

NHLBI Evidence Table: RF9-RCT

PMO	First Author	Title	Year	Study Type	CVD	RF by CO	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p<0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question		
273205	Nader PR	A family approach to cardiovascular risk reduction: results from the San Diego Family Health Project	1989	RCT	None	Q5 (RF4, RF5, RF9, RF11) Q 10, 11, 13 (RF4, RF5, RF8, RF11)	USA	Community (other)	Double	1 yr	2 yr	Evaluate the effectiveness of a family-based cardiovascular disease risk reduction intervention in 2 ethnic groups	623 (206 families)	Parental/Family/Caregiver	5th-6th grade student Mexican-American (MexAm) & non-Hispanic White families (AngloAm) Low-to-middle-income	NR	203 families (NR)	Behavioral	Arm 1: Family health education Family intervention sessions designed to decrease the whole family's intake of high salt, high fat foods, and to increase regular physical activity 3 mo of weekly intervention, followed by 9 mo of monthly or bimonthly maintenance sessions	203 families (NR)	Control Arm: No education sessions (CON)	Primary: Family change score for fat [t value (p)] Family change score for salt [t value (p)] Family change in food frequency [t value (p)] Family change score for SBP [t value (p)] Family change score for LDL-C [t value (p)] Change in knowledge score [t value (p)] Treatment vs CON differences: Food frequency index 24 hr recall total fat(% cal) 3-day fat (score) 3-day salt (score) Knowledge score	Primary: AngloAm: 2.39 MexicanAm: NR AngloAm: 2.39 MexicanAm: NR MexicanAm: -2.00 AngloAm: NR AngloAm: 2.24 MexicanAm: NR AngloAm: 2.14 MexicanAm: NR AngloAm: -1.92 MexicanAm: -2.70 (Ad=adult; Ch = child) AngloAm Ad: 0.242; Ch: 0.115 MexAm Ad: No change; Ch: 0.135 AngloAm Ad: -5.6; Ch: No change MexAm Ad: No change; Ch: No change AngloAm Ad: -6.2; Ch: -4.1 MexAm Ad: No change; Ch: No change AngloAm Ad: -31.6; Ch: -26.7 MexAm Ad: -17.8; Ch: No change AngloAm Ad: No change; Ch: 0.287 MexAm Ad: 0.105; Ch: 0.115	S NS S NS S NS NS p=.059 S*	None	Ethnicity and SES status were confounded with greater and more significant changes in AngloAm families than MexAm families. Ethnicity and SES status were confounded. There was a change in LDL-C only in Anglo-American adults.	Q5, 10, 11, 13. A family intervention based in neighborhood schools resulted in moderate improvements in CV health knowledge, diet exercise and BP; greater in AngloAm families than in MexAm families. Ethnicity and SES status were confounded. There was a change in LDL-C only in Anglo-American adults.	Q5, 10, 11, 13. A family intervention based in neighborhood schools resulted in moderate improvements in CV health knowledge, diet exercise and BP; greater in AngloAm families than in MexAm families. Ethnicity and SES status were confounded. There was a change in LDL-C only in Anglo-American adults.		
273206	Nader PR	A family approach to cardiovascular risk reduction: results from the San Diego Family Health Project	1989	RCT																	Secondary: LDL-C SBP [mmHg] DBP [mmHg] Physical activity recall Cardiovascular fitness levels - submaximal exercise testing	Secondary: AngloAm Ad: -0.351; Ch: No change MexAm Ad: No change; Ch: No change AngloAm Ad: -3.01; Ch: No change MexAm Ad: -2.2; Ch: No change AngloAm Ad: No change; Ch: -2.81 MexAm Ad: -3.3; Ch: -3.07 No significant change vs CON for any group No significant change vs CON for any group	S*; NS NS; NS S*; NS NS; S S*; S NS							
3411756	Killen JD	Cardiovascular disease risk reduction for tenth graders. A multiple-factor school-based approach	1988	RCT	None	Q 10, 13 (RF4, RF8, RF9, RF10, RF11)	USA	Community (schools)	None	7 wk	4 mo	Study the affect of CVD prevention education on older adolescents	1447 (4 schools)	Pediatric/Young Adults	10th grade	Age: 14 yr: 14% 15 yr: 70% 16 yr: 14% Boys: Arm 1: 55.5% Control Arm: 52.5% White: 69.0% Black: 2.0% Asian: 13.1% Hispanic: 6.4% American Indian: 0.3% Pacific Islander: 0.4% Other race/ethnicities: 8.9% Father completed ≥ 4 yr college: 50%	NR (622) 2 schools (2 schools)	Behavioral	Arm 1: CVD prevention education 20 50-min classroom sessions delivered 3 d/wk for 7 wk as part of the regular physical education curriculum Included 5 program modules: physical activity, nutrition, cigarette smoking, stress, personal problem-solving	NR (508) 2 schools (2 schools)	Control Arm: No prevention education	Primary: Mean change in CV knowledge scores Mean change in BMI [weight/height ²] Mean change in triceps skin fold thickness [mm] Mean change in subscapular skin fold thickness [mm] Mean change in SBP [mmHg] Mean change in DBP [mmHg (SD)] Mean change in HR [beats/min (SD)] Change from baseline experimental smoking to regular smoking [%] Baseline experimental smokers who reported quitting [%]	Primary: INT M: +11.1 vs CON M: -1.4 INT F: +14.2 vs CON F: +0.8 INT M: +0.1 vs CON M: +0.4 INT F: -0.2 vs CON F: 0 INT M: -0.1 vs CON M: -0.5 INT F: -0.4 vs CON F: -2.5 INT M: -0.1 vs CON M: +0.2 INT F: -0.5 vs CON F: +0.9 INT M: +4.0 vs CON M: +1.9 INT F: -1.8 vs CON F: +3.0 INT M: +1.0 vs CON M: +0.2 INT F: -0.5 vs CON F: -1.9 INT M: -2.3 vs CON M: +0.4 INT F: -4.1 vs CON F: +0.4 INT: +5.6% vs CON: +10.3% INT: 28.5% vs CON: 17.6%	S** (INT vs CON) S (INT vs CON) S* (INT vs CON) S* (INT vs CON) NS (INT vs CON) S*, CON=INT S** (INT vs CON) S* (INT vs CON) S* (INT vs CON)	None reported	Initial results are promising but long term results needed. Changes in HR could have reflected familiarity with procedure.	A learning-based intervention in high schools increased knowledge re: CV risk factors and affected behavior change reflected in smoking rates and selected anthropometric & physiologic variables.	Q10, 13. A learning-based intervention in high schools increased knowledge re: CV risk factors and affected behavior change reflected in smoking rates and selected anthropometric & physiologic variables.		
8784330	McKenzie J	Change in nutrient intakes, number of servings, and contributions of total fat from food groups in 4- to 10-year-old children enrolled in a nutrition education study	1996	RCT	None	Q13 (RF9)	USA	Mult settings	None/NR	2 wk	3 mo	Determine change in nutrient intakes, number of servings, and contributions of total fat from food groups in children who lowered their dietary fat intake	261	Parental/Family/Caregiver	4-10 yr Hypercholesterolemia (LDL-C > 80th percentile and < 95th percentile for age and gender)	NR	Arm 1: 86 (77) Arm 2: 88 (71)	Behavioral	Arm 1: Dietary counseling (RD) Children and caregivers received 1 face-to-face counseling session with a dietitian and printed materials to take home that promoted adherence to the National Cholesterol Education Program (NCEP) diet Arm 2: Diet education program (PCAT) An at-home parent and child auto tutorial program consisted of audiobook lessons with accompanying audiotapes about healthy eating patterns according to NCEP guidelines	Control Arm 1: 87 (79) Control Arm 2: 81 (76)	Control Arm 2: No formal nutrition education (CON) Control Arm 1: No nutrition education + typical eating habits with high TC (TCCon)	Primary: Mean total fat intake [t%] Mean cholesterol intake/1000kcal Mean saturated fat intake [t%] Mean calorie intake Subjects meeting RDA of protein, thiamine, riboflavin, niacin, folacin, calcium, phosphorus, magnesium, iron, zinc, selenium, vitamins A,D,C,E,B-6 & B-12. [% children]. Secondary: Mean change total fat intake from [g]: Meats Eggs Dairy Fats/oils Breads Vegetables Fruits Desserts Beverages Grains/sauces No change	Primary: PCAT: 29 to 27.5; RD: 29.4 to 27.8 TCCon: 29.8 to 30; NCCon: 29.9 to 29.4 PCAT: 98 to 82; RD: 104 to 92; TCCon: 107 to 102; RD: 101 to 97 PCAT: 10.9 to 10.2; RD: 11.1 to 10.1; TCCon: 11.2 to 11.3; NCCon: 11.6 to 11.3 PCAT: 1537 to 1478; RD: 1555 to 1512; TCCon: 1706 to 1762; NCCon: 1723 to 1770 After 3 months, children in every study group had mean intakes of all nutrients except vitamin D greater than 67% of the RDA Secondary: PCAT: -3.5; RD: -1; TCCon: +1.2; NCCon: -0.4 No change PCAT: -2.3; RD: -2.0; TCCon: -0.4; NCCon: -0.3 PCAT: -2; RD: -1.2; TCCon: -0.7; NCCon: +0.5 No change PCAT: -2.5; RD: -0.1; TCCon: +1.5; NCCon: -0.9 No change No change	S for PCAT & RD S for PCAT & RD S for PCAT & RD S for PCAT & RD	None reported	Reported elsewhere these diet changes resulted in a significant decrease in LDL-C. A successful as RD counseling in lowering dietary fat intake with preservation of required nutrition.	In a low fat, low sat fat intervention for pre-school children with elevated cholesterol, a parent-child auto tutorial was as successful as RD counseling in lowering dietary fat intake with preservation of required nutrition.	Q10. In a low fat, low sat fat intervention for pre-school children with elevated cholesterol, a parent-child auto tutorial was as successful as RD counseling in lowering dietary fat intake with preservation of required nutrition.		
9280175	Niinikoski H	Intake and indicators of iron and zinc status in children consuming diets low in saturated fat and cholesterol: the STRIP baby study. Special Turku Coronary Risk Factor Intervention Project for Babies	1997	RCT	None	Q11 (RF9) Q13 (RF7, RF9)	Finland	Clinical	None	3 yr 5 mo	3 yr 5 mo	Examine whether long-term supervised use of a diet low in saturated fat and cholesterol influences intake or serum indicators of iron and zinc in children	79	Parental/Family/Caregiver	7 mo	Boys: 38	40 (NR)	Behavioral	Arm 1: Family counseling (INT) At intervals of 1-6 mo, families received individualized counseling aimed at reducing exposure of the children to known environmental risk factors for atherosclerosis Aim was to replace foods with large amounts of cholesterol or saturated fat with foods with more favorable fatty acid composition	39 (NR)	Control Arm: General health education (CON) General health education currently given at Finnish well-baby clinics	Primary: Mean fat intake [t% (SD)] Mean saturated fat intake [t% (SD)] Mean iron intake [mg (SD)] Indicators of iron status: Hgb, MCV, Iron, Ferritin, Transferrin, Tf) Mean zinc intake [mg (SD)] Mean CRP [pmol/L (SD)] Secondary: Decreased (24 mo, 36 mo). No diff (48 mo) Decreased (13, 24, 36, 48 mo) No difference (13, 24, 36, 48 mo) No difference (13, 24, 36, 48 mo) No difference (13, 24, 36, 48 mo) No difference (13, 24, 36, 48 mo)	S** S** S** S** S** NS NS NS	None	Children on the low saturated fat diet had a more favorable lipid profile.	Supervised low saturated fat diets in young children do not adversely affect iron or zinc intakes or markers of iron status.	Supervised dietary modification beginning in infancy for 3.5 years targeting the reduction of saturated fat and cholesterol with partial replacement by more favorable fats yielded continuously lower saturated fat intakes. No differences were seen in iron or zinc intakes or blood indicators of iron status.			
9551002	Perry CL	Changing fruit and vegetable consumption among children: the 5-Day Power Plus program in St. Paul, Minnesota	1998	RCT	None	Q5 (RF9) Q6 (RF2, RF9) Q13 (RF9)	USA	Community (schools)	None/NR	7 mo	1 yr	Evaluate a randomized school-based trial that sought to increase fruit and vegetable consumption among children using a multi-component approach	1750 total 487 gr students 1,612 questionnaires (20 schools) 652 randomly selected for diet/lunch observat on 536 for 24-hr recalls. Parent surveys 636	Pediatric/Young Adults	4th grade	Males: 203 ?? 4th grade at baseline Native American: 1.3% Hispanic: 6.4% African American: 19.1% Asian American: 25.2% White: 48.0% Received free or reduced-cost school lunches: >60%	10 schools (10 schools) 1,271 questionnaires 424 lunch observation 411 24-hr diet recalls 325-324 parent telephone survey	Behavioral	Arm 1: Behavioral curricula + parental involvement/education + school food service change + industry involvement and support Two curricula (one in 4th grade, March through May and one in 5th grade, Oct. through January), each included 10 40 to 45-min classroom sessions implemented twice a wk for 8 wk that involved skill building, problem solving activities, snack preparation and taste testing 4th grade parental involvement consisted of 5 information/activity packets brought home by the student. 5th grade parental involvement consisted of 4 snack packs that students brought home. Snack packs were prepared by the school food service Food Service intervention included: point-of-purchase promotion of F&V; enhancing attractiveness of F&V; increasing variety & choice of F&V; and providing an additional fruit item when a baked fruit was served.	Control Arm: No intervention	Primary: Mean fruits and vegetables intake from lunchroom observations [servings (95% CI)] Mean fruits intake from lunchroom observations [serving (95% CI)] Mean vegetables intake from lunchroom observations [serving (95% CI)] Mean fruits & vegetables intake from 24-hr recall [servings (95% CI)] Mean fruits intake from 24-hr recall [serving (95% CI)] Mean vegetables intake from 24-hr recall [serving (95% CI)] Secondary: Mean total fat from lunchroom observation [t% (95% CI)] Mean saturated fat from lunchroom observation [t% (95% CI)] Mean calcium intake from lunchroom observation [mg (95% CI)] Mean fiber intake from lunchroom observation [g (95% CI)]	Primary: INT vs CON: 0.47(0.21,0.72) INT vs CON: 0.30(0.13,0.46) INT vs CON: 0.16(0.07,0.39) INT vs CON: 0.58(0.15,1.31) INT vs CON: 0.62(0.10,1.14) INT vs CON: -0.02(0.43,0.48) Secondary: No significant change No significant change No significant change No significant change	S** S** NS NS S NS NS NS NS	None	Parent participation was very poor. Sending information and foods home did not change parent behavior. There were better results at lunch than the whole day. Girls increased their vegetable intake while boys did not (assessed by lunchroom observations).	Intervention students consumed more fruits and more total F&V consumption at lunch, and girls' consumption of vegetables, dietary intake, but not lunch room observation, showed that non-white students reported decreased fat intake compared to white students.	Q13. A school-based intervention can increase children's fruit consumption and combined F&V consumption at lunch, and girls' consumption of vegetables, dietary intake, but not lunch room observation, showed that non-white students reported decreased fat intake compared to white students.			
9551002	Perry CL	Changing fruit and vegetable consumption among children: the 5-Day Power Plus program in St. Paul, Minnesota	1998																											

