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A Cholesterol-Lowering Diet Does Not Produce Adverse Psychological Effects in Children: Three-Year Results From the Dietary Intervention Study in Children

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The Dietary Intervention Study in Children (DISC), a 2-arm, multicenter intervention study, examined the efficacy and safety of a diet lower in total fat, saturated fatty acids, and cholesterol than the typical American child's diet. A total of 663 8- to 10-year-old children with elevated low-density lipoprotein cholesterol levels were randomly assigned to either an intervention or a usual-care group. Intervention included group and individual counseling sessions to assist participants in adopting a dietary pattern containing 28% or less of calories from total fat (<8% as saturated fat, up to 9% as polyunsaturated fat, and 11% as monounsaturated fat) and dietary cholesterol intake of less than 75 mg/1,000 kcal. The dietary intervention reduced low-density lipoprotein cholesterol levels, and 3-year results showed no adverse effects for children in the intervention group in terms of academic functioning, psychological symptoms, or family functioning.

Key words: dietary intervention, cholesterol-lowering diets, psychosocial safety

The National Cholesterol Education Program (NCEP) provides dietary recommendations for lower intake of total fats, saturated fatty acids, and dietary cholesterol to reduce serum cholesterol levels in children and adolescents (NCEP Expert Panel on Blood Cholesterol Levels in Children and Adolescents, 1992). Although many experts believe that cholesterol-lowering diets are nutritionally adequate, concerns have been raised about their potentially harmful effects on an individual's psychological and physical well-being (Lifshitz & Moses, 1989; Mauer, 1985; Muldoon & Manuck, 1992; Muldoon, Manuck, & Matthews, 1990; Newman, Browner, & Hulley, 1990; Pugliese, Weyman-Daum, Moses, & Lifschitz, 1987). Essential fatty acids are important components of cerebral tissue (Neuringer, Anderson, & Connor, 1988; Neuringer & Connor, 1986). Although dietary studies with animals have yielded conflicting results (Caffrey & Patterson, 1971; Greenwood & Winocur, 1990), they have raised the possibility that diets low in essential fatty acids may adversely affect cognitive development and learning in humans (Bourre, Piciotti, Dumont, Pascal, & Durand, 1990). Monkeys fed diets low in cholesterol exhibit more contact aggression than those fed a higher-cholesterol diet (Kaplan, Manuck, & Shively, 1991). Diets deficient in essential fatty acids may have neurologic sequelae (Bjerve, Mostad, & Thoresen, 1987), and critics have suggested that neurologic development may be at risk when cholesterol intake is limited (Barness, 1987). To our knowledge, how-

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ever, no research on the effects of low-fat, low-cholesterol diets on children's cognitive development has been conducted.

A meta-analytic review has suggested that primary prevention trials designed to lower cholesterol levels in adults may result in increases in aggression, violence, conduct disorders, and suicide (Muldoon et al., 1990), although there has been disagreement about whether non-illness-related deaths in these studies were associated with drug rather than dietary interventions (Davey Smith & Pekkanen, 1990; Muldoon & Manuck, 1992). Other critics have suggested that adherence to a low-fat diet may result in psychological problems for children and adolescents (Cayler, Lynn, & Stein, 1973; Mauer, 1985; Newman et al., 1990; Thelin, McNeil, Aspegren-Jansson, & Sveger, 1985). Discussions of the potential psychological effects of reduced-fat diets, however, tend to be nonspecific, failing to suggest either particular behavior problems (e.g., hyperactivity) or cognitive deficits (e.g., decreases in attention span, language difficulties, and decreases in overall IQ) that may occur. Also, critics have not specified the pathways through which such problems may develop (e.g., direct effects of lower fat and cholesterol on brain functioning, affecting behavior; problems with "labeling," affecting attitudes toward the child; lowered self-esteem; and increased family conflict). Violence, suicide, and criminal behavior noted in adult meta-analytic studies are low-frequency events among children and young adolescents, making it difficult to study such events directly in children. In order to understand the possible impact of lower-fat diets on children and adolescents, it seemed most appropriate to examine a broad range of possible behavior and cognitive problems that might result from such diets, including precursors to the adult problems noted in the meta-analytic studies, such as problems with anxiety, depression, and aggressive behavior.

