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Mediterranean Diet

The Mediterranean diet is one of the most extensively researched dietary patterns. The database includes over 1,000 human studies, of which nearly 300 are controlled investigations. The most notable finding: the majority of studies examine **metabolic and cardiovascular effects**, while other areas of application have significantly less evidence.

1,609

STUDIES IN
TOTAL

1,015

IN HUMANS

299

OF WHICH
CONTROLLED

24

IN ANIMALS

3

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

Mediterranean Diet at a Glance

ORIGIN:

The Mediterranean diet is a traditional, culturally influenced dietary pattern observed in the 1960s in countries such as Greece, Italy, and Spain.

1,609 evaluated studies · 299 controlled human trials · 716 observational studies · 164 review articles · 24 animal studies · 1 cell culture study

STRONGEST EVIDENCE:

- **Metabolism/Cardiovascular:** Controlled trials such as *PREDIMED* demonstrate consistent effects on metabolic parameters (e.g., visceral fat, HbA1c) and cardiovascular risk factors, particularly in high-risk populations. The dietary pattern investigated includes combinations with olive oil or nuts, and effects are observed for the combined intervention.
- **Cognition:** Intervention studies such as *DIRECT-PLUS* report dose-dependent changes in hippocampal volume with polyphenol-rich variants of the dietary pattern, especially in older participants.
- **Gut/Microbiome:** Studies such as *PREDIMED-Plus* show significant microbiome changes (e.g., increases in *Prevotella* and *Roseburia*), which correlate with metabolic improvements. In irritable bowel syndrome (IBS), the dietary pattern as a whole leads to gastrointestinal and psychological symptom relief.
- **Inflammatory Processes:** Reviews from *PREDIMED* document reductions in inflammatory markers (e.g., TNF-α) and oxidative stress through increased polyphenol intake, associated with microbiome modulation (e.g., *Faecalibacterium prausnitzii*).
- **Oncology:** Observational studies suggest a reduced risk of colorectal cancer, particularly in men, likely via anti-inflammatory and microbiome-mediated mechanisms of the dietary pattern.

LIMITATIONS:

- **Long-term Data:** Most studies have follow-ups of less than 5 years; hard endpoints such as dementia incidence or cardiovascular events are rarely documented.
- **Differential Efficacy:** Lack of analyses on genotypes (e.g., APOE-ε4, FTO risk allele), sex, or comorbidities; effects vary by population.
- **Generalisability:** Studies predominantly recruit older, Mediterranean populations with high cardiovascular risk; applicability to non-Mediterranean groups is unclear.

The Mediterranean diet is a culturally influenced, holistic dietary pattern with documented protective effects on metabolism, cognition, and inflammatory processes. However, its efficacy strongly depends on adherence, population, and lifestyle factors.

1. What the Mediterranean Diet Is

The Mediterranean diet describes a traditional dietary pattern observed in the 1960s in countries such as Greece, Italy, and Spain. It is **not a standardised protocol** but a **holistic concept** characterised by high proportions of plant-based foods (vegetables, fruit, legumes, nuts, whole grains), olive oil as the primary fat source, moderate consumption of fish and poultry, and low intake of red meat and sweets. Alcohol—particularly red wine—is consumed in moderation, usually with meals. The diet is **culturally influenced** and varies regionally, for example, in the proportions of dairy products or fish.

For research, the **operationalisation** of the Mediterranean diet is crucial. Adherence is often measured using **adherence scores**, such as the *Mediterranean Diet Score* (MDS) or the *PREDIMED-Score*, which evaluate the consumption of specific food groups. These scores enable the **quantitative assessment** of the dietary pattern in observational and interventional studies. However, **varying definitions** and **regional adaptations** complicate the comparability of results. Additionally, the Mediterranean diet is often combined with other lifestyle factors, such as physical activity, which **hinders the isolation of individual effects** in studies.

2. What the Studies Show in Detail

The key human studies and most important reviews—by application area, including population, duration, preparation, outcome measures, and results, as reported in the original publications. Numbers are included only where the study specifies them.

