Evaluation of an Intervention to Reduce Sun Exposure in Children

Design and Baseline Results

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The Kidskin Study is a 5-year intervention study (1995–1999) involving 1,776 5- and 6-year-old children attending 33 primary schools in Perth, Western Australia. The aim of the study is to design, implement, and evaluate an intervention to reduce sun exposure in young children. There are three study groups: a control group, a "moderate intervention" group, and a "high intervention" group. The control schools receive the standard Western Australian health education curriculum, while the moderate and high intervention schools receive a specially designed curricular intervention. In addition, children in the high intervention group receive program materials over the summer holidays, when exposure is likely to be highest, and are offered sun-protective swimwear at low cost. The main outcome measure is the number of nevi on the back. Other outcomes include nevi on the chest (boys only), face, and arms, levels of suntanning, degree of freckling, and sun-related behaviors. At baseline, the three groups were similar with respect to nevi and freckling after adjustment for observer and month of observation. Sun exposure was slightly higher in the high intervention group. The groups were also similar with respect to most potential confounders, although they differed with respect to Southern European ethnicity and parental education.

Melanoma is a serious health problem in populations of European origin. In Australia, melanoma is the fourth most common cancer (excluding nonmelanocytic skin cancers) in men and the third most common cancer in women (1). While it is less common elsewhere, its incidence has been rising steadily in most White populations for many years (2).

Sun exposure is the main cause of melanoma (3, 4), and evidence from case-control and migrant studies suggests that childhood exposure is particularly important (2). Therefore, preventive efforts are likely to be most effective if they involve young children. Although programs encouraging sun protection among Australian children exist (5, 6), levels of exposure remain high (7–9).

In 1995, we began "Kidskin," a 5-year intervention study involving 1,776 children recruited from 33 primary schools in Perth, Western Australia. The aim of the study is to design, implement, and evaluate an intervention to reduce sun exposure in children. The subjects commenced school (first grade) in February 1995 at 5 or 6 years of age. Here, we describe the study design and present baseline results.

MATERIALS AND METHODS

The intervention

The intervention is school- and home-based and involves two levels. The lower level is the level of intervention that might be sustainable in Australian schools, while the higher level is a rigorous attempt to minimize exposure. Both levels include the same specially designed curriculum involving classroom- and home-based activities. The children's usual teachers are trained in the use of the curriculum and teach it during the spring each year (except 1999). Children are encouraged to reduce their sun exposure by staying indoors during the middle of the day, when solar ultraviolet radiation is highest, and by protecting themselves when outdoors by using shade, clothing, hats, and sunscreen. Schools also receive guidelines on how to improve sun protection at school.

The higher-level intervention involves additional components; children receive program materials over the summer holidays, when exposure is likely to be highest, and are offered low-cost swimwear that covers the trunk, upper arms, and thighs. Our aim in providing this swimwear is to reduce exposure at these
Study design

There are three study groups: a control group, a “moderate intervention” group receiving the lower level of intervention, and a “high intervention” group receiving the higher level of intervention. The control schools receive the standard Western Australian health education curriculum (10).

Information on first-grade enrollment in all Perth schools for 1995 was obtained from the Education Department of Western Australia. Schools located within 30 km of the center of Perth with 50 or more first-grade students were eligible for participation. These 97 schools were plotted on a map using MapInfo (MapInfo Corporation, Troy, New York). Because socioeconomic status was considered a potentially confounding variable, each school was assigned a socioeconomic rating from 1 to 4 based on the Australian Bureau of Statistics index of “social disadvantage” (derived from income, educational level, occupation, and housing conditions in census collection districts) (11), and was color-coded according to this variable. Public swimming pools were plotted on the same map.

Prevention of contamination between the intervention and control groups was our primary aim in selecting schools and assigning them to groups. If schools assigned to different groups were close to one another, contamination might have occurred by contact between parents, students, and school staff. In parts of Perth, primary schools may be separated by as little as 1 km. Contamination between groups might also have occurred at local swimming pools and beaches, because of the swimwear supplied to children in the high intervention schools.

We grouped eligible schools into a number of geographic “clusters.” Schools were placed in the same cluster if they were within 3 km of each other or if children attending them were likely to share a local swimming pool or beach. Fifteen clusters of schools were constructed, and all schools within a cluster were eligible for selection into one group only. We attempted to reduce travel costs by designating clusters closest to the center of Perth as part of the high intervention group (because schools in this group are visited more often by project staff), while the clusters located farthest from the center of Perth were designated control group clusters.

