






Abstract

Effect of an Energy-Restricted Mediterranean Diet, Physical Activity and Behavioral Support Lifestyle Intervention on Body Composition in Older Adults with Metabolic Syndrome: Three-Year Results of the PREDIMED-Plus Trial[†]

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Abstract: Background and objectives: Large and long-term randomized controlled trials (RCT) that test the effect of a weight-loss lifestyle intervention on the changes in the directly quantified body composition are scarce. Here, we aimed to evaluate the effect of an intensive nutritional and behavioral weight-loss intervention with an energy-restricted (er) Mediterranean Diet (MedDiet) on the changes in age-related overall and regional body composition objectively measured over three years. Methods: Body composition was measured with dual energy X-ray absorptiometry (DXA) in a subsample of 1521 participants (aged 55–75 years with overweight/obesity and metabolic syndrome) in the PREDIMED-Plus trial assigned (1:1) to multifactorial intervention with erMedDiet, increased physical activity (PA) and behavioral support (intervention) or usual care with advices to follow MedDiet without energy restriction or PA promotion (control group). The primary outcomes were 3-year changes in total fat and lean mass (expressed as % DXA-derived total body mass) and visceral fat (in grams). The potential interactions of study arm with time were tested in crude and multivariable linear-mixed effects models with repeated measurements at baseline and at 1 and 3 years. Results: After a 3-year follow-up, in the completers-only analysis adjusting for baseline characteristics, participants in the intervention vs. control group showed higher reductions in the % of total fat (mean difference of -0.38% , 95% CI -0.64 ; -0.12 , $p < 0.001$) and the grams of visceral fat (-70.4 g, -126 ; -15.2 , $p < 0.001$), as well as an increase in the % of total lean mass (0.34% , 0.09 ; 0.60 , $p < 0.001$). Discussion: The PREDIMED-Plus lifestyle weight-loss-focused intervention approach with erMedDiet and PA may suppress the age-dependent changes in body composition by reducing total and visceral fat and delaying the loss of lean mass in relation to the total body mass in older overweight/obese adults with metabolic syndrome.

Keywords: PREDIMED-Plus trial; Mediterranean Diet; physical activity; body composition; visceral fat

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Institutional Review Board Statement: The PREDIMED-Plus study protocol was reviewed and approved by the institutional review boards from all 23 participating centers.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: There are restrictions on data availability for the PREDIMED-Plus trial due to the signed consent agreements around data sharing, which only allow access to external researchers for studies following the project purposes. Requestors wishing to access the PREDIMED-Plus trial data used in this study can make a request to the PREDIMED-Plus trial Steering Committee chair: jordi.salas@urv.cat. The request will then be passed to members of the PREDIMED-Plus Steering Committee for deliberation.

Conflicts of Interest: Jordi Salas-Salvadó reported receiving personal fees from Instituto Danone Spain Member as a member of the advisory board, fees or travel expenses for meeting attendant from Danone Institute International and International Nut and Dried Fruit Foundation; and grants from the International Nut and Dried Fruit Foundation grant to his institution; and is an unpaid member of the advisory board outside the submitted work. No other disclosures were reported.

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