Improving Sun-Protection Behavior among Children: Results of a Cluster-Randomized Trial in Italian Elementary Schools. The "SoleSi SoleNo-GISED" Project

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A history of sunburns in early life nearly doubles the risk of developing malignant melanoma in adulthood. From 2001 to 2004, we conducted a cluster-randomized trial of an educational intervention to reduce sunburn rates (primary outcome) and improve sun-protection behavior (secondary outcome) in schoolchildren. A total of 122 Italian primary schools (grades 2 and 3) were randomized to receive, or not, an intervention consisting of an educational curriculum at school, conducted by trained teachers, which included the projection of a short video and the distribution of booklets to children and their parents. Behavior while in the sun was assessed at baseline and 14–16 months after baseline. In a subgroup (44% of the total sample), melanocytic nevi were also counted. Of the 11,230 children enrolled, 8,611 completed the study. A total of 1,547 children (14%) reported a history of sunburns at baseline. At follow-up, no difference in sunburn episodes was documented between the study groups (odds ratio 0.97, 95% confidence interval 0.84-1.13) and similar sun-protection habits were reported. No significant impact of the proposed educational program was documented at 1-year follow-up. Innovative strategies need to be developed to increase the effectiveness of future educational interventions in this area.

Journal of Investigative Dermatology (2007) **127,** 1871–1877; doi:10.1038/sj.jid.5700835; published online 26 April 2007

INTRODUCTION

Excessive sun exposure and interaction with constitutional factors regulating skin pigmentation seem to play a crucial role in the development of skin cancer (Armstrong and Kricker, 2001; Chaudru *et al.*, 2004). It has been largely documented that a history of sunburn in early life nearly doubles the risk of developing malignant melanoma in adulthood (Naldi *et al.*, 2000). In most epidemiological studies, the number of melanocytic nevi represents the strongest risk predictor for developing malignant melanoma and it has been established that the density of melanocytic nevi in childhood is in turn influenced by sun exposure and sunburn in early infancy (Carli *et al.*, 2002; Darlington *et al.*, 2002).

Broad agreement exists that sun-protection habits should begin early in life and be taught as part of routine preventive health care (Litt, 1996; Marks, 1998; Buller and Borland, 1999). Despite a general belief in its effectiveness, scarce data are available concerning the impact of educational interventions targeting children. A systematic review (Saraiya *et al.*, 2004; search updated to June 2000) concluded that education approaches to increasing sun-protective behaviors were effective when implemented in primary schools and in recreational settings and that insufficient evidence was available for implementation in other settings. However, of the 20 qualifying studies that considered educational interventions in primary schools, only one evaluated effects in reducing sunburns, documenting a 43% reduction in reported sunburns (Bastuji-Garin *et al.*, 1999). A few additional studies have been published subsequently, suggesting less impressive and even negative results (Dietrich *et al.*, 1998, 2000; Buller *et al.*, 1999; Crane *et al.*, 1999; Glanz *et al.*, 2000; Bauer *et al.*, 2005; English *et al.*, 2005a, b). Most of the analyzed studies came from high-risk, fair-skinned populations, and it is unclear whether their results could be extrapolated to populations with different prevalent phenotypes. In 1998, we conducted a survey of melanocytic nevi in Italian schoolchildren, documenting a lifetime rate of reported sunburns close to 60% (Carli *et al.*, 2002). Together with the increasing incidence and mortality

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Abbreviations: OR, odds ratios; CI, confidence interval

Received 3 August 2006; revised 12 February 2007; accepted 20 February 2007; published online 26 April 2007

of melanoma documented in the country until the early 1990s (Franceschi *et al.*, 1994; Vinceti *et al.*, 1999), these data formed the basis for designing a study to evaluate the impact of an educational intervention to reduce sunburn episodes and to improve sun-protection behavior among Italian schoolchildren.

The resulting ''SoleSi SoleNo-GISED project'' was conceived as a cluster-randomized study in which schools rather than individuals were randomized. Several reasons exist for favoring cluster randomization in this trial, the principal one being to avoid experimental contamination, which could occur when the same personnel are asked to give both interventions to different participants and when knowledge of the intervention may influence the responses of participants in the control group. A further reason is that, having a program administratively set up within a school, it would seem much more likely to function effectively if all staff members, and not just some, were involved (Wood and Freemantle, 1999).

