

Clinical trials of diet

TrialResults-center www.trialresultscenter.org

1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
low fat diet vs mediterranean-style diet			
Tuttle , 2008 n=NA follow-up: 24 months	low-fat versus Mediterranean-style diets	First MI survivors	Parallel groups open

More details and results :

- cholesterol lowering intervention for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q45>

References

Tuttle, 2008:

Tuttle KR, Shuler LA, Packard DP, Milton JE, Daratha KB, Bibus DM, Short RA Comparison of low-fat versus Mediterranean-style dietary intervention after first myocardial infarction (from The Heart Institute of Spokane Diet Intervention and Evaluation Trial). Am J Cardiol 2008;101:1523-30 [[18489927](#)]

2 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
diet vs control			
NORDIET n=45/43 follow-up:	healthy Nordic diet versus control diet (subjects usualWestern diet)	mildly hypercholesterolaemic subjects	Sweden
BARON n=NA	-	-	
HPT n=NA	-	-	
Kumanyika n=NA	-	-	

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Trial	Treatments	Patients	Trials design and methods
TAIM n=NA	-	-	
DISH n=NA	-	-	
Burr (DART 2) , 2003 n=1571/1543 follow-up: 36-108 months	dietary advice (to eat more oily fish) versus No such dietary advice or capsules	men being treated for angina	Parallel groups open UK
Burr (DART) , 1989 n=1015/1018 follow-up: 24 months	dietary advice (to eat more oily fish) versus No such dietary advice or capsulesish)ag	post-MI	Parallel groups open UK
Mate-Jimenez , 1991 n=19/19 follow-up: 24months	diet advice versus no advice	people with inactive Crohns disease	Parallel groups open with blind assessment Spain
Mediterranean diet vs control			
Lyon n=302/303 follow-up:	-	-	
Mediterranean diet with EOVV vs control			
PREDIMED (olive oil) , 2013 [ISRCTN35739639] n=2543/2450 follow-up: 4.8 years	Mediterranean diet supplemented with extra-virgin olive oil versus control diet (advice to reduce dietary fat)	participants who were at high cardiovascular risk, but with no cardiovascular disease	Parallel groups open Spain
Mediterranean diet with nuts vs control			
PREDIMED (nuts) , 2013 [ISRCTN35739639] n=2454/2450 follow-up: 4.8 years	Mediterranean diet supplemented with mixed nuts versus control diet (advice to reduce dietary fat)	participants who were at high cardiovascular risk, but with no cardiovascular disease	open Spain
diet vs usual diet			
Black , 1994 n=56/55 follow-up: 2.0 years	diet with 20 percent of total caloric intake as fat versus usual diet	patients with nonmelanoma skin cancer	Parallel groups open
DART (Burr) , 1989 n=NA follow-up: 2 years	diet advice versus usual diet	men who had recovered from MI	Factorial plan open, blind assessment

