

Randomized Controlled Trial of a Primary Care and Home-Based Intervention for Physical Activity and Nutrition Behaviors

PACE+ for Adolescents

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Objective: Many adolescents do not meet national guidelines for participation in regular moderate or vigorous physical activity (PA); limitations on sedentary behaviors; or dietary intake of fruits and vegetables, fiber, or total dietary fat. This study evaluated a health care-based intervention to improve these behaviors.

Design: Randomized controlled trial.

Setting: Primary care with follow-up at home.

Participants: Eight hundred seventy-eight adolescent girls and boys aged 11 to 15 years.

Interventions: Two experimental conditions: (1) Primary care, office-based, computer-assisted diet and PA assessment and stage-based goal setting followed by brief health care provider counseling and 12 months of monthly mail and telephone counseling and (2) a comparison condition addressing sun exposure protection.

Main Outcome Measures: Minutes per week of moderate plus vigorous PA measured by self-report and accelerometer; self-report of days per week of PA and sedentary behaviors; and percentage of energy from fat and servings per day of fruits and vegetables measured by three 24-hour diet recalls. Body mass index (calculated as weight in kilograms divided by the square of height in meters) was a secondary outcome.

Results: Compared with adolescents in the sun protection condition, girls and boys in the diet and PA intervention significantly reduced sedentary behaviors (intervention vs control change, 4.3 to 3.4 h/d vs 4.2 to 4.4 h/d for girls, respectively [$P = .001$]; 4.2 to 3.2 h/d vs 4.2 to 4.3 h/d for boys, respectively [$P = .001$]). Boys reported more active days per week (intervention vs control change: 4.1 to 4.4 d/wk vs 3.8 to 3.8 d/w, respectively [$P = .01$]), and the number of servings of fruits and vegetables for girls approached significance (intervention vs control change, 3.5 to 4.2 servings/d vs 3.5 to 3.9 servings/d, respectively [$P = .07$]). No intervention effects were seen with percentage of calories from fat or minutes of PA per week. Percentage of adolescents meeting recommended health guidelines was significantly improved for girls for consumption of saturated fat (intervention vs control change, 23.4% to 41.0% vs 18.5% to 31%, respectively [relative risk, 1.33; 95% confidence interval, 1.01-1.68]) and for boys' participation in d/wk of PA (intervention vs control change, 45.3% to 55.4% vs 41.9% to 38.0%, respectively [relative risk, 1.47; 95% confidence interval, 1.19-1.75]). No between-group differences were seen in body mass index.

Conclusions: Improvements in some diet, PA, and sedentary behaviors in adolescents can be enabled through the use of a 1-year, integrated intervention using the computer, health provider counseling, mail, and telephone. The amount of intervention received may contribute to its efficacy.

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THERE IS A NEED TO IMPROVE diet, physical activity (PA), and sedentary behaviors in childhood and adolescence.^{1,2} Poor dietary behaviors are a known risk factor for the development of obesity, as well as for the nation's 3 leading causes of death: coronary heart disease, cancer, and stroke. A diet rich in fruits and vegetables and low in fat is recommended for preventing these chronic diseases.^{1,3-10} Energy intake has increased from the 1970s to 2000; according to the Na-

tional Health and Nutrition Examination Survey,¹¹ children aged 6 to 11 years were consuming 133 kcal/d more in 2000 than

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they were just a decade earlier. Although national surveys indicate a decline in the average proportion of calories from total and saturated fat over the past several decades, the Centers for Disease Control and Prevention (Atlanta, Ga) estimated in 2000 that

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only 38% of individuals aged 2 years and older met the recommendation for total fat intake, and 41% met the recommendation for saturated fat intake.¹¹

There is strong evidence of the health benefits of PA,^{1,12} including improvements in longevity, cardiovascular diseases, cardiovascular disease risk factors, diabetes, obesity, osteoporosis, immune functioning, certain types of cancer, and mental health. Recent guidelines from the Dietary Guidelines for Americans¹³ and an international consensus group recommend 60 minutes of daily PA for youth.^{14,15} Although national survey data in the United States indicate that about two thirds of adolescent boys and one half of adolescent girls are meeting an adult-oriented recommendation for vigorous activity,¹⁶ objective measures suggest less than 40% of teens are meeting the 60-minute guideline.¹⁷ Girls, older adolescents, minorities, and disadvantaged youth are even less likely to be meeting this recommendation.¹

Sedentary behaviors, particularly television viewing, are the most consistent behavioral predictor of obesity in adolescence.¹⁸ Intervention studies show that decreasing television time is an effective method of reducing body mass index (BMI [calculated as weight in kilograms divided by the square of height in meters]) in children.¹⁹ Substitution of PA for sedentary behaviors and increases in activity level predict 6- and 12-month reductions in BMI.²⁰ In addition, targeting either decreased sedentary behaviors or increased PA is associated with significant decreases in percentages of overweight people and body fat and improved aerobic fitness.²¹

Obesity in adolescence is becoming increasingly prevalent. Thirty years ago, the prevalence of obesity among adolescents aged 12 to 19 years was approximately 6%. As of the year 2002, more than 16% of adolescents were obese in the United States,²² and this increased prevalence of childhood obesity has been universal in all age, sex, and ethnicity classifications. Childhood obesity is increasingly recognized as one of the nation's most important health issues.²

Interventions to improve diet, PA, and sedentary behaviors in youth can be implemented with families, in schools and communities, or in conjunction with health care. The evidence of effectiveness of most interventions is modest,²³⁻²⁵ and evidence of the efficacy of health care-based interventions for these behaviors is limited to obese children and their families.²⁶ Based on promising feasibility and acceptability data from adolescents, their parents, and clinicians,^{27,28} we conducted a randomized controlled trial of a multimodal intervention, Patient-centered Assessment and Counseling for Exercise + Nutrition (PACE+), to improve diet and PA behaviors in adolescents that could be initiated in primary care. We hypothesized that, compared with control adolescents, adolescents who completed computer-generated tailored Progress Plans addressing PA and diet behaviors, followed by brief provider counseling and 1 year of tailored telephone and mail guidance, would significantly improve PA, diet, and sedentary behaviors.

