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

Luigi Naldi[1], Liliane Chatenoud[2], Paola Bertuccio[2], Cornelia Zinetti[1], Anna Di Landro[1], Lorenza Scotti[2], Carlo La Vecchia[2] and the Oncology Cooperative Group of the Italian Group for Epidemiologic Research in Dermatology (GISED)[3]

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

[1]*CentroStudi GISED, Bergamo, Italy and* [2]*Istituto di Ricerche Farmacologiche M. Negri, Milano, Italy*

[3]*See list in the acknowledgments.*

Correspondence: Dr Luigi Naldi, Centro Studi GISED, Ospedali Riuniti, L.go Barozzi 1, Bergamo 24100, Italy. E-mail: luigi.naldi@gised.it

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

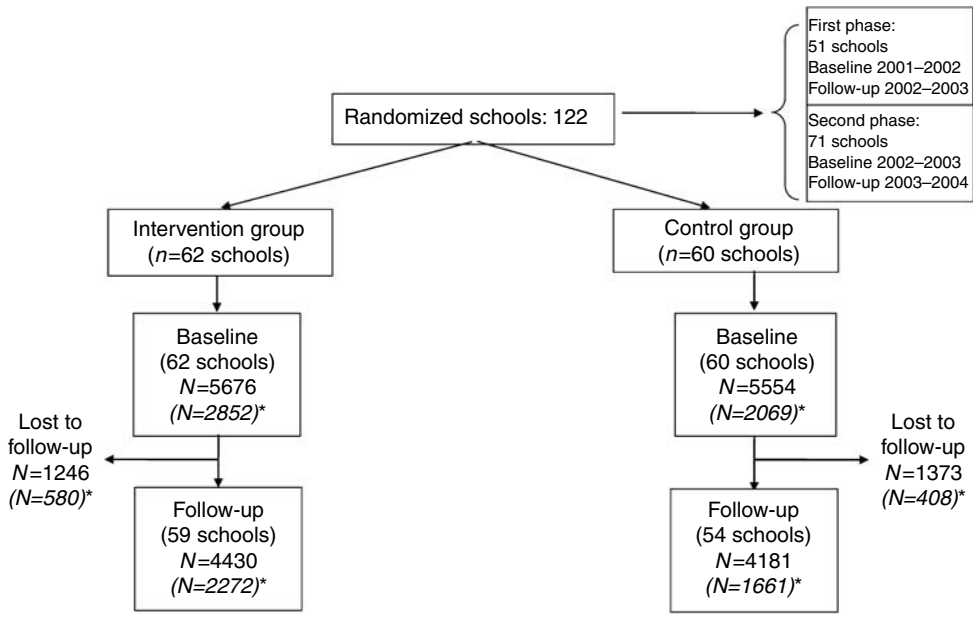

Figure 1. ''SoleSi SoleNo-GISED'' project: patient enrollment and follow-up.