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Trial	Treatments	Patients	Trials design and methods
Finnish Mental Hospital (Miettinen) , 1985 n=612/610 follow-up: 6.0 years	cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats) versus usual diet	middle-aged institutionalized women without CHD	Cluster-randomized cross-ove open, blind assessment Finland
Finnish Mental Hospital (Turpeinen) , 1979 n=NA follow-up: 6.0 years	cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats) versus usual diet	middle-aged institutionalized men without CHD	Cluster-randomized cross-ove open, blind assessment Finland
Goteborg , 1986 n=10004/20028 follow-up: 10 years	multifactorial intervention programme versus no intervention	men, 47-55 years old at entry	Parallel groups open Sweden
Gteborg (Wilhelmsen) , 1986 n=10004/20028 follow-up: 10.0 years	multifactorial intervention programme versus usual care	men, 47-55 years old at entry	Parallel groups open
Hjermann , 1981 n=604/628 follow-up: 6.5 years	diet versus usual diet	healthy, normotensive men at high risk of coronary heart disease	Parallel groups open Sweden
Kallio , 1979 n=188/187 follow-up: 3.0 years	diet (multifactorial intervention programme) versus usual diet	patients below 65 years who had an acute myocardial infarction	Parallel groups open
Los Angeles VA (Dayton) , 1969 n=424/422 follow-up: 65279;8.0 y	diet versus usual diet	men in domiciliary care, age>55, with or without CHD	Parallel groups double blind USA
Minnesota coronary survey (Frantz) , 1975 n=2197/2196 follow-up: 1.1 y (max 4.5y)	cholesterol lowering diet versus control diet	65279;Adult residents ofmental hospitals; no illness restrictions, no cholesterol concentration requirements	Parallel groups double-blind USA
MRC low fat , 1965 n=123/129 follow-up: 3 y	-	-	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
MRC Soya , 1968 n=199/194 follow-up: 3.5 y	Rgime pauvre en graisses satures + 85 g/j d'huile de soja versus usual diet	ambulatory men with recent MI	Parallel groups open, blind assessment
MRFIT , 1982 n=6428/6438 follow-up: 6.5 y	multifactor intervention program versus usual diet	high-risk men aged 35 to 57 years	Parallel groups open
Ornish , 1990 n=28/20 follow-up: 1.0 y	low-fat vegetarian diet, stopping smoking, stress management training, and moderate exercise versus usual-care	Patients with angiographically documented coronary artery disease	Parallel groups open USA
Oslo Diet Heart Study (Leren) , 1966 n=206/206 follow-up: 5 y (11y)	diet versus usual care	middle-aged ambulatory men with prior MI	Parallel groups open, blind assessment
Rose , 1965 n=28/26 follow-up: 1.2 years	Rgime restreint en graisses + 80 g/j huile de mas versus usual diet	men, <70 years	Parallel groups open
Singh , 1992 n=204/202 follow-up: 65279;2.0 years	strict diet versus usual diet	patients with suspected acute myocardial infarction	Parallel groups open
STARS (St Thomas, diet) , 1992 n=30/30 follow-up: 3.0 years	dietary advice versus usual diet	patients with angina or past myocardial infarction	open, blind assessment
Veterans Ad. (Dayton) , 1969 n=424/422 follow-up: 3.6 and 8 y	cholesterol lowering diet versus usual diet	men in domiciliary care, age>55, with or without CHD	Parallel groups double blind USA
WHI low fat , 2005 [NCT00000611] n=19541/29294 follow-up: 8.1y mean	dietary modification intervention to promote dietary change with the goals of reducing intake of total fat to 20% of energy and increasing consumption of vegetables and fruit to at least 5 servings daily and grains to at least 6 servings daily versus usual diet	postmenopausal women, aged 50 to 79 years, without prior breast cancer	Parallel groups open US

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Trial	Treatments	Patients	Trials design and methods
WHO Collaborative , 1986 n=30489/26971 follow-up: 5.5 years	multifactorial prevention versus usual diet	middle-aged men	Parallel groups open Belgium, Italy, Poland, UK
Woodhill , 1966 n=221/237 follow-up: <7 years	diet versus usual diet	men, 30-59 years	Parallel groups open
low fat diet vs mediterranean-style diet			
Tuttle , 2008 n=NA follow-up: 24 months	low-fat versus Mediterranean-style diets	First MI survivors	Parallel groups open

More details and results :

- cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD at <http://www.trialresultscenter.org/go-Q5>
- cholesterol lowering intervention for cardiovascular prevention in patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>
- omega-3 fatty acids for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q121>
- omega-3 fatty acids for cardiovascular prevention in patients at high risk at <http://www.trialresultscenter.org/go-Q123>
- omega-3 fatty acids for cardiovascular prevention in pateints at low risk at <http://www.trialresultscenter.org/go-Q124>
- cholesterol lowering intervention for cardiovascular prevention in all chronical situations at <http://www.trialresultscenter.org/go-Q154>
- lifestyle intervention for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q282>
- diet for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q568>
- statins for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q689>

References

NORDIET, :

Adamsson V, Reumark A, Fredriksson IB, Hammarstrm E, Vessby B, Johansson G, Risrus U Effects of a healthy Nordic diet on cardiovascular risk factors in hypercholesterolaemic subjects: a randomized controlled trial (NORDIET). J Intern Med 2011;269:150-9 [20964740] [10.1111/j.1365-2796.2010.02290.x](https://doi.org/10.1111/j.1365-2796.2010.02290.x)

BARON, :

Baron JA, Gleason R, Crowe B, Mann JI Preliminary trial of the effect of general practice based nutritional advice. *Br J Gen Pract* 1990;40:137-41 [[2115348](#)]

HPT, :

The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. Hypertension Prevention Trial Research Group. *Arch Intern Med* 1990;150:153-62 [[2404477](#)]

Kumanyika, :

