NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
2232019	Epstein LH	Ten-year follow-up of behavioral, family-based treatment for obese children	1990	RCT	None	Q10 (RF8) Q11 (RF8) Q13 (RF8)	USA	Mult settings	None/NR	8 mo	10 yr	Examine the effects of behavioral family-based treatment on percent overweight and growth over 10 yr in obese children	76 or 75	Parental/ Family/ Caregiver	6-12 yr Obese > 20% above ideal weight for age, sex, and height Triceps skinfold > 95th percentile for age ≥ 1 obese parent Both parents living at home	Mean age (SD): Arm 1: 9.4 yr (1.8) Arm 2: 10.4 yr (1.2) Males: Arm 1: 6 Arm 2: 7 Mean % Overweight: Arm 1: 41.7 (16.3) Arm 2 43.5 (16.1) Mean wt (kg): Arm 1: 47.2 (12.7) Arm 2: 54.9 (12.6) Mean family SES (SD): Arm 1: 49.3 (13.1) Arm 2: 48.1 (9.6) White: 53 (of 55) families Parents with college degrees: Fathers: 44% Mothers: 33%	Arm 1: NR (20) Arm 2: NR (16)	Behavioral	Arm 1: Child and parent targeted behavioral intervention (P+C) 8 weekly treatment meetings and 6 additional meetings over following 6 mo Reinforcement of parent and child behavior change and weight loss Traffic Light Diet with 1,200-1,500 calorie limit Instructed to begin aerobic exercise program Variety of behavioral procedures were also used including contracting and self-monitoring Arm 2: Child targeted behavioral intervention (C alone) Reinforcement of child behavior change and weight loss	NR (19)	Mean age: 9.9 yr (2.3) Males: 6 Mean % Overweight: 46.2 (15.4) Mean wt (kg) 53.2 (13.7) Mean family SES (SD): 44.9 (11.8)	**Primary:** Mean percent overweight [%] Change in percent overweight between baseline and over 10 years (%) Mean wt (kg) Mean weight gain between baseline and 10 years (kg):	**Primary:** P+C: 41.7+16.3 to 22% at 6m, 31% at 5y, 32% at 10y C alone: 43.5±16.1 to 6% at 6m, 41% at 5y 45% at 10y CON: 46.2±15.4 to 27% at 6m, 55% at 5y, 63% at 10y. (% overweight estimated from graph) P+C: -7.5%;C Alone: 4.5%; CON:+ 14.3% (% change estimated from graph) P+C: 47.2+/-12.7 to 72 at 5y, 85 at 10y . C alone: 54.9+/-12.6 to 83 at 5y, 95 at 10y CON: 46.2 +/-15.4 to 83 at 5y and 100 at 10y; (Results estimated from graph) P+C: 34.0: Arm 2: C Alone: 43.1 CON: 46.6 (Results estimated from graph)	**S at 5 yr and at 10 yr between P+C (group 1) and both C Alone (group 2) and CON.** **S between P+C and both Calone and CON.** **S at 5 yr and at 10 yr between P+C (group 1) and both C Alone (group 2) & CON.** **S between P+C (group 1) and both C Alone (group 2) and CON.**	One child who did not complete the initial 8 wk training period developed an eating disorder. At 10y F/U , 6/61 children from the original group of 75 had developed significant psychiatric problems.	No significant changes in % overweight for participating parents.	In obese children, a family-based treatment program can result in long term weight regulation when initiated at 6-12y of age. Children in the child plus parent group showed significantly greater decreases in percent overweight after 5 and 10 years than children in a non-specific control group; children in a child alone group showed increases in percent overweight that were in between the other two groups, though not significantly different from either group.	Q10,13. In obese children, a family-based treatment program can result in long term weight regulation when initiated at 6-12y of age. Q11. Weight control can be sustained in a family-based program targeting and reinforcing parents and children.
2232019	Epstein LH	Ten-year follow-up of behavioral, family-based treatment for obese children	1990													Patient characteristics only pertain to 55 families with data at 10 yr follow-up			Same meeting schedule, diet, exercise and behavioral information as in Arm 1								
2826563	Gropper SS	The therapeutic effect of fiber in treating obesity	1987	RCT (crossover)	None	Q10 (RF8) Q13 (RF9)	USA	Clinical	Double	4 wk	8 wk	Examine the influence of ingestion of 15 g of dietary fiber daily for 4 wk on weight change and serum iron concentrations in obese children	8	Pediatric/ Young Adults	Obese (≥ 120% of ideal body weight)	Age: Boys: 9-12 yr Girls: 6-10 yr Boys: 3 White: 7 Black: 1	8 (8)	Dietary Supplements	Intervention: Fiber supplement + diet Fiber supplement tid for 4 wk Supplement consisted of 5 g dietary fiber, 60 kcal, 1 g protein, 14 g CHO, 2 g fat Prescribed diet of 500 kcal less than diet intake assessed 1 wk prior to study	8 (8)	Control: Placebo + diet Placebo supplement tid for 4 wk Placebo supplied 100 kcal and no fiber Prescribed diet of 500 kcal less than diet intake assessed 1 wk prior to study	**Primary:** Mean weight loss [g] **Secondary:** Mean energy intake [kcal (SD)] Mean crude fiber intake [g (SD)] Mean iron intake [mg (SD)]	**Primary:** FIBER: 336 vs CON: 33 **Secondary:** FIBER: 1644+/-287 vs CON: 1590+/-196 FIBER: 3.5+/-2.6 vs CON: 3.2+/-1.7 FIBER:10.5+/-2.7 vs CON:15.5 +?_5.2	**NS** **NS** **NS** **NS**	None	Very small study. Although failure to consume fiber supplements is mentioned, this is not documented. Mean wt loss given but SD not provided.	Fiber supplements were not associated with improved wt loss in obese children.	Q10,13. Fiber supplements did not result in improved weight loss in obese children.
2929526	Epstein LH	The effect of weight control on lipid changes in obese children	1989	RCT	None	Q6 (RF5, RF8, RF11) Q10 (RF8) Q13 (RF5, RF11)	USA	Clinical	None/NR	6 mo	5 yr	Study the effects of weight change on serum lipid changes in obese children	56	Parental/Family/Caregiver	8-12 yr At least 1 child and 1 natural parent > 20% over ideal weight for age, sex, and height Child's triceps skinfolds > 95th percentile for age and sex	Mean age (SD): Arm 1 and Arm 2: 10.5 yr (1.3) Control Arm: 10.3 yr (1.2)	37 (28) Arm 1: 18 (NR) Arm 2: 19 (NR)	Behavioral	Arm 1: Diet Arm 2: Diet + lifestyle and exercise Diet for children in both study arms set between 3,800 and 5,000 kJ/d and monitored by a nutritionist to maintain nutrient adequacy Information on diet, exercise, stimulus control, reinforcement, modeling, and contingency contracting presented to parents and children in 8 weekly sessions, followed by 4 monthly sessions	19 (16)	Control Arm: No treatment (waiting list) Final follow-up occurred at 6 mo for the Control Arm; children in the Control Arm were provided treatment after 6 mo	**Primary:** Mean percent overweight (SD) Weight change [kg(SD)] Mean serum cholesterol [mmol/L (SD)] Mean serum HDL-C [mmol/L (SD)] Mean serum TG [mmol/L (SD)] Mean fitness [percentile (SD)]	**Primary: [6mos]** INT: - 17.4(10) vs CON: -0.8(8.7) INT: - 3.6(4.0) vs CON: +5.2 (3.0) INT: -0.27(0.47) vs CON: +0.09(0.50) INT: +0.20(0.16) vs CON:+0.06(0.13) INT: -0.55(0.53) vs CON:-0.12(0.30) INT: +33.1(29.0) vs CON: +3.4(25.1)	**S**** **S**** **S** **S*** **S*** **S****	None	At 5 y F/U, results not as good but trends continued.	A diet and exercise program in 10 y old children resulted in significant weight loss and improvement in serum lipids at 6 mos. A sub-set at 5 years showed no change in % overweight and HDL significantly above baseline.	Q6. Obesity and lipid abnormalities are associated in childhood. Q10,11,13. A diet and exercise program in 10 y old children resulted in significant weight loss and improvement in serum lipids at 6 mos. A sub-set at 5 years showed no change in % overweight and HDL significantly above baseline.
3288957	Rocchini AP	Blood pressure in obese adolescents: effect of weight loss	1988	RCT	None	Q6 (RF4, RF8, RF11) Q10 (RF4, RF8, RF11) Q13 (RF11)	USA	Clinical	None/NR	20 wk	20 wk	Determine effect of weight loss on blood pressure in obese children	73	Pediatric/Young Adults	Obese Weight/height > 75th percentile for age and sex; triceps and subscapular skin folds > 80th percentile for age and sex	Mean age (SD): 12.6 yr (3.0) Boys: 34	51 (45) Arm 1: 26 (22) Arm 2: 25 (23)	Multiple Interventions	Arm 1: Diet + behavior change Caloric exchange program designed to produce weight loss of approximately 2.2 kg (~1 lb)/wk Behavior change composed of a 1-hr class/wk consisting of record keeping, stimulus control, changing eating behavior, reinforcement of altered behavior Arm 2: Diet + behavior change + exercise In addition to diet and behavior change, exercise component consisted of 3 1-hr exercise sessions per wk Aerobic activities used for total body activities designed to maintain heart rate for at least 40 min at greater than 70% to 75% maximal exercise HR	22 (18)	Control Arm: No weight-loss program 10 non-obese adolescents served as a reference group	**Primary:** Mean SBP [mmHg (SD)] Mean DBP [mmHg (SD)] Mean weight [kg (SD)] Mean body fat [% (SD)] Forearm blood flow at rest [mmHg/mL/min (SD)] Foream resistance post ischemia [mmHg/mL/min/100mL of forearm volume(SD)] Mean submaximal HR [beats/min (SD)]	**Primary: B/L POST** DIET: 127(14) 117(8) EX: 129(9) 113(6) CON: 126(13) 139(14) DIET: 80(11) 68(9) EX: 79(11) 66(7) CON: 78(10) 77(15) DIET: 73(14) 70.5(15) EX: 72(12) 69.6(11) CON: 73(14) 77(16) DIET: 43(8) 39(8) EX: 41(6) 35(4) CON: 41(6) 42(8) DIET: 13.4(8) 11.2(15) EX: 12.9(8) 9.2(10) CON: 13.7(7) 13.1(9) DIET: 3.0(1.7) 2.2(1.3) EX: 2.9(1.5) 1.5(0.6) CON: 2.6(1.0) 2.6(1.4) DIET: 144(21) 140(21) EX: 138(13) 125(11) CON: 2.6(1.0) 2.6(1.4)	**S from B/L; S vs CON** **S from B/L; S vs DIET & CON** **NS from B/L** **S from B/L; S vs CON** **S from B/L; S vs CON** **NS from B/L** **S from B/L; S vs CON** **S from B/L; S vs CON** **NS from B/L** **S from B/L; S vs CON** **S from B/L; S vs CON** **NS from B/L** **NS from B/L; NS between groups** **S from B/L; S vs DIET** **N/S from B/L** **S from B/L** **S from B/L; S vs Diet** **NS from B/L** **NS from B/L** **S from B/L** **NS from B/L**	Not addressed	Obese adolescents had significantly higher SBP, DBP and HR (all,p<S*) when compared with lean subjects. The z score BP distribution for the obese subjects was significantly skewed to the right when compared with the normal BP distributions for age and sex(p=S*).	In obese adolescents, exercise and diet and diet alone were both associated with significant weight loss compared with no intervention but the exercise group also had significant decreases in BP and vascular resistance.	Q10,13 In obese adolescents, exercise and diet and diet alone were both associated with significant weight loss compared with no intervention but the exercise group also had significant decreases in BP and vascular resistance.
3288957	Rocchini AP	Blood pressure in obese adolescents: effect of weight loss	1988																			Mean submaximal oxygen consumption [mL/min (SD)]	DIET: 1226(189) 1200(156) EX: 1349(302) 1109(216) CON: 1225(222) 1277(252)	**NS from B/L** **S from B/L; S vs DIET** **NS from B/L**				
3305355	Rocchini AP	Insulin and blood pressure during weight loss in obese adolescents	1987	RCT	None	Q6 (RF4, RF8, RF14) Q10 (RF8) Q13 (RF 8,4,14)	USA	Clinical	None/NR	20 wk	20 wk	Evaluate the role of insulin in the regulation of blood pressure in obese adolescents before and after a 20-wk weight loss program	50	Pediatric/ Young Adults	Adolescents Obese (weight for height > 75th percentile for age and sex and triceps and subscapular skinfolds > 80th percentile for age and sex)	Mean age (range): 12.4 yr (10-16 yr)	Arm 1: 15 (15) Arm 2: 18 (18)	Behavioral	Arm 1: Weight-loss program consisting of diet and behavior change Diet was a modification of the caloric exchange program and was designed to produce a weight loss of approximately 1 lb (0.45 kg)/wk Behavior change consisted of 1-hr class each wk for 20 wks focused on record keeping, stimulus control, changing eating typography, and reinforcement of altered behavior Arm 2: Weight-loss program consisting of diet, behavior change and exercise Diet and behavior change elements were the same as in Arm 1 Exercise program consisted of 3 1-hr exercise classes/wk for 20 wks that centered around total body activities designed to maintain HR for ≥ 40 min at > 70-75% of maximal exercise HR	17 (17) obese PLUS 10 (10) non-obese	No weight loss program 10 nonobese adolescents served as a reference group Age (range): 12.2 yr (10-14 yr)	**Primary:** Mean weight [kg (SD)] Mean percentage of fat [% (SD)] Mean SBP [mmHg (SD)] Mean DBP [mmHg (SD)] Mean fasting insulin [µU/mL (SD)] Mean fasting glucose [mg/dL (SD)]	**Primary:** D + E: 71.2 +/- 12 to 68.4 +/- 10 D alone: 72 +/-14 to 69.1 +/- 14 CON: 72.6 +/- 14 to 76.4 +/- 15 D + E: 40 +/- 5 to 34 +/- 4 D alone: 42 +/- 6 to 39 +/- 6 CON: 40 +/- 6 to 41 +/- 7 D + E: 128 +/-8 to 114 +/- 7 D alone: 125 +/- 15 to 115 +/- 7 CON: 126 +/- 13 to 131 +/- 16 D + E: 78 +/- 10 to 69 +/- 6 D alone: 79 +/- 12 to 69+/- 9 CON: 73 +/- 12 to 77 +/- 14 D + E: 22 +/- 11 to 15 +/- 16 D alone: 25 +/- 12 to 20 +/- 8 CON: 25 +/- 10 to 31 +/- 11. No change in any group	**S compared with B/L & CON** **S compared with B/L & CON** **S compared with B/L** **S compared with B/L,CON & D alone** **S compared with B/L & CON.** **NS compared with B/L** **S compared with B/L & CON** **S compared with B/L & CON** **NS compared with B/L** **S compared with B/L & CON** **S compared with B/L & CON** **NS compared with B/L** **S compared with B/L & CON** **S compared with B/L & CON** **NS compared with B/L** **All, NS.**	None reported.		In obese adolescents, weight loss resulted in normalization of BP and reduction in fasting INS.	Q6 Obesity is associated with hypertension and hyperinsulinemia in obese adolescents. Q10. In obese adolescents, weight loss resulted in normalization of BP and reduction in fasting INS.

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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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
3357722	Becque MD	Coronary risk incidence of obese adolescents: reduction by exercise plus diet intervention	1988	RCT	None	Q6 (RF4, RF5, RF8, RF11) Q10 (RF8,RF5,RF4,RF11)	USA	Clinical	None/NR	20 wk	20 wk	Examine the incidence of coronary heart disease risk factors and effects of 20 wk of diet and exercise in obese adolescents	36	Pediatric/ Young Adults	Body weight > 75th percentile for age and sex Triceps skinfold > 75th percentile for age and sex	Mean age (SEM): Boys: 12.7 yr (0.5) Girls: 12.8 yr (0.3) Boys: 15 Family history (father, mother, grandparents, siblings) of coronary heart disease (myocardial infarctions, angina pectoris) and/or high BP (SBP > 150; DBP > 90 mmHg): 61%	Arm 1: 11 (11) Arm 2: 11 (11)	Behavioral	Arm 1: Diet + behavior change (D + B) Arm 2: Diet + behavior change + exercise(Ex,D + B) Exercise program was conducted 3 times/wk for 50 min each and included activities such as walking, jogging, and swimming. The duration of aerobic exercise for the first 2 wk was 15 min and increased by 5 min each wk until 40 min per session was reached by wk 7 and 8 Subjects met with a dietician and behavior therapist once a wk for 1 hr Behavior program components included record keeping and self-monitoring Caloric intake set to elicit loss of 0.45 to 0.90 kg (1 to 2 lb) per wk based on the American Dietetic Association exchange program	14 (14)	Control Arm: No diet, exercise, or behavior change (CON) Adolescents were encouraged not to change their basic lifestyle	**Primary:** Mean body weight [kg (SEM)] Mean fat [% (SEM)] Mean TG [mg/dL (SEM)] Mean HDL-C [mg/dL (SEM)] Mean TC [mg/dL (SEM)] Mean SBP [z score (SEM)] Mean DBP [z score (SEM)] Reduction in number of risk factors--Total risk reduction [%]	**Primary:** Ex,D + B: 67.9+/- 2.8 to 66.3+/- 3.0 vs D + B: 77.2+/- 6.6 to 76.8+/- 6.6 vs CON: 68.7+/- 4.5 to 71.9 +/- 4.8 Ex,D + B: 38.3+/-1.2 to 35.3 +/- 1.6 vs D + B: 44.0 +/- 2.3 to 40.5 +/-1.9 vs CON: 39.8 +/- 1.8 to 40.5 +/-2.0 Ex,D + B: 135.8 +/- 16.5 to 91.6 +/-18.4 vs D + B: 117.3 +/- 13.9 to 99.9 +/- 17.4 vs CON: 117.8 +/-15.8 to 122.2 +/- 13.6 Ex,D + B: 35.3 +/- 2.3 to 43.4 +/- 2.2 vs D + B: 34.5 +/- 2.7 to 38.4 +/- 3.0 vs CON: 29.5 +/- 1.6 to 32.0 +/- 1.5 Ex,D + B: 170.6 +/- 10.2 to 149.3 +/- 9.2 vs D + B: 181.2 +/- 12.3 to 171.9 +/- 11.4 vs CON: 176.9 +/- 10.7 to 167.1 +/- 9.0 Ex,D + B: 1.3 +/- 0.1 to -0.1 +/- 0.2 vs D + B: 1.6 +/- 0.4 to 0.5 +/- 0.4 vs CON: 1.1 +/- 0.3 to 1.4 +/- 0.3 Ex,D + B: 0.6 +/- 0.3 to -0.5 +/- 0.2 vs D + B: 1.3 +/- 0.5 to 0.5 +/- 0.4 vs CON: 0.4 +/- 0.3 to 0.8 +/- 0.4 Ex,D + B = 41.4% vs D + B: 14.8% vs CON: 10.3%	**NS within & between groups** **NS within & between groups** **NS within & between groups** **S within D+E+B group (pre vs. post); S between groups post-INT (D+E+B vs Cont and vs D+B).** **NS within & between groups** **S within D+E+B group (pre vs. post); S between D+E+B & CON** **S within D+E+B and D+B groups, pre vs. post), NS for CON; S between groups(D+E+B vs CON & vs D+B).** **S* between groups**	None	None	A supervised diet, exercise & behavior change program in obese adolescents resulted in significant reduction in C-V risk with minimal weight change.	Q10. C-V risk factors can be significantly reduced with a diet, exercise and behavior program in obese adolescents. Q6. C-V risk factors are strongly related to obesity.
3819254	Mellin LM	Adolescent obesity intervention: validation of the SHAPEDOWN program	1987	RCT	None	Q10 (RF8) Q11 (RF8) Q13 (RF8)	USA	Clinical	None/NR	3 mo	15 mo	Evaluate the effectiveness of the adolescent obesity intervention program SHAPEDOWN	66	Parental/ Family/ Caregiver	Obese adolescents Recruitment sites: Rural health department: 1 Rural nutrition private practice: 1 Suburban medical clinic: 1 Urban medical center outpatient clinic: 1	Mean age: Arm 1: 15.6 yr Control Arm: 15.6 yr Boys: Arm 1: 7 Control Arm: 7	37 (34)	Behavioral	Arm 1: SHAPEDOWN group weight management program Group weight management program was conducted by a leader for 14 weekly, 90-min sessions for test group subjects Each session included voluntary weigh-in, leader-facilitated group interaction, and an exercise period	29 (29)	Control Arm: No SHAPEDOWN program	**Primary:** Mean relative weight at 3 mo [% (SD)] Mean relative weight at 15 mo [% (SD)] Mean weight change [kg] at 3 mo Mean weight change [kg] at 15 mo	**Primary:** INT: - 5.9(6.75) vs CON:- 0.3(6.61) INT: -9.9(14.98) vs CON: - 0.1(13.20) INT: -3.11 vs CON: +0.13 INT: -3.88 vs CON:+1.27	**S**** **S*** **Not reported** **Not reported**	None	Self esteem improved in both groups but depression only decreased in INT.	A combined diet and exercise program resulted in significant weight loss in teenagers.	Q 10,13. Shapedown, a combined diet and exercise program in obese teenagers improved relative weight, self esteem and depression.
4032130	Epstein LH	Effect of diet and controlled exercise on weight loss in obese children	1985	RCT	None	Q10 (RF8) Q13 (RF11)	USA	Mult settings	None/NR	1 yr	1 yr	Study the effects of adding exercise to diet for weight control in obese children	23 (22 families)	Parental/ Family/ Caregiver	Girls 8-12 yr ≥ 20% over ideal weight for height and age No medical problems that would contraindicate weight loss, exercise, or fitness testing	--	NR (10)	Behavioral	Arm 1: Diet + exercise 8 wk treatment program followed by 10 monthly maintenance sessions Children exercised 3 times/wk during initial 6 wk of treatment Children and parents participated jointly in exercise program after each monthly maintenance treatment session Participants adhered to the Traffic Light Diet Behavioral methods to promote eating and exercise habit changes included self-monitoring, praise and modeling, therapist contact, measurement and contracting	NR (9)	Control Arm: Diet 8 wk treatment program followed by 10 monthly maintenance sessions Participants adhered to the Traffic Light Diet Behavioral methods to promote eating and exercise habit changes included self-monitoring, praise and modeling, therapist contact, measurement and contracting	**Primary:** Mean weight [kg (SD)] Mean percent overweight [% (SD)] **Secondary:** Mean PWC [kpm/kg (SD)]	**Primary:** **B/L 6m 12m** **D + E:** 53.77(19.6) 46.95(17.0) 49.91(19.1) **D:** 53.95(17.5) 50.14(19.4) 52.59(19.0) **D + E:** 48.0(23.2) 20.5(22.6) 22.6(29.3) **D:** 48.1(17.6) 29.3(22.3) 29.4(22.5) **Secondary:** **D + E:** 6.6(1.0) 7.9(0.7) 9.1(1.5) **D:** 6.5(1.4) 6.9(1.2) 7.6(1.9)	**S* at 6m & 12 m; S vs D alone at 6 m** **S* at 6 m.** **S* at 6m & 12 m; S vs D alone at 6 m** **S* at 6m & 12 m** **S at 6m, S* at 12m; S* vs D alone at 12m**	No difference in height between groups		In obese girls, adding supervised exercise to diet resulted in significantly greater decrease in weight and % overweight than diet alone at 6 and 12 m follow-up. Exercise was associated with improved fitness.	Q10,13.In obese girls, adding supervised exercise to diet resulted in significantly greater decrease in weight and % overweight than diet alone at 6 and 12 m follow-up. Exercise was associated with improved fitness.
7789345	Epstein LH	Effects of decreasing sedentary behavior and increasing activity on weight change in obese children	1995	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	USA	Clinical	None/NR	6 mo	1 yr	Test the influence of reinforcing children to be more active or less sedentary on child weight change	61 families	Parental/ Family/ Caregiver	8-12 yr 20%-100% overweight Exclusions: Medical conditions preventing exercise	Mean age: 10.1 yr Male: 27% White: 96% Mean Hollingshead SES 4-factor index (SD): 48.7 (10.5); equivalent to medium business, minor professional, and technical professions	61 families (55 families)	Behavioral	Arm 1: Decreased sedentary activity + diet (SED) Reinforced a decrease in sedentary activities that were not academically related Arm 2: Increased physical activity + diet (EX) Reinforced an increase in physical activity that was not already sanctioned during the school day Arm 3: Decreased sedentary activity + increased physical activity + diet (COMB) Traffic Light Diet was used to decrease energy intake and promote a balanced diet All parents and children attended concurrent and separate weekly treatment meetings for 4 mo, followed by 2 monthly meetings Meetings consisted of individualized counseling, monitoring, and goal-setting	N/A	N/A	**Primary:** Mean change in percent overweight Mean change in percent BF Mean fitness [watts] Mean change in preference for high-intensity activities	**Primary: [1yr]** SED: -20% vs EX:- 14% vs COMB: - 17% SED: - 5% vs EX: -3% vs COMB: - 4.5% 59.5 watts to 63.3 watts for all 3 groups combined All groups increased from baseline, highest significance for SED group	**S between groups** **S between groups** **S* from baseline - no difference between groups** **S for combined groups, S* for SED group**	None		A weight loss program that compared reduction in sedentary activity to increased activity and to a combination showed the greatest weight loss in the sedentary change group. Being aware of the harm that sedentary activity brings is important in a weight reduction program and is at least (perhaps more) important than increasing activity alone.	Q10,13. A weight loss program that compared reduction in sedentary activity to increased activity and to a combination showed the greatest weight loss in the sedentary change group.
7805631	Epstein LH	Ten-year outcomes of behavioral family-based treatment for childhood obesity	1994	RCT	None	Q10 (RF8) Q11 (RF8) Q13(RF8)	USA	Mult settings	None/NR	6-12 mo	10 yr	Present 10-yr outcomes for obese children treated in four RCTs	185 families	Parental/Family/Caregiver	6-12 yr 20%-100% overweight for age, sex, and height For studies 2 and 4, families could not have medical problem that limited exercise For all studies except Study 3, ≥ 1 obese parent	Mean age (SD): 10.4 yr (1.6) Boys: 42 Mean family SES (SD): 45.2 (12.0) (middle-class Social Strata IV)	NR (NR)	Behavioral	Study 1: Arm 1: Parent + child targeted for weight loss Arm 2: Child targeted for weight loss Study 2: Arm 1: Diet + lifestyle exercise Arm 2: Diet + information Study 3: Arm 1: Weight loss targeted at children with ≥ 1 obese parent Study 4: Arm 1: Diet + aerobic exercise Arm 2: Diet + lifestyle exercise Basic treatment for all groups included weekly treatment meetings for 8-12 wk and monthly meetings for 6-12 mo from the start of the program All families provided the Traffic Light Diet	NR (NR)	Study 1: Control Arm: Non-targeted weight loss Study 2: Control Arm: No treatment Study 3: Control Arm: Weight loss targeted at children with no obese parents Study 4: Control Arm: Diet + calisthenics	**Primary:** Change in percent overweight [%]	**Primary:** 30% of children were not obese at 10 y F/U; 1/3 had a decrease to <= 20% overweight. No difference between groups. From the figures, weight loss was improved by including parents in the intervention and all forms of exercise except calisthenics were beneficial in promoting weight loss. ****Major findings are presented as figures with specific results of each study not reported.**	**S***	6 girls reported that they were treated for eating disorders. 19 other children developed major psychiatric disorders requiring hospitalization and/or long-term medication use. Adjustment for these subjects did not change findings	The best predictor of change over the 10 years was change during the first 5 years. Major findings are presented as figures with specific results not reported.	This is a combined report of results of 4 different studies. These findings provide the first evidence that weight regulation in children can be achieved and maintained over extended periods from childhood through adolescence to adulthood. The studies point to two treatment variables that can be replicated and extended in subsequent studies: (1)In intact families effects are improved for children by including a parent with the child in treatment. (2)Exercise enhances the long-term effects of diet interventions.	Q10,11,13. Weight regulation in children can be achieved and maintained over extended periods from childhood through adolescence to adulthood. The studies point to two treatment variables that can be replicated and extended in subsequent studies: (1)In intact families effects are improved for children by including a parent with the child in treatment. (2)Exercise enhances the long-term effects of diet interventions.
7830214	Israel AC	An evaluation of enhanced self-regulation training in the treatment of childhood obesity	1994	RCT	None	Q10 (RF8) Q11 (RF8)	USA	Home	None/NR	26 wk	3.5 yr	Evaluate an enhanced self-regulation training for obese children.	34 families	Parental/ Family/ Caregiver	8-13 yr > 20% overweight according to weight for height, age, and gender norms	Mean age (SD): 10 yr 11 mo (1 yr 2 mo)	16 (9)	Behavioral	Arm 1: Enhanced child involvement (Child) Comprehensive training with greater emphasis on child self-regulation and less emphasis on parental control	18 (11)	Control Arm: Standard treatment (PAR) Comprehensive training with emphasis on parent responsibility for the completion of homework assignments and for the motivation of their children to follow program rules or prescriptions	**Primary:** Mean percentage overweight [% (SD)] Mean percentage over triceps norm [% (SD)]	**Primary:** **B/L 6m 1y 3y** PAR: 45.9(17.1) 33.4(17.0) 45.2(23.9) 52.3(24.3) Child: 48.1(18.3) 32.6(17.4) 42.3(22.5) 43.3(21.2) PAR: 131.7(56.3) 101.3(59.9) 129.8(65.1) Child: 118.4(27.1) 83.0(39.6) 132.7(77.3)	**S*, B/L to 6m & 1y; NS at 3y for both groups; NS between groups** **S*, B/L to 6m; NS at 1y for both groups; NS between groups**	Not addressed	Small study groups.	In 8 - 13 y old obese children, there was no difference in weight change in those who received a parents-only focus vs an enhanced approach to the child.	Q10,13. In 8 - 13 y old obese children, there was no difference in weight change in those who received a parents-only focus vs an enhanced approach to the child.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
8036961	Epstein LH	Effects of mastery criteria and contingent reinforcement for family-based child weight control	1994	RCT	None	Q10 (RF8) Q11 (RF8) Q13 (RF9, RF11)	USA	Mult settings	None/NR	6 mo	2 yr	Test the effects of mastery criteria and contingent reinforcement in a family-based behavioral weight control program for obese children and their parents	44 families	Parental/ Family/ Caregiver	8-12 yr Obese Child ≥ 20% and ≤ 100% above average weight for height Neither parent > 100% overweight	Mean age (SD): 10.2 yr (1.1) Males: 26% Obese parents: 54% Mean family SES (SD): 45.0 (10.3)	NR (17) NR (17 families)	Behavioral	Arm 1: Diet + activity + behavioral intervention with mastery criteria and contingent reinforcement 26 weekly meetings and 6 monthly meetings Targeted and reinforced behavior skills for mastery of diet, exercise, weight loss, and parenting skills Parents and children were required to master behavioral skills at each level and show evidence of weight loss before advancement to the next level Diet was based on the Traffic Light Diet Other components included a lifestyle education program, parent manuals with behavioral principles, quizzes, contracting, and a parent skills lottery	NR (22) NR (22 families)	Control Arm: Diet + activity + behavioral intervention with non-contingent reinforcement 26 weekly meetings and 6 monthly meetings Taught behavior-change strategies and provided non-contingent reinforcement at a pace matched to Arm 1 Received same behavioral family-based educational components, activity, and dietary intervention as Arm 1	**Primary:** Mean change in percent overweight [% (SEM)] **Secondary:** Mean change in consumption of red foods [number/wk (SD)] Mean time in calorie range [d (SD)] Mean time meeting exercise goal [wk (SD)]	**Primary:** INT: - 30% at 6 m, - 26% at 12 m, - 16% at 24 m CON: - 20% at 6 m, - 17% at 12 m , - 10% at 24 m **Secondary:** INT: -35.8 +/- 18.8 vs CON: - 28.6 +/- 15.7 INT: +1.2+/-2.8 vs CON: -1.0+/-3.2 INT: 4.8 +/- 2.4 vs CON: 3.2 +/- 2.7	**S at 6 & 12 mos, NS at 24 mos** **S** **S** **NS**	None		A behavioral family-based treatment for obese children based on mastery criteria significantly improved BMI change in obese children through 1 yr but advantage was lost by 24 mos.	Q10. Obesity can be decreased by a family-based treatment based on mastery criteria of diet and exercise change.
