## Systematic Review of the Mediterranean Diet for Long-Term Weight Loss

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#### ABSTRACT

**BACKGROUND:** Although the long-term health benefits of the Mediterranean diet are well established, its efficacy for weight loss at  $\geq 12$  months in overweight or obese individuals is unclear. We therefore conducted a systematic review of randomized controlled trials (RCTs) to determine the effect of the Mediterranean diet on weight loss and cardiovascular risk factor levels after  $\geq 12$  months.

**METHODS:** We systematically searched MEDLINE, EMBASE, and the Cochrane Library of Clinical Trials for RCTs published in English or French and with follow-up  $\geq 12$  months that examined the effect of the Mediterranean diet on weight loss and cardiovascular risk factor levels in overweight or obese individuals trying to lose weight.

**RESULTS:** Five RCTs (n = 998) met our inclusion criteria. Trials compared the Mediterranean diet to a lowfat diet (4 treatment arms), a low-carbohydrate diet (2 treatment arms), and the American Diabetes Association diet (1 treatment arm). The Mediterranean diet resulted in greater weight loss than the low-fat diet at  $\geq$ 12 months (range of mean values: -4.1 to -10.1 kg vs 2.9 to -5.0 kg), but produced similar weight loss as other comparator diets (range of mean values: -4.1 to -10.1 kg vs -4.7 to -7.7 kg). Moreover, the Mediterranean diet was generally similar to comparator diets at improving other cardiovascular risk factor levels, including blood pressure and lipid levels.

**CONCLUSION:** Our findings suggest that the Mediterranean diet results in similar weight loss and cardiovascular risk factor level reduction as comparator diets in overweight or obese individuals trying to lose weight. © 2016 Elsevier Inc. All rights reserved. • The American Journal of Medicine (2016) 129, 407-415

KEYWORDS: Cardiovascular disease; Diet; Mediterranean; Systematic review; Weight loss

In the 1950s, the landmark Seven Countries Study identified a population in the Mediterranean region that enjoyed reduced rates of cardiovascular disease and cardiovascular mortality.<sup>1</sup> These individuals adhered to a regional diet that consisted of a high consumption of fruits and vegetables, monounsaturated fats (primarily from olive oil), and cereals; a moderate consumption of poultry, fish, and dairy products;

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and little to no consumption of red meat.<sup>2,3</sup> Observational studies have associated this Mediterranean diet with good overall health.<sup>3</sup> Although the long-term health benefits of following the Mediterranean diet are well established, its efficacy for weight loss at  $\geq 12$  months in overweight or obese individuals is unclear. We therefore conducted a systematic review of randomized controlled trials (RCTs) to examine the long-term effects of the Mediterranean diet on weight loss and cardiovascular risk factor levels among overweight and obese individuals trying to lose weight.

#### METHODS

Our systematic review was conducted according to a prespecified protocol and is described according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>4</sup>

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**Conflict of Interest:** The authors have no conflicts of interest to declare.

Authorship: All authors had access to the data and had a role in writing the manuscript.

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#### Search Strategy

We systematically searched MEDLINE (via Ovid), EMBASE (via Ovid), and the Cochrane Library of Clinical Trials from inception to January 2015 to identify RCTs that examined the effect of the Mediterranean diet on  $\geq$ 12-month weight loss and cardiovascular risk reduction in overweight or obese individuals

aged >18 years who were trying to lose weight. Our search terms consisted of medical subject headings, Emtree terms, and keywords for the Mediterranean diet (Appendices 1-3, available online). The search was restricted to RCTs published in English or in French. Moreover, we limited our MEDLINE and EMBASE searches to RCTs using a modified version of the McMaster RCT hedge.<sup>5</sup> We hand-searched the references of relevant RCTs, reviews, and meta-analyses retrieved by our database searches to identify additional RCTs.

