The Sunless Study

A Beach Randomized Trial of a Skin Cancer Prevention Intervention Promoting Sunless Tanning

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Objective: To examine the impact of a skin cancer prevention intervention that promoted sunless tanning as a substitute for sunbathing.

Design: Randomized controlled trial.

Setting: Public beaches in Massachusetts.

Participants: Women (N=250) were recruited to participate in the study during their visit to a public beach.

Intervention: The intervention included motivational messages to use sunless tanning as an alternative to UV tanning, instructions for proper use of sunless tanning products, attractive images of women with sunless tans, a free trial of a sunless tanning product, skin cancer education, and UV imaging. The control participants completed surveys.

Main Outcome Measures: The primary outcome was sunbathing 2 months and 1 year after the intervention. Secondary outcomes included sunburns, sun protection use, and sunless tanning.

Results: At 2 months, intervention participants reduced their sunbathing significantly more than did controls and reported significantly fewer sunburns and greater use of protective clothing. At 1 year, intervention participants reported significant decreases in sunbathing and increases in sunless tanning relative to control participants but no differences in the other outcomes.

Conclusion: This intervention, which promoted sunless tanning as an alternative to UV tanning, had a short-term effect on sunbathing, sunburns, and use of protective clothing and a longer-term effect on sunbathing and sunless tanning.

Trial Registration: clinicaltrials.gov Identifier: NCT00403377

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RECENTLY, UV RADIATION (UVR) was upgraded to the highest cancer risk category, joining arsenic and mustard gas.1 It is linked to more cancers worldwide than is any other carcinogen.7 Although skin cancer is preventable,3,4 rates of unprotected sun exposure remain high.5 Whereas UVR exposure can be incidental, many people intentionally expose themselves to UVR for tanning. The desire to be tan to improve physical appearance is the strongest predictor of intentional UVR exposure.6-11 People who desire a tan are also the most resistant to sun safety recommendations.12-14 A novel approach to reaching tan seekers is to promote sunless tanning products (ie, fake tanning). Products provide a tan without UVR exposure using a substance called dihydroxyacetone, a colorless vegetable-derived sugar that interacts with dead surface cells in the epidermis to stain the skin.15 Dihydroxyacetone was approved by the US Food and Drug Administration as a color additive for cosmetics in 1973.16 Data on whether sunless tanning is a helpful or harmful sun safety recommendation are scant.17-23 One promising randomized trial observed college students for 1 month after an intervention that included sunless tanning and UV imaging and found significant increases in self-efficacy and intentions to use sunscreen and a nonsignificant trend toward less sunbathing and greater sun protection compared with a control group, suggesting no evidence of harm in promoting sunless tanning.23 The promotion of sunless tanning might have even greater impact in higher-risk populations, such as sunbathers.

The present study extends this research by examining the impact of a beach-based intervention targeting female sunbathers and
promoting sunless tanning as a safe alternative to sunbathing in the context of general sun safety recommendations. The primary goal of this study was to reduce sunbathing 2 months and 1 year after the intervention compared with controls.

A detailed description of the study methods is reported elsewhere. The protocol was approved by the institutional review board at the University of Massachusetts Medical School. Two public beaches in Massachusetts were randomly assigned to the intervention or control condition on 11 days in June and July 2006. Data collection occurred during peak UV hours (11 AM to 4 PM) on weekdays and weekends. Research assistants were given specific instructions to invite sunbathers to participate in a study on sunbathing that required 20 minutes (intervention group) or 10 minutes (control group) to complete. Only female beach visitors (N=250) were invited to participate because the acceptability of sunless tanning in men requires exploration given that most sunless tanners are women. The eligibility criteria included 18 years or older, English speaking, sixth-grade reading level, and willingness to provide 2 or more types of contact information. A total of 479 women were approached, 257 agreed to participate, and 250 were eligible and enrolled (Figure). Typical reasons for refusal included not wanting to be bothered during leisure time, planning to leave the beach shortly, or attending to small children by oneself. Of the 7 participants ineligible at recruitment, 2 were excluded because they were not English speaking, 2 had to leave the beach before completing the surveys, 2 did not provide contact information, and 1 was younger than 18 years. Intervention participants were told that participation would require completing questionnaires, taking a UV photograph, and trying free product samples. Control participants were told that participation would require completing questionnaires. Eligible individuals were escorted to an unmarked study tent where they provided informed consent and completed questionnaires. Intervention participants were given the intervention described in the following subsection, and control participants were given free cosmetic samples (unrelated to skin health), had their picture taken with an instant camera, and were notified that they would be contacted for follow-up.