8247594	Vido L	Childhood obesity treatment: double blinded trial on dietary fibres (glucomannan) versus placebo	1993	RCT	None	Q10 (RF8) Q13 (RF5)	Italy	Clinical	Double	2 mo	2 mo	Evaluate the efficacy and the side effects of glucomannan in child obesity management, particularly in controlling body weight and lipidic metabolism	60	Pediatric/ Young Adults	< 15 yr Primary obesity	Mean age: 11.2 yr Males: Arm 1: 17 Control Arm: 16	30 (30)	Dietary Supplements	Arm 1: Glucomannan 2 g/d + diet (INT) 1 g capsules with 2 glasses of water given 1 hr before every meal bid Normocaloric diet evaluated every 2 wk by a dietetic record book	30 (30)	Control Arm: Placebo + diet (CON) Normocaloric diet evaluated every 2 wk by a dietetic record book	**Primary:** Mean percent overweight [SD] **Secondary:** Mean TC [mg/dL (SD)] Mean TG [mg/dL (SD)] Mean apo-a-protein [g/dL (SD)] Mean apo-b-protein [g/dL (SD)]	**Primary: (at 6 m)** INT: 49.5% to 41% vs CON: 43.9% to 41.7% **Secondary:** No change INT: 73.2(37.9) to 96.9(70.2) No change INT: No change CON: 1.02(0.26) to 0.92(0.22)	**Both groups S**; NS between groups.** **NS** **INT: S; CON: NS** **NS** **INT: NS; CON: S**	None		Glucomannan did not increase weight loss in obese children and was associated with adverse changes in lipids.	Q1`0,13 Glucomannan did not increase weight loss in obese children and was associated with adverse changes in lipids.
8267303	Sallis JF	Effects of physical education on adiposity in children	1993	RCT	None	Q10 (RF8)	USA	Community (schools)	None/NR	2 yr	3 yr	Determine the effects of a 2 y school physical education program on relative weight and adiposity in elementary school children.	7 schools	Pediatric/ Young adult	Grades 4 & 5	Age 9.25(0.50) y 85% white, 6% Asian/ Pacific Islander, 7% Latino, 1% African American	305 boys/ 244 girls	Behavioral	Arm 1: PE & self-management classes led by certified PE specialists Arm 2: PE & self-management classes led by classroom teachers	NR	Control arm: Usual PE classes	**Primary:** BMI [kg/m2(SD)] Sum of triceps & calf skinfolds [mm(SD)]	**Primary:** Results are only presented as graphs. There were no significant differences between groups for any measure at 2 y assessment except both INT group girls had higher BMI than controls.	**NS**	None reported.	Girls in both INT grps had higher BMI at 2 y evaluation. There was a trend towards lower SSFs in the INT grps but this was not significant.	A 2 y school-based PE and self-management curriculum had no significant effects on adiposity measures in elementary school children.	Q10. A 2 y school-based PE and self-management curriculum had no significant effects on adiposity measures in elementary school children.
8408368	Duffy G	The effectiveness of cognitive self-management as an adjunct to a behavioural intervention for childhood obesity: a research note	1993	RCT	None	Q10 (RF8) Q13 (RF9)	Australia	Clinical	None/NR	8 wk	6 mo	Investigate the effectiveness of cognitive self-management training as an adjunct to the behavioural management of childhood obesity	29	Parental/ Family/ Caregiver	7-13 yr Exceeding 15% of ideal weight for age, height, and sex	Mean age (SD): 118.71 mo (20.16) Males: 6	NR (9)	Behavioral	Arm 1: Cognitive self-management + behavior therapy(BEH+SM) 8 weekly sessions of 90 min duration for a total of 12 therapy hr, including 9 hr behavioral intervention and 3 hr of cognitive self-management input	NR (8)	Control Arm: Behavior therapy + attention placebo control methods (BEH+Rel) 8 weekly sessions of 90 min duration for a total of 12 therapy hr, including 9 hr behavioral intervention and 3 hr progressive muscular relaxation training	**Primary:** Mean weight [kg (SD)] Mean percentage overweight [% (SD)]	**Primary: [6mos]** BEH+Rel: 56.63(13.14) to 58.25(13.31) BEH+SM: 57.22(19.30) to 60.44(21.23) BEH+Rel: 46.28(19.32) to 37.09(21.71) BEH+SM: 45.96(18.55) to 37.02(24.58)	**S** from baseline in both groups; NS between groups** **S** from baseline in both groups; NS between groups**	None		A weight control program that compared behavior therapy to behavior therapy plus cognitive self management showed no difference between groups.	Q10,13. A weight control program that compared behavior therapy to behavior therapy plus cognitive self management showed no difference between groups. Cognitive self-mgt had no additional effect over a std behavioral approach
8427238	Figueroa-Colon R	Comparison of two hypocaloric diets in obese children	1993	RCT	None	Q10 (RF8) Q11 (RF5, RF8) Q13 (RF5)	USA	Clinical	None/NR	58 wk	58 wk	Examine whether a protein-sparing modified fast diet and a hypocaloric balanced diet are safe and effective for children in an outpatient weight reduction program	19	Parental/ Family/ Caregiver	Weight for height > 40% above the mean weight for age, sex, and height per NCHS Middle SES	Mean age (SD): Arm 1: 11.5 yr (2.0) Arm 2: 11.3 yr (3.3) Males: Arm 1: 4 Arm 2: 4	Arm 1: 10 (7) Arm 2: 9 (4)	Behavioral	Arm 1: Period 1: Protein-sparing modified fast diet(PSMF) + weight reduction program wk 0-10 Period 2: Maintenance diet wk 11-58 Protein-sparing modified fast diet consisted of 1.5-2 g/d of protein per kg of ideal body weight and vitamin and mineral supplementation Arm 2: Period 1: Hypocaloric balanced diet(HCB) + weight reduction program wk 0-10 Period 2: Maintenance diet wk 11-58	N/A	N/A	**Primary:** Mean change in BMI [kg/m2 (SD)] Mean change in weight [kg (SD)] Mean change in percent overweight (SD) **Secondary:** Mean change in BF [kg (SD)] Mean change in lean body mass [kg (SD)] SBP [mmHg(SD)] DBP [mmHg(SD)] Mean TC [mg/dL (SD)] Mean TG [mmol/L (SD)]	**Primary: 10 wks:** PSMF: -5.2(1.3) vs HCB: -2.4(1.4) PSMF: -11.2(4.4) vs HCB: -5.1(4.1) PSMF: -29.5(7.4) vs HCB: -13.8(7.7) **Secondary:** PSMF: -1.1(1.0) vs HCB: -0.3(0.5) PSMF: +0.1(2.8) vs HCB: -0.8(3.6) PSMF + HCB: B/L: 128(14) 6m: 118(15) 14.5m: 112(17) B/L: 85(7) 6m: 77(7) 14.5m: 71(9) Not reported Not reported	**S**** **S*** **S**** **S** **NS** **S*** **S****	None	At 6 m F/U, PSMF groups still had statistically greater wt loss. By 14.5 m, mean weight had returned to B/L levels in both groups but there were still differences in %overweight & BMI in the PSMF grp.	In obese 7 - 15 y olds, a protein-sparing modified fast diet was significantly more effective than a hypocaloric balanced diet in reducing all weight measures. When diet groups are combined, wt loss was associated with a significant decrease in systolic and diastolic BP.	Q10. In obese 7-15 y olds, a protein-sparing modified fast diet was significantly more effective than a hypocaloric balanced diet in reducing all weight measures at 10 wk and 6 mo F/U. When diet groups are combined, wt loss was associated with a significant decrease in systolic and diastolic BP. By 14.5 m, mean weight had returned to B/L levels in both groups but there were still differences in %overweight & BMI in the PSMF group.
8769361	Vogiatzi MG	Dehydroepiandrosterone in morbidly obese adolescents: effects on weight, body composition, lipids, and insulin resistance	1996	RCT	None	Q10 (RF8)	USA	Clinical	Double	8 wk	10 wk Includes 2 wk run in period	Determine effects of hormone dehydroepiandrosterone treatment on obesity and related physiologic conditions in adolescents and young adults	19	Pediatric/ Young Adults	Morbidly obese Adolescents and young adults Exclusions: Diabetes mellitus Concurrent participation in any other weight reduction program	Mean age: Subjects who completed study: 16.5 yr Males: Arm 1: 1 Control Arm: 2 White: Arm 1: 1 Control Arm: 3 Black: Arm 1: 3 Control Arm: 2 Hispanic: Arm 1: 3 Control Arm: 0	NR (7)	Pharmacologic	Arm 1: (DHEA) Dehydroepiandrosterone 40 mg bid	NR (6)	Control Arm: Placebo (CON)	**Primary:** Mean weight [kg (SD)] Mean fat by DXA [kg (SD)] Mean lean by DXA [kg (SD)] **Secondary:** Mean TC [mmol/L (SD)] Mean LDL-C [mmol/L (SD)] Mean HDL-C [mmol/L (SD)] Mean VLDL [mmol/L (SD)] Mean TG [g/L (SD)] Mean insulin sensitivity [min-1 * µU-1 * mL-1 (SD)]	**Primary:** DHEA: 129(32) to 129.2(29) CON: 144.2(55) to 146.1(53) DHEA: 50(4.3) to 49.9(5.3) CON: 56.7(10.3) to 58.6(11.3) DHEA: 56.7(8.8) to 57.2(8.6) CON: 56.6(8.3) to 55.7(5.4) **Secondary:** DHEA: 4.09(0.75) to 4.82(2.45) CON: 5.45(2.33) to 5.38(2.37) DHEA: 56.7(8.8) to 57.2(8.6) CON: 56.6(8.3) to 55.7(5.4) DHEA: 0.91(0.26) to 0.77(0.13) CON: 1.04(0.24) to 0.94(0.20) DHEA: 0.64(0.19) to 0.60(0.17) CON: 0.54(0.22) to 0.63(0.10) DHEA: 1.25(0.38) to 1.16(0.33) CON: 1.04(0.41) to 1.22(0.22) DHEA: 1.2(1.2) to 1.79(1.13) CON: 1.33(0.88) to 0.92(0.72)	**NS for all comparisons.**	None	Significant baseline differences between groups in weight and BMI.	In morbidly obese adolescents, treatment with sublingual DHEA did not change any weight, lipid or insulin resistance parameter during a 7 wk trial.	Q10. In morbidly obese adolescents, treatment with sublingual DHEA did not change any weight, lipid or insulin resistance parameter during a 7 wk trial.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
8860788	Fardy PS	Coronary disease risk factor reduction and behavior modification in minority adolescents	1996	RCT	None	Q10 (RF8)	USA	Community (schools)	None/NR	11 wk	11 wk	Evaluate the impact of a school-based program of exercise, helath education and behavior modification on health knowledge, health behaviors and CV fitness in minority adolescents	511 students enrolled/ 346 completed	Pediatric/ Young adult	9th - 12th grade students	80% freshmen & sophomores, 20% juniors & seniors 9% Asian Amricans;7% blacks; 21% Hispanics 58% girls	181/NR	Behavioral	Arm 1: 30 min classes 5X/wk for 11 wks with 20-25 mins on circuit training exercise & 5 mins on health behavior training	165/NR	Control arm: traditional PE sport-skill classes in volleyball	**Primary:** BMI [kg/m2(SD)] Total cholesterol [mg/dl (SD)] SBP [mmHg(SD)] DBP [mmHg(SD)] % body fat from SSF [%(SD)] VO2max [ml/kg(-1)/min(-1)(SD)] CV health knowledge [n(SD)] Food focus frequency [times/wk(SD)]	**Primary:** No difference from B/L or between groups Girls INT: 165(39) to 149(36);CON:154(33) to 150(29) Boys: No difference from B/L or between groups No difference fromB/L or between groups No difference fromB/L or between groups No difference fromB/L or between groups Girls: INT: 33(3.0) to 38(4.0); CON:33(3.0) to 34(3.0) Boys: No difference fromB/L or between groups Girls: INT: 51(15) to 56(19); CON:53(16) to 48(18) Boys:INT: 44(14) to 50(16); CON:47(16) to 40(19) Girls:INT:50(21) to 45(19); CON: 47(19) to 47(19) Boys: No difference fromB/L or between groups	**NS** **S*** **NS** **NS** **NS** **NS** **S**** **NS** **S*** **S**** **S** **NS**	None reported.		An 11 week school-based program of exercise, health education and behavior modification of health knowledge, health behaviors and CV fitness in minority adolescents significantly improved health knowledge scores in males & females and improved dietary habits, lowered cholesterol and improved fitness only in girls immediately post the intervention.	Q10. An 11 week school-based program of exercise, health education and behavior modification of health knowledge, health behaviors and CV fitness in minority adolescents significantly improved health knowledge scores in males & females and improved dietary habits, lowered cholesterol and improved fitness only in girls immediately post the intervention.
9198730	Grugni G	Dexfenfluramine in the treatment of juvenile obesity	1997	RCT	None	Q6 (RF5, RF8) Q10 (RF8) Q13 (RF4, RF5)	Italy	Clinical	Double	60 d	60 d	Investigate the potential of dexfenfluramine for reducing cardiovascular risk factors and improving compliance towards diet in young patients hospitalized for essential obesity of high degree	103	Pediatric/ Young Adults	Adolescents Hospitalized for essential obesity of high degree (BMI ≥ 35 kg/m^2) Exclusions: Presence of reduced glucose tolerance	Mean age (SE): 15.4 yr (0.2) Males: 27	51 (51)	Pharmacologic	Arm 1: Diet + dexfenfluramine 15 mg bid (DEX) All patients received a very low calorie diet consisting of 2,512 kJ/d, 48 g protein, 20.7 g lipids and 62.1 g of CHO	52 (52)	Control Arm: Diet + placebo (CON) All patients received a very low calorie diet consisting of 2,512 kJ/d, 48 g protein, 20.7 g lipids and 62.1 g of CHO	**Primary:** Mean SBP [mmHg (SE)] Mean DBP [mmHg (SE)] Mean TC [mg/dL (SE)] Mean HDL-C [mg/dL (SE)] Mean TG [mg/dL (SE)] **Secondary:** Mean weight [kg (SE)] Mean BMI [kg/m^2 (SE)]	**Primary:** DEX: 133(1) to 117(1) CON: 132(1) to 118(1) DEX: 81(1) to 73(1) CON: 79(1) to 74(1) DEX: 176(5) to 130(13) CON: 181(4) to 132(3) DEX: 39(2) to 31(1) CON: 36(1) to 28(1) DEX: 84(5) to 66(2) CON: 93(6) to 65(2) **Secondary:** DEX: 99.1(2.1) to 81.9((1.6) CON: 98.8(2.5) to 82.3(1.9) DEX: 36.7(0.5) to 30.1((0.4) CON: 37.0(0.6) to 30.8(0.5)	**Primary:** **S* from B/L in both groups; NS between groups** **S* from B/L in both groups; NS between groups** **S** from B/L in both groups; NS between groups** **S* from B/L in both groups; NS between groups** **S** from B/L in both groups; NS between groups** **Secondary:** **S** from B/L in both groups; NS between groups** **S** from B/L in both groups; NS between groups**	None reported.	Dexfenfluramine group reported less hunger at 1 and 2 months.	In severely obese adolescents, an inpatient very low calorie diet was as effective as the diet plus dexfenfluramine in decreasing weight and BMI and improving all CV risk measures. DF group did experience less hunger and this may be useful support in the treatment of obesity. There were no side effects with DF:	Q10,13.In severely obese adolescents, an inpatient very low calorie diet was as effective as the diet plus dexfenfluramine in decreasing weight and BMI and improving all CV risk measures. DF group did experience less hunger and this may be useful support in the treatment of obesity. There were no side effects with DF:
9625084	Golan M	Parents as the exclusive agents of change in the treatment of childhood obesity	1998	RCT	None	Q5 (RF8) Q10 (RF8)	Israel	Clinical	None/NR	1 yr	1 yr	Compare the efficacy of a family-based approach for the treatment of childhood obesity, in which the parents served as the exclusive agents of change, with that of the conventional approach, in which the children served as the agents of change	60	Parental/ Family/ Caregiver	6-11 yr Weight > 20% of the recommended weight-for-age, weight-for-height, and weight-for-sex Both parents living at home	Mean age (SD): Arm 1: 8.9 yr (0.3) Control Arm: 9.2 yr (0.2) Boys: Arm 1: 12 Control Arm: 11 Most subjects were of middle class	30 (29)	Behavioral	Arm 1: Counseling targeted to parents (parents as the sole agents of change) (Parent) Parent-only group session included 14 hr-long support and educational group sessions conducted by a clinical dietitian	30 (21)	Control Arm: Counseling targeted to child (child as the agent of change) (Child) Each child was prescribed a diet providing 6.3 MJ/d; intervention included 30 hr-long support and educational sessions conducted by a clinical dietitian	**Primary:** Mean percent overweight (SD) Differences between groups	**Primary: [1 yr]** Parent : 39.6% to 24.9% Child : 39.1% to 31% (results from graph) Parent only group decreased more with 35% reaching non-obese status vs 14% in child only group By 18 mos, mean % overwt in child only group returned to baseline while parent only group remained at 27%. Drop-out rate was 9X higher in the child only group.	**S** from B/L for Parent grp,S* for Child grp; S between groups**	none	Parent only group better maintained wt lost in F/U, 85% vs 40%. Fathers in the parent only group also had a significant decrease in % overweight; there was no change in mothers.	In prepubertal children, a weight control program directed at parents only was significantly more effective in decreasing overweight and in sustaining improvement post intervention. Parents as sole agents of change worked much better;	Q10,11,13. In prepubertal children,a weight control program directed at parents only was significantly more effective in decreasing overweight and in sustaining improvement post intervention. Family programs are a must, children alone did not do as well with higher drop out
9877257	Golan M	Role of behaviour modification in the treatment of childhood obesity with the parents as the exclusive agents of change	1998	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	Israel	Clinical	None/NR	12 mo	12 mo	Examine the reduction in overweight and changes in eating-related behaviors in obese children treated with a family-based approach, in which the parents were the exclusive agents of change vs. control, where children are responsible for their own weight loss.	60	Parental/ Family/ Caregiver	6-11 yr Obese Weight > 20% over expected weight for age, height, and gender Attend public school system in middle-class town	Mean age: 9 yr Mean weight: 45 kg Mean percent overweight: 39%	NR	Behavioral	Arm 1: Parents serve as agents of change (PAR) Only parents attended 14 1-hr group sessions conducted by a clinical dietician and 4 15-min individual sessions Taught to alter family sedentary lifestyle, provide diet with reduced saturated fats, etc., and decrease the family's exposure to food stimuli. Parents' role to control the quality and patterno of the food environment; to limit eating to the "five onlys"--only in the dining room, only while sitting, only from a propoer plate, only when not doing anything else and only when hungry.	NR	Control Arm: Children serve as agents of change (CHILD) Only children attend 30 1-hr group sessions conducted by a clinical dietician Taught how to follow prudent diet, restrict energy intake, increase exercise, etc. Individual counseling offered when child missed group session or needed extra support	**Primary:** Mean degree of overweight (% of expected for height, age and sex) **Secondary:** Mean duration of activity [hr/wk(SD)] Mean television viewing time [hr/d (SD)] Mean energy intake [MJ/d] Presence of food stimuli in home	**Primary:** PAR: -14.6% vs CHILD: -8.4% **Secondary:** PAR: 3.70+/-0.6 to 4.47+/-0.5 CHILD: 3.45+/-0.4 to 3.54+/-0.6 PAR: 3.10+/-0.1 to 2.72+/-0.1 CHILD:2.80+/-0.1 to 2.69+/-0.1 PAR: -26.5% CHILD: -17% Reduction in food stimuli in home: snacks (S**); sweets (S*); cakes (S*) and ice cream (S**). CHILD: Reduction in ice cream (S*). Difference between groups-greater reduction for PAR vs. CHILD for snacks (S**), sweets (S) and cakes (S).	**S** PAR, S* CHILD, S between groups** **NS for each group** **NS for each group** **S** between groups** **S**, S*, S*, S**** **S*** **S**, S, and S**	None	No change in parents' overweight status during the intervention. There were sig. reductions in four negative eating styles (eating while standing, eating while watching TV, eating following stress, and eating between meals) in the PAR group, but only in eating between meals in the CHILD group. The overall reduction in poor eating habits was sig greater in the PAR vs. CHILD group.	In a family-based intervention for 6-11 y old obese children, there was significantly greater weight loss in children whose parents were the sole agents of change compared with a program where children were the sole agents of change.	Q10. A family-based intervention focused on parents as the sole agents of change was effective in decreasing weight and improving eating habits in obese children.
10075321	Gutin B	Plasma leptin concentrations in obese children: changes during 4-mo periods with and without physical training	1999	RCT	None	Q10 (RF8)	USA	Clinical	None/NR	8 mo	8 mo	Determine the effects of 2 4-mo periods with and without physical training on leptin in obese children; explore the determinants of leptin at baseline and in response to physical training	34	Pediatric/ Young Adults	7-11 yr Obese (triceps skinfold thickness > 85th percentile) No involvement in any other weight-control or exercise program No restrictions on their physical activity	Mean age (SD): 9.4 yr (1.0) Boys: 10 White: 19 Black: 15	15 (16) Study used a procedure which allowed for unequal sample sizes at different time points	Behavioral	Arm 1: Physical training for 4 mo followed by no physical training for 4 mo 40 min sessions 5 d/wk Target HR > 150 bpm	19 (17) Study used a procedure which allowed for unequal sample sizes at different time points	Control Arm: No physical training for 4 mo followed by physical training for 4 mo Same physical training regimen as in Arm 1	**Primary:** Mean change in plasma leptin [mcg/L (SD)] **Secondary:** Mean change in fat mass [kg (SD)] Mean change in FFM [kg (SD)] Mean change in total mass [kg (SD)] Mean change in BF [% (SD)] Mean change in insulin [pmol/L (SD)] Mean change in glucose [mmol/L (SD)] Mean change in insulin:glucose ratio (SD) Mean change in moderate physical activity [hr/wk (SD)] Mean change in VPA [hr/wk (SD)] Mean change in submaximal HR [bpm (SD)] Mean HR [bpm (SD)] Mean energy expenditure [kJ/session (SD)]	**Primary:** -6.7(11.7) **Secondary:** No significant change +1.5(1.1) +1.8(1.9) -1.1(2.0) -17.9(47.3) No significant change 0.01(0.04) No significant change +1.3(2.8) No significant change No significant change No significant change	**S** **NS** **S** **S** **S** **NS** **S** **NS** **S** **NS** **NS** **NS**	None		In obese children, leptin decreased during a 4 m physical training program and increased during a subsequent 4 month period without training. Fat mass was highly correlated with baseline leptin and greater reductions in leptin during the 4 month training program were seen in children with higher pretraining leptin and in those whose total mass increased least.	Q10. In obese children, leptin decreased during a 4 m physical training program and increased during a subsequent 4 month period without training. Fat mass was highly correlated with baseline leptin and greater reductions in leptin during the 4 month training program were seen in children with higher pretraining leptin and in those whose total mass increased least.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
10201726	Gortmaker SL	Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health	1999	RCT	None	Q10(RF8, RF9, RF11) Q13 (RF8, RF9, RF11)	USA	Community (schools)	None/NR	2 school yr	2 school yr	Evaluate the impact of a school-based health behavior intervention known as Planet Health on obesity	1,560 (10 schools)	Pediatric/ Young Adults	Grades 6 and 7 Enrolled in 1 of 10 schools in 4 Massachusetts communities	Mean age (SD): Arm 1: 11.7 yr (0.7) Control Arm: 11.7 yr (0.7) Boys: Arm 1: 331 Control Arm: 337 White: Arm 1: 69% Control Arm: 63% African American: Arm 1: 11% Control Arm: 15% Hispanic: Arm 1: 11% Control Arm: 16% Asian/Pacific Islander: Arm 1: 9% Control Arm: 7%	NR (641) 5 schools (5 schools)	Behavioral	Arm 1: Planet Health program Focused on 4 behavioral changes: reduced TV viewing to < 2 hr/d, increased MVPA, decreased consumption of high-fat foods, and increased consumption of fruits and vegetables to ≥ 5 servings/d Included teacher training workshops, classroom lessons, physical education materials, wellness sessions, and fitness funds	NR (654) 5 schools (5 schools)	Control Arm: Usual health curricula and physical education classes	**Primary:** Mean obesity prevalence (%) **Secondary:** Mean obesity* incidence (%) Mean obesity* remission (%) Adjusted difference in total TV/video [hr/d (95% CI)] Adjusted difference in fruit and vegetable consumption [servings/d (95%CI)] Adjusted difference in MVPA[h/d (95%CI)] Adjusted difference in total energy from fat [% (95% CI)] Adjusted difference in total energy intake [joules/d (95% CI)] * Obesity defined by a composite measure of BMI and triceps SF.	**Primary:** OR: Girls 0.47 (0.24,0.93); Boys 0.85 (0.52,1.39) **Secondary:** OR: Girls: 0.77(0.23,2.38) Boys: 1.12(0.71,1.75) OR: Girls: 2.16(1.07,4.35) Boys: 1.37(0.44,4.24) OR: Girls: - 0.58(-0.85,-0.31) Boys: -0.40(-0.56,-0.4) OR: Girls: +0.32(0.14,0.50) Boys: +0.18(-0.21,0.56) No significant change from B/L for any of the remaining variables.	**S** **NS** **NS** **NS** **S** **NS** **S**** **S*** **S*** **NS** **NS for all remaining variables.**	No eating disorders		A school-based intervention based on behavior change theory to reduce obesity by increasing physical activity, decreasing sedentary behavior decreasing consumption of high fat foods and increasing fruit & vegetable consumption in 6th to 8th grade students was successful in decreasing obesity prevalence in girls but not in boys. Combined TV/video time decreased in boys and girls. There was no change in activity despite focus on this as a major part of the intervention.	Q10,13. A school-based intervention based on behavior change theory to reduce obesity by increasing physical activity, decreasing sedentary behavior decreasing consumption of high fat foods and increasing fruit & vegetable consumption in 6th to 8th grade students was successful in decreasing obesity prevalence in girls but not in boys. Combined TV/video time decreased in boys and girls. There was no change in activity despite focus on this as a major part of the intervention.
10201726	Gortmaker SL	Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health	1999													American Indian: Arm 1: 2% Control Arm: 2% Other ethnicity: Arm 1: 5% Control Arm: 9%										
10357730	Ferguson MA	Effects of physical training and its cessation on the hemostatic system of obese children	1999	RCT	None	Q10 (RF8) Q13 (RF11)	USA	Clinical	None/NR	8 mo	8 mo	Examine the effects of a physical training program on hemostatic variables in a bi-ethnic group of children	43	Pediatric/ Young Adults	7-11 yr > 85th percentile in triceps skinfold thickness for sex, ethnicity, and age Not involved in other weight control or exercise programs No restrictions on physical activity	Mean age (SD): 9.5 yr (1.0) Boys: 14 Black: 19 White: 23 Asian: 1	22 (NR)	Behavioral	Arm 1: Physical training for 4 mo followed by no physical training for 4 mo 40 min sessions 5 d/wk Target HR > 150 bpm	21 (NR)	Control Arm: No physical training for 4 mo followed by physical training for 4 mo Same physical training regimen as in Arm 1	**Primary:** Hemostatic values(Fibrinogen,PAI-1, D-dimer) **Secondary:** Mean change in BMI [kg/m2 (SD)] Mean change in percentage BF [% (SD)] Mean change in fat mass [kg (SD)] Mean change in FFM [kg (SD)]	**Primary: [4mo + 4mo]** No change **Secondary:** -0.1(0.9) -1.1(1.9) -0.3(1.5) +1.6(1.1)	**NS** **NS** **S*** **NS** **S***	None	Children with higher BMI had a greater reduction in hemostatic factors but difference was not significant.	An exercise training program which minimally affected BMI and body fat did not significantly affect measured hemostatic variables.	Q10,13. An exercise training program which minimally affected BMI and body fat did not significantly affect measured hemostatic variables.
10490792	Ferguson MA	Effects of exercise training and its cessation on components of the insulin resistance syndrome in obese children	1999	RCT (crossover)	None	Q10 (RF8)	USA	Clinical	None/NR	4 mo	8 mo	Determine the effect of exercise training on components of insulin resistance syndrome in obese children	79	Pediatric/ Young Adults	7-11 yr Obese Triceps skinfold thickness > 85th percentile for gender, ethnicity, and age No involvement in any other weight control or exercise program No restriction from engaging in physical activity	Mean age (SD): 9.5 yr (1.0) Boys: 26 White: 34 Black: 44 Asian: 1	79 (70)	Behavioral	Intervention: Exercise training program (EX) Training program offered 5 d/wk Each 40 min session was divided into 2 20-min halves in which subjects first exercised on machines and then played group games Arm 1: Exercise Training mos 1-4, No Ex mos 5-8 Arm 2: No ET mos 1-4, Ex mos 5-8	NR (NR)	Control: No exercise training (CON)	**Primary:** LS submaximal Ex HR (bpm) LS mean fat [%] LS mean insulin [pmol/L] LS mean glucose [mmol/L] LS mean TG [mmol/L] **Secondary:** LS mean TC [mmol/L] LS mean HDL-C [mmol/L] LS mean LDL-C [mmol/L] LS mean apo A-I [g/L] LS mean apo B [g/L] LS mean glycosylated hemoglobin [%]	**Primary:**EX1:B/L to Ex to CON; EX2:B/L to CON to EX EX 1: 120(1.5) to 116(1.6) to 121(1.7) EX 2: 124(1.5) to 125(1.5) to 122(1.7) EX 1: 44.6(0.3) to 42.4(0.4) to 43.7(0.4) EX 2: 43.9(0.3) to 43.9(0.3) to 42.8(0.3) EX 1: 155.5(7.9) to 140.6(7.9) to 167.2(7.9) EX 2: 170.0(7.9) to 176.5(7.9) to 140.6(7.9) No change EX 1:1.15(0.01) to 0.95(0.01) to 0.89(0.01) EX 2: 0.98(0.01) to 1.10(0.01) to 0.82(0.01) **Secondary:** No significant change in any of these parameters during or post Ex.	**(p values for group X time interaction)** **NS (p<0.06)** **S**** **S**** **NS** **S** **All, NS**	None	None	Regular exercise training without dietary intervention led to favorable changes in aspects of the MetS constellation. However, plasma insulin concentrations and % body fat rebounded following cessation of the Ex training. Plasma TG concentrations decreased after periods of Ex training in both groups and levels did not rebound as much as the other measures.	Q10. Exercise training improves insulin resistance but changes are not sustained when exercise training is discontinued.
10519718	Schwingshandl J	Effect of an individualised training programme during weight reduction on body composition: a randomised trial	1999	RCT	None	Q10 (RF8)	Austria	Clinical	None/NR	12 wk	1 yr	Study the effect of a standardized training program focusing on maintenance of FFM during weight reduction by energy reduction in obese children	30	Pediatric/ Young Adults	Obese	Mean age (SD): Arm 1: 11.0 yr (2.5) Arm 2: 12.2 yr (2.7) Boys: Arm 1: 6 Arm 2: 7	Arm 1: 14 (10) Arm 2: 16 (10)	Behavioral	Arm 1: Diet + physical training program(D&E) Advice given by group teaching on achieving a balanced diet ratio of protein, fat, and CHO at 20%/ 30%/ 50% of total energy Energy intake was restricted to 4,180 kJ/day, 5,016 kJ/d for girls and 5,852 kJ/d for boys older than 14 yr Individualized physical training sessions twice a wk Arm 2: Diet alone (D) Advice given by group teaching on achieving a balanced diet ratio of protein, fat, and CHO at 20%/ 30%/ 50% of total energy Energy intake was restricted to 4,180 kJ/day, 5,016 kJ/d for girls and 5,852 kJ/d for boys older than 14 yr	N/A	No control	**Primary:** Mean change in BMI-SDS {SEM] Mean change in FFM [kg(SD)] Mean change in wt [kg(SD)]	**Primary:** **D&E: B/L:** 5.58+/-2.46; **12w:** 5.06+/-2.34 **D: B/L:** 5.33+/-1.79; **12w:** 4.82+/-1.33 **D&E: B/L:** 34.3+/-8.0; **12w:** 37.0 +/- 10.9 **D: B/L:** 37.1+/-10.5; **12w:** 37.5+/-10.2 **D&E: B/L**: 63.3+/-16.5; **12 w:** 62.6+/-14.8 **D: B/L:** 69.2 +/-20.6; **12w**: 68.7+/-19.7	**S**** **S*** **S** **NS** **NS** **NS**	None	Change in FFM at 12 wks was inversely correlated with change in body wt at 1 yr (r = -0.44,p=S)	In obese children and adolescents, a resistance training program plus energy reduction significantly increased FFM when compared with energy reduction alone. There was no difference in wt lost or BMI change with the 2 methods.	Q10(RF8): Addition of resistance training to energy restriction increased FFM during attempted wt loss. There was no difference in wt lost or BMI change with the 2 methods.