### **Study Selection**

We included RCTs that examined the efficacy of the Mediterranean diet for weight loss and cardiovascular risk factor level reduction with follow-up  $\geq$ 12 months. Inclusion was restricted to RCTs comparing a diet that was described explicitly as "Mediterranean," "Mediterranean-Style," or "Mediterranean-inspired" to any active comparator diet, including but not limited to low-fat diets, low-carbohydrate diets, calorie-restricted diets, and diets that are part of the usual care for certain medical conditions. Trials with an exercise prescription or nutritional counseling in intervention or comparator arms were eligible for inclusion provided that  $\geq$ 2 arms of the trial received the same exercise prescription or nutritional counseling. This was done to isolate the effect of the Mediterranean diet.

We excluded trials conducted in participants with malignancies or posttransplantation, as well as weight maintenance trials. We also excluded trials with a crossover design, unless the initial phase of the trial preceding the crossover was randomized, controlled, and lasted  $\geq 12$ months; the initial phase of such trials was included. Finally, nonrandomized trials, uncontrolled trials, and those that did not provide counseling or exercise interventions equally to  $\geq 2$  arms of the trial were designated as having an inappropriate control group and were thus excluded.

#### **Data Extraction and Synthesis**

Data were extracted by 2 independent reviewers, with disagreements resolved by consensus. Extracted data included data on study characteristics, study population, demographic and clinical characteristics, intervention characteristics, and use of any co-interventions such as exercise or counseling. All outcome data were extracted at 12 months, as well as at 6 months and in 6-month increments beyond 12 months, if available, until maximum follow-up.

Our primary endpoint was sustained weight loss, reported as mean weight change in kilograms or as a mean percentage change, at  $\geq 12$  months or longest follow-up.

## CLINICAL SIGNIFICANCE

- The long-term efficacy of the Mediterranean diet for weight loss in overweight or obese individuals was previously unclear.
- The Mediterranean diet is superior to low-fat diets for long-term weight loss.
- Given the popularity of the Mediterranean diet and the importance of weight management in light of the current obesity epidemic, this review provides essential information for public health improvement.

Secondary endpoints included mean change in body mass index (BMI), body fat, waist circumference, waist-hip ratio, total choleslow-density lipoprotein terol. cholesterol, high-density lipoprocholesterol, triglycerides, tein systolic blood pressure, diastolic blood pressure, fasting glucose, fasting insulin, homeostatic model assessment, and glycated hemoglobin (HbA1c) levels.

The quality of included trials was assessed using the Cochrane Collaboration's tool for assessing risk of bias in RCTs.<sup>6</sup> Quality assessment was conducted by 2 independent reviewers, with disagreements resolved by consensus.

Given the amount of heterogeneity that was present in the designs, populations, and comparators among the included RCTs, we were unable to statistically pool data across trials.

## RESULTS

#### **Search Results**

Our search yielded 2432 potentially relevant publications (Appendix 4, available online). Following the removal of duplicates, 1069 publications underwent title and abstract screening. Of these, 78 were retrieved for full-text screening, and 5 were included in the systematic review.

### **Study Characteristics**

The 5 included RCTs (n = 998) randomized participants to a Mediterranean diet (6 treatment arms; n = 492) or a lowfat diet (4 treatment arms; n = 312), a low-carbohydrate diet (1 treatment arm; n = 109), or the American Diabetes Association diet (1 treatment arm; n = 85) (**Table 1**). Followup ranged from 12 to 48 months, with 2 studies also reporting 6-month outcomes.<sup>7,8</sup>

The 5 RCTs possessed varying degrees of bias, according to the Cochrane Collaboration's risk of bias assessment tool for RCTs. Most trials had a low or unclear risk of bias for sequence generation (5 trials), allocation concealment (4 trials), and blinding (4 trials). However, 1 RCT<sup>7</sup> was deemed to have a high risk of selective outcome reporting. Moreover, 2 RCTs<sup>9,10</sup> were found to be high risk in 3 and 4 domains, respectively. In particular, these RCTs were at high risk of bias for incomplete outcome data and selective outcome reporting due to a high rate of loss to follow-up and

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