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10401802	Nader PR	Three-year maintenance of improved diet and physical activity: the CATCH cohort	1999	RCT	None	Q10, 11, 13 (RF4, RF5, RF6, RF9, RF10, RF11)	USA	Community (schools)	None	3 yr	6 yr	Assess differences through grade 8 in diet, physical activity and related health indicators of students who participated in the Child and Adolescent Trial for Cardiovascular Health (CATCH) school and family intervention from grades 3 through 5	3714	Pediatric/Young Adults	Participated in elementary school CATCH intervention	NR	Not reported for the participants in Phase III	NR (NR)	Behavioral	Arm 1: Cardiovascular health promotion program Multi-component intervention including classroom curricula, food service modifications, physical education changes, and family reinforcement. The study design of the CATCH trial is described in detail in other studies	NR (NR)	Control Arm: NR The study design of the CATCH trial is described in detail in other studies	Primary: Mean energy intake [kcal (SEM)] Mean fat intake [gE (SEM)] Mean saturated fat intake [gE (SEM)] Mean vigorous activity [min (SEM)] Secondary: Mean CHO intake [gE (SEM)] Mean protein intake [gE (SEM)] Mean dietary cholesterol intake [mg (SEM)] Mean sodium intake [mg (SEM)] Mean total activity [min (SEM)] Vigorous activity [min (SEM)] Mean BMI [kg/m2 (SEM)] Health behavior score: Knowledge Intention INT: 9238(134) vs CON: 9368(176) INT: 30.6(0.3) vs CON: 31.6(0.3) INT: 11.3(0.1) vs CON: 11.8(0.2) INT: 30.2 vs CON: 22.1 Secondary: INT: 56.6(0.3) vs CON: 55.4(0.4) No difference between groups. INT: 3298(53) vs CON: 3456(79) No difference between groups. INT: 40.7(1.4) vs CON: 30.6(1.5) No difference between groups. INT: 5.2 vs CON: 4.9 INT: 4.6 vs CON: 4.1	NS S* S S* NS NS NS NS S** NS S**	None		This large multicenter school-based diet and exercise intervention for middle school children resulted in sustained improvement in diet and exercise with significantly lower saturated fat intake and significantly more vigorous physical activity in intervention schools assessed 3 yrs after the end of the program. There were no differences in BMI or cholesterol.	Q10, 11, 13. This large multicenter school-based diet and exercise intervention for middle school children resulted in sustained improvement in diet and exercise with significantly lower saturated fat intake and significantly more vigorous physical activity in intervention schools assessed 3 yrs after the end of the program. There were no differences in BMI or cholesterol.
10401802	Nader PR	Three-year maintenance of improved diet and physical activity: the CATCH cohort	1999																				NS for all measures					
10709795	Baranowski T	Gimme 5 fruit, juice, and vegetables for fun and health: outcome evaluation	2000	RCT	None	Q5 (RF9) Q6 (RF2, RF9) Q13 (RF9)	USA	Community (schools)	None	6 wk	2.5 yr	Study the theory-based multi-component intervention (Gimme 5), which is designed to impact 4th- and 5th grade children's fruit, juice, and vegetable consumption and related psychosocial variables	3,347 (16 schools)	Pediatric/Young Adults	4th and 5th grade students	African American: 15.3% Euro-American: 84.7%	NR (NR)	Behavioral	Arm 1: Gimme 5 intervention 12 45- to 55-min sessions of Gimme 5 curriculum encouraged and assisted students to eat more fruit, juice and vegetables Gimme 5 Daily newsletters taken home to parents weekly to provide suggestions and recipes for increasing fruit, juice and vegetable intake 3 10- to 14-min "MTV" format videotapes sent to parents at 2-wk intervals Point-of-purchase education conducted each yr at 2 grocery stores per school that parents most frequented, which presented suggestions for selecting, storing and preparing fruit, juice and vegetables	NR (NR)	Control Arm: No Gimme 5 curriculum	Primary: Mean fruit and vegetable consumption [LSM (SE)] Mean all vegetable consumption [LSM (SE)] Mean fruit and juice consumption [LSM (SE)] Mean fruit and vegetable: weekday lunch consumption [LSM (SE)] Mean fruit and vegetable: all other times [LSM (SE)] Self-efficacy: Eating F & V [LSM (SE)] Self-efficacy: eating & shopping [LSM (SE)] Asking behavior [LSM (SE)] Knowledge [LSM (SE)] INT: 2.3(0.1) vs CON: 2.1(0.1) INT: 1.1(0.1) vs CON: 1.1(0.1) INT: 1.1(0.1) vs CON: 1.0(0.1) INT: 0.9(0.1) vs CON: 0.8(0.1) INT: 1.6(0.1) vs CON: 1.5(0.1) INT: 41.5(1.0) vs CON: 40.6(1.0) INT: 42.7(0.5) vs CON: 42.4(0.5) INT: 17.0(0.3) vs CON: 16.0(0.3) INT: 11.9(0.3) vs 11.0(0.3)	S S* NS p<0.10 NS p<0.10 NS S S	None reported	Intervention appeared to mitigate what would have been a decline in the F&V intake these students. All changes were greater in girls. Changes were greater in African Americans. No evidence of changes at home or elsewhere. Long term impact not known.	A game-based school nutrition education program can change elementary school-aged children's F&V consumption but changes were small and persistence is unknown. Q5. There was no gender or racial/ethnic difference in response.		
10731460	Reynolds KD	Increasing the fruit and vegetable consumption of fourth-graders: results from the high 5 project	2000	RCT	None	Q11 (RF9) Q13 (RF9)	USA	Community (schools)	None	1 yr	2 yr	Evaluate the effects of a school-based dietary intervention program to increase fruit and vegetable consumption among fourth-graders	28 schools (1698 families)	Parental/Family/Caregiver	4th grade	Mean age: 8.7 yr Males: 50% European-American: 83% African-American: 16% Other: 1% Median household income between \$40,000 and \$50,000 Parent (90% mother) completing questionnaire Mean parental education: 14 yr	NR (NR)	Behavioral	Intervention included: classroom component taught by curriculum coordinators hired by High 5 project + parent component (kick-off plus homework) + food service component (training plus rewards for completing intervention activities) Learning methods in 14-lesson classroom component included modeling, self-monitoring, problem-solving, reinforcement, taste testing, and other methods; curriculum included three-day cycle with a High 5 Day sandwiched between two 30 to 45 min lessons each week delivered 3 consecutive d/wk Parents encouraged to support behavior change and to complete a homework book Food service component focused on guidance on purchasing, preparing and promoting fruit and vegetables	NR (NR)	Control Arm: No nutritional education	Primary: Mean fruit intake based on 24-hr recall [servings (95% CI)] Mean vegetables intake based on 24-hr recall [servings (95% CI)] Mean fruit and vegetables intake based on 24-hr recall [servings (95% CI)] Mean fruit intake based on cafeteria observation [servings (95% CI)] Mean vegetables intake based on cafeteria observation [servings (95% CI)] Mean fruit and vegetables intake based on cafeteria observation [servings (95% CI)] Mean fruit intake based on parent FFQ [servings (95% CI)] Mean vegetables intake based on parent FFQ [servings (95% CI)] Mean fruit and vegetables intake based on parent FFQ [servings (95% CI)] Secondary: Mean energy intake [kcalories (95% CI)] Mean fat intake [gE (95% CI)] Mean saturated fat intake [gE (95% CI)] Mean CHO intake [gE (95% CI)] Mean protein intake [gE (95% CI)] Mean fiber intake [g (95% CI)] INT: 1.00(0.88, 1.14) 1.71(1.45, 1.99) 1.21(1.01, 1.41) 0.65(0.51, 0.82) INT: 1.32(1.17, 1.48) 1.84(1.61, 2.09) 1.60(1.42, 1.79) 1.25(1.08, 1.43) INT: 2.61(2.36, 2.86) 3.96(3.51, 4.44) 3.20(2.89, 3.52) 2.21(1.94, 2.49) INT: 0.22(0.12, 0.33) 0.16(0.09, 0.25) 0.09(0.04, 0.16) CON: 0.13(0.07, 0.22) 0.14(0.07, 0.24) 0.15(0.07, 0.25) INT: 0.42(0.31, 0.54) 0.38(0.28, 0.52) 0.38(0.25, 0.52) CON: 0.41(0.32, 0.52) 0.38(0.25, 0.52) 0.38(0.25, 0.52) No difference between groups at any observation. No difference between groups at any observation. NS, S*, S** NS, S*, S* NS, S*, S** NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, S NS, S*, S NS, S*, S NS, NS, NS NS, S*, S	NS, S*, S** NS, S*, S* NS, S*, S** NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, S NS, S*, S NS, S*, S NS, NS, NS NS, S*, S	None	INT group vs CON significantly increased intake of folate, beta carotene and vitamin C. Program was more effective in children with married parents. The intervention also resulted in significant decreases in total and saturated fat intake.	Q11, 13. A school-based dietary intervention delivered by program staff that included parent involvement resulted in significant increases in children's intake of F, V, and F&V combined at 1 yr and at 2 yrs F&V by 24 hr recall. However, these changes were not confirmed by cafeteria observation. The intervention also resulted in significant decreases in total and saturated fat intake.		
10731460	Reynolds KD	Increasing the fruit and vegetable consumption of fourth-graders: results from the high 5 project	2000																				NS, NS, NS NS, S*, S NS, S*, S NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, NS NS, NS, S NS, S*, S NS, S*, S NS, NS, NS NS, S*, S					
10830450	Heino T	Sodium intake of 11 to 5-year-old children: the STRIP project. The Special Turku Coronary Risk Factor Intervention Project	2000	RCT	None	Q10, 11, 13 (RF9)	Finland	Clinical	None	4 yr	4 yr	Evaluate the impact of individualized and repeated dietary counseling on exposure of the children to known coronary heart disease risk factors during childhood	200	Parental/Family/Caregiver	7 mo	Males: 100	100 (100)	Behavioral	Arm 1: Individualized dietary counseling Individualized dietary counseling focused on the amount and type of fat in the children's diet Counseling was based on previous food habits of the families Salt reduction in the children's diet was not included in the counseling before children were aged 5 yr Arm 2: Nutrition education letters Letters were tailored to one's personal fat intake levels, motivation to reduce fat intake, awareness of personal fat intake, and attitudes and self-efficacy expectations related to fat reduction NR (86)	20 families (17 families)	Control Arm: No individualized dietary counseling	Primary: Mean sodium intake [mg/d (SD)] Secondary: Mean relative sodium intake [mg/4.2 MJ (SD)] INT: 13 mi: INT: 162(489) vs CON: 156(563) 3 yr: INT: 194(485) vs CON: 189(623) 5 yr: INT: 224(521) vs CON: 221(543) Secondary: No difference between groups at any age. *No gender difference in sodium intake at any age.	NS NS NS NS	None	None	A 5 yr intervention to lower fat and sat fat intake in infants and young children resulted in no difference in sodium intake.	Q10, 11, 13. A 5 yr intervention to lower fat and sat fat intake in infants and young children resulted in no difference in sodium intake.	
11066462	De Bourdeaudhuij I	Tailoring dietary feedback to reduce fat intake: an intervention at the family level	2000	RCT	None	Q13 (RF9)	Belgium	Clinical	None	4 wk	6 wk	Investigate the impact of tailored versus standardized nutrition education on fat intake and on psychosocial determinants of fat intake on families	160 (40 families)	Parental/Family/Caregiver	2-parent families Families with at least 2 adolescents between ages 12 and 18	NR	NR (72)	Behavioral	Arm 1: Nutrition education letters Letters were tailored to one's personal fat intake levels, motivation to reduce fat intake, awareness of personal fat intake, and attitudes and self-efficacy expectations related to fat reduction NR (68)	20 families (17 families)	Control Arm: General nutrition education letters	Primary: Questionnaire score [7 point scale from 1(-) to 7(+)] Secondary: Mean total fat [gE] Mean saturated fat [gE] Mean MUFA [gE] Mean PUFA [gE] INT: 12.53(12.13, 12.93) 11.07(10.60, 11.54) 11.49(11.04, 11.94) CON: 12.54(12.13, 12.95) 12.00(11.51, 12.49) 12.24(11.77, 12.71) INT: 52.27(51.18, 53.36) 55.82(54.49, 57.15) 55.18(54.07, 56.30) CON: 51.99(50.87, 53.10) 53.26(51.89, 54.81) 53.17(52.01, 54.34) No difference between groups at any observation.	S for tailored group, all family members & parents alone vs CON S*, all family members S S NS NS	None reported	With further analysis, only mothers benefited from the tailored intervention	A family-based tailored feedback approach to fat intake resulted in stronger awareness of personal fat intake and to decreased fat & sat fat intake of family members with highest impact on mothers.	Q13. A family-based tailored feedback approach to fat intake resulted in stronger awareness of personal fat intake and to decreased fat & sat fat intake of family members with highest impact on mothers.	
11135795	Dixon LB	Diet quality of young children who received nutrition education promoting lower dietary fat	2000	RCT	None	Q10 (RF5) Q13 (RF9)	USA	Mult settings	None	3 mo	3 mo	Evaluate the impact of nutrition education promoting lower dietary fat on the overall diet quality in children using a multidimensional index that measures nutrient and food intakes in relation to US dietary recommendations	303 (227 families)	Parental/Family/Caregiver	4-10 yr	Elevated LDL-C between 80th and 98th percentiles	Int Arm 1: 71 (71) Int Arm 2: 77 (77)	Behavioral	Arm 1: Parent-child auto tutorial program (PCAT) vs standard counseling by registered dietitian (RD) Children in tutorial program received a home-based self-instruction program comprised of 10 "talking book" lessons about healthy eating patterns for children with an accompanying audiotape, picture booklet, paper and pencil activities workbook and parent manual Dietary goal was to meet the National Cholesterol Education Program step 1 dietary guidelines (≤ 30% calories from fat, < 10% calories from saturated fat, < 300 mg cholesterol) NR (86)	20 families (18 families)	Control Arm 1: No nutrition education + typical eating habits (TCCO) Control arm 2: age- and gender-matched children with non-elevated TC served as a reference group (CON)	Primary: DQI score Secondary: Reduced total fat intake to: < 30%LE [gE of children] Reduced SFA intake to: < 10%LE [gE of children] Reduced cholesterol to: < 300 mg/d [gE of children] Eat ≥ 5 servings/d of vegetables and fruits [% of children] PCAT: 0.6(0.2); RD: -0.4 (0.2) TCCO: +0.3(0.2); CON: -0.1(0.2) Secondary: PCAT: 60.6% to 67.6% RD: 53.2% to 63.6% TCCO: 46.8% to 45.6% CON: 48.7% to 56.6% PCAT: 39.4% to 45.1% RD: 33.8% to 45.4% TCCO: 29.1% to 25.3% CON: 30.3% to 31.6% No change in any group. No change in any group	S for all grps comparing % who met recommendation at 3m vs those who did not meet recommendation S for all grps comparing % who met recommendation at 3m vs those who did not meet recommendation NS NS	No adverse events	Children who received nutrition education counseling did not improve their intake of fruit & veg. complex carbohydrates or calcium.	Children who received nutrition education counseling did not improve their intake of total fat, saturated fat, protein and sodium. There was no effect on percentage meeting recommended intakes for fruits and vegetables, complex carbohydrates or calcium.	Nutrition education (from a "talking book" or a dietitian) resulted in improved dietary quality (i.e. greater percentage met recommended intakes for total fat, saturated fat, protein and sodium. There was no effect on percentage meeting recommended intakes for fruits and vegetables, complex carbohydrates or calcium.	