10546696	Robinson TN	Reducing children's television viewing to prevent obesity: a randomized controlled trial	1999	RCT	None	Q13 (RF8, RF9, RF11)	USA	Mult settings	Other	6 mo	September 1996-April 1997	Assess the effects of reducing TV, videotape, and video game use on changes in adiposity, physical activity, and dietary intake	227 (2 schools)	Pediatric/ Young Adults	3rd and 4th grade students in public elementary school	Mean age (SD): Arm 1: 8.95 yr (0.64) Control Arm: 8.92 yr (0.70) Males: Arm 1: 55.4% Control Arm: 51.5% White: Arm 1: 80% Control Arm: 70% Parents are college graduates: Arm 1: 45% Control Arm: 21% Parents are married: Arm 1: 77% Control Arm: 67%	106 (92) 1 school (1 school)	Behavioral	Arm 1: Program to reduce TV, videotape, and video game use(INT) 18 lessons of 30-50 min/lesson added to the standard curriculum Following initial lessons, children were challenged to watch no TV, videogames, or videotapes for 10 d After TV turnoff, children were encouraged children to limit TV, video, and videogame time to 7 hr/wk Each household received an electronic TV time manager to monitor budgeted viewing time	121 (100) 1 school (1 school)	Control Arm: No intervention (CON)	**Primary:** Mean adjusted change in BMI [kg/m2 (95% CI)] Mean adjusted change in triceps skinfold thickness [mm (95% CI)] Mean adjusted change in waist circumference [cm (95% CI)] Mean physical activity, metabolic equivalent-weighted [min/wk (SD)] Mean adjusted change in TV watching [hr/wk (95% CI)] Mean adjusted change in videotape watching [hr/wk (95% CI)] Mean adjusted change in video game playing [hr/wk (95% CI)] Mean adjusted change in time spent engaging in other sedentary behaviors [hr/d (95% CI)]	**Primary:** INT vs CON: -0.45 (CI:-0.73,-0.17) INT vs CON: -1.47(CI:-2.41,-0.54) INT vs CON: -2.30(CI: -3.27,-1.33) No difference between groups INT vs CON: -5.53(CI: -8.64,-2.42) No difference between groups. INT vs CON: -2.54(CI:-4.48,-0.60) No difference between groups.	**S*** **S*** **S**** **NS** **S**** **NS** **S*** **NS**	None		A school based program to reduce television viewing resulted in significant decreases in BMI, triceps skinfold, waist circumference and waist to hip ratio. It also reduced hours per week of television and video games played and reduced eating in front of the TV. This type of intervention may be a promising population based approach to preventing childhood obesity.	Q13. A school based program to reduce television viewing resulted in significant decreases in BMI, triceps skinfold, waist circumference and waist to hip ratio. It also reduced hours per week of television and video games played and reduced eating in front of the TV. This type of intervention may be a promising population based approach to preventing childhood obesity.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
10546696	Robinson TN	Reducing children's television viewing to prevent obesity: a randomized controlled trial	1999																			Mean adjusted change in 20-m shuttle test [laps (95% CI)] Mean daily servings of high-fat foods (SD) NC Mean meals in front of TV [0-3 scale (SD)] decreased Mean frequency of snacking in front of TV [1-3 scale (SD)] NC	No difference between groups. No difference between groups. INT vs CON: -0.54(CI: -0.98,-0.12) No difference between groups.	**NS** **NS** **S*** **NS**				
10710017	Epstein LH	Decreasing sedentary behaviors in treating pediatric obesity	2000	RCT	None	Q10 (RF8, RF11) Q11 (RF8, RF11)	USA	Clinical	None/NR	6 mo	2 yr	Compare the influence of targeting decreases in sedentary behavior vs. increases in physical activity in the comprehensive treatment of obesity	90 families	Parental/ Family/ Caregiver	8-12 yr Child 20-100% overweight	Mean age (SD): Arm 1: 10.0 yr (1.3) Arm 2: 10.7 yr (1.3) Arm 3: 10.6 yr (1.1) Arm 4: 10.7 yr (1.0) Males: Arm 1: 6 Arm 2: 5 Arm 3: 8 Arm 4: 5 Mean SES (SD): Arm 1: 46.3 (9.7) Arm 2: 46.7 (8.6) Arm 3: 49.0 (12.1) Arm 4: 47.8 (10.4)	90 families (76 families)	Behavioral	Arm 1: High Activity increase + nutritional and weight-control counseling + diet Energy expenditure of 32.2 km/wk (HiEx) Arm 2: Low Activity increase + nutritional and weight-control counseling + diet Energy expenditure of 16.1 km/wk (LowEx) Arm 3: High sedentary decrease + nutritional and weight-control counseling + diet (HiSed) Decrease targeted sedentary behaviors to ≤ 20 h/wk Arm 4: Low sedentary decrease + nutritional and weight-control counseling + diet (LowSed) Decrease targeted sedentary behaviors to ≤ 10 h/wk Participants across groups were provided with information about the Traffic Light Diet, including instructions for losing and maintaining weight	NA	No control	**Primary:** Mean overweight % [%,SD] **Secondary:** Mean weight [kg (SD)] Mean BF [% (SD)] Mean PWC at a HR of 150 bpm [kpm (SD)] Mean active time [% (SD)] Mean targeted sedentary time [% (SD)]	**Primary: 24 mos:** HiEx: -13.2(16.4) LowEx: -12.4 (13.3) HiSed: -14.3 (16.9) LowSed: -11.6 (21.9) **Secondary:** HiEx: 9.0(7.2) LowEx:8.9(7.9) HiSed: 9.0(9.3) LowSed: 9.1(10.4) HiEx: -2.1(5.8) LowEx: -0.9(4.2) HiSed: -2.8(3.9) LowSed: -1.9(3.8) HiEx: 200.5(128.3) LowEx: 201.3(79.0) HiSed: 156.8(111.0) LowSed: 202.0(115.9) HiEx: 9.7(26) LowEx: 5.8(12.8) HiSed: 9.6(17.8) LowSed: 2.7(23.8) HiEx: -8.4(25.6) LowEx: -10.9(19.6) HiSed: -12.0(24.7) LowSed: -0.6(25.2)	**S** for all groups combined vs B/L; **NS between groups** **S** for all groups combined vs B/L; **NS between groups** **S** for all groups combined vs B/L; **NS between groups** **S** for all groups combined vs B/L; **NS between groups** **S for all groups combined vs B/L;** **NS between groups** **S for all groups combined vs B/L;** **NS between groups**	Not addressed	No control group makes it hard to interpret these findings	Family-based interventions in obese prepubertal children that targeted increasing activity or decreasing sedentary time combined with diet change were equally effective in producing significant decreases in % overweight, body fat and improved fitness at 2 yr F/U. Intensity of the intervention did not affect the results. Effects seen at 0-24 mo were about 1/2 of what was seen at 0-6 mo.	Q10,11.Family-based interventions in obese prepubertal children that targeted increasing activity or decreasing sedentary time combined with diet change were equally effective in producing significant decreases in % overweight, body fat and improved fitness at 2 yr follow-up.
10965646	Epstein LH	Problem solving in the treatment of childhood obesity	2000	RCT	None	Q10 (RF8) Q11 (RF8)	USA	Clinical	None/NR	6 mo	2 yr	Determine the effects of adding problem-solving training for parents and children or children alone to a comprehensive family-based behavioral childhood obesity treatment	67 families	Parental/ Family/ Caregiver	Child > 20% overweight	Mean age (SD): 10.3 yr (1.1) Males: 25 Caucasian: 97% African-American: 2% Hispanic: 2%	Arm 1: NR (17) Arm 2: NR (18)	Behavioral	Arm 1: Problem solving taught to parents and child (Parent+child) Arm 2: Problem solving taught to child (Child) Group problem solving sessions provided training in problem solving for parents and/or children	NR (17)	Control Arm: Standard family-based treatment (STD) Sessions used didactic methods and provided worksheets and homework not based on problem solving	**Primary:** BMI z score (SD) BMI z score (SD)	**Primary: [B/L to 6 mos]** STD: 2.7+/-0.8 to 1.2+/- 0.8 vs Child: 2.6+/-0.9 to 1.2+/-0.8 vs Parent + child: 2.8+/-0.9 to 1.5+/-0.9 **[Baseline vs 24 mos]** STD: 2.7+/-0.8 to 1.6+/- 1 vs Child: 2.6+/-0.9 to 1.7+/-0.9 vs Parent + child: 2.8+/-0.9 to 2.3+/-1.1	**S for STD vs other groups** **S for STD vs other groups**	None	Behavior problems decreased over time in all groups.	In family-based interventions in obese prepubertal children, standard diet change and exercise program had better results than added problem solving training.	Q10.In family-based interventions in obese prepubertal children, standard diet change and exercise program had better results than added problem solving training.
11323442	Epstein LH	Increasing fruit and vegetable intake and decreasing fat and sugar intake in families at risk for childhood obesity	2001	RCT	None	Q10 (RF8) Q13 (RF9)	USA	Clinical	None/NR	6 mo	12 mo	Evaluate the effect of a parent-focused behavioral intervention on parent and child eating changes and on percentage of overweight changes in families that contain at least 1 obese parent and a non-obese child	30 families	Parental/ Family/ Caregiver	6-11 yr Non-obese (BMI < 85th percentile) At least 1 obese parent (BMI > 85th percentile) No family member on an alternative weight control program No dietary or activity restrictions on participating parent or child	Mean age (SD): Arm 1: 8.8 yr (1.8) Arm 2: 8.6 yr (1.9) Males: Arm 1: 6 Arm 2: 3 Mean number of immediate family members with stroke (SD): Arm 1: 0.6 (0.9) Arm 2: 0.5 (0.7)	30 families (27 families) Arm 1: 15 Arm 2: 15	Behavioral	Arm 1: Parent-focused behavioral intervention + increased fruit and vegetable consumption (Inc F+V) Goal of increasing intake of fruits and vegetables to ≥ 2 servings/d of fruits and 3 servings/d of vegetables Arm 2: Parent-focused behavioral intervention + decreased high-fat/high-sugar food consumption (Dec HiFat/HiSugar) Goal of consuming ≤ 10 servings/wk of high-fat/high-sugar foods All parents received weight control treatment during 8 weekly meetings, 4 biweekly and 2 monthly meetings, and met with an individual therapist and attended a group meeting Parents had a goal of ≥ 30 min/d of moderately intense physical activity ≥ 6 d/wk	N/A	No control	**Primary:** Mean change in fruit and vegetable intake [servings/d (SD)] Mean change in high-fat/high-sugar food intake [servings/d (SD)] **Secondary:** Mean change in percentage of overweight [% (SD)]	**Primary:** Inc F+V: +0.72+/-1.11 Dec HiFat/Hi Sugar: -0.55+/-1.31 Inc F+V: -4.50+/-7.97 Dec HiFat/HiSugar: -8.50+/-7.58 **Secondary**: Inc F+V: -1.10+/-5.29 Dec HiFat/Hi Sugar: -2.40+/-5.39	**NS** **S**** **NS** ** Parents in the Inc F+V group had a significantly greater increase in F+V (p=S*) and a significantly greater decrease in % overweight compared with the Dec HiFat/Hi Sugar group (p=S).	None	None	Interventions targeting obese parents with non-obese children can change diet composition to increase intake of fruits and vegetables (parents) and decrease intake of fat and sugar (parents and children). In this small study, increased fruit and vegetable intake resulted in significantly greater decrease in % overweight in the adult parents but the diet changes did not significantly affect weight status in children.	Q10,13. Diet composition in children can be improved.
11323442	Epstein LH	Increasing fruit and vegetable intake and decreasing fat and sugar intake in families at risk for childhood obesity	2001																Overweight parents followed the Traffic Light Diet and consumed 1,200-1,500 kcal/d Child materials were sent home with the parents each wk									
11331684	Faith MS	Effects of contingent television on physical activity and television viewing in obese children	2001	RCT	None	Q6 (RF8, RF11) Q10 (RF8, RF11)	USA	Home	None/NR	10 wk	12 wk Includes 2 wk baseline phase	Test the effects of contingent TV on physical activity and TV viewing in obese children	10	Pediatric/ Young Adults	BMI > 85th percentile for age and sex Watch ≥ 2 h TV/d Do not engage in regular physical activity	Mean age (SD): Arm 1: 10.2 yr (1.5) Control Arm: 10.0 yr (1.6) Males: Arm 1: 4 Control Arm: 3	6 (NR)	Behavioral	Arm 1: TV viewing contingent on pedaling a stationary cycle ergometer (INT) TV was activated when participants pedaled at a rate corresponding to at least 50% of their maximal oxygen consumption First 3 participants earned 1 min of TV for 1 min cycling (1:1), while second 3 participants earned 2 min TV for 1 min cycling (2:1)	4 (NR)	Control Arm: TV viewing not contingent on cycling (CON)	**Primary:** Mean TV viewing time [hr/wk (SD)] Mean pedaling time [min/wk (SD)] **Secondary:** Mean BMI [kg/m^2 (SD)] Mean weight [kg (SD)] Mean total percent BF [% (SD)] Mean % leg fat [%(SD)]	**Primary:** INT: 22.8(3.8) to 1.1(0.3) CON: 19.8(3.2) to 18.0(3.2) INT: 31.0(6.7) to 55.3(16.5) CON: 53.0(36.0) to 1.5(0.7) **Secondary:** INT: 30.2(3.7) --> 29.9(4.0) CON: 26.0(2.1) --> 27.0(2.5) INT: 67.2(17.1) --> 69.4(18.2) CON: 62.0(10.7) --> 66.8(9.6) INT: 44.5(3.6)-->43.3(2.7) CON: 37.1(3.9) -->38.0(3.7) INT: 48.7(6.6)-->47.1(6.6) CON: 39.0(5.--> 40.0(4.4)	**(p values for difference between groups)** **S**** **S** **NS** **NS** **p=0.06** **S**	None		Contingent TV viewing significantly increased physical activity and reduced TV viewing among participants in a3 month intervention in a very small study group.	Q6 (RF8, RF11) An increase in physical activity and a decrease in sedentary TV time is associated with reduced measures of adiposity. Q10 (RF8, RF11) Physical activity can be increased and sedentary time decreased with associated improvement in measures of adiposity.
11335776	Freemark M	The effects of metformin on body mass index and glucose tolerance in obese adolescents with fasting hyperinsulinemia and a family history of type 2 diabetes	2001	RCT	None	Q10 (RF8) Q13 (RF5, RF6)	USA	Clinical	Double	6 mo	6 mo	Study the effects of metformin on BMI, serum leptin, glucose tolerance, and serum lipids in obese adolescents with fasting hyperinsulinemia and a family history of type 2 diabetes	32	Pediatric/ Young Adults	12-19 yr Obese (BMI > 30 kg/m^2) Fasting insulin concentration > 15 µU/mL At least 1 first- or second-degree relative with type 2 diabetes	Mean age (SE): Arm 1: 14.4 yr (0.6) Control Arm: 15.4 yr (0.5) Males: Arm 1: 3 Control Arm: 8 White: Arm 1: 9 Control Arm: 7 Black: Arm 1: 5 Control Arm: 8	15 (14)	Pharmacologic	Arm 1: Metformin 500 mg bid (MET)	17 (15)	Control Arm: Placebo (CON)	**Primary:** Mean BMI SDS Mean serum leptin [ng/mL (SE)] Mean glucose [mg% (SE)] Mean insulin [µU/mL (SE)] **Secondary:** Mean BMI [kg/m^2 (SE)] Mean TC [mg% (SE)]	**Primary:** MET: -0.12 SD; CON: + 0.23 SD MET females: 57.0(5.4) to 53.8(5.6);no change in males CON females:47.7(7.4) to 55.3(10.9);no change in males MET: 84.9(4.5) to 75.1(1.6); CON: 77.2(2.2) to 82.3(2.7) MET: 31.5(3.4) to 19.2(1.5); CON: 28.0(3.2) to 26.4(7.7) **Secondary:** MET: - 0.5kg/m2; CON: + 0.9 kg/m2 No change	**S between grps** **S; S between grps for females** **NS** **S; NS; S between grps** **S; NS; S between grps** **S; S; S between grps** **NS**	40% of treated patients had abdominal discomfort and diarrhea no episodes of lactic acidosis or vomiting	Insulin sensitivity index improved but insulin sensitivity with the minimal model did not change.	In obese adolescents with hyperinsulinemia, metformin therapy was associated with significant improvement in BMI, fasting glucose and hyperinsulinemia.	Q10,13. In obese adolescents with hyperinsulinemia, metformin therapy was associated with significant improvement in BMI, fasting glucose and hyperinsulinemia.
11691759	Sahota P	Randomised controlled trial of primary school based intervention to reduce risk factors for obesity	2001	RCT	None	Q13 (RF8, RF9, RF11)	England	Community (schools)	None/NR	1 academic yr (Sept 1996-July 1997)	1 academic yr (Sept 1996-July 1997)	Assess if a school based intervention was effective in reducing risk factors for obesity	634 (10 schools)	Pediatric/Young Adults	7-11 yr	Mean age (SD): Arm 1: 8.36 yr (0.63) Control Arm: 8.42 yr (0.63) Boys: Arm 1: 161 Control Arm: 189 Ethnic minority students in schools: 1-42% Students entitled to free school meals: 7-29%	314 (292)	Behavioral	Arm 1: Active program promoting lifestyle education in schools (APPLES) Teacher training, modifications of school meals, and the development and implementation of school action plans designed to promote healthy eating and physical activity	322 (303)	Control Arm: Usual health curriculum	**Primary:** Weighted mean difference in BMI (95% CI) **Secondary:** Weighted mean difference in vegetable intake (95% CI) Weighted mean difference in 24 hr recall of: Foods high in fat (95% CI) Food and drinks high in sugar (95% CI) Fruit intake (95% CI) Weighted mean difference in 3 d diary: Foods high in fat (95% CI) Food and drinks high in sugar (95% CI) Fruit intake (95% CI) Vegetable intake (95% CI) Weighted mean difference in physical activity (95% CI) Weighted mean difference in sedentary behavior (95% CI)	**Primary:** 0 (CI: -0.1,0.1) **Secondary:** 0.3 (CI: 0.2,0.4) No change in any variable below.	**NS** **S** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS**	None		A primary school intervention lasting 1 academic year slightly increased vegetable consumption but had no effect on BMI, any other diet measure or activity.	Q10,13.A primary school intervention lasting 1 academic year slightly increased vegetable consumption but had no effect on BMI, any other diet measure or activity

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
11735093	Kay JP	Beneficial effects of metformin in normoglycemic morbidly obese adolescents	2001	RCT	None	Q10 (RF8) Q13 (RF5, RF14)	USA	Clinical	Double	8 wk	9 wk Includes 1 wk lead-in with hypocaloric diet and placebo	Evaluate the anti-obesity effect of metformin	24	Pediatric/ Young Adults	Adolescents Caucasian Obese (BMI > 30 kg/m^2) Hyperinsulinemic Nondiabetic Exclusions: Fasting glucose > 120 mg/dL HgbA1c ≥ 7.0% History of glucose intolerance, diabetes, renal disorders, previously identified endocrine disorders, and CVD	Mean age (SE): Arm 1: 15.6 yr (0.4) Control Arm: 15.7 yr (0.5) Boys: Arm 1: 5 Control Arm: 4	12 (12)	Pharmacologic	Arm 1: Metformin 850 mg bid + diet (MET) Subjects were initially started on 850 mg metformin once daily and were transitioned to 850 mg metformin bid after 1 wk All subjects received comprehensive nutrition assessments and were instructed to follow a calorie-controlled meal plan of 1,500 and 1,800 calories for females and males, respectively	12 (12)	Control Arm: Placebo (CON) Subjects were initially started on 850 mg placebo once daily and were transitioned to 850 mg placebo bid after 1 wk All subjects received comprehensive nutrition assessments and were instructed to follow a calorie-controlled meal plan of 1,500 and 1,800 calories for females and males, respectively	**Primary:** Mean weight change [kg (SE)] **Secondary:** Mean change in weight [% (SE)] Mean change in body fat [kg (SE)] Mean change in fasting glucose [mg/dL (SE)] Mean change in fasting insulin[uU/mL) Mean change in glucose:insulin ratio [mg/10-4 U (SE)] Mean change in fasting cholesterol [mg/dL (SE)] Mean change in fasting TG [mg/dL (SE)] Mean change in FFM [kg (SE)] Mean change in fasting leptin [ng/mL (SE)]	**Primary:** MET: -6.1 kg +/- 0.7 CON: -3.2 +/- 0.50 **Secondary:** MET: 6.5 +/-0.8 CON: 3.9 +/-0.4 MET: -6.0+/-0.6 CON: -2.7+/-0.51 No difference between groups. MET: -21 +/-6 CON: 11+/-5 No difference between groups. MET: -22+/- 5 CON: -4+/- 7 MET: -39+/-9 CON: -13+/-9 No difference between groups.	**S* between groups** **S between groups** **S* between groups** **NS** **S between groups** **NS** **S between groups** **S between groups** **NS**	Some adverse sx's in metformin group: 3 nausea, 2 dizzy, 2 loose stool -- all resolved; did not report whether controls had adverse sx's.		In obese adolescents with high insulin, metformin resulted in significant weight/fat loss, with accompanying lower insulin and lower TC level.	In obese adolescents with high insulin, metformin resulted in significant weight/fat loss, with accompanying lower insulin and TC levels
11735093	Kay JP	Beneficial effects of metformin in normoglycemic morbidly obese adolescents	2001																			Mean change in OGTT AUC glucose (SE) Mean change in OGTT AUC insulin (SE) Mean change in OGTT AUC glucose:AUC insulin ratio [mg/10-4U (SE)] Mean change in OGTT 2 hr glucose:insulin ratio [mg/10-4U (SE)]	No difference between groups. MET: -11,537+/-2,323 CON: -4219+/-1,967 MET: 0.65+/-0.14 CON: 0.16+/-0.09 MET: 0.64+/-0.14 CON: 0.15+/-0.1`0	**NS** **S** **S*** **S****				
11743058	Epstein LH	Sex differences in obese children and siblings in family-based obesity treatment	2001	RCT	None	Q6 (RF2, RF8) Q10 (RF8)	USA	Clinical	None/NR	6 mo	12 mo	Evaluate sex differences in child weight control programs that targeted increasing physical activity or the combination of reducing sedentary behavior and increasing physical activity	67 families	Parental/ Family/ Caregiver	8-12 yr ≥ 85th BMI percentile for age and sex < 100% over the average BMI for age and sex No medical restrictions on participating parent or child that would prevent exercise	Mean age of children (SD): 10.4 yr (1.2) Boys: 29 White: 94.6% African American: 3.6% Hispanic: 1.8% Mean Hollingshead 4-factor index of SES (SD): 50.0 (0.1)	Arm 1: NR (29 children) Arm 2: NR (27 children)	Behavioral	Arm 1: Increased physical activity + family-based obesity treatment (Ex alone) Reinforced for increases in moderate or greater intensity levels of physical activity defined as 3 multiples of resting metabolic rate or greater; goal to increase activity/wk in 30-min increments from baseline level up to 180 min/wk Arm 2: Increased physical activity + family-based obesity treatment (Combined) Reinforced for increases in moderate or greater intensity levels of physical activity defined as 3 multiples of resting metabolic rate or greater; goal to increase activity/wk in 30-min increments from baseline level up to 180 min/wk AND Reinforced for decreases in TV viewing by 5hr/wk from baseline levels to meet final goal of 15hr/wk	N/A	N/A	**Primary:** Mean percent overweight change (SEM) Mean BMI [kg/m^2 (SD)]	**Primary: [At 12mos]** **Combined:** Boys: -15.8% vs Girls: -1.0% **Ex alone:** Boys: -9.3% vs Girls: -7.6% **Combined**: Boys: -1.76(1.86) vs Girls: +1.00 (1.73) **Ex alone:** Boys: 0.65(1.37) vs Girls: -0.27(1.37)	**S** between sexes for combined** **NS between sexes for Ex alone** **S** between sexes for Combined** **NS between sexes for Ex alone**	None	Adherence to treatment was significantly greater in boys	Family-based interventions in obese prepubertal children that targeted increasing activity and decreasing sedentary time were more effective in males than increasing activity alone. Gender plays a role in how well family based programs work with significantly less change with either intervention in girls	Q6,10. Family-based interventions in obese prepubertal children that targeted increasing activity and decreasing sedentary time were more effective in males than increasing activity alone. Gender plays a role in how well family based programs work with significantly less change with either intervention in girls
11743058	Epstein LH	Sex differences in obese children and siblings in family-based obesity treatment	2001																Both arms were given family-based obesity treatments which included counseling, information about diet and behavior change techniques, and the Traffic Light Diet								
11786598	Saelens BE	Behavioral weight control for overweight adolescents initiated in primary care	2002	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	USA	Clinical	None/NR	4 mo	7 mo	Evaluate the post-treatment and short-term follow-up efficacy of, as well as participant satisfaction for, a 4-month behavioral weight control program for overweight adolescents initiated in a primary care setting and extended through telephone and mail contact	44	Pediatric/Young Adults	12 -16 yr 20%-100% > median (50th percentile) BMI for sex and age Interested in weight control Not currently engaged in another weight control program	Mean age (SD): 14.2 yr (1.2) Boys: 26 (59.1%) White: 70.5% Hispanic: 15.9% African American: 4.5% Asian: 2.3% Multi-ethnic: 6.8% Single parent homes: 24% Parents reported median household income: $60,000-$69,000	23 (18)	Behavioral	Arm 1: Healthy Habits weight control program (HH) Individualized guidance plans were delivered through a computer program adopted from the Patient Centered Assessment and Counseling for Exercise plus Nutrition (PACE+) software or over the telephone to increase physical activity/decrease sedentary behavior, decrease dietary fat or increase fruits/vegetables, or decrease overeating/snacking Goal of reducing caloric intake to 1200-1500 kcal/d Goal of ≥ 60 min moderate intensity physical activity 5 d/wk Assistance was given to overcome personal barriers	21 (19)	Control Arm: Typical care (CON) 1 session of weight counseling provided by a pediatrician Pediatricians assessed and encouraged motivation for weight-related behavior change, provided information about short- and long-term health consequences of high weight and benefits of weight control, making recommendation of healthful eating consistent with the Food Guide Pyramid, review of physical activity recommendations of 60 min/d for adolescents and encourage consistency and persistence with health behavior change	**Primary:** BMI z scores Mean BMI [kg/m2 (SD)] Mean weight [kg (SD)] **Secondary:** Mean physical activity [kcal/kg/d (SD)] Mean sedentary behavior [min/d (SD)] Mean calories from fat [% (SD)] Mean calories [kcal/d (SD)]	**Primary:** HH: 2.07 to 2.02 at 4m and 2.0 at F/U CON: 2.1 to 2.15 at 4m and at F/U. HH: 31.0(-3.5) to 30.9(3.8) at 4 m, 31.1(4.5) at F/U CON: 30.7(-3.1) to 31.8(3.4) at 4m & 32.1(-3.8) at F/U. HH: 85.5(13.9) to 86.1(14.0) at 4m & 87.5(16.0) at F/U CON: 80.5(13.5) to 84.1(13.8) at 4m & 85.8(14.6) at F/U **Secondary:** No change within or between groups. No change within or between groups. No change within or between groups. HH: 2010(903) to 1919(653) at 4m & 1820(677) at F/U CON: 2062(564) to 1715(540) at 4m & 1640(608) at F/U.	**S for group by time interaction.** **All other results NS.**	None		A 4 m multiple component behavioral intervention initiated in primary care with continuing telephone and mail contact vs. a single session of physician counseling "usual care" led to a modest decrease in weight status (BMI Z-score) among overweight adolescents.	Q10. A 4 m behavioral intervention initiated in primary care with continuing telephone and mail contact can lead to a modest decrease in weight status among overweight adolescents. Q13. There were no measurable changes in diet or exercise behavior.
11976154	Gutin B	Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents	2002	RCT	None	Q10 (RF8)	USA	Clinical	None/NR	8 mo	2 school yr Study was conducted in 2 8-mo cohorts	Determine the effects of physical training intensity on cardiovascular fitness, percentage of body fat, and visceral adipose tissue of obese adolescents	80	Pediatric/ Young Adults	13-16 yr Obese (triceps skinfold thickness > 85th percentile for sex, ethnicity, and age) No involvement in any other weight control or exercise program No restriction from engaging in physical activity	Mean age (SD): White boys: 14.5 yr (0.4) White girls: 15.3 yr (0.3) Black boys: 14.1 yr (0.3) Black girls: 15.2 yr (0.2) Boys: 26 White: 25 Black: 55	80 (61)	Behavioral	Arm 1: Lifestyle education (Ed) 1 h every 2 wk Information on nutrition, physical activity, behavior modification, and psychosocial factors related to obesity Arm 2: Lifestyle education + moderate-intensity physical training (ModEx) Physical training 5 d/wk Energy expenditure of 55-60% of peak VO2 Estimated energy expenditure held at approximately 1,045 kJ/session Arm 3: Lifestyle education + high-intensity physical training (HiEx) Physical training 5 d/wk	N/A	No control	**Primary:** LS mean change in fat mass [kg (SEM)] LS mean change in percent BF [% (SEM)] LS mean change in fat-free soft tissue [kg (SEM)] LS mean change in VO2-170 [mL/kg/min (SEM)] LS mean change in VO2max [mL/kg/min (SEM)] LS mean change in moderate physical activity [min/d (SEM)] LS mean change in VPA [min/d (SEM)] Visceral adipose tissue [cm3] Dietary energy[kJ/d]	**Primary:** Ed: +1.62 +/-0.92 vs Mod+HiEx:-0.73+/-0.87 Ed: 0.19+/-0.62 vs Mod+HiEx: -3.57+/-0.80 Ed: 1.80+/-0.55 vs Mod+HiEx:1.69+/-0.52 Ed: -0.33 +/-0.51 vs Mod+HiEx: 3.56+/-0.58 Ed: -0.40+/-0.71 vs Mod+HiEx: 1.72 +/-0.60 Ed: 3.63+/-4.79 vs Mod+HiEx: -0.87+/-4.43 Ed: -3.63 +/- 6.10 vs Mod+HiEx: 6.40 +/- 5.66 Ed: -11.0(10.0) vs Mod+HiEx:-42.0(9.3) Ed: 84(397) vd Mod+HiEx: 407(369)	**NS** **S** between groups** **NS** **S**** **S** **NS** **NS** **S** **S***	None	When exercise groups are separated, the only significant changes were higher degree of fitness in high intensity exercise group.	In obese adolescents, a combined lifestyle education and exercise program sustained for 8 months produced significant improvements in C-V fitness and decreases in total body fat, and visceral abdominal fat despite higher calorie intake.	Q10. A combined lifestyle education and exercise program improved C-V fitness and body composition in obese youths despite higher calorie intake.
11976154	Gutin B	Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents	2002																Energy expenditure of 75-80% of peak VO2 Estimated energy expenditure held at approximately 1,045 kJ/session								

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
11986479	Mitchell BM	Left ventricular structure and function in obese adolescents: relations to cardiovascular fitness, percent body fat, and visceral adiposity, and effects of physical training	2002	RCT	LV mass	Q2 (RF8, RF11) Q10 (RF8) Q13 (RF11)	NR	Clinical	None/NR	8 mo	8 mo	Determine the correlations of cardiovascular fitness and adiposity to left ventricular parameters in obese adolescents and to see the effect of 8 months of physical training at low and high intensities	81	Pediatric/ Young Adults	13-16 yr Tricep skin fold thickness > 85th percentile for gender, ethnicity, and age No involvement in any other weight control or exercise program No restriction from engaging in physical activity	Mean age (SD): 14.9 (1.3) Boys: 26 Black: 55 White: 25	Arm 1: NR (15) Arm 2: NR (20)	Behavioral	Arm 1: Lifestyle education (ED) LSE sessions offered once every 2 wk. Included principles of learning and behavior modification, information about nutrition and physical training, discussions of various aspects of food consumption process, psychosocial factors related to obesity and problem/coping skills Arm 2: LSE+ physical training (moderate or high intensity) (EX) LSE sessions offered once every 2 wk. Included principles of learning and behavior modification, information about nutrition and physical training, discussions of various aspects of food consumption process, psychosocial factors related to obesity and problem/coping skills	N/A	N/A	**Primary:** LVM [g (SEM)] **Secondary:** Visceral adipose tissue [cm3 (SEM)] Body fat [% (SEM)] VO2-170 [mL/kg/min (SEM)] MFS [(%)SEM)] RWT [(cm)(SEM)] IVSD [(cm)(SEM)] LVPWD [(cm)(SEM)] RWT [(cm)(SEM)]	**Primary:** ED: 1290.3(6.8) to 143.3(9.1) EX: 117.5(7.4) to 131.0(5.7) **Secondary:** ED: 196(29) to 286(29) EX: 302(28) to 254(21) ED: 45.5(1.6) to 45.3(1.7) EX: 44.8(1.4) to 43.0(1.5) ED: 20.1(1.1) to 19.8(1.0) EX: 19.1(0.9) to 21.8(1.0) No change in any of these echo measures.	**NS** **S between groups** **S between groups** **S between groups** **NS**	None	No difference between high and moderate physical activity groups so in their analysis, the groups were combined.	In obese adolescents, an 8 m physical training program which improved CV fitness and slightly reduced general and visceral adiposity had no effect on LV mass.	Q2,10,13. In obese adolescents, an 8 m physical training program which improved CV fitness and slightly reduced general and visceral adiposity had no effect on LV mass.