METHODS

PARTICIPANTS

Adolescents between the ages of 11 and 15 years were recruited through their primary care providers. A total of 45 pri-

mary care providers from 6 private clinic sites in San Diego County, California, agreed to participate in the study. A representative group of healthy adolescents seeing primary care providers was sought by contacting parents of adolescents who were already scheduled for a well child visit and by outreach to families with adolescents. Adolescents were excluded if they had health conditions that would limit the ability to comply with PA or diet recommendations. Parents gave written consent for their child to participate and each adolescent provided signed assent. Participants and parents knew the study involved randomization to either a PA and diet intervention or the comparison sun protection intervention and were not blinded to the intervention. After baseline measures but before seeing the provider, participants were randomized to either the PACE+ intervention condition or the sun protection control condition. The study was approved by the participating health care organizations and university institutional review boards for research with human subjects.

INTERVENTION

The PACE+ intervention (**Figure 1**) was designed to promote adoption and maintenance of improved eating and PA behaviors through a computer-supported intervention initiated in primary health care settings. This was coupled with a printed manual to take home and 12 months of stage-matched telephone calls and mail contact. There was a parent intervention intended to help parents encourage behavior change attempts through praise, active support, and positive role-modeling. The intervention was based on a behavioral determinants model,²⁹ social cognitive theory,³⁰ and the Transtheoretical Model of Behavior Change.³¹ The initial intervention component used a computer expert system on a kiosk in the clinical office to assess 2 nutrition target behaviors (total intake of fat, servings per day of fruits and vegetables), PA target behaviors (moderate and vigorous PA), and sedentary behaviors. A brief screening survey was used to identify patients with disordered eating, and the computer encouraged the adolescent to ask a parent or guardian for assistance with completing the assessment if needed. Stage of readiness to make a behavior change was assessed for each behavior using a simplified 3-stage model. The computer then guided the adolescent to develop stage-appropriate and tailored behavior-change Progress Plans for 1 nutrition and 1 PA behavior (either increasing minutes of PA per day or decreasing sedentary behaviors). All Progress Plans enabled the adolescent and provider to sign it as a behavioral contract.

After the adolescent completed the computer assessment, a printed Provider Summary highlighted patient-reported behaviors (both PA and nutrition), compared them with national guidelines, and displayed the behaviors the adolescent targeted for change. The Provider Summary alerted providers to areas of concern related to weight, disordered eating, or unwillingness to make changes. Providers were trained in 2-hour group sessions that included review of written materials and role-playing examples. Providers were taught to spend approximately 3 to 5 minutes counseling patients, endorse or modify the plans, and encourage full participation in the intervention.

The next component of the intervention was delivered by a 16-section printed Teen Guide, mail, and telephone using stage-based cognitive and behavioral strategies to support changes in target behaviors. The Teen Guide was provided to the adolescent after completion of the provider visit, and each section provided 2 to 3 pages of information or rationale on a specific target behavior or behavior change strategy (eg, decisional balance, self-monitoring). Most sections had worksheets to enhance the adolescent's participation in learning and applying the given strategy to each target behavior. Over the 12-month intervention, manuals were supplemented by mailed worksheets and tip sheets

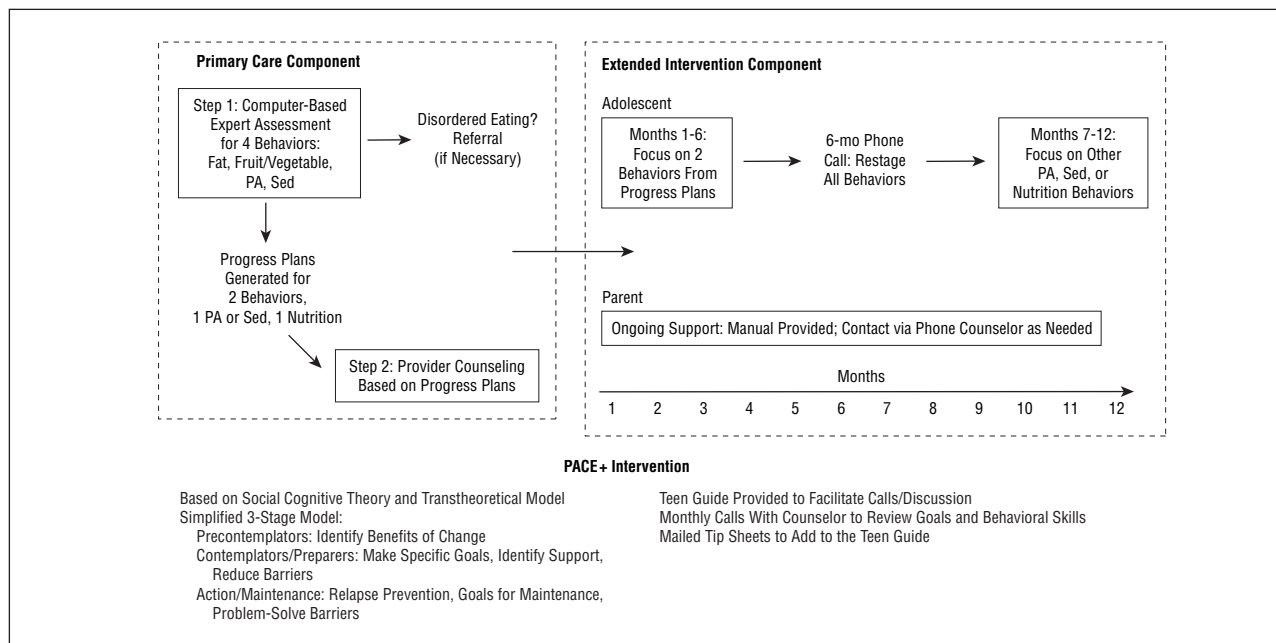


Figure 1. Patient-centered Assessment and Counseling for Exercise + Nutrition (PACE+) intervention overview. PA indicates physical activity; Sed, sedentary.

that allowed further tailoring by providing more guidance on change strategies, more information on foods or activities, or answers to frequently asked questions. Telephone counselors selected the most relevant tip sheets for each target behavior based on the content of each counseling call and participant questions/comments (discussed later in this article). Manuals and mailings were written at approximately a fifth-grade reading level. A companion parent manual was provided at the provider visit that supported intervention elements.

