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## Mediterranean Diet and Patients With Psoriasis

The MEDIPSO Randomized Clinical Trial

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See "[Mediterranean Diet May Offer Psoriasis Benefits](#)." in *JAMA*, 10.1001/jama.2025.17495.

## Key Points

### Question

Does a Mediterranean diet intervention improve psoriasis severity in patients with mild to moderate disease?

### Findings

In this randomized clinical trial of 38 adults with mild to moderate psoriasis, a 16-week intensive Mediterranean diet intervention led to a significant reduction in the Psoriasis Area and Severity Index compared with a control group receiving low-fat dietary advice.

### Meaning

These findings suggest that a Mediterranean diet may be an effective adjunctive therapeutic strategy to improve skin outcomes in patients with mild to moderate psoriasis.

This randomized clinical trial assesses whether a 16-week Mediterranean diet intervention improves psoriasis severity in adult patients with mild to moderate disease.

## Abstract

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### Importance

Despite growing interest on the role of diet in the prevention and treatment of psoriasis, randomized clinical trials are lacking. The Mediterranean diet is known for its anti-inflammatory and cardiometabolic benefits, which may be relevant to psoriasis pathophysiology.

### Objective

To assess whether a 16-week Mediterranean diet intervention would improve psoriasis severity in patients with mild to moderate disease.

### Design, Setting, and Participants

MEDIPSO (Impact of the Mediterranean Diet on Patients With Psoriasis), an open-label, single-center, single-blinded (evaluator) randomized clinical trial, was conducted from February 2024 to March 2025 at a dermatology referral clinic in Madrid, Spain. Participants were adults with mild to moderate psoriasis (Psoriasis Area and Severity Index [PASI] of 2-10, with higher scores indicating maximal disease) receiving stable topical therapy.

### Interventions

Participants were randomized 1:1 to the intervention or control group. The intervention group received a 16-week, dietitian-guided Mediterranean diet program, including nutritional counseling, educational materials, and weekly provision of extra virgin olive oil. The control group received standard low-fat dietary advice without dietitian supervision.

### Main Outcomes and Measures

The primary outcome was the change in the PASI from baseline to week 16. Secondary outcomes included changes in Mediterranean diet adherence, anthropometric and metabolic parameters, serum inflammatory cytokines, and patient-reported outcomes. Estimated marginal means (EMMs) at baseline and for the change from baseline to week 16 were reported, with the intervention effect presented as the between-group difference.

### Results

Among 45 individuals screened, 38 participants were enrolled and randomized (mean [SD] age, 46.4 [12.8] years; 25 males [65.8%]); 19 were randomized to the intervention group and 19 were randomized to the control group; 37 individuals (97.4%) completed the study. The EMM PASI change at week 16 was  $-3.4$  (95% CI,  $-4.4$  to  $-2.4$ ) in the intervention group and  $0.0$  (95% CI,  $-1.0$  to  $1.0$ ) in the control group; the between-group EMM difference was  $-3.4$  (95% CI,  $-4.8$  to  $-2.0$ ;  $P < .001$ ). Nine of 19 participants in the Mediterranean diet group (47.4%) achieved PASI 75 (a 75% reduction in PASI) compared with none in the control group. A significant reduction in EMM hemoglobin A<sub>1c</sub> (glycated hemoglobin) was observed in the intervention group as compared with the control group (between-group EMM difference,  $-4.1$  mmol/mol [95% CI,  $-6.9$  to  $-1.3$  mmol/mol];  $P = .01$ ).

## Conclusions and Relevance

This randomized clinical trial found that a 16-week Mediterranean diet intervention significantly improved psoriasis severity in patients with mild to moderate disease receiving stable topical therapy. These findings suggest that incorporating dietary strategies may be beneficial as an adjunctive therapy in psoriasis management.

## Trial Registration

ClinicalTrials.gov Identifier: [NCT06257641](https://clinicaltrials.gov/ct2/show/study/NCT06257641)

## Introduction

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Psoriasis is a prevalent chronic inflammatory skin disorder that affects over 60 million people worldwide.<sup>1</sup> Its pathogenesis involves a complex interaction between the innate and adaptive immune systems, with the interleukin-23/interleukin-17 axis playing a central role.<sup>2</sup> Currently, therapeutic approaches focus on targeting key proinflammatory cytokines.<sup>3</sup>

Robust evidence supports the beneficial impact of weight loss in individuals with psoriasis, particularly among those with overweight or obesity.<sup>4</sup> However, current clinical guidelines and expert consensus offer limited dietary recommendations, primarily endorsing weight loss for patients with overweight or obesity and a gluten-free diet for those with confirmed celiac disease,<sup>5</sup> without discussing the benefit of specific dietary patterns. This underscores the need for evidence-based dietary approaches with anti-inflammatory benefits independent of weight loss, for patients of all body weights.

The traditional Mediterranean diet is characterized by a high intake of extra virgin olive oil (EVOO), fruit, nuts, vegetables, legumes, and whole-grain cereals; a moderate intake of fish and poultry; a low intake of whole-fat dairy products, red or processed meat, and sweets; and wine in moderation, consumed with meals.<sup>6</sup> The PREDIMED (Effects of a Mediterranean Diet Enriched With Virgin Olive Oil or Mixed Nuts Versus a Low Fat Diet on the Primary Prevention of Cardiovascular Disease) randomized clinical trial,<sup>7</sup> conducted in 7447 individuals with high cardiovascular risk, demonstrated that a Mediterranean diet intervention reduced major

cardiovascular events compared with a low-fat diet. Given the Mediterranean diet's anti-inflammatory properties, investigating its effects in psoriasis is particularly relevant. However, to date, evidence evaluating the effects of the Mediterranean diet in prevention or treatment of psoriasis is limited to observational studies,<sup>[8,9,10,11,12,13](#)</sup> and, to our knowledge, no randomized clinical trials have been conducted to support this relationship.

This is the rationale behind the MEDIPSO (Impact of the Mediterranean Diet on Patients With Psoriasis) trial, based on the primary hypothesis that a Mediterranean diet intervention can lead to clinical improvement in psoriasis.<sup>[14](#)</sup> Additionally, it proposes that such a dietary intervention may also improve quality of life, as well as metabolic and inflammatory parameters. For this aim, a nutritional intervention based on the Mediterranean diet was conducted to assess psoriasis clinical scores alongside laboratory parameters and quality-of-life measurements.