Distribution of **controlled human trials** by application area—the numbers are not additive, as one study may be assigned to multiple areas:

APPLICATION AREA	CONTROLLED TRIALS
Metabolism	157
Heart and Circulation	116
Cognition and Mental Health	65
Inflammatory Processes	57
Safety and Tolerability	52
Gut and Microbiome	35
Fatigue and Stress	30

APPLICATION AREA	CONTROLLED TRIALS
Musculoskeletal System	23

Cognition and Mental Health

The study examined the effects of a calorie-reduced MIND diet (a hybrid of the Mediterranean diet and the DASH diet, focusing on green leafy vegetables, berries, nuts, olive oil, whole grains, and fish) over 3 years, not the Mediterranean diet specifically. The intervention group (IG) followed this diet, while the control group (CG) received a calorie-reduced standard diet. Both groups received nutritional counselling and support for weight loss. The primary endpoint was the change in a global cognitive score (comprising 12 tests) and four cognitive domains. The study was limited by the lack of blinding and a selective population (predominantly white, educated participants).

The **DIRECT-PLUS study (2022, ⁴)** compared three dietary strategies over 18 months in 284 participants with abdominal obesity/dyslipidaemia (mean age 51 years, 88% male, BMI 31.2 kg/m²): 1) standard dietary recommendations (HDG), 2) Mediterranean diet (MED: 28 g walnuts/day, +440 mg polyphenols), 3) 'Green-MED' (additional 3–4 cups of green tea/day and 100 g Mankai shake/day, +800 mg polyphenols). All groups received free gym memberships. Primary endpoints were changes in brain volume (MRI-based: hippocampal occupancy score [HOC] and lateral ventricle volume expansion [LVV]). The Green-MED group showed a significantly smaller decrease in HOC (-0.06% vs. -1.0% in the HDG group; $p<0.001$) and reduced LVV expansion (1.3% vs. 3.2%; $p<0.001$), particularly in participants aged ≥ 50 years. The effects were dose-dependent: higher polyphenol intake correlated with smaller decreases in brain volume. Limitations: no placebo control, short follow-up for neurodegenerative endpoints.

B. Memory) were inconsistent. B. Movement).

Lack of long-term data on causal effects on dementia incidence and differential efficacy in risk groups (e.g., APOE- $\epsilon 4$ carriers).

Gut and Microbiome

The **PREDIMED-Plus substudy (2021, ²)** examined 362 overweight/obese participants (55–75 years) with metabolic syndrome over 1 year. The intervention group (IG) received a calorie-reduced Mediterranean diet (MedDiet) plus physical activity promotion, while the control group (CG) received a non-calorie-reduced MedDiet. After 1 year, the IG showed significant weight loss (-4.2 kg vs. -0.2 kg; $p<0.001$) and changes in the microbiome: decreases in *Butyrivibrio*, *Haemophilus*, *Ruminiclostridium* 5, and *Eubacterium hallii* (all $p<0.05$), while *Prevotella* and *Roseburia* increased. The microbiome changes correlated with improvements in metabolic parameters (e.g., fasting glucose, HDL cholesterol). Limitations: No placebo control, short follow-up duration, and the microbiome analysis was based on 16S rRNA sequencing (no metagenomics).

The **IBS study (2024, ⁹)** randomised 59 adults with irritable bowel syndrome (Rome IV criteria) and mild-to-moderate anxiety/depressive symptoms into a 6-week Mediterranean dietary intervention ($n=29$) or habitual diet ($n=30$). The IG received individualised counselling on the Mediterranean diet (e.g., olive oil, fish, legumes, nuts) and showed significantly higher adherence after 6 weeks (Mediterranean Diet Adherence Screener: 7.5 vs. 5.7; $p<0.001$). 83% of the IG vs. 37% of the CG were gastrointestinal responders ($p<0.001$), and 52% vs. 20% showed clinically relevant improvement in depression ($p=0.015$). FODMAP intake did not differ between groups ($p=0.51$). Microbiome analysis (metagenomics) revealed increases in *Faecalibacterium prausnitzii* and *Roseburia* in the IG ($p<0.05$), which were associated with reduced inflammatory markers (e.g., calprotectin). **Hypothesis:** The effects may be mediated via modulation of the gut-brain axis, as microbiome changes correlated with psychological symptoms.