Eleven telephone counseling calls were scheduled throughout the 1-year intervention period, each lasting 10 to 15 minutes and conducted by trained research staff. During the first 6 months, 5 intervention calls were directed at the nutrition and PA behaviors that the adolescent chose to target in the initial clinical visit. A call after the 6-month measurement visit used staging data gathered in that visit to develop new Progress Plans for the remaining 2 target behaviors. Five calls were then made over the next 6 months directed primarily at the remaining 2 target behaviors. Counseling calls were structured interactions using the teen guide to help adolescents learn and apply relevant cognitive or behavioral change strategies to modify diet and PA behaviors. Up to 6 attempts were made to reach adolescents for each call. If calls were missed, the next completed call briefly addressed topic areas that would have been covered in the missed call.

Adolescents randomized to the comparison condition received an adaptation of the SunSmart sun protection behavior program developed at the University of Rhode Island, Kingston.³² SunSmart was based on the transtheoretical model and entailed an initial primary care, office-based, computer assessment of sun protection behaviors followed by computer-generated, printed, stage-based recommendations for improvement such as wearing protective clothing and use of sunscreen. Brief counseling telephone calls were provided by the health counselor at 3 months and 6 months each, followed by a mailed feedback report and tip sheet to encourage continued sun protection behavior. Adolescents received \$10 for completing the baseline measures, \$15 for completing the 6-month measures, and \$20 for completing the 12-month measures. On completion of scheduled measurement visits and monthly telephone

calls, adolescents in both the control and intervention groups received lottery tickets for small cash prizes (\$10-\$50) in lotteries conducted every 6 months.

PRIMARY OUTCOME MEASURES

Assessments were performed by trained staff at baseline before the adolescents went to the provider offices for their initial PACE+ counseling visits and at 6 and 12 months. The 7-day Physical Activity Recall is one of the most widely studied self-report measures of PA and has been evaluated with children and adolescents.³³ Subjects report hours spent in sleep and in moderate, hard, and very hard activities over the previous 7 days. The interview takes about 10 minutes to administer and focuses on salient PAs. Standardized interviewer protocol and training methods have produced same-day reliabilities across interviewers of 0.86.³⁴ In a sample of 102 5th-, 8th-, and 11th-grade boys and girls, the overall test retest reliability was $r=0.77$. Reliability was not affected by obesity status or memory skills.³³ Validity of the Physical Activity Recall is strongly supported by objective measures.³⁵ Physical activity was calculated as the sum of reported minutes of moderate, hard, and very hard activities. The number of active days per week was calculated by summing the number of days out of 7 that an adolescent attained at least 30 minutes of vigorous activity, at least 60 minutes of moderate activity, or at least 60 minutes of a combination of vigorous and moderate activity.

Three 24-hour recalls assessed dietary intake at each assessment point. Trained data collectors conducted dietary recalls for 2 weekdays and 1 weekend day using the University of Minnesota Nutrition Data System for Research software.³⁶ Participants were taught how to measure food portions with 3-dimensional food models. The first interview was conducted in person and the second and third by telephone (participants were given 2-dimensional food models to use for the second and third assessments). Nutrient variables (percentage of calories from total fat and saturated fat, number of servings of fruits and vegetables, grams of fiber) were calculated by averaging values from the 3 intake records.

Participants completed a self-report measure of recent school day and non-school day time spent watching television, play-

ing computer/video games, sitting talking on the telephone, and sitting listening to music. This survey was modified from a validated survey developed by Robinson.¹⁹ Participants responded with an 8-point scale ranging from “none” to “6 hours or more.” A composite score of sedentary behavior was calculated from a weighted sum of the school day and non-school day responses, with weights of 5 and 2, respectively.

Physical activity and dietary intake data were used to develop separate variables for direct comparison with national guidelines for number of minutes of PA per day,¹⁵ number of hours of television per day,³⁷ percentage of calories from total fat and percentage of calories from saturated fat,³⁷ fruits and vegetables (number of servings per day), and amount of dietary fiber (grams per day).³⁸ Meeting the active guideline was defined as 5 or more active days per week. The television viewing guideline variable was estimated in the same way as the total sedentary variable using only the television self-report item. A cutpoint of greater than 2 hours per day defined adolescents who were not meeting the television time guideline.

OTHER MEASURES

A wall stadiometer was used to measure standing height. Weight was measured with a calibrated digital scale. Each measure was taken twice and the average of the 2 readings calculated. Body mass index was calculated as weight in kilograms divided by the square of height in meters. Body mass index for age was determined from Centers for Disease Control and Prevention national norms using age to the nearest month and sex-specific median, standard deviation, and power of the Box-Cox transformation.³⁹

Physical activity was measured with the Computer Science and Applications accelerometer (WAM 7164; Computer Science and Applications, Shalimar, Fla). This uniaxial accelerometer is small (5.1 × 3.8 × 1.5 cm), lightweight (45 g), and worn on a belt snugly around the waist. Accelerometers stored data as 1-minute averages for a 7-day period. In laboratory and field settings, Computer Science and Applications accelerometers have been shown to be a valid measure for quantifying children’s activity levels.⁴⁰ Physical activity estimates of daily minutes of moderate (3–5.9 metabolic equivalents [METs]) plus vigorous PA (≥6 METs) were calculated by averaging across valid days of monitoring for each participant. Accelerometer data were considered a secondary outcome because of considerable missing data due to lost and malfunctioning monitors and compliance with participants wearing the monitor as instructed. Complete and valid data (≥3 days of 10 h/d of monitoring) from the activity monitors were available for 330 participants at baseline and 12 months. Data on numbers of calls completed to intervention participants were used to categorize adolescents into low-dose treatment and high-dose treatment groups.

