

# Clinical trials of lifestyle intervention 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 usual Western 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

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<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>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

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## 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>			
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
<b>Mediterranean diet with nuts vs control</b>			

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Trial	Treatments	Patients	Trials design and methods
<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

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## 3 Multiple risk factor interventions

Trial	Treatments	Patients	Trials design and methods
<b>Multiple risk factor interventions vs control</b>			
<b>CELL , 1995</b> n=339/320 follow-up: 18 months	intensive" health care advice through six group sessions versus usual care	subjects aged 30-59 years, with at least two cardiovascular risk factors in addition to moderately high lipid concentrations: total cholesterol >or = 6.5 mmol/l on three occasions, triglycerides <4.0 mmol/l, and ratio of low density lipoprotein cholesterol to high density lipoprotein cholesterol >4.0	Factorial plan open

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Family Heart , 1994</b> n=3436/5912 follow-up: 1 y	Nurse led programme using a family centred approach with follow up according to degree of risk. Counselling on diet, weight, smoking, exercise, alcohol versus control	men aged 40-59 and their partners	Parallel groups double-blind UK
<b>Gteborg Study , 1986</b> n=10004/20018 follow-up: 11.8 yr	multifactorial intervention programme on coronary heart disease versus no intervention	random sample of men age 47-55 y	open Sweden
<b>HDFP , 1979</b> [NCT00000498] n=5485/5455 follow-up: 5 yr	Stepped care: Antihypertensive drugs, diet, smoking advice, weight control, exercise versus usual primary care	persons with high blood pressure	Parallel groups open USA
<b>Helsinki Businessmen Study , 1985</b> n=612/610 follow-up: 5 yr	Multifactorial prevention of cardiovascular diseases versus no intervention	healthy men 40-58 y at high risk	Parallel groups open Finland
<b>Johns Hopkins , 1983</b> n=350/50 follow-up: 5 yr	health education interventions versus control	hypertensives men and women	Factorial plan open USA
<b>Meland , 1997</b> n=69/58 follow-up: 1 y	patient-centred, self-directive intervention of lifestyle changes in general practice versus conventional care	men with high coronary heart disease risk	Parallel groups open
<b>MRFIT , 1982</b> [NCT00000487?acronym=] n=6428/6438 follow-up: 6 yr	special intervention (SI) program consisting of stepped-care treatment for hypertension, counseling for cigarette smoking, and dietary advice for lowering blood cholesterol levels versus no intervention	high-risk men aged 35 to 57 years	Parallel groups open
<b>Oslo , 1981</b> n=612/610 follow-up: 5 yr	recommendation to lower their blood lipids by change of diet and to stop smoking versus no intervention	healthy, normotensive men at high risk of coronary heart disease	Parallel groups open Oslo, Norway
<b>OXCHECK , 1994</b> n=8307/2783 follow-up: 3 yr	health checks by nurses versus no intervention	patients from general practice aged 35-64 years	Parallel groups open UK
<b>WHO Factories , 1982</b> n=30489/26971 follow-up: 6 years	multifactorial prevention of coronary heart disease versus no intervention	men employed in 80 factories in Belgium, Italy, Poland, and the UK	Parallel groups open Belgium, Italy, Poland, and the UK

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## **4 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.