Lack of studies on long-term effects on the microbiome and clinical endpoints (e.g., remission in IBS).

Metabolism

Participants were randomised into one of three groups within the broader PREDIMED framework: 1) MedDiet + extra virgin olive oil, 2) MedDiet + nuts, or 3) low-fat control diet. The study examined plasma amino acids (BCAA/AAA) via LC-MS/MS across all groups. Limitation: No direct measurement of insulin resistance (e.g., HOMA-IR).

In the PREDIMED-Plus substudy, the IG received a calorie-reduced MedDiet plus physical activity promotion, while the CG received a non-calorie-reduced MedDiet. The primary endpoint was change in body composition (DXA measurement). The IG showed greater reductions in visceral fat (-35 g; $p<0.001$) and android/gynoid fat ratio (-0.02 vs. -0.5 kg; $p<0.001$). Effects were more pronounced in men (p for interaction=0.02). Limitation: No blinding, and DXA measurements were limited to subcentres.

HYPOTHESIS The metabolic effects may be mediated via reduction of inflammatory markers.

Lack of long-term studies on hard endpoints (e.g., diabetes incidence) and differential effects by genotype (e.g., FTO risk allele).

Inflammatory Processes

Simultaneously, higher physical activity (LTPA) correlated with reduced MetS severity ($p<0.001$). Limitation: Cross-sectional design, no proof of causality.

The **PCOS study (2019, ¹⁶)** compared 112 women with PCOS and 112 controls (matched for age/BMI). Limitation: No intervention, only associative data.

The **review (2018, ¹⁷)** summarised data from the PREDIMED study: Mediterranean diet increased activity of endogenous antioxidants (e.g., superoxide dismutase: +12%; $p=0.001$) and reduced oxidative DNA damage (-20%; $p=0.01$). Higher polyphenol intake (particularly from olive oil and nuts) was associated with lower inflammatory markers (TNF- α : -15%; $p=0.004$). **Hypothesis:** The anti-inflammatory effects may be mediated via microbiome modulation, as suggested by the **review (2024, ¹⁸)**: Mediterranean diet promotes *Faecalibacterium prausnitzii* and *Bifidobacteria*, which produce short-chain fatty acids and strengthen the gut barrier.

Lack of RCTs on anti-inflammatory effects in specific diseases (e.g., rheumatoid arthritis).

Oncology

Sex-specific analysis showed stronger protection in men (HR=0.85 [0.75–0.97]; $p=0.01$) than in women (HR=0.88 [0.79–0.99]; $p=0.03$). **Hypothesis:** Preclinical data suggest potential mechanisms via reduction of inflammatory markers (e.g., IL-6) and microbiome modulation (e.g., increased *Lactobacillus* levels), though these effects remain to be confirmed in human studies.

Lack of RCTs on oncological endpoints and mechanisms (e.g., DNA damage, apoptosis).

Musculoskeletal System

Effects remained significant after adjustment for BMI, physical activity, and protein intake. Limitation: Cross-sectional design, no proof of causality, and the sample was small and homogeneous (women only).

Lack of interventional studies on musculoskeletal endpoints (e.g., sarcopenia, fracture risk).

Overall Picture

The Mediterranean diet shows protective effects on cognitive function, metabolic parameters, and inflammatory markers. Controlled trials support **cognitive resilience** (^{1, 4, 7}), **reduction of visceral fat and metabolic syndrome** (^{5, 6}), and **microbiome modulation** (^{2, 9}). Effects on depressive symptoms (⁸) and colorectal cancer risk (¹¹) showed promising results but are limited by heterogeneous study designs and lack of long-term data. **Hypothesis:** The synergistic effects of the Mediterranean diet (e.g., combination of polyphenols, unsaturated fatty acids, and fibre) may act via multiple mechanisms, including anti-inflammatory effects, oxidative stress reduction, and microbiome modulation (^{15, 18}).

Significant gaps remain in **differential efficacy** (e.g., by genotype, sex, comorbidities), **long-term effects** (most studies have follow-ups <5 years), and **generalizability to non-Mediterranean populations**. Additionally, RCTs are lacking for specific diseases such as rheumatoid arthritis or inflammatory bowel disease. The **combination with other lifestyle factors** (e.g., physical activity, fasting) is scarcely studied systematically, though synergistic effects are likely (⁵).

