

COVER PAGE

Study Title: Addressing Health Disparities in Childhood Obesity, One Summer at a Time

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Study Protocol

Background

Childhood obesity is one of the most urgent health challenges of our time. Obesity rates of Native American and Hispanic children are far higher than national averages, placing these children at high risk for early mortality, cardiovascular and metabolic conditions including diabetes, depression and overall poor quality of life.¹⁻³ By the 5th grade, approximately 50% of Hispanic and Native children are already overweight, and Native children have type 2 diabetes rates 9 times higher than non-Hispanic Whites.⁴ In our area, obesity rates are highly concentrated: most obese and overweight children are enrolled in 4 of the 10 elementary schools, which include primarily underserved Hispanic and Native American children.

Recent research has further demonstrated that the 'obesity gap' facing minority students is largely due to summer weight gain.⁵⁻⁹ Based on local data, it was confirmed that children in our school district were much more likely to worsen their weight-related health status during the summer than during the schoolyear. However, statewide, only 22% of children participate in summer activities, despite 65% of parents expressing interest.¹⁰ Finally, ages 7 to 11 have been found in national data to see a sharp increase in obesity rates.¹¹ Indeed, locally in 2015, approximately 20% of 7 year-olds are overweight or obese, but 35% of 11-year olds. Thus, we know which populations are at highest risk, at what developmental age changes occur most rapidly (ages 7-11) and that interventions are most needed in the summer, but that this need is not being met.

A modest amount of research has evaluated summer programming, but almost none among Native Americans/Hispanics. In the early 2000s, the CDC developed a 'Summer Scorecard' intervention,¹² a partnership with local businesses to provide children with a 'scorecard' of subsidized or free local activities. The VSS has not been tested among Hispanic and Native American children. Therefore, this study assessed the effectiveness of the VSS among children ages 5-13 in the 4 highest risk schools in the Flagstaff area. Outcomes included body composition (BMI) percentile score, reported physical activity and self-efficacy using survey instruments previously developed and tested by the CDC.

VERB Summer Scorecard Program Description: In 2001, the CDC launched VERB It's What You Do!, a 5-year year national social marketing campaign to increase awareness, improve attitudes, and increase physical activity among 9-13 year olds ("tweens"). The campaign was developed after extensive formative research, grounded in a logic model that shows a pathway to chronic disease reduction,⁴⁵ and tested in 3 follow-ups using a nationally representative sample.¹³⁻¹⁶ The campaign was coordinated with local vendors who provided opportunities to be active. In 2004, the VERB Summer Scorecard (VSS) intervention was developed in 2004. The VSS consists of a 'scorecard' including 24 squares, each representing an activity of at least one hour (see Appendix A for our local version). In collaboration with community partners, children were provided with free or discounted opportunities for a variety of activities. When children attend either an activity at a participating facility or supervised activity at home for a minimum of 60 minutes, they received either a stamp from the community partner or a parent's signature on one of the squares.

Activities:

Each participating child was provided with a scorecard including 24 activities (see Appendix A). Children received 12 free passes to utilize local facilities including a local aquatic center, athletic club (including gym, indoor/outdoor swimming pool, basketball and racquetball courts etc.), climbing gym, ice skating rink and activity center (including bouncy houses, laser tag etc.) and classes offered by a local health program. Other activities could be done on their own and included hiking local trails, going to parks and could be signed off by a parent. Children were instructed to return the card at the end of the summer and receive an incentive prize for returning the card.

Measures:

Demographic variables. Child's age (in years), sex (male or female), ethnicity (American Indian/Alaskan Native, Hispanic, White, Black/African American, Native Hawaiian/Pacific Islander or Two or more), grade level and school membership were collected by the school district. Height and weight were collected at each school during the school day by a community outreach coordinator trained in research quality measurements, supported by the school nurse and volunteers. Children were asked to take shoes and jackets off and items out of their pockets. Height to the nearest quarter inch was measured twice with a Charder HM200P Portstad Portable Stadiometer. Weight was measured to the nearest 0.1 pounds with a Health O Meter 752KL Heavy Duty Remote Display Digital Scale. Children's first weight status was considered their baseline, with $\leq 5^{\text{th}}$ BMI percentile for their age and sex considered underweight, 5^{th} to 85^{th} percentile healthy weight, $\geq 85^{\text{th}}$ percentile overweight and $\geq 95^{\text{th}}$ percentile as having obesity

Behavioral constructs. Health behavior constructs (13 questions) aligned with Social Cognitive Theory were assessed. Key constructs include self-efficacy ("I think I can be physically active even if it is hot or cold outside."), social norms (example: "My friends think that doing physical activity is fun"), and access or barriers to participation in physical activity and summer programs ("There are lots of places near where I live where I can do physical activities").