NHLBI Evidence Table: RF9-RCT

PMO	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p≥0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question
1135795	Dixon LB	Diet quality of young children who received nutrition education promoting lower dietary fat	2000																			Increased intake of starches and other complex CHO by eating: Children receive 1 hr of face-to-face nutrition counseling from a registered dietitian who provided materials that complied with National Cholesterol Education Program Maintained protein intake at: ≤ 200% recommended daily allowance (% of children) Higher among nut counseling vs. cont Limited total daily intake of sodium to: ≤ 2400 mg (% of children) Higher among nut counseling vs. cont Maintain calcium intake at: ≥ 100% of dietary reference intake (% of children) No change in any group	NS S S NS					
1135795	Dixon LB	Diet quality of young children who received nutrition education promoting lower dietary fat	2000																			OR of meeting total fat recommendation (95% CI) No difference between groups OR of meeting saturated fat recommendation (95% CI) PCAT 2.46 (1.21, 5.06) OR of meeting cholesterol recommendation (95% CI) PCAT 2.51 (1.20, 5.35) OR of meeting vegetables and fruits recommendation (95% CI) No difference between groups OR of meeting complex CHO recommendation (95% CI) PCAT 0.84 (0.30, 2.28) OR of meeting protein recommendation (95% CI) PCAT 0.90 (0.43, 1.90) OR of meeting sodium recommendation (95% CI) PCAT 2.18 (1.08, 4.43) OR of meeting calcium recommendation (95% CI) PCAT 2.06 (0.98, 4.39) PCAT 0.94 (0.44, 2.00)	NS S S NS S S S S S					
11360130	Rasanen M	Nutrition knowledge and food intake of seven-year-old children in an atherosclerosis prevention project with onset in infancy: the impact of child-targeted nutrition counseling given to the parents	2001	RCT	None	Q13 (RF9)	Finland	Clinical	None/NR	6 yr 3 mo	6 yr 3 mo	Compare nutrition knowledge and food intake in 7 yr old intervention and control children in an atherosclerosis risk factor intervention trial after 6.5 yr of nutrition counseling given to the parents	140	Parental/Family/Caregiver	Participant of the Special Turku Coronary Risk Factor Intervention Project (STRIP)	7 mo Boys: 74	70 (70)	Behavioral	Arm 1: Nutritional counseling (INT) "Low fat" score: Counseling aimed at reduction of child's saturated fat and cholesterol intake, first at child's ages of 6, 13 and 18 mo and then at 6 mo intervals Optimal diet of the child was defined to contain energy as follows: protein 10-15%E, CHO 50-60 %E, and fat 35-45 %E before the age of 2 yr, and then 30 %E hereafter Arm 2: Conventional nutritional teaching (CON) Cow's milk with at least 1.5% fat was suggested for use	70 (70)	Control Arm: Basic health education routinely given at Finnish well baby clinics (CON) Cow's milk with at least 1.5% fat was suggested for use	Primary: Mean proportion of food intake score (SD) "Low fat" score: "Low salt" score: "Heart healthy" score: Total score Secondary: Mean energy [kcal (SD)] No difference between groups Mean fat intake [%E (SD)] No difference between groups Mean saturated intake [%E (SD)] INT: 11.1 +/- 2 vs CON: 13.3 +/- 3.1 Mean MUFA intake [%E (SD)] No difference between groups Mean PUFA intake [%E (SD)] No difference between groups but girls had significantly lower intake than boys Mean sodium intake [mg (SD)]	Primary: Games: 48.8 (0.4) vs CON: 46.1 (0.4) Secondary: Games: 1596 (13) vs CON: 1899 (14) Games: 46.4 (0.2) vs CON: 45.7 (0.2) Games: 37.1 (0.1) vs CON: 37.6 (0.2) Games: 16.5 (0.1%) vs CON: 16.7 (0.1%) Games: 11.5 (0.1) vs CON: 12.2 (0.2) Games: 77 (9) vs CON: 73 (9) * Games group also had better nutritional content at meals & snacks.	S** NS NS S** NS NS S** F-M	None	None	A 6 year intervention to decrease sat fat intake from infancy and decrease sodium intake after age 5 y using repeated parental nutritional counseling resulted in lower saturated fat intake but no change in sodium intake. Intervention children had better knowledge of a heart healthy diet.	Q10,11,13. A 6 year intervention to decrease sat fat intake using repeated parental nutritional counseling resulted in lower saturated fat intake but no change in sodium intake. Intervention children had better knowledge of a heart healthy diet.
11547219	Tumin MC	Evaluation of microcomputer nutritional teaching games in 1,876 children at school	2001	RCT	None	Q13 (RF9)	France	Community (schools)	None/NR	5 wk	5 wk	Evaluate microcomputer nutritional teaching games and their contribution to the children's acquisition of nutritional knowledge and improvement of eating habits	1,876 (16 schools)	Pediatric/Young adults	Last 3 grades in primary school	Mean age: 9 yr Boys: 47.5% 3rd grade primary (7-8 yr): 30.9% 4th grade primary (9-10 yr): 35.8% 5th grade primary (11-12 yr): 33.3% Overweight (BMI > 90th percentile): 23.7% Obese (BMI > 97th percentile): 11.1%	NR (1,003)	Behavioral	Arm 1: Computer games + conventional nutritional teaching (Games) 2 hr/wk Arm 2: Conventional nutritional teaching (CON) 2 hr/wk	NR (873)	Control Arm: Conventional nutritional teaching (CON) 2 hr/wk	Primary: Childs nutritional knowledge Secondary: Mean energy intake [kcal (SE)] Mean CHO intake [%E (SE)] Mean fat intake [%E (SE)] Mean protein intake [%E (SE)] Mean saccharose (nutriment calcs/total calcs) Mean calcium intake [mg (SE)]	Primary: Games: 48.8 (0.4) vs CON: 46.1 (0.4) Secondary: Games: 1596 (13) vs CON: 1899 (14) Games: 46.4 (0.2) vs CON: 45.7 (0.2) Games: 37.1 (0.1) vs CON: 37.6 (0.2) Games: 16.5 (0.1%) vs CON: 16.7 (0.1%) Games: 11.5 (0.1) vs CON: 12.2 (0.2) Games: 77 (9) vs CON: 73 (9) * Games group also had better nutritional content at meals & snacks.	S** NS S S S S** S**	None reported	Games group did better with less snacking & eating F&V every day	A computer game-based intervention was associated with better nutritional knowledge and better food choices than a conventional curriculum.	Q10,13. A computer game-based intervention was associated with better nutritional knowledge and better food choices than a conventional curriculum. A game approach is suitable for teaching children better eating behaviors
11885948	Svahn JC	Different quantities and quality of fat in milk products given to young children: effects on long chain polyunsaturated fatty acids and trans fatty acids in plasma	2002	RCT	None	Q13 (RF9)	Sweden	Clinical	Double	3 mo	3 mo	Investigate differences in fatty acid content of plasma lipid fractions and serum lipid concentrations among young children	54	Pediatric/Young adults	11 mo, term, AGA No history of feeding or growth problems in the first yr Exclusions: Milk intolerance Severe disease Parent or investigator choice	NR	Arm 1: NR (8) Arm 2: NR (9) Arm 3: NR (9) Arm 4: NR (11)	Dietary Supplements	All children: no other milk or dairy products except provided milk Arm 1: Low-fat cow's milk (1.0 g/dL of fat) (LF) Arm 2: Standard-fat cow's milk (3.5 g/dL) (SF) Arm 3: Partial vegetable-fat milk diet (3.5 g/dL fat; 50% vegetable from rapeseed oil and 50% cow's milk fat) (PVF) Arm 4: Full vegetable-fat milk diet (3.5 g/dL fat; 100% vegetable fat from palm, coconut and soybean oil) (FVF)	N/A	N/A	Primary: Plasma cholesterol ester fatty acids [mg/L] Phospholipid fatty acids [mg/L] Plasma TG fatty acids [mg/L] Plasma linoleic acid Plasma alpha-linolenic acid Plasma arachidonic acid Plasma docosahexaenoic acid Total trans fatty acids Plasma alpha tocopherol Secondary: Mean dietary PUFA intake [%E (SD)] Mean vitamin D intake [mcg/d (SD)] Mean dietary linoleic acid intake [g/d] Mean dietary linolenic acid intake [g/d]	Primary: LF > PVF No difference between groups No difference between groups FVF > LF & SF PVF > SF & LF No difference between groups No difference between groups FVF > FVF-SF FVF > SF & PVF Secondary: PVF & FVF > LF and SF SF > LF, PVF & FVF SF, PVF & FVF > LF; PVF > SF; FVF > PVF PVF, FVF > LF & SF	S* NS NS S* S NS NS S S S** S** S** S*	No major safety problems.	Low fat milk does not adversely affect plasma levels of LC PUFAs. Plasma levels of ALA and DHA were not affected by the diet studied.	One year old infants consuming diets with milk fat replaced by vegetable fat had higher intakes of LA and ALA, resulting in higher plasma LA and ALA, without any effects on plasma long-chain PUFAs.	Q13. Replacement of milk fat with vegetable fat results in higher plasma LA and ALA, but does not affect plasma long chain PUFAs.
12127382	McMurray RG	A school-based intervention can reduce body fat and blood pressure in young adolescents	2002	RCT	None	Q10,13 (RF4, RF11)	USA	Community (schools)	None/NR	8 wk	8 wk	Determine the effect of increasing the aerobic component of the school's physical activity program and improving the knowledge about weight control and blood pressure on the blood pressure and body fat of early adolescents	1140 (5 schools)	Pediatric/Young Adults	Rural middle schools participating in the Cardiovascular Health in Children and Youth Study (CHIC II) Geographically separated schools Schools with a good proportion of African-American students	Mean age (SD): 12 yr (1) Males: 510 White: 64% African-American: 24.4% Other race/ethnicity: 11.6% Parental education: < High school: 17.4% Some college: 49.4% College graduates: 33.2% Annual family income: < \$30,000: 29.2% \$30,000-\$50,000: 23.6% ≥ \$50,000: 28.7%	893 (893)	Behavioral	Arm 1: Exercise only (EX) 30 min of aerobic exercise 3 d/wk Arm 2: Education only (ED) 2 class periods/wk providing information on nutrition, smoking, and exercise Arm 3: Exercise + education (EX + ED) 30 min of aerobic exercise 3 d/wk 2 class periods/wk providing information on nutrition, smoking, and exercise	247 (247)	Control Arm: Normal health curriculum + regular physical education class (CON) Health curriculum did not emphasize CVD risk factors, and physical education class focused on skill development rather than aerobic exercise	Primary: Mean SBP [mmHg (SE)] Mean DBP [mmHg (SE)] Secondary: Mean aerobic power [mL/kg/min (SE)] Mean weight [kg (SE)] Mean BMI [kg/m² (SE)] Mean sum of skin folds [mm (SE)]	Primary: EX: -2.5 +/- 0.5 ED: -1.1 +/- 0.6 CON: +1.8 +/- 0.6 EX + ED: -2.0 +/- 0.6 CON: +1.8 +/- 0.6 EX: -4.8 +/- 0.6 ED: 0.1 +/- 0.6 EX + ED: -0.5 +/- 0.6 CON: +1.4 +/- 0.7 Secondary: EX: -0.5 +/- 0.3 ED: -1.1 +/- 0.4 EX + ED: +0.8 +/- 0.4 CON: -0.3 +/- 0.4 No significant change. No significant change. EX: +1.4 +/- 0.3 ED: +1.9 +/- 0.4 EX + ED: +0.9 +/- 0.3 CON: +3.7 +/- 0.4	S** S** S** NS NS S** S**	None	None	An 8 wk school-based program to increase aerobic activity was associated with decreased SBP & DBP in intervention groups and increased SBP & DBP in controls despite no significant improvement in aerobic power in EX alone group. Control group increased SSF but there was no significant change in SSFs in ED, EX or EX + ED groups.	Q10,13. An 8 wk school-based program to increase aerobic activity was associated with decreased SBP & DBP in intervention groups and increased SBP & DBP in controls despite no significant improvement in aerobic power in EX alone group. Control group increased SSF but there was no significant change in SSFs in ED, EX or EX + ED groups.

