Bright Start: Description and Main Outcomes From a Group-Randomized Obesity Prevention Trial in American Indian Children

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The aim of the Bright Start study was to develop and test the effectiveness of a school environment intervention, supplemented with family involvement, to reduce excessive weight gain by increasing physical activity and healthy eating practices among kindergarten and first-grade American Indian children. Bright Start was a group-randomized, school-based trial involving 454 children attending 14 schools on the Pine Ridge Reservation in South Dakota. Children were followed from the beginning of their kindergarten year through the end of first grade. Main outcome variables were mean BMI, mean percent body fat, and prevalence of overweight/obese children. The goals of the intervention were to: increase physical activity at school to at least 60 min/day; modify school meals and snacks; and involve families in making behavioral and environmental changes at home. At baseline, 32% of boys and 25% of girls were overweight/obese. Although the intervention was not associated with statistically significant change in mean levels of BMI, BMI-Z, skinfolds or percentage body fat, the intervention was associated with a statistically significant net decrease of 10% in the prevalence of overweight. Intervention children experienced a 13.4% incidence of overweight, whereas the control children experienced a corresponding incidence of 24.8%; a difference of −11.4% (P = 0.033). The intervention significantly reduced parent-reported mean child intakes of sugar-sweetened beverages, whole milk, and chocolate milk. Changes in duration of school physical activity were not significant. Because obesity is the most daunting health challenge facing American Indian children today, more intervention research is needed to identify effective approaches.
fat served and taken at school meals (17,18) and increased obesity-related knowledge, attitudes, and behaviors (19) were achieved. Nevertheless, there were no significant intervention-related effects on the two main outcome variables, mean BMI and percentage of body fat (20).

After careful review of the Pathways experience, Bright Start (Ohiyu Iyajian in the Lakota language) was developed specifically to address aspects that, in retrospect, may have improved the outcomes of the Pathways intervention, while retaining those aspects that appeared successful. Major departures from the Pathways model included focusing primarily on a school environmental intervention, targeting younger children, emphasizing more physical activity, increasing parental involvement, and gaining tighter control of intervention activities by conducting them through a single research institution. In Pathways, a standardized intervention was required across all seven sites disallowing tribal culturally specific or geographic adaptations.

Herein, we describe the Bright Start study and report the main outcomes of the intervention in kindergarten and first-grade Lakota children attending 14 schools on the Pine Ridge Reservation in South Dakota.

**METHODS AND PROCEDURES**

**Study design**

The primary aim of Bright Start was to reduce excessive weight gain by increasing physical activity and healthy eating practices through changes in school and household environments. The study followed children from the beginning of their kindergarten year through the end of first grade. The main outcome variables were mean BMI, mean percent body fat, prevalence of overweight children (BMI ≥85th percentile and <95th percentile for age and gender), and the prevalence of obese children (BMI ≥95th percentile for age and gender). Secondary outcomes were percentage of calories from fat and nutrient content in school meals, duration of physical activity at school, and food intake at home.

Bright Start was a group-randomized trial with school as the unit of randomization and intervention. All 14 schools on the reservation were recruited into the study in one of two cohorts of six and eight schools, respectively. Within each cohort, schools were randomized to intervention and control conditions following baseline data collection. The intervention began in kindergarten (2005 and 2006) following child recruitment, baseline data collection, randomization, and after teacher and food-service training had been accomplished; and it continued as long as school was in session through the following spring. The intervention in kindergarten began in January, and in first grade in September shortly after school started and teachers and food-service staff had been trained. The average total time the intervention was in place in the seven schools was 14 weeks in kindergarten and 31 weeks during first grade.

Families of children attending kindergarten were recruited and enrolled in the study. Of the 472 kindergarten children on the records of the 14 schools, parent/caregiver (hereafter referred to as parents) consents were obtained for 99% of the children and 97% of those consenting agreed to participate in the study. Pooling the two cohorts, 454 children (96% of total eligibles) had baseline measurements. Of these study children, 417 had a parent who completed a study survey in a nearby community center or their home. Based on parent report and school records, 99.3% of children were of American Indian heritage, with almost all children from what is commonly known as the Oglala Sioux Tribe, but more correctly the Lakota people.

