

# Clinical trials of lifestyle intervention for cardiovascular prevention in primary prevention

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 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 $\geq$ 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
<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>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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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

## References

### CELL, 1995:

Lindholm LH, Ekblom T, Dash C, Eriksson M, Tibblin G, Schersten B The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. *BMJ* 1995;310:1105-9 [[7742677](#)]

Lindholm LH, Ekblom T, Dash C, Isacson A, Schersten B Changes in cardiovascular risk factors by combined pharmacological and nonpharmacological strategies: the main results of the CELL Study. *J Intern Med* 1996;240:13-22 [[8708586](#)]

### Family Heart, 1994:

Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. Family Heart Study Group. *BMJ* 1994;308:313-20 [[8124121](#)]

### Gteborg Study, 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](#)]

### Helsinki Businessmen Study, 1985:

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](#)]

Strandberg TE, Salomaa VV, Naukkarinen VA, Vanhanen HT, Sarna SJ, Miettinen TA Long-term mortality after 5-year multifactorial primary prevention of cardiovascular diseases in middle-aged men. *JAMA* 1991;266:1225-9 [[1870247](#)]

Strandberg TE, Salomaa VV, Vanhanen HT, Naukkarinen VA, Sarna SJ, Miettinen TA Mortality in participants and non-participants of a multifactorial prevention study of cardiovascular diseases: a 28 year follow up of the Helsinki Businessmen Study. *Br Heart J* 1995;74:449-54 [[7488463](#)]

### Johns Hopkins, 1983:

Morisky DE, Levine DM, Green LW, Shapiro S, Russell RP, Smith CR Five-year blood pressure control and mortality following health education for hypertensive patients. *Am J Public Health* 1983;73:153-62 [[6849473](#)]

### Meland, 1997:

Meland E, Laerum E, Ulvik RJ Effectiveness of two preventive interventions for coronary heart disease in primary care. *Scand J Prim Health Care* 1997;15:57-64 [[9101627](#)]

Meland E, Maeland JG, Laerum E The importance of self-efficacy in cardiovascular risk factor change. *Scand J Public Health* 1999;27:11-7 [[10847665](#)]

### MRFIT, 1982:

Mortality rates after 10.5 years for participants in the Multiple Risk Factor Intervention Trial. Findings related to a priori hypotheses of the trial. The Multiple Risk Factor Intervention Trial Research Group. *JAMA* 1990;263:1795-801 [[2179590](#)]

Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. JAMA 1982;248:1465-77 [7050440]

#### **Oslo, 1981:**

Anderssen S, Holme I, Urdal P, Hjerermann I Diet and exercise intervention have favourable effects on blood pressure in mild hypertensives: the Oslo Diet and Exercise Study (ODES). Blood Press 1995;4:343-9 [8746601]

Hjerermann I, Holme I, Leren P Oslo Study Diet and Antismoking Trial. Results after 102 months. Am J Med 1986;80:7-11 [3511692]

Hjerermann 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]

Holme I, Hjerermann I, Helgeland A, Leren P The Oslo Study: diet and antismoking advice. Additional results from a 5-year primary preventive trial in middle-aged men. Prev Med 1985;14:279-92 [3903733]

#### **OXCHECK, 1994:**

Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. Imperial Cancer Research Fund OXCHECK Study Group. BMJ 1994;308:308-12 [8124120]

#### **WHO Factories, 1982:**

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]

Multifactorial trial in the prevention of coronary heart disease: 2. Risk factor changes at two and four years. Eur Heart J 1982;3:184-90 [7084265]

## **2 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.