NHLBI Evidence Table: RF1-RCT

	ID First Autho	Title Yea	Study Type CVD	RF by CQ	Country	Setting	Blinding Int Lengt	Total Study Duration	Main Study Objective	Total N Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
1438	10 Walker R	Reduction of ischemic heart disease insix markers in the teenage children of heart attack patients	RCT None	Q 10, 13 (RF4, F	FFS, Australia	Home	None/NR 12 mo	12 mo		144 (97 Parentaly families) Family Caregiver	11-20 yr Natural or adopted children of patients who suffered acute myocardial infarction or angina	Mean age (SD): Arm 1: 15.5 yr (2.0) Control Arm: 15.6 yr (2.3) Males: Arm 1: 53.8% Control Arm: 54.7% Never smoked: Arm 1: 70.0% Control Arm: 79.7% Ex-smokers: Arm 1: 12.5% Control Arm: 3.1% Current smokers: Arm 1: 17.5% Control Arm: 17.2%	80 (58)		Arm 1: Home-based behavioral advice Intervention included 3 visits to the family home, a group discussion session, follow-up telephone calls and teleters, and a from checkup risk marker screening session	64 (49)	Control Arm: No advice Advice was withheld until after the final outcome measures were assessed at 12 mo 76 subjects whose parents did not have CVD or conditions requiring dietary fat manipulation were included as a reference group	Primary: Mean fat intake [%E (SE)] Mean saturated fat intake [%E (SE)] d Heart disease knowledge score Mean TC [mmol/L (SE)] Secondary: Mean SBP [mmHg (SE)] Mean DBP [mmHg (SE)] Mean BMI [kg/m² (SE)] Mean HDL-C [mmol/L (SE)]	Primary: Baseline vs FU: EARLY: -3.3 at -1.00 LATE: -0.58 ±1-0.00 CON: -0.53 ±1-0.70 EARLY: -2.46 ±1-0.56 LATE: -0.54 ±1-0.80 CON: -0.38 ±1-0.39 EARLY: -4.7 ±1-0.50 CON: -1.7 ±1-0.5 CON: +1.7 ±1-0.5 EARLY: -0.17 ±1-0.11 CON: -0.08 ±1-0.11 CON: -0.08 ±1-0.11 CON: -0.08 ±1-0.11 CON: -0.08 ±1-0.07 Secondary: No significant difference between groups for any of these parameters.	S, early vs late groups S, early vs late groups NS S, control vs late group Secondary: NS for all of these parameters	None	None	An intervention focusing on children from families with a parent with recent or > 12 month past CAD events resulted in recent of several past of the p	and sat fat in those who received the early intervention but no decrease in lipid or
1587	991 Tonstad S	Effect of lifestyle changes on atherogenic lipids and endothelial cell adhesion molecules in young adults with familial premature coronary heart disease.	RCT None	Q10 (RF5, RF10) Norway	Clinical	None/NR 8 mo	8 mo	Evaluate the effects of a lifestyle modification program on lipids and novel risk markers in young relatives of patients with premature CHD	172 Pediatrio' Young Adults	18-39 yr Fasling cholesterol concentration of 5-8 mmol/L 2 1 of the following lipid abnormalities: LDL-C≥ 4 mmol/L, TG≥ 1.5 mmol/L, TG≥ C≥ TG≥ TG≥ TG≥ TG≥ TG≥ TG≥ TG≥ TG≥ TG≥ TG	Males: Arm 1: 61 Control Arm: 56 Daily cigarette smokers: Arm 1: 42% Control Arm: 36% Social smokers and/or snuff users: 1: 23% Control Arm: 23% First degree relative with	95 (82)		Arm 1: Intensified lifestyle change with dietary advice Dietary advice included nutritional goals of reducing lirake of cholesterol to < 300 mg/d, saturated fat to < 10%E, tolal aft to < 30%E, to substitute some of the saturated fat increase vegetables and fruits, physical activity and motivation. If the subject smoked at least ≥ 1 cigaretted and was willing to make a quit attempt, the study physician provided motivational support, counselling, and follow-up.		Control Arm. General lifestyle advice General lifestyle advice given by study physician included stop smoking, increase exercise, decrease saturated fat intake and lasted about 5-10 min	Mean cholesterol intake [mg/1000 kcal (SD) Mean fat intake [%E (SD)]	Primary: Baseline vs FIU: INT: 120 +/- 28 to 11 0+/- 27 CON: 116 +/- 34 to 122 +/- 36 INT: 327 +/- 510 31.6 +/- 5.1 CON: 32.8 +/- 5 to 32.5 +/- 5.5 INT: 127 +/- 2.3 to 11.4 +/- 2.2 CON: 12.3 +/- 2.0 to 12.6 +/- 2.3 Secondary: Baseline vs FIU: INT: 241 +/- 36 to 232 +/- 36 CON: 25.5 +/- 36 to 233 +/- 36 INT: 46 +/- 13 to 45 +/- 12 CON: 45 +/- 11 to 44 +/- 12 CON: 45 +/- 11 to 44 +/- 13 CON: 150 +/- 178 to 171 +/- 108 INT: 13.4 +/- 23 to 18.3 +/- 130 CON: 150 +/- 178 to 171 +/- 108 INT: 1.31 +/- 0.24 to 1.24 +/- 0.23 CON: 1.27 +/- 0.22 to 1.25 +/- 0.24 INT: 31 +/- 0.24 to 1.24 +/- 0.23 CON: 1.27 +/- 0.22 to 1.25 +/- 0.24 INT: 3.1 +/- 0.24 to 1.24 +/- 0.23 CON: 1.27 +/- 0.22 to 1.25 +/- 0.24 INT: 3.1 +/- 0.24 to 1.24 +/- 0.23 CON: 1.27 +/- 0.22 to 1.25 +/- 0.24 INT: 4.3 +/- 0.24 to 1.24 +/- 0.23 CON: 1.27 +/- 0.22 to 1.25 +/- 0.24 INT: 4.3 +/- 0.24 to 1.25 +/- 0.24 INT: 4.3 +/- 0.24 to 1.25 +/- 0.24 INT: 4.3 +/- 0.25 to 1.25 +/- 0.24	Primary: S* for change between groups NS S** for change between groups Secondary: NS for change between groups NS for change between groups S* for change between groups NS for change between groups	None	None	A program advocating smoking cessation and detay change in detay change in John Change in John Change in German Change in detay change in dead smoking status with accompanying decreases in LDL-d, coldized LD Land circulating adhesion molecules.	Q 10.13. A program advocating smoking cessation and dietary colors in young relative colors with the colors of the
1587	991 Tonstad S	Effect of lifestyle changes on atherogenic lipids and endothelial cell adhesion molecules in young adults with familial premature coronary heart disease									History of CVD History of diabetes History of FH Cholesterol level > 8 mmol/L BMI > 40 kg/m² Secondary hypertipidemia Hypertension Hypertipidemia							E-selectin [ng/mL (SD)] Intercellular adhesion molecule-1 [ng/mL (SD)] Mean hs-CRP [mg/L (SD)] Carbon monoxide levels [ppm (SD)] Von Willebrand factor [% (SD)] Plasminogen activator inhibitor-1 [U/L (SD)] Plasminogen andivator inhibitor-1 [mg/mL (SD)] Vascular cell adhesion moleculre-1 [ng/mL (SD)] P-selectin [ng/mL (SD)] Tumor necrosis factor o [pg/mL (SD)] Interleukin-8 [pg/mL (SD)]	of these paprameters.	S S NS between groups for any of these parameters				