The Dietary Intervention Study in Childhood (DISC) was a randomized clinical trial examining the efficacy and safety of a cholesterol-lowering diet for American children 8 to 10 years old at baseline and with elevated serum low-density lipoprotein cholesterol (LDL-C) levels (DISC Collaborative Research Group, 1993). After 3 years of intervention, dietary intakes in the intervention group compared to the usual-care group were lower in total fat (29% and 33%, respectively), saturated fat (10% and 13%, respectively), monounsaturated fat (11% and 13%, respectively), and cholesterol (95.5 mg/1,000 kcal and 112.0 mg/1,000 kcal, respectively; DISC Collaborative Research Group, 1995b). The dietary intervention group achieved a modest reduction in LDL-C while maintaining adequate growth, iron stores, and nutritional adequacy. For the intervention group, the level of LDL-C decreased by 0.40 mmol/L (15.4 mg/dl); for the usual-care group, the decrease was 0.31 mmol/L (11.9 mg/dl). The mean difference between the groups after adjustment for baseline values, sex, and imputing values for missing data was −0.08 mmol/L (−3.23 mg/dl). A psychosocial assessment battery revealed no treatment group differences, with the exception of the depression score which, after 3 years, was lower in the intervention group than in the usual-care group. Here we describe in detail the 3-year psychosocial safety results, in which a wide range of possible behavior and cognitive problems were assessed.

Methods

Participants

Recruitment began with broad-based community efforts at each of six clinical sites to prescreen over 44,000 children through pediatric practices, clinics, and schools. Eligible children were then seen for additional on-site screening. Children were eligible if the average of two screening LDL-C values was at or above the 80th percentile and below the 98th percentile for their age and gender (111.5 to 164.5 mg/dl for boys and 117.5 to 164.5 mg/dl for girls; Lipid Research Clinics, 1980), if they were 8 to 10 years old, and if they were prepubescent (Tanner Stage 1). Children were excluded from the DISC for the following reasons: taking medication that affected growth or blood cholesterol levels; onset of puberty; the child, parent, or cook did not speak English; the child had repeated two or more grades or was in a remedial special education class; high maternal or paternal alcohol consumption (three or more drinks per day, 7 days per week, or more than five drinks every day for 2 or more days per week); or the child had a total behavior problem score on the Child Behavior Checklist (CBCL; Achenbach, 1992) above the 98th percentile. Of the 1,130 children screened with the CBCL, 13% were excluded. Similar rates of elevated CBCL scores have been found in other medical samples (Costello et al., 1988).

A total of 663 children who met the study criteria were enrolled between 1988 and 1990 and were randomly assigned to either a dietary intervention group ($n = 334$) or a usual-care group ($n = 329$; DISC Collaborative Research Group, 1993). Mean ages at enrollment were 9.7 years for the boys and 9.0 years for the girls. The overall enrollment provided sufficient power for analyzing changes in cholesterol levels as well as safety measures (DISC Collaborative Research Group, 1995b).

The psychosocial assessment battery was administered at baseline and 3 years after the start of treatment. A total of 96% of the intervention participants and 92% of the usual-care participants returned for the 3-year follow-up visit. The mean length of follow-up was 36.2 months for both treatment groups. Psychosocial follow-up data were available for 88% to 93% of parent-reported measures and approximately 93% of child-reported measures. 483 participants were self-classified as White, 24 as African American, 5 as Asian, and 9 as "other." There were 299 boys and 261 girls who participated in the 3-year follow-up and from whom all relevant data were available for assessing psychosocial safety.

Regression analyses were performed on data from children who participated in both the baseline and 3-year follow-up examinations and for whom household income data were also available. Children missing self-report or parental data at the 3-year follow-up visit did not differ significantly from children with data at Year 3 ($p > .05$), on baseline measures of mathematics and reading achievement, family cohesion or conflict, total behavior problems, internalizing or externalizing behavior, total social competence, trait anxiety, or depression.

Interventions

Usual Care

The parents of children randomized to the usual-care group were informed that their child had a high level of blood cholesterol and

were given informational pamphlets available to the general public on heart-healthy diets.