Kumanyika SK, Hebert PR, Cutler JA, Lasser VI, Sugars CP, Steffen-Batey L, Brewer AA, Cameron M, Shepek LD, Cook NR Feasibility and efficacy of sodium reduction in the Trials of Hypertension Prevention, phase I. Trials of Hypertension Prevention Collaborative Research Group. *Hypertension* 1993;22:502-12 [[8406655](#)]

TAIM, :

Davis BR, Oberman A, Blafox MD, Wassertheil-Smoller S, Zimbaldi N, Kirchner K, Wylie-Rosett J, Langford HG Lack of effectiveness of a low-sodium/high-potassium diet in reducing antihypertensive medication requirements in overweight persons with mild hypertension. TAIM Research Group. Trial of Antihypertensive Interventions and Management. *Am J Hypertens* 1994;7:926-32 [[7826557](#)]

DISH, :

Langford HG, Blafox MD, Oberman A, Hawkins CM, Curb JD, Cutter GR, Wassertheil-Smoller S, Pressel S, Babcock C, Abernethy JD Dietary therapy slows the return of hypertension after stopping prolonged medication. *JAMA* 1985;253:657-64 [[3881608](#)]

Burr (DART 2), 2003:

Ness AR, Gallacher JE, Bennett PD, Gunnell DJ, Rogers PJ, Kessler D, Burr ML Advice to eat fish and mood: a randomised controlled trial in men with angina. *Nutr Neurosci* 2003 Feb;6:63-5 [[12608739](#)]

Burr (DART), 1989:

Burr ML, Fehily AM, Gilbert JF, Rogers S, Holliday RM, Sweetnam PM, Elwood PC, Deadman NM Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). *Lancet* 1989 Sep 30;2:757-61 [[2571009](#)]

Ness AR, Whitley E, Burr ML, Elwood PC, Smith GD, Ebrahim S The long-term effect of advice to eat more fish on blood pressure in men with coronary disease: results from the diet and reinfarction trial. *J Hum Hypertens* 1999 Nov;13:729-33 [[10578215](#)]

Mate-Jimenez, 1991:**Lyon, :**

de Lorgeril M, Renaud S, Mamelle N, Salen P, Martin JL, Monjaud I, Guidollet J, Touboul P, Delaye J Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. *Lancet* 1994;343:1454-9 [[7911176](#)]

De Lorgeril M, Salen P, Martin JL, Mamelle N, Monjaud I, Touboul P, Delaye J Effect of a mediterranean type of diet on the rate of cardiovascular complications in patients with coronary artery disease. Insights into the cardioprotective effect of certain nutriment. *J Am Coll Cardiol* 1996;28:1103-8 [[8890801](#)] [10.1016/S0735-1097\(96\)00280-X](#)

de Lorgeril M, Renaud S, Mamelle N, Salen P, Martin JL, Monjaud I, Guidollet J, Touboul P, Delaye J Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. *Lancet* 1994;343:1454-9 [[7911176](#)]

De Lorgeril M, Salen P, Martin JL, Mamelle N, Monjaud I, Touboul P, Delaye J Effect of a mediterranean type of diet on the rate of cardiovascular complications in patients with coronary artery disease. Insights into the cardioprotective effect of certain nutriment. *J Am Coll Cardiol* 1996;28:1103-8 [[8890801](#)] [10.1016/S0735-1097\(96\)00280-X](#)

PREDIMED (olive oil), 2013:

Estruch R, Ros E, Salas-Salvad J, Covas MI, D Pharm, Corella D, Ars F, Gmez-Gracia E, Ruiz-Gutierrez V, Fiol M, Lapetra J, Lamuela-Raventos RM, Serra-Majem L, Pint X, Basora J, Muñoz MA, Sorl JV, Martínez JA, Martínez-González MA Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. *N Engl J Med* 2013 Feb 25;: [23432189] [10.1056/NEJMoa1200303](https://doi.org/10.1056/NEJMoa1200303)

PREDIMED (nuts), 2013:

Estruch R, Ros E, Salas-Salvad J, Covas MI, D Pharm, Corella D, Ars F, Gmez-Gracia E, Ruiz-Gutierrez V, Fiol M, Lapetra J, Lamuela-Raventos RM, Serra-Majem L, Pint X, Basora J, Muñoz MA, Sorl JV, Martínez JA, Martínez-González MA Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. *N Engl J Med* 2013 Feb 25;: [23432189] [10.1056/NEJMoa1200303](https://doi.org/10.1056/NEJMoa1200303)

Black, 1994:

Black HS, Herd JA, Goldberg LH, Wolf JE Jr, Thornby JI, Rosen T, Bruce S, Tschen JA, Foreyt JP, Scott LW Effect of a low-fat diet on the incidence of actinic keratosis. *N Engl J Med* 1994;330:1272-5 [[8145782](https://doi.org/10.1056/NEJMoa1200303)]

DART (Burr), 1989:

Burr ML, Fehily AM, Gilbert JF, Rogers S, Holliday RM, Sweetnam PM, Elwood PC, Deadman NM Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). *Lancet* 1989;2:757-61 [[2571009](https://doi.org/10.1056/NEJMoa1200303)]

Finnish Mental Hospital (Miettinen), 1985:

European collaborative trial of multifactorial prevention of coronary heart disease: final report on the 6-year results. World Health Organisation European Collaborative Group. *Lancet* 1986;1:869-72 [[2870351](https://doi.org/10.1056/NEJMoa1200303)]

Miettinen TA, Huttunen JK, Naukkarinen V, Strandberg T, Mattila S, Kumlin T, Sarna S Multifactorial primary prevention of cardiovascular diseases in middle-aged men. Risk factor changes, incidence, and mortality. *JAMA* 1985;254:2097-102 [[4046137](https://doi.org/10.1056/NEJMoa1200303)]

Miettinen M, Turpeinen O, Karvonen MJ, Pekkarinen M, Paavilainen E, Elosuo R Dietary prevention of coronary heart disease in women: the Finnish mental hospital study. *Int J Epidemiol* 1983;12:17-25 [[6840954](https://doi.org/10.1056/NEJMoa1200303)]

Finnish Mental Hospital (Turpeinen), 1979:

Turpeinen O, Karvonen MJ, Pekkarinen M, Miettinen M, Elosuo R, Paavilainen E Dietary prevention of coronary heart disease: the Finnish Mental Hospital Study. *Int J Epidemiol* 1979;8:99-118 [[393644](https://doi.org/10.1056/NEJMoa1200303)]

Goteborg, 1986:

Wilhelmsen L, Berglund G, Elmfeldt D, Tibblin G, Wedel H, Pennert K, Vedin A, Wilhelmsson C, Werk L The multifactor primary prevention trial in Gteborg, Sweden. *Eur Heart J* 1986;7:279-88 [[3720755](https://doi.org/10.1056/NEJMoa1200303)]

Gteborg (Wilhelmsen), 1986:

Wilhelmsen L, Berglund G, Elmfeldt D, Tibblin G, Wedel H, Pennert K, Vedin A, Wilhelmsson C, Werk L The multifactor primary prevention trial in Gteborg, Sweden. *Eur Heart J* 1986;7:279-88 [[3720755](https://doi.org/10.1056/NEJMoa1200303)]

Hjermann, 1981:

Hjermann I, Velve Byre K, Holme I, Leren P Effect of diet and smoking intervention on the incidence of coronary heart disease. Report from the Oslo Study Group of a randomised trial in healthy men. *Lancet* 1981;2:1303-10 [[6118715](https://doi.org/10.1056/NEJMoa1200303)]

Kallio, 1979:

Kallio V, Hmlinen H, Hakkila J, Luurila OJ Reduction in sudden deaths by a multifactorial intervention programme after acute myocardial infarction. *Lancet* 1979;2:1091-4 [[91836](https://doi.org/10.1056/NEJMoa1200303)]

Los Angeles VA (Dayton), 1969:

Rogers MC Sir John Scott Burdon-Sanderson (1828-1905): a pioneer in electrophysiology. *Circulation* 1969;40:1-2 [4893441]

Dayton S, Pearce ML Diet high in unsaturated fat. A controlled clinical trial. *Minn Med* 1969;52:1237-42 [4896402]

Minnesota coronary survey (Frantz), 1975:

Frantz ID Jr, Dawson EA, Ashman PL, Gatewood LC, Bartsch GE, Kuba K, Brewer ER Test of effect of lipid lowering by diet on cardiovascular risk. The Minnesota Coronary Survey. *Arteriosclerosis* 1989;9:129-35 [2643423]

MRC low fat, 1965:

, Low-fat diet in myocardial infarction: A controlled trial. *Lancet* 1965; 2:501-4 [4158171]

MRC Soya, 1968:

, Controlled trial of soya-bean oil in myocardial infarction. *Lancet* 1968; 2:693-9 [4175085]

MRFIT, 1982:

Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. *JAMA* 1982;248:1465-77 [7050440]