RESULTS

Participant flow and follow-up

A total of 122 schools were initially randomized, 62 to the intervention and 60 to the control group. Nine schools did not return follow-up questionnaires (three in the intervention and six in the control group) (Figure 1). A total of 11,230 children were initially enrolled (5,676 in the intervention and 5,554 in the control group). There were 5,654 boys and 5,505 girls; the mean age was 8 years, with SD 0.7. A total of 8,611 (77%) children completed the study with a successful merging of data from baseline and follow-up. A subgroup of 4,921 children (44% of the total baseline sample), 2,852 in the active intervention and 2,069 in the control group, underwent assessment of phenotype and upper limb nevus count at baseline. Of these, 988 (20%) were lost to follow-up (580 in the intervention and 408 in the control group). The median time spent by teachers on the educational intervention at school was 6 hours (range 4–19 hours). Twenty-six teachers (87%) of a sample of 30 considered the intervention relevant or very relevant and were willing to replicate the experience in the future, if possible.

Analysis

Table 1 presents demographic information and data on skin phenotype and nevus count at baseline for both the intervention and the control group. Skin, hair, and eye color distributions were similar in the two study arms. Only 24 children were redheaded (0.2% of the whole sample). Therefore, despite the expected major risk of sunburn in this category, no separate analysis was performed for them. The geometric mean of nevus count on upper limbs at baseline was 5.1 in both subgroups; the median values were 6 and 7, respectively (data not shown).

Table 2 presents data on sun exposure and sun-protective behavior at baseline and at follow-up. A history of sunburns was reported by 1,548 children (14%). The regular use of sunscreens was reported by about 71% of the sample (63% used high-protection-factor sunscreens), wearing a hat regularly was reported by 38% of the sample, and wearing a long-sleeved shirt by 20%. At follow-up, no differences emerged in sunburn experience or number of episodes of sunburn between groups, even if a slight (but not significant) improvement was observed in the intervention group. All the odds ratios (ORs) were around unity and nonsignificant.

As for melanocytic nevus count, no differences emerged between the subgroups analyzed. At baseline, the geometric mean of nevus count was 5.1 in both the intervention and the

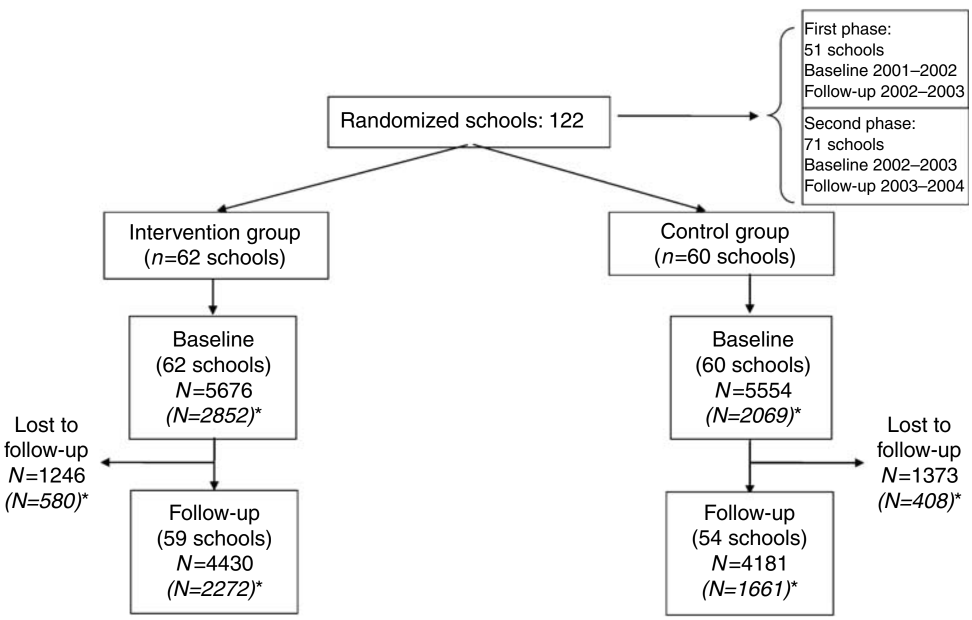

Figure 1. ''SoleSi SoleNo-GISED'' project: patient enrollment and follow-up.

