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Mediterranean Diet, Cereals, 4-Dimension Carbohydrate Quality and the New PREDIMED-PLUS Trial

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COLUMN ARTICLE

A traditional Mediterranean diet (MedDiet) represents an ideal choice for preventing cardiovascular disease [1], including heart failure [2], peripheral artery disease [3] and atrial fibrillation [4]. In addition, a MedDiet, rich in extra-virgin olive oil, obtained strong reductions in the risk of breast cancer [5] and type-2 diabetes [6]. In this context, PREDIMED was a landmark randomized trial (www.predimed.es) which showed important benefits for chronic disease prevention [7,8]. The Lyon secondary prevention trial [9] and a large number of observational prospective studies contribute in supporting causality [10-12].

A high consumption of cereals is included in most definitions of the MedDiet [13]. However, in PREDIMED no intervention was done to increase total cereal amount [14], and, furthermore, cereal intake was not included in the 14-item screener used for the intervention [15]. The reason was that refined cereals (mainly white bread in Spain) exert detrimental cardio-metabolic effects [16]. Moreover, the SUN study (a Mediterranean prospective cohort assessing the risk of cardiovascular disease) reported that the 4 most important beneficial characteristics of carbohydrate quality, beyond their total intake amount, were: 1) solid carbohydrates instead of liquid forms (e.g. sugar-sweetened beverages); 2) whole grains rather than refined grains (or products prepared with refined flours), 3) carbohydrate foods with a low glycemic index; and 4) a high dietary fiber intake [17].

In the context of the current pandemics of obesity and diabetes, an energy-restricted MedDiet with physical activity and weight loss might be the most sensible option for dietary interventions [18]. Restriction of refined carbohydrates and ensuring a high 4-dimension quality index of carbohydrates seems essential. Fortunately, a new large primary prevention trial (PREDIMED-PLUS) aims to go beyond the Mediterranean food pattern, by adding energy restriction, weight loss and physical activity. PREDIMED-PLUS is a multi-center Spanish trial which completed its recruitment by November 2016. The trial has randomized > 6,500 men and women (55 - 75 years, with metabolic syndrome and body mass index between 27 - 40 kg/m2) to 2 equally-sized arms: 1) energy-restricted MedDiet (30% reduction in calories) plus physical activity and weight loss (intensive intervention); 2) only MedDiet without energy restriction or physical activity (control group). The intensive intervention includes reductions in white bread ($\leq 1 \text{ serving/d}$), refined grains, rice and pasta (≤ 3 serving/wk), bakery, cookies and sweets (\leq 3 serving/wk) and sugar-sweetened beverages (≤ 1 serving/wk) and, on the other side, increases in the consumption of whole grains (≤ 5 servings/wk). This trial received funding from the European Research Council [19] and the Spanish Instituto de Salud Carlos III (www.isciii.es). The results of PREDIMED-PLUS (expected in 2021) may represent powerful evidence-based answers on the role of restricting poor-quality carbohydrates and other lifestyle options to combat the current epidemics of

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obesity, diabetes, cardiovascular disease and other chronic diseases.

Keywords: Carbohydrates; Mediterranean Diet; Cardiovascular Disease; Primary Prevention; Clinical Trial

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