NHLBI Evidence Table: RF9-RCT

PMID	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p≥0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question
12137237	Birbaum AS	Are differences in exposure to a multicomponent school-based intervention associated with varying dietary outcomes in adolescents?	2002	RCT	None	Q13 (RF9)	USA	Community (schools)	None/NR	2 yr	2 yr	Report outcomes associated with varying levels of exposure to a school-based nutrition intervention, Teens Eating for Energy and Nutrition at School (TEENS)	3503 (16 schools)	Pediatric/ Young adults	School with at least 20% of students approved for the free and reduced-price lunch program	Males: Arm 1: 426 (60.4%) Arm 2: 343 (60.7%) Arm 3: 105 (46.5%) Control Arm: 900 (51.3%) White: 68.7% African American: 10.4% Asian or Pacific Islander: 6.9% Multiracial: 5.6% Other race/ethnic group: 8.5% 2 parents with full-time employment: Arm 1: 359 Arm 2: 309 Arm 3: 110 Control Arm: 873 1 parent with full-time employment: Arm 1: 300 Arm 2: 244 Arm 3: 85 Control Arm: 659 Neither parent with full-time employment: Arm 1: 186 Arm 2: 124 Arm 3: 31 Control Arm: 223	Arm 1: 845 (NR) Arm 2: 677 (NR) Arm 3: 226 (NR)	Behavioral	Arm 1: School environment (ENV only) School environment focused on promoting fruits and vegetables as part of the school lunch and promoting fruits, vegetables, and lower fat foods as healthy snacks available in school a la carte lines and vending machines Arm 2: School environment + classroom curriculum (ENV + Curr) 10 curriculum sessions involving fruit, vegetable, and fat-related self-assessment and goal setting with progress checks, as well as practice in coming up with realistic options for making healthy food choices in a variety of social settings Students received 3 "Parent Packs," which contained activities and intervention-related messages and were mailed home to their parents or guardians Control Arm: No school environment + no classroom curriculum + no peer leaders (CON)	1755 (NR)	Control Arm: No school environment + no classroom curriculum + no peer leaders (CON)	Primary: Mean fruits and vegetables intake [servings/d] (SD) Mean fruit intake [servings/d] Mean vegetables intake [servings/d] Secondary: Mean usual food choices [score]	Primary: PEER: 4.89+/-0.06 to 5.80+/-0.05 ENV + Curr: 4.51+/-0.04 to 4.95+/-0.04 ENV only: 4.76+/-0.03 to 4.44+/-0.04 CON: 4.76+/-0.04 to 4.80+/-0.03 Time X Exp: F=4.39, df=3,14, p=0.023 Time X Exp: F=5.05, df=3,14, p=0.014 Time X Exp: F=1.03, df=3,14, p=1.07 * Within groups, pattern of response similar to that for F + V; best slope for PEER; next best for ENV + Curr; then ENV only & no change for CON. Secondary: Time X Exp: F=5.51, df=3,14 PEER: 5.90+/-0.16 to 6.54+/-0.16 ENV + Curr: 5.68+/-0.12 to 6.32+/-0.12 ENV only: 5.60+/-0.12 to 5.85+/-0.12 CON: 5.51+/-0.10 to 5.88+/-0.12	S NS (p=.056) NS NS S NS S* NS NS	None reported	Even children who had healthy eating habits in elementary school did less well in middle school. School environment changes alone are inadequate to improve diet; home changes are needed as well. Peer led intervention appears to be effective.	Diet outcomes varied with exposure differences in a middle school intervention, with significant and best response to a peer-led intervention. School environment plus home changes were important.	Q13. Diet outcomes varied with exposure differences in a middle school intervention, with significant and best response to a peer-led intervention. School environment plus home changes were important.
12137237	Birbaum AS	Are differences in exposure to a multicomponent school-based intervention associated with varying dietary outcomes in adolescents?	2002	RCT	None	Q13 (RF9)	USA	Community (schools)	None/NR	2 yr	2 yr	Report outcomes associated with varying levels of exposure to a school-based nutrition intervention, Teens Eating for Energy and Nutrition at School (TEENS)	3503 (16 schools)	Pediatric/ Young adults	School with at least 20% of students approved for the free and reduced-price lunch program	Males: Arm 1: 426 (60.4%) Arm 2: 343 (60.7%) Arm 3: 105 (46.5%) Control Arm: 900 (51.3%) White: 68.7% African American: 10.4% Asian or Pacific Islander: 6.9% Multiracial: 5.6% Other race/ethnic group: 8.5% 2 parents with full-time employment: Arm 1: 359 Arm 2: 309 Arm 3: 110 Control Arm: 873 1 parent with full-time employment: Arm 1: 300 Arm 2: 244 Arm 3: 85 Control Arm: 659 Neither parent with full-time employment: Arm 1: 186 Arm 2: 124 Arm 3: 31 Control Arm: 223	Arm 1: 845 (NR) Arm 2: 677 (NR) Arm 3: 226 (NR)	Behavioral	Arm 3: Peer leaders + classroom curriculum + school environment (PEER) Peer leaders helped teachers deliver the classroom curriculum by leading small-group activities and discussions	1755 (NR)	Control Arm: No school environment + no classroom curriculum + no peer leaders (CON)	Primary: Mean fruits and vegetables intake [servings/d] (SD) Mean fruit intake [servings/d] Mean vegetables intake [servings/d] Secondary: Mean usual food choices [score]	Primary: PEER: 4.89+/-0.06 to 5.80+/-0.05 ENV + Curr: 4.51+/-0.04 to 4.95+/-0.04 ENV only: 4.76+/-0.03 to 4.44+/-0.04 CON: 4.76+/-0.04 to 4.80+/-0.03 Time X Exp: F=4.39, df=3,14, p=0.023 Time X Exp: F=5.05, df=3,14, p=0.014 Time X Exp: F=1.03, df=3,14, p=1.07 * Within groups, pattern of response similar to that for F + V; best slope for PEER; next best for ENV + Curr; then ENV only & no change for CON. Secondary: Time X Exp: F=5.51, df=3,14 PEER: 5.90+/-0.16 to 6.54+/-0.16 ENV + Curr: 5.68+/-0.12 to 6.32+/-0.12 ENV only: 5.60+/-0.12 to 5.85+/-0.12 CON: 5.51+/-0.10 to 5.88+/-0.12	S NS (p=.056) NS NS S NS S* NS NS	None reported	Even children who had healthy eating habits in elementary school did less well in middle school. School environment changes alone are inadequate to improve diet; home changes are needed as well. Peer led intervention appears to be effective.	Diet outcomes varied with exposure differences in a middle school intervention, with significant and best response to a peer-led intervention. School environment plus home changes were important.	Q13. Diet outcomes varied with exposure differences in a middle school intervention, with significant and best response to a peer-led intervention. School environment plus home changes were important.
12554024	Baranowski T	Squire's Quest! Dietary outcome evaluation of a multimedia game	2003	RCT	None	Q13 (RF9)	USA	Community (schools)	None/NR	5 wk	9 wk	Examine if use of a psychoeducational multimedia game increases fruit, juice, and vegetable consumption among children	1578 (26 schools)	Pediatric/ Young adults	4th grade	Age range: 8-12 yr Boys: 736 African American: 268 Euro-American: 690 Hispanic: 476 Other ethnicity: 105	785 (749)	Behavioral	Arm 1: Multimedia game Squire's Quest!, an interactive multimedia game, is comprised of 10 25-min sessions Before the end of each session, children set goals to make the recipe (prepared in the virtual kitchen) during that session, eat another fruit, juice, or vegetable serving at a meal or as a snack, or to ask for their favorite fruit, juice or vegetable to be more available at home Control Arm: No game	793 (740)	Control Arm: No game	Primary: INT vs CON: Mean fruit intake [servings (SD)] Mean juice intake [servings (SD)] Mean regular vegetable intake [servings (SD)] Secondary: Mean high-fat vegetable intake [servings (SD)] Mean total fruit, juice, and vegetable intake [servings (SD)] Mean total fruit, juice and high-fat vegetable intake [servings (SD)]	Primary: INT vs CON: Increased 0.52 serv (8/9 wk) No diff (8/9 wk) Increased 0.24 serv (8/9 wks) Secondary: No change Increased 0.9 serv (8/9 wk) Increased 1.0 serv (8/9 wks)	S* NS S NS S* S**	NR	Intervention did not reach goal of 5 serv of F&V per day. Change differed across intake quartiles, with less decline among highest quartile and greater increase among lowest quartile.	Psychoeducational media games have the potential to change short-term dietary behavior in elementary school aged children resulting in increased intake of fruits, vegetables and juice at short term assessment.	Q13. Use of psychoeducational media games increased children's short-term fruit, vegetable and juice intake.
14594792	Caballero B	Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren	2003	RCT	None	Q10, 13 (RF8, RF9, RF11)	USA	Community (schools)	None/NR	3 yr	3 yr	Evaluate the effectiveness of a school-based, multicomponent intervention for reducing percentage BF in American Indian schoolchildren	1,704 (41 schools)	Parental/ Family/ Caregiver	2nd-5th grade American Indian School selection based on: ≥ 90% of 3rd grade children of American Indian ethnicity	Mean age (SD): 7.6 yr (0.6)	879 (727)	Behavioral	Arm 1: Classroom curriculum + food service + physical education + family involvement (INT) Classroom curriculum included 2 45-min lessons/wk for 12 wk during 3rd and 4th grades; decreased to 8 wk during 5th grade Food service component included nutrient guidelines and practical tools for reducing fat content of school meals Physical education included ≥ 3 30-min sessions/wk of MVPA and exercise breaks during the d Families were given take-home materials and attended 9 family events at schools Control Arm: NR (CON)	825 (682)	Control Arm: NR (CON)	Primary: Mean percentage BF (% (95% CI)) Secondary: Mean BMI [kg/m ²] (95% CI) Mean triceps skinfold thickness [mm (95% CI)] Mean subscapular skinfold thickness [mm (95% CI)] Mean energy intake from 24-h dietary recall [kcal/d] (95% CI) Mean fat intake from 24-h dietary recall [g (95% CI)] Mean energy intake from school-lunch observation [kcal/d] (95% CI) Mean fat intake from school-lunch observation [g (95% CI)] Knowledge & attitudes by questionnaire Mean physical activity by motion sensor [average vector magnitude/min (95% CI)] Mean self-reported physical activity (95% CI)	Primary: PRE: INT: 32.8 vs CON: 33.3 POST: INT: 40.3 vs CON: 40.0 Difference at FU: 0.2 (CI:0.84,1.31) Secondary: No difference between groups No difference between groups No difference between groups INT: 1892 vs CON: 2157; Difference: -265 (CI: -437, -94) INT: 31.1 vs CON: 33.6 Difference: -2.5 (-3.9, -1.1) No difference between groups 28.2 vs CON: 32.4 Difference: -4.2 (CI:-7.1,-1.3) Higher knowledge & better intention in INT group. No difference between groups No difference between groups	NS NS NS NS S* S** NS S* NS NS	None	A school-based intervention targeting diet and exercise did not reduce body fat despite improvement in knowledge and attitudes. % of energy from fat was reduced by recall and by observation.	Q10,13. A school-based intervention targeting diet and exercise did not reduce body fat despite improvement in knowledge and attitudes. % of energy from fat was reduced by recall and by observation.	
14636809	Himes JH	Impact of the Pathways intervention on dietary intakes of American Indian schoolchildren	2003	RCT	None	Q10, (RF9)	USA	Community (schools)	None/NR	3 yr	3 yr	Report the impact of the Pathways intervention on diet, using data from direct observation of children eating school lunch and 24-hr dietary recalls	NR (41 schools)	Pediatric/ Young Adults	3rd grade students	NR	NR (301)	Behavioral	Arm 1: School curriculum + physical activity education + school food service + family component School curriculum and family component emphasized healthy eating and low-fat food alternatives School food service intervention focused on nutrient and behavioral guidelines to reduce the amount of fat in school meals Control Arm: Normal instruction and activities provided by local school districts	NR (319)	Control Arm: Normal instruction and activities provided by local school districts	Primary: SCHOOL LUNCH: Mean change in total fat intake from school lunch observation [g (SE)] Mean change in saturated fat intake from school lunch observation [g (SE)] Mean change in CHO intake from school lunch observation [g (SE)] Mean change in energy intake from school lunch observation [kcal (SE)] Mean change in total fat intake from school lunch observation [g (SE)] Mean change in CHO intake from school lunch observation [g (SE)] Mean change in protein intake from school lunch observation [g (SE)] Mean change in PUFA intake from school lunch observation [g (SE)] Mean change in dietary fiber from school lunch observation [g (SE)]	Primary: Adjusted diff: INT-CON -3.6% +/- 1.7 -2.1% +/-0.7 +3.7% +/- 1.7 No significant difference for intervention effect for any of these school lunch parameters.	S S* S NS	None reported	There were no differences in BMI between control & intervention schools at the end of the study.	A school-based intervention for native Americans resulted in decreasing % of calories from fat & sat fat in observed school lunch and decreased calorie, fat, sat fat, PUFA and protein intake on 24 hr recall. However, no differences in BMI were observed.	Q10. A school-based intervention for native Americans was successful in decreasing % of calories from fat & sat fat in observed school lunch and decreased calorie, fat, sat fat, PUFA and protein intake on 24 hr recall. However, no differences in BMI were observed.