STATISTICAL ANALYSIS

All outcome analyses were conducted using the 12-month primary study end points as dependent variables. Analyses were conducted under the intent-to-treat assumption by replacing missing values at the 12-month end point with the most recent available data from either the 6-month or baseline assessment. Dependent variables with nonnormal distributions were either log or square-root transformed. The primary analyses compared differences between the PACE+ and control group on 5 outcome variables using analysis-of-covariance models controlling for the corresponding baseline outcome measure as well as age (in months), ethnicity (white non-Hispanic, all other races/ethnicities), and BMI z score. These covariates were selected a priori. Secondary analyses used logistic regression models to compare the proportion of PACE+ and control participants meeting 6 recommended health guidelines at 12 months. These guidelines were also tested with

logistic regression models comparing low and high intervention dose levels with the control group. The logistic regression models included the corresponding baseline variable as well as age, ethnicity, and BMI z score as covariates. To aid interpretation of the logistic regression models, odds ratios and 95% confidence interval (CI) boundaries were corrected to risk ratios (RRs) using the method proposed by Zhang and Yu.⁴¹ Because previous research has suggested sex differences in response to PA and diet behavior interventions,^{42,43} all analyses were conducted separately for girls and boys and analyzed using SPSS version 12.0 (SPSS Inc, Chicago, Ill). *P* values were not adjusted for multiple tests. All reported *P* values are for 2-sided tests with effects considered statistically significant at *P* < .05.

RESULTS

Recruitment occurred from May 2001 through June 2002. **Figure 2** displays the flow diagram of participants through the study. An initial letter was sent to all patients in the eligible age range from participating physicians, informing them that they may receive a telephone call in the next year about a health promotion study. Parents were given the option to send back a postcard requesting that they not be contacted about the study. A total of 1172 (7%) households returned opt-out cards. In response to the letter, some parents called to learn more about the study. After the initial mailing, adolescents were recruited in 2 ways: by calling patients of participating providers when they had an upcoming scheduled doctor’s visit and by “cold-calling” patients of participating providers at random who did not return an opt-out postcard from the initial mailing. Baseline assessments were completed by 878 adolescents, 819 of whom began the intervention at the doctor’s office and are included in the intent-to-treat analysis.

No differences were found between randomized participants who began the intervention and those who did not begin the intervention (*n* = 59) in terms of age, sex, ethnicity, provider site location, highest household education level, body weight status, or treatment group. No differences were found between intervention and comparison condition groups for sex, age, highest household education level, or body weight status at baseline. More nonwhite adolescents were randomized to the treatment group (45%) compared with the control group (38%). **Table 1** displays demographic and anthropometric characteristics of the study sample. While not fully representative of the San Diego community, in which those aged 10 to 17 years are 35% Hispanic, 7% African American, 12% Asian or other, and 45% non-Hispanic white (San Diego Association of Governments, March 7, 2003), the study sample was diverse with approximately 42% from races/ethnicities other than non-Hispanic white. Participants completing assessments at 12 months did not differ from non-completers by treatment group, provider site location, sex, ethnicity, or highest household education level. However, completers were more likely than noncompleters to have a BMI below the 85th percentile (*P* < .01).

EFFECT ON BEHAVIORAL OUTCOMES

The only significant (*P* < .001) between-group difference that was found for both girls and boys was im-

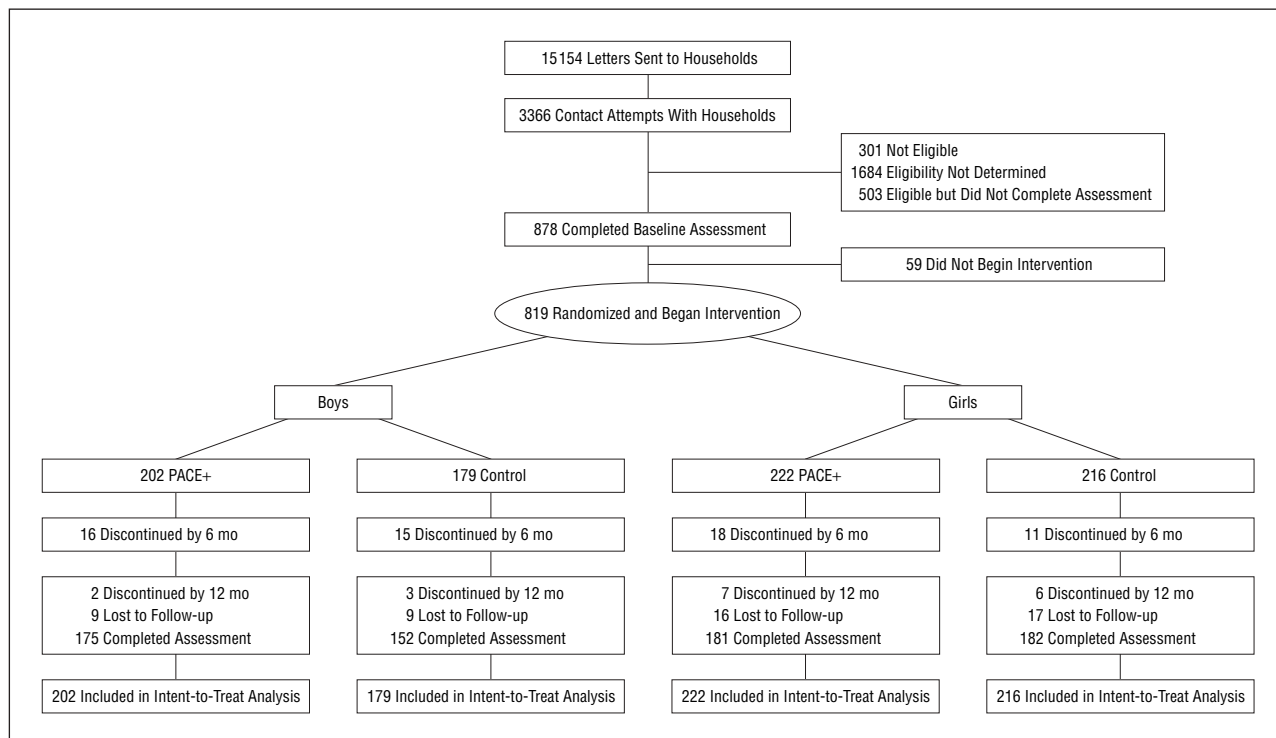


Figure 2. Study flow diagram. Because of the limited recruitment period (12 months), of households sent a letter (n=15 154), only 3366 had contact attempts made. Among these, eligibility could not be determined for 1684 households because of a wrong number (n=462), refusal to participate (n=892), or not reaching a household member after 8 attempts (n=330). Of the remaining eligible to participate, 503 did not complete the initial baseline assessment and 59 who completed the baseline assessment did not begin the intervention. PACE+ indicates Patient-centered Assessment and Counseling for Exercise + Nutrition.