12218734	Humphries MC	Relations of adiposity and effects of training on the left ventricle in obese youths	2002	RCT	LV mass	Q2 (RF4) Q4 (RF4, RF8) Q10 (RF8) Q12a (RF8) Q13 (RF4, RF11)	USA	Clinical	None/NR	8 mo	8 mo	Determine the relations of LV structure and function to total body composition, VAT, and hemodynamics in obese children; determine the effects of 4 mo of physical training on LV structure and function and hemodynamics; and explore determinants of individual variability in response to physical training	79	Pediatric/ Young Adults	7-11 yr Obese (triceps skinfold thickness > 85th percentile) No involvement in any other weight control or exercise program No restrictions on their physical activity Not involved in sports training Not on a special diet	Mean age (SE): Boys: 9.8 yr (0.19) Girls: 9.4 yr (0.13)	40 (37)	Behavioral	Arm 1: Formal physical training for 4 mo followed by no physical training for 4 mo 40 min sessions 5 d/wk Target HR > 150 bpm	39 (33)	Control Arm: No physical training for 4 mo followed by formal physical training for 4 mo Same physical training regimen as in Arm 1	**Primary:** Mean change in percent BF [% (SE)] Mean change in FFM [kg (SE)] Mean reactive HR [bpm (SE)] Mean LV mass [g (SE)] Mean change in LV mass corrected for height [g·m (SE)] **Secondary:** Mean LV mass corrected for height [g·m (SE)] Mean resting SBP [mmHg (SE)] Mean change in resting SBP [mmHg (SE)] Mean reactive SBP [mmHg (SE)] Mean change in reactive SBP [mmHg (SE)] Mean change in fat mass [kg (SE)] Mean resting HR [bpm (SE)] Mean change in resting HR [bpm (SE)] Mean change in reactive HR [bpm (SE)]	**Primary: [After 4m INT]** - 1.60 (0.34) + 1.93 (0.16) - 3.89 (1.86) + 8.22 (2.94) No change **Secondary:** NC NC NC NC NC NC NC NC NC	**S**** **S**** **S** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS**	None		A 4 mo training program for obese adolescent males resulted in decreased body fat ,increased FFM, decreased mean reactive HR and increased LV mass. However, LVM corrected for height did not change. LV mass increases with VAT as does CO.	Q2,4,10,12a,13. Elevated LV mass is associated with general and visceral adiposity. A 4 month training program reduced some measures of adiposity but had no effect on LV mass/ht.
12471297	Kang HS	Physical training improves insulin resistance syndrome markers in obese adolescents	2002	RCT	None	Q6 (RF2, RF4, RF5, RF8, RF11) Q10 (RF8)	USA	Clinical	None/NR	8 mo	20 mo Study was conducted in 2 cohorts such that half of subjects participated in first yr and half in second yr	Test the hypothesis that physical training, especially high-intensity physical training, would have a favorable effect on components of the insulin resistance syndrome in obese adolescents	80	Pediatric/ Young Adults	13-16 yr Obese Tricep skinfold thickness > 85th percentile for gender, ethnicity, and age No involvement in any other weight control or exercise program No restriction from engaging in physical activity	Mean age (SE): White boys: 14.5 yr (0.4) White girls: 15.3 yr (0.3) Black boys: 14.1 yr (0.3) Black girls: 15.2 yr (0.2) Boys: 26 White: 25 Black: 55	80 (59)	Behavioral	Arm 1: Lifestyle education classes 1 hr every 2 wk (Ed) Information on nutrition and physical activity, behavior modification, psychosocial factors related to obesity, and problem solving/coping skills Arm 2: Lifestyle education classes + moderate-intensity physical activity 5 d/wk (ModEx) Mean prescribed HR of 137 bpm with estimated energy expenditure held constant at approximately 1,045 kJ Arm 3: Lifestyle education classes + high-intensity physical activity 5 d/wk (HiEx)	N/A	N/A	**Primary:** Mean change in BF [% (SEM)] Mean change in VAT [cm3 (SEM)] Mean change in glucose [mmol/L (SEM)] Mean change in insulin [pmol/L (SEM)] Mean change in DBP [mmHg (SEM)] Mean change in SBP [mmHg (SEM)] Mean change in plasma TG [mmol/L (SEM)] Mean change in LDL-C [mmol/L (SEM)] Mean change in HDL-C [mmol/L (SEM)] Mean change in VLDL-C [mmol/L (SEM)] Mean change in TC [mmol/L (SEM)] Mean change in LDL size (A) Mean change in cardiovascular fitness [ml/kg*min (SEM)]	**Primary:** Ed: 0.19(0.62) vs Mod+HiEx:-3.57(0.80) Ed: -11.00(10.0) vs Mod+HiEx: -42.00(9.3) Ed: 0.46(0.07) vs Mod+HiEx: 0.40(0.07) Ed:23.42(17.07) vs Mod+HiEx:-17.85(17.32) Ed: -1.30(1.40) vs Mod+HiEx: -4.16(1.30) Ed: 1.50(2.92) vs Mod+HiEx:-3.73(2.70) Ed: 0.12(0.08) vs Mod+HiEx:-0.22(0.08) Ed: -0.02(0.11) vs Mod+HiEx: -0.08(0.10) Ed: -0.03(0.04) vs Mod+HiEx: -0.03(0.04) Ed: 0.12(0.04) vs Mod+HiEx:0.04(0.04) Ed: 0.24(0.10) vs Mod+HiEx: -0.03(0.09) Ed: -1.92(1.71) vs Mod+HiEx: 4.18(1.96) Ed: -0.33(0.51) vs Mod+HiEx: +3.56(0.58)	**S**** **S** **NS** **NS** **NS** **S*** **NS** **NS** **S**** **NS** **S*** **S****	None	When exercise groups are separated, the only significant changes were higher degree of fitness, greater decrease in TGs & VLDL and greater increase in LDL particle size with high intensity exercise.	A combined LSE and exercise program sustained for 8 months produced significant improvement in C-V fitness and decreases in total body fat, visceral abdominal fat, TGs and VLDL plus an increased LDL particle size.	Q6 Increased total body fat and abdominal fat cluster with features of the MetS. Q10 A decrease in total body fat and abdominal fat and an improvement in metabolic variables can be achieved with lifestyle education and exercise.
12640371	Sondike SB	Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents	2003	RCT	None	Q10 (RF8) Q13 (RF5, RF9)	USA	Clinical	None/NR	12 wk	12 wk	Compare effects of low-CHO diet with those of low-fat diet on weight loss and serum lipids in overweight adolescents	39	Pediatric/ Young Adults	12-18 yr BMI > 95th percentile for age Exclusions: Diabetes mellitus FH	Mean age (SD); Arm 1: 14.4 yr (1.9) Control Arm: 15.0 yr (1.8)	20 (16)	Behavioral	Arm 1: Low-CHO diet (LoCARB) < 20 g/d of CHO for 2 wk, followed by < 40 g/d of CHO for 10 wk, and consumption of low-CHO foods according to hunger	19 (14)	Control Arm: Low-fat diet (Lo Fat) < 40 g/d of fat, with 5 servings/d of starch (15 g of CHO/serving) and an ad libitum intake of fat-free dairy foods, fruits, and vegetables	**Primary:** Mean BMI [kg/m2 (SD)] Mean weight change[kg(SD)] Mean TC [mg/dL (SD)] Mean LDL-C [mg/dL (SD)] Mean HDL-C [mg/dL (SD)] Mean TG [mg/dL (SD)] Mean non HDL-C [mg/dL (SD)] **Secondary:** Mean energy intake [kcal/d (SD)] Mean fat intake [% total daily cal] Mean cholesterol intake [mg/d (SD)] Mean saturated fat intake [% total daily cal]	**Primary:** **Lo CARB:** -3.3(3.0) vs **LoFat:** -1.5(1.7) **Lo CARB:** -9.9(9.3) vs **Lo Fat:** -4.1(4.9) **Lo CARB:** -3.7(18.0) vs **LoFat:** -17.3(15.8) **Lo CARB:** +3.8(13) vs **LoFat:** -25.1(25.3) No change in either group **Lo CARB:** -48.3(29.0) vs **LoFat:** -5.9(70.0) **Lo CARB:** -26.0(22.3) vs **LoFat:** -13.6(13.4) **Secondary:** **Lo CARB:** 1830(615) vs LoFat: 1100(297) **Lo CARB:** 59.6(10.0) **vs LoFat:** 12.3(1.6) **Lo CARB:** 667(216) **vs LoFat:** 164(57) **Lo CARB:** 22.0(16) vs **LoFat:** 6.8(6.3)	**S between grps** **S between grps** **NS vs S from baseline; NS between grps** **NS vs S from baseline; S* between grps** **NS** **S vs NS from baseline; p=.07 between grps** **S from B/L for both; S between grps** **S** **S**** **S*** **S****	None		In overweight adolescents, a low carbohydrate diet was more effective in decreasing wt and BMI than a low fat, low calorie diet. Total and LDL cholesterol levels decreased significantly more with the low fat diet but there were no adverse effects on lipid profile with the low carbohydrate diet.	Q10,13. In overweight adolescents, a low carbohydrate diet was more effective in decreasing wt and BMI than a low fat, low calorie diet. Total and LDL cholesterol levels decreased significantly more with the low fat diet but there were no adverse effects on lipid profile with the low carbohydrate diet.
12684359	Berkowitz RI	Behavior therapy and sibutramine for the treatment of adolescent obesity: a randomized controlled trial	2003	RCT	None	Q6 (RF5, RF8, RF14) Q10 (RF8) Q13 (RF5, RF14)	USA	Clinical	Double	12 mo Includes 6 mo open-label period	12 mo	Examine whether increased weight loss in obese adolescents is induced when sibutramine is added to a family-based, behavioral weight control program	82	Parental/ Family/ Caregiver	13-17 yr Boys and girls BMI of 32-44 kg/m^2 Exclusions: CVD Type 1 or 2 diabetes mellitus Cigarette smoking	Mean age (SD): 14.1 yr (1.2) Males: 27 White: 45 Black: 34 Other race: 3 Mean maternal level of education (SD): 3.1 yr (1.1)	43 (34)	Pharmacologic	Arm 1: Behavior therapy + sibutramine 5-25 mg/d Period 1: Placebo controlled Placebo wk 0-1 Sibutramine 5 mg/d wk 2 Sibutramine 10 mg/d wk 3-6 Sibutramine 25 mg/d wk 7-24 Period 2: Open-label treatment Sibutramine 25 mg/d wk 25-48 13 weekly family-based behavioral weight-loss sessions, followed by biweekly sessions and then monthly sessions; adolescents were prescribed a restricted diet and physical activity Participants whose SBP or DBP increased 10 mmHg or more (or who had increases in pulse rate) had their medication dose reduced in 5 mg decrements until acceptable values were obtained	39 (23)	Control Arm: Behavior therapy + placebo Period 1: Placebo controlled Placebo wk 0-24 Period 2: Open-label treatment Sibutramine 25 mg/d wk 25-48 13 weekly family-based behavioral weight-loss sessions, followed by biweekly sessions and then monthly sessions; adolescents were prescribed a restricted diet and physical activity During Period 2, participants were treated with sibutramine following the same dose titration schedule used by Arm 1 in Period 1	**Primary:** Mean difference in weight [kg (95%CI)] Mean difference in BMI [% (95%CI)] Mean difference in BMI z score (95%CI) **Secondary:** Mean difference in waist circumference [cm (95%CI)] Mean change in TG [% (SD)] Mean change in TC [% (SD)] Mean change in HDL-C [% (SD)] Mean change in LDL-C [% (SD)] Mean change in insulin [% (SD)] Mean change in serum glucose [% (SD)] Mean change in HOMA [% (SD)]	**Primary:** 4.6 (2.0, 7.4) 4.5 (1.8, 7.2) 0.1 (0.04, 0.2) **Secondary:** 5.4 cm (2.5, 8.2) No significant differences in other secondary outcomes	**S** between groups** **S** between groups** **S* between groups** **S***	None	SBP ~0.5 mm Hg higher in active than placebo, after efforts throughout to lower dose to manage bp elevation Pulse higher by 5-7 bpm 19 of 43 in active group had dosage lowered due to higher pulse or BP.		In obese adolescents, the addition of sibutramine to a behavioral wt loss program significantly increased wt loss over 6 mos, less over 12 mos. There is concern re: slightly higher BP with sibutramine.	Q10,13. In obese adolescents, the addition of sibutramine to a behavioral wt loss program significantly increased wt loss over 6 mos, less over 12 mos. There is concern re: slightly higher BP with sibutramine.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
12912783	Ebbeling CB	A reduced-glycemic load diet in the treatment of adolescent obesity	2003	RCT	None	Q10 (RF8) Q13 (RF9, RF14)	USA	Clinical	None/NR	6 mo	12 mo	Compare the effects of an ad libitum, reduced-glycemic load diet with those of an energy-restricted, reduced-fat diet in obese adolescents	16	Pediatric/ Young Adults	13-21 yr Obese (BMI > sex- and age-specific 95th percentile)	Males: 5 White: 13 Non-white: 3	8 (7)	Behavioral	Arm 1: Reduced glycemic load dietary treatment + behavioral therapy + physical activity recommendations(GLY) 6 mo intensive intervention (12 treatment sessions) plus 6 mo follow-up (2 treatment sessions) Diet emphasized selection of CHO-containing foods that are characterized by a low to moderate glycemic index Target proportions of energy from CHO and fat were 45-50% and 30-35%, respectively	8 (7)	Control Arm: Reduced fat dietary treatment + behavioral therapy + physical activity recommendations(CONV) Diet was based on current recommendations for weight loss and diabetes prevention, with emphasis on limiting dietary fat intake and increasing the intake of grains, vegetables, and fruits Subjects were counseled to obtain 55-60% of energy from CHO, 25-30% from fat, and the remainder from protein	**Primary:** Mean change in BMI [kg/m2 (SEM)] Mean change in fat mass [kg (SEM)] Mean HOMA [mU/mL·mmol/L (SEM)] **Secondary:** Mean glycemic load[g/1000 kcal (SEM)] Mean fat intake [%E (SEM)] Mean energy intake [kcal (SEM)] Mean CHO intake [%E (SEM)]	**Primary:** GLY: -1.3+/-0.7 vs CONV: + 0.7+/-0.5 GLY: -3.0+/-1.6 vs CONV:+ 1.8+/-1.8 GLY: -0.4+/-0.9 vs CONV: + 2.6 +/-1.2 **Secondary:** GLY: 86.5+/-5 to 69+/-6. NC in CONV. NC in GLY. CONV: 33+/-1 to 29+/-3. GLY: 2214 +/- 294 to 1621 +/- 159; CONV: 1752 +/- 140 to 1439 +/- 104 GLY: 58 +/- 3 to 52 +/-4; CONV: 52+/-1 to 55+/-2 By bivariate analysis, GL was a strong predictor of change in body fat in both groups (r squared = 0.51, p=S*). No association with dietary fat.	**S vs. NS from B/L; S between groups** **S* vs. NS from B/L; S between groups** **S between groups** **S* vs. NS from B/L** **NS vs. S from B/L** **NS from B/L; NS between groups** **NS from B/L** **S (6 mo); NS (12 mo)** **NS**	None	Change in glycemic load was a strong predictor of change in body fat from 0 to 6 mos, explaining 51% of the variance in both groups combined, whereas change in dietary fat was not significantly associated with change in body fat (R2 = .14, p=NS).	In obese, insulin resistant adolescents, all measures of adiposity decreased significantly more in response to a low glycemic load diet than to a conventional low fat, reduced calorie diet. In addition, insulin resistance did not change in the reduced glycemic load group while increasing significantly in the reduced fat group.	Q10. In obese, insulin resistant adolescents, all measures of adiposity decreased significantly more in response to a low glycemic load diet than to a conventional low fat, reduced calorie diet. Q13. Diet changes were sustained by both the low glycemic load and low fat groups at 12 m post initiation.
14513074	Balagopal P	Effect of lifestyle changes on whole-body protein turnover in obese adolescents	2003	RCT	None	Q6 (RF8, RF11) Q10 (RF8) Q13 (RF11, RF14)	USA	Clinical	None/NR	3 mo	3 mo	Investigate the effect of lifestyle changes on whole-body protein turnover in obese adolescents	16	Parental/ Family/ Caregiver	14-18 yr Obese (BMI > 30 kg/m^2) Normal fasting glucose levels Exclusions: Actively participating in any exercise ≥ 20 min 2 times per wk or more Participating in any diet programs Heart disease Diabetes Chronic liver or renal disease Smokers	Mean age (SEM): Arm 1: 15.6 yr (0.3) Control Arm: 15.9 yr (0.5)	8 (8)	Behavioral	Arm 1: Moderate physical activity and lifestyle changes Program was based on a weight management program called "Shapedown" and involved regular physical activity and changes in diet and behavior Physical activity 45 min 3 times/wk; family joined 1 session/wk Met with nutritionist once/wk and restricted calories	8 (7)	Control Arm: No changes to basic lifestyle 6 lean adolescents matched for age served as a reference group	**Primary:** Whole body protein turnover (WBPT) **Secondary:** Mean weight [kg (SE)] Mean BMI[kg/m2(SD)] Mean Body Fat [% (SE)] Mean FFM [% (SE)] Resting energy expenditure Mean fasting insulin concentration [pmol/L (SEM)]	**Primary:** Whole body protein turnover increased in obese vs lean controls; post intervention, there was a significant decrease in WBPT in OB INT but not in OB CON. **Secondary:** INT: 105.8+/-5.2 to 104.5+/-5.3 CON: 115.9+/-12.8 to 117.3+/-12.9 INT: 38.1(3.1) to 37.5(2.1) CON: 41.2(4.2) to 42.4(4.4) INT: 45.5+/-2.3 to 39.2+/-2.3 vs CON: 43.6 +/- 2.0 to 44.3 +/- 1.9 INT: 57.3(3.8) to 63.6(4.1) CON: 58.2(3.2) to 58.1(3.2) No significant change Results as figure only - decreased in INT, NC in CON	**Primary:** **Ob vs lean S; Ob INT vs Ob CON S** **Secondary:** **NS for decrease;S between groups** **S for increase** **NS for decrease;S between groups** **S for increase** **S* for decrease;S** between groups** **S* for increase** **S* for increase** **NS** **NS for both groups** **S* for INT, NS for CON**	None	Although weight did not change body composition did. Very small study groups.	Abnormalities in protein metabolism occur early in the clinical course of obesity These abnormalities are modifiable by moderate lifestyle changes without significant weight change but with decreased BF and increased FFM in obese adolescents	Abnormalities in protein metabolism occur early in the clinical course of obesity These abnormalities are modifiable by moderate lifestyle changes without significant weight change but with decreased BF and increased FFM in obese adolescents.
14559927	Zhi J	The effect of short-term (21 day) orlistat treatment on the physiologic balance of six selected macrominerals and microminerals in obese adolescents	2003	RCT	None	Q10 (RF8)	USA	Clinical	Double	21 d	21 d	Assess whether orlistat affects the physiologic balance of 3 macrominerals (calcium, phosphorus and magnesium) and 3 microminerals (iron, zinc and copper)	32	Pediatric/ Young adults	12-16 yr Obese BMI ≥ 85th percentile adjusted for age and gender	Mean age (SD): Arm 1: 14 yr (1) Control Arm: 14 yr (1) Males: Arm 1: 7 Control Arm: 6 Caucasian: Arm 1: 6 Control Arm: 9 Black: Arm 1: 4 Control Arm: 3 Hispanic: Arm 1: 6 Control Arm: 4	16 (15)	Pharmacologic	Arm 1: Orlistat 120 mg tid + diet (ORL) Hypocaloric diet consisting of 30% fat every 3 d Diet mineral composition met US Dietary Reference Intakes for children	16 (15)	Control Arm: Placebo tid + diet (PLAC) Hypocaloric diet consisting of 30% fat every 3 d Diet mineral composition met US Dietary Reference Intakes for children	**Primary:** Calcium balance [mmol(SE) Copper balance[umol(SEM)] Iron balance [umol(SEM)] Magnesium balance [mmol(SEM)] Phosphorus balance [mmol(SEM)] Zinc balance [mmol(SEM)] **Secondary:** Mean weight loss [%]	**Primary:** ORL: 2.3(1.2) vs PLAC: 1.9(1.5) ORL: 0.6(0.7) vs PLAC: 0.1(0.7) ORL: -64.7(20.4) vs PLAC: -40.4(10.1) ORL:3.0(0.2) vs PLAC: 2.7(0.2) ORL:6.4(1.3) vs PLAC: 5.8(1.3) ORL:7.6(8.9) vs PLAC: 5.0(5.3) **Secondary:** ORL: 7.0 vs PLAC: 7.8	**NS** **NS** **NS** **NS** **NS** **NS** **NS**	No major AEs in either group. Orlistat group had more GI complaints.	Negative iron balance in both groups, not explained - larger in orlistat group but difference with placebo not significant. Orlistat inhibited fat absorption by ~27%.	In a small study of mineral balance during orlistat treatment in obese adolescents, there were no significant differences in mineral balance during a 21 day trial.	Q 10. In a small study of mineral balance during orlistat treatment in obese adolescents, there were no significant differences in mineral balance during a 21 day trial.
14636810	Going S	The effects of the Pathways Obesity Prevention Program on physical activity in American Indian children	2003	RCT	None	Q10 (RF8,RF11)	USA	Community (schools)	None/NR	NR	3 yr	Test the effectiveness of school- and family-based interventions for the primary prevention of obesity in American Indian students	1,704 (41 schools)	Parental/ Family/ Caregiver	American Indian	Mean age (SE): 7.6 yr (0.8)	NR (238)	Behavioral	Arm 1: Physical activity intervention (EX) Physical education ≥ 3 times/wk for at least 30 min per class; daily recess ≥ 15 min and 1-2 exercise breaks per d for 5-10 min encouraged Focused on increasing the frequency and quality of physical education classes and activity breaks, promoted positive attitudes toward physical activity, and sought to develop motor skills to cultivate and sustain an active lifestyle	NR (219)	Control Arm: No treatment (CON)	**Primary:** Mean TriTrac average vector magnitude [trt/time (SE)] Mean BMI [kg/m^2 (SE)] Mean percent fat (SE)	**Primary:** 24h: EX: 267.9(12.8) vs CON: 248.6(12.8) 9-7: EX: 479.2(33.5) vs CON: 433.2(33.9) EX: 22.5(1.16) vs CON:22.5(1.15) EX: 40.4(0.98) vs CON: 40.1(0.95) INT group 7-10% more active	**NS** **NS** **NS** **NS**	None	Only 16% of subjects had activity level measured at both baseline and F/U.	A school-based intervention to increase physical activity showed no significant changes in physical activity measured by accelerometer or obesity measures at 3 y F/U.	Q10. A school-based intervention to increase physical activity showed no significant change at 3 y F/U.
14695360	Warren JM	Evaluation of a pilot school programme aimed at the prevention of obesity in children	2003	RCT	None	Q13 (RF8, RF9, RF11)	UK	Community (schools)	None/NR	20 wk	20 wk	Evaluate effectiveness of pilot school program to prevent obesity in children	218 (3 schools)	Pediatric/ Young Adults	5-7 yr	Mean age (SD): 6.1 yr (0.6) Males: 111 Caucasian: 89% Percent of parents with either a degree or a post graduate qualification: 39%	164 (NR) Arm 1: 56 (NR) Arm 2: 54 (NR) Arm 3: 54 (NR)	Behavioral	Arm 1: Nutrition education group, "Eat Smart" Included promotion of fruit and vegetable consumption, positive messages about high starch foods, and quizzes, flash cards, and craftwork as teaching aids Arm 2: Physical activity group, "Play Smart" Explored concepts of energy and activity and promoted playground activity and reduction in television viewing Arm 3: Combined nutrition education and physical activity group, "Eat Smart Play Smart"	54 (NR)	Control Arm: Educational program, "Be Smart" Educated children about food in a non-nutrition sense	**Primary:** Overweight subjects [%] Obese subjects [%] Mean weekly frequency of vegetable consumption Mean weekly frequency of salad consumption Mean weekly frequency of fruit consumption Subjects active during morning playground break [%] Subjects active during lunchtime playground break [%] Subjects with increased nutrition knowledge [%]	**Primary:** PRE: 8% to POST: 8% PRE: 4% to POST: 3% Increased No change Increased Increased but not significant Increased but change not significant Increased in all groups	**NS from B/L; NS between groups** **NS from B/L; NS between groups** **S** **NS** **S*** **NS** **NS** **S* - S******	None	Low prevalence of obesity across all groups at baseline (< 5%).	In 5-7 y olds, there was no change in prevalence of overweight/ obesity after a school-based intervention despite small changes in eating behavior and significant increase in nutrition knowledge.	Q120,13.In 5-7 y olds, there was no change in prevalence of overweight/ obesity after a school-based intervention despite small changes in eating behavior and significant increase in nutrition knowledge.
15066949	Woo KS	Effects of diet and exercise on obesity-related vascular dysfunction in children	2004	RCT	Multiple	Q 9,10,12a	Hong Kong/ Australia	Clinical	Single	1 yr 6 wk	1 yr 6 wk	Evaluate the reversibility of obesity-related arterial dysfunction and carotid intima-media thickening by weight change related to a dietary and/or exercise intervention program.	170	Parental/ Family/ Caregiver	9-12 yr Overweight or obese (BMI ≥21) No known medical illness and no alternative cause for their obesity No family history of premature CVD Not taking any regular medications or vitamin supplementation Have resting brachial artery diameter > 2.5 mm Exclusions: History of diabetes, renal disease, or CVD Sexual maturity status more advanced than Tanner stage 2	Mean age: 9.9 yr Males: 54 54 chidren were obese (BMI>23) and 28 were overweight (BMI 21-23)	41 (41)	Behavioral	Phase I: Dietary modification and regular supervised exercise program for 6 wk (D + EX) Phase II: Continued weekly exercise program or stopped exercise program but continued twice monthly diet monitoring program for 1 yr (No EX; CT EX) Dietary intervention included interviews with same dietician used by comparison group (twice weekly for first 6 wk and then twice monthly for 1 yr) and diet that provided 900-1200 kcal daily. Diet was low in fat, high in complex carbohydrate, and sufficient in protein to support growth. Exercise training supervised by same physiotherapist team and consisted of 18 workout stations; each child did 9 stations , twice a week for 6 wk, then once weekly for 1 yr.	41(41)	Phase I: Dietary modification (D) Phase II: Continued twice monthly diet monitoring program for 1 yr Dietary intervention included interviews with same dietician used by comparison group (twice weekly for first 6 wk and then twice monthly for 1 yr) and diet that provided 900-1200 kcal daily. Diet was low in fat, high in complex carbohydrate, and sufficient in protein to support growth.	**Primary:** Endothelium dependent arterial function(EDD)[%(SD)] Carotid intima media thickness(CIMT)[mm(SD)] **Secondary:** BMI [kg/m2(SD)] Body fat percent [%(SD)] Waist-hip ratio[SD] Total cholesterol[mmol(SD)] LDL-C [mmol(SD)] HDL-C [mmol(SD)] TG [mmol(SD)] **AT 1 YEAR:** Endothelium dependent arterial function(EDD)[%(SD)] Carotid intima media thickness(CIMT)[mm(SD)] BMI [kg/m2(SD)]	**Primary: At 6 weeks:** D + EX: 6.8(2.0) to 8.0(1.8); D: 6.9(2.0) to 7.5(1.9) D + EX: 0.47(0.04) to 0.46(0.04); D: 0.47(0.05) to 0.47(0.04) **Secondary: At 6 weeks:** D + EX: 25.4(3.1) to 25.3(3.2);D:24.5(2.9) to 24.1(2.7) D + EX: 37.9(3.6) to 37.3(4.0);D:37.3(3.8) to 37.0(3.5) D + EX: 0.88(0.05) to 0.85(0.09);D: 0.89(0.07) to 0.86(0.05) D + EX: 4.8(0.9) to 4.5(0.8);D:4.8(0.9) to 4.5(0.8) D + EX: 2.9(0.9) to 2.6(0.8); D:2.9(0.9) to 2.7(0.7) No change No change **AT 1 YEAR:** No EX: 6.7(2.3) to 7.4(2.5); CT EX:6.9(1.5) to 8.6(1.8); D: 6.9(2.0) to 7.1(1.5) No EX: 0.47(0.05) to 0.46(0.03); CT EX:0.48(0.04) to 0.46(0.03); D:0.47(0.05) to 0.45(0.04) No EX: 26.1(4.0) to 26.1(4.2); CT EX: 25.3(2.4) to 25.4(2.4); D: 24.7(3.1); 24.5(3.3)	**S**;** S**;** S* between grps** **NS; NS; NS between grps** **NS; NS; NS between grps** **NS; NS; NS between grps** **S*; S ; NS between grps** **S*; S; NS between grps** **S*; NS; NS between grps** **NS** **NS** **S; S**; NS** **NS; S**; S*** **NS; NS; NS**	None		At 6 wks, both diet alone and diet + exercise were associated with decreased waist/hip ratio, decreased TC and improvement in EDD. At 1 year, the continued exercise & previous exercise groups had significant improvement in EDD; the continued exercise & diet only groups had a significant decrease in CIMT. The diet only & continued exercise groups had a significant decrease in LDL-C. The continued exercise group had an improvement in HDL-C. The only obesity change was a decrease in body fat in the continued exercise group.	Q10. Changes in diet and exercise decrease some measures of obesity, improve lipid results and improve vascular function measures. Q12b. Sustained exercise is associated with improvement in vascular function and decreased CIMT plus decreased body fat and improved lipid parameters.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
15066949	Woo KS	Effects of diet and exercise on obesity-related vascular dysfunction in children	2004																			Body fat percent [%(SD)] Waist-hip ratio[SD] Total cholesterol[mmol(SD)] LDL-C [mmol(SD)] HDL-C [mmol(SD)] TG [mmol(SD)]	No EX: 37.1(3.1) to 39.2(6.1); CT EX: 38.9(3.8) to 33.9(5.0); D: 37.3(3.8) to 36.0(4.1) No EX: 0.89(0.05) to 0.86(0.06); CT EX: 0.87(0.05) to 0.87(0.06); D: 0.89(0.07) to 0.88(0.07) No EX: 4.7(0.7) to 4.6(1.1); CT EX: 4.8(1.1) to 4.8(1.1); D: 4.7(0.9) to 4.5(0.8) No EX: 2.7(0.8) to 2.5(0.9); CT EX: 3.0(0.9) to 2.7(1.0); D: 2.9(0.9) to 2.5(0.7) No EX: 1.4(0.4) to 1.4(0.3); CT EX: 1.2(0.3) to 1.4(0.3); D: 1.3(0.3) to 1.5(0.3) N EX: 1.3(0.6) to 1.4(0.7); CT EX: 1.3(0.6) to 1.4(0.7); D: 1.2(0.5) to 1.4(0.7)	**NS; S*; NS** **NS; NS; NS** **NS; NS; S** **NS; S; S*** **NS; S*; NS** **NS; NS; NS**				
15126996	Watts K	Effects of exercise training on vascular function in obese children	2004	RCT (crossover)	FMD	Q10 (RF8) Q12a (RF11) Q13 (RF4, RF5, RF14)	Australia	Clinical	None/NR	8 wk	18 wk Includes 2 wk assessment preceding random assignment	Characterize the impact of obesity on vascular function in young children and determine whether an exercise program reverses abnormalities in vascular function	14	Pediatric/ Young Adults	Obese children	Mean age (SD): 8.9 yr (1.6) Boys: 6 White: 13 Asian descent: 1 Exclusions: Cigarette smokers	14 (14)	Behavioral	Intervention: Exercise training Exercise regimen consisted of 3 1-hr sessions of whole body exercise each wk	14 (14)	Control: No training 7 lean subjects matched for age and physical activity levels served as a reference group	**Primary:** FMD [% (SEM)] **Secondary:** Mean body weight [kg (SEM)] Mean BMI [kg/m^2 (SEM)] Mean waist girth [cm (SEM)] Mean sum of 6 skinfolds [mm (SEM)] Mean tricep skinfold [mm (SEM)] Mean subscapular skinfold [mm (SEM)] Mean supraspinale skinfold [mm (SEM)] Mean abdominal skinfold [mm (SEM)] Mean thigh skinfold [mm (SEM)] Mean calf skinfold [mm (SEM)]	**Primary:** **OB:** B/L: 6.00%(0.69) to POST: 7.35%(0.99) **Secondary:** No significant changes in any secondary outcome.	**S**	Not addressed	At baseline, FMD in obese subjects was compared with lean controls and was found to be significantly lower: OB: 6.00(0.69) CON: 12.3 (3.14) p=S**	A crossover trial of supervised exercise in a small number of obese children showed a significant improvement in FMD after 8 wks of training with no change in weight parameters.	Q10,12a,13. A crossover trial of supervised exercise in a small number of obese children showed a significant improvement in FMD after 8 wks of training with no change in weight parameters.