Ornish, 1990:

Ornish D, Brown SE, Scherwitz LW, Billings JH, Armstrong WT, Ports TA, McLanahan SM, Kirkeeide RL, Brand RJ, Gould KL Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet* 1990;336:129-33 [1973470]

Oslo Diet Heart Study (Leren), 1966:

Leren P, The Oslo diet-heart study. Eleven-year report. *Circulation* 1970; 42:935-42 [5477261]

Rose, 1965:

ROSE GA, THOMSON WB, WILLIAMS RT CORN OIL IN TREATMENT OF ISCHAEMIC HEART DISEASE. *Br Med J* 1965 Jun 12;1:1531-3 [14288105]

Singh, 1992:

Singh RB, Rastogi SS, Verma R, Laxmi B, Singh R, Ghosh S, Niaz MA Randomised controlled trial of cardioprotective diet in patients with recent acute myocardial infarction: results of one year follow up. *BMJ* 1992;304:1015-9 [1586782]

STARS (St Thomas, diet), 1992:

Watts GF, Lewis B, Brunt JN, Lewis ES, Coltart DJ, Smith LD, Mann JI, Swan AV Effects on coronary artery disease of lipid-lowering diet, or diet plus cholestyramine, in the St Thomas' Atherosclerosis Regression Study (STARS) *Lancet* 1992;339:563-9 [1347091]

Veterans Ad. (Dayton), 1969:

Dayton S, Pearce ML, Hashimoto S, Dixon WJ, Tomiyasu U. A controlled clinical trial of a diet high in unsaturated fat in preventing complications of atherosclerosis. *Circulation* 1969; 40(supp 2):1-55 [0]

WHI low fat, 2005:

Howard BV, Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, Kuller LH, LaCroix AZ, Langer RD, Lasser NL, Lewis CE, Limacher MC, Margolis KL, Mysiw WJ, Ockene JK, Parker LM, Perri MG, Phillips L, Prentice RL, Robbins J, Rossouw JE, Sarto Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *JAMA* 2006 Feb 8;295:655-66 [16467234]

WHO Collaborative, 1986:

European collaborative trial of multifactorial prevention of coronary heart disease: final report on the 6-year results. World Health Organisation European Collaborative Group. *Lancet* 1986;1:869-72 [2870351]

Woodhill, 1966:

Woodhill JM, Palmer AJ, Leelarthaeapin B, McGilchrist C, Blacket RB, Low fat, low cholesterol diet in secondary prevention of coronary heart disease. Adv Exp Med Biol 1978; 109:317-30 [727035]

Tuttle, 2008:

Tuttle KR, Shuler LA, Packard DP, Milton JE, Daratha KB, Bibus DM, Short RA Comparison of low-fat versus Mediterranean-style dietary intervention after first myocardial infarction (from The Heart Institute of Spokane Diet Intervention and Evaluation Trial). Am J Cardiol 2008;101:1523-30 [18489927]

3 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
AHA 2 diet vs AHA 1 diet			
Liao , 2002 n=70 follow-up: 22 months	American Heart Association (AHA) step 2 diet (<30% of total calories as fat, <7% saturated fat, 55% carbohydrate, and <200 mg cholesterol daily) plus endurance exercise for 1 h three times a week versus AHA step 1 diet (30% of total calories as fat, 10% saturated fat, 50% carbohydrate, and <300 mg cholesterol) plus stretching exercise three times a week	Japanese American subjects with impaired glucose tolerance (WHO criteria 1998)	Parallel groups open USA
intensive dietary advice vs routine dietary advice			
Wein , 1999 n=200 follow-up: 4.24 y	intensive dietary advice versus routine dietary advice	women with previous gestational diabetes and currently with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups open USA

More details and results :

- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>

References

Liao, 2002:

Liao D, Asberry PJ, Shofer JB, Callahan H, Matthys C, Boyko EJ, Leonetti D, Kahn SE, Austin M, Newell L, Schwartz RS, Fujimoto WY Improvement of BMI, body composition, and body fat distribution with lifestyle modification in Japanese Americans with impaired glucose tolerance. Diabetes Care 2002;25:1504-10 [12196418]

Wein, 1999:

Wein P, Beischer N, Harris C, Permezel M A trial of simple versus intensified dietary modification for prevention of progression to diabetes mellitus in women with impaired glucose tolerance. Aust N Z J Obstet Gynaecol 1999;39:162-6 [[10755770](#)]