Data were collected on four occasions or rounds: Baseline, fall of kindergarten (round 1); spring of kindergarten (round 2); fall of first grade (round 3); and spring of first grade (round 4). Measures of child height, weight, and percent body fat, and surveys from participating teachers were collected in all four data collection rounds. Other data were collected at baseline and at round 4 only, including child data for skinfolds (at school); parental height and weight, parental survey; and data on school meals and school physical activity. Process evaluation data were collected throughout the two academic years.

The study was designed to follow principles of intention-to-treat so data for children were analyzed according to the original assignments of study condition. In practice, however, there were only three children whose families moved from intervention to control schools during the trial so any effects on results were negligible. The accommodations for children who were lost to follow-up were described with the other statistical analyses.

All aspects of the study were approved by the institutional review board at the University of Minnesota, the Oglala Sioux Tribal institutional review board, and the Aberdeen Area institutional review board.

**Intervention overview**

**Formative assessment.** Formative assessment is a crucial element when designing and implementing interventions for ethnically diverse populations. The goals of our formative assessment were to: (i) inform the design and delivery of an obesity prevention intervention program appropriate for Lakota schools and families; (ii) pilot test selected intervention components; and (iii) plan a program that was feasible, culturally appropriate, and sustainable to allow long-term integration into the community. Formative assessment was conducted during the first year of the study and included interviewing 30 key informants who were Lakota parents/caregivers, community members, and elders, as well as interviews with all the school principals, and selected school superintendents, classroom and physical education (PE) teachers, food-service directors, and cook managers. Components of the intervention were tested including the motivational encouragement calls, classroom action breaks, PE class and outside walks, and selected family activities. Intervention components of the Bright Start program are described below.

**Physical activity at school.** The physical activity intervention goal was to achieve a total of at least 60 min of physical activity at school each day. This was accomplished through a variety of approaches, including school PE, class walks outdoors, in-class action breaks, and active recess. Kindergarten and first-grade teachers were trained in all approaches through a 2-day structured training. The in-class “action breaks” were teacher-led, fun, active movements and dancing accompanied by American Indian music, counting, reciting the alphabet, using Lakota words, etc. Teachers were provided with an “action toolbox” of various easy and developmentally age-appropriate ways to implement exercise throughout the school day. Class walks of 20 min were scheduled at least twice a week. During the walks, children did fun activities such as follow the leader, animal walks, pass along beanbags and balls, sang songs, and counted in the Lakota language. They were also provided objects like sun visors and ribbon wands to enhance the appeal of walking.

Active daily recess to provide moderate-to-vigorous physical activity was promoted, and playground equipment, such as balls and jump ropes were provided to intervention schools. PE teachers were trained by a CATCH PE expert to incorporate CATCH PE (21), an established intervention program designed to encourage maximum child participation and to emphasize moderate-to-vigorous activities throughout the PE class period. Active Native American games adapted from Pathways (22) were also integrated into the PE classes.

**Healthy eating at school.** The school-based dietary intervention goal was to improve the quality of children’s diets at school, specifically to increase fruits and vegetables, and decrease sugar-sweetened beverages and high-fat foods. Food-service staff at the intervention schools were trained during each of the 2 years on specific goals, including to:
offer 1% white milk instead of 2% or whole milk, eliminate chocolate or other flavored milks, serve recommended portion sizes, purchase and use low-calorie/fat foods, offer low-fat salad dressing in a portion-controlled container, provide more fruits and vegetables, and offer second helpings only on fruits and vegetables.

Teachers were trained to limit daily snacks in the classroom, and if used, to be only low-fat and low-sugar foods. Students were regularly encouraged to drink water if thirsty instead of other beverages. Rewards for classroom performance were encouraged to be non-food items, and teachers received a large supply of such items, e.g., stickers, stamps, pencils.