Table 1. PACE+ Adolescent Sample Demographic Characteristics

Variable	Girls		Boys		Overall
	PACE+	Control	PACE+	Control	
Participants, No.	222	216	202	179	819
Age, mean (SD), y	12.8 (1.3)	12.6 (1.4)	12.6 (1.4)	12.8 (1.3)	12.7 (1.3)
Ethnicity, No. (%)					
Asian or Pacific Islander	9 (4.1)	2 (0.9)	8 (4.0)	7 (3.9)	26 (3.2)
African American	19 (8.6)	6 (2.8)	17 (8.4)	12 (6.7)	54 (6.6)
Native American	2 (0.9)	2 (0.9)	1 (0.5)	1 (0.6)	6 (0.7)
Hispanic	33 (14.9)	28 (13.0)	28 (13.9)	18 (10.1)	107 (13.1)
White	121 (54.4)	135 (62.5)	111 (55.0)	111 (62.0)	478 (58.4)
Multiethnic or other	38 (17.2)	43 (19.9)	37 (18.4)	30 (16.7)	148 (18.0)
Highest household education level, No. (%)*					
From no high school degree to associate's-level degree	82 (37.8)	80 (37.6)	60 (30.2)	47 (27.3)	269 (33.6)
Bachelor's-level degree	66 (30.4)	51 (38.5)	68 (34.2)	53 (30.8)	238 (29.7)
Graduate or professional degree	69 (31.8)	82 (38.5)	71 (35.7)	72 (41.9)	294 (36.7)
Body mass index† for age, No. (%)					
<85th percentile	118 (53.2)	112 (51.9)	116 (57.7)	97 (54.4)	443 (54.2)
≥85th to <95th percentile	42 (18.9)	49 (22.7)	29 (14.4)	31 (17.3)	151 (18.4)
≥95th percentile	62 (27.9)	55 (25.5)	56 (27.9)	51 (28.5)	224 (27.4)

Abbreviations: PACE+, Patient-centered Assessment and Counseling for Exercise + Nutrition.

*n = 801.

†Calculated as weight in kilograms divided by the square of height in meters.

provement in sedentary behaviors (**Table 2**.) In addition, boys in the PACE+ group increased their number of active days per week ($P = .01$) compared with control adolescents. For the remaining behaviors, girls and boys in both the intervention and control groups im-

proved in all behaviors, but these changes did not differ between groups.

Accelerometer data were available at baseline and 12 months on 180 girls and 150 boys. Mean \pm SE accelerometer estimates of average minutes per day of PA

Table 2. Intent-to-Treat ANCOVA Analysis of Primary Outcomes for Girls and Boys*

Outcome	Girls			Boys		
	PACE+, Mean (SD)	Control, Mean (SD)	P Value	PACE+, Mean (SD)	Control, Mean (SD)	P Value
Calories from fat, %						
Preintervention	32.6 (5.5)	33.3 (7.2)	.86	32.6 (5.7)	32.3 (6.2)	.31
Postintervention	31.4 (7.0)	31.7 (6.6)		31.2 (6.3)	31.6 (5.9)	
Change, %	-3.7	-4.8		-4.3	-2.2	
Fruit and vegetable servings/d†						
Preintervention	3.5 (1.5)	3.5 (1.8)	.07	3.5 (1.6)	3.7 (1.6)	.49
Postintervention	4.2 (1.8)	3.9 (1.7)		4.2 (1.7)	4.4 (1.6)	
Change, %	20.0	11.4		20.0	20.0	
Sedentary behaviors, h/d						
Preintervention	4.3 (3.4)	4.2 (3.4)	.001	4.2 (3.7)	4.2 (2.8)	.001
Postintervention	3.4 (2.6)	4.4 (3.7)		3.2 (2.6)	4.3 (3.5)	
Change, %	-21	4.8		-24	2.4	
Physical Activity Recall mod + vig, min/wk‡						
Preintervention	316.1 (49.2)	284.3 (45.8)	.90	418.4 (54.5)	374.0 (55.0)	.17
Postintervention	324.6 (61.5)	313.9 (62.2)		486.0 (75.3)	419.8 (79.2)	
Change, %	2.7	10.4		16.2	12.2	
Active d/wk						
Preintervention	3.3 (2.1)	3.1 (2.0)	.88	4.1 (2.0)	3.8 (2.1)	.01
Postintervention	3.4 (2.1)	3.3 (2.1)		4.4 (2.1)	3.8 (2.1)	
Change, %	.03	.06		7.3	0.0	

Abbreviations: ANCOVA, analysis of covariance; mod, moderate; PACE+, Patient-centered Assessment and Counseling for Exercise + Nutrition; vig, vigorous. *Controlling for age, ethnicity, body mass index z score, and baseline variable. Girls: PACE+, n = 222; control, n = 216; boys: PACE+, n = 202; control, n = 179. †Geometric mean. ‡Square root transformed for analyses; squared means and SDs presented in this table.

(moderate + vigorous) were not found to be different between the PACE+ and the control group for girls (53.5 ± 2.3 minutes vs 52.8 ± 2.0 minutes, *P* = .80) or boys (72.8 ± 3.4 minutes vs 71.3 ± 3.3 minutes, *P* = .76).

EFFECT ON MEETING HEALTH GUIDELINES

The proportion of adolescents meeting recommended health guidelines before and after the intervention are displayed in **Table 3**. More girls in the PACE+ group compared with the control group met the guideline for maximum percentage of daily calories from saturated fat at 12 months (RR, 1.33; 95% CI, 1.01-1.68). Changes in the proportion of girls meeting the other guidelines were not different between groups. More boys in the PACE+ group compared with the control group were meeting the PA guideline at 12 months (RR, 1.47; 95% CI, 1.19-1.75). All other changes in meeting guidelines did not differ between groups for boys.