Table 1. "SoleSi SoleNo-GISED" project: study subjects demographic and other characteristics at baseline (total sample: 11,230 children) including data on pigmentary traits and melanocytic nevi count in a subgroup of 4,921 children. Italy, 2001–2004

	Active Intervention[1] N (%)	Control Group[1] N (%)
Gender		
Boys	2864 (50.5)	2790 (50.2)
Girls	2765 (48.7)	2740 (49.3)
Unknown	47 (0.8)	24 (0.4)
Geographic area of residence (latitude)[2]		
Northern Italy (45.6−44.5)	815 (14.4)	898 (16.2)
Central Italy (44.2−43.6)	1237 (21.8)	1241 (22.3)
Southern Italy (41.5−37.4)	3624 (63.8)	3415 (61.5)
Eye color[3]		
Black/dark brown	1384 (48.5)	979 (47.3)
Light brown/brown green	790 (27.7)	592 (28.6)
Gray/green/hazel	466 (16.3)	383 (18.5)
Hair color[3]		
Black/dark brown	1252 (43.9)	940 (45.4)
Brown	999 (35.0)	730 (35.3)
Red/blond	386 (13.5)	281 (13.6)
Skin color[3]		
Light	1747 (61.3)	1316 (63.6)
Dark	882 (30.9)	634 (30.6)
Freckles on the face[3]		
Yes	188 (6.6)	110 (5.3)
No	2432 (85.3)	1832 (88.6)
Number of melanocytic nevi on upper limbs[3]		
⩽5	1380 (48.4)	968 (46.8)
6–10	786 (27.6)	552 (26.7)
11–15	388 (13.6)	295 (14.3)
16–20	151 (5.3)	134 (6.5)
>20	142 (5.0)	114 (5.5)

[1]Sum may not add up to the total because of missing values.
[2]χ^2 for heterogeneity was significant at $P<0.001$.
[3]Active intervention 2,852 children, control group 2,069 children.

control group. At follow-up, the geometric means were 6.8 in the intervention and 6.4 in the control group. The ratio of relative change was 1.06 (95% confidence interval (CI) 1.02–1.10).

No major differences emerged between the first and the second study phases either at baseline or at follow-up (data not shown).

DISCUSSION

In this study, based on the collaboration of a large number of Italian elementary schools, there was no significant impact from an educational program on sunburn episodes or melanocytic nevi evaluated 14–16 months from baseline, that is, about 1 year after completion of the intervention. Some limitations in our study may have affected results. The rate of sun protection was already high in the examined population and the expected size of the effect was large. A larger study would have been required to assess more limited effects. The drop-out rate may also be a matter of some concern. This was mainly because a few schools were not able to comply with our study requirements. However, it was partly reassuring that a comparison between children who dropped out of the study and those who continued did not disclose any major difference in any of the relevant variables influencing sun exposure (data not shown). We relied on sunburn history reported by parents. It is possible that some parents wanted to please investigators by reporting more healthy habits for their children. However, this potential bias is, in principle, more prone to be experienced by parents in the intervention rather than in the control group. A more objective measure of sun exposure effect could be represented by nevus count. This was performed only in a subset of children in a limited number of schools selected by the local investigators before randomization. With this limitation in mind, the study showed no variations in nevus counts between groups. Possibly, the intervention was too short and therefore insufficient time elapsed to document effects on behavioral changes and number of nevi. Interestingly, limited effects on nevus counts were reported by a nonrandomized interventional study in Western Australia of a sun-protection program at a 6-year follow-up (English *et al.*, 2005a).

Despite some limitations in knowledge, exposure to UV radiation appears to be the major environmental risk factor for nonmelanoma skin cancer and melanoma, in addition to being the most important avoidable cause. The aim of primary skin cancer prevention is therefore to limit UV light exposure. The effectiveness of skin cancer educational programs depends on several factors, including the perceived possible outcome of behavior change and the magnitude of the value attached to the outcome. Most health educators agree that the greatest long-term benefits are expected to occur when targeting children. Childhood is an excellent time to form life-long prevention habits: early preventive behaviors may be less resistant to change than those acquired in adulthood. The best way to assess the effectiveness of an educational campaign is by a randomized controlled trial comparing either two or more alternative educational strategies or one strategy with no strategy at all. Relevant outcomes are influences on the incidence/mortality of skin cancer. Behavior attitudes with reduction in sun exposure and number of sunburn cases are surrogate outcome measures.