Dietary Intervention

Families assigned to the intervention group received counseling to alter their eating habits. The first year of intervention consisted of 15 group sessions and at least 5 individual family counseling sessions. After the first year, families entered a 2-year dietary maintenance phase consisting of four group training sessions and three individual family visits per year. These sessions were designed to assist the child and family in adopting a dietary pattern containing 28% or less of calories from total fat (<8% as saturated fat, up to 9% as polyunsaturated fat, and 11% as monosaturated fat) and dietary cholesterol intake of less than 75 mg/1,000 kcal. Group sessions were led by nutritionists, psychologists and, at some centers, teachers or health educators. Each group session provided information about a specific topic (e.g., food categories, meal selection, and food preparation) and involved activities designed to enhance dietary adherence (e.g., behavior modification techniques). Individual sessions were designed to help solve diet-related family problems. Attendance at intervention sessions (including makeup sessions) was about 90% overall at 3 years. Further details on the DISC intervention are presented elsewhere (DISC Collaborative Research Group, 1995a; Hartmuller et al., 1994).

Psychosocial Safety Outcomes

Child Behavior Problems and Competencies

CBCL. Each parent was asked to complete the CBCL (Achenbach, 1992). It provided a total behavior problem standardized score (T score) and similar scores for internalizing problems (i.e., those that the child experiences internally, such as anxiety, depression, and somatic complaints) and externalizing problems (i.e., "acting-out" symptoms, such as aggression, hyperactivity, and noncompliance with adult directives). The CBCL also provided a total social competence standardized score, which encompassed social, academic, and recreational functioning. Because the CBCL norms were revised during the course of the study, all scores were converted to the more recent 1991 norms.

Seventy-six percent of mothers completed baseline CBCL forms, whereas only 22% of fathers completed baseline CBCL forms. Because of the low return rate from fathers, only data from mothers are reported. A total of 501 mothers completed forms at baseline, and 466 (93%) completed forms at the 3-year follow-up. Of the latter, 399 mothers also supplied information on income; data from these 399 mothers were used in regression analyses (see Table 1).

State–Trait Anxiety Inventory for Children. The trait form of the State–Trait Anxiety Inventory for Children (STAIC) asks the child to describe how he or she feels in general (Spielberger, Edwards, Lushene, Montuori, & Platzek, 1973). Raw scores were used in analyses. Of a total of 626 children completing this form at baseline, 579 (93%) also completed it at the 3-year follow-up. For the latter cases, 560 parents (97%) provided information on income; data from these parents were used in regression analyses (see Table 2).

Child Depression Inventory. The Child Depression Inventory (CDI) is a widely used child-completed measure of depression in children (Kovacs, 1983). Raw scores were used in analyses. Numbers of participants completing forms at baseline and at 3 years and numbers used in regression analyses were the same as those for the STAIC (see Table 2).

Diagnosed eating disorders and suicide threats. During a routine medical history taken at the 1-year and 3-year visits, parents were asked whether a doctor had told them in the last 12 months that their child had anorexia or bulimia. Parents and children were also asked at baseline and at 3-year visits about the child's expressed attitude toward committing suicide. Responses on the CBCL and CDI were also examined at the 3-year follow-up to determine whether suicidal threats or behavior were acknowledged.

Academic Achievement

The Woodcock–Johnson Psycho-Educational Battery (W–J) is a standardized battery of cognitive and achievement tests suitable for use with children aged 3 years to adults. Achievement subtests related to reading (letter–word identification, word attack, and passage comprehension) and mathematics (calculation and applied problems) were administered because of the important role of these items in academic performance (Hessler, 1984). At baseline, 625 participants (94%) completed this form; 576 (92%) returned it after 3 years. Regression analyses were completed for data from 558 parents who also supplied information on income (see Table 3).

Family Environment

The Family Environment Scale (FES; Moos & Moos, 1986) is a parent-completed measure assessing the social environment of the family. Scores on the Conflict and Cohesion subscales were chosen as safety outcomes because they were the most likely to detect family disruptions that might result from a cholesterol-lowering diet. A total of 536 mothers (81%) completed the baseline form; 474 (88%) returned a completed form after 3 years. Complete information for regression analyses was available for 428 Year 3 participants (see Table 4).

Procedures

The psychosocial assessment battery was administered at baseline and 3 years after the start of treatment.

Statistical Methods

Treatment Group × Gender interactions were compared at baseline and 3 years by use of means, standard deviations for continuous variables, and proportions for categorical measures.

