



Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative)

Assessment Report for Individual Study

Study title

Effect of a Nutritional and Behavioral Intervention on Energy-Reduced Mediterranean Diet Adherence Among Patients With Metabolic Syndrome: Interim Analysis of the PREDIMED-Plus Randomized Clinical Trial

PMID

31613346

Journal

JAMA

Type of Publication and Period of assessment

Randomized Clinical Trials, SEES Pack 12

Note: The COVID-19 pandemics we are going through is very challenging and totally unprecedented. However, through it we can see that science conducted in an open, transparent and reproducible way is more than an ideal, it is a necessity. In this sense, we decided to keep our activities. However, we emphasize this evaluation was possibly not reviewed/questioned by the article authors due to the moment we are all going through. Thank you for your time and consideration.
SEES Initiative team.

| Component | Item | SEES assessment |
|----------------------|---|-----------------|
| Transparency | Registration: Is the study registered in a clinical trial database? | Yes |
| Transparency | Protocol: Is there referral of a publicly available methodological protocol? | Yes |
| Completeness | Title: Is the study identified as a randomized? | Yes |
| Intervention | Abstract: Does the abstract list the study interventions? | Yes |
| Outcome | Abstract: Does the abstract inform the primary outcome (variable of interest)? | Yes |
| Outcome | Abstract: If any quantitative result is reported, is it accompanied by the respective precision estimate (e.g., standard deviation, confidence intervals, etc)? | Yes |
| Completeness | Intro/Methods-TID2: Is there a rationale, theory, or goals described to present the essential elements of the intervention? | Yes |
| Critical appraisal | Introduction: Is there a hypothesis stated for the outcomes of interest? (Note: if there is not a directional hypothesis, but there is explanation for an exploratory approach, answer "Yes") | Yes |
| Completeness | Methods: Is there a description for the trial design (e.g., parallel, factorial, cluster)? | Yes |
| Participants | Methods: Is there a detailed description of eligibility criteria for participants? (i.e., information that would allow to replicate the inclusion and exclusion decisions) | Yes |
| Outcome | Methods: Are primary and secondary outcomes listed as well as their measurements specified? | Yes |
| Methodological rigor | Methods: Is the type of randomization sufficiently described? (Note: (i) type, such as computer; (ii) allocation ratio; and (iii) methods of restriction (if any) such as stratification or blocking should be considered) | Yes |
| Methodological rigor | Methods: Is there a mention regarding the mechanism for allocation concealment? | Yes |
| Methodological rigor | Methods: Is there a description of blinding/masking for measurements or analysis of outcomes? | Yes |
| Methodological rigor | Methods: Is there a description of sample size calculation? | Yes |
| Completeness | Methods/Intro-TID1: Is there a brief name or a phrase that describes the intervention? | Yes |
| Intervention | Methods-TID3: Is there a description of physical and information materials used as part of the intervention? (i.e., information that would allow to replicate the intervention with materials for participants or intervention providers) | No |
| Intervention | Methods-TID4: Is there a description of activities or procedures used to carry out the intervention? (i.e., information that would allow to replicate the necessary steps to run the intervention) | No |
| Participants | Methods-TID5: Is there a description of individuals involved in providing the intervention? (i.e., information that would allow to replicate the necessary workforce to run the intervention) | Yes |
| Intervention | Methods-TID6: Is there a description of modes of delivery of the intervention? (i.e., information that would allow to replicate the delivery to run the intervention, such as face-to-face, telephone, individually or in a group) | Yes |
| Intervention | Methods-TID7: Is there a description of location(s) where the intervention occurred? (Note: infrastructure and relevant features should be considered) | Yes |

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| Intervention | Methods/Results-TID8: Is there a description regarding the period, amount, intensity and schedule of delivery? (i.e., information that would allow to replicate 'when' and 'how much') | Yes |
| Intervention | Methods/Results-TID9: If any form of individual tailoring for the intervention was used (such as, variable exercise intensity), is there a description for the rationale and guide for tailoring? | Yes |
| Intervention | Methods/Results-TID11: Is there a description of materials/strategies used in regard to intervention adherence? | Yes |
| Intervention | Methods/Results-TID12: Is there a description of results of intervention adherence? (i.e., attrition rates)? | Yes |
| Critical appraisal | Methods: Is there a description of statistical methods used to compare groups for primary and secondary outcomes? | Yes |
| Participants | Results: Is there a participant flow (in text or diagram) reporting the numbers of participants who were assigned, received intervention, and were analyzed for the primary outcome? | Yes |
| Completeness | Results: Is there a description regarding the dates/periods of recruitment? (Note: if the follow-up has a variable length, the min-median-max durations should be considered) | Yes |
| Outcome | Results: Are baseline data for each group presented? | Yes |
| Outcome | Results: Is there a description on the actual number of participants analyzed? (Note: if numbers are reported only for the primary outcome, we choose "Yes") | Yes |
| Outcome | Results: Are the effect sizes described along with their precision measures? (e.g., continuous outcomes with standard deviation and binary outcomes with risk measures and absolute numbers) | Yes |
| Intervention | Results-TID10: Is there a description for non-planned modifications to the intervention during the course of the study? (Note: regards to the study level, and what-why-when for changes should be considered). | No |
| Intervention | Results: Is there a description for harm outcomes or adverse events? (Note: whether related or unrelated to interventions) | No |
| Critical appraisal | Discussion: Is there a discussion of potential bias, imprecision, multiplicity of analyses or other limitations? | Yes |
| Critical appraisal | Discussion: Is there a potential spin bias based on a specific reporting strategy to highlight that the experimental treatment is beneficial? | No |
| Transparency | Is there a statement regarding the data availability (data sharing plan)? | Yes |
| Completeness | Is there a statement regarding the sources of funding? | Yes |
| Completeness | Did the trial authors declare whether they had any conflicts of interest (COI)? | Yes, authors declare financial and non-financial COIs |