

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
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	-	-	
TAIM n=NA	-	-	
DISH n=NA	-	-	
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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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 of mental 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
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

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Trial	Treatments	Patients	Trials design and methods
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
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

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2 Mediterranean diet

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

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Trial	Treatments	Patients	Trials design and methods
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

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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.

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