To test whether the dietary intervention affected psychosocial safety outcomes at the 3-year visit, a multiple linear regression procedure (Kleinbaum, Kupper, & Muller, 1988) was used with each safety outcome as the dependent variable. Terms for treatment group, child gender, baseline measure of the safety outcome, yearly household income, two- versus one-parent family structure, and Gender × Treatment Group interaction were entered into a separate model for each dependent outcome variable. An unadjusted model containing only terms for treatment group and the baseline value of the outcome variable was also tested for each outcome variable assessed at the 3-year visit. Baseline measures of the safety outcomes were treated as continuous variables; child gender, treatment group, two-parent family, and household income (less than $20,000; $20,000 to $49,999; and $50,000 or more) were coded categorically. Treatment group, gender, the baseline value of the outcome variable, and demographic measures were always retained in the models, and nonsignificant ($p > .05$) Treatment Group × Gender interactions were dropped.

In addition to the above safety outcomes, cutpoints were chosen

Table 1
Maternal Reports of Child Behavior Problems (n = 399) and Social Competence (n = 354) and the Effects of Treatment at 3 Years

Group and study visit	Intervention			Usual care			Adjusted treatment difference at 3 years[a]	
	n	*M*	*SD*	*n*	*M*	*SD*	*M* ± 95% CI	*p*
CBCL Total behavior problem								
Boys								
Baseline	98	46.8	8.5	103	47.5	8.9		
3 Years	98	47.4	10.5	103	47.1	10.2		
Girls								
Baseline	105	48.1	9.7	93	47.6	10.3		
3 Years	105	46.6	10.0	93	46.8	10.6		
Total							0.02 ± 1.51	.981
CBCL Internalizing								
Boys								
Baseline	98	49.3	9.0	103	48.7	10.3		
3 Years	98	47.5	10.5	103	47.3	10.3		
Girls								
Baseline	105	50.8	8.6	93	50.6	9.7		
3 Years	105	48.6	9.3	93	50.3	10.6		
Total							−0.96 ± 1.67	.257
CBCL Externalizing								
Boys								
Baseline	98	44.8	8.7	103	47.6	8.7		
3 Years	98	48.5	9.3	103	48.4	9.9		
Girls								
Baseline	105	47.1	8.7	93	46.3	9.0		
3 Years	105	47.3	9.1	93	46.0	9.4		
Total							1.20 ± 1.45	.105
CBCL Social Competence								
Boys								
Baseline	86	51.1	10.1	94	51.8	9.2		
3 Years	86	49.6	8.7	94	51.9	8.6		
Girls								
Baseline	92	50.1	7.3	82	50.9	7.9		
3 Years	92	51.2	7.7	82	53.1	9.6		
Total							−1.44 ± 1.47	.056

Note. CI = confidence interval. CBCL = Child Behavior Checklist.
[a]Estimates of the overall difference between intervention and usual-care groups at 3 years, adjusted for baseline value, gender, household income, and number of parents in the household.

for some outcomes on the basis of published criteria. Scores outside cutpoints indicated potential problems (>45 for the STAIC anxiety score [Spielberger et al., 1973]; ≥14 for the CDI depression score [Finch, Saylor, & Edwards, 1985]; >63 for the CBCL total behavior problem, internalizing, and externalizing scores [Achenbach, 1992]; and below the age-specific 25th percentile on the W–J reading and mathematics achievement tests). The frequency of scores outside these clinical cutpoints for intervention-group participants was compared to the frequency for usual-care-group participants by use of logistic regression (Hosmer & Lemeshow, 1989), with adjustment for the baseline value of the outcome, child gender, household income, and number of parents in the household, as defined in the primary analyses. Nonsignificant ($p > .05$) Treatment Group × Gender interactions were dropped from the models. Coefficients from the logistic models were used to estimate the relative increase in the odds (odds ratio [OR]) that the value for a safety outcome exceeded the clinical cutpoint for the intervention group.

Results

Baseline Demographics

Detailed data on the baseline characteristics of DISC participants have been published (DISC Collaborative Research Group, 1993). Briefly, the mean ages for DISC participants were 9.7 years for boys and 9.0 years for girls; 55% of DISC participants were male; and 87% were White, 8% were Black, and 5% were of other races. Annual household income was <$20,000 for 11% of participants, $20,000 to $49,000 for 53%, and ≥$40,000 for 35%; 35% of mothers and 47% of fathers were college graduates. At baseline, mean intakes of nutrients targeted for dietary intervention were 34% of calories from total fat, 13% of calories from saturated fat, and 116 mg/1,000 kcal from cholesterol. With minor exceptions, treatment groups were