## Methods

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### Trial Design and Participants

The MEDIPSO study is an open-label, single-blinded (evaluator) randomized clinical trial, conducted from February 2024 to March 2025.<sup>[14](#)</sup> Recruitment took place between February and September 2024. The last participant completed the follow-up in January 2025, and data collection finalized in March 2025. The trial concluded upon reaching the sample size established in the study protocol. Patients provided written informed consent, and the trial protocol ([Supplement 1](#)) was approved by the Institutional Review Board of the Hospital Universitario Ramón y Cajal in July 2023. This study followed the Consolidated Standards of Reporting Trials ([CONSORT](#) [✉](#)) reporting guideline.

Patients with mild to moderate psoriasis, defined by a Psoriasis Area and Severity Index (PASI) between 2 and 10 (with higher scores indicating maximal disease), were included. At the time of enrollment, all participants were receiving stable topical treatment as the only therapy for psoriasis. Patients were randomly assigned in a 1:1 ratio to either the Mediterranean diet intervention group or the control group. Participants in the intervention group underwent a high-intensity, 16-week nutritional program that was guided by dietitians (L.G. and Z.V.-R.) aimed at promoting adherence to the Mediterranean diet. By contrast, patients in the control group were provided with standard recommendations for a low-fat diet, without dietitian supervision. The instructions for the use of topical psoriasis treatments remained unchanged throughout the study, and no systemic therapies were initiated during the study period. The inclusion and exclusion criteria are presented in eTable 1 in [Supplement 2](#).

All participants were patients with psoriasis who were regularly followed up at the Hospital Universitario Ramón y Cajal clinic. All in-person visits took place at the Hospital Universitario Ramón y Cajal. The dietary intervention was conducted remotely (using telephone calls and email).

### Protocol and Intervention

The study protocol is summarized in the eFigure in [Supplement 2](#). The intervention period lasted 16 weeks and included 3 face-to-face visits for all participants, along with 4 additional remote visits for those in the intervention group.

During the baseline visit (visit 1), patients provided informed consent, underwent randomization, had clinical information collected, underwent a physical examination, and provided fasting blood samples. For patients randomized to the intervention group, this visit also included the provision of educational materials, distribution of EVOO, and initiation of the nutritional intervention. Patients assigned to the control group received standard lowfat diet recommendations without further discussion. All participants received standardized recommendations for topical treatment. They were instructed to apply a combination of topical corticosteroid and calcipotriene once daily until complete lesion clearance, followed by a twice-weekly application for maintenance. This treatment was prescribed as part of usual care.

At week 8, a second face-to-face visit (visit 2) was conducted to assess clinical status, to ensure that participation in the study did not delay access to systemic treatment if clinically necessary. During the final visit (visit 3), clinical information was collected, a complete physical examination was performed, fasting blood samples were drawn, and participants provided study feedback.

For the intervention, a hybrid approach combining remote and face-to-face interactions was implemented. Visit 1 involved initial dietary recommendations and supportive materials (Mediterranean diet guidelines, infographics, sample menus, and recipes) (eAppendices in [Supplement 2](#)). Thereafter, experienced dietitian-nutritionists (L.G., Z.V.-R.) who had previously participated in Mediterranean diet intervention trials, such as PREDIMED and PREDIMAR (Mediterranean Diet Plus Extravirgin Olive Oil in the Prevention of Recurrent Arrhythmias),<sup>7,15</sup> conducted monthly 20-minute telephone consultations, setting individualized dietary goals. Participants in the intervention group received EVOO (500 mL) at no cost weekly, distributed during clinic visits, and were encouraged to consume at least 4 tablespoons daily.

The dietary recommendations followed the eating habits outlined by the validated questionnaire energy-restricted Mediterranean Diet Adherence Screener (er-MEDAS), in which scores range from 0 to 17, with higher scores indicating greater adherence.<sup>16</sup> The nutritional intervention did not prescribe a specific caloric intake or macronutrient distribution. A detailed description of er-MEDAS eating recommendations is included in the eMethods in [Supplement 2](#). Materials given to the patients are also provided in the eMethods in [Supplement 2](#).

## Outcomes

The primary outcome was the change from baseline in the PASI at week 16. Secondary outcomes included the change from baseline at week 16 in the following measures: (1) adherence to the Mediterranean diet, assessed using the er-MEDAS<sup>16</sup>; (2) anthropometric parameters, including weight, body mass index (BMI), and waist circumference; (3) the impact of the disease on patients' lives, including changes in quality of life, assessed using the Dermatology Life Quality Index (DLQI) questionnaire, in which scores range from 0 to 30, with higher scores indicating maximum impairment<sup>17</sup>; sleep quality, assessed using the Insomnia Severity Index (ISI), in which scores range from 0 to 28, with higher scores indicating more severe insomnia<sup>18</sup>; and emotional well-being,

assessed using the Hospital Anxiety and Depression Scale (HADS), in which scores range from 0 to 42, with higher scores indicating greater symptom severity<sup>19</sup>; (4) metabolic blood parameters, including total serum cholesterol level, low-density lipoproteins, high-density lipoproteins, lipoprotein(a), apolipoprotein A-1, apolipoprotein B, insulin, hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub> [glycated hemoglobin]), and C-reactive protein (CRP); (5) serum inflammatory protein levels, including 93 inflammatory cytokines and related proteins that were analyzed with an Olink multiplex assay (Olink Target 96 Inflammation, Olink Proteomics), based on proximity extension assay technology.<sup>20</sup> For more detailed information, see the eMethods in [Supplement 2](#).

## Sample Size

Based on previous literature,<sup>21</sup> assuming a 2-sided  $\alpha$  risk of .05 and a  $\beta$  risk below .20, a sample size of 19 participants per group would be required to detect a difference of 1 or more units in the PASI change. A common SD of 1 and an anticipated 15% loss to follow-up were assumed.

## Randomization and Blinding

Participants were randomly assigned in a 1:1 ratio using a computer-generated randomization list created by an independent statistician (F.N.S.) who was blinded to the trial and was not involved in participant recruitment. Allocation concealment was ensured using sequentially numbered virtual containers.