15145107	Watts K	Exercise training normalizes vascular dysfunction and improves central adiposity in obese adolescents	2004	RCT (crossover)	FMD	Q10 (RF8) Q12a (RF11)	Australia	Clinical	None/NR	8 wk	16 wk	Characterize the impact of obesity on vascular function in adolescents and determine whether an exercise program reverses abnormalities in endothelial function	19	Pediatric/ Young Adults	Obese children Exclusions: SBP > 140 mmHg DBP > 85 mmHg Smoking TC > 213 mg/dL LDL-C > 116 mg/dL	Mean age (SD): 14.3 yr (1.5) Males: 9	19 (19)	Behavioral	Intervention: Exercise training Subjects were told not to modify their diet	19 (19)	Control: No training period 20 non-randomized lean subjects were used as a reference group	**Primary:** Endothelium depependent FMD(%) Exercise HR at matched workload **Secondary:** Mean abdominal fat mass [kg (SE)] Mean truncal fat mass [kg (SE)] Muscle strength (sum of 5 contractions)[kg(SE)] Mean body weight [kg (SE)] Mean BMI [kg/m2 (SE)] Mean waist girth [mm (SE)] Mean resting HR (bpm) Mean TC [mg/dL (SE)] Mean HDL-C [mg/dL (SE)] Mean LDL-C [mg/dL (SE)] Mean TG [mg/dL (SE)] Mean glycosylated hemoglobin [%] Mean fasting blood glucose [mg/dL (SE)]	**Primary: [8wks]** Increased Decreased **Secondary:** Decreased Decreased Increased No change in any of the variables below.	**S** **S** **S** **S** **S*** **NS**	None	None	Exercise training decreased central obesity improved muscle strength & reversed vascular dysfunction in obese adolescents even without changes in BMI.	Q10, 12a. Exercise training is of benefit in decreasing central obesity improving muscle strength & reducing vascular dysfunction in obese adolescents even w/o changes in weight or BMI.
15264973	Epstein LH	The effect of reinforcement or stimulus control to reduce sedentary behavior in the treatment of pediatric obesity	2004	RCT	None	Q10	USA	Clinical	No	12 mo	12 mo	Compare stimulus control to behavior reinforcement as a method to reduce sedentary activity as part of a weight loss program for obese children.	63 families	Parental/ Family/ Caregiver	8-12 y BMI > 85th%ile for age/sex	Age 9.8(1.3) y 23 M/31 F 90.3% white,6.5% black, 1.6% Hispanic	63/62	Behavioral	Arm 1: Reinforcement group - Received rewards for meeting sedentary activity targets (REIN) Both groups received the same diet training and sedentary activity targets	NR	Arm 2: Stimulus group - positively reinforced for recording sedentary behavior but no reward for behavior change.(STIM)	**Primary:** z-BMI [(SD)] Change in sedentary activity [% of time,SD] Change in MVPA(>/=3 METS) time [%,SD] Change in activity level [METS(SD)]	**Primary:** STIM: B/L:3.3(1.0) to 2.3(1.0) at 6m, 2.4(1.0) at 12mo REIN: B/L: 3.2(1.0) to 2.2(1.1) at 6m, 2.6(1.0) at 12 m -2.2(7.4) for all subjects combined + 2.9(4.0) for all subjects combined +0.11(0.20) for all subjects combined	**S** for both groups at 6 and 12 mos;** **NS between groups.** **S** **S**** **S**	None reported.	When subjects regrouped by combined change in activity and decrease in sedentary time, those who substituted activity for reduced sedentary time showed greater decrease in z-BMI. However, there was no relationship between this behavior change and intervention group assignment.	Both stimulus control and reinforcement had equal impact in a family-based weight loss program for prepubertal children.	Q10. Both stimulus control and reinforcement had equal impact in a family-based weight loss program for prepubertal children.
15378354	Ozkan B	Addition of orlistat to conventional treatment in adolescents with severe obesity	2004	RCT	None	Q10 (RF8)	Turkey	Clinical	None/NR	Mean duration of treatment (SD): Arm 1: 11.7 mo (3.7) Control Arm: 10.2 mo (3.7)	Arm 1: 5-15 mo Control Arm: 6-17 mo	Investigate the efficacy and tolerability of orlistat in obese adolescents	42	Pediatric/ Young Adults	10-16 yr Severe exogenous obesity (weight for height index > 140% in otherwise healthy subjects) not associated with endocrinopathy, genetic syndromes or medications	Mean age (SD): Arm 1: 12.9 yr (2.4) Control Arm: 12.5 yr (2.2) Males: Arm 1: 5 Control Arm: 5	22 (15)	Multiple Interventions	Arm 1: Orlistat 120 mg tid + daily multivitamin preparation + lifestyle modification program Lifestyle modification program included a diet component (20% reduction in daily calories calculated for age and sex) and an increase in activity level throughout the study period (at least 30 min/d of moderate exercise)	20 (15)	Control Arm: Lifestyle modification program Lifestyle modification program included a diet component (20% reduction in daily calories calculated for age and sex) and an increase in activity level throughout the study period (at least 30 min/d of moderate exercise)	**Primary:** Mean BMI [kg/m^2 (SD)] Mean change in BMI [kg/m^2 (SD)] Mean change in body weight [kg (SD)] Mean change in body weight [% (SD)]	**Primary:** INT: 32.5 --> 30.5 +/- 6.0 CON: 31.2 --> 31.1 +/- 4.2 INT: - 4.09 +/- 2.9 CON: + 0,11 +/- 2.49 INT: - 6.27 +/- 5.4 CON: + 4.16 +/- 6.45 INT: - 7.65 +/- 6.5 CON: + 5.7 +/- 8.3	**Primary:** **NS** **S**** **S**** **S****	7 pts in orlistat group dropped out because of side effects attributed to the drug. All subjects on orlistat experienced frequent stools.	5 pts in control group dropped because of non-compliance.	A one year diet and exercise program + orlistat resulted in significant wt loss not achieved with diet & exercise program alone.	Q10. Wt loss can be achieved with combined, diet, exercise & drug treatment in obese children.
15562127	Pereira MA	Effects of a low-glycemic load diet on resting energy expenditure and heart disease risk factors during weight loss	2004	RCT	None	Q10 (RF8) Q13 (RF4, RF5, RF7, RF11, RF14)	USA	Clinical	None/NR	Final measurements were taken after patient achieved a 10% reduction in body weight Mean time (SE): Arm 1: 65.2 d (3.3) Arm 2: 69.4 d (3.8)	January 4, 2001 - May 6, 2003 Includes 9 d run-in period and 3 d admittance to a metabolic unit	Test whether dietary composition affects the physiological adaptations to weight loss, as assessed by resting energy expenditure	46	Pediatric/ Young Adults	18-40 yr BMI ≥ 27 kg/m^2 Weight < 135 kg Non smoker	Mean age (SD): Arm 1: 28.8 yr (6.3) Arm 2: 32.6 yr (4.3) Males: Arm 1: 5 Arm 2: 4 White: Arm 1: 13 Arm 2: 8 Black: Arm 1: 4 Arm 2: 5 Latino: Arm 1: 4 Arm 2: 3 Other race: Arm 1: 1 Arm 2: 1	Arm 1: 23 (22) Arm 2: 23 (17)	Behavioral	Arm 1: Low-glycemic load diet (LOW Gly) Designed to be as low in glycemic load as possible, while providing more than ample CHO to prevent ketosis Arm 2: Low-fat diet (LOW Fat) Low in fat, high in CHO and glycemic load, and generally consistent with the NCEP guidelines for a heart healthy diet Total energy intake for both arms was 60% of energy requirements, with a minimum of 1,100 kcal/d	N/A	N/A	**Primary:** Mean REE [kcal/d (SE) **Secondary:** Mean weight [kg (SD)] Mean lean mass [kg (SE)] Mean fat mass [kg (SE)] Mean TG [adjusted % change] Mean HDL-C [mg/dL (SE)] Mean LDL-C [mg/dL (SE)] Mean SBP [mmHg (SE)] Mean DBP [mmHg (SE)] Mean arterial pressure [adjusted % change] Mean HOMA score [adjusted % change] Mean exercise [min/wk (SE)] Mean CRP [adjusted % change]	**Primary:** **LOW Gly:** -96 (24) **vs LOW Fat:** -176(27) **Secondary:** No difference between groups No difference between groups No difference between groups **LOW Gly:**-3.5(4.63) **vs LOW Fat:**-16.2(5.24) No difference between groups No difference between groups No difference between groups No difference between groups **LOW Gly:**-6.5(1.12) **vs LOW Fat**:-3.0(1.27) **LOW Gly:** -33.9(4.51) vs **LOW Fat:** -15.8(5.13) **No difference between groups** **LOW Gly:** -47.7(11.94) vs **LOW Fat:** -5.1(13.61)	**S between groups** **Secondary:** **NS** **NS** **NS** **S*** **NS** **NS** **NS (p=.07)** **NS (p=.07)** **S** **S*** **NS** **S**	None	Low glycemic diet subjects reported less hunger over the last 24 hrs.	In overweight/obese young adults aged 18-40 yrs, a low glycemic load diet resulted in reduced resting energy expenditure but no difference in weight or lean or fat mass when compared to a low fat diet with the same degree of weight loss. Weight loss with the low glycemic load diet was associated with reduced insulin resistance, TG,CRP and mean BP.	Q10,13. In overweight/obese young adults aged 18-40 yrs, a low glycemic load diet resulted in reduced resting energy expenditure but no difference in weight or lean or fat mass when compared to a low fat diet with the same degree of weight loss. Weight loss with the low glycemic load diet was associated with reduced insulin resistance, TG,CRP and mean BP. Reduction in glycemic load may aid in the treatment of obesity by being able to affect physiologic adaptations that defend body weight.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
15580192	Kelly AS	Inflammation, insulin, and endothelial function in overweight children and adolescents: the role of exercise	2004	RCT	FMD	Q6 (RF4, RF5, RF7, RF8, RF11, RF14) Q10 (RF8) Q12a (RF11) Q13 (RF4, RF5, RF7, RF9, RF11, RF14)	USA	Clinical	None/NR	8 wk	8 wk	Assess subclinical inflammation, fasting insulin, and endothelial function before and after exercise in overweight children and adolescents	25 at baseline 20 at randomization	Pediatric/ Young Adults	Children and adolescents BMI > 85th percentile for age and gender	Mean age (SEM): 10.9 yr (0.4) Males: 12 Metabolic syndrome: 11	10 (10)	Behavioral	Arm 1: Exercise (EX) Exercise consisted of stationary cycling 4 times per wk, starting at 50% to 60% of VO_2 peak for 30 min per session. Every week, either the intensity or the duration was increased until subjects were exercising at 70% to 80% VO_2 peak for 50 min during the last 2 wk	10 (10)	Control Arm: No exercise (CON) Maintained current levels of physical activity	**Primary:** Mean FMD [% (SEM)] FMD AUC [%.sec(SEM)] **Secondary:** Mean HDL-C [mmol/L (SEM)] Mean VO2 peak [mL/kg/min (SEM)] Mean BMI [kg/m^2 (SEM)] Mean weight [kg (SEM)] Mean BF [% (SEM)] Mean caloric intake [kcal/d (SEM)] Mean SBP [mmHg (SEM)] Mean DBP [mmHg (SEM)] Mean TC [mmol/L (SEM)] Mean LDL-C [mmol/L (SEM)] Mean TG [mmol/L (SEM)]	**Primary:** EX: 6.8(.5) to 7.9(.7) CON: 6.8(0.7) to 6.1(.6) EX: 746(66) to 919(94); CON: 731(102) to 515(73) **Secondary:** EX:1.02(.03) to1.10(.04) CON:1.08(.07) to 0.99(.09) EX: 21.8(2.1) to 23.2(1.5) CON: 23.4(1.6) to 20.9(2.2) **No significant change from B/L and no difference between groups for any other variable.**	**NS** **S between groups** **S from B/L; NS between groups** **S between groups**	Not addressed		In overweight preadolescents, supervised exercise improved FMD and increased fitness over 8 weeks with no change in weight. There was no change in any other RF.	Q10,13. In overweight preadolescents, supervised exercise appears to improve FMD and increased fitness over 8 weeks with no change in weight. There was no change in any other RF.
15622423	de Mello ED	Individual outpatient care versus group education programs. Which leads to greater change in dietary and physical activity habits for obese children?	2004	RCT	None	Q10 (RF5, RF8, RF9, RF11)	Brazil	Clinical	None/NR	6 mo	6 mo	Compare two strategies for childhood obesity management: ambulatory assistance (individual) and educational program (in group)	38	Parental/ Family/ Caregiver	7-13 yr	Mean age: 9.9 yr	38 (NR)	Behavioral	Arm 1: Group educational program (GRP) Included monthly meetings consisting of lectures with parent participation and group work Arm 2: Individual ambulatory assistance (IND)	N/A	N/A	**Primary: Baseline vs 6 mos** BMI [kg/m2(SD)] Sporting activity [%(SD)] Walks [%(SD)] Fruit & vegetable intake Mean TC [mg/dL (SD)] HDL-C[mg/dL (SD)] TG[mg/dL (SD)]	**Primary: [6mos]** IND: 28.9(3.7) to 28.8(4.3) GRP: 29.0(3.5) to 28.4(3.7) IND: 44.4%(8) to 66.7%(12) GRP: 10%(2) to 60%(12) IND: No change; GRP: Increased IND: Increased; GRP: No change. IND: 169.3(52.3) to 161.1(35.2) GRP: 190.6(28.6) to 173.2(29.9) IND: 43.3(9.2) to 45.2(7.3) GRP: 50.7(13.4) to 44.8(9.8) IND: 101.8(52.2) to 101.0(52.6) GRP: 114.9(55.6) to 105.2(34.2)	**NS; NS between groups** **NS** **NS;S* between groups** **S** **NS; S* between groups** **S*** **NS** **S*** **NS; NS between groups** **S*** **NS; NS between groups** **NS** **NS; NS between groups** **NS**	None mentioned		An attempt to compare individual vs group counseling for diet and activity change showed better behavior change and some increase in activity with group counseling but no difference in BMI or lipid measures.	Q 10. An attempt to compare individual vs group counseling for diet and activity change showed better behavior change with group counseling but no difference in BMI. Not a good study with a small sample size. Results suggest no advantage from individual sessions
15756217	Balagopal P	Lifestyle-only intervention attenuates the inflammatory state associated with obesity: a randomized controlled study in adolescents	2005	RCT	None	Q6 (RF7, RF8, RF14) Q10 (RF8, RF14)	USA	Clinical	None	3 mo	3 mo	Understand the relationship among the inflammatory factors, CRP, interleukin-6, and fibrinogen, and indices of obesity in normoglycemic, insulin-resistant adolescents and to investigate the impact of a lifestyle-only intervention on these nontraditional risk factors for CVD	15	Parental/ Family/ Caregiver	Adolescents Normoglycemic Insulin-resistant BMI > 30 kg/m^2 Exclusions: Active participation in any exercise activity ≥ 20 min 2 times per wk or more Participation in any organized diet programs Tobacco use; Alcohol abuse Heart disease Diabetes Liver disease; Renal disease	Mean age (SE): Arm 1: 15.6 yr (0.3) Control Arm: 15.9 yr (0.3) Males: Arm 1: 4 Control Arm: 4	8 (NR)	Behavioral	Arm 1: Lifestyle intervention program (INT) Physical activity, diet-based intervention Met with nutritionist once a wk Advised to perform physical activity for 45 min 3 times a wk Other lifestyle changes included dietary changes; limit TV watching; behavioral counseling	7 (NR)	Control Arm: No treatment (CON) 6 lean subjects served as a reference group	**Primary:** Mean weight [kg (SE)] Mean BMI[kg/m2(SD)] Mean Body Fat [% (SE)] Mean FFM [% (SE)] Mean HOMA-IR [(SE)] Mean CRP [mg/L (SE)] Fibrinogen (mg/dL) IL-6 (pg/ml) Mean LDL-C/HDL-C (SE)	**Primary:** INT: 105.8+/-5.2 to 104.5+/-5.3 CON: 115.9+/-12.8 to 117.3+/-12.9 INT: 38.1(3.1) to 37.5(2.1) CON: 41.2(4.2) to 42.4(4.4) INT: 45.5+/-2.3 to 39.2+/-2.3 vs CON: 43.6 +/- 2.0 to 44.3 +/- 1.9 INT: 57.3(3.8) to 63.6(4.1) CON: 58.2(3.2) to 58.1(3.2) Mean decrease of ~24%in INT group vs no change in CON. Mean decrease of ~30% in INT group vs no change in CON. Mean decrease of ~24% in INT group vs no change in CON. Mean decrease of ~25% in INT group vs no change in CON. Mean decrease of ~28% in INT group (4.4 +/- 0.4 to 3.4 +/- 0.2) vs no change in CON (3.9 +/- 0.5 to 4.4 +/- 0.6) . With regression analysis, BMI, %BF and HOMA-IR all correlated significantly with fibrinogen and IL-6.	**NS for decrease;S between groups** **S for increase** **NS for decrease;S between groups** **S for increase** **S* for decrease;S** between groups** **S* for increase** **S* for increase** **NS** **S* vs NS.** **S vs NS** **S vs NS** **S vs NS.** **S vs NS.**	None	Very small study group.	Obesity was associated with evidence of an inflammatory state in insulin-resistant adolescents and this was shown to be reversible with decreased body fat accomplished with a lifestyle-only intervention.	Q6. Obesity clusters with lipid abnormalities, insulin resistance and evidence of inflammation in adolescence. Q10. Insulin resistance, lipid abnormalities and inflammation are all reversible with decreased body fat accomplished with a lifestyle-only intervention
15805347	Nemet D	Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity	2005	RCT	None	Q10 (RF5, RF8, RF9, RF11) Q11 (RF8, RF9, RF11)	Israel	Clinical	None/NR	3 mo	15 mo	Examine short- and long-term effects of a 3 mo combined dietary-behavioral-physical activity intervention on anthropometric measures, body composition, dietary and leisure-time habits, fitness, and lipid profiles among obese children	54	Parental/ Family/ Caregiver	6-16 yr Obese	Mean age (SD): Arm 1: 10.9 yr (1.9) Control Arm: 11.3 yr (2.8) Males: Arm 1: 14 Control Arm: 12	30 (20)	Behavioral	Arm 1: Dietary counseling + hypocaloric diet + exercise program (INT) Subjects met with dietitian 6 times Hypocaloric diet consisted of 5,021 to 8,368 kJ Exercise program consisted of twice weekly training; subjects were encouraged throughout the program to reduce sedentary activities	24 (20)	Control Arm: Ambulatory nutritional consultation + physical activity (CON) Subjects were referred to an ambulatory nutritional consultation at least once Subjects were instructed to perform physical activity 3 times/wk on their own	**Primary:** Mean BMI [kg/m2 (SD)] Mean body weight [kg (SD)] Mean BF [% (SD)] Mean caloric intake [kJ/d (SD)] Mean habitual activity [units (SD)] Mean screen time [hr/d (SD)] Mean endurance [sec (SD)]	**Primary; AT 1 YEAR:** INT: 27.7 +/- 5.2 --> 28.1 +/- 17.7 CON: 28.0 +/- 5.2 --> 28.6 +/- 5.8 INT: 59.1 +/- 15.4 --> 59.7 +/- 17.7 CON: 63.4 +/- 23.6 --> 68.6 +/- 24.8 INT: 40.6 +/- 6.7 --> 38.3 +/- 12.5 CON: 40.9 +/- 9.5 --> 44.4 +/- 9.7 INT: 7878 +/- 1778 --> 5908 +/- 1573 CON: 8318 +/- 1661 --> 7736 +/- 3088 INT: 4.6 +/- 1.7 --> 3.3 +/- 1.2 CON: 4.7 +/- 1.7 --> 3.4 +/- 1.7 INT: 25.0 +/- 12.4 --> 34.1 +/- 21.1 CON: 26.2 +/- 20.0 --> 18.9 +/- 14.4 INT: 614.7 +/- 184.2 --> 799.8 +/- 167.2 CON: 629.0 +/- 128.1 --> 669.3 +/- 157.8	**S between groups** **S between groups** **S between groups** **NS** **S within groups** **S between groups** **S between groups**	None	No other measures made at 1 y F/U. At 3 months, TC & LDL were significantly decreased in INT group.	A combined nutrition & exercise program can effectively decrease wt, BMI & BF as well as change eating habits and activity behavior at 1 year post intervention.	Q10: A combined nutrition & exercise program can effectively decrease wt, BMI & BF as well as change eating habits and activity behaviors. Q11. These changes are sustained at 1 year post intervention.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
15870664	Fitzgibbon ML	Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children	2005	RCT	None	Q11 (RF8, RF9, RF11) Q13 (RF8, RF9, RF11)	USA	Community (schools)	None/NR	14 wk	2 yr	Assess the impact of a culturally proficient dietary/physical activity intervention on changes in BMI	409 (12 schools)	Parental/ Family/ Caregiver	Head Start preschool program	Mean age (SD): Arm 1: 48.6 mo (7.6) Control Arm: 50.8 mo (6.4) Males: Arm 1: 50.3% Control Arm: 49.5% Black: Arm 1: 99% Control Arm: 80.7% Latino: Arm 1: 0.0% Control Arm: 12.7% Multiracial/Other: Arm 1: 1.0% Control Arm: 6.6% Mean parental education (SD): Arm 1: 12.4 yr (1.8) Control Arm: 12.7 yr (1.7)	197 (146)	Behavioral	Arm 1: Healthy diet + exercise activity (INT) Thrice weekly lesson plans incorporated two major components: 20-min lesson that introduced a healthy eating or exercise concept with an activity and 20 min of ongoing physical activity	212 (154)	Control Arm: General health intervention (CON) Weekly 20 min class on general health concepts (e.g., dental health, immunization) No information on diet or physical activity was presented	**Primary:** Mean BMI [kg/m2 (SE)] Mean BMI z score (SE) **Secondary:** Mean weight [kg (SE)] Mean total fat intake [% kcal (SE)] Mean fiber [g/1000 (SE)] Mean SFA intake [% kcal (SE)] Mean TV viewing [hr/d (SE)] Mean exercise frequency [% ≥ 7 times/wk (SE)] Mean exercise intensity [Borg scale (SE)]	**Primary:** **1 Y:** INT: vs CON: -0.53(CI:-0/91,0.14) **2Y:** INT vs CON: -0.54(CI:-0.98,-0.10) **1 Y:** INT vs CON: -0.19(CI:-0.35,0.03) **2 Y:** INT vs CON: -0.14(CI:-0.25, -0.03) **Secondary:** NC NC NC **1 Y:** INT: 11.6% vs CON:12.8% **2 Y:** No difference between groups NC NC NC	**S*** **S** **S** **S** **NS** **NS** **NS** **S*** **NS** **NS** **NS** **NS**	None	Saturated fat intake lower in INT at one year, not after 2 years.	A culturally-based program for preschool children, Hip-Hop to Health Jr, was effective in reducing subsequent increases in BMI in preschool children. This represents a promising approach to prevent progressive overweight in minority children in the preschool years.	A culturally-based program for preschool children, Hip-Hop to Health Jr, was effective in reducing subsequent increases in BMI in preschool children. This represents a promising approach to prevent progressive overweight in minority children in the preschool years.
15870664	Fitzgibbon ML	Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children	2005													Married parents: Arm 1: 19.9 Control Arm: 31.7											
15883418	Ebbeling CB	Effects of an ad libitum low-glycemic load diet on cardiovascular disease risk factors in obese young adults	2005	RCT	None	Q10 (RF4, RF5, RF8, RF9, RF14)	USA	Clinical	None/NR	12 mo	12 mo	Evaluate the efficacy of an ad libitum low-glycemic load diet, without strict limitation on carbohydrate intake, as an alternative to a conventional low-fat diet	34	Pediatric/Young Adults	18-35 yr BMI > 27 kg/m2 Weight < 136 kg (300 lbs) Absence of major medical illness	Mean age (SEM): Arm 1: 29.8 yr (1.7) Control Arm: 27.2 yr (1.3) Males: 4	17 (11)	Behavioral	Arm 1: Low glycemic load (GLY) diet + behavioral therapy + physical activity recommendation Low GL diet requires the consumption of CHO-containing low glycemic index, protein and healthy fat at every meal and snack, and to each to satiety and snack when hungry; 45-50% energy from CHO; 30-35% of energy from fat, and remainder from protein Behavioral therapy focused on enhancing self-efficacy for lifestyle change Physical activity recommendations were consistent with public health guidelines	17 (12)	Control Arm: Low fat diet + behavioral therapy + physical activity recommendation (CON) Low fat diet emphasizes restricting energy intake and reducing dietary fat with 55-60% energy from CHO, < 30% from fat, and the remainder from protein Behavioral therapy focused on enhancing self-efficacy for lifestyle change Physical activity recommendations were consistent with public health guidelines	**Primary:** Mean % change in weight [kg (CI)] **Secondary:** Mean TC [mg/dL (SEM)] Mean LDL-C [mg/dL (SEM)] Mean HDL-C [mg/dL (SEM)] Mean TG [mg/dL (SEM)] Mean SBP [mmHg (SEM)] Mean DBP [mmHg (SEM)] Mean insulin sensitivity index [(SEM)]	**Primary:** **6 m** **12 m** GLY -8.4(-11.4,-5.3) -7.8(-13.0,-2.2) CON -7.8(-10.7,-4.9) -6.1(-11.2,-0.7) **Secondary:** GLY: -9.9(-16.7,-2.5) -8.5(-17.4,1.5) CON: -2.1(-9.2,5.5) -6.2(-15.0,3.5) GLY: -9.1(-18.6,1.4) -9.7(-21.6,3.9) CON: -2.6(-12.3,8.2) -7.4(-19.1,6.0) GLY: 2.3(-6.0,11.3) 12.2(2.9,22.3) CON: -0.3(-8.1,8.2) 1.1(-6.9,9.8) GLY: -35.4(-44.6,-24.7) -7.1(-19.8,7.6) CON: -7.1(-19.8,7.6) -19.1(-32.2,-3.6) GLY: -0.9(-5.9,4.2) 0.2(-4.7,5.3) CON: -0.5(-5.3,4.4) 0.6(-4.1,5.5) GLY: -2.0(-7.2,3.4) -0.3(-6.2,6.0) CON :0.3(-4.8,5.6) 1.4(-4.4,7.6) GLY: 6.4(1.5,11.5) 5.8(1.1,10.7) CON: 5.8(1.1,10.7) 8.7(2.3,15.5)	**S** from B/L for both groups; NS between groups** **NS between groups** **NS between groups** **S** from B/L for both groups; NS between groups** **NS between groups** **NS between groups** **NS between groups**	Not addressed		In obese adolescents, a 6 m intervention comparing an ab libitum low glycemic-load diet to a low fat, low calorie diet showed no advantage in weight loss but was associated with a greater decrease in TG at 1 yr assessment.	Q10. In obese adolescents, a 6 m intervention comparing an ab libitum low glycemic-load diet to a low fat, low calorie diet showed no advantage in weight loss but was associated with a greater decrease in TG at 1 yr assessment.
15956632	Chanoine JP	Effect of orlistat on weight and body composition in obese adolescents: a randomized controlled trial	2005	RCT	None	Q10 (RF8)	USA, Canada	Clinical	Double	52 wk	54 wk (August 2000-October 2002) Includes 2 wk lead in period	Determine safety and efficacy of orlistat in weight management of adolescents	539 (randomized) 533 (baseline)	Pediatric/ Young Adults	12-16 yr BMI ≥ 2 units above 95th percentile based on age and sex Minimum BMI for boys is 28.5 kg/m^2 at 12 yr to 31.8 kg/m^2 at 16 yr Minimum BMI for girls is 29.5 kg/m^2 at 12 yr to 31.9 kg/m^2 at 16 yr Exclusions: BMI ≥ 44 kg/m^2 Body weight < 55 kg or ≥ 130 kg	Mean age (SD): Arm 1: 13.8 yr (1.3) Control Arm: 13.5 yr (1.2) Males: Arm 1: 124 Control Arm: 52 White: Arm 1: 264 Control Arm: 141 Black: Arm 1: 65 Control Arm: 25 Other race: Arm 1: 23 Control Arm: 15 Metabolic syndrome: 25%	352 (232)	Pharmacologic	Arm 1: Diet + exercise counseling + behavioral modification program + orlistat 120 mg tid (ORL) Participants maintained a nutritionally balanced, hypocaloric diet designed to produce an initial weight loss of 0.5-1.0 kg/wk Exercise counseling included guidelines to encourage regular physical activity and reduce sedentary behavior Behavioral modification program included recording food intake and activity, limiting high-calorie and high-fat foods, and restricting food intake to the dining area at meal times	181 (117)	Control Arm: Diet + exercise counseling + behavioral therapy + placebo tid (CON) Participants maintained a nutritionally balanced, hypocaloric diet designed to produce an initial weight loss of 0.5-1.0 kg/wk Exercise counseling included guidelines to encourage regular physical activity and reduce sedentary behavior Behavioral modification program included recording food intake and activity, limiting high-calorie and high-fat foods, and restricting food intake to the dining area at meal times	**Primary:** % with > 5% decrease in BMI % with > 10% decrease in BMI LS mean BMI [kg/m2] **Secondary:** LS mean weight [kg (SD)] LS mean waist circumference [cm] Mean TC [mg/dL (SD)] LS mean TC [mg/dL] Mean HDL [mg/dL (SD)] LS mean HDL [mg/dL] Mean LDL [mg/dL (SD)] LS mean LDL [mg/dL] Mean TG [mg/dL (SD)] LS mean TG [mg/dL] Mean insulin [µIU/mL (SD)] LS mean insulin [µIU/mL]	**Primary:** ORL: 26.5% vs CON: 15.7% ORL:13.3% vs CON: 4.5% ORL: -0.55 vs CON: +0.31 **Secondary:** ORL: +0.53 vs CON:+3.13 ORL: -1.33 vs CON: +0.12 No significant change No significant change No significant change No significant change No significant change No significant change No significant change No significant change No significant change	**S*** **S*** **S**** **S**** **S** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS**	7-15% of ORL grp and 0.6-5.5% of CON grp complained of G-I symptoms.	In a subset undergoing DEXA scan, ORL grp lost significantly more fat than did the CON grp.	In obese adolescents, treatment with 120 mgms of Orlistat tid X 52 wks combined with diet and exercise significantly improved weight loss	Q10. Weight loss can be achieved on obese adolescents with the combination of diet, exercise and drug treatment.
