

# Clinical trials of diet for cardiovascular prevention in all type of patients

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## 1 diet

Trial	Treatments	Patients	Trials design and methods
<b>diet vs control</b>			
<b>NORDIET</b> n=45/43 follow-up:	healthy Nordic diet versus control diet (subjects usualWestern diet)	mildly hypercholesterolaemic subjects	Sweden
<b>BARON</b> n=NA	-	-	
<b>HPT</b> n=NA	-	-	
<b>Kumanyika</b> n=NA	-	-	
<b>TAIM</b> n=NA	-	-	
<b>DISH</b> n=NA	-	-	
<b>diet vs usual diet</b>			
<b>Black , 1994</b> 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
<b>DART (Burr) , 1989</b> n=NA follow-up: 2 years	diet advice versus usual diet	men who had recovered from MI	Factorial plan open, blind assessment
<b>Finnish Mental Hospital (Miettinen) , 1985</b> 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
<b>Finnish Mental Hospital (Turpeinen) , 1979</b> 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
<b>Goteborg , 1986</b> n=10004/20028 follow-up: 10 years	multifactorial intervention programme versus no intervention	men, 47-55 years old at entry	Parallel groups open Sweden

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Gteborg (Wilhelmsen) , 1986</b> n=10004/20028 follow-up: 10.0 years	multifactorial intervention programme versus usual care	men, 47-55 years old at entry	Parallel groups open
<b>Hjermann , 1981</b> 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
<b>Kallio , 1979</b> 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
<b>Los Angeles VA (Dayton) , 1969</b> 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
<b>Minnesota coronary survey (Frantz) , 1975</b> n=2197/2196 follow-up: 1.1 y (max 4.5y)	cholesterol lowering diet versus control diet	65279;Adult residents of mental hospitals; no illness restrictions, no cholesterol concentration requirements	Parallel groups double-blind USA
<b>MRC low fat , 1965</b> n=123/129 follow-up: 3 y	-	-	Parallel groups open
<b>MRC Soya , 1968</b> 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
<b>MRFIT , 1982</b> 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
<b>Ornish , 1990</b> 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
<b>Oslo Diet Heart Study (Leren) , 1966</b> n=206/206 follow-up: 5 y (11y)	diet versus usual care	middle-aged ambulatory men with prior MI	Parallel groups open, blind assessment
<b>Rose , 1965</b> 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
<b>Singh , 1992</b> n=204/202 follow-up: 65279;2.0 years	strict diet versus usual diet	patients with suspected acute myocardial infarction	Parallel groups open

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>STARS (St Thomas, diet) , 1992</b> n=30/30 follow-up: 3.0 years	dietary advice versus usual diet	patients with angina or past myocardial infarction	open, blind assessment
<b>Veterans Ad. (Dayton) , 1969</b> 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
<b>WHI low fat , 2005</b> [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
<b>WHO Collaborative , 1986</b> n=30489/26971 follow-up: 5.5 years	multifactorial prevention versus usual diet	middle-aged men	Parallel groups open Belgium, Italy, Poland, UK
<b>Woodhill , 1966</b> n=221/237 follow-up: <7 years	diet versus usual diet	men, 30-59 years	Parallel groups open
<b>low fat diet vs mediterranean-style diet</b>			
<b>Tuttle , 2008</b> n=NA follow-up: 24 months	low-fat versus Mediterranean-style diets	First MI survivors	Parallel groups open

## References

### **NORDIET, :**

Adamsson V, Reumark A, Fredriksson IB, Hammarström 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, Blaurock 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]

**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]

**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]

**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]

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]

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]

**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]

**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]

**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]

**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]

**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]

**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, Leelarthapin 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]

## 2 Mediterranean diet

Trial	Treatments	Patients	Trials design and methods
<b>Mediterranean diet vs control</b>			
Lyon n=302/303 follow-up:	-	-	
<b>Mediterranean diet with EOVV vs control</b>			

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CT

Trial	Treatments	Patients	Trials design and methods
<b>PREDIMED (olive oil) , 2013</b> [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
<b>Mediterranean diet with nuts vs control</b>			
<b>PREDIMED (nuts) , 2013</b> [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

## References

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 nutriments.* *J Am Coll Cardiol* 1996;28:1103-8 [8890801] [10.1016/S0735-1097\(96\)00280-X](https://doi.org/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 nutriments.* *J Am Coll Cardiol* 1996;28:1103-8 [8890801] [10.1016/S0735-1097\(96\)00280-X](https://doi.org/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)

## 3 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.