Table 2
Child-Reported Anxiety (n = 560) and Depression (n = 560) and the Effects of Treatment at 3 Years

Group and study visit	Intervention			Usual care			Adjusted treatment difference at 3 years[a]	
	n	*M*	*SD*	*n*	*M*	*SD*	*M* ± 95% CI	*p*
				STAIC Anxiety				
Boys								
Baseline	152	32.0	6.5	147	32.7	6.0		
3 Years	152	28.8	5.3	147	29.5	6.0		
Girls								
Baseline	137	33.4	6.8	124	33.8	6.9		
3 Years	137	30.0	6.1	124	31.4	7.0		
Total							−0.83 ± 0.94	.085
				CDI Depression				
Boys								
Baseline	152	6.0	5.3	147	5.8	4.4		
3 Years	152	4.2	3.7	147	4.8	4.4		
Girls								
Baseline	137	6.2	5.3	124	5.1	4.2		
3 Years	137	4.4	4.4	124	4.9	4.9		
Total							−0.75 ± 0.69	.031

Note. CI = confidence interval. STAIC = State–Trait Anxiety Inventory for Children. CDI = Child Depression Inventory.
[a]Estimates of the overall difference between intervention and usual-care groups at 3 years, adjusted for baseline value, gender, household income, and number of parents in the household.

comparable at baseline on most demographic, dietary, and anthropometric measures (DISC Collaborative Research Group, 1993).

Psychosocial Baseline Results

Tables 1 to 4 show baseline and 3-year means for W–J achievement measures, child-reported measures of anxiety (STAIC) and depression (CDI), family conflict and cohesion (FES), and CBCL scores. Scores from other CBCL and FES subscales of less importance in assessing safety are discussed but are not presented in Tables 1 to 4. (Further detail is available from the authors.)

The numbers of participants for whom data are reported in Tables 1 to 4 vary. The largest differences occur between parent-reported and child-reported measures, as fewer par-

Table 3
Child Mathematics (n = 558) and Reading (n = 558) Achievement and the Effects of Treatment at 3 Years

Group and study visit	Intervention			Usual care			Adjusted treatment difference at 3 years[a]	
	n	*M*	*SD*	*n*	*M*	*SD*	*M* ± 95% CI	*p*
				W–J Mathematics (age percentile)				
Boys								
Baseline	153	66.8	27.5	147	67.1	27.4		
3 Years	153	64.4	29.8	147	64.4	28.3		
Girls								
Baseline	135	67.0	25.7	122	68.8	22.4		
3 Years	135	68.9	25.5	122	70.6	21.9		
Total							0.35 ± 3.06	.824
				W–J Reading (age percentile)				
Boys								
Baseline	153	60.2	26.5	147	59.4	23.7		
3 Years	153	57.9	26.2	147	59.4	23.7		
Girls								
Baseline	137	65.4	23.9	121	64.8	21.2		
3 Years	137	62.9	24.7	121	63.8	22.4		
Total							−0.33 ± 2.49	.797

Note. CI = confidence interval. W–J = Woodcock–Johnson Psychological Battery.
[a]Estimates of the overall difference between intervention and usual-care groups at 3 years, adjusted for baseline value, gender, household income, and number of parents in the household.

Table 4
Maternal Reports of Family Cohesion (n = 428) and Conflict (n = 427) and the Effects of Treatment at 3 Years

Group and study visit	Intervention			Usual care			Adjusted treatment difference at 3 years[a]	
	n	*M*	*SD*	*n*	*M*	*SD*	*M* ± 95% CI	*p*
				FES Cohesion				
Boys								
Baseline	107	59.3	9.2	115	59.5	11.4		
3 Years	107	58.4	11.4	115	58.3	12.2		
Girls								
Baseline	110	58.1	9.7	96	56.9	11.9		
3 Years	110	58.5	9.9	96	56.2	14.4		
Total							0.85 ± 1.90	.380
				FES Conflict				
Boys								
Baseline	105	47.4	11.5	116	48.2	10.1		
3 Years	105	47.0	11.6	116	48.1	11.3		
Girls								
Baseline	110	48.5	10.1	96	48.4	10.0		
3 Years	110	47.0	10.4	96	48.3	11.2		
Total							−1.09 ± 1.68	.208