NHLBI Evidence Table: RF9-RCT

PMO	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p≥0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question	
14636809	Himes JH	Impact of the Pathways intervention on dietary intakes of American Indian schoolchildren	2003																			<p>24 HR DIET RECALL: Adjusted mean energy intake from 24-hr recall [kcal (SE)]</p> <p>Adjusted mean protein intake from 24-hr recall [g (SE)]</p> <p>Adjusted mean total fat intake from 24-hr recall [g (SE)]</p> <p>Adjusted mean saturated fat intake from 24-hr recall [g (SE)]</p> <p>Adjusted mean PUFA intake from 24-hr recall [g (SE)]</p> <p>% calories from total fat intake from 24-hr recall [% (SE)]</p> <p>% calories from saturated fat from 24-hr recall [% (SE)]</p> <p>% calories from CHO from 24-hr recall [% (SE)]</p> <p>CHO intake from 24-hr recall [g (SE)]</p> <p>Adjusted mean dietary fiber from 24-hr recall [g (SE)]</p>	<p>NT: 1887±88 vs CON: 2150±88</p> <p>NT: 67.8±2.4 vs CON: 77.3±2.4</p> <p>NT: 67.3±3.7 vs CON: 82.4±3.6</p> <p>NT: 24.9 ± 1.5 vs CON: 30.9 ± 1.5</p> <p>NT: 11.9 ± 0.7 vs CON: 14.1 ± 0.7</p> <p>NT:31.1± 0.6 vs CON:33.5 ± 0.6</p> <p>NT: 11.6 ± 0.4 vs CON: 12.8 ± 0.4</p> <p>NT: 55.6± 0.8 vs CON: 53.1 ± 0.8</p> <p>No difference between groups</p> <p>No difference between groups</p>	<p>S</p> <p>S</p> <p>S*</p> <p>S*</p> <p>S</p> <p>S*</p> <p>S*</p> <p>S</p> <p>NS</p>					
1470957	Tahia S	A randomized intervention since infancy to reduce intake of saturated fat, calorie (energy) and nutrient intakes up to the age of 10 years in the Special Turku Coronary Risk Factor Intervention Project	2004	RCT	None	Q6 (RF2, RF9) Q11 (RF9) Q13 (RF9)	Finland	Clinical	None/NR	9 yr 5 mo	9 yr 5 mo	Evaluate the longitudinal impact of dietary counseling on children's nutrient intake	1,062	Parental/ Family/ Caregiver	5 mo. Need to review original paper	Boys: 392 481 usable	940 (289) 481 usable	Behavioral	Arm 1: Dietary counseling to reduce dietary saturated fat (INT) Counseling aimed at achieving protein intake of 10-15%E, CHO intake of 50-60%E; fat intake restricted to 30-35%E between age 1-2 yr, and 30%E after age 2 yr with a 2:1 ratio of unsaturated to saturated fat. Family counseling by a nutritionist at 1-3 mo intervals until age 2 yr, followed by biannual counseling sessions thereafter Children and parents were given separate individualized counseling sessions after age 7 yr	522 (268)	Control Arm: No atherosclerosis-focused dietary counseling (CON) Cow's milk with ≥ 1.5% fat was recommended after age 12 mo Families attended general counseling sessions biannually until the child reached age 7 yr, attending 1 session per yr thereafter	<p>Primary: INT vs CON: Mean total fat intake [% (SD)] Mean SFA intake [% (SD)] Mean PUFA intake [% (SD)] Mean MUFA intake [% (SD)]</p> <p>Secondary: Mean caloric intake [calories/d (SD)] Mean protein intake [% (SD)] Mean CHO intake [% (SD)] Mean calcium intake [mg (SD)] Mean zinc intake [mg (SD)] Mean vitamin D intake [µg (SD)] Mean iron intake [mg (SD)]</p>	<p>Primary: INT vs CON: Decreased (10 yr) Decreased (4, 7, 10 yr) Increased (4, 7, 10 yr) Decreased for girls (4, 10 yr); Increased for girls (7 yr) Increased for boys (4, 7, 10 yr)</p> <p>Secondary: Int-Con, boys; No diff. girls Increased (4, 7, 10 yr) Increased (4, 10 yr) Increased (4, 7, 10 yr) Increased (4, 7, 10 yr) Increased (4, 7, 10 yr) Increased (4, 7, 10 yr)</p>	<p>S*</p> <p>S**</p> <p>S**</p> <p>S</p> <p>NS</p> <p>S* boys; NS girls</p> <p>S* boys, S* girls</p> <p>NS</p> <p>NS</p> <p>S*</p> <p>NS</p>	No differences in vitamin & mineral intake	Vitamin D intake below recommend levels for boys & girls, but increased in Int vs Con.	Individual dietary counseling begun in infancy favorably influences children's fat & sat fat intake without any adverse effects on intake of nutrients. Target in total fat easily reached but 2:1 ratio of PUFA to sat fat not achieved @ 10 yrs. Counseling during wellness visits improves the intake of PUFA without harming nutrient or mineral intake.	Q10.13. Individual dietary counseling begun in infancy favorably influences children's fat & sat fat intake without any adverse effects on intake of nutrients. Target in total fat easily reached but 2:1 ratio of PUFA to sat fat not achieved @ 10 yrs. Counseling during wellness visits improves the intake of PUFA without harming nutrient or mineral intake.	
15090126	Lyle LA	School-based approaches to affect adolescents' diets: results from the TEENS study	2004	RCT	None	Q13 (RF9)	USA	Community (schools)	None/NR	2 yr	2 yr	Report on the outcomes of the Teens Eating for Energy and Nutrition at School (TEENS) study, a 2-yr intervention study conducted in 16 middle schools with a goal of increasing students' intakes of fruits, vegetables, and lower fat foods	16 schools	Parental/ Family/ Caregiver	7th grade ≥ 20% of students in school district qualify for free or reduced-price lunch	Males: 223 (49.0%) White: 311 (68.4%) African American: 38 (8.4%) Asian or Pacific Islander: 38 (8.4%) Hispanic/Latino: 14 (3.1%) Native American: 7 (1.5%) Multiracial: 23 (5.1%) Other race: 24 (5.3%) Living with 2 parents: 74.1% Receiving reduced price lunch: 104 (22.9%) Parents with full-time employment: 2 parents: 213 (46.8%) 1 parent: 163 (36.8%) Neither parent: 73 (17.4%)	NR (1,452) 8 schools (8 schools)	Behavioral	Arm 1: Counseling + policy change (INT) 10 behaviorally-based nutrition education sessions of the TEENS curriculum in grade 7 and grade 8 Provision of a family education component including 3 newsletters, parental tips on diet improvement, family games, behavioral coupons related to diet, and homework assignments for 7th graders Changes were made to school food policy and food service staff were trained to modify the school food environment to promote healthier food choices	NR (1,431) 8 schools (8 schools)	Control Arm: No intervention (CON) Intervention materials and training received after completion of follow-up period	<p>Primary Mean energy from fat based on 24-hr recall [kcal/1000 kcal] Mean energy from fruits and vegetables from 24-hr recall [kcal/1000 kcal]</p> <p>Secondary Mean fruit servings from 24-hr recall [servings/d (SE)] Mean vegetable servings from 24-hr recall [servings/d (SE)] Mean servings of fruit and vegetables from 24-hr recall [servings/d (SE)] Mean food choice score based on survey (SE)</p>	<p>Primary: INT:30.92 vs CON: 30.28 Diff: 0.635 (CI: -0.866,2.137) INT: 3.60 vs CON: 4.09 Diff: -0.492(CI: -1.032, 0.049)</p> <p>Secondary: No difference between groups for any combination of fruit / vegetable intake. INT: 6.15 vs CON: 5.78 Diff: 0.375 (CI: 0.038,0.713)</p>	<p>NS</p> <p>NS</p> <p>NS</p> <p>S*</p>	None	Actual delivery of intervention components was limited.	A school-based program to decrease carbonated beverage intake produced a significant change at 12 mos. BMI increased less in INT groups but difference was not significant. Proportion of INT group found to be overweight/obese at 12 mos was significantly lower in INT group.	Q10.11. A school-based intervention to increase fruit, vegetable and lower fat food intake in middle schools which had been successful at 1 y evaluation showed no diet change at 2nd y evaluation.	
15090126	Lyle LA	School-based approaches to affect adolescents' diets: results from the TEENS study	2004																										
15107313	James J	Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial	2004	RCT	None	Q6 (RF2, RF8, RF9) Q13 (RF8, RF9)	England	Community (schools)	None/NR	1 yr	1 yr	Determine if a school-based educational program aimed at reducing consumption of carbonated drinks can prevent excessive weight gain in children	644 (6 schools, 29 classes)	Pediatric/ Young adults	7-11 yr	Mean age (SD): 8.7 yr (0.9)	325 (295) 15 classes (15 classes)	Behavioral	Arm 1: Focused educational program on nutrition (NT) 1-hr session consisting of teacher-administered lessons and creative games to discourage the consumption of carbonated drinks with positive affirmation of a balanced healthy diet	319 (276) 14 classes (14 classes)	Control Arm: No intervention (CON) Intervention materials and training received after completion of follow-up period	<p>Primary: Mean change in total carbonated drink intake (# glasses per 3 d (95%CI))</p> <p>Secondary: Prevalence of overweight and obesity(%)</p> <p>Mean BMI [kg/m² (SD)]</p> <p>Mean z score (SDS)</p> <p>Water consumption [glasses over 3 d(SD)]</p>	<p>Primary: AI 12 mos: Mean difference between groups: 0.7 (0.1, 1.3) INT: -0.6(-1.0,-0.1) vs CON: + 0.2(-0.2, 0.5)</p> <p>INT: 20.3±6.3 to 20.1±6.7 vs CON: 19.4±8.4 to 28.9±12.3 Mean difference = 7.7%(CI: 2.2 to 13.1)</p> <p>Secondary: INT: 17.4±0.6 to 17.9±0.7 vs CON: 17.6±0.7 to 18.3±0.8 INT: 0.50±0.23 to 0.48±0.23 vs CON: 0.47±0.2 to 0.60±0.19 INT: 3.1±1.1 to 4.3±2.0 vs CON: 2.9±0.3 to 5.1±2.0</p>	<p>S, between groups</p> <p>S</p> <p>S for change, between groups</p> <p>NS</p> <p>NS</p> <p>S from B/L; NS between groups S from B/L</p>	None reported	Water intake increased in both groups.	A school-based program to decrease carbonated beverage intake produced a significant change at 12 mos. BMI increased less in INT groups but difference was not significant. Proportion of INT group found to be overweight/obese at 12 mos was significantly lower in INT group.	Q10.13. A school-based program to decrease carbonated beverage intake produced a significant change at 12 mos. BMI increased less in INT groups but difference was not significant. Proportion of INT group found to be overweight/obese at 12 mos was significantly lower in INT group.	
15159241	Ulbak J	Diet and blood pressure in 2.5-y-old Danish children	2004	RCT	None	Q10 (RF4, RF9) Q13 (RF4, RF9)	Denmark	Clinical	Double	4 mo	2.5 yr	Investigate whether maternal intakes of n-3 LC-PUFAs during lactation and current intakes of macronutrients affect BP in children	122	Parental/ Family/ Caregiver	Pregnant women Fish intake below 44th percentile (< 0.40 g n-3 LC-PUFAs/d) BMI < 30 No metabolic disorders Intention to breastfeed for ≥ 4 mo	NR	122/100	Dietary Supplements	Arm 1: 17 g/d fish oil (INT) Received a 1:2 mixture of 2 microencapsulated fish oil capsules, with 47 mg eicosapentaenoic acid per g of fish oil and 32 mg DHA per g fish oil and with 16 mg eicosapentaenoic acid per g of fish oil and 75 mg DHA per g fish oil, respectively This mixture provided 4.5 g fish oil and 1.5 g n-3 LC-PUFA, which is equivalent to the habitual intake of the women in the population with the highest fish intake (90th percentile)	60 (50)	Control Arm: 17 g/d olive oil (CON) Received microencapsulated olive oil	<p>Primary: Mean DBP [mmHg (SD)] at 31 mos Mean SBP [mmHg (SD)] at 31 mos</p> <p>Secondary: Mean BF [%; Difference between groups (95%CI)] Mean physical fitness score [points %; Difference between groups (95%CI)] Mean dietary fiber [g/d; Difference between groups (95%CI)] Mean energy intake from saturated fat [%; Difference between groups (95%CI)]</p>	<p>Primary: INT: 67±2 vs CON: 67±2 vs REF: 63±2 INT:112±2 vs CON:108±2 vs REF: 108±2</p> <p>**With MVA, higher protein intake at 2.5 yrs of age was associated with significantly lower SBP & DBP.</p>	<p>NS</p> <p>NS</p> <p>S for SBP & DBP</p>	None	(1) Fish oil supplementation to increase maternal intake of n-3 PUFA in lactating mothers had no impact on BP measured 2 y later. (2) Higher protein intake at 2.5 y was associated with lower SBP & DBP.	Q10. Fish oil supplementation to increase maternal intake of n-3 PUFA in lactating mothers had no impact on BP measured 2 y later. Q10. Higher protein intake at 2.5 y was associated with lower SBP & DBP.		
15351759	Trevino RP	Impact of the Bienestar school-based diabetes mellitus prevention program on fasting capillary glucose levels: a randomized controlled trial	2004	RCT	None	Q10, 13 (RF6, RF8, RF9, RF11)	USA	Community (schools)	None/NR	7 mo	8 mo	Evaluate impact of a school-based diabetes mellitus prevention program on low-income fourth-grade Mexican American children	1,419 (27 schools)	Parental/ Family/ Caregiver	4th grade Exclusions: Previous exposure to Bienestar Alternative schools Age > 12 yr Previously diagnosed with type 1 or type 2 diabetes mellitus Extreme dietary values 3-day average calorie intake < 800 or > 4,800 Other ethnic group Disadvantaged students (SD): Arm 1: 94.40% (7, 16) Control Arm: 85.10% (4, 01) Mean household income: Arm 1: \$11,000 Control Arm: \$12,000	713 (619) 13 schools (NR)	Behavioral	Arm 1: Health and physical education + health club participation + family program + school cafeteria program (INT) 50 sessions of health programming distributed throughout 7 mo 1.45-min health education class per wk; 4.45-min physical activity sessions per wk Health club for 1 h/wk after school to promote leisure-time physical activity Parent meetings held every other month 1 lunch visit/wk to persuade children to eat more fruit and vegetables and less fatty foods	706 (602) 14 schools (NR)	Control Arm: NR (CON)	<p>Primary: Mean fasting capillary glucose [Difference between groups(mg/dL);(95%CI)]</p> <p>Secondary: Mean BF [%; Difference between groups (95%CI)] Mean physical fitness score [points %; Difference between groups (95%CI)] Mean dietary fiber [g/d; Difference between groups (95%CI)] Mean energy intake from saturated fat [%; Difference between groups (95%CI)]</p>	<p>Primary: -2.24 (-4.20,-0.28)</p> <p>Secondary: 0.18(-0.45,0.61) 1.87(0.09, 3.65) 0.99 (0.30, 1.68) -0.68 (-2.01,0.65)</p>	<p>S</p> <p>NS</p> <p>S</p> <p>S*</p> <p>NS</p>	none reported	SFA did not differ between groups No measures of insulin resistance were reported.	A school-based diet and exercise intervention reduced fasting glucose, improved fitness scores and increased fiber intake in Mexican American elementary-school aged children.	Q10.13. A school-based diet and exercise intervention reduced fasting glucose, improved fitness scores and increased fiber intake in Mexican American elementary-school aged children.		