The investigator responsible for enrolling participants and assigning them to each group was J. P-B., who was not blinded to group assignment. Neither the patients nor the dietitian-nutritionist (L.G. and Z.V.-R.) conducting the intervention were blinded. Clinical outcome evaluators (E.B.-R., R.C.-M., J.N.-R., and A.G.-C.) were blinded to group allocation.

## Statistical Analysis

Dichotomous variables were reported as absolute (number) and relative (percentage) frequencies. Continuous variables were expressed as mean (SD) or median (IQR) if not normally distributed.

Primary and secondary outcomes were analyzed using linear mixed models to assess changes from baseline to week 16, adjusting for each participant's baseline outcome and PASI. Estimated marginal means (EMMs) at baseline and for the change from baseline to week 16 were reported, with the intervention effect presented as the between-group difference.

For targeted proteomics, changes were calculated as week 16 minus baseline values, and group differences were assessed with the Mann-Whitney *U* test. Treatment adherence (categorized as deintensification, maintenance, and intensification) was compared using the  $\chi^2$  test.

Correlation between PASI improvement and er-MEDAS scores was assessed with Spearman rank correlation. Age, sex, and BMI were included as covariates in a multiple linear regression model.

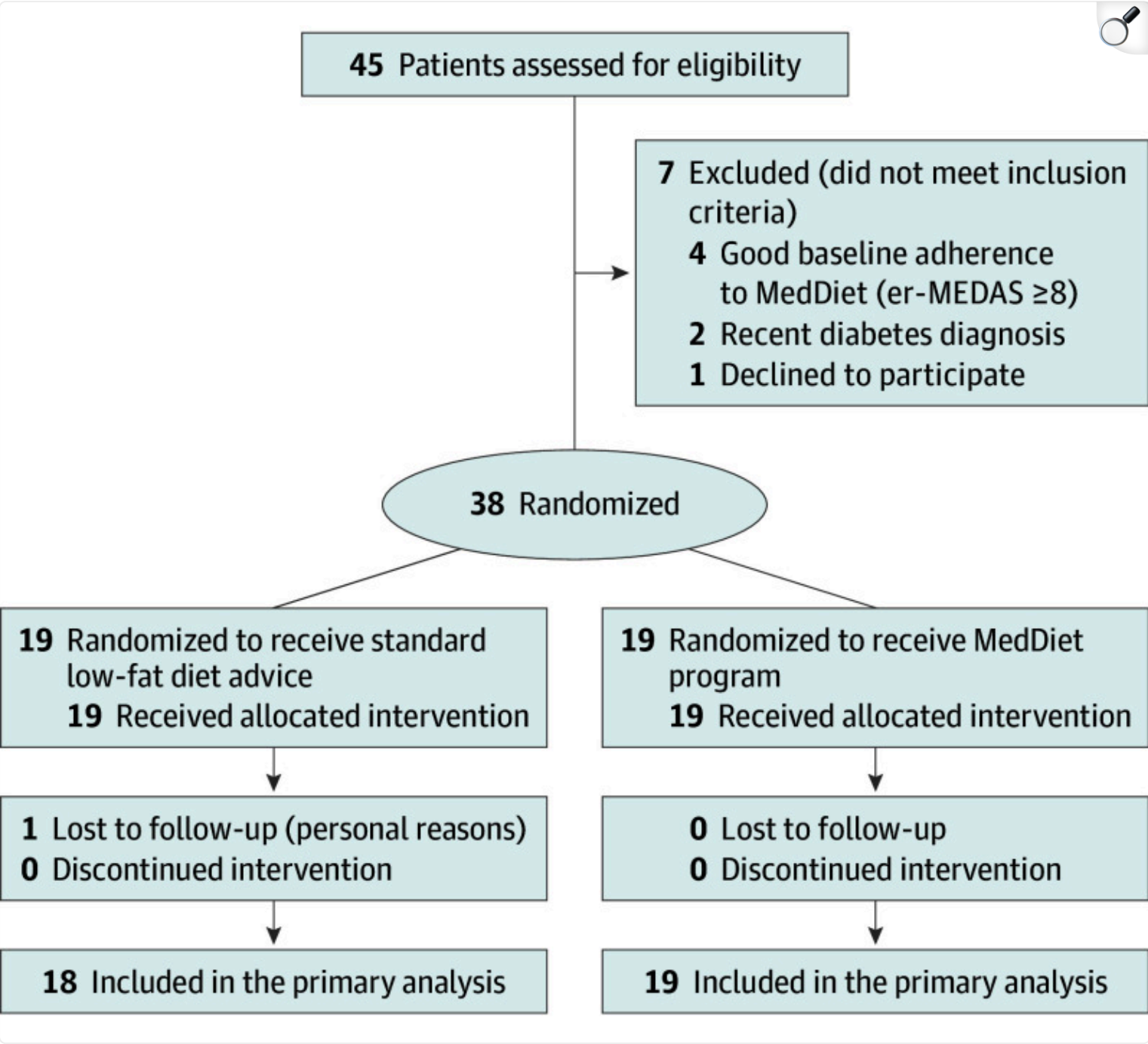
Analyses were conducted using R, version 4.4 (R Project for Statistical Computing) or Stata/IC 17 (StataCorp LLC). Two-sided *P* values <.05 were considered statistically significant.

## Results

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A total of 45 patients were screened for eligibility, of whom 7 were excluded ([Figure 1](#)). The remaining 38 participants (mean [SD] age, 46.4 [12.8] years; 13 females [34.2%] and 25 males [65.8%]) were enrolled and randomized (19 to the intervention group and 19 to the control group). All participants completed the follow-up per the protocol, except for 1 individual in the control group who was lost to follow-up due to personal reasons; thus, 37 individuals (97.4%) completed the study.

Figure 1. Flow Diagram of Participants Assessed for the MEDIPSO Randomized Clinical Trial.



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MEDIPSO indicates The Impact of the Mediterranean Diet on Patients With Psoriasis randomized clinical trial; PASI, Psoriasis Area and Severity Index.