Next, all schools were weighted by the number of students in the first grade, and after stratification by socioeconomic status and proximity to the beach, individual schools were randomly selected from the relevant clusters. Weighting by school size ensured that each child had the same probability of selection. The numbers of schools in the three groups (14 control groups, 11 moderate intervention groups, and 8 high intervention groups) were chosen to maximize the statistical power of the study for the least cost. The cost per subject in the high intervention group is at least three times that in the control group.

Outcome measures

Outcomes will be measured in the cohort of children whose parents consented to their participation in 1995. Wherever possible, we will obtain outcome data on children who leave the study schools.

Our main outcome measure is the number of benign melanocytic nevi on the back. We chose nevi because they are strongly related to history of sun exposure (12–15) and to risk of melanoma (16) and are common in children (12, 17, 18). The back is a common site for nevi (18) and melanoma (19), and nevi there are relatively easy to count (20). Using melanoma as the outcome is not feasible because of the delay in its occurrence and its relative rarity.

Other study outcomes include: number of nevi on the face, arms, and, for boys, chest and abdomen; levels of suntanning (derived from skin reflectance) on the back and forearms; degree of freckling on the face and arms at the end of summer; and sun-related behavior. The schedule for the measurement of these outcome variables is presented in table 1. Because skin reflectance was measured during the winter in 1995, we have no baseline data on suntanning. Similarly, our winter measurements of freckling cannot be used as a measure of sun exposure over the previous summer. However, these measurements are important when assessing the validity of the baseline data on nevi, because nevi and freckles may be easily confused. Thus, since freckling is also an outcome measure, it will be measured in both summer and winter in 1999.

Longitudinal analyses of the change in number of nevi between 1995 and 1999 will be performed. All other outcomes will be analyzed cross-sectionally, since they reflect exposure over the previous summer rather than cumulative exposure.

Data collection

During the winter of 1995, we collected data on nevi, freckling, skin reflectance, hair color, eye color, height, and weight. A nevus was defined as a brown-to-black pigmented macule or papule of any size that was darker in color than the surrounding skin. Trained observers counted all nevi, regardless of size, to mini-
mimize interobserver variability (20). Sites for counting nevi were defined according to anatomic landmarks. Nevi were counted on the face and arms (inner and outer surfaces), and slide photographs were taken of the trunk (front and back for boys, back for girls) so that nevi in defined areas at these sites could be counted later. The trunk is easy to photograph, and in a previous study, counts made from photographs taken of the back were the same as those made by counting nevi directly (20). Counting nevi on the face and arms from photographs is too difficult because of the curved surfaces. Photographs of the trunk taken at the start and end of the study are useful for longitudinal analysis, since they can be displayed alongside each other and new nevi can be identified readily. For the baseline comparison, approximately half of the slide photographs were randomly selected, and the nevi on the children's backs were counted by a single trained observer.

We measured skin reflectance (at 425 nm) on the inner surface of the arm (i.e., an unexposed site) using a reflectance spectrophotometer (model 99; Diffusion Systems, London, United Kingdom). Hair color was graded against hairdressers' color samples, eye color against artificial irises of different colors, and degree of freckling against a 10-point scale of freckle density (21). Height and weight were recorded using a stadiometer and digital scales. They were measured so that we could calculate body surface area, which might be a determinant of the number of nevi.

Reflectance measures, nevus counts, freckling ratings, and hair and eye color assessment were all subject to ongoing tests of inter- and intrarater reliability. Ten percent of the children were assessed twice by the same observer, and another 10 percent by two different observers. Subjects were randomly selected for these reliability tests. The first observer was unaware that a second assessment would be made, and although the second observer knew that the child had been assessed once already, she was blind to the first set of results. Approximately 10 percent of the slides (n = 102) were examined twice by the same observer several weeks apart, to assess intrarater reliability for the counts of nevi on the trunk.

In September 1995, parents completed a questionnaire on their child's ethnicity, sun exposure during the previous summer, and skin's sensitivity to sunlight. The parents' educational level was also recorded, and we used the higher educational level of the two parents when examining the effect of parental education on the outcomes of interest.