Methodology of the Study Landscape

The evidence is based on a mix of

RANDOMISED CONTROLLED TRIALS (RCTS)

(e.g., PREDIMED, PREDIMED-Plus, DIRECT-PLUS) and observational studies, with follow-ups ranging from 6 months to 8 years. Most controlled studies examined subgroups or secondary endpoints. Typical endpoints included **cognitive scores** in a trial of the related but distinct MIND diet (¹), brain atrophy in a Mediterranean diet and physical activity trial (⁴), **metabolic parameters** (e.g., HbA1c, visceral fat; ^{5, 6}), and **microbiome composition** (²). Another trial examined gastrointestinal and psychological symptoms (⁹). The study cited for **inflammatory markers** examined dietary patterns and body composition (¹⁶). Systematic reviews (e.g., ^{7, 11}) summarised findings on cognitive health and colorectal cancer; observational findings remain subject to confounding and selection bias. Systematic weaknesses include: 1) **lack of blinding** in dietary studies, 2) **short follow-ups** for neurodegenerative and oncological endpoints, 3) **heterogeneous adherence measurements** (e.g., PREDIMED score vs. 7-day protocols), 4) **limited generalisability** (most studies recruited older, Mediterranean populations with high cardiovascular disease risk). **Missing approaches:** No studies on dose-response relationships, no systematic investigation of interactions with medications (e.g., statins, antidiabetic drugs) or genetic predispositions (e.g., APOE-ε4).

Mediterranean Diet: A Dietary Pattern or a Lifestyle?

The Mediterranean diet is often discussed as an

ISOLATED DIETARY CONCEPT

, although in most studies it is **part of a broader lifestyle**. In intervention studies such as *PREDIMED* or *PREDIMED-Plus*, additional measures are frequently integrated, including **physical activity**, **behavioural change training**, or **social support**. These combinations complicate the **attribution of effects** to diet alone. Even in studies explicitly examining diet, **behavioural changes** (e.g., communal eating, mindful food selection) cannot be separated from the dietary pattern. The Mediterranean diet is thus **not a pure dietary pattern** but a **culturally influenced behaviour** that cannot be readily transferred to other populations.

A further issue is the

STANDARDISATION

of the Mediterranean diet in research. While traditional definitions are based on **regional differences** (e.g., higher fish consumption in coastal areas, more dairy products inland), studies often use **standardised scores** that do not reflect this diversity. Additionally, the **reference values** for “high adherence” vary between studies, limiting **comparability**. The Mediterranean diet is therefore **not a static concept** but a **dynamic pattern**, its definition shifting depending on the research question and population. This raises the question of whether the observed effects are attributable to **specific foods** or to the **holistic pattern**.

3. How Robust the Research Is

Research on the Mediterranean diet is **broadly based**, with a clear focus on **metabolic and cardiovascular diseases**. Over half of human studies are observational, while controlled trials, such as *PREDIMED* and *PREDIMED-Plus*, test the dietary pattern in **randomised, controlled designs**. Observational studies provide **only indications of associations**, not causal effects. Basic research focuses on **mechanisms**, such as the role of polyphenols, unsaturated fatty acids, or the gut microbiota.

The **methodological quality** of the studies is heterogeneous. Controlled investigations like *PREDIMED* are considered **high-quality** due to their randomised design and large participant numbers. However, **long-term data** are rare, and many studies combine diet with other interventions (e.g., exercise), complicating the **attribution of effects**. Observational studies are prone to **confounding**, such as socioeconomic factors or health-conscious behaviour. Furthermore, **dose-dependent analyses** are often lacking, as the Mediterranean diet is studied as a **holistic pattern** rather than individual components. The **transferability** to non-Mediterranean populations remains an open question.

