

Effects of Mediterranean diet on the primary prevention of cardiovascular disease

Submission date 02/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/07/2026	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Red G03/140

Study information

Scientific Title
Effects of a Mediterranean diet enriched with virgin olive oil or mixed nuts versus a low fat diet on the primary prevention of cardiovascular disease: a randomised controlled trial

Acronym

PREDIMED

Study objectives

A Mediterranean-style diet enriched with virgin olive oil or mixed nuts prevents cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the Hospital Clinic at Barcelona, Spain, 16/07/2002

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Participants are randomly assigned into three equal groups:

1. Mediterranean-style diet with added virgin olive oil
2. Mediterranean-style diet with added nuts
3. Low-fat diet according to American Heart Association guidelines

Added 07/05/2009:

All participants in the three arms will be treated and followed-up yearly from their inclusion to the second semester of 2011.

Intervention Type

Other

Primary outcome(s)

A composite endpoint of cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke.

Added 07/05/2009:

All participants are evaluated yearly for primary and secondary endpoints.

Key secondary outcome(s)

Death of any cause and incidence of angina leading to a revascularisation procedure, heart failure, diabetes mellitus, dementia, and cancer.

Other outcomes:

1. Changes in blood pressure
2. Body weight
3. Adiposity measures
4. Blood sugar
5. Lipid profile
6. Markers of inflammation
7. Other intermediate markers of cardiovascular risk

Added 07/05/2009:

All participants are evaluated yearly for primary and secondary endpoints.

Completion date

31/12/2011

Eligibility

Key inclusion criteria

Participants are community-dwelling high-risk persons aged 55 to 80 for men and aged 60 to 80 for women, without a history of cardiovascular disease (CHD), who fulfill at least one of the two following criteria:

1. Type 2 diabetes
2. Three or more of the risk factors:
 - 2.1. Current smoker
 - 2.2. Hypertension
 - 2.3. Hypercholesterolemia (low density lipoprotein cholesterol [LDL-cholesterol] more than 160 mg/dl or treatment with hypolipidemic drugs)
 - 2.4. High density lipoprotein cholesterol (HDL-cholesterol) less than 40 mg/dl
 - 2.5. Overweight or obesity (body mass index more than 25 kg/m²)
 - 2.6. Family history of premature CHD

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

55 Years

Upper age limit

80 Years

Sex

All

Total final enrolment

7447

Key exclusion criteria

1. Previous history of cardiovascular disease
2. Any severe chronic illness
3. Immunodeficiency or human immunodeficiency virus (HIV) positive status
4. Illegal drug use or chronic alcoholism
5. History of allergy to olive oil or nuts
6. Low predicted likelihood of changing dietary habits according to the Prochaska and DiClemente stages of change model

Date of first enrolment

01/10/2003

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

Spain

Study participating centre

Servicio de Medicina Interna

Barcelona

Spain

08036

Sponsor information**Organisation**

Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain)

ROR

<https://ror.org/00ca2c886>

Funder(s)**Funder type**

Industry

Funder Name

Instituto de Salud Carlos III (ref: G03/140)

Alternative Name(s)

SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Funder Name

Communal Patrimony Olivarero Foundation (Fundación Patrimonio Comunal Olivarero) (Spain)

Funder Name

Hojiblanca SA (Spain)

Funder Name

Borges SA (Spain)

Funder Name

Morella Nuts SA (Spain)

Funder Name

California Walnut Commission (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/07/2006		Yes	No
Results article	results	11/06/2007		Yes	No
Results article	results	08/12/2008		Yes	No
Results article	results	01/06/2011		Yes	No
Results article	results	01/09/2011		Yes	No
Results article	results	01/11/2011		Yes	No
Results article	results	01/01/2012		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	sub-study results	01/05/2012		Yes	No
Results article	results	01/06/2012		Yes	No
Results article	kidney function results	01/09/2012		Yes	No
Results article	phylloquinone intake results	01/11/2012		Yes	No
Results article	sub-study results	06/11/2012		Yes	No
Results article	primary results	04/04/2013		Yes	No
Results article	lifestyle and risk factor results	29/04/2013		Yes	No
Results article	white blood cell results	01/07/2013		Yes	No
Results article	mortality risk results	16/07/2013		Yes	No
Results article	sTWEAK concentration results	01/08/2013		Yes	No
Results article	transcriptomic results	01/09/2013		Yes	No
Results article	blood pressure results	19/09/2013		Yes	No
Results article	depression results	20/09/2013		Yes	No
Results article	gazpacho consumption results	01/10/2013		Yes	No
Results article	polyphenols results	01/10/2013		Yes	No
Results article	iron-induced insulin resistance results	22/10/2013		Yes	No
Results article	polymorphism results	01/11/2013		Yes	No
Results article	heme iron intake results	04/11/2013		Yes	No
Results article	cognition sub-study results	01/12/2013		Yes	No