Note. CI = confidence interval. FES = Family Environment Scale.
[a]Estimates of the overall difference between intervention and usual-care groups at 3 years, adjusted for baseline value, gender, household income, and number of parents in the household.

ents than children responded to psychosocial questionnaires. In addition, psychosocial measures were administered as separate questionnaires, and both parents and children had the option of refusing any part of the annual examination. On the basis of comparisons to normative data for specific tests, mean scores on achievement measures at baseline were all in the high average range, whereas scores on CBCL behavior problem and competence measures and family environment measures were all in the average range. The numbers and percentages of intervention-group and usual-care-group children for whom data exceeded clinical cutpoints at baseline are shown in Table 5; total sample size (*N*) for each safety cutpoint is also shown. For example, data for 8 of 203 intervention-group participants exceeded the CBCL total behavior problem cutpoint at baseline. Treatment group differences were small; data for neither group consistently exceeded clinical cutpoints on all baseline measures. For CBCL variables, data for a slightly higher percentage of usual-care-group participants exceeded clinical cutpoints on total behavior problems (3% more) and internalizing problems (3% more). For externalizing problems, data for 1% more intervention-group participants exceeded the cutpoint. Children above the 98th percentile on the CBCL total behavior problem score were excluded from the DISC at the outset. Data for a slightly lower percentage of intervention-group than of usual-care-group participants fell below cutpoints for mathematics achievement (1% less). Data for a higher percentage fell below cutpoints for reading achievement (4% more). For trait anxiety, data for intervention-group participants exceeded the cutpoints 0.1% more; for depression, the value was 3.6% more.

Psychosocial Results at the 3-Year Follow-Up

Treatment Group Differences on Standardized Measures

At 3 years, there were no significant treatment group differences in CBCL total behavior problem, externalizing, or internalizing scores (see Table 1). However, the intervention group scored significantly lower than the usual-care group on the CBCL Thought Problems subscale ($-0.22, p < .01$) and the Social Competence subscale ($-1.44, p < .05$) at 3 years. For the CBCL Anxious-Depressed subscale, there was a significant Treatment Group × Gender interaction. Intervention-group girls had lower Anxious-Depressed subscale scores than usual-care-group girls ($-0.029, p < .05$), whereas the treatment group difference for boys was not significant ($p > .05$). There were no treatment group differences in CBCL Aggression or Conduct Problem subscale scores (data are not shown in Table 1 for the various subscales). Child self-reports of anxiety (STAIC) showed no treatment group difference, but self-reports of depression (CDI) were significantly lower for the intervention group than for the usual-care group ($-0.75, p < .05$).

There were also no significant treatment group or Treatment Group × Gender effects for W–J mathematics and reading achievement scores (Table 3) or the FES Cohesion and Conflict subscales (Table 4). Significant treatment group differences were noted at 3 years on some of the less important FES subscales (data not shown): The Intellectual–Cultural Orientation score ($1.79, p < .05$) and the Moral–Religious Orientation score ($1.28, p < .05$) were higher in the intervention group. A significant Treatment Group × Gender interaction was noted for FES Achievement Orienta-

Table 5
Children Over or Under Psychosocial Safety Cutpoints by Visit and Adjusted Logistic Regression Odds Ratios (OR) and 95% Confidence Intervals (CI) for the Effect of Intervention Group Membership at 3 Years

	Intervention			Usual care			Intervention group membership		
Study visit	*n*	%	*N*	*n*	%	*N*	OR[a]	95% CI	*p*
CBCL Total behavior problem score >63									
Baseline	8	3.9	203	14	7.1	196			
3 Years	12	5.9	203	14	7.1	196			
Total							0.93	0.34–2.52	.881
CBCL Internalizing score >63									
Baseline	14	6.9	203	24	12.2	196			
3 Years	13	6.4	220	20	11.2	196			
Total							0.56	0.24–1.31	.180
CBCL Externalizing score >63									
Baseline	6	2.9	203	4	2.0	196			
3 Years	8	3.9	203	13	6.6	196			
Total							0.61	0.21–1.76	.363
STAIC Anxiety score >45									
Baseline	14	4.8	289	11	4.0	271			
3 Years	4	1.4	289	10	3.7	271			
Total							0.40	0.12–1.36	.143
CDI Depression score ≥14									
Baseline	26	9.0	289	16	5.9	271			
3 Years	6	2.1	289	18	6.6	271			
Total							0.24	0.09–0.65	.005
W–J Mathematics age percentile score ≤25									
Baseline	26	9.0	288	26	9.7	269			
3 Years	33	11.4	288	20	7.4	269			
Total							1.54	0.76–3.11	.229
W–J Reading age percentile score ≤25									
Baseline	28	9.6	290	16	6.0	268			
3 Years	36	12.4	290	27	10.1	268			
Total							1.09	0.53–2.23	.821

