

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 |

continued...

| Trial | Treatments | Patients | Trials design and methods |
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| 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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