### Study Participants

Demographic and baseline clinical characteristics were balanced between the Mediterranean diet and control groups (Table 1), including the main variable, baseline PASI (median, 4.8 [IQR, 3.5-7.1] vs median, 3.8 [IQR, 3.6-6.2]). Differences were only observed in the HADS anxiety assessment (HADS-A) score, which was higher in

the Mediterranean diet group (median, 8.0 [IQR, 6.0-11.0]) compared with the control group (median, 5.0 [IQR, 3.0-7.0]), and for the CRP (median, 0.4 mg/dL [IQR, 0.2-0.4 mg/dL] in the intervention group vs median, 0.1 mg/dL [IQR, 0-0.2 mg/dL] in the control group) (to convert to milligrams per liter, multiply by 10).

Table 1. Baseline Demographic and Disease Characteristics of Participants.

| Characteristic                                                 | Participants, No. (%)  |                             |
|----------------------------------------------------------------|------------------------|-----------------------------|
|                                                                | Control group (n = 19) | Intervention group (n = 19) |
| Sex                                                            |                        |                             |
| Female                                                         | 4 (21.1)               | 9 (47.4)                    |
| Male                                                           | 15 (78.9)              | 10 (52.6)                   |
| Age, mean (SD), y                                              | 47.6 (14.2)            | 45.3 (11.4)                 |
| Depression                                                     | 2 (10.5)               | 2 (10.5)                    |
| Anxiety                                                        | 3 (15.8)               | 3 (15.8)                    |
| Psoriatic arthritis                                            | 1 (5.3)                | 1 (5.3)                     |
| MASLD                                                          | 4 (21.1)               | 4 (21.1)                    |
| HTA                                                            | 3 (15.8)               | 3 (15.8)                    |
| Dyslipidemia                                                   | 4 (21.1)               | 2 (10.5)                    |
| Disease duration, median (IQR), y                              | 14.0 (2.0-24.0)        | 10.0 (1.0-14.0)             |
| Previous use of systemic drugs                                 | 3 (15.8)               | 5 (26.3)                    |
| Current use of topical steroids                                | 19 (100.0)             | 19 (100.0)                  |
| Smoking status                                                 |                        |                             |
| Nonsmoker                                                      | 9 (47.4)               | 5 (26.3)                    |
| Smoker                                                         | 4 (21.1)               | 8 (42.1)                    |
| Former smoker                                                  | 6 (31.6)               | 6 (31.6)                    |
| Alcohol consumption                                            | 13 (68.4)              | 14 (73.7)                   |
| Physical activity, median (IQR), min/d                         | 20.0 (0-40.0)          | 0 (0-20.0)                  |
| PASI, median (IQR) <sup>a</sup>                                | 3.8 (3.6-6.2)          | 4.8 (3.5-7.1)               |
| BSA, median (IQR)                                              | 4.0 (3.0-5.0)          | 4.0 (3.0-8.0)               |
| MedDiet adherence (er-MEDAS score <sup>b</sup> ), median (IQR) | 6.0 (4.0-7.0)          | 6.0 (5.0-6.0)               |
| DLQI, median (IQR) <sup>c</sup>                                | 4.0 (1.0-9.0)          | 6.0 (3.0-12.0)              |
| ISI, median (IQR) <sup>d</sup>                                 | 3.0 (1.0-13.0)         | 9.0 (5.0-12.0)              |
| HADS-A score, median (IQR) <sup>e</sup>                        | 5.0 (3.0-7.0)          | 8.0 (6.0-11.0)              |
| HADS-D score, median (IQR) <sup>e</sup>                        | 2.0 (0-5.0)            | 2.0 (2.0-6.0)               |
| Weight, mean (SD), kg                                          | 82.1 (16.2)            | 85.3 (18.0)                 |

| Characteristic                                  | Participants, No. (%)  |                             |
|-------------------------------------------------|------------------------|-----------------------------|
|                                                 | Control group (n = 19) | Intervention group (n = 19) |
| BMI, mean (SD)                                  | 27.9 (4.4)             | 29.5 (4.6)                  |
| Waist perimeter, mean (SD), cm                  | 96.8 (12.9)            | 102.8 (11.6)                |
| Systolic blood pressure, mean (SD), mm Hg       | 127.9 (18.0)           | 135.7 (16.6)                |
| Diastolic blood pressure, mean (SD), mm Hg      | 86.9 (9.3)             | 94.2 (12.9)                 |
| Total cholesterol level, mean (SD), mg/dL       | 191.2 (45.7)           | 197.6 (41.3)                |
| Low-density lipoprotein, mean (SD), mg/dL       | 117.4 (39.0)           | 122.6 (36.4)                |
| High-density lipoprotein, median (IQR), mg/dL   | 53.0 (42.0-65.0)       | 45.0 (40.0-59.0)            |
| Triglycerides, median (IQR), mg/dL              | 100.0 (70.0-124.0)     | 118.0 (57.0-173.0)          |
| Lipoprotein(a), median (IQR), mg/dL             | 9.1 (4.5-18.2)         | 10.3 (4.9-19.2)             |
| Apolipoprotein A-1, mean (SD), mg/dL            | 173.0 (35.9)           | 169.3 (39.9)                |
| Apolipoprotein B, mean (SD), mg/dL              | 96.4 (27.6)            | 101.2 (26.3)                |
| Fasting serum insulin, median (IQR), $\mu$ IU/L | 7.3 (3.9-10.9)         | 7.3 (5.7-10.2)              |
| HOMA-IR, median (IQR)                           | 1.7 (0.9-2.4)          | 1.6 (1.3-2.4)               |
| HbA <sub>1c</sub> , median (IQR), mmol/mol      | 34.0 (33.0-37.0)       | 36.5 (32.0-40.0)            |
| Estimated average glucose, mean (SD), mg/dL     | 107.1 (11.3)           | 110.4 (11.3)                |
| hs-CRP, median (IQR), mg/dL <sup>f</sup>        | 0.1 (<0.1-0.2)         | 0.3 (0.2-0.4)               |

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Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BSA, body surface area; DLQI, Dermatology Life Quality Index; er-MEDAS, energy-restricted Mediterranean Diet Adherence Screener; HADS-A, Hospital Anxiety and Depression Scale (anxiety assessment); HADS-D, HADS (depression assessment); HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; HOMA-IR, homeostasis model assessment of insulin resistance (assessed as fasting insulin [milliunits per liter]  $\times$  fasting glucose [milligrams per deciliter]/405); hs-CRP, high-sensitivity C-reactive protein; HTA, arterial hypertension; ISI, Insomnia Severity Index; MASLD, metabolic dysfunction-associated steatotic liver disease; MedDiet, Mediterranean diet; PASI, Psoriasis Area and Severity Index.