PMID	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p≥0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question	
15351759	Trevino RP	Impact of the Bienestar school-based diabetes mellitus prevention program on fasting capillary glucose levels: a randomized controlled trial	2004													First- or second-degree relative with diabetes mellitus: Arm 1: 55% Control Arm: 60%													
15930237	Van Horn L	Children's adaptations to a fat-reduced diet: the Dietary Intervention Study in Children (DISC)	2005	RCT	None	Q6 (RF2, RF5, RF8, RF9) Q13 (RF9)	USA	Clinical	None/NR	3 yr	7 yr	Compare children's self-selected eating patterns and approaches to achieving adherence to the DISC fat-reduced diet intervention with children in the usual-care group at the end of the 3-year intervention.	663	Pediatric/ Young adults	8-10 yr LDL-C levels from 80th to < 98th percentile based on age-gender distributions Prepubertal Exclusions: SBP ≥ 125 mmHg DBP ≥ 80 mmHg	Mean age (SD): Arm 1: 9.6 yr (0.7) Control Arm: 9.6 yr (0.7) Boys: 363 Minority ethnicity: Arm 1: 12.4% Control Arm: 13.1%	306 (NR)	Behavioral	Arm 1: Diet + nutritional education Recommended intake of total fat was 28 %E, with < 8% from saturated fat, up to 9% from polyunsaturated fat, and < 75 mg/4200 kJ of cholesterol, not to exceed 150 mg/d Series of DISC intervention sessions built around various food groups that constitute a complete diet for children During first 6 mo, 6 wkly sessions followed by 6 bi-wkly group sessions Second 6 mo included 4 group sessions and 2 individual sessions, followed by maintenance sessions health 4 to 6 times per yr during second and third yr	289 (NR)	Control Arm: Usual care Children provided educational publications on heart-healthy eating that were generally available to the public	Primary: Total go foods (% of energy) Total go foods (% of fat energy) Total whole foods (% of energy) Total whole foods (% of fat energy) Mean change in intake of "Go Foods" low-saturated fat and cholesterol foods from BL to 3y (servings/d): Bread/Grains Dairy Desserts Fats/Oils Fruit Meat/Fish/Poultry Pizza Snacks Vegetables Mean change in intake of "Whoa Foods" atherogenic foods from BL to 3y (servings/d): Bread/Grains Dairy Desserts Fats/Oils Fruit Meat/Fish/Poultry Pizza Snacks Vegetables	Primary: INT: BL 57.0% to 3y: 67.4%; CON: BL 57.1% to 3y: 56.8% INT: BL 12.4% to 3y: 13.7%; CON: BL 13.1% to 3y: 12.8% INT: BL 43.0% to 3y: 32.8%; CON: BL 42.9% to 3y: 43.2% INT: BL 21.3% to 3y: 15.4%; CON: BL 21.2% to 3y: 20.7% (Shown as figure) Increased in INT & CON Increased in INT, decreased in INT Increased in INT & CON Decreased in INT & CON, more in CON Increased in INT, decreased in CON Increased in INT & CON Increased in INT & CON No change in either group (Shown as figure) Decreased in INT, increased in CON Decreased in INT & CON Decreased in INT & CON Decreased in INT, increased in CON Decreased in INT, increased in CON Increased in INT & CON Decreased in CON, increased in CON	Not reported Not reported Not reported Not reported NS between groups S between groups S between groups NS between groups NS between groups NS between groups NS between groups S between groups S* between groups S between groups S between groups S* between groups NS between groups S between groups S* between groups	Not reported	Pizza, snacks, and desserts make up 1/3 of daily calories for most children, regardless of intervention. Largest between group differences seen in dairy, fats/oils, & desserts NS between groups S* between groups S between groups NS between groups NS between groups NS between groups NS between groups NS between groups S between groups S* between groups S between groups S between groups S* between groups NS between groups NS between groups S between groups S* between groups	An intensive 3-year educational intervention to reduce children's dietary intake of saturated fat and cholesterol by changing their eating patterns was successful in increasing intake of recommended foods and decreasing intake of non-recommended choices. The intervention group vs. control group consumed more servings of foods low in saturated fat and cholesterol from the dairy, fats/oils and meat/fish/poultry groups, and fewer high saturated fat/cholesterol foods from the bread/grains, dairy, fats/oils, meat/fish/poultry and snack groups. However, there were major secular influences on diet with snacks, desserts and pizza making up one third of intake in both groups.	An intensive 3-year educational intervention to reduce children's dietary intake of saturated fat and cholesterol by changing their eating patterns was successful in increasing intake of recommended foods and decreasing intake of non-recommended choices. The intervention group vs. control group consumed more servings of foods low in saturated fat and cholesterol from the dairy, fats/oils and meat/fish/poultry groups, and fewer high saturated fat/cholesterol foods from the bread/grains, dairy, fats/oils, meat/fish/poultry and snack groups.	
15930237	Van Horn L	Children's adaptations to a fat-reduced diet: the Dietary Intervention Study in Children (DISC)	2005																										
15930237	Van Horn L	Children's adaptations to a fat-reduced diet: the Dietary Intervention Study in Children (DISC)	2005																										
15930237	Van Horn L	Children's adaptations to a fat-reduced diet: the Dietary Intervention Study in Children (DISC)	2005																										
16157415	Hendy HM	Kids Choice school lunch program increases children's fruit and vegetable acceptance	2005	RCT	None	Q13 (RF9)	USA	Community (schools)	None/NR	18 meals (3 meals (lunches) per week)	7 mo	Evaluate the effectiveness of the "Kids Choice" school lunch program	346	Pediatric/ Young adults	First, second, and fourth graders Mean age (SD): 8.0 yr (1.4) Boys: 169 Caucasian > 95%	346 (158 at 2 weeks F/U. Four classes for each grade; half of classes were randomized to reinforcement for fruit and half for vegetables.	Behavioral	Arm 1: Token reinforcement program for fruit consumption (FRT) "Kids Choice" school lunch program Received token for eating at least 1/8 cup of fruit Token reinforcement for up to 18 meals (3 meals per week). Weekly token exchange; 3 tokens for a non-food reward. Arm 2: Token reinforcement program on vegetable consumption (VEG) "Kids Choice" school lunch program Received token for eating at least 1/8 cup of vegetables Token reinforcement for up to 18 meals (3 meals per week). Weekly token exchange; 3 tokens for a non-food reward.	-	Students reinforced for eating vegetables were control for those reinforced for eating fruits, and vice versa. (CON)	Primary: Mean fruit consumption [number of meals (SD)] Mean vegetable consumption [number of meals (SD)] Secondary: Preference for fruits [3-point scale, mean for 8 fruits (SD)] Preference for vegetables [3-point scale, mean for 8 vegetables (SD)]	Primary: By repeated measures ANOVA, fruit consumption increased for all 3 grades during the time block when children were being reinforced for eating fruits; at 7 months, no diff from baseline. By repeated measures ANOVA, vegetable consumption increased in all 3 grades during the time blocks when children were being reinforced for eating vegetables; at 7 months, no diff from baseline. Secondary: BL: 2.47(0.07); 7 mos: 2.49(0.05); at 2 weeks, significant increase shown for each grade separately as a graph BL: 2.09(0.06); 7 mos: 2.15(0.05); at 2 weeks, near significant increase shown for each grade separately as a graph	S**_NS S**_NS S*NS NS (p=0.07), NS	None	Children prefer fruits over vegetables; increased amounts of F & V are eaten with increasing age regardless of preference. Reinforcing eating fruits was associated with an increase in preference for fruits but no change in preference for vegetables at 2 weeks post intervention. Reinforcing eating vegetables was associated with an increase in preference for veg but no change in preference for fruits at 2 weeks post intervention.	A school lunch intervention for 1st to 4th grade students increased F & V consumption by selectively reinforcing their eating fruits or vegetables at very short term F/U. However the increase did not persist when assessed 7 mos after the intervention.	Q10, 13. A school lunch intervention for 1st to 4th grade students increased F & V consumption by selectively reinforcing their eating fruits or vegetables at very short term F/U. However the increase did not persist when assessed 7 mos after the intervention.		
16201856	Salminen M	Effects of a controlled family-based health education/counseling intervention	2005	RCT	None	Q10 (RF9, RF10, RF11)	Finland	Mult settings	None/NR	Sept 1997-June 2000	Sept 1997-June 2000	Describe the effects of a controlled family-based health education/counseling intervention on health behaviors of children with a familial history of CVD	1283	Parental/ Family/ Caregiver	6-17 yr Family history of early onset coronary heart disease, myocardial infarctions, or brain infarctions among parents or grandparents, or a general family history of FH (early onset defined as having first attack before age of 55 yr for men and 65 yr for women)	Boys: 546 Mean age (SD): Arm 1: Boys: 10.7 yr (3.0) Girls: 10.9 yr (2.9) Control Arm 1: Boys: 11.4 yr (2.9) Girls: 11.9 yr (2.9) Control Arm 2: Boys: 11.5 yr (2.8) Girls: 11.7 yr (2.7)	515 (432)	Behavioral	Arm 1: Health education and counseling (INT) Children were individually counseled about diet and nutrition, exercise, cigarette smoking, and drugs and alcohol Reading materials were provided with content on effects of nutrition, cholesterol concentration, alcohol, exercise and smoking on BP and coronary heart disease, and effects of nutrition and exercise on weight control; the use of fats and fiber was stressed in the nutrition handouts Control Arm 2: Non high-risk families receiving no health counseling + regular health service options (CON 2) Consisted of children not belonging to high-risk families	Control Arm 1: 245 (200) Control Arm 2: 523 (423)	Control Arm 1: High-risk families receiving no health counseling + regular health service options (CON 1) Families having members with early onset myocardial infarction, coronary heart disease, brain infarction, or FH were considered high-risk. Control Arm 2: Non high-risk families receiving no health counseling + regular health service options (CON 2) Consisted of children not belonging to high-risk families	Primary: Butter at table [n(%)] Veg oil used in cooking [n(%)] Frequency of adding salt to food: [n (%)] Subjects reporting rarely adding salt Subjects reporting adding salt when food does not taste salty enough/ almost always Frequency of exercise practice: [n (%)] Subjects exercising every d Subjects exercising 2-6 d/wk Subjects exercising once a wk Subjects exercising < 3 times/mo Exertion of exercise: [n (%)] Heavily breathless and sweating Moderately breathless and sweating Neither breathless nor sweating	Primary: Baseline vs FU: INT vs CON1: INT: 13% to 8% CON: 15% to 13% INT: 2% to 14% CON: 3% to 5% INT: 83% to 91% CON: 85% to 91% INT: 17% to 9% CON: 15% to 19% INT: 22% to 20% CON: 27% to 22% INT: 51% to 57% CON: 55% to 50% INT: 19% to 17% CON: 11% to 17% INT: 9% to 6% CON: 7% to 10% INT: 8% to 12% CON: 12% to 13% INT: 80% to 84% CON: 82% to 81% INT: 12% to 4% CON: 8% to 6%	S** between groups at FU S** between groups at FU S* between groups at FU for both measures Overall frequency of exercise NS NS	None	No difference in smoking - no results given. In children from families with a (+) hx of early CV disease, a family-oriented health education program produced favorable changes in dietary use of fat and salt but no major changes in exercise and none in smoking.	Q10. In children from families with a (+) hx of early CV disease, a family-oriented health education program produced favorable changes in dietary use of fat and salt but no major changes in exercise and none in smoking.		

NHLBI Evidence Table: RF9-RCT

PMO	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/Ci	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p<0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question
16219630	Bere E	Free school fruit-sustained effect 1 year later	2006	RCT	None	Q10(RF9), Q11(RF9)	Norway	Community (schools)	None/NR	2 yr	2 yr	Report the effects of a school-randomized fruit and vegetable intervention consisting of a subscription to the Norwegian School Fruit Programme and the Fruit and Vegetables Make the Marks (FVMM) educational program	577 (19 schools)	Parental/Family/Caregiver	6th grade	Mean age: 11.3 yr Boys: 271 Girls 246	NR (286) 9 schools (9 schools)	Behavioral	Arm 1: FVMM educational program + school fruit program In yr 1, the FVMM educational program was offered and subscription for the Norwegian School Fruit Programme at no cost to the parents for all 9 intervention schools In yr 2, there was no FVMM educational program offered, 5 schools opted to participate in a standard School Fruit Programme in which fruit is paid for, and the remaining 4 schools did not engage in any school fruit program	NR (231) 10 schools (10 schools)	Control Arm 1: No FVMM school program + school fruit program In yr 1, 25 students from 2 schools participated in a standard School Fruit Programme in which fruit is paid for; 8 schools did not have a school fruit program In yr 2, 17 students from 3 schools participated in a standard School Fruit Programme in which fruit is paid for; 7 schools did not have a school fruit program	Primary: Adjusted mean effect of intervention on fruit and vegetable intake at school (95% CI) Adjusted mean effect of intervention on fruit and vegetable intake all d (95% CI) Secondary: Y2 Paid fruit vs no fruit Adjusted mean effect of intervention on fruit and vegetable intake at school (95% CI) Adjusted mean effect of intervention on fruit and vegetable intake all d (95% CI)	Primary: Follow-up 1: INT: 0.30(0.11,0.49) to 0.84(0.68,1.00) CON: 0.37(0.19,0.55) to 0.27(0.11,0.43) Follow-up 2: INT: 0.39(0.23,0.54); CON: 0.19(0.04,0.33) Follow-up 1: INT: 2.19(1.78,2.59) to 2.47(2.11,2.83) CON: 2.52(2.12,2.91); 1.84(1.49,2.19) 1 Y Post Intervention: INT: 2.09(1.75,2.42) vs CON: 1.57(1.24,1.89) Secondary: Y2 Paid fruit vs no fruit: FU 1 PF: 0.40(0.08,0.71) to 0.81(0.42,1.21) No PF: 0.21(-0.08,0.49) to 0.52(0.47,1.18) Y2 Paid fruit vs no fruit: FU 2 PF: 0.60(0.33,0.87) vs NoPF: 0.20(-0.04,0.44) No difference between groups for all day intake.	NS between groups at BL; S** at FU 1 p=.07 between groups NS between groups at BL; S at FU 1 S between groups S from BL for both groups; NS between groups at BL and FU 1 S between groups at FU 2	None reported	No effect of educational intervention. This effect is sustained as long as free access is provided. There is no separate effect of a F & V educational program.	Direct provision of F&V increases intake in children and this effect is sustained as long as free access is provided. There is no separate effect of a F & V educational program.	