4. Common Claims—and What the Data Show

CLAIM	EVIDENCE
Mediterranean diet prevents dementia	Controlled studies show evidence of cognitive effects , particularly in older individuals. However, the evidence is limited by short durations and heterogeneous
The diet is effective in children and adolescents	The data situation is still emerging . The few controlled studies primarily examine metabolic markers , not clinical endpoints. Observational studies show assoc
Mediterranean diet is effective for all inflammatory diseases	Controlled studies primarily exist for metabolically induced inflammations . For other inflammatory conditions (e.g., rheumatoid arthritis), the evidence is still c
The diet is effective against cancer	The data situation is very sparse . The few controlled studies show no clear effects . Observational studies suggest associations , but are prone to confounding

5. The Most Robust Studies

Ranked by evidential strength, not by prominence. The full evaluation includes significantly more studies; here, only the most robust are listed.

Controlled Human Studies

- ¹ Trial of the MIND Diet for Prevention of Cognitive Decline in Older Persons (2023)
- ² Effect on gut microbiota of a 1-y lifestyle intervention with Mediterranean diet compared with energy-reduced Mediterranean diet and physical activity (2021)
- ³ Plasma branched chain/aromatic amino acids, enriched Mediterranean diet and risk of type 2 diabetes: case-cohort study within the PREDIMED Trial (2018)
- Leisure-Time Physical Activity, Sedentary Behaviour and Diet Quality are Associated with Metabolic Syndrome Severity: The PREDIMED-Plus Study (2020)
- ⁴ The effect of a high-polyphenol Mediterranean diet (Green-MED) combined with physical activity on age-related brain atrophy: the Dietary Intervention (2022)
- Contribution of ultra-processed foods in visceral fat deposition and other adiposity indicators: Prospective analysis nested in the PREDIMED-Plus trial (2021)
- ⁵ An Energy-Reduced Mediterranean Diet, Physical Activity, and Body Composition: An Interim Subgroup Analysis of the PREDIMED-Plus Randomized Clinical Trial (2023)
- Effects of Nutrition on Cognitive Function in Adults with or without Cognitive Impairment: A Systematic Review of Randomized Controlled Clinical Trials (2021)
- ⁶ Carbohydrate quality changes and concurrent changes in cardiovascular risk factors: a longitudinal analysis in the PREDIMED-Plus randomised trial (2020)
- ⁷ Association between the Mediterranean diet and cognitive health among healthy adults: a systematic review and meta-analysis (2022)
- ⁸ The impact of the Mediterranean diet on alleviating depressive symptoms in adults: a systematic review and meta-analysis of randomised controlled trials (2025)
- Mediterranean Diet and Cardiometabolic Biomarkers in Children and Adolescents: A Systematic Review and Meta-Analysis (2024)
- ⁹ Clinical trial: A Mediterranean diet is feasible and improves gastrointestinal and psychological symptoms in irritable bowel syndrome (2024)
- Physical fitness and physical activity association with cognitive function and quality of life: baseline cross-sectional analysis of the PREDIMED-Plus trial (2020)
- Total and Subtypes of Dietary Fat Intake and Its Association with Components of the Metabolic Syndrome in a Mediterranean Population at High Cardiovascular Risk (2019)

- ¹⁰ The Effect of Adherence to the Mediterranean Diet on Late-Life Cognitive Disorders: A Systematic Review (2020)
- Longitudinal changes in adherence to the Portfolio and DASH dietary patterns and cardiometabolic risk factors in the PREDIMED-Plus study (2021)
- ¹¹ Adherence to the Mediterranean diet and its protective effects against colorectal cancer: a meta-analysis of 26 studies involving 2,217,404 participants (2025)
- Isotemporal substitution of inactive time with physical activity and time in bed: cross-sectional associations with cardiometabolic health in the PREDIMED-Plus trial (2019)
- Effectiveness of the physical activity intervention programme in the PREDIMED-Plus study: a randomised controlled trial (2018)
- Water intake, hydration status and 2-year changes in cognitive performance: a prospective cohort study (2023)
- ¹² Interplay between cognition and weight reduction in individuals following a Mediterranean Diet: Three-year follow-up of the PREDIMED-Plus trial (2021)
- ¹³ Long-term impact of the Mediterranean diet on cardiovascular disease prevention: A systematic review and meta-analysis of randomised controlled trials (2024)
- ¹⁴ Longitudinal association of changes in diet with changes in body weight and waist circumference in subjects at high cardiovascular risk: the PREDIMED study (2019)