### Data analysis

We used individual-level data when comparing groups and, wherever possible, methods appropriate for normally distributed data. The numbers of nevi were log-normally distributed, and to adjust for potential confounding while taking account of the cluster sampling in this analysis, we used the mixed model procedure in SAS (SAS Institute, Cary, North Carolina). School was treated as a random effect (22), nested within the intervention group so that variation attributable to the schools would not be incorrectly attributed to the group (23). Freckling was rare and was collapsed to a binary variable. We used the GENMOD procedure in SAS for this analysis, using generalized estimating equations (GEE) (24) to take account of the correlated data. As in the mixed model, the school effect was nested within the group, and an exchangeable covariance matrix was assumed.

Median nevus counts and freckling ratings were also calculated for children at each school, and these were then averaged across schools in each group. This approach may be considered more readily interpretable, as it does not involve complex statistical modeling.

The information provided in the parents' questionnaire was used to develop a composite measure of sun exposure for each child. We estimated the total number of hours that each child had been exposed to the sun over the previous summer, and after adjusting for the more intense ultraviolet radiation in the middle of the day, we reduced these hours according to the amount
of protection applied to the face, back, and arms. Clothing and sunscreen were considered to afford 100 percent and 90 percent protection, respectively, while protection to the face afforded by different types of hats varied from approximately 50 percent to 75 percent (25). Shade was considered to offer 50 percent protection. Our estimate of the dose of ultraviolet radiation that each child received was expressed in terms of “midday hour equivalents.” This measure is equivalent to hours of unprotected midday exposure received during the previous summer holidays. Data on this variable were log-normally distributed, and, as in the analysis of nevi, we used the mixed model procedure to adjust for potential confounding. Thirty-three children who had lived elsewhere during the summer holidays were excluded from these analyses, because their exposure was significantly lower than that for children living in Perth. Another 15 children who had been away from Perth for the entire holiday period were also excluded.

Ethnic origin, the skin’s sensitivity to sunlight, hair and eye color, and parental education were categorical variables, so we compared distributions of data on these variables among the groups. Data on inner arm skin reflectance and body surface area were normally distributed; we calculated mean values and standard deviations for each group. All confidence intervals presented in this paper are 95 percent confidence intervals. We do not present $p$ values, since it is the magnitude of the differences between groups at baseline that is of interest, not whether any such differences have occurred by chance.

Intraclass correlation coefficients, as measures of inter- and intrarater reliability for continuous variables, were calculated using one-way analysis of variance (26). We calculated weighted kappa values for ordinal variables and unweighted kappa values for nominal variables to estimate the degree of agreement within and between observers (26).

Power calculations

Our estimates of power were based on change in the number of nevi on the back between 1995 and 1999 in relation to a 25 percent reduction in sun exposure to the back. The choice of a 25 percent reduction was arbitrary, but our pilot study, conducted over the summer of 1993–1994, suggested that it was realistic (unpublished observations). We believed that smaller changes did not justify the intensity and cost of the intervention.

To our knowledge, no published data on the quantitative relation between sun exposure and change in number of nevi exist. Therefore, we used unpublished data from a cross-sectional study of nevi that we conducted in 1985 to estimate the effect of the intervention (18). First, we developed a regression equation to estimate the number of nevi on the back as a function of age and the average ambient sun exposure (global radiance) in places where the children had lived. Second, we used this equation to estimate the change in the number of nevi on the back between age 5 and age 9 in the present study’s control and intervention groups, assuming a 25 percent reduction in sun exposure in the intervention groups. In doing this, we assumed that there would be a 2-year lag time between children’s receiving the intervention and any effect on number of nevi. Thus, the last 2 years of exposure were ignored. We also assumed that this reduced sun exposure was only maintained during the years in which the child actually received the intervention.

No data on the variance of change in number of nevi on the back among children of this age were available. We estimated the variance from a 3-year follow-up study of children who were aged 8 years in 1985 (unpublished observations). To allow for the allocation to intervention group by school, we assumed that the intraclass correlation for the change in number of nevi among children attending the same school was 0.25 (27). Given the large variability between children in numbers of nevi (13), we expect that it will actually be lower.

Two sets of calculations were performed: comparison of controls with the high intervention group and comparison of controls with the high and moderate intervention groups combined. We performed the calculations using the number of children participating in the study and assumed that, each year, 10 percent of children in the intervention schools would move to control schools or nonparticipating schools. However, we assumed that we would examine each child at the end of the study.