**Family environment.** The family-focused intervention goal was to modify the home environment to reduce excessive caloric intake, reduce television watching, and increase physical activity. Each intervention school had three family night events related to nutrition and physical activity during the intervention period and one summer event. Family events were held at the schools and included a meal for the family, several interactive and experiential station booths, and engaging physical activities designed to encourage home environment goals. Specific behavioral messages for the family included eating more fruits and vegetables, substituting water for sugar-sweetened beverages, limiting high-fat and high-sugar snacks and fast foods, drinking skim or 1% milk, promoting physical activity, and limiting TV and video time. Parents attending family nights set specific behavioral goals with trained Bright Start research staff regarding changes that could be made in the home environment to foster healthy eating and physical activity (23). They were also provided take-home incentives (e.g., magnets with behavioral messages, refrigerator water dispenser, vegetable steamer, basketball, jump rope, and fresh fruits/vegetables).

Parents received motivational encouragement telephone calls from trained Lakota research staff to set behavioral goals, encourage them in their efforts, and to help them evaluate their progress. Motivational calls were suspended after the second family fun night for both cohorts due to difficulty in reaching families. Families of intervention children also received a quarterly newsletter with color photographs of Bright Start classrooms and family events, and practical tips on healthy eating and family physical activities.

**Data collection**

Anthropometric measurements were taken by a team of local American Indian data collection staff traveling to each school. Staff were trained and standardized in measurement protocols by one of the authors (J.H.H.). Height was measured to the nearest 0.1 cm using a portable stadiometer (Perspective Enterprises, Portage, MI). Weight and percent body fat were measured using Tanita scales, model TBF-300 (Tanita, Arlington, IL) to the nearest 0.1 kg. Triceps and subscapular skinfolds were measured using Lange calipers to the nearest 0.5 mm. Waist circumference was measured at the level of the superior border of the iliac crest to the nearest 0.1 cm using an unstretchable tape. Measurement protocols followed those recommended by Lohman et al. (24). BMI was calculated as weight (kg)/height (m)^2. Exact percentiles and z-scores for BMI were calculated relative to the CDC 2000 growth charts (25). Children considered overweight had BMI ≥85th and <95th percentiles for age and gender, and those considered obese had BMI ≥95th percentiles for age and gender (26).

Nutrients in school meals were calculated from analyses of menus, recipes, and vendor products for breakfast, lunch, and snacks served for five consecutive days at baseline and during the round 4 data collection in each school. All children on reservation schools receive free breakfast and lunch, thus almost all children had breakfast, lunch, and at least one snack at school. Food and ingredient data were entered into the Nutrition Data System for Research software (NDSR, University of Minnesota, MN), which produced individual nutrients for each school day, and the nutrients were averaged across the 5 days to provide daily intake estimates at school. Data collection protocols, data entry rules, and weighting of data were developed and carried out in cooperation with the Nutrition Coordinating Center at the University of Minnesota, and followed the approach used for the Pathways study (27).

At each round of data collection, classroom and PE teachers in both intervention and control schools completed a survey on the frequency and duration of recess and PE classes. For intervention schools, classroom teachers kept daily logs of the timing of action breaks, recess, class walks, and PE class, as well as the number of days school was held. The logs were collected and reviewed weekly; total physical activity was defined as the sum of the durations of the various physical activity sources and was expressed as minutes per day that class was held.

Parents completed in-person surveys at baseline and at round 4, and reported the frequencies of their child’s food and beverage consumption over the past month. Response categories included: “never,” “1–3 times last month,” “1–2 times a week,” “3–4 times a week,” “5–6 times a week,” “once a day,” “more than once a day.” Categories of foods included, fruits, vegetables, whole milk, skim milk, 100% fruit juice, bottled water, and fast food. A three-item scale describing consumption of sugar-sweetened beverages was created (Cronbach’s α = 0.64) based on consumption frequency of fruit drinks, Kool-Aid, and regular soda. The response categories were converted to times per day and modeled as continuous variables in the analyses.