6. Summary

Studies of the Mediterranean diet and lifestyle interventions incorporating it show **protective effects** on metabolic parameters (e.g., visceral fat, insulin resistance). Cognitive scores, brain atrophy and inflammatory markers (TNF- α , oxidative DNA damage) are distinct outcomes. Data from randomised controlled trials such as *PREDIMED* suggest effects of the dietary pattern; in *DIRECT-PLUS* the pattern was combined with physical activity, so the effects of individual components (e.g., polyphenols, unsaturated fatty acids, dietary fibre) cannot be separated. Modulation of the microbiome (e.g., increase in *Faecalibacterium prausnitzii*) has been observed in lifestyle interventions and may contribute to metabolic and mental health improvements. Observational studies also indicate a reduced risk of colorectal cancer; however, randomised long-term data are lacking here.

HYPOTHESIS

The effects may be based on multiple mechanisms, including anti-inflammatory action, reduction of oxidative stress and microbiome modulation. Synergistic effects with other lifestyle factors such as physical activity are plausible, though these are rarely studied in isolation.

Conclusions: The Mediterranean diet could serve as a preventive measure for metabolic syndrome, cognitive decline and chronic inflammation, provided cultural and individual adaptations are considered. However, targeted RCTs are lacking for specific conditions (e.g., rheumatoid arthritis, neurodegenerative diseases). Furthermore, it remains unclear whether the effects are attributable to individual food components (e.g., olive oil) or the holistic dietary pattern.

A **clarifying study** would need to address the following aspects: 1) **long-term follow-ups** (≥ 10 years) on hard endpoints such as dementia incidence or cardiovascular events, 2) **differential efficacy** by genotype (e.g., APOE- $\epsilon 4$ carriers), sex and comorbidities, 3) **dose-response relationships** of individual components (e.g., polyphenols vs. dietary fibre), 4) **interactions with medications** (e.g., statins, antidiabetic drugs) and 5) **transferability** to non-Mediterranean populations using standardised adherence scores. Additionally, synergistic effects with other lifestyle interventions (e.g., fasting, exercise) should be systematically investigated to understand the holistic impact of this dietary pattern.

7. Unresolved Questions

- **Long-term effects:** It remains unclear whether the Mediterranean diet influences **clinically relevant endpoints** (e.g., dementia, myocardial infarction) over the long term. Most studies last **under five years**.
- **Dose-response relationship:** There is **no standardised definition** of the adherence threshold at which effects occur. Most studies compare **high vs. low adherence**, not gradual differences.
- **Transferability:** Whether the effects are reproducible in **non-Mediterranean populations** is uncertain. Cultural differences in food choices and eating behaviours may play a role.

Frequently Asked Questions

Can the Mediterranean diet be used as a therapy for metabolic syndrome?

Controlled studies show **improvements in metabolic markers** (e.g., blood glucose, lipids) in individuals with metabolic syndrome. However, the effects are **moderate** and often combined with other lifestyle interventions. The Mediterranean diet can be used **supportively**. The evidence is **heavily influenced by the PREDIMED study**, the results of which are not universally applicable.

How is adherence to the Mediterranean diet measured in studies?

Frequently used are **scores** that assess the consumption of specific food groups. The *Mediterranean Diet Score* (MDS) and the *PREDIMED-Score* are the most common tools. These scores are based on **questionnaires** and define **thresholds** for 'Mediterranean' vs. 'non-Mediterranean'. However, **reference values** vary between studies, limiting comparability. Additionally, the scores do **not capture qualitative aspects** (e.g., preparation methods, food combinations).

Are there differences between the traditional Mediterranean diet and modern adaptations?

Modern adaptations (e.g., *Green-MED*, *MIND diet*) incorporate **additional components**, such as higher proportions of polyphenols or specific foods for cognitive effects. These variants are **not identical** to the traditional Mediterranean diet, which is **culturally and regionally influenced**. Studies on modern adaptations are **more recent and less extensive**, making their effects **harder to interpret**. The traditional form remains the **most thoroughly researched variant**.

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International Health Research

Research, put in context. Every statement leads to the original paper; the decision in the individual case rests with the treating professional.
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