SI conversions: To convert total cholesterol level and low-density and high-density lipoproteins to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113; lipoprotein(a) to milligrams per liter, multiply by 0.1; apolipoproteins A-1 and B to grams per liter, multiply by 0.01; fasting serum insulin to picomoles per liter, multiply by 6.945; estimated average glucose to millimoles per liter, multiply by 0.0555; and hs-CRP to milligrams per liter, multiply by 10.

<sup>a</sup> Scores range from 2 to 10, with higher scores indicating maximal disease.

<sup>b</sup> Scores range from 0 to 17, with higher scores indicating greater adherence.

<sup>c</sup> Scores range from 0 to 30, with higher scores indicating maximum impairment.

<sup>d</sup> Scores range from 0 to 28, with higher scores indicating more severe insomnia.

<sup>e</sup> Scores range from 0 to 21, with higher scores indicating greater symptom severity.

<sup>f</sup> Patients who presented hs-CRP values of 1 mg/dL or more were excluded from the analysis. Patients analyzed (n = 31): control group (n = 14); intervention group (n = 17).

## Changes in PASI

Patients in the Mediterranean diet intervention group experienced a significantly greater reduction in PASI compared with the control group. The EMM change in PASI from baseline to visit 3 was  $-3.4$  (95% CI,  $-4.4$  to  $-2.4$ ) in the intervention group and  $0$  (95% CI,  $-1.0$  to  $1.0$ ) in the control group ([Table 2](#)). The EMM between-group difference was  $-3.4$  (95% CI,  $-4.8$  to  $-2.0$ ;  $P < .001$ ). In total, 13 of 19 participants (68.4%) in the intervention group achieved PASI 50 (a 50% reduction in PASI) compared with only 2 of 18 participants (11.1%) in the control group ( $P < .001$ ). Moreover, in the intervention group, 9 participants (47.4%) reached PASI 75 ( $P < .001$ ), 5 (26.3%) reached PASI 90 ( $P = .046$ ), and 2 (10.5%) achieved PASI 100 ( $P = .49$ ), whereas none in the control group reached these thresholds.

Table 2. Estimated Marginal Means for the Change From Baseline at Week 16 for Disease Characteristics of Participants and Primary and Ranked Secondary End Points<sup>a</sup>.

| Characteristic                                   | Control group<br>(n = 18) | Intervention group<br>(n = 19) | Between-group<br>differences | P value |
|--------------------------------------------------|---------------------------|--------------------------------|------------------------------|---------|
| PASI score <sup>b</sup>                          | 0 (−1.0 to 1.0)           | −3.4 (−4.4 to −2.4)            | −3.4 (−4.8 to −2.0)          | <.001   |
| PASI 50, No. (%)                                 | 2 (11)                    | 13 (68)                        | NA                           | <.001   |
| PASI 75, No. (%)                                 | 0                         | 9 (47)                         | NA                           | <.001   |
| PASI 90, No. (%)                                 | 0                         | 5 (26)                         | NA                           | .046    |
| PASI 100, No. (%)                                | 0                         | 2 (11)                         | NA                           | .49     |
| BSA                                              | 0.3 (−0.8 to 1.4)         | −3.1 (−4.2 to −2.1)            | −3.5 (−5.0 to −1.9)          | <.001   |
| MedDiet adherence (er-MEDAS score <sup>c</sup> ) | 1.3 (0.4 to 2.2)          | 8.2 (7.3 to 9.1)               | 6.9 (5.7 to 8.2)             | <.001   |
| DLQI <sup>d</sup>                                | −1.1 (−3.1 to 0.9)        | −4.2 (−6.1 to −2.2)            | −3.1 (−5.8 to −0.3)          | .03     |
| ISI <sup>e</sup>                                 | −0.4 (−2.1 to 1.4)        | −2.9 (−4.6 to −1.2)            | −2.5 (−5.0 to −0.1)          | .04     |
| HADS-A score <sup>f</sup>                        | 0.8 (−0.8 to 2.4)         | −2.0 (−3.6 to −0.4)            | −2.8 (−5.0 to −0.6)          | .01     |
| HADS-D score <sup>f</sup>                        | 0.8 (−0.8 to 2.5)         | −1.2 (−2.8 to 0.5)             | −2.0 (−4.3 to 0.3)           | .09     |
| Weight, kg                                       | −1.3 (−2.7 to 0.1)        | −0.3 (−1.7 to 1.1)             | 1.0 (−1.0 to 3.0)            | .31     |
| BMI                                              | −0.5 (−1.1 to −0)         | −0 (−0.5 to 0.5)               | 0.5 (−0.2 to 1.3)            | .15     |
| Waist perimeter, cm                              | −0.8 (−4.2 to 2.7)        | 0.9 (−2.6 to 4.4)              | 1.7 (−3.2 to 6.5)            | .49     |
| Systolic blood pressure, mm Hg                   | −4.1 (−12.2 to 4.0)       | −9.1 (−17.4 to −0.9)           | −5.0 (−16.6 to 6.6)          | .38     |
| Diastolic blood pressure, mm Hg                  | −6.0 (−10.5 to −1.4)      | −3.8 (−8.4 to 0.8)             | 2.1 (−4.3 to 8.6)            | .50     |
| Physical activity, min/d                         | 7.2 (−4.2 to 18.5)        | 6.8 (−4.3 to 18.0)             | −0.3 (−16.3 to 15.6)         | .97     |