16219631	Bere E	Outcome and process evaluation of a Norwegian school-randomized fruit and vegetable intervention: Fruits and Vegetables Make the Marks (FVMM)	2006	RCT	None	Q13 (RF8)	Norway	Community (schools)	None/NR	7 mo	21 mo	Study the effect of the Fruits and Vegetables Make the Marks (FVMM) intervention, a school-based fruit and vegetable intervention	450 (19 schools)	Parental/Family/Caregiver	6th grade	Mean age: 11.3 yr Boys: 169	NR (190) 9 schools (NR)	Behavioral	Arm 1: Home economics classroom lessons + parental newsletters + school fruit and vegetable subscription program available for \$ 7-session curriculum (345-minute lessons per session) delivered by home economics teachers in home ec classroom over a 7-mo period introducing health benefits of eating fruit and vegetables and recommendations regarding healthy levels of fruit and vegetable intake. Taste-testing, individual F&V monitoring and goal setting, F&V event 6 newsletters distributed to parents, aiming to increase communication between parents and children concerning fruit and vegetables and to stimulate increased availability and accessibility of fruit and vegetables at home Schools are offered option to participate in a national fruit and vegetable subscription program	NR (179) 10 schools (NR)	Control Arm: school fruit and vegetable subscription program available for \$	Primary: Adjusted mean effect of FVMM intervention on fruit and vegetable intake at school (95% CI) Adjusted mean effect of FVMM intervention on daily fruit and vegetable intake (95% CI) Adjusted mean effect of FVMM intervention on awareness of 5-a-day (95% CI) Secondary: Association of curriculum enjoyment with adjusted mean daily fruit and vegetable intake (95% CI) Association of usage of parental newsletters with adjusted mean daily fruit and vegetable intake (95% CI)	Primary: No change in either group No change in either group INT: BL: 3.4(3.1,3.8) to FU 1: 4.1(3.8,4.4) to FU 2: 3.9(3.7,4.1) CON: BL: 3.6(3.3,3.9) to FU 1: 3.4(3.2,3.7) to FU 2: 3.5(3.3,3.7) Secondary: Linear mixed model: High enjoyment of curriculum assoc'd with increased daily F&V intake at FU 1 & 2. High use of parental newsletters assoc'd with increased daily F&V intake at FU 1 & 2.	NS NS NS at BL; S* at FU 1; S* at FU 2 NS at BL; S* at FU 1; S* at FU 2 S at BL; S** at FU 1 & 2	Not reported	F&V intake did increase among those who reported high enjoyment of the curriculum and high use of parental newsletters. However, they had higher F&V intakes at baseline.	A school-based intervention for 6th grade children had no significant impact on fruit and vegetable intake but did result in increased awareness of 5-a-day recommendation.	
16234839	Tahva S	Longitudinal trends in consumption of vegetables and fruit in Finnish children in an atherosclerosis prevention study (STRIP)	2006	RCT	None	Q10 (RF8), Q11 (RF9), Q13 (RF9)	Finland	Clinical	None/NR	10 yr 5 mo	10 yr 5 mo	Assess prospectively the consumption of fruit and vegetables and its' correlation to the parental consumption in boys and girls taking part in an atherosclerosis prevention study	1,062	Parental/Family/Caregiver	7 mo of age at enrollment	Boys: 490/ Girls: 572	540 (228)	Behavioral	Arm 1: Individualized nutritional counseling Nutrition counseling aimed at reduction of the child's saturated fat intake Nutritionist met with families at 1- to 3-mo intervals until child was 2 yr old, and biannually thereafter Counseling given mainly to parents, but after child's age of 7 yr, separate sessions organized for child and parents Optimal diet was defined to contain energy without any restrictions, fat 30-35 %E between 13 mo and 2 yr and 30 %E with an unsaturated to saturated fatty-acid ratio of 2:1 after age of 2 yr	522 (253)	Control Arm: No nutritional counseling Families did not receive routinely receive any detailed counseling focused on the risk factors of atherosclerosis At the age of 12 mo, cow's milk with at least 1.5% fat was recommended No other detailed suggestions concerning quality or quantity of fat were given, and dietary issues were discussed only briefly	Primary: % of total energy intake from fruits & vegetables (including potatoes)(%SD) Secondary: Mean fruit and berry consumption [g (SD)] Mean vegetable consumption [g (SD)] Mean potato consumption [g (SD)]	Primary: For girls: Difference between INT & CON +0.5% (CI:0.02,0.94) For boys: Difference between INT & CON + significantly greater at 6 of 10 age points (%)(CI: 0.5-2.1, to 2.1% (CI: 1.2-3.0)) Secondary: No difference between groups for girls. For boys, INT vs CON: mean difference=10.1 g(d)(5.3,14.9) INT group(boys & girls) consumed more vegetables than CON (mean diff=2.4g)(CI: 1.2-3.5) No difference between INT & CON groups	S S** NS S S** NS	None	Finland children consumed only small amounts of fruit and vegetables in % of energy from F&V in boys and girls, but effect was significantly greater in boys. Overall, fruit and vegetable consumption was markedly low and decreased with increasing age. Mother's consumption correlated with that of daughters & sons; father's consumption correlated only with that of sons.	Q10.11.13. Nutrition counseling which focused on fat intake was associated with a small increase in % of energy from F&V in boys and girls, but effect was significantly greater in boys. Overall, fruit and vegetable consumption was markedly low and decreased with increasing age.	
16336114	Cottrill L	A kindergarten cardiovascular risk surveillance study: CARDIAC-Kinder	2005	RCT	None	Q10 (RF9, RF11)	USA	Home	None/NR	4 wk	4 wk	Evaluate an intervention aimed at increasing family physical activity and parent education about diet and activity for kindergarten students and issues related to their children's BMI	437 (29 schools)	Parental/Family/Caregiver	4-6 yr	Male: 53.3% Mean age (SD): 5 (0.64) White: 98.0% Overweight or at risk: 31.0% Family history of: 1 Heart disease: 58.7% Diabetes: 43.9%	14 schools (14 schools) NR (26 parent-child dyad)	Behavioral	Arm 1: 2 pedometers + step log + information packet 1 pedometer was for the child and the other was for the participating parent to use during the project period with the daily step log to record each participant's steps Received information about the age-appropriate diet and exercise guidelines for kindergarten children Received information on ways to increase exercise, particularly steps	15 schools (15 schools) NR (26 parent-child dyad)	Control Arm: 1 pedometer + step log + information packet Children received 1 pedometer and a step log for their sole use Received information about the age-appropriate diet and exercise guidelines for kindergarten children	Primary: Mean number of child's steps [number/wk (SD)] Mean sweets intake [number/wk (SD)] Secondary: Mean fruit intake [number/wk (SD)] Mean vegetable intake [number/wk (SD)] Mean meat intake [number/wk (SD)] Mean bread intake [number/wk (SD)]	Primary: WEEK 4 CON: 7914+3073 vs INT: 9815+3910 CON: 9.1+/-3.9 vs INT: 8.4+/-3.1 Secondary: WEEK 4 CON: 8.7+/-3.4; INT: 10.0+/-8.3 CON: 8.0+/-4.1 vs INT: 9.6+/-7.8 CON: 8.3+/-4.7 vs INT: 8.3+/-6.8 CON: 11.0+/-4.8 vs INT: 12.5+/-2.2	S S NS NS NS NS	None reported	Perceptions of parents re: PA and weight were not accurate. Intervention increased parental awareness and was associated with a measurable increase in activity and decrease in consumption of sweets in children.	Q10. A kindergarten and family-based educational intervention increased parental awareness and was associated with a measurable increase in activity and decrease in consumption of sweets in children.	
16365065	Damsgaard CT	Fish oil affects blood pressure and plasma lipid profile in healthy Danish infants	2006	RCT	2 by 2 factorial design (fish oil vs no fish oil) and cow's milk vs infant formula.	Q13 (RF4, RF5, RF8, RF9)	Denmark	Clinical	None/NR	3 mo	3 mo	Investigate effects of fish oil on blood pressure and lipid profile in infancy	84 Only 2.6% who were invited to participate e. did so.	Pediatric/ Young Adults	7-8 mo at enrollment, 9 mo at randomization	Mean age (SD): Arm 1 & 2: 9.1 mo (0.3) Control Arm 1 & 2: 9.1 mo (0.3) Males: Arm 1 & 2: 19 Control Arm 1 & 2: 23	Arm 1: 19 (15) Arm 2: 26 (25)	Dietary Supplements	Randomized to cow's milk or formula, and then each group was randomized to fish oil (+FO) or no fish oil (-FO). Arm 1: Fish oil 5 mL/d + cow's milk Arm 2: Fish oil 5 mL/d + infant formula Fish oil contained 352 g/L (n=3) LC-PLA and 3 g/L cholesterol Groups combined in the analysis as FO.	Control Arm 1: 27 (23) Control Arm 2: 22 (20)	Control Arm 1: Cow's milk Control Arm 2: Infant formula Groups combined in the analysis as CON.	Primary: (at 12m) FO: 100.4(2.4) vs CON: 106.7(2.2) No difference between groups. No difference between groups. No difference between groups. No difference between groups. No difference between groups. Secondary: No difference between groups FO: 17.4(1.2) vs CON: 16.9(1.0) FO: 16(4) vs CON: 18(3) FO: 6(2) vs CON: 4(1) Increased from baseline in FO; no change in no FO Increased from baseline in FO; no change in no FO Decreased from baseline in FO; no change in no FO	S NS NS NS S NS NS S S S** S** S	None	The consumption of cow's milk vs. infant formula was associated with higher total cholesterol levels (S), however, after adjustment for covariables, the differences were not significant. FO intake correlated significantly with RBC EPA content at 12 moe (n=86; p<S**). There was no correlation between RBC EPA and SBP.	Q10. Daily fish oil supplementation in infants is associated with short term evidence of lower systolic blood pressure and increased plasma concentrations of LDL cholesterol at 12 m of age.		
16365066	Damsgaard CT	Fish oil affects blood pressure and plasma lipid profile in healthy Danish infants	2006	RCT	None	Q13 (RF4, RF5, RF8, RF9)	Denmark	Clinical	None/NR	3 mo	3 mo	Investigate effects of fish oil on blood pressure and lipid profile in infancy	84 Only 2.6% who were invited to participate e. did so.	Pediatric/ Young Adults	7-8 mo at enrollment, 9 mo at randomization	Mean age (SD): Arm 1 & 2: 9.1 mo (0.3) Control Arm 1 & 2: 9.1 mo (0.3) Males: Arm 1 & 2: 19 Control Arm 1 & 2: 23	Arm 1: 19 (15) Arm 2: 26 (25)	Dietary Supplements	Randomized to cow's milk or formula, and then each group was randomized to fish oil (+FO) or no fish oil (-FO). Arm 1: Fish oil 5 mL/d + cow's milk Arm 2: Fish oil 5 mL/d + infant formula Fish oil contained 352 g/L (n=3) LC-PLA and 3 g/L cholesterol Groups combined in the analysis as FO.	Control Arm 1: 27 (23) Control Arm 2: 22 (20)	Control Arm 1: Cow's milk Control Arm 2: Infant formula Groups combined in the analysis as CON.	Primary: (at 12m) FO: 100.4(2.4) vs CON: 106.7(2.2) No difference between groups. No difference between groups. No difference between groups. No difference between groups. Secondary: No difference between groups FO: 17.4(1.2) vs CON: 16.9(1.0) FO: 16(4) vs CON: 18(3) FO: 6(2) vs CON: 4(1) Increased from baseline in FO; no change in no FO Increased from baseline in FO; no change in no FO Decreased from baseline in FO; no change in no FO	S NS NS NS S NS NS S S S** S** S	None	The consumption of cow's milk vs. infant formula was associated with higher total cholesterol levels (S), however, after adjustment for covariables, the differences were not significant. FO intake correlated significantly with RBC EPA content at 12 moe (n=86; p<S**). There was no correlation between RBC EPA and SBP.	Q10. Daily fish oil supplementation in infants is associated with short term evidence of lower systolic blood pressure and increased plasma concentrations of LDL cholesterol at 12 m of age.		
16567815	Kaikkonen T	Low-saturated fat dietary counseling starting in infancy improves insulin sensitivity in 9-year-old healthy children: the Special Turku Coronary Risk Factor Intervention Project for Children (STRIP) study	2006	RCT	None	Q10(RF4, RF5, RF8, RF9, RF14), Q11 (RF4, RF5, RF8, RF9, RF14), Q13 (RF4, RF5, RF8, RF9, RF14)	Finland	Clinical	None/NR	9 yr	9 yr	Study effect of infancy onset biannual dietary counseling on markers of insulin resistance in healthy 9 yr old children	167	Parental/Family/Caregiver	200 consecutive children who were randomized at 7 mo of age to either biannual diet low fat, low sat fat counseling or usual diet. Of these, 167 returned for 7 y check-up and had study lab work performed.	Arm 1: 35 M, 43 F Control Arm: 47 M, 42 F	100 (78)	Behavioral	Arm 1: Individualized dietary counseling twice 9 yr Counseling aimed at fat intake of 30%E, protein intake of 10-15%E, and CHO 55-60%E	100 (89)	Control Arm: Basic health education	Primary: Total fat intake (E%) Sat fat intake (E%) PUF fat intake (E%) Mean insulin [mU/L (SD)] Mean HOMA-IR Secondary: Mean serum TC [mmol/L (SD)] Mean HDL-C [mmol/L (SD)] Mean LDL-C [mmol/L (SD)] Mean apo A1 [g/L (SD)]	Primary: M: INT: 30.8+/-3.9 vs CON: 31.8+/-4.3 F: INT: 29.1+/-4.6 vs CON: 32.6+/-4.4 M: INT: 11.2+/-1.9 vs CON: 12.8+/-2.1 F: INT: 11.2+/-2.8 vs CON: 14.2+/-2.3 M: INT: 6.03+/-1.12 vs CON: 5.39+/-1.20 F: INT: 5.49+/-1.19 vs CON: 4.8+/-1.02 M: INT: 3.94+/-1.33 vs CON: 5.00+/-1.90 F: INT: 5.23+/-2.06 CON: 5.76+/-2.06 M: INT: 0.82+/-0.29 vs CON: 1.03+/-0.41 F: INT: 1.08+/-0.45 vs CON: 1.15+/-0.44 Secondary: No difference between groups for anthropometric or lipid variables.	S* between groups, S** between groups S* between groups S* between groups, S** between sexes S between groups, S* between sexes	None	There were no significant differences in anthropometric or lipid variables between groups in this subset of the STRIP trial. There were no significant differences in anthropometric or lipid variables between groups in this subset of the STRIP trial.	Q10.11.13. A low fat diet can be initiated and sustained in childhood. Seven years of biannual low fat and low sat fat diet counseling resulted in diminished intake of saturated fat and higher intake of polyunsaturated fat plus better insulin resistance assessed by HOMA-IR. There were no significant differences in anthropometric or lipid variables between groups in this subset of the STRIP trial.	