15956632	Chanoine JP	Effect of orlistat on weight and body composition in obese adolescents: a randomized controlled trial	2005												Weight loss ≥ 3 kg within 3 months prior to screening Diabetes Obesity associated with genetic disorders							Mean glucose [mg/dL (SD)] LS mean glucose [mg/dL] Mean DBP [mmHg (SD)] Mean SBP [mmHg (SD)]	No significant change No significant change ORL: -0.51 vs CON:+1.30 No significant change	**NS** **NS** **S** **NS**				
16158087	Jelalian E	'Adventure therapy' combined with cognitive-behavioral treatment for overweight adolescents	2006	RCT	None	Q10 (RF8)	USA	Mult settings	None/NR	16 wk	10 mo Includes 2 wk diet record run-in period	Evaluate the efficacy of adding peer-based 'adventure therapy' to a standard cognitive-behavioral weight control program for overweight adolescents	89	Parental/ Family/ Caregiver	13-16 yr 20-80% overweight defined by BMI Exclusions: Taking medications that might impact weight loss Medical comorbidities that would impact participation in the diet and physical activity prescription Enrolled in another counseling or weight loss program	Mean age (SD): 174.08 mo (11.19) Males: 29% Caucasian: 79% Mean SES based on Hollingshead score (SD): 44.85 (10.94)	Arm 1: 39 (25) Arm 2: 37 (31)	Behavioral	Arm 1: Cognitive-behavioral weight loss intervention + aerobic exercise (CBT + EXER) 60-min weekly supervised exercise session Arm 2: Cognitive-behavioral weight loss intervention + peer-enhanced adventure therapy (CBT + ADV) Weekly peer-based activity session including physical activity, a primary challenge for the group, processing of the activity, and establishing weekly goals Both arms received 16 weekly sessions with parents and adolescents attending separate meetings and 4 monthly maintenance sessions; adolescents also attended bi-weekly meetings with the participating parent	13 (7)	Control Arm: Standard care 3 individual meetings with a nutritionist Control Arm was discontinued due to patient and parent concerns with treatment acceptability and associated significant difficulties with retention; no results are reported	**Primary:** Mean weight loss [kg (SD)] BMI [kg/m2] Participants with ≥ 4.5 kg weight loss [%] Participants with ≥ 10% weight loss [%]	**Primary:** 4 months: CBT + ADV: - 5.31 +/- 5.61 CBT + EXER: - 3.20 +/- 3.61 10 mos: CBT + ADV: - 3.4 +/- 8.16 CBT + EXER: - 0.67 +/- 5.50 4 months: CBT + ADV: 32.2 --> 29.6 CBT + EXER: 32.8 --> 30.7 10 mos: CBT + ADV: --> 29.8 CBT + EXER: --> 31.2 4 months: CBT + ADV: 48% CBT + EXER: 32% 10 mos: CBT + ADV: 33% CBT + EXER: 12% 4 months: CBT + ADV: 26% CBT + EXER: 10% 10 mos: CBT + ADV: 23% CBT + EXER: 4%	**S* (from baseline)** **S* (from baseline)** **NS between groups** **S* (from baseline)** **S* (for wt gain from 4 -10 m)** **NS between groups** **S* (from baseline)** **S* (from baseline)** **NS between groups** **S (from baseline)** **S (from baseline)** **NS between groups** **NS between groups** **S between groups** **NS between groups** **S between groups**	None	When groups split by age, older group with CBT + ADV lost more than 4X as much weight as the CBT+ Ex group and maintained this loss at 10 mos. Both groups improved measures of self esteem at 4 & 10 mos.	Adding a novel peer-based adventure component to a cognitive-behavioral wt loss program resulted in effective weight loss at 4 mos which was sustained at 10 mos post initiation.	Q10. Effective weight loss maintained through intermediate F/U can be accomplished with adolescents. Addition of peers to the intervention helped to sustain wt improvements.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
16158087	Jelalian E	'Adventure therapy' combined with cognitive-behavioral treatment for overweight adolescents	2006																Both arms were prescribed a balanced deficit diet (1400-1600 calories) and asked to gradually increase physical activity to ≥ 30 min/d for 5 d/wk (including 30 min on-site physical activity) Both arms received psycosocial assessment at abseline , end of treatment & 10 mos post randomization.									
16277142	Williamson DA	Efficacy of an internet-based behavioral weight loss program for overweight adolescent African-American girls	2005	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	USA	Mult settings	None/NR	6 mo	6 mo	Test the efficacy of an internet-based lifestyle behavior modification program for weight management in African-American girls	57	Parental/ Family/ Caregiver	11-15 yr Girls African-American At risk for overweight (BMI > 85th percentile for age and gender) At least 1 obese (BMI > 30 kg/m^2) biological parent Exclusions: Insulin-dependent diabetes	Mean age (SD): 13.19 yr (1.37)	28 (23)	Behavioral	Arm 1: Interactive behavioral internet program (INT) 4 face-to-face therapy sessions over a 12 wk period and regular e-mail correspondence Nutrition education and counseling for behavior modification targeting lifestyle, eating and physical activity habits of overweight adolescents and their parents	29 (27)	Control Arm: Internet health education program (CON) 4 face-to-face therapy sessions over a 12 wk period and regular e-mail correspondence Passive (non-interactive) program that provided useful health education for the parents and adolescents via electronic links to other health-related websites	**Primary:** Mean change in weight [kg (SE)] Mean change in BMI [kg/m2 (SE)] Mean change in BF [% (SE)] **Secondary:** Mean change in total energy intake from Food Frequency Questionnaire [kJ/d (SE)] Mean change in total energy intake from 24-hr recall [kJ/d (SE)] Mean change in protein intake from Food Frequency Questionnaire [%E (SE)] Mean change in protein intake from 24-hr recall [%E (SE)] Mean change in CHO intake from Food Frequency Questionnaire [%E (SE)]	**Primary:** INT parents -2.43+/-0.66 CON parents -0.35 +/- 0.64 INT adolescents + 0.70 +/- 0.59 CON adolescents + 2.29 +/- 0.56 INT parents -1.03 +/- 0.28 CON parents + 0.06 +/- 0.77 INT adolescents + 0.19 +/- 0.24 CON adolescents + 0.65 +/- 0.23 INT parents -0.58 +/- 0.34 CON parents 0.18 +/- 0.34 INT adolescents - 1.12 +/- 0.47 CON adolescent 0.43 +/- 0.47 **Secondary:** Decreased for adolescents NC Decreased for adolescents NC Decreased for adolescents **Decreased for adolescents**	**S between groups** **NS between groups** **S between groups** **S between groups** **NS between groups** **S between groups** **S**** **NS** **S** **NS** **NS** **S**	None	Changes in weight loss behavior attitudes greater in treatment group. Control group lower levels of concern about diet and body weight.	In adolescent girls and their parents, an internet-based behavioral intervention was superior to internet based health education and yielded decreased body fat and BMI for adolescent girls and decreased body weight for parents at 6 mos F/U.	An internet-based behavioral intervention was superior to internet based health education and yielded decreased body fat for adolescent girls and decreased body weight for parents at 6 mos F/U.
16277142	Williamson DA	Efficacy of an internet-based behavioral weight loss program for overweight adolescent African-American girls	2005																			Mean change in CHO intake from 24-hr recall [%E (SE)] Mean change in fat intake from Food Frequency Questionnaire [%E (SE)] Mean change in fat intake from 24-hr recall [%E (SE)] Mean change in exercise (SE)	NC Decreased in adolescents NC NC	**NS** **S** **NS** **NS**				
16286521	Resnicow K	Results of go girls: a weight control program for overweight African-American adolescent females	2005	RCT	None	Q10 (RF8) Q13 (RF4, RF5, RF11, RF14)	USA	Community	None/NR	6 mo	12 mo	Determine the effects of a church-based nutrition and physical activity program designed for overweight African-American adolescent females	147 (10 churches)	Parental/ Family/ Caregiver	12-16 yr Girls African American BMI > 90th percentile for age and gender Middle or upper SES Churches with majority of members' household income > $40,000	Mean age (SD): Completed study through 6 mo: 13.6 yr (1.43) Lost to follow-up at 6 mo: 13.9 yr (1.56)	NR (53) 5 churches (NR)	Behavioral	Arm 1: 20-26 weekly group behavioral sessions (high-intensity intervention) (HIGH) Session include an experiential, interactive behavioral activity, at least 30 min of moderate to vigorous physical exercise, and preparation and/or consumption of low-fat portion-controlled meals or snacks 1-d retreat at a national park or facility before each intervention cycle Received 2-way paging device and 4-6 motivational interviewing calls by telephone Parents attended every other session	NR (70) 5 churches (NR)	Control Arm: 6 monthly group sessions (moderate intensity intervention) (MOD) Sessions were selected from pool provided to Arm 1 and topics included fat facts, barriers to physical activity, fad diets, neophobia, and benefits of physical activity Parents attended 3 sessions	**Primary: 6 month outcomes:** Mean BMI [kg/m2 (SD)] **Secondary:** Mean waist circumference [cm (SD)] Mean BF [% (SD)] Mean SBP [mmHg (SD)] Mean DBP [mmHg (SD)] Mean TC [mg/dL (SD)] Mean insulin [µU/mL (SD)] Mean glucose [mg/dL (SD)] Mean PACER laps (SD)	**Primary: 6 month --> 1 y outcomes:** **HIGH:** B/L 32.0(5.8) to 31.9(5.5) to 33.3(5.9) **MOD:** B/L 33.2(7.3) to 33.6(7.8) to 33.7(8.4) **Secondary:** Favorable trends in WC & body fat but both differences small and non-significant. No significant differences on any secondary outcomes.	**NS between groups at both times** **NS for all secondary outcomes.**	Not addressed.		In black adolescent girls, a well designed trial comparing a moderate to high intensity diet and exercise intervention showed no significant differences for any outcome measure.	Q 10,13. In black adolescent girls, a well designed trial comparing a moderate to high intensity diet and exercise intervention showed no significant differences for any outcome measure.
16336071	Epstein LH	The challenge of identifying behavioral alternatives to food: clinic and field studies	2005	RCT	None	Q10 (RF8) Q11 (RF8) Q13 (RF9, RF11)	USA	Clinical	None/NR	2 yr	2 yr	Compare a comprehensive family-based behavioral treatment program or an experimental treatment that incorporated reinforcing children for engaging in alternative behaviors to eating	41 families	Parental/ Family/ Caregiver	8-12 yr Overweight or obese (BMI ≥ 85th percentile) No medical restrictions on diet or activity that could interfere with participation No family member currently involved in another weight control program	Mean age (SD): Arm 1: 10.2 yr (1.1) Control Arm: 10.1 yr (1.3) Males: Arm 1: 9 Control Arm: 9 SES (SD): Arm 1: 49.1 (12.5) Control Arm: 47.7 (9.3)	19 families (18 families)	Behavioral	Arm 1: Family-based behavioral intervention + targeting an increase in behaviors incompatible with eating Participants earned 1 point for each "Alternative Behavior to Eating" as additional reinforcement Other intervention components were the same as in the Control Arm	22 families (17 families)	Control Arm: Standard family-based behavioral intervention Program aimed to reduce energy intake and intake of high-fat, low-nutrient-density foods and to increase physical activity through structured aerobic activity programs 8 treatment sessions in the first 7 wks, followed by 4 biweekly sessions and 2 bimonthly sessions through the first 6 mo of treatment; booster sessions provided on a monthly basis from mo 6-12 and on as-needed basis from mo 12-24 Provided basic information about the Traffic Light Diet, Food Pyramid, and healthy eating with a caloric target range of 1,000-1,500 kcal/d Goal of 30 min moderate physical activity 6 d/wk. Provided a reinforcement system to motivate children for behavior change	**Primary:** Mean change in z-BMI **Secondary:** Percent overweight [%] Mean MVPA [min/wk (SEM)] Mean time engaging in behaviors incompatible with eating [min/wk (SEM)] Eating and drinking episodes [episodes/d]	**Primary: All subjects at 2y** Decreased in all subjects at 2y **Secondary:** Decreased in all subjects at 2y Increased in all subjects at 2y Increased in intervention subjects at 2y Decreased in all subjects at 2y Behavioral economic group did participate in more activities defined as alternative to eating and standard care group were more active but there was no difference between groups for BMI results.	**S from B/L; no difference between groups** **S** from B/L; no difference between groups** **S from B/L; no difference between groups** **S from B/L; no difference between groups** **S** from B/L; no difference between groups**	none	Both groups lost weight but not related to change in distraction behavior	Alternative behavior to replace eating did not offer an advantage to standard diet and exercise program in losing more wt. No data on energy intake during meals.	Q 10,13. Alternative behavior to replace eating did not offer an advantage in losing more wt; no control for eating during meals
16446743	Hakanen M	Development of overweight in an atherosclerosis prevention trial starting in early childhood. The STRIP study	2006	RCT	None	Q11 (RF8) Q13 (RF8)	Finland	Clinical	None/NR	9 yr 5 mo	9 yr 5 mo	Evaluate the impact of repeatedly given, individualized dietary and lifestyle counseling on the prevalence of overweight during the first 10 years of life	1,062	Pediatric/ Young Adults	5 mo (at recruitment), 7 mo (at randomization)	NR	540 (284)	Behavioral	Arm 1: Dietary and lifestyle counseling (INT) Individualized dietary counseling at 1-3 mo intervals until the child was 2 yr old and 2 times/yr thereafter Families were encouraged to gradually change the child's eating and physical activity towards a healthier lifestyle Initially, nutrition counseling was mainly aimed at reducing the child's intake of saturated fat Suggestions were made to increase the child's amount of everyday physical activity	522 (301)	Control Arm: Basic health education (CON) Received basic health education as routinely given at Finnish well-baby clinics and school health care Counseling 2 times/yr until child was 7 yr old and once/yr thereafter	**Primary:** Proportion of overweight children (weight for height more than 20% above Finnish mean) [%] Proportion of obese children (weight for height more than 40% above Finnish mean) [%] Proportion of slim children (weight for height more than 15% below Finnish mean) [%] Weight for height	**Primary: (F=Female;M= Male)** At 10 y, 10.2% of INT Fs vs 18.8% of CON Fs were overweight. No difference in Ms (INT:11.6% vs CON:12.1%) No mean difference between groups but only 2 INT Fs and 1 M were ever obese vs 8 CON Fs and 6 Ms. No mean difference between groups No mean difference between groups	**S** **NS** **NS** **NS**	None	Overweight Fs entered puberty before Fs of normal weight.	Repeated nutrition & lifestyle counseling beginning in infancy decreased development of overweight in Fs at age 10 y.	Q11,13. Repeated nutrition & lifestyle counseling beginning in infancy decreased development of overweight in Fs at age 10 y.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
16510646	Ebbeling CB	Effects of decreasing sugar-sweetened beverage consumption on body weight in adolescents: a randomized, controlled pilot study	2006	RCT	None	Q10 (RF9) Q13 (RF8, RF11)	USA	Home	None/NR	25 wk	25 wk	Examine the effect of decreasing sugar-sweetened beverage consumption on body weight	103	Pediatric/ Young Adults	13-18 yr Reported consuming at least 1 serving/d of sugar-sweetened beverages Exclusions: Currently dieting for the purpose of weight loss or taking prescription medications that might affect body weight Smoking at least 1 cigarette in the past wk BMI < 25th percentile	Mean age (SD): Arm 1: 16.0 yr (1.1) Control Arm: 15.8 yr (1.1) Males: Arm 1: 24 Control Arm: 23 White: Arm 1: 18 Control Arm: 19 Nonwhite: Arm 1: 35 Control Arm: 31 Hispanic: Arm 1: 11 Control Arm: 7 Non-Hispanic: Arm 1: 42 Control Arm: 43 Household income: < $30,000: Arm 1: 19 Control Arm: 20 $30,000-$59,999: Arm 1: 16 Control Arm: 14 ≥ $60,000: Arm 1: 10 Control Arm: 7	53 (53)	Behavioral	Arm 1: Weekly home deliveries of noncaloric beverages (INT) Target of 4 servings/d of noncaloric beverages Subjects advised to drink the noncaloric beverages delivered to their homes and not to buy or drink sugar-sweetened beverages Monthly counseling by telephone	50 (50)	Control Arm: Usual beverage consumption (CON)	**Primary:** Mean change in BMI [kg/m2 (SE)] Mean change in energy intake from sugar-sweetened beverages [kJ (SD)] **Secondary:** Mean change in physical activity [MET level (SD)] Mean change in TV viewing [hr (SD)] Mean change in total media time [hr (SD)]	**Primary:** INT: 0.07(0.14) vs CON: 0.21(0.15) **In regression analysis, baseline BMI significantly affected this outcome - for those in the top tertile for BMI: INT: -0.63(0.23) vs CON:+0.12(0.26) INT: -82% vs CON: No change **Secondary:** No change in any of these variables in either group	**NS** **S** **S** for INT group vs baseline** **NS for all**	None	Although BMI did not change, it was a significant modifier in that for individuals with BMI>26 there was a significant decrease in BMI.	Replacing sugar-sweetened beverages with noncaloric beverages almost completely eliminated SSB consumption in a diverse group of adolescents. The beneficial effect on body weight was seen only in those individuals with an increased initial body weight and fatness.	Q10,13.Replacing sugar-sweetened beverages with noncaloric beverages almost completely eliminated SSB consumption in a diverse group of adolescents. The beneficial effect on body weight was seen only in those individuals with an increased initial body weight and fatness.
16510646	Ebbeling CB	Effects of decreasing sugar-sweetened beverage consumption on body weight in adolescents: a randomized, controlled pilot study	2006													Residing in subsidized housing: Arm 1: 10 Control Arm: 7											
16524859	Maahs D	Randomized, double-blind, placebo-controlled trial of orlistat for weight loss in adolescents	2006	RCT	None	Q10 (RF8) Q13 (RF5, RF7, RF14)	USA	Clinical	Double	6 mo	Dec 2002 - Sept 2003	Evaluate the efficacy of orlistat to enhance weight loss in obese adolescents	40	Pediatric/ Young Adults	14-18 yr BMI > 85th percentile for age and sex Exclusions: Known secondary causes for obesity (e.g., hypothyroidism, daily corticosteroid exposure > 30 d, history of significant exposure to corticosteroids for chronic illness during the past yr, and known genetic causes of obesity)	Mean age (SD): Arm 1: 15.8 yr (1.5) Control Arm: 15.8 yr (1.4) Males: Arm 1: 8 Control Arm: 5 Hispanic: Arm 1: 12 Control Arm: 13	20 (16)	Multiple Interventions	Arm 1: 120 mg orlistat tid + low fat diet + exercise counseling (ORL) All subjects were given multivitamins daily. They were also encouraged to exercise at least 3 times per wk for at least 30 min on each occasion and to consume a low fat (30%) exchange diet	20 (18)	Control Arm: Placebo + low fat diet + exercise counseling (CON) All subjects were given multivitamins daily. They were also encouraged to exercise at least 3 times per wk for at least 30 min on each occasion and to consume a low fat (30%) exchange diet	**Primary:** Decrease in BMI[kg/m2(SE)] **Secondary:** Mean weight [kg (SE)] % body fat Vit D level[ng/ml(SE)] Mean TG [mg/dL (SE)] Mean TC [mg/dL (SE)] Mean HDL-C [mg/dL (SE)] Mean LDL-C [mg/dL (SE)] Mean CRP [µg/dL (SE)] Mean glucose [mg/dL (SE)] Mean HbA1c [% (SE)] Mean insulin [µU/mL (SE)]	**Primary:** ORL: -1.3(1.6) vs CON: -0.8(3.0) **Secondary:** No significant difference between groups for any measure.	**S for each vs baseline; NS between groups **NS for all measures between groups.**	GI side effects significantly more prevalent in orlistat group.	Underpowered trial with suggestion of more decrease in BMI with orlistat; baseline imbalance in BMI 39.2 v. 41.7 could explain lack of effect. Main analysis is per protocol although authors say no difference with ITT.	In this small trial of severely obese adolescents, orlistat did not significantly reduce BMI in comparison with placebo at 6 mos.	Q10,13. In this small trial of severely obese adolescents, orlistat did not significantly reduce BMI in comparison with placebo at 6 mos.
16595599	Srinivasan S	Randomized, controlled trial of metformin for obesity and insulin resistance in children and adolescents: improvement in body composition and fasting insulin	2006	RCT (crossover)	None	Q10 (RF8, RF14)	Australia	Clinical	Double	6 mo	54 wk Includes 2 wk washout period	Assess the effect of metformin on body composition and insulin sensitivity in pediatric subjects with exogenous obesity	28	Pediatric/ Young Adults	9-18 yr Obese (as defined by the International Obesity Task Force) Clinical suspicion of insulin resistance as defined by either (fasting insulin (mU/L) to glucose (mmol/L) ratio > 4.5 or the presence of acanthosis nigricans Exclusions: Known type 1 or 2 diabetes mellitus Weight > 120 kg due to technical difficulties with dual-energy x-ray absorptiometry scans	Mean age (SD): 12.5 yr (2.2) Males: 13 From ethnic backgrounds with high prevalence of insulin resistance and metabolic syndrome (e.g., Indian subcontinent, Pacific islands): 18 Northern European background: 7 Mixed ethnic background: 3 Family history of features of metabolic syndrome in either first- or second-degree relatives: 25 Acanthosis nigricans: 25	28 (22)	Pharmacologic	Intervention: Metformin 1 g bid Metformin dose was gradually built up over a 3-wk period to a final dose of 1 g bid Standardized information on healthy eating and exercise was also provided	28 (22)	Control Arm: Placebo 1 g bid Placebo dose was gradually built up over a 3-wk period to a final dose of 1 g bid Standardized information on healthy eating and exercise was also provided	**Primary:** Weight [kg] Weight z-score BMI [kg/m^2] BMI z-score Waist circumference [cm] Waist circumference z-score Fasting insulin [mU/L] Fasting glucose [mmol/L] Insulin sensitivity [(mU/L)$^{-1}$·min^{-1}]	**Primary:[6 mos on med]** **Treatment effect:** -4.35 -0.09 -1.26 -0.12 -2.8 -0.05 -2.2 -0.2 +0.17	**S** **S*** **S*** **S*** **S*** **S*** **S*** **S** **NS**	2 subjects had to decrease dose (nausea)		A six month trial of metformin in obese insulin resistant adolescents significantly decreased wt, BMI, waist circumference, insulin and fasting glucose but not insulin sensitivity.	Q10. A six month trial of metformin in obese insulin resistant adolescents significantly decreased wt, BMI, waist circumference, insulin and fasting glucose but not insulin sensitivity.
16611394	Golan M	Childhood obesity treatment: targeting parents exclusively v. parents and children	2006	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	Israel	Clinical	None/NR	6 mo	18 mo	Evaluate the relative efficacy of treating childhood obesity via a family-based health-centered intervention, targeting parents alone versus parents and overweight/obese children together	37 (32 families)	Parental/ Family/ Caregiver	6-11 yr Children > 20% overweight (BMI for age and sex > 85th percentile) Parents agree to attend program meetings. No current participation of any family member in a weight loss program No restriction regarding participation in a physical activity program for children and parents	Mean age (SD): Arm 1: 8.75 yr (1.9) Arm 2: 8.7 yr (2.0) Boys: Arm 1: 7 Arm 2: 10	Arm 1: 17 (13) 14 families (NR) Arm 2: 20 (18) 18 families (16 families)	Behavioral	Arm 1: Comprehensive educational and behavioral program with only parents as the agents of change (PARENT) 16 1-hr support and education groups for parents only 40-50 min individual appointments were also held once/mo for each family Program emphasized healthy eating patterns, encouraged an increase in daily physical activity to a goal of 4 hr/wk, and a decrease in sedentary behaviors to a goal of < 3 hr/d Parents were encouraged to adopt an authoritative feeding style and assume a leadership role in changing the home environment Arm 2: Comprehensive educational and behavioral program with parents and children as the agents of change (P + C)	N/A	No control	**Primary:** Mean BMI z-score (SD) Mean overweight percentage [% (SD)] **Secondary: (At 6 m)** Mean physical activity [hr/d (SD)] Mean TV viewing [hr/d (SD)] Mean eating between meals score (SD) Exposure to food stimuli (items) Obesogenic load (total score)	**Primary:** **PARENT:** -0.4 vs **P + C**: -0.1 at 6 m. **PARENT: -1.28 vs P + C: + 0.32** at 18 m F/U **PARENT**: -9.5% [47.0(22.1) to 37.5(22.0)] vs **P + C:** -2.4%[48.5%(18.1) to 46.1(17.8)] at 6 m. **PARENT:** - 12.6% vs **P + C:** + 0.4% at 18 m F/U. **Secondary: (At 6 m)** **PARENT**: 3.4+/-1.9 to 4.5 +/-1.7 vs **P + C:** 4.0+/-1.6 to 5.0+/-1.7 **PARENT**: 3.8+/-1.2 to 3.0+/-1.4 vs. **P + C**: 3.9+/-1.2 to 2.9+/-1.3 **PARENT**: 2.9+/-0.6 to 1.8+/-0.7 vs **P + C**: 2.3+/-0.7 to 1.8+/-0.4 **PARENT:** 14.5+/-4.3 to 5.2 +/-2.7 vs **P + C**: 12.7+/-3.5 to 6.6+/-3.2 **PARENT:** 30.1 +/-7.7 to 23.5 +/- 7.3 vs. **P + C**: 28.9 +/- 6.9 to 24.6 +/- 4.1	**S only for PARENT grp S only for PARENT grp S only for PARENT grp S only for PARENT grp; S between groups S for both groups S for both groups S for both groups S* for both groups; S between groups S* for PARENT, S for P+C**	None of significance	By regression analysis, attendance at sessions accounted for a significant amount of wt change in PARENT grp. as did treatment grp and change in home environment - total r2= 0.49. By regression analysis, the level of attendance at sessions, the treatment grp and improvement in obesogenic load in the home environment explained 49% of the variability in child BMI z-score.	In this small study, targeting healthy lifestyle training to parents only significantly improved children's weight loss during and after treatment when compared with targeting parents + children.	Q10. A healthy lifestyle training program focused on parents alone can significantly decrease BMI z-score or overweight percentage in overweight or obese young children. Q13. Obesogenic home environment and adverse diet and activity behaviors can be changed in young children by targeting parental behavior.
16611394	Golan M	Childhood obesity treatment: targeting parents exclusively v. parents and children	2006																16 1-hr support and education groups for parents and children Content of program was the same as for Arm 1								

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
16818530	Goldfield GS	Effects of open-loop feedback on physical activity and television viewing in overweight and obese children: a randomized, controlled trial	2006	RCT	None	Q10 (RF8, RF9, RF11)	Canada	Home	Other	8 wk	8 wk	Evaluate the effects of open-loop feedback plus reinforcement versus open-loop feedback alone on physical activity, targeted sedentary behavior, body composition, and energy intake in overweight and obese youth	30	Parental/ Family/ Caregiver	8-12 yr Overweight or obese defined as a BMI > 85th percentile for age and gender Watching ≥ 15 hr of television per wk, including VCR/DVD use and video-game playing Engaging in <30 min/d of MVPA No conditions that would limit physical activity Agreement that the child or parent would not participate in any other exercise or weight control program during the course of the study	Mean age (SD): Arm 1: 10.0 yr (0.90) Control Arm: 10.7 yr (1.4) Males: Arm 1: 6 Control Arm: 7 Combined parental income: < $50,000: Arm 1: 2 (14.3%) Control Arm: 4 (25%) $50,000-$75,000: Arm 1: 5 (362%) Control Arm: 6 (38%) > $75,000: Arm 1: 7 (50%) Control Arm: 6 (38%)	14 (14)	Behavioral	Arm 1: Open-loop feedback + reinforcement (INT) Children were provided objective feedback on their physical activity by wearing a physical activity monitor; for every 400 counts of physical activity on pedometers, subjects earned 1 hr of TV/VCR/DVD time, which was controlled by a Token TV electronic device placed in each home	16 (16)	Control Arm: Open-loop feedback (CON) Children wore activity monitors and were provided feedback on physical activity but had free access to TV independent of physical activity	**Primary:** Mean weight [kg (SD)] Mean BMI [kg/m2 (SD)] Mean physical activity [counts/d (SD)] Mean MVPA [min/d (SD)] Mean VPA [min/d (SD)] Mean targeted sedentary behavior [min/d (SD)]	**Primary:** INT: 61.5 +/-16.9 --> 61.6 +/- 17.1 CON: 65.6 +/- 13.9 --> 67.2 +/- 15.0 INT: 28.9 +/- 6.2 --> 28.3 +/- 6.6 CON: 28.2 +/- 3.0 --> 28.5 +/- 3.1 INT: 247 +/- 131.2 --> 407.8 +/- 192.4 CON: 206.8 +/- 119 --> 239.8 +/- 130.2 INT: 14.4 +/- 7.8 --> 23.8 +/- 17.0 CON: 12.0 +/- 11.3 --> 12.3 +/- 8.9 INT: 3.7 +/- 4.9 --> 9.5 +/- 14.6 CON: 1.2 +/- 1.6 --> 4.3 +/- 4.7 INT: 160.5 +/- 93.7 --> 44.4 +/- 26.5 CON: 152.1 +/- 86.5 --> 166.3 +/- 102.7	**S for group X time** **S for group X time** **S between groups** **S between groups** **S between groups** **S* between groups**	None	No change in non-targeted sedentary behavior. INT group decreased intake of fat, total snacks and snacks while watching TV (all , p=S) Despite no dietary intervention, there were significant improvements in wt and BMI.	Open loop feedback of physical activity counts to earn reward of TV time significantly increased activity levels and reduced sedentary TV time.	Q10. Activity behavior can be favorably altered in children with accompanying changes in weight & BMI over time.
16818530	Goldfield GS	Effects of open-loop feedback on physical activity and television viewing in overweight and obese children: a randomized, controlled trial	2006												No regular participation in swimming or strength training												
16826016	Shaibi GQ	Effects of resistance training on insulin sensitivity in overweight Latino adolescent males	2006	RCT	None	Q10 (RF8) Q13 (RF6, RF11, RF14)	USA	Clinical	None/NR	16 wk	16 wk	Examine the effects of a 16-wk resistance training exercise intervention on insulin sensitivity in youth at high risk for developing type 2 diabetes	28	Pediatric/ Young Adults	Adolescent Male Latino ethnicity (parents and grandparents of Latino descent by self-report) Age and gender specific BMI ≥ 85th percentile Exclusions: Using a medication or diagnosed with a condition known to influence body composition or insulin/glucose metabolism Orthopedic condition that would limit ability to perform exercise	Mean age (SEM): Arm 1: 15.1 yr (0.5) Control Arm: 15.6 yr (0.5) Impaired fasting glucose: 4 Impaired glucose tolerance: 6	14 (11)	Behavioral	Arm 1: Resistance training program (INT) Took place on 2 nonconsecutive d/wk and did not exceed 1 hr in duration Designed to stimulate protein adaptation by incorporating moderate-intensity higher-volume training while incorporating multiple sets with continued increases in load as tolerated Consisted of compound lower-body exercises and isolated upper-body exercises on the first training of the wk and compound upper-body exercises and isolated lower-body exercises on second training of the wk	14 (11)	Control Arm: No training program (CON) Participants were called periodically throughout the program by research staff and offered the training program following the acquisition of posttesting data	**Primary:** Change in insulin sensitivity [%(SEM)] **Secondary:** Mean insulin sensitivity[x 10-4 min-1·μU-1·mL-1 (SEM)] Mean fasting insulin [μU/ml (SEM)] Mean change in percent BF [% (SEM)] Mean change in lean mass [kg (SEM)] Mean 1-repetition maximum bench press [kg (SEM)] Mean 1-repetition maximum leg press [kg (SEM)] Mean fasting glucose [μU/ml (SEM)] Mean VO2peak [L/min (SEM)] Mean weight [kg (SEM)] Mean BMI [kg/m2 (SEM)] Mean total fat mass [kg (SEM)]	**Primary:** INT: +45.1%(7.3) vs CON: -0.9%(12.9) **Secondary:** INT:2.3(0.3) to 3.2(0.3); CON:1.7(0.4) to 1.8(0.6) INT: 12.8(2.1) to 11.5(2.5) CON:17.4(2.1) to 19.1(2.7) INT: -6.7(2.3) vs CON:-1.5(2.2) INT: +7.4(1.6) vs CON: +3.4(0.9) INT: +10.5(1.5) vs CON: +4.1(1.6) INT: +50.9(7.3) vs CON:+9.7(9.9) No change in any variable below this.	**S* between groups** **S, pre vs post; NS between groups** **NS, pre vs post** **S, pre vs post; NS between groups** **NS, pre vs post** **S between groups** **S between groups** **S between groups** **S between groups**	None		A twice weekly 16 wk resistance program significantly increased insulin sensitivity in overweight Latino adolescent males independent of changes in body weight.	A twice weekly 16 wk resistance program significantly increased insulin sensitivity in overweight Latino adolescent males independent of changes in body weight.