EFFECT OF INTERVENTION DOSE

The effect of intervention dose was tested by comparing the high and low dose levels with the control group using logistic regression analyses (**Table 4**). The number of completed counselor calls ranged from 0 to 11 out of 11 possible calls. Based on a median split, the “low dose” of 0 to 8 calls was received by 36% of adolescents, while the “high dose” of 9 to 11 calls was received by 64% of adolescents. For girls, receiving the low dose did not lead to meeting

any of the health guidelines compared with control group participants while receiving the high dose was related to increased likelihood of meeting the guidelines for saturated fat (RR, 1.36; 95% CI, 1.02-1.73), fruit and vegetable consumption (RR, 1.50; 95% CI, 1.02-2.03), and sedentary behavior (RR, 1.13; 95% CI, 1.01-1.21). Compared with boys in the control group, boys who received both a low dose (RR, 1.74; 95% CI, 1.35-2.06) and high dose (RR, 1.39; 95% CI, 1.06-1.71) of the intervention were significantly more likely to meet the PA guideline.

EFFECT ON BMI

No differences were found at 12 months between groups for BMI z scores, which were normed for age and sex in models controlling for baseline BMI z score, age, and ethnicity. In an analysis of the subgroup of adolescents with a BMI at or above the 95 percentile (n = 238), mean ± SE BMI z score estimates were 2.08 ± 0.02 for PACE+ adolescents and 2.12 ± 0.02 for control adolescents (*P* = .10).

COMMENT

This is the first randomized controlled trial to evaluate the effects of a behavior change intervention for PA, diet, and sedentary behavior that integrates computer-assisted behavior assessment; health care provider counseling; and extended, tailored telephone and mail outreach. This intervention, leading to significant intervention effects on multiple behaviors, was shown to be feasible, with 64% of adolescents assigned to the intervention condition com-

Table 3. Intent-to-Treat Logistic Regression Analyses for Meeting Recommended Health Guidelines in 438 Girls and 381 Boys*

Guideline	Girls			Boys		
	PACE+	Control	RR (95% CI)†	PACE+	Control	RR (95% CI)†
30% kcal from fat						
Preintervention	31.1	29.6	1.06 (0.83-1.31)	32.2	34.6	1.10 (0.38-1.38)
Postintervention	42.3	39.8		40.6	38.0	
Change, %	36	34		26	10	
10% kcal from saturated fat						
Preintervention	23.4	18.5	1.33 (1.01-1.68)‡	24.4	24.7	1.31 (0.96-1.73)
Postintervention	41.0	31.0		36.1	28.5	
Change, %	43	68		48	15	
≥5 fruit and vegetable servings/d						
Preintervention	7.7	12.0	1.21 (0.85-1.64)	11.9	13.4	0.80 (0.54-1.14)
Postintervention	26.1	23.6		23.3	28.5	
Change, %	239	92		96	113	
Fiber g/d						
Preintervention	12.2	7.9	0.94 (0.47-1.78)	16.3	16.2	0.70 (0.40-1.16)
Postintervention	8.6	7.9		14.4	19.9	
Change, %	-30	0		-12	23	
≤2 h/d of TV viewing						
Preintervention	71.1	71.8	1.07 (0.95-1.15)	72.8	70.4	1.04 (0.92-1.13)
Postintervention	80.6	76.4		80.7	77.7	
Change, %	13	6		11	10	
Physical activity, d/wk						
Preintervention	37.8	27.8	0.83 (0.61-1.10)	45.3	41.9	1.47 (1.19-1.75)‡
Postintervention	33.6	36.1		55.4	38.0	
Change, %	-11	30		22	-9	

Abbreviations: CI, confidence interval; PACE+, Patient-centered Assessment and Counseling for Exercise + Nutrition; RR, relative risk; TV, television.

*Girls (PACE+, n = 222; control, n = 216), boys (PACE+, n = 202; control, n = 179). Values are percentages of participants unless otherwise indicated.

†Relative risk and 95% CI estimated from corrected adjusted odds ratio controlling for age, ethnicity, body mass index (calculated as weight in kilograms divided by the square of height in meters) z score, and baseline status on guideline.

‡These findings differed meaningfully postintervention given that the 95% confidence intervals postintervention did not overlap.

Table 4. Logistic Regression Analyses of the Effect of Receiving High or Low Intervention Dose Compared With the Control Condition on Meeting Recommended Health Guidelines*

Guideline	Girls RR, (95% CI)*		Boys RR, (95% CI)*	
	Low Dose (0-8 Calls) vs Control (n = 77)	High Dose (9-11 Calls) vs Control (n = 140)	Low Dose (0-8 Calls) vs Control (n = 73)	High Dose (9-11 Calls) vs Control (n = 125)
% kcal from fat	1.04 (0.73-1.39)	1.06 (0.80-1.34)	1.03 (0.70-1.13)	1.13 (0.84-1.45)
% kcal from saturated fat	1.31 (0.91-1.76)	1.36 (1.02-1.73)†	1.17 (0.76-1.68)	1.34 (0.96-1.77)
Fruit and vegetable servings/d	0.81 (0.44-1.39)	1.50 (1.02-2.03)†	0.70 (0.39-1.15)	0.83 (0.54-1.21)
Fiber g/1000 kcal per day	0.80 (0.30-2.01)	0.82 (0.43-1.87)	0.68 (0.31-1.34)	0.69 (0.36-1.23)
Physical activity, d/wk	0.80 (0.51-1.17)	0.83 (0.58-1.12)	1.74 (1.35-2.06)†	1.39 (1.06-1.71)†
≤2 h/d of TV viewing	1.01 (0.96-1.18)	1.13 (1.01-1.21)†	1.02 (0.83-1.14)	1.06 (0.92-1.16)

Abbreviations: CI, confidence interval; RR, relative risk; TV, television.

*Relative risk and 95% CI estimated from corrected adjusted odds ratio controlling for age, ethnicity, body mass index (calculated as weight in kilograms divided by the square of height in meters) z score, and baseline status on guideline.