**Statistical analysis**

Owing to the overall level of poverty on the reservation, a measure of relative socioeconomic status (rSES), applicable only to families on this reservation, was developed using data comprised of parental education level attained, material resources in the home, household income, work-status of family members, and public assistance using a principal components factor analysis. The development of the rSES measure was informed based on the paper by Filmer and Pritchett (28).

The primary study outcomes are differences between intervention and control school means at round 4. Statistical analysis was by repeated measures of the outcomes at baseline, rounds 2, 3, and 4, adjusting for age deviations with mean age at a round, for gender, and rSES, with school nested within the experimental condition as a random effect. Nesting of school within condition accounts for homogeneity of response of students within any school; the resulting t-test is based on 36 degrees of freedom. Some measures were gathered only at baseline and round 4 (e.g., skinfolds, menu data); for these the error degrees of freedom are 12. The same model was used for secondary outcomes.

Post-experiment stratification examined whether the intervention had different effects on those who were obese, overweight, or of normal BMI-for-age at baseline by including an interaction of baseline status with the intervention effect. Incidence of obesity or overweight differing by experimental condition was examined at round 4 by restricting the dataset to those of normal BMI-for-age (i.e., nonoverweight) at baseline.

“Dose” or physical activity implemented was also examined. In the intervention schools, teachers logged for each week the amount of time devoted to PE, recess, class walks, and “action breaks.” Logs from multiple teachers were averaged per week and then averaged over the total intervention weeks to give an average “dose” of physical activity. Schools had differing mean days of operation, so both an actual dose (dividing weekly mean total by 5) and a scaled dose (dividing weekly mean total by the number of days that school was held) were calculated. These dosages (intervention schools only) were correlated with the BMI-for-age changes from baseline to round 4.

For the parent-reported food intakes, the effect of the intervention was examined for each targeted intake variable using an analysis of covariance for the experimental condition, adjusting for the baseline level of intake, rSES, and child gender; school was treated as a random effect within condition. Although some of the intake distributions were skewed, the analysis of a group-randomized trial such as this depends on the adjusted means per school which will be normally distributed across schools. In a further analysis, the consistency of change in child’s frequency of intake of targeted foods and drinks was examined by treating the eight outcomes as repeated measures correlated within individuals,
and thus, effectively pooling the estimates of the intervention effect while allowing for the dependency between the separate tests.

RESULTS
Main outcomes
Selected obesity-related characteristics of the Bright Start children at baseline are summarized in Table 1 by gender and condition. The mean triceps skinfold thicknesses approximate the 65th percentile for gender and age for all US children, and the mean subscapular skinfolds approximate the 80th percentile (29). The mean waist circumferences approximate the 80th percentile for National Health and Nutrition Examination Survey (NHANES) III children of the same age (30). Corresponding patterns indicating high levels of mean BMI result in 32% of boys and 25% of girls considered as overweight/obese. The generally similar means for variables by intervention condition within each gender indicate that the randomization process for schools yielded satisfactory correspondence for mean levels for individuals at baseline.

The adjusted means for the fatness-related outcome variables and the intervention-associated effects are presented in Table 2. The intervention was not associated with statistically significant change in mean levels of BMI, BMI-Z, skinfolds, or percentage body fat. However, the Bright Start intervention was associated with a statistically significant net decrease of 10% in the prevalence of overweight, defined as BMI between percentiles 85 and 94.99. No significant change was observed in the corresponding prevalence of obese children (BMI ≥95th percentile). No interactions of the intervention effect with either baseline weight status nor with gender were found.

The significant intervention-related change in prevalence of overweight was confirmed in post-hoc analyses examining the incidence of overweight. Intervention children (n = 164) who were not overweight or obese at baseline experienced a 13.4% incidence of overweight (n = 19) or obesity (n = 3), whereas the control children (n = 109) experienced a corresponding incidence of 24.8% (n’s = 21 and 6), a net difference of −11.4% (P = 0.033). This prevention of new incident cases of overweight/obesity was reduced in magnitude and significance after adjusting for covariates (−9.4%, P = 0.081). Remission in weight status occurred in only nine children, three from intervention schools and six from control schools.