| Characteristic                    | Control group<br>(n = 18) | Intervention group<br>(n = 19) | Between-group<br>differences | P value |
|-----------------------------------|---------------------------|--------------------------------|------------------------------|---------|
| Total cholesterol level, mg/dL    | 4.1 (−7.5 to 15.7)        | 0.9 (−10.5 to 12.4)            | −3.2 (−19.5 to 13.1)         | .69     |
| Low-density lipoprotein, mg/dL    | 7.1 (−2.8 to 17.0)        | 0.4 (−9.4 to 10.1)             | −6.8 (−20.7 to 7.1)          | .33     |
| High-density lipoprotein, mg/dL   | −2.5 (−5.4 to 0.5)        | −0.6 (−3.5 to 2.3)             | 1.9 (−2.2 to 6.0)            | .36     |
| Triglycerides, mg/dL              | −3.3 (−23.4 to 16.8)      | 2.8 (−17.0 to 22.6)            | 6.1 (−22.1 to 34.3)          | .66     |
| Lipoprotein(a), mg/dL             | 2.4 (0 to 4.7)            | −1.0 (−3.3 to 1.3)             | −3.4 (−6.7 to −0.1)          | .04     |
| Apolipoprotein A-1, mg/dL         | −6.0 (−14.2 to 2.3)       | −5.5 (−13.6 to 2.6)            | 0.4 (−11.1 to 12.0)          | .94     |
| Apolipoprotein B, mg/dL           | 1.9 (−5.1 to 9.0)         | −0.4 (−7.3 to 6.6)             | −2.3 (−12.2 to 7.6)          | .64     |
| Fasting serum insulin, $\mu$ IU/L | −1.6 (−4.8 to 1.6)        | −0.3 (−3.5 to 2.9)             | 1.3 (−3.2 to 5.9)            | .55     |
| HOMA-IR                           | −0.5 (−1.3 to 0.4)        | 0 (−0.8 to 0.9)                | 0.5 (−0.7 to 1.7)            | .40     |
| HbA <sub>1C</sub> , mmol/mol      | 2.3 (0.4 to 4.3)          | −1.8 (−3.8 to 0.2)             | −4.1 (−6.9 to −1.3)          | .01     |
| Estimated average glucose, mg/dL  | 6.1 (1.0 to 11.2)         | −4.4 (−9.6 to 0.8)             | −10.5 (−17.8 to −3.2)        | .01     |
| hs-CRP, mg/dL <sup>§</sup>        | 0.0 (−0.1 to 0.1)         | 0.0 (−0.1 to <0.1)             | 0.0 (−0.1 to 0.1)            | .71     |

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Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BSA, body surface area; DLQI, Dermatology Life Quality Index; er-MEDAS, energy-restricted Mediterranean Diet Adherence Screener; HADS-A, Hospital Anxiety and Depression Scale (anxiety assessment); HADS-D, HADS (depression assessment); HbA<sub>1C</sub>, hemoglobin A<sub>1C</sub>; HOMA-IR, homeostasis model assessment of insulin resistance (assessed as fasting insulin [milliunits per liter]  $\times$  fasting glucose [milligrams per deciliter]/405); hs-CRP, high-sensitivity C-reactive protein; ISI, Insomnia Severity Index; MedDiet, Mediterranean diet; NA, not applicable; PASI, Psoriasis Area and Severity Index (50, 75, 90, and 100 indicate percentage reduction).

SI conversions: To convert total cholesterol level and low-density and high-density lipoproteins to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113; lipoprotein(a) to milligrams per liter, multiply by 0.1; apolipoproteins A-1 and B to grams per liter, multiply by 0.01; fasting serum insulin to picomoles per liter, multiply by 6.945; estimated average glucose to millimoles per liter, multiply by 0.0555; and hs-CRP to milligrams per liter, multiply by 10.

<sup>a</sup> Data are presented as estimated marginal mean (95% CI) unless otherwise indicated.

<sup>b</sup> Scores range from 2 to 10, with higher scores indicating maximal disease.

<sup>c</sup> Scores range from 0 to 17, with higher scores indicating greater adherence.

<sup>d</sup> Scores range from 0 to 30, with higher scores indicating maximum impairment.

<sup>e</sup> Scores range from 0 to 28, with higher scores indicating more severe insomnia.

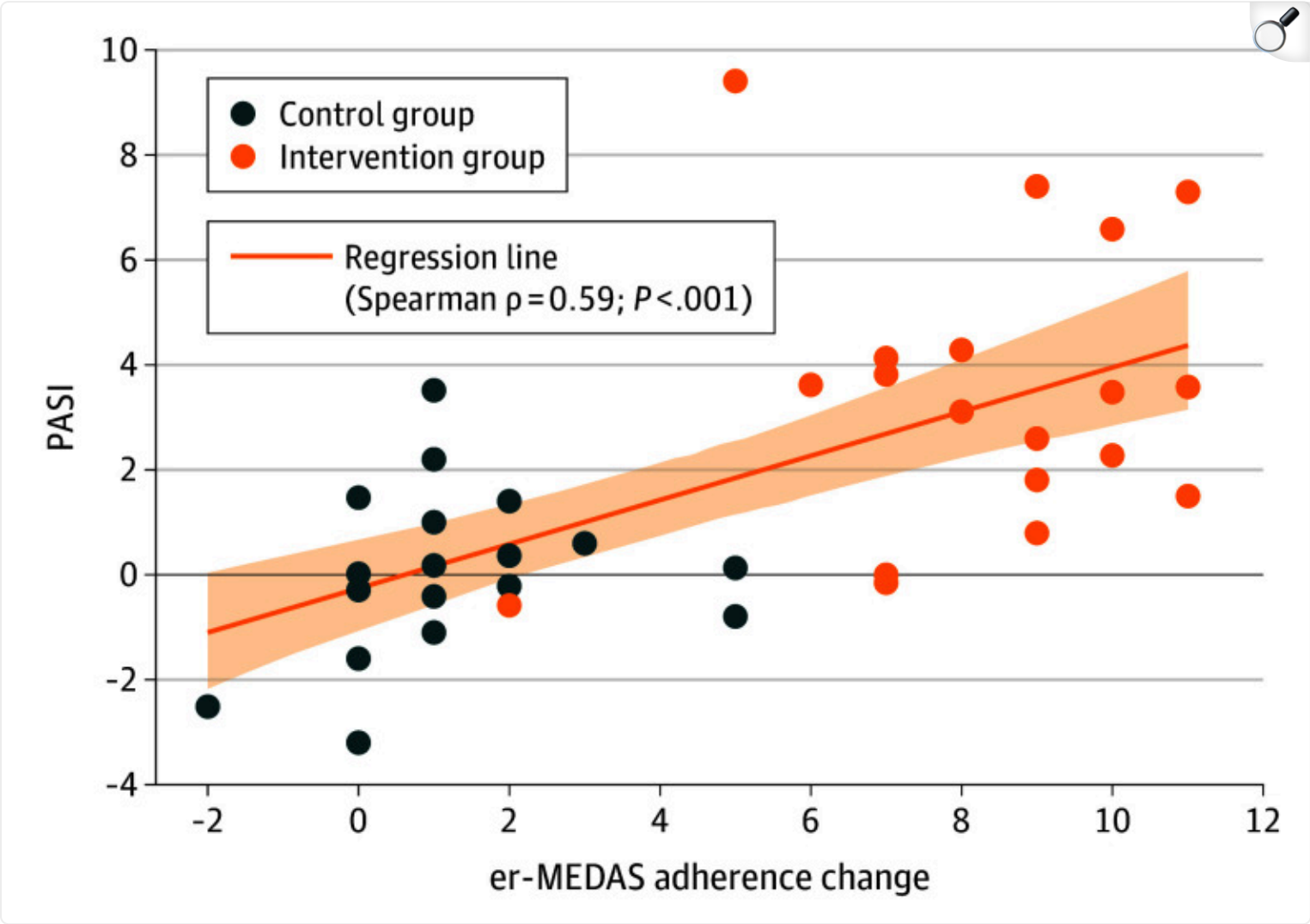
<sup>f</sup> Scores range from 0 to 21, with higher scores indicating greater symptom severity.