Reported activity and sedentary behaviors. A total of 8 questions ask about participation in the VERB program, types of activity in the past 7 days and participation in other summer programs. The number of activities reported were counted and compared before and after the intervention.

Recruitment:

Children were recruited directly at each school by research staff in collaboration with school physical education or health and wellness instructors. Recruitment occurred by providing flyers and tables at school events and drop-off/pick up. Parents were provided with a consent form and children with an assent form explaining the risks and benefits. English and Spanish versions were available. Upon completion of both forms, participants were measured and surveyed (see measurements below).

Sample Size calculations: The estimated sample size needed to have sufficient power to detect a moderate effect size (using a Cohen's d of 0.3 as the reference) is 240 children, or 120 per arm. Based on our preliminary data, for each academic year, the average BMI change ranges from 0.35 to 0.55 units, with a standard deviation that varies across ethnic groups and years from 0.80

to 1.00. An example of an effect between two groups or time points that would match a Cohen's d of 0.3 would be one group in which the children on average increases their BMI by 0.5 units, and another group where participants increase their BMI by 0.2 units (0.3 unit difference), with standard deviations of 1.0. These effects (BMI difference of 0.3kgm^2) are just above the mean weighted effect size reported in the most comprehensive and recent meta-analysis on childhood obesity studies of 0.30kg/m^2 .^{9,10} With a two-tailed test and alpha level of 0.05, a sample size of 80 children per arm (a retention rate of 67%) would result in an associated statistical power $\geq 80\%$ to detect intervention effects between arms from one time point to the next. With very similar parameters and sample sizes, prior research has indicated that based on simulation studies,¹⁷ these parameters demonstrated excellent power ($\geq 80\%$) in detecting these size differences.

Institutional Review Board:

All protocol activities were approved by the Institutional Review Board of Northern Arizona University (protocol #1193689) and the Flagstaff Unified School District. Parental consent forms and children assent were attained for each participant.

References:

1. Pan L, McGuire LC, Blanck HM, May-Murriel AL, Grummer-Strawn LM. Racial/Ethnic Differences in Obesity Trends Among Young Low-Income Children. *Am J Prev Med.* 2015;48(5):570-574.
2. Rossen LM, Schoendorf KC. Measuring health disparities: trends in racial- ethnic and socioeconomic disparities in obesity among 2-to 18-year old youth in the United States, 2001–2010. *Ann Epidemiol.* 2012; 22(10):698-704.
3. Caballero B, Clay T, Davis SM, Ethelbah B, Holy Rock B, Lohman T, Norman J, Story M, Stone EJ, Stephenson L, Stevens J. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr.* 2003;78(5):1030-1038.
4. US Department of Health and Human Services. Diabetes in American Indians and Alaskan Natives Facts at a Glance, 2012. Available at: https://www.ihs.gov/MedicalPrograms/Diabetes/HomeDocs/Resources/FactSheets/Fact_sheet_AIAN_508c.pdf
5. von Hippel PT, Powell B, Downey DB, Rowland NJ. The effect of school on overweight in childhood: gain in body mass index during the school year and during summer vacation. *Am J Public Health.* 2007;97, 696–702.
6. Baranowski T, O'Connor T, Johnston C, Hughes S, Moreno J, Chen TA, et al. School year versus summer differences in child weight gain: a narrative review. *Child Obes.* 2014;10(1):18-24.
7. Franckle R, Adler R, Davison K. Accelerated weight gain among children during summer versus school year and related racial/ethnic disparities: a systematic review. *Prev Chronic Dis.* 2014;11:E101.
8. Mahoney JL. Adolescent summer care arrangement and risk for obesity the following school year. *J Adolesc.* 2011;34(4), 737-49.
9. Beets MW. Does Summertime Weight Gain Undermine Youth Obesity Prevention Efforts? Active Living Research (ALR) Research Brief. May 2015. Available at: <http://activelivingresearch.org/does-summertime-weight-gain-undermine-youth-obesity-prevention-efforts>
10. Afterschool Alliance. America After 3pm. Special Report on Summer: Missed Opportunities, Unmet Demand. DC: 2010.
11. Cunningham SA, Kramer MR, Narayan KV. Incidence of childhood obesity in the United States. *NEJM.* 2014;370(5):403-411.
12. Centers for Disease Control and Prevention. VERB it's what you do! Accessed January 21st 2018: <https://www.cdc.gov/youthcampaign/index.htm>
13. Price SM, Huhman M, Potter, LD. Influencing the parents of children aged 9 –13 years: Findings from the VERB™ campaign. *Am J Prev Med.* 2008;34(6S): S267-S274.
14. Debate RD, Baldwin JA, Thompson Z, Nickelson J, Alfonso ML, Bryant CA, et al. VERB Summer scorecard: Findings from a multi-level community-based physical activity intervention for tweens. *Am J Community Psych.* 2009;44(3): 363-373.
15. Alfonso ML, McDermott RJ, Thompson Z et al. Vigorous Physical Activity Among Tweens, VERB Summer Scorecard Program, Lexington, Kentucky, 2004-2007. *Prev Chron Dis.* 2011 Sep; 8(5): A104.
16. Centers for Disease Control and Prevention (CDC). Designing a successful VERB Scorecard campaign in your community. <https://cdc.thehcn.net/promisepractice/index/view?pid=401>
17. Robinson TR, Matheson D, Desai M, Wilson DM, Weintraub DL, Haskell WL, McClain A, McClure S, Banda JA, Sanders LM, Haydel KF, Killen JD. *Family, community and clinic collaboration to treat overweight and obese children: Stanford GOALS—A randomized controlled trial of a three-year, multi-component, multi-level, multi-setting intervention.* *Contemporary Clinical Trials.* 2013; 36:421–435.

Appendix A: Scorecard

SUMMER SCORECARD

June-August 6



For each activity you complete:

1. Write the date.
2. Have your parent or guardian initial the box or get a Fit Kids stamp at the front desk when you check in at the Aquaplex, Cabin Fever, Flagstaff Athletic Club (FAC) or Jay Lively Activity Center.

Each activity is worth three points. Earn bonus points for completing more activities!

- **Complete 12 for 40 points (four bonus pts.)**
- **Complete 18 for 60 points (six bonus pts.)**
- **Complete all 24 for 80 points (eight bonus pts.)**

Activities must be completed by Sunday, Aug. 6. Turn in your Scorecard to Fit Kids staff during the month of August to receive your points.

<p>Fit Kids Summer Series Bowling</p>	<p>Fit Kids Summer Series Running Club</p>	<p>Swim and play at FAC</p>	<p>Hike Fat Man's Loop 3 bonus points for a picture along the trail!</p>	BONUS
<p>Family swim at FAC East 2 bonus points for a family picture!</p>	<p>Hike one of the Campbell Mesa Trails</p>	<p>Ride your bike for 60 minutes</p>	<p>Play a sport for 60 minutes If you're on a team, practice or games count!</p>	
<p>Ice skating at Jay Lively</p>	<p>Your choice 60 minutes of activity</p>	<p>CrossFit Kids workout</p>	<p>Explore the lava tubes 3 bonus points for a picture in the cave!</p>	
<p>Walk the big loop at Buffalo Park 2 bonus points for a picture with the buffalo!</p>	<p>Go to: NEW ROOTS FLAGSTAFF, AZ Summer Series Class</p>	<p>Flagstaff Community Market Local flavor at root level!</p>	<p>Family swim at FAC East</p>	
<p>Play a sport for 60 minutes If you're on a team, practice or games count!</p>	<p>Hike Sedona's Red Rocks 3 bonus points for a picture along the trail!</p>	<p>Swim and play at Flagstaff Aquaplex</p>	<p>5K Walk/Run 2 bonus points for participating in the Machine Solutions Run for Kids on Aug. 5. Fit Kids get free entry!</p>	
<p>CABIN Fever Laster tag, climbing and inflatables</p>	<p>Hike Mt. Humphreys 10 bonus points for a picture at the summit!</p>	<p>Your choice 60 minutes of activity</p>	<p>Round of Disc Golf</p>	