Only a few randomized studies have been conducted on schoolchildren to evaluate the impact of an educational intervention to improve sun-protection behavior and reduce sunburn episodes. Although some of these studies reported a

Table 2. "SoleSi SoleNo-GISED" project: subjects' sun-protection behavior at baseline and follow-up according to their randomization allocation. OR and (95% CI). Italy, 2001–2004

	Baseline/follow-up		
	Active intervention[1] 5676/4430 children (%)	Control group[1] 5554/4181 children (%)	OR (95% CI)[2,3]
Did your child experience intense sun exposure last year?			
No[4]	863 (15.2)/658 (14.9)	915 (16.5)/709 (17.0)	1
Yes	4484 (79.0)/3562 (80.4)	4355 (78.4)/3297 (78.9)	0.88 (0.77–1.01)
Unknown	145 (2.6)/172 (3.9	163 (2.9)/137 (3.3)	
Do you think that your child was adequately protected from sun exposure last year?			
Yes[4]	4937 (87.0)/3863 (87.2)	4762 (85.7)/3622 (86.6)	1
No	385 (6.8)/280 (6.3)	483 (8.7)/307 (7.3)	0.86 (0.71–1.04)
Unknown	111 (2.0)/136 (3.1)	118 (2.1)/131 (3.1)	
Did your child experience sunburn episodes last year?			
No[4]	4633 (81.6)/3687 (83.2)	4581 (82.5)/3475 (83.1)	1
Yes	783 (13.8)/579 (13.1)	764 (13.8)/565 (13.5)	0.97 (0.84–1.13)
Unknown	82 (1.4)/125 (2.8)	86 (1.6)/102 (2.4)	
Could you specify the number of sunburn episodes experienced by your child during the last year?			
0[4]	4634 (81.6)/3687 (83.2)	4582 (82.5)/3475 (83.1)	1
1–2	574 (10.1)/418 (9.4)	570 (10.3)/415 (9.9)	0.96 (0.81–1.13)
⩾3	87 (1.5)/74 (1.7)	87 (1.6)/68 (1.6)	1.10 (0.75–1.62)
Did your child regularly use sunscreens while in the sun last year?			
Always[4]	4059 (71.5)/3284 (74.1)	3925 (70.7)/3026 (72.4)	1
Sometimes	930 (16.4)/699 (15.8)	967 (17.4)/771 (18.4)	0.86 (0.75–0.98)
Occasionally/never	546 (9.6)/444 (10.0)	577 (10.4)/384 (9.2)	1.11 (0.92–1.32)
Did your child usually wear a hat while in the sun last year?			
Always[4]	2154 (38.0)/1525 (34.4)	2082 (37.5)/1404 (33.6)	1
Sometimes	2236 (39.4)/1884 (42.5)	2188 (39.4)/1819 (43.5)	0.96 (0.86–1.08)
Occasionally/never	1147 (20.2)/1020 (23.0)	1202 (21.6)/958 (22.9)	1.02 (0.89–1.17)
Did your child usually wear a long-sleeved shirt while in the sun last year?			
Always[4]	1126 (19.8)/901 (20.3)	1089 (19.6)/776 (18.6)	1
Sometimes	2339 (41.2)/1902 (42.9)	2356 (42.4)/1821 (43.6)	0.91 (0.79–1.04)
Occasionally/never	2072 (36.5)/1626 (36.7)	2026 (36.5)/1584 (37.9)	0.90 (0.78–1.03)

CI, confidence interval; OR, odds ratio.
[1]Sum may not add up to the total because of missing values.
[2]ORs lower than 1 may be interpreted as an improvement in children behavior and sun experience at follow-up in the intervention group.
[3]Multiple logistic regression estimates adjusted for gender, geographic area, and number of weeks spent on holiday in sunny area at baseline and the protection behavior from sun exposure at baseline.
[4]Reference category.

positive influence of the educational interventions (Bastuji-Garin *et al.*, 1999), others suggested less impressive and even negative results (Dietrich *et al.*, 1998, 2000; Buller *et al.*, 1999; Crane *et al.*, 1999; Glanz *et al.*, 2000; Bauer *et al.*, 2005).

Our study was unable to document an effect of the proposed intervention. This may be attributed in part to the already high levels of awareness concerning sun-protection behavior in our population. Sunburn was reported by only 14% of children, a lower proportion than documented in other similar populations (Gallagher *et al.*, 2000; Bauer *et al.*, 2005; Harrison *et al.*, 2005), whereas 71% of the sample used sunscreens regularly, again a larger proportion compared with estimates in similar age groups from other countries (Naylor and Robinson, 2005; Thieden *et al.*, 2005). Recent surveys indicate that the use of sun-protection modalities has increased substantially over recent years in young European adults (Peacy *et al.*, 2006). In this situation, attempts to increase public awareness further by mass educational campaign may have limited effects on sun-protection behavior.

Our data argue against conducting generic educational interventions at school that involve the distribution of written materials and the application of a short curriculum to improve sun-protection behavior. Future educational programs should evaluate alternative educational methods and adopt a more objective assessment of outcome. In addition, interventions conducted in areas where the rate of sun protection is already high should be better targeted to more susceptible subgroups or individualized to the needs of those people who do not appear to comply with sun-protective behavior (Gerrard *et al.*, 1999).

MATERIALS AND METHODS

Study design and protocol

The SoleSi SoleNo-GISED Project was a trial of an educational intervention with cluster randomization at the school level. The study design has been described elsewhere (Oncology Cooperative Group, 2003) and it is summarized in Figure 1. The study was approved by the ethical committee of the coordinating center (Mario Negri Institute, Milan) and was conducted under the principles of the Declaration of Helsinki. Parents gave their informed consent. Information was made available to parents concerning the responses of their children at baseline and at follow-up and on study results as aggregated data, if required. The trial was registered in the Cochrane Skin Group Database, CSG26, on July 13, 2005.

Participants

Data were collected between 2001 and 2004 in two phases, a first phase (2001–2003) (Oncology Cooperative Group, 2003) involving 51 schools and a second phase (2002–2004) involving 71 schools in a total of 18 Italian cities. The cities were a convenience sample selected according to the presence of a dermatology center participating in the clinical network of the Italian Group for Epidemiological Research in Dermatology (GISED). They were located in northern Italy, latitude 45.6−44.5 N (Bergamo, Cremona, Ferrara, Verona), central Italy, latitude 44.2−43.6 N (Ancona, Macerata, Ravenna, Reggio Emilia, Rome, Siena), and southern Italy, latitude 41.5−37.4 N (Benevento, Cagliari, Chieti, Foggia, Lecce, Naples, Salerno, Taranto). The main reason for conducting the study in two phases was the need to get reliable estimates of the rate of sunburn episodes at baseline to substantiate the final sample size calculation. The results of the first phase were not available in terms of efficacy when the second study phase was started (Figure 1).

The study was locally coordinated by a dermatologist, a member of the GISED network. The district directors of education were briefed on the purpose of the study and provided the local GISED coordinator with a list of the available schools. The study was presented to the schools, which were centrally randomized into active intervention or control group. Within each school, all the children attending the second or third years were eligible. A total of 125 schools were initially contacted and 122 schools consented to the study and were randomized to receive an educational intervention or to be in the control group (three schools declined participation). A total of 11,238 children were enrolled at baseline. Children were assessed at baseline and at follow-up, 14–16 months from baseline.

Intervention

The educational intervention was developed with the help of educational psychologists and epidemiologists and was conducted as soon as baseline assessment was completed during a 3-month period. The intervention involved the distribution of educational booklets to parents and their children and the application of a short curriculum at school, based on a resource developed for health teachers. Direct and active involvement of teachers and families was pursued. Details of the intervention and educational materials are available as Supplementary Materials. The control arm did not receive any specific intervention.

Masking

No intervention-masking procedure was adopted.

Data collection

At baseline and 14–16 months after baseline, a questionnaire was filled out by parents with information concerning their children's sun exposure and sun-protective behavior during the previous year. A standardized self-administered questionnaire, developed by our team, was adopted. In a previous study, the questionnaire had been assessed for intrarater reliability and validity against a structured face-to-face interview. On the basis of this evaluation, the instrument was considered to provide reliable information (Carli *et al.*, 2002).

In a subset of 36 schools (30% of the total) selected as a convenience sample in the two randomized groups by the local investigator, skin phenotype (eye, hair, and skin color) and freckles on the face were assessed and melanocytic nevi were counted over the upper limbs. These assessments were performed using a standardized questionnaire, which had also been assessed for intra- and interrater reliability in a previous study, providing satisfactory results (Carli *et al.*, 2002). Phenotype assessment and nevus count were performed by a dermatologist, during a classroom exercise coordinated by the teacher, in which each child had to assess a schoolmate for skin phenotype. We did not establish a threshold in diameter for nevus count. To calculate within-child changes, an individual code was used for each child, which linked baseline information with that obtained at follow-up. To evaluate if the intervention was properly received by the teachers, data on the time spent in the educational intervention at school, comments on the materials proposed, and willingness to replicate the experience were also collected from teachers.