RESULTS

Response

Of the 33 schools originally selected for the study, 28 agreed to participate. Five replacement schools were then randomly selected from the same clusters and socioeconomic status strata as those that had declined to take part; all of these schools participated. All first-grade children in these schools were invited to participate. Consent was obtained for 1,776 (70 percent) of the 2,528 children invited, and we examined 1,762 (70 percent) of the 2,528 invited children at the baseline survey in 1995 (65 percent of the control group, 73 percent of the moderate intervention group, and 76 percent of the high intervention group). We received completed parents’ questionnaires for 1,687 children.
Non-European children (n = 102), most of whom were of Asian descent, had lower skin reflectance (darker skin) (mean = 38.6) and fewer nevi on the back, face, and arms (median numbers were 1.0, 2.0, and 2.0, respectively) than the other children in the study, and were therefore excluded from all subsequent analyses. Melanoma and other types of skin cancer are rare among people of Asian descent (28). We were unable to identify these children a priori.

The 1,585 children who were classified as being of European descent included 91 children whose parents were unsure of their ethnic origin but who did not qualify to be classified as non-European. For example, some parents said that their ancestors were definitely not Asian, African, or Australian Aboriginal, but they were unsure where they came from. The nevus counts and skin reflectance for this latter group were almost identical to those of European children; thus, given the likelihood that these children’s ancestors were actually from Europe, we included these children in the European group.

Baseline equivalence: potentially confounding variables

The pigmentary characteristics of hair color and eye color and the skin’s sensitivity to sunlight (the propensity to burn and ability to tan) were evenly distributed among the three study groups (table 2). Inner arm skin reflectance was similar for children in each group; the mean values were 50.3 (standard deviation (SD) 6.15) in the control group, 49.8 (SD 6.06) in the moderate intervention group, and 50.1 (SD 6.30) in the high intervention group. Mean body surface area was also similar in the three groups: 0.84 m² in the control (SD 0.09) and moderate intervention (SD 0.08) groups and 0.85 m² (SD 0.09) in the high intervention group.

Nevus counts and freckling ratings varied by observer and month of observation, which differed among study groups; therefore, these potentially confounding variables were controlled for in the analysis of these outcomes. Children of Southern European origin (n = 139) had fewer nevi and less freckling than...
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other European children; because these children were unevenly distributed among the three study groups, we also adjusted for this factor in these analyses.

Although the schools were chosen to ensure that the three groups had similar distributions with regard to the index of social disadvantage, parental education differed substantially across groups (table 2). Parental educational level was not related to nevus counts at any site, but it was related to freckling and sun exposure, and was therefore controlled for in the analysis of these outcomes. Southern European ethnicity was also related to sun exposure, and was therefore controlled for in this analysis. We adjusted for sex in all analyses. Where appropriate, we adjusted for potentially confounding variables in two stages: firstly for factors related to data collection and secondly for factors inherent in the child. Where this occurred, results for both stages of adjustment are presented in the tables.

Baseline equivalence: outcome variables

Nevi. Eight hundred of the 1,762 slides of children’s backs were examined. Three slides were rated “impossible to count” by the observer and 80 as “somewhat difficult.” The analysis was undertaken with and without the inclusion of these 80 slides, and the results were almost identical. Therefore, 797 slides were included in the analysis. Data from 1,585 children were included in the analysis of nevi on the face and arms. The mean values of the school medians were similar in all study groups (table 3); the control group had the highest mean for the back but the lowest for the other two sites. For all three sites, both the crude and adjusted mean nevus counts from the mixed model analysis were similar across groups. The results of the analysis that was adjusted only for observer and month of observation were almost identical to those from the analysis that was also adjusted for sex and Southern European origin (table 3).

Freckling. The level of freckling was generally very low. For freckling on the arms, 32.7 percent of the children were rated 0 (no freckles), 49.4 percent were rated 1, and 17.9 percent were rated 2 or higher. For freckling on the face, 10.2 percent of children were rated 0, 35.3 percent 1, 20.4 percent 2, and 9.3 percent 3, with the remaining 24.8 percent of children being rated 4 or higher. The mean of the school medians for both sites was lowest in the control group, although the differences among the groups were small (table 4). When collapsing freckling into a binary variable for the GEE analysis, we grouped arm freckling into none versus any, but for freckling on the face, we grouped freckling into the categories 0–1 and 2–10. GEE analysis at both levels of adjustment produced elevated odds ratios for arm freckling in the moderate intervention group relative to the control group (table 4). Most other odds ratios were close to unity (table 4).

Sun exposure. On average, children had received the equivalent of 8.5 hours of unprotected midday exposure over the previous summer holidays. This

TABLE 3. Mean nevus counts on the back, face, and arms among children in the three study groups at baseline (1995), Kidskin Study, Perth, Western Australia, 1995–1999

<table>
<thead>
<tr>
<th>Study group*</th>
<th>Mean of school medians</th>
<th>Standard deviation</th>
<th>Geometric mean of ( \text{&quot;nevsi + 1&quot;} )†</th>
<th>Ratio of means‡</th>
<th>95% confidence interval</th>
<th>Geometric mean of ( \text{&quot;nevsi + 1&quot;} )§</th>
<th>Ratio of means¶</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Back</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control ((n = 360))</td>
<td>3.75</td>
<td>1.26</td>
<td>4.41</td>
<td>1.00†</td>
<td>4.36</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate ((n = 240))</td>
<td>3.45</td>
<td>0.79</td>
<td>3.86</td>
<td>0.88</td>
<td>0.77–0.99</td>
<td>3.87</td>
<td>0.89</td>
<td>0.78–1.01</td>
</tr>
<tr>
<td>High ((n = 197))</td>
<td>3.31</td>
<td>0.46</td>
<td>4.37</td>
<td>0.99</td>
<td>0.84–1.17</td>
<td>4.48</td>
<td>1.03</td>
<td>0.87–1.21</td>
</tr>
<tr>
<td><strong>Face</strong></td>
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<td></td>
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</tr>
<tr>
<td>Control ((n = 727))</td>
<td>3.68</td>
<td>0.95</td>
<td>4.26</td>
<td>1.00</td>
<td>4.29</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate ((n = 464))</td>
<td>4.00</td>
<td>0.78</td>
<td>4.45</td>
<td>1.04</td>
<td>0.93–1.18</td>
<td>4.43</td>
<td>1.03</td>
<td>0.92–1.16</td>
</tr>
<tr>
<td>High ((n = 394))</td>
<td>3.94</td>
<td>0.78</td>
<td>4.25</td>
<td>1.00</td>
<td>0.86–1.16</td>
<td>4.22</td>
<td>0.98</td>
<td>0.85–1.14</td>
</tr>
<tr>
<td><strong>Arms</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Control ((n = 727))</td>
<td>9.00</td>
<td>2.42</td>
<td>9.34</td>
<td>1.00</td>
<td>9.24</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate ((n = 464))</td>
<td>9.36</td>
<td>1.64</td>
<td>9.87</td>
<td>1.06</td>
<td>0.98–1.17</td>
<td>9.93</td>
<td>1.07</td>
<td>0.98–1.18</td>
</tr>
<tr>
<td>High ((n = 394))</td>
<td>9.68</td>
<td>1.16</td>
<td>9.09</td>
<td>0.97</td>
<td>0.86–1.10</td>
<td>9.21</td>
<td>1.00</td>
<td>0.88–1.13</td>
</tr>
</tbody>
</table>

* There were 14 schools in the control group, 11 schools in the moderate intervention group, and 8 schools in the high intervention group.
† Adjusted for month of observation and, for the face and arms, observer.
‡ Group mean divided by control group mean.
§ Adjusted for month of observation, sex, Southern European origin, and, for the face and arms, observer.
¶ Reference category.
TABLE 4. Degree of freckling on the arms and face among children in the three study groups at baseline (1995), Kidskin Study, Perth, Western Australia, 1995-1999

<table>
<thead>
<tr>
<th>Study group*</th>
<th>Mean of school medians</th>
<th>Standard deviation</th>
<th>Odds ratio†</th>
<th>95% confidence interval</th>
<th>Odds ratio†</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arms</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control (n = 727)</td>
<td>0.50</td>
<td>0.53</td>
<td>1.00§</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (n = 464)</td>
<td>0.91</td>
<td>0.30</td>
<td>1.55</td>
<td>1.01–2.37</td>
<td>1.56</td>
<td>1.00–2.43</td>
</tr>
<tr>
<td>High (n = 394)</td>
<td>0.86</td>
<td>0.36</td>
<td>0.84</td>
<td>0.47–1.51</td>
<td>0.78</td>
<td>0.42–1.44</td>
</tr>
<tr>
<td><strong>Face</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Control (n = 727)</td>
<td>1.44</td>
<td>0.50</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (n = 464)</td>
<td>1.82</td>
<td>0.40</td>
<td>1.03</td>
<td>0.89–1.32</td>
<td>0.94</td>
<td>0.73–1.22</td>
</tr>
<tr>
<td>High (n = 394)</td>
<td>1.79</td>
<td>0.73</td>
<td>1.00</td>
<td>0.75–1.33</td>
<td>0.91</td>
<td>0.69–1.21</td>
</tr>
</tbody>
</table>

* There were 14 schools in the control group, 11 schools in the moderate intervention group, and 8 schools in the high intervention group.
† Adjusted for observer and month of observation.
‡ Adjusted for observer, month of observation, sex, parental education, and Southern European origin.
§ Reference category.

translates to a daily average of 12 minutes. After adjustment for Southern European origin, parental education, and sex, the mean number of midday hour equivalents was 8.1 (95 percent confidence interval (CI) 7.2–9.1) (12 minutes) in the control group, 8.5 (95 percent CI 7.4–9.8) (12 minutes) in the moderate intervention group, and 9.5 (95 percent CI 8.1–11.1) (14 minutes) in the high intervention group. The results were the same when the analysis was restricted to children who had been with their parents most or all of the time during the holidays.

Reproducibility of measurements

The intraclass correlation for nevus counts on the back from the slide photographs was 0.95 (95 percent CI 0.93–0.97). The intra- and interrater reliability for nevus counts on the face and arms were also high; for both sites, the intrarater reliability coefficient was 0.98 (95 percent CI 0.97–0.99), and the interrater reliability coefficients were 0.86 (95 percent CI 0.81–0.90) for the face and 0.86 (95 percent CI 0.79–0.90) for the arms. There was a high level of intra- and interobserver reliability for the measurement of skin reflectance on the inner arm; the intrarater reliability coefficient was 0.95 (95 percent CI 0.92–0.96), and the interrater reliability coefficient was 0.86 (95 percent CI 0.80–0.90). For intra- and interrater reliability of ratings of freckling on the face, the values of the weighted kappa statistic were 0.92 (95 percent CI 0.88–0.95) and 0.75 (95 percent CI 0.70–0.81), respectively; and for ratings of freckling on the arms, the values were 0.80 (95 percent CI 0.70–0.90) and 0.64 (95 percent CI 0.52–0.76), respectively.

The kappa statistics for eye color were 0.95 (95 percent CI 0.89–1.00) for intrarater agreement and 0.89 (95 percent CI 0.82–0.96) for interrater agreement. For hair color, they were 0.84 (95 percent CI 0.75–0.93) and 0.52 (95 percent CI 0.40–0.64), respectively. The somewhat lower value for agreement between observers on hair color was largely due to differences in the classification of light brown hair versus blonde hair.

Power calculations

Based on the number of children participating in the study, we estimated the power to be 0.85 to detect a 25 percent reduction in exposure when comparing controls with the high intervention group and 0.99 when comparing the control group with the two intervention groups combined. The actual sample size was slightly larger than the target sample size, so the actual power is greater than that predicted before the study began.

DISCUSSION

At baseline in the Kidskin Study, children in the three study groups were similar with respect to number of nevi and degree of freckling, after adjustment for confounding. Sun exposure was slightly higher in the high intervention group.

The way in which we selected schools and allocated them to treatment groups was a consequence of concerns about contamination between neighboring schools. However, this constraint precluded us from randomizing schools into treatment groups. Furthermore, for practical reasons, schools in the high intervention group were located closest to the center of Perth. Thus, there is potential for bias. However, the three study groups were similar at baseline with respect to most potentially confounding variables: the
pigmentary characteristics, the skin’s sensitivity to sunlight, and body surface area. The similar levels of freckling in the three groups indicate that the nevus counts are likely to be equally valid across the groups. Groups did differ with respect to parental education, Southern European ethnicity, and reported sun exposure. Adjustment for Southern European ethnicity did not have any noticeable effect on between-group differences in number of nevi, nor did adjustment for ethnicity and parental education have an effect on between-group differences in freckling. The slightly higher sun exposure in the high intervention group could not be explained by Southern European origin or by differences in parental education.

The between-group differences in parental education occurred despite our stratifying by socioeconomic status when selecting schools. The most likely explanation is that people living closer to the center of Perth are generally more highly educated, even though other measures of socioeconomic status do not show this geographic distribution. Because parental education is likely to have a direct effect on children’s sun exposure, we will adjust for it when examining the effect of the intervention.

The high response rates in this study, both from schools and from the children, mean that the participants are likely to be representative of the target population. We consider the exclusion of children of non-European origin justified on the grounds that these children are at low risk of skin cancer and there were too few of them for us to calculate separate results for them.

We are confident that our measures for assessing the effect of the intervention are valid and reproducible. Nevus counts using methods and definitions similar to our own have been strongly related to risk of melanoma (16) and have also been related to sun exposure in children (12-15). We demonstrated a high degree of agreement among observers in nevus counts. In the pilot study, skin reflectance on the outer surface of the arm remained constant over the summer in children who were given protective swimwear, but it decreased substantially in children who were not, indicating that this is a valid measure of suntanning (unpublished observations). Our measurement of skin reflectance is also highly reproducible.

Our composite measure of sun exposure has not been evaluated in terms of validity and reliability. However, when we examined the geometric mean against the skin’s sensitivity to sunlight for all children in the study (including non-European children), we found that there was a linear gradient across the categories. For example, for tendency to sunburn, the mean exposures were 6.2, 7.4, 9.9, and 11.8 midday hour equivalents for children in the most sensitive through the least sensitive categories, respectively. These findings provide some support for this measure’s being a valid indicator of children’s sun exposure.

During the summer in Perth, 1 hour of sun exposure between 11:00 a.m. and 2:00 p.m. is equivalent to approximately 4.5 minimal erythemal doses (P. Gies, Australian Radiation Laboratory, personal communication, 1997). This means that white skin would become reddened within 24 hours (29) after approximately 13 minutes of exposure. Therefore, our results suggest that, on average, children in the high intervention group were exposed to enough ultraviolet radiation to redden the skin every day over the 6 weeks of the summer holidays, while children in the other two groups were exposed to slightly less. These are clearly undesirably high levels of exposure. These results provide a useful proxy measure of baseline summer sun exposure for between-group comparisons, in the absence of baseline data on tanning.

Our power calculations assumed a 25 percent reduction in global irradiance (as a proxy for sun exposure) to the back. Several assumptions were made in these calculations, so we erred on the side of caution. Data from the pilot study conducted over the previous summer suggested that the back is a plausible candidate for a site that may be readily protected from the sun by clothing. The reduction in exposure to areas less readily clothed may be smaller; for example, it may be impractical for children to cover their forearms by wearing long-sleeved shirts during the hot Australian summer.

The success of the Kidskin Study is related to two main issues: whether an intervention such as this can bring about behavior change and, if so, whether the change in behavior will result in a demonstrable reduction in the number of nevi developing over the 5 years of the study. Previous studies, including our pilot study, have shown that a primary school-based sun protection intervention can lead to positive self- or parent-reported behavior change within several months of implementation (6, 30, 31). The Kidskin intervention is more comprehensive in that it involves home-based as well as classroom-based activities; thus, it is likely to be more effective than previous programs. The lag time between behavior change and any potential effect on the development of nevi is a more complex issue. The level of sun exposure in childhood influences the number of nevi that develop (15, 17, 32), with Australian children having more nevi than children of the same age living in Britain (by a factor of up to 10) (33-35). We observed that British-born children who had migrated to Perth had far fewer nevi upon arrival than children.
born in Australia, but within 3 years they had almost as many nevi (86 percent) as Australian-born children (unpublished observations). A recent case-control study of melanoma in Germany (36) found that nevus counts were directly associated with holiday sun exposure during the previous 2 years, although a person's recent pattern of sun exposure is likely to be correlated with exposure earlier in life. These results together suggest that the effects of sun exposure may be reflected in nevus counts within 2–3 years. Whether this is so for the effects of a reduction in sun exposure remains to be seen. A US study of migration to Washington State, where ultraviolet radiation is relatively low, found that White adults (aged 18–50 years) who had migrated at 1–12 years of age had fewer nevi than those who had migrated at 13 years of age or older (37). These results suggest that a reduction in sun exposure during childhood does reduce the number of nevi that develop, but the issue of the time lag between cause and effect was not addressed. We are assuming that any effect of the final 2 years of the intervention (1997 and 1998) will not be manifest in terms of nevus counts by the end of the study in 1999. Therefore, we will use the level of tanning in February 1999—at the end of the Australian summer—to measure the effectiveness of the 1998 intervention. This will also allow validation of the behavioral data collected from parent surveys conducted at the same time.

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