Note. CBCL = Child Behavior Checklist; STAIC = Stait–Trait Anxiety Inventory; CDI = Child Depression Inventory; W–J = Woodcock–Johnson Psycho-Educational Battery.
[a]Intervention group compared to usual-care group and adjusted for baseline value, gender, household income, and number of parents in the household. Nonsignificant Treatment Group × Gender interactions were dropped.

tion, with intervention-group girls having significantly lower scores (-2.39, $p < .05$) than usual-care-group girls. The mean treatment group difference in boys (0.96) was not significant ($p > .05$). For all of the above FES subscales of lesser importance, differences were very small.

Secondary analyses of unadjusted models were performed for some of the safety outcomes shown in Tables 1 to 4. These models contained only terms for treatment group and the baseline value of the outcome variable. Results showed no change in the direction or significance of the treatment group effect seen in the primary analyses. The only exception was the CBCL externalizing score, which was marginally significant in the unadjusted model, indicating that intervention-group children had slightly higher externalizing scores than usual-care-group children (1.37, $p < .059$). After adjustment for the effects of gender, income, and two-parent family in the primary analyses, the effect of intervention-group membership on externalizing scores was nonsignificant ($p < .10$).

Treatment Group Differences in the Number of Children for Whom Data Exceeded Clinical Cutpoints on Standardized Measures

Review of the ORs shown in Table 5 supplies no evidence that psychosocial problems were more frequent in intervention-group children than in usual-care-group children at 3 years. Scores exceeding the depression cutpoint were significantly less frequent (OR = 0.24, $p < .001$) among intervention-group children than among usual-care-group children. (An OR of 1.0 indicates no difference; Hosmer & Lemeshow, 1989.) It should be noted that low frequencies for a few cutpoints may have resulted in a loss of power to detect small differences; however, it seems clear

that the overall trend in Table 5 demonstrates the psychosocial safety of the intervention. CBCL total social competence scores do not appear in Table 5 because data for no DISC participant fell below the published clinical cutpoint (<30).

In unadjusted logistic regression models, there were no significant treatment group or Gender × Treatment Group differences in the number of children for whom data exceeded clinical cutpoints.

Treatment Group Differences at 3 Years in Diagnosed Eating Disorders and Children's Expressed Intention to Commit Suicide

No parent reported a diagnosis of anorexia or bulimia at the 3-year visit. Medical histories were not received for 46 children at 1 year and for 64 children at 3 years.

On the CDI completed by 663 participants at baseline, 3 intervention-group participants responded that they wanted to kill themselves and were immediately interviewed by the clinic psychologist for a possible referral. When the measure was repeated for the same children at 3 years, 2 children responded that they no longer wanted to kill themselves, and 1 child repeated the baseline response and was referred. On the baseline-visit CBCL, no mother responded that her child had deliberately harmed himself or herself, attempted suicide, or talked about suicide. At the 3-year visit, 1 mother of an intervention-group participant responded that it was "somewhat or sometimes true" that her child had deliberately harmed himself or herself or attempted suicide, and 10 mothers (of 5 intervention-group and 5 usual-care-group participants) responded that it was "somewhat or sometimes true" that their children had talked about killing themselves. Clinic personnel discussed referral options with all of these parents.

Discussion

With some researchers suggesting that there may be adverse psychological consequences of cholesterol-lowering diets in children, the evaluation of psychosocial safety outcomes has been an important element of the DISC. Critics of cholesterol-lowering diets in children have not specifically identified the kinds of adverse psychological consequences to be expected. As a result, the measures in the DISC battery were selected to assess a wide range of psychosocial adjustment problems, to use both parental and child reports, and to detect changes in critical areas of academic achievement and family environment. The results after 3 years indicate no adverse psychosocial effects for any of the primary outcomes tested with a large sample size and the power to detect small treatment differences. When statistically significant effects were observed, they generally indicated a beneficial effect from the dietary intervention, but mean differences between treatment groups were too small to suggest a clinically important benefit for either group on any measure.

