ISRCTN35739639 https://doi.org/10.1186/ISRCTN35739639

Effects of Mediterranean diet on the primary prevention of cardiovascular disease

Submission date	Recruitment status	[ ] Prospectively registered
02/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/11/2025	Circulatory System	

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

Study design
Randomised controlled trial

Primary study design
Interventional

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/m^2)
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 article	results	01/12/2018		Yes	No
Results article	results	01/05/2019	23/04/2019	Yes	No
Results article	results	01/06/2019		Yes	No
Results article	results	01/02/2018	25/07/2019	Yes	No
Results article	results	01/07/2018	05/08/2019	Yes	No
Results article	results	01/06/2018	13/09/2019	Yes	No
Results article	results	01/04/2018	27/09/2019	Yes	No
Results article	lysine pathway biomarker results	13/11/2019	15/11/2019	Yes	No
Results article	longitudinal association results	27/12/2019	31/12/2019	Yes	No
Results article	6 year follow up results	01/02/2019	26/03/2020	Yes	No
Results article	results	01/04/2020	26/05/2020	Yes	No
Results article	results	11/02/2020	13/08/2020	Yes	No
Results article	results	04/01/2021	10/12/2020	Yes	No
Results article	results	04/01/2021	10/12/2020	Yes	No
Results article	Sub-analysis in participants aged over 70 years	28/11/2021	29/11/2021	Yes	No
Results article	Arginine catabolism metabolites and atrial fibrillation or heart failure risk	16/05/2022	18/05/2022	Yes	No
Results article	Circulating citric acid cycle metabolites and risk of cardiovascular disease	12/01/2023	06/02/2023	Yes	No
Results article	AHA proposed 7 ideal cardiovascular health metrics and risk of atrial fibrillation	16/02/2023	24/03/2023	Yes	No
Results article	Plasma lipidome and risk of atrial fibrillation: results from the PREDIMED trial	01/04/2023	03/04/2023	Yes	No
Results article		16/09/2023	18/09/2023	Yes	No
Results article	Association of diabetes with adherence to Mediterranean diet	29/09/2023	02/10/2023	Yes	No
Results article	Association between nuclear magnetic resonance spectroscopy markers and adherence to Mediterranean diet	08/11/2023	13/11/2023	Yes	No
Results article	Association between serum B12 levels and adherence to Mediterranean diet	04/11/2023	13/11/2023	Yes	No
Results article	Olive oil consumption and T2D and CVD risk	13/12/2023	20/12/2023	Yes	No
Results article	Extra-Virgin Olive Oil and Additional Cardiovascular Outcomes in the PREDIMED Trial: An Outcome-Wide Perspective	02/09/2025	05/09/2025	Yes	No

Other publications	metabolic syndrome status	18/11/2014		Yes	No
Other publications		10/11/2025	17/11/2025	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes