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## A Cluster Randomized Trial of Sun Protection at Elementary Schools:

### Results from Year 2

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### Abstract

**Background**—Elementary schools are one potential venue for sun protection interventions that reduce childhood sun exposure.

**Purpose**—To assess Year-2 results from a cluster randomized trial promoting hat use at schools.

**Design**—Block randomization was used to assign intervention/control status to participating schools. Data were collected from 2006 to 2008 and analyzed in 2007–2010.

**Setting/participants**—Of the 24 schools in the School District of Hillsborough County, Florida enrolled, fourth-graders were targeted in the first year and followed through their 5th-grade year.

**Intervention**—Classroom sessions were conducted to improve sun protection knowledge, foster more positive attitudes about hat use, and change the subjective norm of wearing hats when at school.

**Main outcome measures**—Year-2 outcomes assessed included hat use at school (measured by direct observation), hat use outside of school (measured by self-report) and skin pigmentation and nevi counts (measured for a subgroup of 439 students).

**Results**—The percentage of students observed wearing hats at control schools remained unchanged during the 2-year period (range 0%–2%) but increased significantly at intervention schools (2% at baseline, 41% at end of Year 1, 19% at end of Year 2;  $p < 0.001$  for intervention effect). Measures of skin pigmentation, nevi counts, and self-reported use of hats outside of school did not change during the study period.

**Conclusions**—This intervention increased use of hats at school through Year 2 but had no measurable effect on skin pigmentation or nevi. Whether school-based interventions can ultimately prevent skin cancer is uncertain.

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## Introduction

Childhood is an important period for sun protection because substantial lifetime sun exposure occurs during childhood<sup>1-4</sup>, and many skin cancers have been linked with childhood sun exposure.<sup>5-7</sup> The Sun Protection for Florida's Children (SPF) project was a defined, classroom-based intervention that emphasized the use of wide-brimmed hats when children were outdoors. The intervention targeted 4th-grade students in the first year of the study and continued with the same cohort of students through the subsequent 5th-grade school year. In the first year of follow-up, the SPF intervention increased the proportion of 4th-grade children who wore hats while at school.<sup>8</sup>

The ability to sustain sun protection behaviors beyond 1 year in interventions of this type is uncertain as most studies have been short-term. The SPF project provided booster sessions in Year 2 to help maintain intervention effects. Booster sessions are one strategy to maintain intervention effects<sup>9-13</sup> but have not been well studied in sun protection interventions. Results from the second year of follow-up are now reported in which the hypothesis that intervention effects could be maintained with minimal intervention is tested.

## Methods

The SPF project was a cluster randomized trial that used block randomization to assign participating schools to either control or intervention status (Figure 1). Details of the intervention and study design have been previously reported.<sup>8</sup> In Year 2, one intervention school withdrew from the study before the start of Year-2 data collection or intervention activities. The second-year intervention began with an introductory session with participating 5th-grade students where written assent to participate was obtained from students new to the program. Returning students were given their wide-brimmed hats (stored over the summer) while new students received two new hats (for school and at home). Students received a brief educational lesson that reestablished sun safety guidelines. Research assistants subsequently delivered at least two 60-minute interactive classroom sessions (late Fall, early Spring) that reinforced the importance and benefits of sun protection. Control schools had similar sessions that obtained written assent for new students and that targeted scientific topics other than sun protection.

As in Year 1, data were collected from student participants at three time periods in Year 2; fall, winter, and spring. The primary outcome of the study, hat use at school, was measured by direct observation based on methods described by Milne and colleagues.<sup>14, 15</sup> Hat use at times outside of school (a secondary outcome) was measured by self-report.<sup>16</sup>

An analysis of the impact of the intervention on skin pigmentation among a convenience sample of students (200 intervention, 239 control) who agreed to undergo additional measurements (fall, winter, spring, measured in Year 1 and 2) was conducted.<sup>8</sup> Skin pigmentation (melanin index, range 0%–100%) was repeatedly measured on the forehead using a DermaSpectrometer (Cortex Tech., Hadsund Denmark).<sup>17, 18</sup> At each measurement point (after the baseline measure), students' current melanin values were compared to their previous reading and categorized as either tanned (melanin value was greater) or nontanned (melanin value was the same or lower). Each student, therefore, could potentially contribute six measures of tanning.

Nevi counts are a marker of cumulative UV exposure and subsequent melanoma risk<sup>19, 20</sup> and have been successfully used as measures of cumulative UV exposure in other sun protection interventions.<sup>21-23</sup> Nevi were assessed in areas protected by hats (the head and neck area) based on recommended methods of assessment.<sup>24</sup> Inter-rater reliability of nevi

count measurement between the project director and research assistants was assessed (correlation coefficients 0.89 –0.96).

### Statistical Analysis

Two endpoints were examined: directly observed hat use at schools and self-reported hat use outside of schools measured at six time points over the 2-year study period. The clustered design was accounted for in the generalized linear mixed model. Allocation arm (intervention vs control), date of data collection (represented by a linear or quadratic term), and their interaction were included as fixed effects in the generalized linear mixed model. Several fixed covariates were tested in multivariable models as confounding factors (e.g., age, gender, race, and school uniform policy). Pigmentation changes were analyzed by use of a generalized linear mixed model. Nevi counts were similarly compared over time between intervention and control students using a generalized linear mixed model (PROC MIXED).

### Results

Directly observed hat use at school is shown in Figure 2. Hat use remained essentially unchanged at control schools throughout the 2-year study period. At intervention schools there was an increase in observed hat use that peaked in the spring of Year 1 at 41% and then gradually diminished during Year 2. Changes in hat use over time were significantly different for intervention students compared to control students ( $p < 0.0001$  for both linear and quadratic interaction terms,  $ICC = 0.002$ ). Self-reported use of hats while outside of school did not differ by the end of the study (control 9.9%, intervention 11.5%;  $p = 0.14$  for intervention effect,  $ICC = 0.00006$ ).

The likelihood that students tanned between observation sessions was explored among 439 students who provided comparison data (total of 1184 measures). Among intervention students, 42.0% of observations showed an increase in melanin from the prior value. Among control students, 45.6% of observations showed an increase in melanin from the prior reading. This difference was not significant ( $p = 0.94$ ,  $ICC = 0.001$ ). Nevi counts were similar at baseline (control  $M = 9.8$ , intervention  $M = 9.0$ ) and not significantly different at the end of the study (control  $M = 9.1$ ; 95%  $CI = 7.7, 10.5$ , intervention  $M = 6.8$ ; 95%  $CI = 5.6, 8.0$ ;  $p = 0.07$  for changes in nevi counts over time comparing intervention and control students,  $ICC = 0.0006$ ).

### Discussion

Previous studies have attempted to change sun protection behaviors in elementary school settings, some successfully<sup>25–28</sup>, others less so.<sup>29–33</sup> Interventions relying on single sessions with students have generally not proven successful<sup>29, 34</sup> while strategies that targeted students over the course of the school year have proven more successful.<sup>25, 34</sup>

There are several possible reasons for diminished effects in Year 2. First, approximately 25% of students were new to the project in Year 2 and had not received the full intervention the previous year. Second, social norms that were developed over the course of the year encouraging hat use may have been disrupted in Year 2 as students were assigned to new classes with new peers. Finally, the effects of behavioral interventions often simply wane with time.<sup>35</sup> The specific benefits of booster sessions could not be assessed, as participants were not randomly assigned to this intervention in Year 2.

The intervention did not lead to physiologic differences in the skin of targeted children. These measurements were conducted on a subgroup of participants, however, which may

have biased the results. The increased use of hats at school appears unlikely to have been of sufficient magnitude to affect skin measures of the overall sample. It is also possible that UV exposure outside of school had greater impact on these measures than did exposures at school. Given these results, the ability of school-based interventions to prevent skin cancer is uncertain.

Strengths of this study include its group randomized design, the ability to affect hat use in the second year of follow-up, and the ability to measure this outcome through direct observation. Given the limited intervention effect, further research is needed to develop effective sun protection curricula and policies that permanently change the culture of sun protection at schools. As UV exposure during school hours is limited, it is also important that these efforts generalize to other settings, something this intervention was unable to demonstrate.

Given their broad reach, though, schools remain an attractive vehicle for delivering sun protection education to children.<sup>36, 37</sup> School-based interventions are one potential method of increasing hat use at schools while booster sessions can help address sustainability. Future research is needed on methods to more generally and permanently change the culture of sun protection in schools and to affect change in behaviors outside of school.

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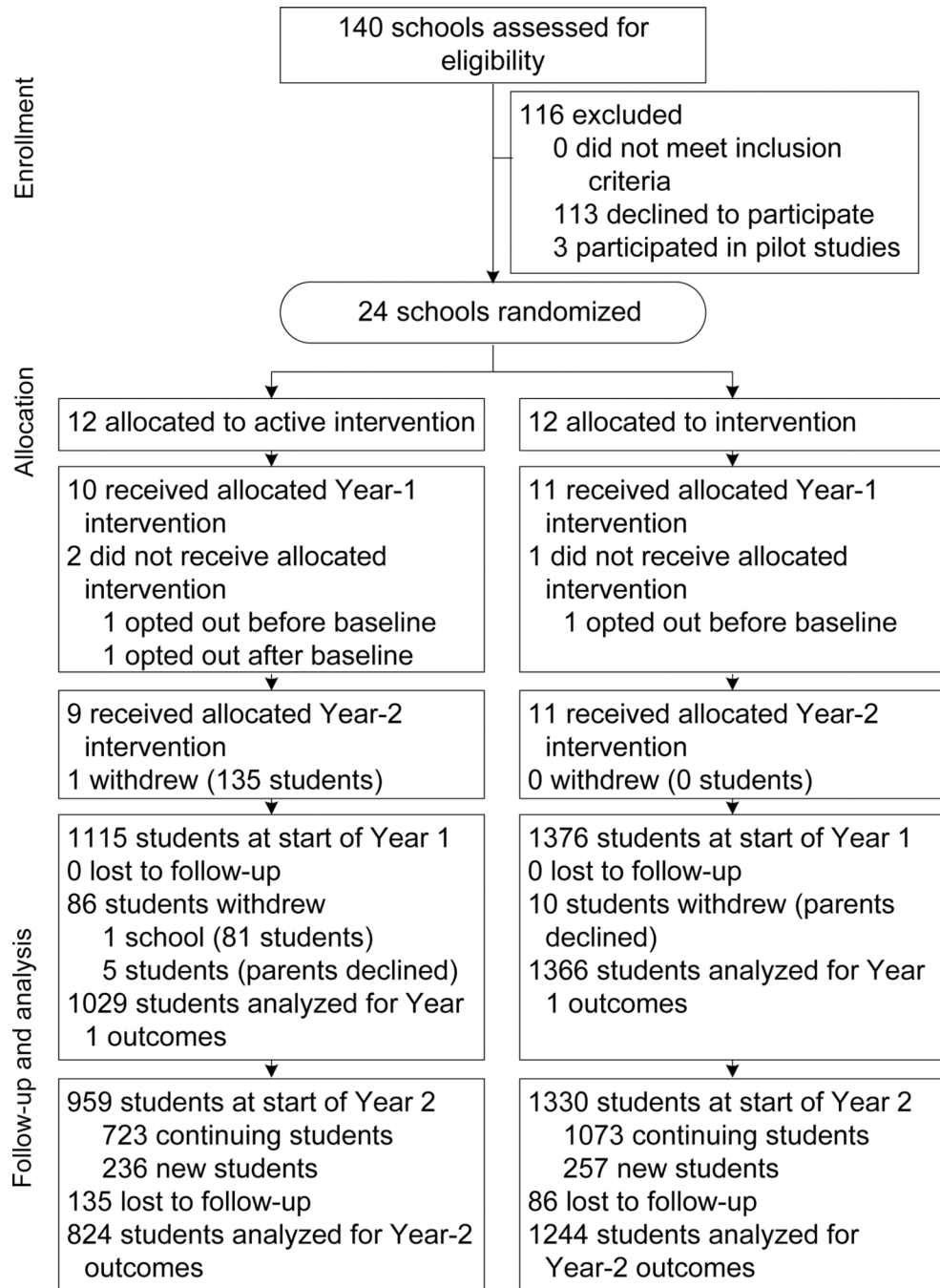
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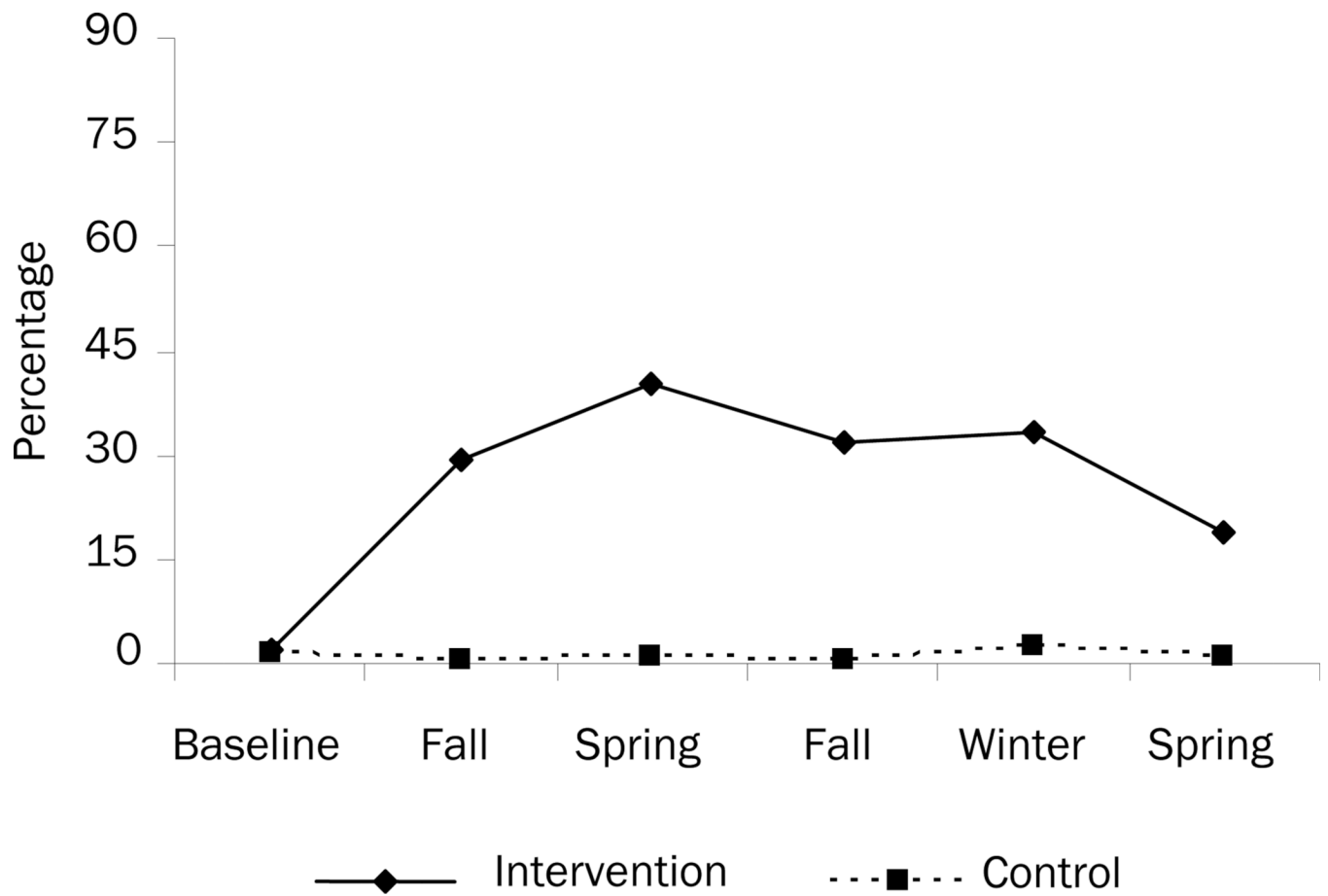
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**Figure 1.** Comparison of intervention and control schools in the Sun Protection for Florida’s Children project





**Figure 2.**  
Percentage of students directly observed wearing hats while at school