Secondary outcomes and process measures
Table 3 presents the adjusted mean levels of selected nutrients served at breakfast, lunch, and snacks at baseline and at round 4 by study condition. The Bright Start intervention significantly reduced the mean total fat (−8%) and saturated fat (−4%) expressed as a percentage of calories.

The means of combined physical activity from recess and PE class expressed as minutes per week as reported by teacher surveys in intervention and control schools are presented in...
Figure 1 by data collection period. The overall pattern shows greater mean physical activity in intervention schools after the start of the intervention (rounds 2–4) compared to control schools, although the overall difference between adjusted means for the intervention groups was not statistically significant.

The means for total physical activity (min/day) in intervention schools were 64.2 (SD = 9.7) in kindergarten and 64.3 (SD = 12.3) in first grade, with school-specific means ranging from 51.4 to 89.6 min/day. The mean physical activity from class walks was 12.9 min/day (SD = 8.9) in kindergarten and 8.5 min/day (SD = 3.9) in first grade. Corresponding means for action breaks were 9.6 min/day (SD = 9.6) and 5.7 min/day (SD = 3.3) for kindergarten and first grade, respectively.

Across the intervention schools, the mean number of days per week that school was held during the intervention period was 4.0 (SD = 0.3) in kindergarten and 4.3 (SD = 0.3) in first grade. The range of means for individual intervention schools for number of days per week that school was held was 3.5–4.6.
half (48.7%) of the children and their families attended the first family fun night, and percentage attendance decreased progressively at subsequent family night events. Only 7.9% of families attended the summer event. At least one attempt was made to call parents following each of the first two family night events, but the percentage of completed calls was only moderate (53–69%).

Parent reports of the frequencies of child intake for selected foods in the past month were intended to reflect the impact of the Bright Start intervention on the home environment. The adjusted means for number of times the foods were eaten per day at round 4 and the estimated intervention effects from the regression models are presented in Table 5. Statistically significant intervention-related decreases occurred for mean frequency of child intakes of sugar-sweetened beverages, whole milk, and 100% juice (data not shown). For children whose initial BMI ≥85th but <95th percentiles (overweight; \( n = 292 \)), there were significant intervention-related decreases in whole milk and chocolate milk, but a significant increase in reported frequency of fast-food intake (data not shown). No statistically significant intervention-related changes in reported frequencies were observed for children whose baseline BMI ≥95th percentile (obese; \( n = 129 \)).

**DISCUSSION**

Bright Start was a group-randomized and school-based trial to prevent development of overweight and obesity in young American Indian children. When analyzed as continuous outcomes, there were no significant intervention-related effects on adjusted means of BMI, percent body fat, or skinfold thicknesses. However, when changes in the prevalences of overweight and obesity were examined, the intervention prevented a significant net increase in the proportion of children who were overweight (but not obese) compared with the controls. Specifically, the intervention prevented 11.4% of children from becoming overweight compared with controls. Although covariant adjustment of the incidence estimate including only normal BMI children at baseline was reduced to 9.4% and became no longer statistically significant, the results from the full model are the statistically appropriate test of change in prevalence of overweight due to the intervention. This 10% effect of Bright Start is important because it constitutes primary prevention of overweight, not a secondary prevention response of the heaviest children.

Although results from many school-based randomized trials of obesity intervention are reported in the literature (31,32), there are very few with children in kindergarten or first grade with which to compare our results. The Kiel Obesity Prevention Study (KOPS) (33) included 5–7-years-old children attending schools in Kiel, Germany, and the intervention was primarily education focused, and included nutrition and physical activity curricula, teacher training, and parent involvement. No results are provided for BMI; but after a year of intervention, compared with control children, median triceps skinfolds increased less in intervention children, and among a small sample of overweight and obese children, mean percent body fat increased less with the intervention. Mo-suwan and colleagues (34) report results from an exercise-based intervention in Thailand in which kindergarten children had a 15-min walk each day and a 20-min aerobic dance session three times a week, beyond the customary 60 min of PE class per week. Their findings demonstrated significant intervention effects on BMI among girls but not among boys.

