interpreted cautiously and not considered evidence of causality, particularly given the exploratory design and limited sample size. Mediation models rely on assumptions regarding temporal ordering and absence of unmeasured confounding between mediator and outcome, which cannot be fully verified in a small dietary intervention trial. Therefore, these results should be viewed as hypothesis-generating and require confirmation in larger studies specifically powered for mediation analyses.

Although the vegan Mediterranean diet did not result in a greater reduction in the total FIQ score compared to the traditional Mediterranean diet, it was associated with a significant improvement in pain scores, one of the core symptoms of FM. The significant reduction observed in the FIQ pain item should be interpreted with caution, as the total FIQ score did not show significant differences and no adjustment for multiple comparisons was applied. The existing literature on the effects of fully plant-based diets on symptomatology and quality of life in individuals with FM remains scarce. A previous observational study reported significant improvements in FIQ scores after 7 months of following a raw vegan diet [43]. The longer duration of that study, compared to the 6 weeks of the present clinical trial, may partly account for the less pronounced effects observed. Regarding pain perception, other studies evaluating vegan diets in patients with FM have also reported improvements measured by a visual analogue scale of pain [28,44]. In one of these studies, participants self-selected into either the intervention or control group, introducing a potential source of selection bias that limits the internal validity of the findings [28]. The potential beneficial effects of a vegan Mediterranean diet on pain perception in FM may be through multiple mechanisms, including reductions in systemic inflammation, improvements in endothelial function [45,46], and enhanced antioxidant capacity [47]. Interestingly, some previous studies reporting pain improvements in patients with FM also noted an increased intake of lignans [44]. This class of phytoestrogens has gained attention in the context of disorders related to oxidative stress and

inflammation, both key factors in the pathophysiology of chronic pain [48,49]. Although the magnitude of change observed in the FIQ pain item should be interpreted cautiously given the exploratory nature of the analysis and the absence of significant changes in total FIQ score, pain represents one of the core and most burdensome symptoms of fibromyalgia. Therefore, even modest improvements in pain perception may be clinically meaningful from a patient-centered perspective and warrant further investigation in larger and longer-term trials.

Despite the physiological benefits, participants reported lower diet satisfaction with the vegan Mediterranean diet at both weeks 3 and 6. Similarly, a previous study also reported lower satisfaction with a vegan diet compared to an omnivorous diet, although that analysis was descriptive and did not assess statistical differences between groups [25]. No differences were observed in dietary self-efficacy, suggesting that both dietary interventions were perceived as similarly feasible. However, specific barriers differed: the traditional Mediterranean diet was primarily limited by time constraints and busy lifestyles, whereas the vegan version was hindered by perceived lack of willpower and the cost of foods associated with maintaining the dietary pattern. These findings are consistent with a recent systematic review, which identified "powerlessness over food choices" as a recurring barrier to adopting plant-based diets [50]. This barrier was described not only as a lack of knowledge but also as an emotional state characterized by feeling overwhelmed, lacking control, or facing limited options, which are factors that may hinder behavior change regardless of actual nutritional knowledge. It is important to consider that participants' habitual diets were omnivorous, implying that the traditional Mediterranean diet constituted a smaller deviation from their usual eating patterns compared to the vegan Mediterranean diet. Therefore, the lower satisfaction observed with the vegan Mediterranean diet may reflect challenges related to dietary transition, including unfamiliarity with foods, habits, and meal preparation, rather than inherent limitations of the dietary pattern itself. This difference may partly account for the lower satisfaction and higher perceived barriers associated with the vegan diet. Future long-term studies are warranted to determine whether these perceptions change once participants have experienced the potential health benefits of adopting a vegan Mediterranean dietary pattern. With regard to cost, this concern has been consistently reported in previous studies evaluating adherence to plant-based diets [51,52]. Nevertheless, despite the recurring perception of higher costs, previous analyses have reported that a whole-food vegan diet may be up to 25% less expensive than a traditional Mediterranean diet, highlighting a potential gap between perceived and actual affordability [53]. These findings underscore the importance of not only enhancing individual knowledge but also fostering supportive environments and implementing public policies that facilitate the adoption of healthy plant-based diets.