16826016	Shaibi GQ	Effects of resistance training on insulin sensitivity in overweight Latino adolescent males	2006												Performed structured resistance training exercise within 6 mo prior to enrollment												
16847290	Berkowitz RI	Effects of sibutramine treatment in obese adolescents: a randomized trial	2006	RCT	None	Q10 (RF8) Q13 (RF4, RF5, RF14)	USA	Clinical	Double	12 mo	12 mo	Examine whether sibutramine reduces weight more than placebo in obese adolescents receiving a behavior therapy program	498	Pediatric/ Young Adults	12-16 yr BMI ≥ 2 units more than the US weighted mean of the 95th percentile based on age and sex, to the upper limit of 44 kg/m^2 Exclusions: CVD (including arrhythmias) Type 1 or 2 diabetes mellitus Cigarette smoking SBP > 130 mmHg DBP > 85 mmHg Pulse > 95 bpm	Mean age (SD): Arm 1: 13.7 yr (1.3) Control Arm: 13.6 yr (1.3) Men: Arm 1: 126 Control Arm: 50 White: Arm 1: 206 Control Arm: 76 African-American: Arm 1: 80 Control Arm: 25 Hispanic or Mexican American: Arm 1: 60 Control Arm: 18 Other race: Arm 1: 22 Control Arm: 11 Dyslipidemia: 52%	368 (281)	Pharmacologic	Arm 1: Sibutramine 10 mg/d + behavior therapy program (SIB) Behavior therapy program was specific to each participant's needs and included self-monitoring of eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring and social support All participants also received counseling to increase physical activity, decrease sedentary behavior, and encourage development of healthy eating habits At 6 mo, sibutramine doses of all participants who had not lost > 10% of their initial BMI were increased to 15 mg	130 (80)	Control Arm: Placebo + behavior therapy program (PLAC) Behavior therapy program was specific to each participant's needs and included self-monitoring of eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring and social support All participants also received counseling to increase physical activity, decrease sedentary behavior, and encourage development of healthy eating habits At 6 mo, placebo doses of all participants who had not lost > 10% of their initial BMI were increased to 15 mg	**Primary:** Mean treatment difference in BMI [% (CI))] **Secondary:** Mean treatment difference in wt[kg (CI)] Mean treatment difference in WC [cm (SE)] Mean treatment difference in SBP[mmHg (CI)] Mean treatment difference in DBP [mmHg (CI)] Mean treatment difference in HR[bpm(CI)] Mean treatment difference in insulin [pmol/L (CI)] Mean change in HOMA Mean change in TG [mmol/L (SE)] Mean change in HDL-C [mmol/L (SE)] Mean change in LDL-C [% (SE)] Mean change in TC [% (SE)]	**Primary:** SIB vs PLAC: -8.2% (-10.1,-6.2) **Secondary:** SIB vs PLAC: -8.6% (-10.6,-6.6) SIB vs PLAC: -6.4 (-8.2,-4.5) SIB vs PLAC: 1.0(0.1,1.9) SIB vs PLAC: 1.7(1.0,2.5) SIB vs PLAC: +2.5(1.6,3.3) SIB vs PLAC: -42.2(-62.6,-21.7) SIB vs PLAC: -12.3(-18.0,-6.5) SIB vs PLAC: -0.3(-0.4,-0.1) SIB vs PLAC: 0.1(0.04,0.12) No significant change No significant change	**S** **S** **S** **S** **S** **S** **S** **S** **S** **S** **NS** **NS**	Small increase in HR and DBP in SIB group; otherwise no safety differences between groups.	DBP slightly higher in sibutramine treated group, lower in control group. SBP lower in both groups.	In obese adolescents, the addition of sibutramine to a behavioral wt loss program significantly increased wt loss over 12 mos. HR and DBP are slightly higher in the sibutramine group.There is concern re: higher BP with sibutramine.	Q10,13. In obese adolescents, the addition of sibutramine to a behavioral wt loss program significantly increased wt loss over 12 mos. HR and DBP are slightly higher in the sibutramine group.There is concern re: higher BP with sibutramine
16855194	Haerens L	Body mass effects of a physical activity and healthy food intervention in middle schools	2006	RCT	None	Q10 (RF8) Q11 (RF8) Q13 (RF8)	Belgium	Community (schools)	None/NR	2 school yr	2 school yr	Evaluate the effects of a 2 yr middle school physical activity and healthy food intervention, including an environmental and computer-tailored component, on BMI and BMI z-scores in boys and girls	2,991 (15 schools)	Parental/ Family/ Caregiver	7th and 8th graders	Mean age (SD): 13.06 yr (0.81) Boys: 63.4% Lower SES: 67.5%	Arm 1: 1,226 (1,116) 5 schools (NR) Arm 2: 1,006 (838) 5 schools (NR)	Behavioral	Arm 1: Physical activity + diet + parental involvement (INT+P) Physical activity intervention focused on increasing levels of MVPA to ≥ 60 min/d 4 class hr on the promotion of physical activity, including a physical fitness test and a computer-tailored intervention Food intervention included increasing fruit consumption to ≥ 2 pieces/d, reducing soft drink consumption and increasing water consumption to 1.5 L/d, and reducing fat intake 2 class hr were spent on promotion of healthy eating, including a computer-tailored intervention for fat intake and fruit intake Parental involvement was achieved via meetings, newsletters and a CD-ROM	759 (671) 5 schools (NR)	Control Arm: Not specified CON)	**Primary:** BMI Boys BMI z Boys BMI Girls BMI z Girls	**Primary: [2 yrs]** No difference for either INT or CON. No difference for either INT or CON. INT + P vs CON: Less increase INT + P vs INT No P: Less increase INT + P vs CON: Less increase INT + P vs INT No P: Less Increase	**NS** **NS** **S** **S** **S** **S**	None	Interventions were not closely or evenly followed in the schools so impact may have been greater in some schools than in others. Boys may have been more active at baseline.	A school based diet and exercise initiative with parent involvement decreased increase in BMI in girls but not in boys. Having parents in the program helped the girls.	Q 10,11,13. After 2 years, a school based diet and exercise initiative with parent involvement decreased increase in BMI in girls but not in boys. Having parents in the program helped the girls, not boys.
16855194	Haerens L	Body mass effects of a physical activity and healthy food intervention in middle schools	2006																Arm 2: Physical activity + diet (INT) Same physical activity and diet interventions as in Arm 1								

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
16861099	Garcia-Morales LM	Use of sibutramine in obese Mexican adolescents: a 6-month, randomized, double-blind, placebo-controlled, parallel-group trial	2006	RCT	None	Q10 (RF8)	Mexico	Clinical	Double	6 mo	6.5 mo Includes 15 d run-in period to provide dietetic advice to patients	Assess the efficacy and safety of sibutramine in obese Mexican adolescents	51	Pediatric/ Young Adults	14-18 yr Sex-specific BMI for age and sex > 95th percentile Exclusions: SBP ≥ 140 mmHg or DBP ≥ 90 mmHg Genetic disorder associated with obesity	Mean age (SD): Arm 1: 15.2 yr (1.3) Control Arm: 14.7 yr (1.1) Males: Arm 1: 9 Control Arm: 11 High BP (according to definitions of NHLBI): 9 Glucose (defined as > 109.9 mg/dL and < 126 mg/dL): 4 Lipid comorbidities (defined by The Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults) High TG: 24 22 High cholesterol: 10 High LDL: 5 High HDL: 3	26 (21)	Pharmacologic	Arm 1: Sibutramine 10 mg + individually tailored diet and exercise programs (SIB) Both groups were advised to adopt a diet supplying 30 kcal/kg of the current body weight; approx. 50% of the diet's energy derived from CHO, 30% from lipids, and 20% from proteins; all patients received a list of recommended food portions and possible combinations; all patients were advised to perform at least 30 min of aerobic physical activity/d	25 (19)	Control Arm: Placebo + individually tailored diet and exercise programs (PLAC) Both groups were advised to adopt a diet supplying 30 kcal/kg of the current body weight; approx. 50% of the diet's energy derived from CHO, 30% from lipids, and 20% from proteins; all patients received a list of recommended food portions and possible combinations; all patients were advised to perform at least 30 min of aerobic physical activity/d	**Primary:** Mean weight [kg (CI)] Mean BMI [kg/m2 (CI)] Mean percentage of initial BMI (CI) **Secondary:** Mean waist circumference [cm (CI)] Mean percentage of initial waist circumference (CI) LDL (mg/dL)	**Primary:** SIB: -7.3 (-4.6 to -9.9) vs PLAC: - 4.3 (-1.7to-6.9) SIB: -3.2 (-2.3 to-4.1) vs PLAC:-2.0 (-0.9 to-3.0) SIB: 11/23 reduced BMI>/= 10% vs PLAC: 1/23 SIB: -9.2 (-6.9 to -11.3) vs PLAC: -5.2 (-2.4 to -7.0) **Secondary:** SIB:-8.0 (-4.7 to -11.3) vs PLAC: -3.8 (-0.7 to-7.0) SIB: -7.1(-4.3 to-9.9) vs PLAC:-3.2 (-0.4 to-6.1) SIB: -19.3 vs PLAC: - 23.6	**S** **NS** **S*** **NS** **NS** **NS** **S**	None of significance	No significant difference in mean HR or BP or incident elevation in BP or HR between groups. At baseline, 2/23 SIB pts had HTN & 2/21 at termination; in PLAC, 7/23 had HTN at baseline & 2/19 at termination (p=S)	Fixed dose SIB therapy was associated with a significant increase in wt loss and BMI decrease compared with placebo in this small study with no discontinuation due to adverse events.	Q10. In obese children, addition of a fixed moderate dose of sibutramine to a diet and exercise program significantly increases weight loss without adverse side effects.
16899804	Williamson DA	Two-year internet-based randomized controlled trial for weight loss in African-American girls	2006	RCT	None	Q10,11 (RF8)	USA	Home	None/NR	2 yr	2 yr	Test the efficacy of an Internet-based lifestyle behavior modification program for African-American girls	57	Parental/ Family/ Caregiver	11-15 yr Overweight or obese adolescent girls African-American BMI >85th percentile for age and gender based on 1999 National Health and Nutrition Examination Survey (NHANES) ≥1 biological parent with BMI>30 1 parent with BMI>27 willing to participate in the trial Family willing to pay $300 out-of-pocket expenses toward purchase of the computer	Mean age (SD): 13.2 yr (1.4) Mean parent age (SD): 43.2 yr (6.2)	NR (NR)	Behavioral	Arm 1: Interactive Internet-based behavioral weight management program Provided nutrition education and behavior modification using family-oriented format Counseling for behavior modification provided primarily via email communications Web site contained variety of interactive components (e.g., weight and physical activity graphs, lessons and quizzes with instant feedback) allowing for self-monitoring, etc.	NR (NR)	Control Arm: Passive (i.e., non-interactive) Internet-based health education program Provided health education in coordinated program between face-to-face sessions and web site links promoting healthy lifestyles Web site did not provide explicit prescriptions for behavior change, behavioral contracts, or opportunities for self-monitoring	**Primary:** Mean change in weight [kg (SE)] Mean change in BMI [kg/m2 (SE)] Mean change in BF [% (SE)] **Secondary:** Mean web site hits Mean wt chart site hits	**Primary: At 2 years:** INT parents -1.1 +/- 0.91 CON parents -0.60 +/- 0.89 INT adolescents + 4.4 +/- 1.7 CON adolescents + 6.3 +/- 1.6 INT parents -0.55 +/- 0.34 CON parents + 0.04 +/- 0.34 INT adolescents + 0.73 +/- 0.66 CON adolescents + 1.2 +/- 0.65 INT parents +0.36 +/- 0.46 CON parents 0.51 +/- 0.46 INT adolescents -0.08 +/- 0.71 CON adolescent 0.84 +/- 0.72 **Secondary:** Mean web site hits Mean wt chart site hits	**NS between groups** **NS between groups** **NS between groups** **NS between groups** **NS between groups** **NS between groups** Significant differences in web site use during the 1st y of treatment : INT>CON,p=S for parents & adolescents Web site use by both groups essentially disappeared by the end of y 2.	None		Early decreases in wt for parents and BF for adolescents in a web-based program described in a previous paper were not sustained at 24 mo F/U.	Q10 : A web-based program was successful in producing early decreases in wt for parents and BF for adolescents at 6 mos described in previous paper. Q11. These changes were not sustained at 24 mo F/U.
16899804	Williamson DA	Two-year internet-based randomized controlled trial for weight loss in African-American girls	2006												Electricity available in family home Family home had ≥ 1 functional telephone line											
16988082	Rodearmel SJ	A family-based approach to preventing excessive weight gain	2006	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	USA	Home	None/NR	13 wk	14 wk Includes 1 wk baseline measurement period	Evaluate the ability of a family-based program aimed at increasing steps and cereal consumption (for breakfast and snacks) to reduce weight gain in children and adults	118 target children (105 families)	Parental/ Family/ Caregiver	8-12 yr At-risk-for-overweight or overweight (≥ 85th percentile BMI-for-age)	Mean age (SE): Boys: Arm 1: 9.8 yr (0.2) Control Arm: 9.9 yr (0.2) Girls: Arm 1: 10.1 yr (0.2) Control Arm: 9.9 yr (0.4)	93 target children (68 target children) 82 families (62 families)	Behavioral	Arm 1: Increased walking and cereal consumption (INT) Each participating family member was asked to increase walking by at least 2,000 steps/d above baseline levels and encouraged to continue increasing steps/d as much as possible Each participating family member was also asked to consume 2 servings/d of ready-to-eat cereal (at breakfast and for a snack)	25 target children (20 target children) 23 families (19 families)	Control Arm: Maintain usual eating and step patterns (CON)	**Primary:** Mean steps/d [steps (SE)] Cereal consumption[servings/wk(SE)] **Secondary:** Mean change in weight [kg] Mean change in BMI [%] Mean change in BF [%]	**Primary: (F=Female;M=Male)** Increased from B/L in INT Ms and Fs; no change in CONs.(only shown in figure) INT: 8.1(0.17) VS con: 3.62(0.17) **Secondary:** INT: +1.50 vs CON: +1.814 INT: -0.65 vs CON: 0.47 INT: -0.51 vs CON: +0.91	**S between groups, M and F** **S** **NS between groups** **S between groups** **S** between groups**	None	Although the group as a whole experienced a decrease in %BMI this was almost entirely due to changes in the girls and their mothers. Boys and their fathers did not change %BMI with this intervention.	A pilot study designed to increase steps/day and increase cereal consumption at breakfast and as snacks in overweight children and their parents was successful in both outcomes with associated decreases in BMI and body fat. When analyzed by gender, the group difference was found to be almost entirely due to changes in Fs with much less difference in Ms.	Q10,13.Family-based diet and exercise changes are associated with improvements in BMI and body fat, much more significant in Fs than Ms.
17028105	Reilly JJ	Physical activity to prevent obesity in young children: cluster randomised controlled trial	2006	RCT	None	Q6 (RF2, RF11) Q13 (RF8, RF11)	Scotland	Mult settings	Other	24 wk	12 mo	Assess whether physical activity intervention reduces BMI in young children	545 (36 nurseries)	Parental/ Family/ Caregiver	Preschool-aged children	Mean age (SD): Arm 1: 4.2 yr (0.3) Control Arm: 4.1 yr (0.3) Boys: Arm 1: 128 Control Arm: 145 Overweight: Arm 1: 62 Control Arm: 61 Obese: Arm 1: 27 Control Arm: 28	268 (245) 18 nurseries (N/A) All 18 nurseries remained at 6 mo follow-up, but by final 12 mo follow-up, children had left nurseries for schools	Behavioral	Arm 1: Enhanced physical activity program (INT) 3 30-min physical activity sessions/wk in nursery Families received a resource pack of materials containing health education leaflets and guidance on linking physical play and nursery at home	277 (259) 18 nurseries (N/A) All 18 nurseries remained at 6 mo follow-up, but by final 12 mo follow-up, children had left nurseries for schools	Control Arm: Continuation of usual curriculum (CON) No enhancement of physical development and movement curriculum	**Primary:** Mean BMI SDS (SD), cluster **Secondary:** Mean BMI SDS (SD), indiv Mean total physical activity [accelerometer count/min (SD)] Median monitored time sedentary [% (range)] Median monitored time in MVPA [% (range)] Mean fundamental movement skills score (SD)	**Primary:** INT: 0.41(1.05) vs CON: 0.43 (1.10) **Secondary:** No significant change No significant change No significant change No significant change INT:11.5(2.3) vs CON: 10.7(2.5)	**NS** **NS** **NS** **NS** **NS** **S**	Not reported		An enhanced activity program for pre-school children was unsuccessful in changing BMI or improving any activity measure except for movement score.	Q10,13. An enhanced activity program for pre-school children was unsuccessful in changing BMI or improving any activity measure except for movement score.
17030973	Fitzgibbon ML	Hip-Hop to Health Jr. for Latino preschool children	2006	RCT	None	Q5 (RF8,9,11) Q10 & 11 (RF8, RF9, RF11) Q13 (RF8, RF9, RF11)	USA	Community (schools)	None	14 wk	2 yr	Compare changes in BMI in minority preschool children from schools randomized to a weight control intervention (the Hip-Hop to Health Jr. program) or to a control group that received a general health intervention	401 (12 schools)	Parental/ Family/ Caregiver	3-5 yr Head Start sites in Chicago serving primarily Latino children	Mean age (SD): Arm 1: 50.8 mo (7.3) Control Arm: 51.0 mo (7.0) Male: Arm 1: 52.5% Control Arm: 48.7% Black: Arm 1: 15.8% Control Arm: 6.5% Latino: Arm 1: 73.3% Control Arm: 89.4% Multi-racial/other race: Arm 1: 10.9% Control Arm: 4.0% Mean parental education (SD): Arm 1: 11.3 yr (3.6) Control Arm: 10.6 yr (3.7)	202 (171)	Behavioral	Arm 1: Diet + physical activity Culturally proficient weight control intervention consisting of a diet/physical activity curriculum delivered 3 times/wk Each session included 20 min of a nutrition activity and 20 min MVPA Intervention was delivered in both Spanish and English Target behaviors included increasing fruit and vegetable consumption, decreasing fat intake and sedentary behavior, and increasing physical activity Parents received weekly newsletters and 12 homework assignments that mirrored children's curriculum	199 (160)	Control Arm: Health curriculum 1-20 min session/wk with curriculum that taught general health concepts such as seat belt safety, immunization, and dental health Parents received weekly newsletters that mirrored the curriculum, but did not receive homework assignments	**Primary:** Mean change in BMI [kg/m^2 (SE)] Mean adjusted change in BMI [kg/m^2 (SE)] Mean change in BMI z score (SE) Mean adjusted change in BMI z score (SE) **Secondary:** Mean total fat intake [%E (SE)] Mean saturated fat intake [%E (SE)] Mean fiber intake [g/1000 kcal (SE)] Mean TV viewing [h\d (SE)] Mean exercise frequency [% ≥ 7 times/wk (SE)] Mean exercise intensity [Borg scale (SE)]	**Primary: YEAR 1:** INT: +0.33(0.14) vs CON: + 0.48(0.14) INT: 0.31(0.16) vs CON: 0.44(0.17) INT: 0.00(0.07) vs CON: 0.07(0.09) INT:-0.01(0.07) vs CON: 0.11(0.07) **Secondary:** No difference between groups for any diet or activity variable.	**NS** **NS** **NS** **NS**	None	The baseline mean BMI of 29.4 was close to the obese range in these Latina mothers.	In this Head Start-based diet and activity intervention for Latino pre-schoolers, there were no group differences in BMI change, diet or activity measures at follow-up. This is a distinct difference from the results achieved with AA children with the same intervention.	Q10,13. In this Head Start-based diet and activity intervention for Latino pre-schoolers, there were no group differences in BMI change, diet or activity measures at follow-up. Q5. There are racial and ethnic differences in the response to attempted diet and activity interventions in children at risk for overweight.
17030973	Fitzgibbon ML	Hip-Hop to Health Jr. for Latino preschool children	2006													Parents married or living as married: Arm 1: 67.9% Control Arm: 65.9%											

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
17084264	Meyer AA	Improvement of early vascular changes and cardiovascular risk factors in obese children after a six-month exercise program	2006	RCT	Multiple	Q10 (RF8) Q12a (RF4, RF5, RF7, RF8, RF11, RF14)	Germany	Clinical	None/NR	6 mo	6 mo	Assess effect of a 6 mo exercise program in obese children on FMD, IMT, and cardiovascular risk factors	96	Pediatric/ Young Adults	Obese (BMI > 97th percentile for the German pediatric population) Exclusions: Smoking Active participation in any exercise activity ≥ 30 min more than once/wk Participation in organized diet programs Diabetes, heart, renal, or liver disease	Mean age (SD): 14.2 yr (1.9) Boys: 47	50 (33)	Behavioral	Arm 1: Exercise 3x/wk + nutritional consultation (INT) Exercise included swimming, aqua aerobic training, sports games and walking Exercise was progressively intensified as individually tolerated Children in both groups received one consultation with a nutritionist to enhance knowledge about healthy nutrition	46 (34)	Control Arm: Nutritional consultation (CON) Instructed to maintain current levels of physical activity Children in both groups received one consultation with a nutritionist to enhance knowledge about healthy nutrition A separate non-randomized lean control group was compared only at baseline	**Primary:** Flow mediated dilation [%] cIMT [mm] Mean IMT: mean common carotid artery [mm (SD)] Mean IMT:maximum common carotid [mm(SD)] Mean IMT: mean carotid bifurcation [mm (SD)] Mean IMT: maximum carotid bifurcation [mm (SD)] **Secondary:** Mean BMI [kg/m2 (SD)] Mean BMI SDS (SD) Mean BF [% (SD)] Mean insulin [pmol/L (SD)] Mean insulin resistance (SD) Mean HbA1c (SD) Mean TG [mmol/L (SD)] Mean LDL-C [mmol/L (SD)] Mean HDL-C [mmol/L (SD)] Mean CRP [mg/L (SD)]	**Primary:** INT: 4.09(1.76) to 7.71(2.53);CON: 5.49 to 4.33(SD NR) INT:0.48(.08) to 0.44(.08); CON:0.47(.06) to 0.45(.06) INT:0.53(.08) to 0.48(.08); CON:0.51(.07) to 0.50(.06) INT:0.53(.06) to 0.46(.08); CON:0.51(.06) to 0.47(.05) INT:0.58(.07) to 0.51(.09); CON:0.56(.07) to .57(.06) **Secondary:** INT: 29.8(5.93 to 27.2(4.8);CON:31.0(4.42) to 31.3(4.21) Decreased Decreased but NS from B/L for both groups INT:13.8(5.2) to 11.16(4.61);CON:No change INT:3.94(1.75) to 3.12(1.38);CON:No change No change INT:1.41(1.14) to 1.04(0.48);CON:No change INT: 2.71(.70) to 2.57(.66); CON: No change No change in either group INT: 4.84(6.31) to 2.05(2.44); CON: No change	**S** for INT** **S** for INT; NS for CON** **S* for INT; NS for CON** **S** for INT: NS for CON** **S** for INT; NS for CON** **S** for INT; NS for CON** **S**** **NS for both** **S* for INT; NS for CON** **S for INT; NS for CON** **NS for both groups** **S for INT; NS for CON** **S for INT; NS for CON** **NS for both groups** **S for INT; NS for CON**	None	At baseline, both obese groups differed significantly from lean controls in all parameters. At 6 mos, obese CON differed significantly from obese INT in all parameters.	After 6 mos, regular exercise significantly decreased BMI, improved CV risk profile, improved endothelial function and decreased cIMT in obese children.	Q10,12a. A 6 m trial of regular exercise decreased BMI, improved CV risk profile, improved endothelial function and decreased cIMT in obese children
17084264	Meyer AA	Improvement of early vascular changes and cardiovascular risk factors in obese children after a six-month exercise program	2006																			Mean SBP [mmHg (SD)] Mean exercise SBP [mmHg (SD)] Mean LV mass index [g/m^2 (SD)] Mean maximum work capacity at exercise [W/kg (SD)] Mean maximum work capacity at exercise [% normal values (SD)] Mean sport activity [hr/wk]	INT:128(15.7) to 120(13.3);CON; No change No change in INT; increased in CON No change in either group INT: 2.14(.37) to 2.46(.62); CON: No change INT: 64.9(14.3) to 76.9(20.9); CON: No change Not reported With regression analysis, FMD change correlated best with change in hrs of sports/wk(r=-0.537,p=S**) but also with change in BMI,W/H,body fat & INS.	**S** **NS for both groups** **NS for both groups** **S** for INT; NS for CON** **S** for INT; NS for CON** **NR**				
17151157	Klein DJ	A randomized, double-blind, placebo-controlled trial of metformin treatment of weight gain associated with initiation of atypical antipsychotic therapy in children and adolescents	2006	RCT	None	Q10 (RF8) Q13 (RF14)	USA	Clinical	Double	16 wk	16 wk	Evaluate the effectiveness of metformin in managing weight gain among patients who experienced weight gain during treatment with atypical antipsychotics	38	Pediatric/ Young Adults	10–17 yr Gained more than 10% of their predrug weight during < 12 mo of treatment with a targeted atypical antipsychotic agent (i.e., olanzapine, risperidone, or quetiapine) Exclusions: Diabetes mellitus	Mean age (SD): Arm 1: 12.9 yr (2.4) Control Arm: 13.3 yr (2.4) Male: Arm 1: 9 Control Arm: 12 Caucasian: Arm 1: 14 Control Arm: 12 African American: Arm 1: 4 Control Arm: 8	18 (15)	Pharmacologic	Arm 1: Metformin (MET) 500 mg qd wk 1 500 mg bid wk 2 850 mg bid wk 3-16 Nutritional counseling by a registered dietician and "Healthy Food Choices" foldout meal-planning tool	20 (15)	Control Arm: Placebo (CON) Nutritional counseling by a registered dietician and "Healthy Food Choices" foldout meal-planning tool	**Primary:** Mean difference in change in weight [kg (SD)] Mean difference in change in BMI [kg/m^2 (SD)] Mean difference in change in waist circumference [cm (SD)] Mean change in insulin resistance [HOMA-IR value (SD)]	**At 16 weeks:** MET - CON: -4.08(4.06) MET - CON: -1.12(1.43) MET - CON: -4.65(8.17) Significant increase in INS sensitivity at weeks 4 & 8 but not at week 16.	**S**** **S**** **S*** **NS**	No serious AEs in either group.		Metformin effectively controlled excess weight gain in adolescents receiving atypical antipsychotic drugs.	Q10,13. Metformin effectively controlled excess weight gain in adolescents receiving atypical antipsychotic drugs.
17160087	McCallum Z	Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity	2007	RCT	None	Q10 (RF8) Q13 (RF9, RF11)	Australia	Clinical	Other	12 wk	June 2002-March 2004	Reduce gain in BMI in overweight/mildly obese children in the primary care setting	163	Pediatric/ Young Adults	5 yr, 0 mo - 9 yr, 11 mo Overweight or mildly obese Not receiving ongoing weight management in a secondary or tertiary care progam Exclusions: Chromosomal, endocrine or medical condition/disability/medication that could have an impact on weight or growth	Mean age (SD): 7.4 yr (1.6) Males: 79 SES by population quintile for SEIFA Index of Relative Socio-economic Disadvantage: 1 (highest): 44 2: 25 3: 25 4: 27 5 (lowest): 42	82 (70)	Behavioral	Arm 1: Consultations with a general practitioner (INT) 4 consultations over 12 wks; targeted change in nutrition, physical activity and sedentary behavior Supported by purpose-designed family materials	81 (76)	Control Arm: No intervention (CON) Control families were notified of their status via letter and were not identifed to the general practitioners at any time	**Primary:** Mean BMI [kg/m^2 (SD)] Mean UK BMI z-score (SD) **Secondary:** Mean activity time spent in MVPA [% (SD)] Mean daily physical activity (SD) Mean daily nutrition score (SD)	**Primary:** 9 MOS: INT: 21.0(2.6) vs CON:20.8(2.2) 15 MOS: INT:21.7(3.1) vs CON:21.2(2.4) 9 MOS: INT: 1.96(0.64) vs CON: 1.93(0.57) 15 MOS: INT: 2.00(0.68) vs CON: 1.92(0.59) **Secondary:** 9 MOS: INT: 42.9(15.5) vs CON: 36.1(20.5) 15 MOS: 39.2(19.3) vs CON:35.2(20.5) 9 MOS: INT: 3.3(0.5) vs CON: 3.2(0.6) 15 MOS: INT: 3.3(0.5) vs CON: 3.2(0.5) 9 MOS: INT: 19.0(2.7) vs CON: 16.5(2.5) 15 MOS: INT: 18.7(2.0) vs CON: 16.1 (2.7)	**NS between groups** **NS between groups** **NS between groups** **NS between groups** **S between groups** **NS between groups** **p=0.08 between groups** **p=0.08 between groups** **S** between groups** **S** between groups**	None reported	Additional health care costs associated with this intervention would be $873 per intervention child. This would fall as numbers treated increased to $196/child.	A brief, family-based intervention in a primary care setting demonstrated no improvement in BMI despite higher parent-reported activity scores and better parent-reported nutrition scores for the intervention children.	Q10, 13. A brief, family-based intervention in a primary care setting demonstrated no improvement in BMI despite higher parent-reported activity scores and better parent-reported nutrition scores for intervention children.
17264187	Van Mil EG	The effect of sibutramine on energy expenditure and body composition in obese adolescents	2007	RCT	None	Q10 (RF8) Q13 (RF11)	The Netherlands	Clinical	Double	12 wk	24 wk	Examine the effect of treatment with sibutramine on body composition and energy expenditure in obese adolescents	24	Pediatric/ Young Adults	12-18 yr BMI ≥ 97th percentile Triceps skinfold thickness ≥ 97th percentile for age and sex with persisting obesity despite professionally supervised weight loss attempts Exclusions: Endocrine causes or other secondary causes of obesity	Mean age (SD): Arm 1: 14.1 yr (1.0) Control Arm: 13.8 yr (1.5) Males: 11	12 (11)	Pharmacologic	Arm 1: 5 mg sibutramine qd + diet and exercise plan Sibutramine was administered for 12 wk; after 2 wk, dose was increased to 10 mg sibutramine qd Treatment included an energy-restricted diet and an exercise plan; emphasis throughout the trial on lifestyle modification Second phase consisted of 12-wk follow-up period with continuation of diet and exercise plan, but without study medication	12 (9)	Control Arm: Placebo + diet and exercise plan Treatment included an energy-restricted diet and an exercise plan; emphasis throughout the trial on lifestyle modification Second phase consisted of 12-wk follow-up period with continuation of diet and exercise plan, but without study medication	Mean change in BMI SDS (SD) Mean change in FFM [kg (SD)] Mean change in percent fat mass [% (SD)] Mean change in sleeping metabolic rate [MJ/d (SD)] Mean change in basal metabolic rate [MJ/d (SD)] Mean change in adjusted basal metabolic rate [MJ/d (SD)] Mean change in total energy expenditure [MJ/d (SD)] Mean change in residual total energy expenditure [MJ/d (SD)] HR [bpm(SD)] SBP[mmHg (SD)] DBP[mmHg (SD)]	SIB: -1.5 (0.82) vs CON: -0.09 (0.13) SIB: -0.60(2.69) vs CON: 0.10(2.01) SIB: -1.62(2.39) vs CON: -1.31 (1.74) SIB: -0.36(0.45) vs CON: -0.28(0.40) SIB: -0.10(0.52) vs CON: -0.52(0.85) SIB: 0.20(1.01) vs CON: -0.67(1.52) SIB: -1.10(1.67) vs CON: 0.52(1.50) SIB: -1.10 (1.67) vs CON: 0.52(1.50) In follow-up, BMRadj decreased in the SIB group [-0.56(1.44)] and increased in the CON group [+0.87(1.47)]. SIB: 74.4(11.3) to 86.2(18.8) CON:68.3(7.4) to 74.0(8.2) SIB: 112.3(6.8) to 118.7(9.0) CON: 115/7(8.6) to 119.8(10.6) SIB: 69.3(6.9) to 68.2(7.3) CON:74.6(8.1) to 65.0(8.2)	**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.** **NS, baseline to INT; NS between groups** **NS, baseline to INT** **NS, baseline to INT; NS between groups** **NS, baseline to INT** **NS, baseline to INT; NS between groups** **S**, baseline to INT.**	No significant difference in AE reporting between groups. One SIB subject dropped out because of depression.		In this metabolic study of lifestyle change + sibutramine, both treatment groups decreased BMI-SDS similarly with no additional effect of sibutramine.	Q10. In this metabolic study of lifestyle change + sibutramine, both treatment groups decreased BMI-SDS similarly with no additional effect of sibutramine. Differences in metabolic measures between groups were minimal.