While the few studies available for direct comparisons are limited, our finding of primary prevention of overweight appears unique among the studies in young children. In school-based studies in older children, however, reduced prevalences of overweight or obesity have been reported to baseline weight status. For children whose initial BMI was <85th percentile (not overweight; \( n = 19 \)), there were significant intervention-related decreases in Kool-Aid (within sweetened beverages), whole milk, and 100% juice (data not shown). For children whose initial BMI ≥85th but <95th percentiles (overweight; \( n = 292 \)), there were significant intervention-related decreases in whole milk and chocolate milk, but a significant increase in reported frequency of fast-food intake (data not shown). No statistically significant intervention-related changes in reported frequencies were observed for children whose baseline BMI ≥95th percentile (obese; \( n = 129 \)).

**Table 4** Frequency of intervention children in both cohorts attending family events and participating in motivational calls

| Family fun night events | Children attending event | Children eligible for call | At least one call attempted | Completed calls |
|-------------------------|-------------------------|---------------------------|----------------------------|----------------|
| Event 1                 | 130 (48.7)              | 94                        | 100                        | 69.1           |
| Event 2                 | 95 (35.6)               | 47                        | 100                        | 53.2           |
| Event 3                 | 59 (22.1)               | 31                        | —                          | —              |
| Summer                  | 21 (7.9)                | 11                        | —                          | —              |

Motivational calls suspended after event 2 due to lack of telephone access.
The effects of Bright Start on secondary outcomes indicate that there were demonstrable intervention-related effects on the nutrient content of meals served, such that percentage of energy from total fat and saturated fats were reduced. The intervention did not bring about significant changes in mean energy from total fat and saturated fats were reduced. The effects of intervention were calculated from the regression models. Regression models were adjusted for food intake at baseline, gender, school (random within condition), SES score, and intervention condition.

There was not strong parental attendance at the family events. The events were of high quality; but the long travel distances, inclement weather, and competing school and community activities were difficult for the intervention to overcome. Clearly, additional work is required to develop programs for parental involvement. Our results are similar to other school-based studies with different populations that have consistently found that it is difficult to have a high level of parental involvement (36–39). This is a continuing challenge that plagues all school-based interventions.

The motivational calls, which during our formative assessment were viewed by parents as feasible and desirable, also proved to be difficult to successfully accomplish because of logistic reasons. Cell phones are the primary means of telephone communication on the reservation. The reservation has many drop spots where adequate service is not available, cell phone numbers were changed often, and many had no voicemail; so it was often impossible to reach or leave messages for parents. Developing a future plan for involving families in an effective way in obesity prevention efforts will need to be creative and account for the challenges of reservation living and a geographically rural area.

A logistical issue that was completely out of control of the Bright Start study was the reduced number of school days in which to conduct the intervention. Schools on the reservation are often used as community centers for funerals or tribal events and inclement weather affects transportation to school more than in other locations. Thus, the potential duration of the intervention was reduced by ~20%. It is impossible to know whether this reduction in days was actually a factor related to the outcomes, but it could have mitigated the intervention effects.

### Conclusions

Obesity is the most daunting health challenge facing American Indian children today and has serious implications for the development of serious chronic diseases, including type 2
diabetes. Early weight gain in childhood is critical. The most effective strategies for child obesity prevention efforts are believed to be those that affect both energy intake and energy expenditure, whereas the most important settings to target are schools, families, and the communities in which children live. To be successful, the entire school needs to be involved in creating and supporting strong policies and practices for healthy eating and physical activity. Reservation schools need to make a greater commitment to physical activity which includes more high quality PE classes, teacher training, and adequate facilities. Second portions of foods during school lunch and breakfast should be limited to fruits and vegetables. Restrictions should be put on serving chocolate milk or other flavored milk that add calories. Efforts to involve parents need to be strengthened. Communities are vital in creating opportunities for healthy eating and physical activity and for making the healthy choice, the easy choice for families and children. Schools, families, and communities all have an important role to play if obesity among American Indian children is to be reversed.

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DISCLOSURE

The authors declared no conflict of interest.

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