An important strength of the DISC is that its recommended diet is similar to the Step II NCEP diet recommended for children with a family history of coronary disease (NCEP Expert Panel on Blood Cholesterol Levels in Children and Adolescents, 1992). No prior studies have evaluated the psychosocial safety of the NCEP Step II diet in children. Reports of the adverse health effects of low-fat diets have usually come from studies of extreme diets not consistent with current recommendations (Lifshitz & Moses, 1989). Recent reviews of studies designed to lower dietary cholesterol and observational studies of children on vegetarian diets have not identified adverse psychosocial effects (Muldoon et al., 1993; Roche, Wilson, Gidding, & Siervogel, 1993).

Likewise, animal studies have limited relevance to the human safety issues addressed in the DISC. In some of these studies, observed adverse effects on the central nervous system from low-fat diets were secondary to linoleic acid deficiency, a polyunsaturated fatty acid abundant in the DISC diet (Hargreaves & Clandinin, 1990). Kaplan et al. (1991) did find an increase in contact aggression among monkeys on a "prudent" versus a "luxury" diet, in which the prudent diet intake of fats was 30% of total intake, a level similar to that in this study. In other studies, however, the diets administered to animals were extreme. However, the low-fat monkey diet was not comparable to current low-fat dietary recommendations for humans, and the fat content of the high-fat monkey diet was far above that in current American human diets (Kaplan et al., 1991). The low-fat monkey diet was similar to their wild diet, leaving open the possibility that the high-fat diet increased "docility," which would be disadvantageous for survival.

The DISC clinical trial has important design features that increase confidence in the psychosocial 3-year results, most notably, the relatively large sample size, long-term follow-up, and high participant retention rate after 3 years of follow-up. However, it is important to note that participants in the DISC, like children and families in other cardiovascular health intervention trials (Hearn et al., 1992), showed certain educational and social advantages. Children in this study generally came from families with well-educated parents, were average to above average academically, and appeared normal on measures of psychological adjustment and competence. This selection of participants is actually somewhat favorable for evaluating the psychosocial safety of the DISC diet, as there were neither "floor" effects limiting possible declines in academic achievement nor "ceiling" effects limiting assessment of the development of emotional or social adjustment problems.

However, it remains to be determined whether there might be adverse psychosocial effects with the implementation of the DISC diet in other socioeconomic groups and with children younger than 8 to 10 years old at the initiation of the diet. In addition, although the total dietary fat intake in the DISC met the study goal of 28% or less of calories from total fat, the overall reduction in LDL-C levels was modest. It is yet to be determined whether a low-saturated-fat, low-cholesterol diet producing greater reductions in lipids might have adverse psychosocial effects. Similarly, the DISC results do not establish the psychosocial safety of more extreme lipid reductions achieved through pharmacological

therapy. The DISC was designed to examine whether a statistically significant reduction in levels of LDL-C in children with elevated levels was safe; it did not address the issue of the safety of reducing LDL-C levels below a designated cutoff. Finally, in the DISC, children with total behavior problem scores on the CBCL above the 98th percentile were eliminated. A cutoff score of the 90th percentile has been suggested to be the best cutoff score for identifying children receiving mental health services (Achenbach, 1992). The DISC did include children with behavior problem scores between the 90th and the 97th percentiles. Children with scores above the 98th percentile may be those most affected by a low-fat diet; however, because their levels of problems are so high, those children are the least likely to show an increase in behavior problem scores because of dietary change. The effects of eliminating from study children with these very high levels of behavior problems remain to be determined.

In spite of these limitations, our evaluation of the psychosocial safety of the DISC diet after 3 years of diet intervention offers no support for concerns about the psychosocial safety of cholesterol-lowering diets in children or young adolescents with elevated LDL-C levels. We conclude that a cholesterol-lowering diet similar to the Step II diet recommended by the NCEP had no adverse psychosocial effects in the DISC population after 3 years of intervention.

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The Publications and Communications Board has opened nominations for the editorships of ***Behavioral Neuroscience, JEP: Applied, JEP: General, Psychological Methods,*** and ***Neuropsychology*** for the years 2002–2007. Michela Gallagher, PhD; Raymond S. Nickerson, PhD; Nora S. Newcombe, PhD; Mark I. Appelbaum, PhD; and Laird S. Cermak, PhD, respectively, are the incumbent editors.

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