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
17321425	Huang JS	Body image and self-esteem among adolescents undergoing an intervention targeting dietary and physical activity behaviors	2007	RCT	None	Q13 (RF8)	USA	Clinical	None	12 mo	12 mo	Determine the effect of a 1-yr intervention targeting physical activity, sedentary behaviors, and diet behaviors among adolescents on self-reported body image and self-esteem	819	Pediatric/ Young Adults		Median age (interquartile range): 13 yr (12, 14) Males: 47% Non-white: 41% Overweight (BMI ≥ 95% for age and gender): 165 (57.5%)	424 (NR)	Behavioral	Arm 1: Patient-Centered Assessment and Counseling for Exercise Plus Nutrition Project (PACE+) intervention	395 (NR)	Control Arm: No details provided	Mean body-image dissatisfaction score[SD] Mean self esteem score [SD] Mean body-image dissatisfaction score[SD] Mean self esteem score [SD]	**GIRLS: Baseline to 12 mos:** PACE +: 27.3(9.1) to 28.5 (5.6) CON: 27.0(9.2) to 28.1(5.7) **BOYS: Baseline to 12 mos:** PACE +: 32.6 (6.8) to 33.4(6.3) CON: 32.5(6.2) to 33.4(6.6) **GIRLS: Baseline to 12 mos:** PACE +: 20.6(5.1) to 21.2(5.7) CON: 20.1(5.5) to 20.2(6.1) **BOYS: Baseline to 12 mos:** Pace +: 20.1(4.7) to 21.2(5.6) CON: 20.2(5.3) to 21.4(5.4) Pace participants analyzed by weight loss or weight gain: **GIRLS: Baseline to 12 mos:** LOSS: 28.0(8.6) to 30.8(9.1) GAIN: 30.0(9.0) to 29.6(9.5) **BOYS: Baseline to 12 mos:** LOSS: 31.3(4.7) to 31.6(7.0) GAIN: 34.7(6.8) to 34.9(6.1) **GIRLS: Baseline to 12 mos:** LOSS: 20.9(4.9) to 21.7(5.5) GAIN: 21.3(4.9) to 21.5(6.0) **BOYS: Baseline to 12 mos:** LOSS: 18.9(5.7) to 19.7(6.1) GAIN: 21.7(4.4) to 22.7(5.7)	**NS within or between groups X time** **NS within or between groups X time** **NS within or between groups X time** **S* within the group X time and p=S between groups over time** **S** between groups at baseline; S between groups X time** **S** between groups at baseline; S between groups at F/U** **NS within or between groups X time** **S* between groups; S X time;**	Not reported		At baseline, overweight girls and boys had lower scores for self esteem and body image than did n/l weight peers. Boys had higher body image and self esteem scores than girls regardless of weight status. There was no reduction in body image or self esteem scores with the PACE+ intervention regardless of weight change status. Girls in the PACE+ program who lost wt improved their body image scores; this was not seen in boys.	There was no reduction in body image or self esteem scores with the PACE+ intervention regardless of weight change status. Girls who lost or maintained wt had improved body image over time. Girls and overweight adolescents of both sexes had lower body image & self esteem compared with boys and normal wt adolescents.
17321425	Huang JS	Body image and self-esteem among adolescents undergoing an intervention targeting dietary and physical activity behaviors	2007																							Girls in PACE+ who lost wt had no change in self esteem scores but boys had increased self esteem regardless of wt change.	
17332205	Golley RK	Twelve-month effectiveness of a parent-led, family-focused weight-management program for prepubertal children: a randomized, controlled trial	2007	RCT	None	Q10 (RF8)	Australia	Clinical	Other	6 mo	12 mo	Evaluate the effectiveness of parenting-skills training, with or without intensive lifestyle education, as part of a parent-led, family-focused weight management program for overweight children	111	Parental/ Family/ Caregiver	6-9 yr Overweight (according to International Obesity Task Force definition) Tanner stage 1 Exclusions: BMI z score > 3.5 Diagnosed with syndromal cause of obesity Using medications that influence weight gain or loss Diagnosis of physical or developmental disability or chronic illness	Mean age (SD): 8.2 yr (1.1) Boys: 41 (36%) Obese: 82 Dual-parent families: 72% White parents: 98% Mean SEIFA index of relative advantage (SD): 997 (73)	Arm 1: 37 (29) Arm 2: 38 (31)	Behavioral	Arm 1: Parenting-skills training alone Parents participated in the Positive, Parenting Program, consisting of 4 weekly 2-hr group sessions followed by 4 weekly, then 3 monthly 15-20 min individual telephone sessions Received "healthy-lifestyle" pamphlet Arm 2: Parenting-skills training + intensive lifestyle education Parents participated in the same parenting program and received the same pamphlet as parents in Arm 1 7 intensive lifestyle support group sessions focused on healthy eating, commencing after completion of 4 weekly parenting sessions, every 2 wk at first, then monthly Children attended activity sessions while parents attended lifestyle sessions	36 (31)	Control Arm: Wait-listed for 12 mo for intervention Received "healthy-lifestyle" pamphlet Contacted by phone 3-4 times for 5 min as retention strategy	**Primary:** Mean BMI z score (SD) Children who increased BMI z score (%) Mean waist circumference z score (SD) **Secondary:** Mean TC (SD) Mean TG (SD) Mean LDL-C (SD) Mean HDL-C (SD) Mean SBP (SD) Mean DBP (SD) Mean glucose (SD) Mean insulin (SD)	**Primary: At 12 MOS**: P alone: 2.76+/-0.58 to 2.56+/-0.79 P+DA: 2.74+/-0.53 to 2.43+/-0.68 CON: 2.75 +/-0.39 to 2.60+/-0.57 P alone: 24% P + DA: 19% CON: 45% P alone: 3.20+/-0.67 to 2.93 +/-0.69 P + DA: 3.27 +/- 0.73 to 2.85+/-0.78 CON: 3.14 +/- 0.56 to 3.14 +/- 0.75 **Secondary:** No differences for any metabolic parameter between groups at baseline or 12 month F/U. * When adjusted for gender, results were much more significant in boys in both INT groups.	**NS for all comparisons** **S** **S, group by time**	None reported.		All 3 groups in this comparison of parenting-skills vs parenting skills + lifestyle training vs controls had a reduction in BMI z-score over 12 months of F/U with no statistical difference between groups. WC decreased significantly more in the intervention groups than in the controls. When adjusted for gender, results were much more significant in boys in both INT groups.	Q 10. All 3 groups in this comparison of parenting-skills vs parenting skills + lifestyle training vs controls had a reduction in BMI z-score over 12 months of F/U with no statistical difference between groups. WC decreased significantly more in the intervention groups than in the controls. When adjusted for gender, results were much more significant in boys in both INT groups.
17396436	Gillis D	A community-based behavior modification intervention for childhood obesity	2007	RCT	None	Q10 (RF8) Q13 (RF5, RF7, RF9, RF11, RF14)	Israel	Mult settings	None	3 mo	6 mo	Determine whether an intervention based on guidance and reinforcement regarding nutrition and exercise modification could show a trend toward improving obesity-related attitudes, reducing weight and decreasing adverse metabolic consequences of obesity	27	Parental/ Family/ Caregiver	7-16 yr BMI > 90th percentile	Mean age (SD): Arm 1: 11.2 yr (2.5) Control Arm: 9.9 yr (2.0)	14 (11)	Behavioral	Arm 1: Instruction on exercise and diet + weekly food diary + weekly telephone calls Children and their parents received 30-min talk on exercise and diet, repeated after 3 mo Instructed to record the contents of food ingested and amount of exercise performed 1 d/wk Called weekly by telephone to review food diary and receive instruction about adherence to the prescribed plan	13 (7)	Control Arm: Instruction on exercise and diet only Children and their parents received 30-min talk on exercise and diet, repeated after 3 mo	Subjects self-reporting change in consumption of sugar-containing drinks [%] Subjects self-reporting change in physical activity [%] Subjects self-reporting change in sweets consumption [%] Mean change in BMI SDS (SD) Mean modified Harvard step test score (SD) Mean change in LDL-C [mg/dL (SD)] Mean change in HDL-C [mg/dL (SD)] Mean change in TG [mg/dL (SD)] Mean change in CRP [mg/dL (SD)] HbA1c Fasting glucose Insulin Glucose/insulin ratio	INT: 80% vs CON:35% INT: 78% vs CON: 75% INT: 90% vs CON: 50% INT: 1.98+/-0.21 to 1.93+/-0.37 CON:2.16+/-0.34 to 2.23+/-0.29 INT: 39.2+/-18.8 to 40.2+/-13.1 CON:33.2+/-16 to 43.0+/-5.2 INT:97.5+/-25.3 to 86.4 +/-23.9 CON: 92.0+/-28.6 to 97.2+/- 21.6 INT: 48.9 +/-19.4 to 48.3 +/- 21.9 CON: 54.0+/-7.1 to 52.4+/-10.3 INT:93.8+/-60.3 to 141 +/-90.3 CON: 64.5 +/-15.2 to 77.0 +/-31.0 All values for CRP, HbA1C,FG & INS nl at baseline and F/U for both groups with no significant change.	**p=.074** **NS** **NS** **NS for change between groups** **NS** **NS** **NS** **NS** **NS** **NS** **NS** **NS**	None reported	None	A community-based program utilizing weekly phone contact resulted in small but insignificant improvement in self-reported obesity promoting behaviors but no change in BMI or metabolic parameters.	Q10. A community-based program utilizing weekly phone contact resulted in small but insignificant improvement in self-reported obesity promoting behaviors but no change in BMI or metabolic parameters.
17514539	Williams CL	Weight control among obese adolescents: a pilot study	2007	RCT	None	Q10 (RF8) Q13 (RF4, RF5, RF9, RF11)	USA	Clinical	None	12 wk	January - September 2004	Evaluate weight loss and compliance outcomes for overweight adolescents assigned to one of two dietary interventions differing in the type of snacks allowed	38	Parental/ Family/ Caregiver	11-15 yr Girls Otherwise healthy, but overweight (BMI > 95th percentile) Exclusions: Significant medical, physical, mental, or social problem that could negatively affect participation or could preclude normal food consumption or daily physical activity Extremely overweight (BMI > 45 kg/m^2)	Mean age (SD): Arm 1: 13.4 yr (1.5) Arm 2: 12.9 yr (1.3) African-American: 44.7% Latino: 34.2% Caucasian: 21.2%	Arm 1: 19 (17) Arm 2: 19 (15)	Behavioral	Arm 1: Calorie-controlled free snack diet (Free) Consisted of a 1,500 kcal/day diet which allowed for 3 meals and 2 150-kcal snacks; one snack had to be chosen from a list of healthy snacks, but the other snack was a free choice as long as it was 150 calories or less Could choose 12 oz of regular soda as free snack Arm 2: Calorie-controlled restricted snack diet (Restricted) Consisted of a 1,500 kcal/day diet which allowed for 3 meals and 2 150-kcal snacks; both snacks were restricted to the healthy snack list Limited to sugar-free beverages (except for milk)	N/A	N/A	**Primary:** Mean change in weight [kg (SD)] Mean change in BMI [kg/m^2 (SD)] **Secondary:** Mean change in waist circumference [cm (SD)] Mean change in waist/hip ratio (SD) Mean change in total skinfold [mm (SD)] Mean change in TC [mmol/L (SD)] Mean change in HDL-C [mmol/L (SD)] Mean change in TG [mmol/L (SD)] Mean change in LDL-C [mmol/L (SD)] Mean change in SBP [mmHg (SD)] Mean change in DBP [mmHg (SD)] Mean change in Digiwalker steps (SD)	**Primary:** Free: -1.32(2.61) vs Restricted: -1.22(1.93) Free: -1.00(1.17) vs Restricted:-1.05(0.67) **Secondary:** Free: -0.95(3.68) vs Restricted:-2.6(3.48) Free:-0.006(.044)vs Restricted:0.001(.048) Free: -7.4(10.9) vs Restricted: -11.4(17.0) Free: -0.46(0.73) to Restricted: -0.5(0.6) Free: -0.15(0.25) vs Restricted: -0.14(0.15) Free: -0.46(0.85) vs Restricted:-40.49(0.67) No significant difference pre- to post for either group or for combined, for this or any of the remaining variables.	**S* for Free, S** for Rest and S** for combined** **S* for Free, S** for Rest and S** for combined** **NS for Free, S for Rest and S for comb.** **NS for all** **S for Free, S for Rest and S* for comb.** **S for Free, S* for Rest and S** for comb.** **S for free, S* for restricted, S** for comb.** **S for free, S for restricted, S* for comb.** **NS for all** **NS for all** **NS for all** **NS for all**	None reported	Degree of satisfaction with the diet was similar for the 2 groups.	Calorie restriction resulted in modest decreases in weight and BMI in obese adolescent low SES girls regardless of whether a free snack was allowed. The weight change was accompanied by a decrease in TC and TGs.	Q10,13. Calorie restriction resulted in modest decreases in weight and BMI in adolescent low SES girls regardless of whether a free snack was allowed. The weight change was accompanied by a decrease in TC and TGs.
17514539	Williams CL	Weight control among obese adolescents: a pilot study	2007												Currently enrolled in another weight loss program Currently taking appetite suppressants or other medications that affect apetite or weight				Both diets consisted of approximately 50% carbohydrate, 21% protein, and 29% fat; subjects were asked to consume a multivitamin supplement as well as a 500 mg/d calcium supplement								

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
17519435	Pena AS	Folic acid does not improve endothelial function in obese children and adolescents	2007	RCT	FMD	Q10 (RF8)	Australia	Clinical	Double	8 wk	24 wk	Evaluate the effect of folate supplementation on endothelial dysfunction in obese children	53	Pediatric/ Young Adults	Mild to moderate obesity Exclusions: Smoking Diabetes Hypertension Lipid-lowering treatment Syndromal obesity and/or endocrinological causes of obesity	Mean age (SD): 13.3 yr (2.2) Males: 26	27 (26)	Dietary Supplements	Arm 1: 5 mg oral folic acid qd (FA)	26 (26)	Control Arm: Placebo (CON)	**Primary:** Mean FMD [% (SD)] **Secondary:** tHcy [umol/l (SD)] Serum folate [nmol/l (SD)] Red cell folate [nmol/l (SD)] GTN dilation [% (SD)] Mean hsCRP [mg/dL (SD)] TC [mg/dl (SD)] TG [mg/dl (SD)] HDL [mg/dl (SD)] LDL [mg/dl (SD)]	**Primary:** FA: 6.42(5.03) to 6.56(4.79) CON: 5.17 (3.54) to 5.79(4.26) **Secondary:** FA: - 0.95 (-1.45 tp -0.45) FA: + 18.4 (13.8-23.0) FA: 240.1 (201 - 364) No change in this or any parameter below this.	**NS** **S*** **S**** **NS** **NS** **NS** **NS** **NS**	None reported		Although folic acid supplementation increased folate-related measures, there was no change in FMD in obese children and adolescents.	Q10. Although folic acid supplementation increased folate-related measures, there was no change in FMD in obese children and adolescents.
17548761	Singh AS	Short-term effects of school-based weight gain prevention among adolescents	2007	RCT	None	Q10, 13 (RF8, RF11)	The Netherlands	Community (schools)	None	8 mo	8 mo	Determine whether a multicomponent health promotion intervention for Dutch adolescents would be successful in influencing body composition and aerobic fitness	1,053	Pediatric/ Young Adults	12-13 yr	Mean age (SD): Arm 1: Boys:12.72 yr (0.47) Girls: 12.61 yr (0.44) Control Arm: Boys:12.83 yr (0.51) Girls: 12.69 yr (0.51) Males: Arm 1: 278 Control Arm: 214	600 (NR)	Behavioral	Arm 1: Multicomponent health promotion intervention Individual component consisted of an educational program that covered 11 lessons in biology and physical education Program aimed to increase awareness and behavioral changes concerning energy intake and energy output Encouraged additional physical education classes and changes at school canteens to facilitate behavioral change	453 (NR)	Control Arm: Regular curriculum	**Primary:** Mean waist circumference change [cm (SD)] Mean waist-hip ratio change (SD) Mean sum of skinfolds change [mm (SD)] Mean BMI change [kg/m^2 (SD)] **Secondary**: Mean shuttle run test change [laps (SD)]	**Difference in Change Between Groups: 95%CI (F=female;M=male)** F: -0.34 (-0.82 to 0.15) M: -0.57(-1.10 to 0.05) F: -0.009(-0.02 to -0.003) M: -0.006(-0/01 to -0.000) F: -2.31(-4.34 to -0.28) M: -0.98 (-2.42 to 0.45) F:-0.05(-0.18 to 0.08) M: -0.02(-0.11 to 0.16) **Secondary:** F: 0.10(-0.44 to 0.64) M: 0.14 (-0.18 to 0.46) ***All changes in favor of INT group.**	**NS** **NS** **S** **S** **S** **NS** **NS** **NS** **NS** **NS**	None reported		A multi-level intervention in low SES Dutch pre-vocational schools led to small changes in favor of the intervention in anthropometry but no change in BMI or fitness.	Q 10,13. A multi-level intervention in low SES Dutch pre-vocational schools led to small changes in favor of the intervention in anthropometry but no change in BMI or fitness.
17557990	Gately PJ	Does a high-protein diet improve weight loss in overweight and obese children?	2007	RCT	None	Q10 (RF8) Q13 (RF4, RF5)	United Kingdom	Community (other)	Single	2-6 wk (mean: 29 d)	NR	Evaluate the effect of a high-protein diet on anthropometry, body composition, subjective appetite, and mood sensations in overweight and obese children attending a residential weight-loss camp	98	Pediatric/ Young Adults	11-17 yr BMI above the cutoff for overweight	Mean age (SD): 14.2 yr (1.9) Boys: 38	NR (41)	Behavioral	Arm 1: High-protein diet (HiP) Comprised of 22.5% protein, 30% fat, and 47.5% carbohydrate Children also took part in daily physical activity and educational sessions as part of the camp program	NR (39)	Control Arm: Standard diet (STD) Comprised of 15% protein, 30% fat, 55% carbohydrate Children also took part in daily physical activity and educational sessions as part of the camp program	**Primary:** Mean weight [kg (SD)] Mean BMI [kg/m^2 (SD)] Mean fat [% (SD)] Mean waist circumference [cm (SD)] **Secondary:** Mean SBP [mmHg (SD)] Mean DBP [mmHg (SD)] Mean TC [mM (SD)] Mean HDL-C [mM (SD)] Mean LDL-C [mM (SD)] Mean TG [mM (SD)]	**Primary:** STD: 93.9(22.9) to 88.4(21.6) HiP: 85.6(17.2) to 80.4(15.9) STD: 34.5(6.0) to 32.4(5.8) HiP: 31.3(3.9) to 29.3(3.5) STD: 43.2(7.5) to 42.6(7.8) HiP: 41.0(6.3) to 37.7(7.3) STD: 98.9(13.1) to 92.5(11.3) HiP: 92.7(8.8) to 87.4(9.2) **Secondary:** STD: 114(9) to 111(10.0) HiP: 113(9) to 108(8) STD: 67(10) to 62(7) HiP: 64(8) to 59(6) STD: 3.99(0.73) to 3.25(0.50) HiP: 4.26(0.79) to 3.40(1.01) STD: 1.15(0.19) to 0.99(0.17) HiP: 1.14(0.28) to 1.03(0.23) STD: 2.48(0.59) to 1.94(0.50) HiP: 2.66(0.68) to 2.03(0.91) STD: 0.82(0.40) to 0.78(0.28) HiP; 1.05(0.52) to 0.83(0.31)	**NS between grps; S**, pre- to post, diet grps combined** **NS between grps; S**, pre- to post, diet grps combined** **NS between groups; S*, pre- to post,diet grps combined** **NS between grps; S**, pre- to post, diet grps combined** **NS between grps; S**, pre- to post, diet grps combined** **NS between grps; S**, pre- to post, diet grps combined** **NS between grps; S*, pre- to post, diet grps combined** **NS between grps; S**, pre- to post, diet grps combined** **NS between grps; S*, pre- to post, diet grps combined**	None reported.	There was an increase in rated hunger over time in both groups.	Regardless of the protein content of their diet, children on a restricted calorie diet lost weight, decreased BMI and reduced CV risk parameters in a residential camp setting.	Q 10,13 Regardless of the protein content of their diet, children on a restricted calorie diet lost weight, decreased BMI and reduced CV risk parameters in a residential camp setting.
17576783	Daniels SR	Cardiovascular effects of sibutramine in the treatment of obese adolescents: results of a randomized, double-blind, placebo-controlled study	2007	RCT	None	Q10 (RF8) Q13 (RF4)	USA	Clinical	Double	12 mo	July 2000-February 2002	Evaluate the efficacy and cardiovascular safety of sibutramine plus a behavioral therapy program in obese adolescents	498	Pediatric/ Young Adults	12-16 yr BMI not less than a lower limit of ≥2 units above the US weight mean for the 95th percentile based on age and gender and ≤44 kg/m^2 Exclusions: SBP>130 mmHg or DBP>85 mmHg Cigarette smoking CVD Type 1 or type 2 diabetes mellitus Use of medications promoting weight loss	Mean age (SD): 13.7 yr (1.3) Males: 176 White: 282 Black: 105 Hispanic/Mexican American: 78 Other race/ethnicity: 33	368 (281)	Pharmacologic	Arm 1: Behavioral therapy + 10 mg sibutramine qd (SIB) After 6 mo, all subjects who had not lost > 10% of their initial BMI were up-titrated in a blinded fashion to 15 mg of sibutramine All participants received instruction in lifestyle behavior modification	130 (80)	Control Arm: Behavioral therapy + placebo (CON) All participants received instruction in lifestyle behavior modification	**Primary:** Mean change in BMI [kg/m^2 (SE)] Mean change in SBP [mmHg (SE)] Mean change in DBP [mmHg (SE)] Mean change in HR [BPM (SE)]	**Primary:** SIB: -2.9 (0.15) vs CON: -0.3(0.24) Treatment diff=2.6kg/m sq.(CI: 2.0-3.1) -2.1 for both SIB & CON groups -0.1 for SIB & -1.1 for CON groups. -0.2 for SIB and -1.8 for CON * BMI reduction of >/= 5% & >/= 10% occurred 62.3% and 38.8% of SIB subjects vs 18.1% & 5.5% of CON subjects	**S**** **NS** **NS** **p=.055** **S** for each**	Tachycardia occurred significantly more often in the SIB group (13%) vs in the CON group (6%). There was no other difference in AEs. One SIB subject had a serious increase in SBP and medication was D/C'd. VS outlier events occurred more often in SIB (32%) vs CON subjects (17%)(p=S**)	47.9% of SIB subjects required a dose increase because of inadequate wt loss at 6 mos. Reductions in BP & HR were greater for subjects with >/= 5% reduction in BMI.	Obese adolescents achieved significantly greater reduction in BMI with sibutramine vs conventional therapy. Sibutramine was well tolerated with no difference in SBP,DBP or HR between sibutramine & placebo groups.	Q 10,13. Obese adolescents achieved significantly greater reduction in BMI with sibutramine vs conventional therapy. Sibutramine was well tolerated with no difference in SBP,DBP or HR between sibutramine & placebo groups.
17595270	Savoye M	Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial	2007	RCT	None	Q10 (RF8)	USA	Mult Settings	None	12 mo	May 2002 - September 2005	Compare effects of a weight management program, Bright Bodies, on adiposity and metabolic complications of overweight children with a control group	209	Parental/ Family/ Caregiver	8-16 yr BMI > 95th percentile based on the CDC growth chart Exclusions: Diabetes Participants taking medications that potentially cause significant weight gain Participants using medications for weight loss or involved in a coexisting weight management program	Mean age (SD): Arm 1 & Arm 2: 11.9 yr (2.5) Control Arm: 12.4 yr (2.3) Males: Arm 1 & Arm 2: 46 Control Arm: 22 Non-Hispanic white: Arm 1 & Arm 2: 40 Control Arm: 24 Non-Hispanic black: Arm 1 & Arm 2: 40 Control Arm: 27 Hispanic: Arm 1 & Arm 2: 25 Control Arm: 18	Arm 1: 105 (75) Arm 2: 35 (0)	Behavioral	Arm 1: Intensive family-based weight management intervention with Better Food Choices program Program was 2x/wk for the first 6 mo and every other wk for the last 6 mo; during the first 6 mo, program consisted of exercise twice (50 min each) and nutrition/behavior modification once (40 min each) per wek Participants and caregivers attended all classes together except behavior modification classes, which were held separately Nutrition education component used the Better Food Choices program Arm 2: Intensive family-based weight management intervention with structured meal plan	69 (44)	Control Arm: Diet and exercise counseling with brief psychosocial counseling Seen in the pediatric obesity clinic every 6 mo Nutrition counseling included decreasing intake of juice, switching to diet beverages, switching from whole to low-fat milk, and bringing lunch to school versus choosing hot lunch Exercise counseling included decreasing sedentary activities and finding an activity the participant enjoyed enough to engage in on a regular basis Participant and caregiver were both involved in setting nutrition and activity goals	**Primary:** Mean change in BMI [kg/m2 (95% CI)] Mean change in weight [kg (95% CI)] Mean change in body fat [% (95% CI)] Mean change in estimated body fat mass [kg (95% CI)] **Secondary:** Mean change in TC [mg/dL (95% CI)] Mean change in fasting insulin [µIU/mL (95% CI)] Mean change in HOMA-IR (95% CI) Mean change in fasting glucose [mg/dL (95% CI)] Mean change in SBP [mmHg (95% CI)] Mean change in DBP [mmHg (95% CI)] Mean change in HDL-C [mg/dL (95% CI)] Mean change in LDL-C [mg/dL (95% CI)] Mean change in TG [mg/dL (95% CI)]	**At 12 mos:** INT: -1.7(-2.3,-1.1) vs CON: +1.6(0.8,2.3) INT: +0.3 (-1.4,2.0) vs CON: +7.7 (5.3,10.0) INT: -4.0(-5.2,-2.8) vs CON: +2.0(0.6,3.5) INT: -3.7(-5.4,-2.1) vs CON: 5.5 (3.2,7.8) **Secondary:** INT: -9.2(-14.8,-3.5) vs CON: 3.7(-3.9,11.3) INT:-6.1 (-8.1,4.0) vs CON: 4.5(0.2,9.6) INT: -1.52 (-1.93,-1.01) vs CON:0.90 (-0.07,2.05) No significant difference in treatment effect between groups for any of these parameters.	**S**** **S**** **S**** **S**** **S*** **S**** **S**** **NS** **NS** **NS** **NS** **NS**	None reported.	There were no differences in any outcome measure between ethnic groups or sexes. High drop-out rate at 12 month F/U (49/105).	An intensive family-based program including nutrition,exercise & behavior modification resulted in significant improvements in body composition and insulin resistance at 6 & 12 mo follow-up in overweight children and adolescents.	Q 10. An intensive family-based program including nutrition,exercise & behavior modification resulted in significant improvements in body composition and insulin resistance at 6 & 12 mo follow-up in overweight children and adolescents
17595270	Savoye M	Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial	2007																Components identical to Arm 1, except that a structured meal plan was used in place of the Better Food Choices program After participants were randomized to the intervention and control arms, they were further randomized to Arm 1 and Arm 2; given a high dropout rate in Arm 2, this arm was disontinued and not included in this analysis							

NHLBI Evidence Table: RF8-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 Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
17925518	Wilfley DE	Efficacy of maintenance treatment approaches for childhood overweight: a randomized controlled trial	2007	RCT	None	Q10,11 (RF8)	USA	Home	NR	2 yr	60 mo	Determine the short-term and long-term efficacy of 2 distinct weight maintenance approaches vs no continued treatment control following standard family-based behavioral weight loss treatment for childhood overweight, and to examine children's social functioning as a moderator of outcome.	204	Pediatric/ Young Adults	Healthy 7 - 12 y olds, 20 - 100% above median BMI for age & sex, with at least 1 overweight parent - After a 5 m state-of-the-art weight loss treatment, children were stratified by sex and ordered by a combination of % overweight change during Rx & baseline levels of social problems. They were than randomized into 3 groups: Behavioral skills maintenance (BSM);Social facilitation maintenance (SFM); Usual care (CON).	Mean age - 9.9 y Mean BMI = 27.5 F = 69.3% W=71%; B= 7.3%, Hisp=18.7% Mean parental BMI = 34.9	Behavioral skills maintenance (BSM): 51 (42) Social facilitation maintenance (FSM): 50 (43)	Behavioral	20-minute family treatment sessions and 40-minute separate child and parent groups. BSM: Cognitive behavioral approach to wt maintenance emphasizing self regulation & relapse prevention strategies. 51 randomized, 48 completed INT. SFM: Helped parents to facilitate child peer networks for social support of healthy eating & activity; targeted peer teasing & body image factors. 50 randomized, 48 completed INT.	49 (37)	Discontinued contact after weight loss program (CON)	BMI BMI z score % overweight Psychosocial targets for BSM & SFM training.	**BMI z score** **BSM** **SFM** **CON** Baseline 2.17(.28) 2.26(0.27) 2.17(0.34) Randomization 1.94(0.34) 2.03(0.42) 1.99(0.39) Maintenance 1.90(0.35() 1.99(0.48) 2.04(0.37) 1 y F/U 1.99(0.39) 2.03(0.51) 2.07(0.38) 2 y F/U 1.98(0.48) 2.02(0.50) 2.11(0.36) **%OVWT** Baseline 61.8(17.4) 68.1(17.6) 63.3(20.8) Randomization 49.7(16.2) 56.5(20.1) 54.2(20.3) Maintenance 49.1(16.9) 56.2(21.8) 57.9(21.2) 1 y F/U 57.0(21.5) 61.2(24.5) 61.6(23.3) 2 y F/U 59.6(24.1) 62.6(25.9) 64.8(22.9) BSM children significantly increased perceived self-efficacy for diet adherence (1 y F/U) (p=S) and for overcoming barrieres to activity(2 y F/U) (p=S). SFM children significantly increased perceived self-efficacy for diet adherence (2 y F/U) (p=S) and for overcoming barrieres to activity(2 y F/U) (p=S) plus increased ability to seek healthy activity alternatives(p=S). SFM children had improved ability to cope with teasing (2 y F/U) (p=S*), increased peer encouragement of healthy eating (1 y F/U)(p=S) & increased ability to enlist peer support for activity (1 y F/U) (p=S). Higher level of baseline social problems significantly affected wt loss and wt loss maintenance in both groups.	**NS between grps** **S** for each vs baseline, NS btwn grps** **BSM vs CON = S*; SFM vs CON = S*** **BSM vs CON,p =.19; SFM vs CON,p = .06** **NS for each** **S** for each vs baseline, NS btwn grps** **S** for BSM+ SFM vs CON, BFM/SFM =S*** **BSM vs CON,p =.19; SFM vs CON,p = .08** **SFM vs CON,p=.08; BSM= NS**	None	Low level of baseline social problems was associated with sustained better outcome especially for the SFM group.	Active maintenance treatment after wt loss treatment resulted in significantly improved wt control during the 4 m maintenance contact period. Maintenance treatment effects decreased over time but BMI rebound was attenuated by maintenance treatment even at 2 y F/U.	Q10,11. Active maintenance treatment after wt loss treatment resulted in significantly improved wt control during the 4 m maintenance contact period. Maintenance treatment effects decreased over time but BMI rebound was attenuated by maintenance treatment even at 2 y F/U.
17999280	Johnston CA	Results of an intensive school-based weight loss program with overweight Mexican American children	2007	RCT	None	Q10 (RF8)	USA	Community (schools)	None	6 mo	6 mo	Evaluate an intensive school-based program designed to result in weight reduction for overweight Mexican American children	71	Parental/ Family/ Caregiver	6th or 7th grade At risk for overweight or overweight (BMI ≥ 85th or 95th percentile for age and gender, respectively) Males: 32 Self-identified as Mexican American: 100%	Mean age (SD): 12.54 yr (0.55)	46 (44)	Behavioral	Arm 1: Intensive school-based behavioral weight management program Instructor/trainer-led intervention for 12 wk of daily sessions and 12 wk of bi-weekly sessions During the first 12 wk, classes consisted of 1 nutrition lesson and 4 physical activity lessons weekly Behavioral strategies (e.g., implementation of a token economy system) were used to encourage adoption of program principles Children with absences, low grades on biweekly quizzes and/or continued weight gain for more than 2 wk received individual education and treatment planning Parents were invited to attend monthly meetings to facilitate adoption of healthy habits	25 (22)	Control Arm: Self help sessions Participants and parents were given instructions to use a manual aimed at improving diet quality and increasing time spent engaging in physical activity 12 weekly sessions followed by maintenance activities	**Primary:** Change in zBMI [%] Mean change in BMI [kg/m^2 (SD)] **Secondary:** Mean change in SBP [mmHg (SD)] Mean change in DBP [mmHg (SD)] Mean change in TC [mg/dL (SD)] Mean change in LDL-C [mg/dL (SD)] Mean change in HDL-C [mg/dL (SD)] Mean change in TG [mg/dL (SD)] Mean change in glucose [mmol/L (SD)] Mean change in insulin [µIU/mL (SD)]	**At 3 mos:** INT:-5.44 vs SH:-1.17 (F=6.15) **At 6 mos:** INT: -7.04 vs SH: +3.03(F=12.61) **At 3 mos:** INT: -0.27(0.77) vs SH: +0.15 (0.77) **Secondary:** No significant changes in any of these parameters at 6 mos.	**S*** **S**** **S**	None reported		This intensive daily intervention in Mexican American children and adolescents using trained professionals resulted in a significant decrease in BMI at 3 & 6 mos.	Q 10. This intensive daily intervention in Mexican American children and adolescents using trained professionals resulted in a significant decrease in BMI at 3 & 6 mos.