This study presents several strengths. The randomized design enhances the internal validity of the findings. Participants received individualized dietary counselling and weekly follow-up, which likely contributed to the high adherence observed throughout the intervention. Furthermore, the two dietary patterns were carefully controlled for total energy and macronutrient composition, allowing for a more specific assessment of the effects attributable to dietary source and quality. However, several limitations should be acknowledged. Although the sample size was adequately powered for the primary outcome (LDL-C), it may have been insufficient to detect smaller between-group differences in secondary outcomes, particularly patient-reported measures. The relatively short duration of the intervention (6 weeks) may have been sufficient to detect changes in cardiometabolic markers, but could be insufficient to observe more stable or long-term effects on fibromyalgia-related outcomes. Therefore, the present findings should be interpreted as reflecting short-term metabolic responses rather than long-term clinical outcomes, which may partly explain the absence of significant changes in anthropometric variables and total FIQ score. Longer-term interventions are warranted to determine whether the observed changes in pain and other FM-related symptoms are sustained over time. In addition, participants were recruited through a patient association and social media outreach, which may have introduced selection bias. Individuals volunteering for a dietary intervention study may be more motivated to adopt healthier behaviors. The study included only women with fibromyalgia aged 18 to 50 years. Therefore, these results should not be extrapolated to men, older adults, or individuals without fibromyalgia. Measures of dietary intake were based on self-reported 24-hour recalls complemented with meal photographs, which may be subject to recall bias, reporting bias, and underreporting. Although these methods are commonly used in nutritional research, the absence of objective biomarkers of dietary adherence (e.g., plasma carotenoids, fatty acid profiles, or urinary markers) may limit the precision in assessing compliance with the assigned dietary patterns. In addition, dietary fiber was assessed as total intake, without distinguishing between soluble and insoluble fractions, which may have different effects on lipid metabolism. The exploratory mediation analysis was conducted in a relatively small sample and may therefore be susceptible to unstable estimates and limited statistical power. Measures of dietary satisfaction and perceived barriers were self-reported and thus may be influenced by recall bias or social desirability bias. Although participants were instructed to maintain their habitual physical activity levels, this variable was not objectively measured, and potential changes in physical activity, sleep, or medication adherence may have influenced the observed outcomes. Finally, although improvements in pain were observed, no objective biomarkers of inflammation or pain were assessed, which limits the ability to elucidate underlying mechanisms.

Conclusion

These findings suggest that a vegan Mediterranean diet may contribute to short-term improvements in LDL-C and selected fibromyalgia-related outcomes under controlled isoenergetic conditions. Moreover, lower acceptability and higher perceived barriers underscore the need for supportive strategies to improve adherence and long-term effectiveness. However, these findings should be interpreted cautiously, particularly in light of the limited sample size and short-term nature of the intervention. Larger and longer randomized trials are needed to confirm these findings and determine their long-term clinical relevance.

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Informed consent

Written informed consent was then obtained, confirming their voluntary participation in the study. The study protocol was approved by the Ethics Committee of Universidad Francisco de Vitoria (approval number 57/2024).

Declaration of competing interest

Miguel López-Moreno reports a relationship with Danone SA that includes: board membership and consulting or advisory. Miguel López-Moreno reports a relationship with Foods For Tomorrow S.L. that includes: consulting or advisory. These activities were unrelated to the submitted work and are not ongoing. At present, he has no active financial relationships with these entities. All the other authors, declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Paula Marrero-Fernández: Writing – original draft, Investigation. **Ujué Fresán:** Writing – review & editing. **Siobhan Nicaudie:** Methodology, Investigation, Formal analysis, Conceptualization. **Noelia Rodrigo Huecas:** Investigation. **Muthanna Abusaada:** Investigation. **Gabriele Bertotti:** Investigation. **Alberto Roldán-Ruiz:** Investigation. **Miguel López-Moreno:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.nut.2026.113303.

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