†P<.05.

pleting at least 9 of the 11 counseling calls. The intervention was effective in reducing sedentary time in both girls and boys, with a net change of approximately 1 hour per day. This is important given that sedentary behaviors can decrease energy intake in nonoverweight adolescents and has been suggested as an important component of interventions to prevent obesity and regulate body weight.⁴⁴ The intervention increased the number of days boys met the PA recommendation and the number of days girls met the

saturated fat recommendation. These changes were documented for 12 months after the initial provider counseling, supporting the promise of ongoing telephone counseling and targeted materials to support long-term behavior changes. The results of the exploratory analysis of the effects of intervention dose suggest, at least among girls, more frequent outreach and contact can help adolescents make changes in multiple behaviors. This finding suggests the need for research on strategies to maximize participation

in effective interventions that target multiple behaviors.

This study helps address the need for research on how multiple health risk behaviors can be evaluated and managed in primary care settings⁴⁵ and contributes knowledge about the efficacy of “interactive behavior change technologies” and their utility as a possible adjunct to primary care.⁴⁶ Strengths of this research include the large and diverse sample of adolescents, the involvement in the study of a range of primary care settings in San Diego, use of high-quality outcome measures, a comparison condition that controlled for many nonspecific aspects of the intervention, and long-term outcome assessment at 12 months.

There are several limitations to this study. Although we attempted to enroll a representative sample of adolescents seen in primary care, self-selection may have led to selection of adolescents and parents with a strong interest in health interventions like those tested and thus might not be generalizable to adolescents at other stages of change. Another concern is that self-report measurement of diet and PA behaviors is always an imprecise process. Although we used measures that have been validated in other studies, this does not overcome their inherent limitations. However, the accelerometer data tend to support our general findings of time spent in PA in accordance with several other studies of adolescent PA.⁴⁷

An additional concern in interpreting results is the potential impact on our findings of measurement reactivity in which self-reported behavior is influenced by the measurement process itself. Repeated assessments of the target behaviors as well as extensive surveys on thoughts and actions used to change behaviors (not described in this article) could have motivated and even instructed adolescents in both conditions to change behaviors, and control participants reported improvements in several diet and PA behaviors. Measurement effects have been demonstrated in studies promoting PA through primary care settings,⁴⁸ and this also may occur with diet assessment. Finally, our intent-to-treat analysis used the last available value of measures for participants who dropped out. If the effect of the intervention was greater in the beginning than it was at the end, this could bias our findings.

The optimal role for health care providers in helping children and adolescents adopt and maintain healthy PA and dietary behaviors has yet to be established. This study among a group of generally healthy adolescents seen in primary care suggests limited effects of provider counseling, even when it is supported by an intervention like PACE+. More intensive interventions, perhaps using a “stepped care” approach that varies the intensity of the intervention, are showing promise in adults⁴⁹ and also may be appropriate in childhood. The increasing prevalence of problems such as childhood obesity that result from poor diet and PA, and the recognition that many childhood diseases such as diabetes and hypertension have better outcomes with improvements in these behaviors, suggest the continued need for research in this area.

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REFERENCES

1. US Department of Health and Human Services. *Physical Activity and Health: A Report of the Surgeon General*. Atlanta, Ga: Centers for Disease Control and Prevention; 1996.
2. Institute of Medicine. *Preventing Childhood Obesity: Health in the Balance*. Washington, DC: National Academy of Sciences; 2004.
3. US Department of Agriculture. Nutrient database for nationwide food surveys, Release 7. Washington, DC: US Dept of Agriculture; 1991.
4. US Department of Agriculture. *The Food Guide Pyramid*. Home and Garden Bulletin No. 252. Washington, DC: US Department of Agriculture; 1992.
5. National Research Council. *Diet and Health: Implications for Reducing Chronic Disease Risk*. Washington, DC: National Academy Press; 1989.
6. National Heart, Lung, and Blood Institute. *Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction*. Bethesda, Md: US Department of Health and Human Services, Public Health Service, National Institutes of Health Publication No. 90-3046; 1990.
7. National Heart, Lung, and Blood Institute. *Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents*. Bethesda, Md: US Department of Health and Human Services, Public Health Service, National Institutes of Health Publication No. 91-2732; 1991.
8. National Cancer Institute (NCI). *Eat More Fruits and Vegetables: 5 a Day for Better Health*. Bethesda, Md: US Department of Health and Human Services, Public Health Service, National Institutes of Health Publication No. 92-3248; 1991.
9. Weinhause S, Bal DG, Adamson R, et al. American Cancer Society guidelines on diet, nutrition, and cancer: the work study group on diet, nutrition, and cancer. *CA Cancer J Clin*. 1991;41:334-338.
10. American Heart Association. Dietary guidelines for healthy American adults. *Circulation*. 1988;77:721A-724A.
11. Wright JD, Wang C, Kennedy-Stephenson J, Ervin RB. Dietary Intake of ten key nutrients for public health, United States:1999–2000. Advance Data from Vital and Health Statistics, Number 334. Atlanta, Ga: Centers for Disease Control and Prevention, April 17, 2003. Available at: <http://www.cdc.gov/nchs/data/ad/ad334.pdf>. Accessed on November 18, 2005.
12. Biddle SJH, Gorely T, Stensel DJ. Health-enhancing physical activity and sedentary behaviour in children and adolescents. *J Sports Sci*. 2004;22:679-701.
13. Dietary guidelines for Americans. US Department of Health and Human Services, US Department of Agriculture. Available at: <http://www.healthier.us.gov/dietaryguidelines>. Accessed on May 17, 2005.
14. Biddle S, Cavill N, Sallis J. Policy framework for young people and health: enhancing physical activity. In: Biddle S, Sallis J, Cavil N, eds. *Young and Active? Young People and Health-Enhancing Physical Activity-Evidence and Implications*. London, England: Health Education Authority;1998:3-16.
15. Cavill N, Biddle S, Sallis JF. Health enhancing physical activity for young people: statement of the United Kingdom Expert Consensus Conference. *Pediatric Exercise Science*. 2001;13:12-25.
16. Pate RR, Long BJ, Heath G. Descriptive epidemiology of physical activity in adolescents. *Pediatric Exercise Science*. 1994;6:434-447.