NHLBI Evidence Table: RF9-RCT

PMID	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p<0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question
16667815	Kaloupek T	Low-saturated fat dietary counseling starting in infancy improves insulin sensitivity in 9-year-old healthy children: the Special Turku Coronary Risk Factor Intervention Project for Children (STRIP) study	2006																									
16733670	Amaro S	Kaleido, a new educational board-game, gives nutritional rudiments and encourages healthy eating in children: a pilot cluster randomized trial	2006	RCT	None	Q10, 13 (RF8, RF9, RF11)	Italy	Community (schools)	None	24 wk	24 wk	Test the efficacy of the Kaleido board game on changes in nutrition knowledge and dietary behavior	291	Pediatric/ Young Adults	Exclusions: Metabolic disorders Mental diseases	Mean age (SD): Arm 1: 12.3 yr (0.8) Control Arm: 12.5 yr (0.7) Males: Arm 1: 78 Control Arm: 55 Caucasian: 100%	188 (153)	Behavioral	Arm 1: Kaleido game play session 15-30 min play sessions once a week with game components designed to provide nutrition knowledge and promote a healthy dietary behavior in children	103 (88)	Control Arm: No intervention 6 classrooms (5 classrooms)	Adj mean nutrition knowledge measure (95% CI) Adj mean BMI z-score (95% CI) Adj mean intake of vegetable [servings/wk (95% CI)] Adj mean physical activity level [hr/d (95% CI)]	INT: 11.24(10.68,11.80) vs CON: 9.24(8.50,9.98) No difference between groups after controlling for BL values. INT: 3.7(3.5,4.1) vs CON: 2.8(2.4,3.3) INT: 2.1(1.9,2.3) vs CON: 2.2(2.0,2.4)	S NS S*	None reported	A board game was effective in increasing nutrition knowledge and weekly vegetable intake in 11-14 y old adolescents.	Q10.13. A board game was effective in increasing nutrition knowledge and weekly vegetable intake in 11-14 y old adolescents.	
17093165	DeJongh ED	Fat mass gain is lower in calcium-supplemented than in unsupplemented preschool children with low dietary calcium intakes	2006	RCT	None	Q6 (RF2, RF8, RF9, RF11) Q10 (RF8, RF9, RF11)	USA	Clinical	Other	1 yr	1 yr	Determine whether an association exists between change in percentage BF or fat mass and calcium intake in children aged 3-5 yr	178	Pediatric/ Young Adults	3-5 yr	Mean age (SD): Boys: Arm 1: 3.9 yr (0.6) Control Arm: 3.9 yr (0.6) Girls: Arm 1: 4.0 yr (0.6) Control Arm: 3.9 yr (0.5) Boys: 93 Patient characteristics pertain only to the 178 children with complete data who were included in the final analysis	NR (88)	Dietary Supplements	Arm 1: Calcium + fine motor activities Fine motor activities were designed to keep children sitting quietly Arm 2: Calcium + gross motor activities Gross motor activities were designed to provide 5 min warm-up, 20 min jumping, hopping, and skipping, and 5 min cool-down Both arms received 2 tablets of TUMS containing 500 mg elemental calcium as calcium carbonate each, 1,000 mg/d calcium In both arms, children participated in physical activities 30 min/d, 5 d/wk	NR (88)	Control Arm 1: Placebo + fine motor activities Control Arm 2: Placebo + gross motor activities In both arms, children participated in physical activities 30 min/d, 5 d/wk	Primary: Mean dietary calcium [mg/d] LS mean change in percentage BF [% (SEM)] Secondary: Mean weight [kg] Mean change in total percentage BF [% (SD)] Mean change in total BF mass [kg (SD)] Mean change in total-body lean mass [kg] Mean dietary energy [kcal] MVPA [% of time]	Primary: M: INT: 1395+237/PLAC: 1028+277 F: INT: 1310+336/PLAC: 860+197 M: INT: 2.0+/-2.5 vs PLAC: -1.1+/-2.2 F: INT: -0.5+/-3.1 vs PLAC: -0.8+/-2.4 Secondary: No difference between INT & PLAC groups within gender for any of these measures.	S* between groups within gender NS between groups, S from BL in all	None reported	Weak benefit reported for children at the very lowest intakes at baseline but not statistically significant	In 3 to 5 y old children, added dietary calcium did not reduce gain in fat mass when baseline intake of calcium was adequate.	Q10.13. In 3 to 5 y old children, added dietary calcium did not reduce gain in fat mass when baseline intake of calcium was adequate.
17150115	Ask AS	Changes in dietary pattern in 15 year old adolescents following a 4 month dietary intervention with school breakfast - a pilot study	2006	RCT	None	Q10, 13 (RF8, RF9)	Norway	Community (schools)	None	4 mo	4 mo	Evaluate if dietary habits and school performance improved in a lower secondary school class as a result of introducing breakfast	54	Pediatric/ Young Adults	15 yr	Males: Arm 1: 15 Control Arm: 14	26 (NR)	Multiple Interventions	Arm 1: Free breakfast + food supplements + healthy diet information (INT) Students were offered a breakfast consisting of low fat milk, orange juice, whole grain bread, different spreads with fish, meat and cheese and a fruit. Food supplement were also offered consisting of vitamins, minerals and omega-3 fatty acids. Students were given information about the importance of a healthy diet	28 (NR)	Control Arm: Healthy diet information (CON) Students were given information about the importance of a healthy diet	Median BMI [kg/m2 (range)] Median weight [kg (range)] Healthy eating index Median food score (range)	M pre 22.8(17.8-33.6) 21.7(17.0-29.4) M post 21.8(17.6-33.8) 22.4(18.6-29.2) F pre 21.8(16.9-27.3) 21.8(16.7-28.4) F post 22.1(17.5-28.1) 22.1(16.9-28.7) M pre 73(55-109) 67(50-90) M post 73(57-111) 70(54-92) F pre 64(49-81) 59(45-77) F post 60(48-76) 61(48-80)	S from BL for CON; NS for INT S from BL for CON; NS for INT S from BL for INT; S** for CON NS from BL for INT; S** for CON S* for INT Ms only	None	Q10.13. Providing breakfast for 10th grade students resulted in no increase in BMI in INT group compared with a significant increase in CONs. INT Ms had an improvement in healthy eating score with no change in any other group. There was no change in school behavior.	Q10.13. Providing breakfast for 10th grade students resulted in no increase in BMI in INT group compared with a significant increase in CONs. INT Ms had an improvement in healthy eating score with no change in any other group. There was no change in school behavior.	
17288625	Mangunakumoro RT	School-based internet-tailored fruit and vegetable education combined with brief counseling increases children's awareness of intake levels	2007	RCT	None	Q10, 13 (RF9)	The Netherlands	Community (schools)	None	NR	3 mo	Apply internet-tailored advice for school children and internet-supported brief dietary counseling (with child and parent) to promote fruit/vegetable intake	486 (30 classes)	Parental/ Family/ Caregiver	7th grade	Mean age (SD): Arm 1: 10.3 yr (0.5) Control Arm: 10.3 yr (0.5) Boys: Arm 1: 45.6% Control Arm: 48.9% Dutch ethnicity: Arm 1: 88.6% Control Arm: 84.6% 2-parent family: Arm 1: 91.3% Control Arm: 95.9%	263 (263) 16 classes	Behavioral	Arm 1: Internet-tailored nutrition advice + dietary counselling (INT) Internet-tailored advice aimed to increase knowledge of recommended intake levels, increase awareness of personal intake levels, and stimulate children's liking of fruit/vegetables 2 wk after internet-tailored advice, child with 1 parent attended 5-min dietary counselling session, which occurred at the end of a routine periodic health examination	223 (223) 14 classes	Control Arm: Usual care (CON) Routine periodic health examination	Primary: Mean fruit frequency previous wk [servings/d (SD)] OR of usual daily fruit intake [% (95% CI)] Mean 24-hr recall vegetable intake [g (SD)] OR of usual daily vegetable intake [% (95% CI)] Secondary: Fruit/veg knowledge by questionnaire (%) Knowledge of recommended V intake [OR(CI)] Awareness of inadequate fruit intake in previous week (%) Daily fruit intake achievable(%) Liking many kinds of fruit(%) Fruit availability at home (%)	Primary: INT: 1.1(0.7) vs CON: 1.2(0.7) INT: 32% vs CON: 34.7; OR=0.82(0.45,1.49) INT: 76.9(68.7) vs CON: 74.9(69.7) INT: 28.1 vs CON: 28.7; OR=0.81(0.44,1.47) Secondary: INT: 57.1% vs CON: 50.7%; OR=1.30(1.75,5.26) OR=2.7(1.8,4.1) INT: 30.8% vs CON: 13.0; OR=3.04(1.75,5.26) INT: 78% vs CON: 79.5%; OR=0.83(0.52,1.31) INT: 73.4% vs CON: 76.7%; OR=0.73(0.38,1.39) INT: 74.5% vs CON: 77.6%; OR=0.89(0.53,1.51)	NS NS NS NS S S NS NS NS	None	An educational intervention with tailored internet feedback had significant effects on knowledge of recommended vegetable intake & awareness of inadequate fruit intake but no impact on actual F or V intake.	Q10.13. An educational intervention with tailored internet feedback had significant effects on knowledge of recommended vegetable intake & awareness of inadequate fruit intake but no impact on actual F or V intake.	
17299114	Fisher JO	Effects of age on children's intake of large and self-selected food portions	2007	RCT (crossover)	None	Q10, 13 (RF9)	USA	Clinical	None	20 min	2 wk Includes 2 1-wk washout periods	Evaluate the effects of age on intake of large and self-selected portions of food among children 2-9 yr of age	75	Pediatric/ Young Adults	In 1 of following age groups: 2-3 yr group: 2.6 yr (0.5) 3-4 yr group: 3.6 yr (0.5) 8-9 yr group: 8.7 yr (0.4) Non-Hispanic white Exclusions: Overweight: 20 Chronic medical condition or medication use affecting food intake Food allergies BMI-for-age < 5th percentile	75 (69)	Behavioral	Intervention: Large portion entrée Macaroni and cheese entrée portion was double the reference portion size Intervention 2: Self-selected portion entrée Macaroni and cheese entrée portion was double the reference portion size, but provided in an individual serving dish 20 min allotted for dinner; children instructed not to share food and to eat as little or as much as desired Each child in each of the 3 age groups was observed in the large portion condition, the self-selected portion condition, and the reference portion condition. Condition sequence was randomly assigned and spaced 1 wk apart	75 (69)	Control: Reference portion entrée Macaroni and cheese entrée portion initially determined by reviewing serving sizes used in previous studies. Serving sizes offered by age group. Pilot testing revealed the need to make upward adjustments to the amount specified for 8-9 yr old group 20 min allotted for dinner; children instructed not to share food and to eat as little or as much as desired	Mean entrée intake [kcal (SD)] during: Large portion condition Self-selected portion condition Reference portion condition Mean total energy intake [kcal (SD)] during: Large portion condition Self-selected portion condition Reference portion condition Mean intake of entrée relative to reference entrée [% (SE)] during: Large portion condition Self-selected portion condition Mean bite size [g/bite (SE)] Mean total number of bites [n (SE)]	2 - 3y: 145(113); 5 - 6y: 290(145); 8 - 9y: 407(258) 2 - 3y: 127(92); 5 - 6y: 241(156); 8 - 9y: 380(270) 2 - 3y: 133(82); 5 - 6y: 223(83); 8 - 9y: 381(173) Overall, entrée intake was 29% greater in large portion condition. 2 - 3y: 294(123); 5 - 6y: 562(179); 8 - 9y: 700(282) 2 - 3y: 280(134); 5 - 6y: 501(179); 8 - 9y: 641(286) 2 - 3y: 276(135); 5 - 6y: 480(128); 8 - 9y: 637(186) Overall, energy intake was 13% greater in large entrée condition. 2 - 3y: +29%(21); 5 - 6y: +43%(14); 8 - 9y: +18%(13) Decreased entrée intake and energy intake only among those with who ate more in large entrée condition. Increased in 67% of children in large size condition; bite size increased as portion size increased No change across conditions	NS between age groups. S** NS between age groups. S** S** S** NS	None	In this study of the effect of age on intake in 2-9 yr old children, there was no age effect but entrée consumption, bite size and energy consumption were all significantly increased in the large portion condition.	Q10.13. In this study of the effect of age on intake in 2-9 yr old children, there was no age effect but entrée consumption, bite size and energy consumption were all significantly increased in the large portion condition.		
17381944	Reinaerts E	Increasing children's fruit and vegetable consumption: distribution of a multicomponent programme?	2007	RCT	None	Q5 (RF9) Q10, 13 (RF9)	The Netherlands	Community (schools)	None	9 mo	9 mo	Measure the effects of 2 school-based interventions on children's intake of fruit and vegetables	1,730 (parents (939 parents) schools (NR))	Parental/ Family/ Caregiver	Primary school children	Mean age (SD): 9.0 yr (2.3) Boys: 48.5%	1,730 parents (939 parents) 6 schools (NR)	Behavioral	Arm 1: Free fruit and vegetable distribution at school (Free) Every school day, all children were provided with 1 serving of fruit (2x/wk), fruit juice (1x/wk) or raw vegetables (2x/wk) Arm 2: Multicomponent school-based program consisting of a classroom curriculum and parental involvement (MC) Children received a lunchbox that was especially designed to bring fruit and vegetables to school Classroom activities were developed with school teachers and adapted to the children's age Recurrent newsletters and homework activities were taken home by children to motivate parents to create a home environment that facilitates fruit and vegetable consumption; environmental efforts (e.g., displaying posters with project mascots at local supermarkets) were also used to remind parents to buy fruit and vegetables	N/A	1,168 children from 6 other schools were used as a reference group (CON)	Mean fruit consumption [portions/d (SD)] Mean vegetable consumption [g/d (SD)] Mean vegetable snacks [times/d (SD)] Mean 24-hr fruit, juice and vegetable intake [times/d (SD)]	Free: 1.3(0.9) to 1.6(0.9) vs CON: 1.2(0.7) to 1.2(0.7) MC: 1.3(0.9) to 1.5(0.8) vs CON: 1.2(0.7) to 1.2(0.7) Free group for older children and non-natives increased veg consumption; MC increased intake in oldest children and girls. Older group increased snack intake - no change for other groups. MC increased F,V in native & non-native children in all age groups; children F free increased intake among youngest & oldest groups.	S** S** S S S S	None	Both a free F & V program and a multi-component intervention increased fruit intake in middle school children. In subsets, the interventions were variably effective in increasing veg intake and overall, fruit+juice+ vegetable intake over 24 hrs.	Q10.13. Both a free F & V program and a multi-component intervention increased fruit intake in middle school children. In subsets, the interventions were variably effective in increasing veg intake and overall, fruit+juice+ vegetable intake over 24 hrs.	

NHLBI Evidence Table: RF9-RCT

PMID	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Final Follow-up)	Int Type	Specific Intervention	Control n at Baseline (n at Final Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance S (p<0.05 or non-overlapping CI); S* (p<0.01); S** (p<0.001); NS (p≥0.05 or overlapping CI)	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question	
1741463	Haerens L	The effects of a middle-school healthy eating intervention on adolescents' fat and fruit intake and soft drinks consumption	2007	RCT	None	Q13 (RF9)	Belgium	Community (schools)	None	9 mo	9 mo	Evaluate the effects of a middle-school healthy eating promotion intervention combining environmental changes and computer-tailored feedback, with and without an explicit parent involvement component	2,840 (15 schools)	Parental/Family/Caregiver	11-15 yr Students in schools offering technical or vocational training	Mean age (SD): 13.1 yr (0.81) Boys: 63.4% Lower SES: 67.5%	10 schools (NR)	Behavioral	Arm 1: Healthy eating intervention with parental support (INT +) Goals of healthy eating intervention included increasing fruit consumption to at least 2 pieces/d, reducing soft drink consumption and increasing water consumption, and reducing fat intake Computer-tailored intervention for fat and fruit intake which provided students with tailored fat and fruit intake advice Environmental strategies and policy changes to help increase the availability of healthy food products (e.g. selling low-cost fruit on-site at school); teachers and schools were also encouraged to organize additional supportive Parents were invited to an interactive meeting and completed an adult computer-tailored intervention; parents were asked to discuss the dietary advice from the computer intervention with children and to support their children in making dietary changes	5 schools (NR) Control Arm: Control condition (CON) No details provided regarding Control Arm	Mean fat intake [g/d] (SD) Mean fat intake [kcal (SD)] Mean percentage exceeding fat intake recommendations [% (SD)] Mean fruit intake [pieces/wk (SD)] Mean percentage not meeting fruit intake recommendations [% (SD)] Soft drinks [glasses/d(SD)] Water [glasses/d(SD)]	INT +: 111(48) to 105(49); INT: 130(54) to 127(56); CON: 108(46) to 104(45) INT +: 38.7(16.3) to 35.1(16.1); INT: 43.7(18.1) to 40.2(17.8); CON: 39.4(16.2) to 36.7(15.7) No significant intervention effects on any of these outcomes.	INT +: S** for girls only INT +: S** for girls only NS	None	None	Computer-tailored feedback plus healthy diet education and increased fruit availability led to a decrease in fat intake in adolescent girls who also had parents involved in the intervention but no change in males and no effect on fruit intake or soft drink consumption.	Q10,13. Computer-tailored feedback plus healthy diet education and increased fruit availability led to a decrease in fat intake in adolescent girls who also had parents involved in the intervention but no change in males and no effect on fruit intake or soft drink consumption.		
1741463	Haerens L	The effects of a middle-school healthy eating intervention on adolescents' fat and fruit intake and soft drinks consumption	2007																										
17451613	Henry CJK	Effects of long-term intervention with low- and high-glycaemic-index breakfasts on food intake in children aged 8-11 years	2007	RCT (crossover)	None	Q10,13 (RF8, RF9)	United Kingdom	Community (schools)	None	10 wk	41 wk Includes 1 wk run-in period, each intervention period of 10 wk was staggered (i.e., groups did not receive concurrent intervention) for a total of 40 wk of intervention	Investigate the effects of long-term intervention of low-glycaemic index (GI) vs. high-GI breakfasts on energy and macronutrient intakes in children	38	Pediatric/Young Adults	8-11 yr Boys: 11	38 (29)	Behavioral	Intervention 1: High-GI breakfast High-GI breakfast included cereal with whole milk or bread with low-fat spread and jam, low-sugar fruit squash, and 1 teaspoon of glucose powder Intervention 2: Low-GI breakfast Low-GI breakfast included cereal with whole milk, porridge, or soya and linseed bread with low-fat spread and reduced sugar jam, and unsweetened fruit juice Children in each group consumed the breakfast for 2 non-consecutive days each wk for 10 wk	N/A	N/A	Mean body weight change over study period [kg (SD)] Mean energy intake at lunch following test breakfasts [kcal (SD)] Mean energy intake over 24 hr of study days [kcal (SD)] Mean protein intake at lunch following test breakfasts [g (SD)] Mean CHO intake at lunch following test breakfasts [g (SD)] Mean fat intake at lunch following test breakfasts [g (SD)] Mean fiber intake at lunch following test breakfasts [g (SD)] Mean protein intake over 24 hr of study days [g (SD)] Mean CHO intake over 24 hr of study days [g (SD)] Mean fat intake over 24 hr of study days [g (SD)] Mean fiber intake over 24 hr of study days [g (SD)]	After Low GI days: 0.6(0.9) vs After HighGI days: 1.8(0.6) LowGI:3057(875) vs HighGI:3132(829) LowGI: 2030(370) vs HighGI: 2091(334) No difference in any of these variables relative to GI breakfast.	S** NS (p=0.406) NS	None	Children increased body weight significantly more during high GI period compared with low GI period.	A long term intervention with low- and high-GI breakfasts had no effect on subsequent calorie intake over the next 24 hrs in 8-11 y old children. However, children increased body weight significantly more during high GI period compared with low GI period.	Q10,13. A long term intervention with low- and high-GI breakfasts had no effect on subsequent calorie intake over the next 24 hrs in 8-11 y old children. However, children increased body weight significantly more during high GI period compared with low GI period.		
17451613	Henry CJ	Effects of long-term intervention with low- and high-glycaemic-index breakfasts on food intake in children aged 8-11 years	2007																										
17473086	Ebbeling CB	Altering portion sizes and eating rate to attenuate gorging during a fast food meal: effects on energy intake	2007	RCT (crossover)	None	RF13 (RF9, RF11)	USA	Community (other)	Other	1 d	9 d Includes 3 1-d food tests and 2 follow-up d after each food test	Evaluate whether altering portion sizes and eating rate could decrease energy intake during an extra-large fast food meal	20	Pediatric/Young Adults	13-17 yr BMI > 80 th percentile Reported eating fast food ≥ 1x/wk Exclusions: Smoking ≥ 1 cigarette in the past wk Taking any prescription medication that may affect food intake	Mean age (SEM): 15.3 yr (0.3) 20 (18) Males: 4 Hispanic or Latino: 1 White: 3 Black: 11 Race not reported: 3 Patient characteristics available only for participants who completed the study	20 (18)	Behavioral	Intervention 1: Fast food meal presented as 1 large serving at a single time point Intervention 2: Fast food meal portioned into 4 smaller servings presented at a single time point Intervention 3: Fast food meal portioned into 4 smaller servings presented at 15-min intervals In all 3 conditions, meal consisted of chicken nuggets, French fries, and cola plus condiments; total amount of each item other than condiments was equal to approximately 125% of the amount consumed during a baseline meal assessment	N/A	N/A	Mean energy intake [kJ (SEM)] Mean energy intake relative to total daily energy expenditure(% (SEM))	STD: 555(357) vs SmServDelay: 5762(500) vs SmServ: 532(433) STD:51.9(3.5) vs SmServDelay: 53.0(4.3) vs SmServ: 48.2(4.0)	NS NS	None	Portioning menu items and slowing the eating rate had no effect on energy intake during a fast food meal in adolescents.	RF13: Portioning menu items and slowing the eating rate had no effect on energy intake during a fast food meal in adolescents.		