

INPLASY2024100072

doi: 10.37766/inplasy2024.10.0072

Received: 16 October 2024

Published: 16 October 2024

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**Mediterranean Diet in Older Adults: Cardiovascular Outcomes and Mortality from Observational and Interventional Studies. A Systematic Review and Meta-Analysis**

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**ADMINISTRATIVE INFORMATION**

**Support** - N/A.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2024100072

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 October 2024 and was last updated on 16 October 2024.

**INTRODUCTION**

**Review question / Objective** 1. To systematically review the evidence currently available around the relationship between high adherence to a Mediterranean diet and all-cause mortality and cardiovascular outcomes among older adults. 2. To clarify whether adopting a Mediterranean Diet may contribute to a better overall health and a lower likelihood of cardiovascular-related health issues in older individuals.

**Condition being studied** Cardiovascular mortality is a leading cause of mortality and disability among adults and promotion of healthy nutrition is an established prevention strategy. Mediterranean Diet (MD) is associated in the general population with a decreased risk of all-cause and cardiovascular mortality, but also of cardiovascular non-fatal events. Definitive data on MD's impact on older adults' global health is conflicting, due to the fact that studies focusing on older adults have

small sample sizes, as they generally include middle-aged adults and older patients represent a minority of the study population. Dietary interventions at an older age may not be as effective as data may suggest. Physiological changes occur during the aging process combined with loss of appetite, cognitive decline and chewing problems render nutritional interventions challenging in older demographics]. Moreover, aging is an independent risk factor for cardiovascular disease, but other risk factors are compounded by additional factors including frailty, obesity and diabetes, which are common conditions in an older population. These risk factors are known to complicate and enhance cardiac risk factors in an older demographic, therefore the positive effect of MD observed in the general population may not directly be extrapolated to an older demographic. The aim of the study is to assess the effectiveness of high adherence to MD in reducing cardiovascular events, cardiovascular mortality, and all-cause mortality among older adults.

## METHODS

**Search strategy** Combinations of the following terms: “Mediterranean diet” AND “cardiovascular”, “mortality” AND “Mediterranean diet”, “Mediterranean diet” AND “elderly”, “Mediterranean diet” AND “aging”, “Mediterranean diet” AND “frailty”, “Mediterranean diet” AND “survival”.

**Participant or population** Study populations with a mean age >60 years or sub-analysis for participants with age over 60 with Mediterranean diet as exposure, any gender, any nationality.

**Intervention** High adherence to Mediterranean diet.

**Comparator** Low adherence to Mediterranean diet.

**Study designs to be included** Cohort studies or randomized controlled trials.

**Eligibility criteria** Inclusion criteria were: 1) MD adherence as exposure; 2) mean age of the study population >60 years of age or sub-analysis for participants with age over 60; 3) all-cause mortality, cardiovascular mortality, and/or cardiovascular non-fatal events as study outcome 4) randomized controlled trials and cohort studies as study design 5) English language. Exclusion criteria were: 1) Studies not in the English language, 2) Full text unavailable.

**Information sources** Pubmed database and references check of the identified studies.

**Main outcome(s)** All-cause mortality, Cardiovascular mortality, Cardiovascular non-fatal events.

**Quality assessment / Risk of bias analysis** In accordance with the MOOSE guidelines, The Newcastle-Ottawa Quality Assessment Scale (NOS) will be used to assess the quality of the observational studies included. Additionally, following the PRISMA guidelines, the Cochrane Risk of Bias 2 (RoB 2) tool will be employed to evaluate the quality of the randomized controlled trials.

**Strategy of data synthesis** For all the study outcomes, the standard error of each study will be calculated. Pooled RR with 95% CI using random-effects models will then be obtained and graphically represented using forest plots.

Heterogeneity across studies will be evaluated using the I<sup>2</sup> statistics. I<sup>2</sup>>50% will be considered to indicate high heterogeneity. Publication bias will be assessed by inspecting the symmetry of funnel plots.

**Subgroup analysis** If possible, a subgroup analysis for subjects over the age of 70 was conducted.

**Sensitivity analysis** A sensitivity analysis including only randomized controlled trials (RCT) was performed.

**Language restriction** English.

**Country(ies) involved** Italy.

**Keywords** Mediterranean diet; mortality; cardiovascular disease.

### Contributions of each author

Author 1 - Michela Furbatto - Investigation, data curation, preparation of the original draft.

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