Results article	magnesium intake results	01/01/2014	Yes	No
Results article	polymorphism results	06/01/2014	Yes	No
Results article	prevention of diabetes results	07/01/2014	Yes	No
Results article	carbohydrate response element binding protein results	01/02/2014	Yes	No
Results article	carotid intima-media thickness results	01/02/2014	Yes	No
Results article	plasma fatty acid composition results	20/03/2014	Yes	No
Results article	beer consumption results	01/04/2014	Yes	No
Results article	heart failure biomarkers results	01/05/2014	Yes	No
Results article	vitamin K intake results	01/05/2014	Yes	No
Results article	olive oil intake results	13/05/2014	Yes	No
Results article	polyphenol intake results	13/05/2014	Yes	No
Results article	re-analysis results	13/05/2014	Yes	No
Results article	habitual polyphenol intake results	01/06/2014	Yes	No
Results article	vascular wall inflammation and plaque vulnerability results	12/06/2014	Yes	No
Results article	atrial fibrillation results	01/07/2014	Yes	No
Results article	results	01/07/2014	Yes	No
Results article	results	29/07/2014	Yes	No
Results article	microRNA-410 regulated lipoprotein lipase variant rs13702 results	01/08/2014	Yes	No
Results article	blood pressure and depression results	26/08/2014	Yes	No
Results article	results	03/10/2014	Yes	No
Results article	fiber intake results	01/12/2014	Yes	No
Results article	plasma nitric oxide and blood pressure results	01/01/2015	Yes	No
Results article	telomere shortening results	01/02/2015	Yes	No
Results article	results	01/03/2015	Yes	No
Results article	results	01/07/2015	Yes	No
Results article	results	01/10/2015	Yes	No
Results article	results	01/10/2015	Yes	No
Results article	results	01/11/2015	Yes	No
Results	results	01/12		

article		/2015		Yes	No
Results	results	01/12		Yes	No
article		/2018			
Results	results	01/05	23/04	Yes	No
article		/2019	/2019		
Results	results	01/06		Yes	No
article		/2019			
Results	results	01/02	25/07	Yes	No
article		/2018	/2019		
Results	results	01/07	05/08	Yes	No
article		/2018	/2019		
Results	results	01/06	13/09	Yes	No
article		/2018	/2019		
Results	results	01/04	27/09	Yes	No
article		/2018	/2019		
Results	lysine pathway biomarker results	13/11	15/11	Yes	No
article		/2019	/2019		
Results	longitudinal association results	27/12	31/12	Yes	No
article		/2019	/2019		
Results	6 year follow up results	01/02	26/03	Yes	No
article		/2019	/2020		
Results	results	01/04	26/05	Yes	No
article		/2020	/2020		
Results	results	11/02	13/08	Yes	No
article		/2020	/2020		
Results	results	04/01	10/12	Yes	No
article		/2021	/2020		
Results	results	04/01	10/12	Yes	No
article		/2021	/2020		
Results	Sub-analysis in participants aged over 70 years	28/11	29/11	Yes	No
article		/2021	/2021		
Results	Arginine catabolism metabolites and atrial fibrillation or heart failure risk	16/05	18/05	Yes	No
article		/2022	/2022		
Results	Circulating citric acid cycle metabolites and risk of cardiovascular disease	12/01	06/02	Yes	No
article		/2023	/2023		
Results	AHA proposed 7 ideal cardiovascular health metrics and risk of atrial fibrillation	16/02	24/03	Yes	No
article		/2023	/2023		
Results	Plasma lipidome and risk of atrial fibrillation: results from the PREDIMED trial	01/04	03/04	Yes	No
article		/2023	/2023		
Results		16/09	18/09	Yes	No
article		/2023	/2023		
Results	Association of diabetes with adherence to Mediterranean diet	29/09	02/10	Yes	No
article		/2023	/2023		
Results	Association between nuclear magnetic resonance spectroscopy markers and adherence to Mediterranean diet	08/11	13/11	Yes	No
article		/2023	/2023		
Results	Association between serum B12 levels and adherence to Mediterranean diet	04/11	13/11	Yes	No
article		/2023	/2023		
Results	Olive oil consumption and T2D and CVD risk	13/12	20/12	Yes	No
article		/2023	/2023		
Results	Extra-Virgin Olive Oil and Additional Cardiovascular Outcomes in the PREDIMED Trial: An Outcome-Wide Perspective	02/09	05/09	Yes	No
article		/2025	/2025		

Results article	Urinary polyphenol signature of the Mediterranean diet is associated with lower cardiovascular disease risk: the PREDIMED trial	18/12/2025	19/12/2025	Yes	No
Results article		18/12/2025	02/01/2026	Yes	No
Results article		16/06/2026	16/06/2026	Yes	No
Other publications	metabolic syndrome status	18/11/2014		Yes	No
Other publications		10/11/2025	17/11/2025	Yes	No
Other publications	Adherence to different dietary patterns and subsequent risk of total, ischemic, and hemorrhagic stroke	23/02/2026	23/02/2026	Yes	No
Other publications	Adipokines and satiety hormones and incidence of Alzheimer's disease and dementia in older adults: a nested case-control study	02/07/2026	02/07/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes