Mediterranean diet and weight loss: meta-analysis of randomized controlled trials

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CRD summary
This review investigated the effect of a Mediterranean diet on weight loss and concluded that it could be effective especially with energy restriction, with increased physical activity, and for longer than six months. These conclusions might not be reliable due to the lack of information on trial quality and high variation between trials.

Authors' objectives
To evaluate the effect of a Mediterranean diet on weight loss.

Searching
The electronic databases PubMed, EMBASE, Scopus and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for items from inception to January 2010. The search terms were provided and no language restrictions were applied. The reference lists of included trials and reviews were examined for additional relevant studies.

Study selection
Randomised controlled trials (RCTs) comparing the effect of a Mediterranean diet with that of a control diet were included. A Mediterranean diet was not defined. The primary outcome measures were the change in body mass index (BMI) and body weight. Trials had to include at least 15 patients and report a follow-up of at least four weeks.

The included trials were conducted in the USA, Europe and Israel. Where described, Mediterranean diets included increased fruit, vegetables and olive oil consumption, sometimes with increased whole grains, bread or both and reduced meat consumption. Where reported, the final monounsaturated fat content of Mediterranean diets ranged from 10% to 26.4% and total fat content was up to 40%. Control diets included low fat diets, high carbohydrate diets, usual care or some form of dietary information or counselling. Trials also included energy restriction or advice to increase physical activity. Where reported, the mean age of participants ranged from 34.6 years to 68.8 years and the mean BMI from 25.8 to 35. Trials included participants free from chronic diseases, those with metabolic syndrome or diabetes, high cholesterol or high cardiovascular risk, or those who had experienced myocardial infarction. Follow-up ranged from 28 days to two years, with one trial having a five-year follow-up.

Study eligibility was assessed independently by two reviewers, with discrepancies resolved after discussion and referral to a third reviewer if necessary.

Assessment of study quality
Methodological quality was assessed using the Jadad scale, for the quality of randomisation, allocation concealment, blinding and description of withdrawals. Use of intention-to-treat analysis was assessed. Scores of three or more out of six were considered to be high quality due to the difficulty of implementing double-blinding.

The authors did not explicitly state how the quality assessment was performed, but they did mention that they followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance.

Data extraction
The extraction of data from the trials was not clearly described, but the weighted mean difference between the intervention and control groups was calculated for weight and BMI.

The authors did not explicitly state how many reviewers extracted the data.

Methods of synthesis
A random-effects meta-analysis was performed. Weighted mean differences, with 95% confidence intervals, were estimated. Model validity was examined, using the influence of each comparison on the estimated regression coefficients, using the Cook distance to detect possible outliers (a Cook distance of greater than three indicated trials causing abnormality of the residuals). The standard error of the log-risk ratio or log-odds ratio in each trial was
estimated from the number of standard errors that the reported relationship differed from zero.

Statistical heterogeneity was assessed using the $I^2$ and $X^2$, with $I^2$ values of over 50% defined as substantial heterogeneity. A probability of less than 0.10 for $X^2$ was considered to indicate a lack of homogeneity among the effects. Subgroup analyses assessed the use of energy restriction diet, increased physical activity, gender, initial BMI greater than or less than 30kg per m² and follow-up. Sensitivity analyses were carried out, excluding each trial in turn.

The presence of publication bias was evaluated using the Begg funnel plot and the Egger test.

**Results of the review**

Sixteen RCTs, with 19 comparisons and 3,436 participants, were included. Four trials scored less than three out of six for quality; six scored three; and six scored four. The full results of the quality assessment were not reported. Drop-out rates were up to 28.2% for intervention groups and 35.3% for control groups.

A Mediterranean diet was found to significantly reduce weight by a mean of 1.75kg (95% CI 0.64 to 2.86; 15 comparisons) and to reduce BMI by a mean of 0.57kg per m² (95% CI 0.21 to 0.93; 18 comparisons). Considerable heterogeneity was present for both of these analyses ($I^2$=94.93% for weight and 91.45% for BMI), but no evidence of publication bias was seen in the funnel plots (not shown) and the Egger test (p=0.24 for weight and 0.14 for BMI).

Larger reductions in body weight were observed where the diets were also energy restricted (WMD -3.88kg, 95% CI -6.54 to -1.21; four trials), included advice to increase physical activity (WMD -4.01kg, 95% CI -5.79 to -2.23; five trials), or had a follow-up longer than six months (WMD -2.69kg, 95% CI -3.99 to -1.38; seven trials). The effect of a Mediterranean diet was not significant in trials with no energy restriction, no increase in physical activity, and with six months or less of follow-up.

Results were not significantly altered in the sensitivity analyses.

**Authors’ conclusions**

The authors concluded that a Mediterranean diet could help to reduce body weight, especially when it was energy restricted, combined with physical activity, and longer than six months. It did not cause weight gain.

**CRD commentary**

The aim and inclusion criteria for this review were clear. A definition of what constituted a Mediterranean diet would have allowed the results to be more generalisable. The electronic literature search appears to have been thorough, in several databases, but no handsearch and no other attempts to identify grey literature were reported, leaving potential for publication bias. No language restrictions were used, suggesting that language bias should not be an issue.

Adequate trial details were provided and appropriate validity assessment was carried out, but the validity results were not given making it difficult to judge the true reliability of the data. Two authors screened studies for inclusion, but the number who conducted other methods was not explicitly stated. Considerable heterogeneity in the trial results was identified both for the primary and the subgroup analyses; several larger trials showed no significant effects and only two smaller trials showed large effects.

Given this variation and the lack of information on trial quality, the authors’ conclusions may not be reliable.

**Implications of the review for practice and research**

The authors did not state any implications for practice and further research.

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Not stated.

**Bibliographic details**

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.