Outcomes

The primary study outcome was the prevalence of reported sunburn episodes at follow-up. Sunburn was defined as an episode of intense erythema, with or without blisters, causing pain and discomfort lasting for at least 3 days. An additional primary outcome in the subset of schools undergoing nevus count was the difference in nevus count between follow-up and baseline. Secondary outcomes included improvement in sun-protection habits, that is, proportion of children regularly using sunscreens, regularly wearing a hat, and long-sleeved shirt while in the sun.

Sample size

Sample size calculation was conducted considering that the unit of randomization was groups or clusters (e.g., schools) rather than single individuals. On the basis of a previous study of more than 3,000 Italian schoolchildren conducted by GISED in 1998, the expected rate of sunburn episodes during the previous year was estimated at approximately 20% (Carli *et al.*, 2002). The end point was defined as a reduction of approximately 30% in the rate of sunburn episodes in the intervention group compared with the control group. Assuming randomization units of about 40 individuals (mean value estimate) and a variability among clusters of approximately 20%, it was calculated that 5,000 children for each study arm were needed to document the expected difference reliably (α error = 0.05, β error = 0.2).

As discussed elsewhere (Oncology Cooperative Group, 2003), the low rate of sunburn episodes estimated during the first study phase (12%) invalidated our assumptions concerning sample size calculation. As it was not realistic to expect a difference larger than 30% in sunburn experience, more clusters than those originally planned were enrolled in the second phase. During the first phase, the mean number of children per cluster (K) was 76 (thus greater than that considered initially in our sample size calculation). Therefore, with 122 clusters the design effect was about 2.5, with an intracluster correlation coefficient $\rho = 0.02$. (Kerry and Bland, 1998a, b). Assuming 5,500 children per group, a difference greater than 25% between groups could be assessed.

Sequence generation and allocation concealment

A centralized randomization plan was adopted. To ensure comparability between the intervention and the comparison group, schools were randomized into strata, taking into account the city and the number of children per school (less than or equal to 100 *vs* over 100). Participants were taken blind into the randomization plan. A telephone call to the coordinating center was required to allocate schools, and details about a school had to be transferred to the coordinating center before a randomization code was allocated to the school.

Statistical methods

All the analyses were performed using SAS software, version 8.1 (SAS Institute, Inc., Cary, NC). For categorical variables, multiple logistic regression with maximum likelihood estimate was applied to calculate OR and their 95% CIs were adjusted for gender and for other variables not uniformly distributed between groups at baseline (i.e., geographic area of residence, number of weeks spent on holiday in the sun during the previous year, and sun-protection behavior at baseline) (Breslow and Day, 1980). We also took into account adjustment for the cluster sampling design. ORs lower than 1 may be interpreted as an improvement in children's behavior and sun experience at follow-up in the intervention group. The association should be considered as statistically significant when the OR 95% CI excludes the unit.

When analyzing nevus counts, relative changes in geometric means at follow-up compared with baseline were calculated and compared between the intervention and the control groups by calculating the ratio of relative change together with its 95% CI. The distribution of nevus counts was skewed by a small number of high counts. The adoption of a logarithmic scale allowed a better approximation to a Gaussian distribution. Owing to the presence of few zero values, the logarithm of 1 plus the nevus count was used. The antilog of the mean of this variable was taken and 1 was subtracted to produce the geometric mean.

CONFLICT OF INTEREST

The authors state no conflict of interest.

ACKNOWLEDGMENTS

We thank Professor Robin Marks for providing helpful suggestions. This study was supported by a research grant from the Italian Cancer League and an unrestricted research grant from L'Oréal Recherche.

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SUPPLEMENTARY MATERIAL

Figure S1. An educational booklet for parents: ''Il mio bambino al sole'' (My child in the sun).

Figure S2. An educational booklet for children: ''Supersole'' (Super-sun).

Figure S3. A resource for health teachers: ''Il progetto SoleSi SoleNo'' (The SoleSi SoleNo project).

Materials and methods.

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