

Abstract

Multicenter Randomized Controlled Trial to Tackle Obesity through a Mediterranean Diet vs. A Low-Fat Diet in Children and Adolescents: Preliminary Results from the MED4YOUTH STUDY [†]

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[†] Presented at the 14th European Nutrition Conference FENS 2023, Belgrade, Serbia, 14–17 November 2023.

Keywords: Mediterranean Diet; youth obesity; BMI; KIDMED; edutainment



Citation: Rosi, A.; Teixo, R.; Batista, N.; Calderón-Pérez, L.; Caimari, A.; Scazzina, F. Multicenter Randomized Controlled Trial to Tackle Obesity through a Mediterranean Diet vs. A Low-Fat Diet in Children and Adolescents: Preliminary Results from the MED4YOUTH STUDY. *Proceedings* **2023**, *91*, 126. <https://doi.org/10.3390/proceedings2023091126>

Academic Editors: Sladjana Sobajic and Philip Calder

Published: 19 January 2024



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Background and objectives: Youth obesity is likely to persist into adulthood, so it is important to tackle it from childhood to prevent associated risks in the future. To this end, the Med4Youth study [1,2] aims to investigate whether a low-calorie Mediterranean Diet (MD) is as effective in counteracting youth obesity and associated risk factors for cardiovascular diseases as the traditional clinical intervention with a low-calorie low-fat diet (LFD). **Methods:** A multicenter randomized controlled trial was carried out in children and adolescents (11–17 years, 50% female) overweight or with obesity (>90th percentile) from Italy (n = 80), Portugal (n = 26), and Spain (n = 42). Both dietary interventions were combined with an educational web-application to increase engagement and knowledge of participants through a “learning-through-playing” approach, using educational materials and games. To assess the efficacy of the intervention, anthropometric and biochemical parameters, as well as adherence to the MD, physical activity, food frequency, sociodemographic, and quality of life questionnaires were evaluated. **Results:** In total, 148 volunteers were recruited and randomized in one of the intervention groups, and so far, 107 finished the 4 months of treatment. The BMI z-score, the primary outcome, showed a significant reduction in both the MD group and the LFD group in all countries, but no significant differences have been found between groups. An increase in the level of adherence to the MD, measured through the KIDMED questionnaire, was also observed in both groups, although the score was higher in the MD group at the end of the intervention. **Discussion:** These preliminary results indicate that the MD intervention did not produce any additional benefits in comparison to the control group, but it is not less effective than the conventional clinical treatment based on a reduction in fat intake. **In conclusion,** the MD could be an effective, easier to follow and more sustainable dietary intervention to treat youth obesity in Mediterranean countries. The final results at the end of the study will allow us to prove, or not, these preliminary conclusions.

Author Contributions: Conceptualization, A.R., L.C.-P., A.C. and F.S.; methodology, A.R., R.T., N.B., L.C.-P., A.C. and F.S.; formal analysis, A.R., R.T., N.B., L.C.-P., A.C. and F.S.; investigation, A.R., R.T., N.B., L.C.-P., A.C. and F.S.; data curation, A.R.; writing—original draft preparation, A.R.; writing—review and editing, R.T., N.B., L.C.-P., A.C. and F.S. All authors have read and agreed to the published version of the manuscript.

Funding: This research is part of the PRIMA programme supported by the European Union. It is financially supported by the Agency for Business Competitiveness of the Government of Catalonia (ACCIÓ) [TECCT11-1-0012], the Centre for the Development of Industrial Technology (CDTI) of the Spanish Ministry of Science and Innovation, the Israel Innovation Agency, the Ministero dell'istruzione, dell'università e della ricerca MIUR, the Scientific Research Support Fund, the Foundation for Science and Technology (FCT).

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and it was approved by the Ethics Committee of the Institut d'Investigació Sanitària Pere i Virgili (Ref. 210/2020; 6 October 2020), the Area Vasta Emilia Nord (AVEN) (Ref. 1378, 14 January 2022), and the Centro Hospitalar e Universitário de Coimbra and Portuguese National Data Protection Commission (Ref. CHUC-197-20, 28 January 2021).

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

Data Availability Statement: The raw data supporting the conclusions of this article will be made available by the corresponding author on request.

Acknowledgments: We would like to express our thanks to all colleagues from Eurecat, University of Parma, University of Coimbra, NOVAPAN S.L., and SHIKMA Field Crops for their contribution in the EU-project MED4YOUTH.

Conflicts of Interest: The authors declare no conflict of interest.

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