17. Pate RR, Freedson PS, Sallis JF, et al. Compliance with physical activity guidelines: prevalence in a population of children and youth. *Ann Epidemiol.* 2002; 12:303-308.
18. Saelens BE. Helping individuals reduce sedentary behavior. In: Andersen RE, ed. *Obesity: Etiology, Assessment, Treatment, and Prevention.* Champaign, Ill: Human Kinetics; 2003:217-238.
19. Robinson TN. Reducing children's television viewing to prevent obesity: a randomized controlled trial. *JAMA.* 1999;282:1561-1567.
20. Epstein LH, Paluch RA, Kilanowski CK, Raynor HA. The effect of reinforcement of stimulus control to reduce sedentary behavior: the treatment of pediatric obesity. *Health Psychol.* 2004;23:371-380.
21. Epstein LH, Paluch RA, Gordy CC, Dorn J. Decreasing sedentary behaviors in treating pediatric obesity. *Arch Pediatr Adolesc Med.* 2000;154:220-226.
22. Ogden CL, Flegal KM, Carroll MD, Johnson CL. Prevalence and trends in overweight among US children and adolescents. *JAMA.* 2002;288:1728-1732.
23. Resnicow K, Robinson T. School-based cardiovascular disease prevention studies: review and synthesis. *Ann Epidemiol.* 1997;7(suppl):S14-S31.
24. Dishman RK, Buckworth J. Increasing physical activity: a quantitative synthesis. *Med Sci Sports Exerc.* 1996;28:706-719.
25. Contento I, Balch GI, Bronner YL, et al. The effectiveness of nutrition education and implications for nutrition education policy, programs, and research: a review of research. *J Nutr Educ.* 1995;27:275-422.
26. Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics.* 1998;101(suppl):554-570.
27. Saelens BE, Sallis J, Wifflay D, Patrick K, Cella J, Buchta R. A randomized trial of a multi-component behavioral weight control treatment initiated in primary care versus typical care for overweight adolescents. *Obes Res.* 2002;10:22-32.
28. Patrick K, Sallis J, Lydston D, et al. Preliminary evaluation of a multi-component program for nutrition and physical activity change in primary care: PACE+ for adolescents. *Arch Pediatr Adolesc Med.* 2001;155:940-946.
29. Sallis JF, Hovell MF. Determinants of exercise behavior. *Exerc Sport Sci Rev.* 1990; 18:307-330.
30. Bandura A. *Social Foundations of Thought and Action.* Englewood Cliffs, NJ: Prentice-Hall; 1986.
31. Prochaska JO, DiClemente CC. *The Transtheoretical Approach: Crossing Traditional Boundaries of Therapy.* Homewood, Ill: Dow Jones-Irwin; 1984.
32. Weinstock MA, Rossi JS. The Rhode Island Sun Smart Project: a scientific approach to skin cancer prevention. *Clin Dermatol.* 1998;16:411-413.
33. Sallis JF, Buono MJ, Roby JJ, Micale FG, Nelson JA. Seven-day recall and other physical activity self-reports in children and adolescents. *Med Sci Sports Exerc.* 1993;25:99-108.
34. Gross LD, Sallis JF, Buono MJ, Roby JJ, Nelson JA. Reliability of interviewers using the seven-day physical activity recall. *Res Q Exerc Sport.* 1990;61:321-325.
35. Montoye HJ, Kemper HCG, Saris WHM, Washburn RA. *Measuring Physical Activity and Energy Expenditure.* Champaign, Ill: Human Kinetics; 1996.
36. Schakel SF, Sievert YA, Buzzard IM. Sources of data for developing and maintaining a nutrient database. *J Am Diet Assoc.* 1988;88:1268-1271.
37. *Healthy People 2010*, Second Edition. US Department of Health and Human Services. Available at: <http://www.healthypeople.gov/Document/tableofcontents.htm#Volume2>. Accessed on November 23, 2005.
38. Williams CL, Bollella M, Wynder EL. A new recommendation for dietary fiber in childhood. *Pediatrics.* 1995;96:985-988.
39. Kuczumarski RJ, Ogden CL, Grummer-Strawn LM, et al. *CDC Growth Charts: United States Advanced Data from Vital and Health Statistics.* Hyattsville, Md: National Center for Health Statistics; 2000.
40. Trost SG, Ward DS, Moorehead SM, Watson PD, Riner W, Burke JR. Validity of the computer science and applications (CSA) activity monitor in children. *Med Sci Sports Exerc.* 1998;30:629-633.
41. Zhang J, Yu KF. What's the relative risk? a method of correcting the odds ratio in cohort studies of common outcomes. *JAMA.* 1998;280:1690-1691.
42. Stone EJ, Baranowski T, Sallis JF, Cutler JA. Synthesis of behavioral research for cardiopulmonary health: emphasis on youth, gender, and ethnicity. *J Health Educ.* 1995;26:S9-17.
43. Sallis JF, McKenzie TL, Alcaraz JE, Kolody B, Faucette N, Hovell MF. The effects of a 2-year physical education program (SPARK) on physical activity and fitness in elementary school students. *Am J Public Health.* 1997;87:1328-1334.
44. Epstein LH, Roemmich JN, Paluch RA, Raynor HA. Influence of changes in sedentary behavior on energy and macronutrient intake in youth. *Am J Clin Nutr.* 2005;81:361-366.
45. Orleans TC. Addressing multiple behavioral health risks in primary care: broadening the focus of health behavior change research and practice. *Am J Prev Med.* 2004;27(suppl 2):1-3.
46. Glasgow RE, Bull SS, Piette JD, Steiner JF. Interactive behavior change technology: a partial solution to the competing demands of primary care. *Am J Prev Med.* 2004;27(2S):80-87.
47. Sirard JR, Pate RR. Physical activity assessment in children and adolescents. *Sports Med.* 2001;31:439-454.
48. van Sluijs E. *Effectiveness of Physical Activity Promotion: The Case of General Practice.* (ISBN 90-5669-088-4.) Wageningen, Netherlands: Ponsen & Looijen BV; 2004:57-70.
49. Counterweight Project Team. A new evidence-based model for weight management in primary care: the Counterweight Programme. *J Hum Nutr Diet.* 2004; 17:191-208.

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