<sup>g</sup> Patients who presented hs-CRP values of 1 mg/dL or more were excluded from the analysis. Patients analyzed (n = 31): control group (n = 14); intervention group (n = 17).

## Changes in Adherence to the Mediterranean Diet

Adherence to the Mediterranean diet increased significantly in the intervention group compared with the control group. The EMM change in the er-MEDAS score from baseline to visit 3 was 8.2 (95% CI, 7.3-9.1) in the intervention group vs 1.3 (95% CI, 0.4-2.2) in the control group. The EMM between-group difference was 6.9 (95% CI, 5.7-8.2;  $P < .001$ ). Notably, there was a positive correlation between the improvement in PASI and the increase in adherence to the Mediterranean diet (Spearman  $\rho = 0.59$ ;  $P < .001$ ) ([Figure 2](#)). This association remained significant after adjustment for age, sex, and BMI in an exploratory analysis.

Figure 2. Scatter Plot of Psoriasis Area and Severity Index (PASI) by Attained Changes in Adherence to the Energy-Restricted Mediterranean Diet (er-MEDAS) 17-Item Score.



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Adherence to the Mediterranean diet was measured by the change in the er-MEDAS score (scores range from 0 to 17, with higher scores indicating greater adherence). PASI ranges from 2 to 10, with higher PASI indicating maximal disease.

### Changes in Anthropometric Parameters

At baseline, no differences were observed in waist circumference or body weight. Furthermore, no differences in the change in body weight (control group:  $-1.3$  kg [95% CI,  $-2.7$  to  $0.1$  kg] vs intervention group:  $-0.3$  kg [95% CI,  $-1.7$  to  $1.1$  kg];  $P = .31$ ) or waist circumference (control group:  $-0.8$  cm [95% CI,  $-4.2$  to  $2.7$  cm] vs intervention group:  $0.9$  cm [95% CI,  $-2.6$  to  $4.4$  cm];  $P = .49$ ) after the intervention were identified.

### Changes in Patient-Reported Outcomes

There was a greater improvement in patient-reported outcomes in the intervention group than in the control group. This included improvement (differences in the EMM change that favored the intervention group) in the DLQI ( $-3.1$  [95% CI,  $-5.8$  to  $-0.3$ ];  $P = .03$ ), in the ISI ( $-2.5$  [95% CI,  $-5.0$  to  $-0.1$ ];  $P = .04$ ), and in the HADS-A ( $-2.8$  [95% CI,  $-5.0$  to  $-0.6$ ];  $P = .01$ ). The HADS depression assessment (HADS-D) did not reach statistical significance ( $-2.0$  [95% CI,  $-4.3$  to  $0.3$ ];  $P = .09$ ).

## Changes in Metabolic Parameters

No differences were observed between groups in the changes of total cholesterol level, high-density lipoproteins, low-density lipoproteins, apolipoprotein A-1, or apolipoprotein B levels after the intervention. However, a reduction in lipoprotein(a) was detected in the intervention group compared with the control group:  $-3.4$  (95% CI,  $-6.7$  to  $-0.1$ ;  $P = .04$ ).

No differences in the homeostatic model assessment for insulin resistance (assessed as fasting insulin [milliunits per liter]  $\times$  fasting glucose [milligrams per deciliter]/405) variation were found. Nonetheless, a significant reduction in median HbA<sub>1c</sub> was observed in the intervention group compared with the control group (between-group EMM difference,  $-4.1$  mmol/mol [95% CI,  $-6.9$  to  $-1.3$  mmol/mol];  $P < .001$ ).

## Changes in Inflammatory Cytokines

A reduction in fibroblast growth factor 23 (FGF23) levels was observed in the control group, with a difference in the median change ( $0.18$  [95% CI,  $0.02$ - $0.51$ ];  $P = .03$ ). No other differences were detected in the variation of these inflammation-related protein levels between the intervention and control groups. These results are shown in eTable 2 in [Supplement 2](#).

## Topical Treatment Adherence

Treatment adherence was assessed at every on-site visit by asking participants to report their current treatment regimen. No differences in treatment use were observed at visit 2. However, greater treatment deintensification was identified in the intervention group at the final study visit, with 12 patients (63.2%) reducing their topical regimen compared with 3 patients (16.7%) in the control group (eTable 3 in [Supplement 2](#)).

## Adverse Events

Several adverse events were identified during the study. In the control group, 1 participant developed an upper respiratory tract infection, and another participant was diagnosed with *Mycoplasma pneumonia*. The intervention group had 1 participant with acute viral bronchitis and 1 with scrotal abscess. None of these was deemed related to the dietary intervention, and none required hospitalization. No other harms or unintended effects were reported in either group.

