# 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<br>n=45/43<br>follow-up: | healthy Nordic diet<br>versus<br>control diet (subjects usualWestern diet) | mildly hypercholesterolaemic subjects | Sweden |
| BARON<br>n=NA | - | - | |
| HPT<br>n=NA | - | - | |
| Kumanyika<br>n=NA | - | - | |
| TAIM<br>n=NA | - | - | |
| DISH<br>n=NA | - | - | |
| **diet vs usual diet** | | | |
| Black , 1994<br>n=56/55<br>follow-up: 2.0 years | diet with 20 percent of total caloric intake as fat<br>versus<br>usual diet | patients with nonmelanoma skin cancer | Parallel groups<br>open |
| DART (Burr) , 1989<br>n=NA<br>follow-up: 2 years | diet advice<br>versus<br>usual diet | men who had recovered from MI | Factorial plan<br>open, blind assessment |
| Finnish Mental Hospital (Miettinen) , 1985<br>n=612/610<br>follow-up: 6.0 years | cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats)<br>versus<br>usual diet | middle-aged institionalized women without CHD | Cluster-randomized cross-ove<br>open, blind assessment<br>Finland |
| Finnish Mental Hospital (Turpeinen) , 1979<br>n=NA<br>follow-up: 6.0 years | cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats)<br>versus<br>usual diet | middle-aged institutionalized men without CHD | Cluster-randomized cross-ove<br>open, blind assessment<br>Finland |
| Goteborg , 1986<br>n=10004/20028<br>follow-up: 10 years | multifactorial intervention programme<br>versus<br>no intervention | men, 47-55 years old at entry | Parallel groups<br>open<br>Sweden |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Gteborg (Wilhelmsen) , 1986<br>n=10004/20028<br>follow-up: 10.0 years | multifactorial intervention programme<br>versus<br>usual care | men, 47-55 years old at entry | Parallel groups<br>open |
| Hjermann , 1981<br>n=604/628<br>follow-up: 6.5 years | diet<br>versus<br>usual diet | healthy, normotensive men at high risk of coronary heart disease | Parallel groups<br>open<br>Sweden |
| Kallio , 1979<br>n=188/187<br>follow-up: 3.0 years | diet (multifactorial intervention programme)<br>versus<br>usual diet | patients below 65 years who had an acute myocardial infarction | Parallel groups<br>open |
| Los Angeles VA (Dayton) , 1969<br>n=424/422<br>follow-up: 65279;8.0 y | diet<br>versus<br>usual diet | men in domicilary care, age>55, with or without CHD | Parallel groups<br>double blind<br>USA |
| Minnesota coronary survey (Frantz) , 1975<br>n=2197/2196<br>follow-up: 1.1 y (max 4.5y) | cholesterol lowering diet<br>versus<br>control diet | 65279;Adult residents ofmental hospitals; no illness restrictions, no cholesterol concentration requirements | Parallel groups<br>double-blind<br>USA |
| MRC low fat , 1965<br>n=123/129<br>follow-up: 3 y | - | - | Parallel groups<br>open |
| MRC Soya , 1968<br>n=199/194<br>follow-up: 3.5 y | Rgime pauvre en graisses satures + 85 g/j d'huile de soja<br>versus<br>usual diet | ambulatory men with recent MI | Parallel groups<br>open, blind assessment |
| MRFIT , 1982<br>n=6428/6438<br>follow-up: 6.5 y | multifactor intervention program<br>versus<br>usual diet | high-risk men aged 35 to 57 years | Parallel groups<br>open |
| Ornish , 1990<br>n=28/20<br>follow-up: 1.0 y | low-fat vegetarian diet, stopping smoking, stress management training, and moderate exercise<br>versus<br>usual-care | Patients with angiographically documented coronary artery disease | Parallel groups<br>open<br>USA |
| Oslo Diet Heart Study (Leren) , 1966<br>n=206/206<br>follow-up: 5 y (11y) | diet<br>versus<br>usual care | middle-aged ambulatory men with prior MI | Parallel groups<br>open, blind assessment |
| Rose , 1965<br>n=28/26<br>follow-up: 1.2 years | Rgime restreint en graisses + 80 g/j huile de mas<br>versus<br>usual diet | men, <70 years | Parallel groups<br>open |
| Singh , 1992<br>n=204/202<br>follow-up: 65279;2.0 years | strict diet<br>versus<br>usual diet | patients with suspected acute myocardial infarction | Parallel groups<br>open |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| STARS (St Thomas, diet) , 1992<br>n=30/30<br>follow-up: 3.0 years | dietary advice<br>versus<br>usual diet | patients with angina or past myocardial infarction | open, blind assessment |
| Veterans Ad. (Dayton) , 1969<br>n=424/422<br>follow-up: 3.6 and 8 y | cholesterol lowering diet<br>versus<br>usual diet | men in domicilary care, age>55, with or without CHD | Parallel groups<br>double blind<br>USA |
| WHI low fat , 2005<br>[NCT00000611]<br>n=19541/29294<br>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<br>versus<br>usual diet | postmenopausal women, aged 50 to 79 years, without prior breast cancer | Parallel groups<br>open<br>US |
| WHO Collaborative , 1986<br>n=30489/26971<br>follow-up: 5.5 years | multifactorial prevention<br>versus<br>usual diet | middle-aged men | Parallel groups<br>open<br>Belgium, Italy, Poland, UK |
| Woodhill , 1966<br>n=221/237<br>follow-up: <7 years | diet<br>versus<br>usual diet | men, 30-59 years | Parallel groups<br>open |
| **low fat diet vs mediterranean-style diet** | | | |
| Tuttle , 2008<br>n=NA<br>follow-up: 24 months | low-fat<br>versus<br>Mediterranean-style diets | First MI survivors | Parallel groups<br>open |



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# 2 Mediterranean diet

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

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| PREDIMED (olive oil) , 2013<br>[ISRCTN35739639]<br>n=2543/2450<br>follow-up: 4.8 years | Mediterranean diet supplemented with extra-virgin olive oil<br>versus<br>control diet (advice to reduce dietary fat) | participants who were at high cardiovascular risk, but with no cardiovascular disease | Parallel groups<br>open<br>Spain |
| **Mediterranean diet with nuts vs control** | | | |
| PREDIMED (nuts) , 2013<br>[ISRCTN35739639]<br>n=2454/2450<br>follow-up: 4.8 years | Mediterranean diet supplemented with mixed nuts<br>versus<br>control diet (advice to reduce dietary fat) | participants who were at high cardiovascular risk, but with no cardiovascular disease | open<br>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.

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.