## Discussion

In the MEDIPSO randomized clinical trial, the findings suggest a clinically meaningful and statistically significant improvement in PASI among participants receiving the intervention with the Mediterranean diet as compared with the control group. Moreover, increased dietary adherence, as measured by the er-MEDAS score, was significantly correlated with improvements in disease severity. The MEDIPSO study is a randomized clinical trial specifically designed to evaluate the effects of a Mediterranean diet intervention on psoriasis. Previous studies have consistently reported an association between poor adherence to the Mediterranean diet and increased psoriasis prevalence or severity, but, to our knowledge, they were only observational in design and did not apply any intervention.<sup>8,9,10,11,12,13</sup> Consequently, those studies were limited by their inherent risk for potential residual confounding. Several dietary intervention studies in psoriasis have reported promising results; however, these have primarily evaluated standard hypocaloric<sup>22</sup> or ketogenic<sup>21,23</sup> diets, which induce significant weight loss that alone could account for the observed PASI improvement.

Notably, the improvements in this study occurred without significant weight loss, suggesting that the attained beneficial effect was independent of body weight changes. Additionally, patients in the intervention group showed greater treatment deintensification, while participants in the control group maintained stable topical regimens. Therefore, the psoriasis improvement cannot be explained by increased use of topical therapy.

Minor baseline differences were observed between groups, with the intervention group showing slightly higher PASI scores (not significant) and HADS-A scores and high-sensitivity (hs)-CRP levels. hs-CRP values greater than 1 mg/dL, deemed nonphysiological, were excluded (5 from the control group and 2 from the intervention group), which likely influenced the higher median hs-CRP in the intervention group. Overall, we believe that these differences are likely due to chance, given the small sample size, and we do not consider them to have significantly impacted the study results, particularly as other potential confounders such as topical treatment use and weight change were accounted for.

The Mediterranean diet may exert beneficial effects in psoriasis through multiple metabolic and molecular pathways relevant to chronic inflammation. It has been shown to reduce systemic inflammation and oxidative stress, largely due to its high content of antioxidant vitamins (eg,  $\beta$ -carotene, vitamins C and E), polyphenols, and phytochemicals that attenuate lipoprotein oxidation and lower proinflammatory markers.<sup>24</sup> Additional mechanisms include cyclooxygenase inhibition by oleocanthal found in olive oil and the inhibition of proinflammatory eicosanoids by omega-3 fatty acids present in oily fish.<sup>25</sup> The Mediterranean diet also improves lipid profiles, enhances insulin sensitivity, and modulates hormonal and growth factor signaling involved in immune activation and keratinocyte proliferation.<sup>26</sup> Furthermore, long-term adherence has been associated with favorable modulation of gut microbiota, particularly increasing short-chain fatty acid-producing species with anti-inflammatory and immunoregulatory effects.<sup>27</sup>

Beyond skin outcomes, a reduction in HbA<sub>1c</sub> was also observed among patients receiving the intervention with the Mediterranean diet. While modest, this change is clinically relevant and supports previous evidence suggesting that Mediterranean diet patterns improve glycemic control.<sup>28</sup> A small reduction in lipoprotein(a) levels was observed. As lipoprotein(a) is primarily genetically determined and generally considered resistant to dietary modification, it may reflect the limited sample size or variability in laboratory measurement methods and therefore should be interpreted with caution.<sup>29</sup> Patient-reported outcomes—including quality of life, insomnia,

and anxiety—improved in the intervention group, which is consistent with the improvement in psoriasis in this group.

In the proteomic analysis, only FGF23 showed a significant between-group difference in the change over time, with greater reduction observed in the control group. FGF23 is a hormone involved in phosphate homeostasis,<sup>30</sup> and previous evidence associated higher FGF23 levels with increased systemic inflammation and a greater PASI.<sup>31</sup> These results may be attributed to limited statistical power and the relatively short follow-up period, as previous studies with larger sample sizes and longer duration were able to detect reductions in circulating inflammatory biomarkers among patients adhering to a Mediterranean diet.<sup>32</sup>

The findings of this study support the incorporation of structured nutritional interventions as part of comprehensive psoriasis management. A Mediterranean diet is not only culturally acceptable and sustainable but may also offer added cardiometabolic benefits in a population at increased risk of cardiovascular disease. Future multicenter trials with larger samples and longer follow-up are warranted to validate these findings and better define the long-term role of dietary interventions in psoriasis.

## Limitations

This study has limitations. Despite blinded outcome assessors, the open-label design could bias subjective outcomes. The intervention group received more frequent contact, which could have increased participant engagement, potentially introducing a Hawthorne effect. The small sample size provided limited power to detect modest changes in secondary outcomes. Several exclusion criteria—such as diabetes or cardiovascular disease—may have affected generalizability. The 16-week duration did not allow conclusions about the long-term sustainability or effects of the intervention.

## Conclusions

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The findings of the MEDIPSO randomized clinical trial found that a 16-week Mediterranean diet intervention significantly improved psoriasis severity in patients with mild to moderate psoriasis with stable topical treatment, independent of weight loss, compared with low-intensity low-fat diet advice. A greater Mediterranean diet adherence correlated with higher improvement, suggesting a causal relationship. These findings underscore the value of structured nutritional interventions as adjunctive therapy in psoriasis and highlight the need for larger, long-term studies to further define the role of diet in disease management.

Supplement 1.

Trial Protocol and Statistical Analysis Plan

[jamadermatol-e253410-s001.pdf](#) (767.8KB, pdf)

Supplement 2.

eMethods

**eTable 1.** Inclusion and Exclusion Criteria for the MEDIPSO Study

**eFigure.** Study Protocol Comprehensive Overview

**eTable 2.** OLINK Results, Expressed as Median (IQR)

**eTable 3.** Topical Treatment Adherence Analysis

**eAppendix 1.** Diet Recommendations Given to Patients: Translated Version

**eAppendix 2.** Diet Recommendations Given to Patients: Original Version

[jamadermatol-e253410-s002.pdf](#) (18.9MB, pdf)

Supplement 3.

Data Sharing Statement

[jamadermatol-e253410-s003.pdf](#) (16.9KB, pdf)

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## Associated Data

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*This section collects any data citations, data availability statements, or supplementary materials included in this article.*

## Supplementary Materials

## Supplement 1.

### Trial Protocol and Statistical Analysis Plan

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## Supplement 2.

### eMethods

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## Supplement 3.

### Data Sharing Statement

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