**SUNLESS INTERVENTION**

Research assistants who were trained in the protocol and use of the UV camera and who were educated about sunless tanning and were users themselves delivered the intervention. They first explained what sunless tanners are and gave written and verbal application instructions and an application demonstration. Participants applied the sunless Tanner on their hand to observe the coloring effect on their skin. They were informed of the benefits of sunless tanning compared with sunbathing and of its safety and limitations (eg, not a source of sun protection), and they viewed sunless tans on female research staff. Participants were strongly encouraged to use sunless tanning instead of sunbathing. Participants also received a pamphlet about skin cancer and had their UV-filtered photograph taken. Photographs taken using a UV-filtered camera reveal melanin deposits on the skin that are invisible to the naked eye. The UV imaging was included to heighten participant's awareness of the sun damage on their skin and to serve as a cue to action to consider sunless tanning as a safe alternative. Participants were informed that the UV camera cannot be used to identify or diagnose a skin condition, including cancer. Participants were given copies of the photographs. Finally, participants were given free samples of sunless tanning lotion and were encouraged to use them for their tanning needs to prevent further sun damage to the skin and reduce their risk of skin cancer. They also received free sunscreen. Ten months later, a UV photograph was mailed to the participant with a reminder to avoid sunbathing in the upcoming summer.

**FOLLOW-UP**

Two months and 1 year after recruitment, participants were contacted by e-mail, telephone, or mail to complete follow-up surveys. Participants received a $10 gift card for completing questionnaires at 2 months and $20 at 1 year. In addition, participants were entered into a lottery to win a $500 gift card for completing each follow-up.

**OUTCOME MEASURES**

**Sunbathing**

The primary outcome was sunbathing. Participants were asked how much time they spent in the sun with the intention of getting a tan in the past 2 months using a 7-point scale ranging from 0 (never) to 7 (every day). Item wording was based on the recommended measurement of sunbathing in community and clinical research. The baseline measure reflects sunbathing in the 2 months previous to the study (May and June), the 2-month follow-up reflects sunbathing in the 2 months after recruitment (July and August), and 1-year follow-up reflects sunbathing in the first 2 months of summer (May and June) 1 year later.

**Sunburns**

Sunburn was assessed as the number of times participants reported a red or painful burn that lasted 1 day or longer in the past 2 months using a 6-point scale from 0 (not at all) to 5 (≥5 times).

**Sunscreen and Other Sun Protection Use**

Participants were asked to respond to a series of questions about how often they applied sunscreen; wore a shirt with sleeves, a
hat, and sunglasses; and stayed in the shade or under an umbrella in the past 2 months. For each item, responses were on a 5-point Likert scale ranging from 0 (never) to 4 (always). Sunscreen and other protection items were examined separately. For the latter, a mean sun protection score was calculated.

Sunless Tanning

Participants read a definition of sunless tanning and then indicated how many times they used sunless tanning products or spray-on tans in the past 2 months and in the past year.

STATISTICAL ANALYSES

The trial was designed to have 80% power at a 5% significance level to test the hypothesized intervention effects at 2 months and 1 year on the primary outcome of sunbathing.

Preliminary Analyses

Independent samples t tests were conducted to examine whether the 2 groups were significantly different regarding age ($t_{110} = -3.13, P = .002$) and skin type ($t_{110} = -0.17, P = .86$). The control group was significantly younger (mean [SD] = 28.79 [10.89] years) than the intervention group (mean [SD] = 33.62 [13.29] years). Age was included as a covariate in all the analyses. Tests revealed no differences in education ($\chi^2 = 2.13, P = .13$) or ethnicity ($\chi^2 = 5.24, P = .39$).

Analytic Plan

Intent-to-treat analyses were used for all outcome variables. Mixed-effects regression modeling, implemented via PROC MIXED (SAS Inc, Cary, North Carolina), which incorporated a random intercept trend and the unstructured covariance as the covariance structure, was used to analyze the continuous outcomes. Generalized linear mixed models, implemented using PROC GLIMMIX (SAS Inc.), which incorporated a random intercept trend and a Poisson distribution, were used to analyze sunless tanning. These analytic approaches include all the participants who have data on at least one time point, which was true for all the randomized cases. For sunbathing, sunburns, sunscreen use, and protective clothing use, all the baseline and follow-up variables used a 2-month time frame that reflects summer months only. One model containing all 3 time points (baseline, 2 months, and 1 year) was run for each dependent variable. Time was dummy coded into 2 variables (baseline and 2 months, baseline and 1 year). Fixed effects included the 2 time variables, the main effect of group, and each time × group interaction to examine whether the intervention condition resulted in greater change than in the control group at 2-month and 1-year follow-ups. Age and beach were included as covariates in the analyses.

Sunless tanning was assessed in 2 ways at baseline: sunless tanning use in the past 2 months and in the past year. Thus, separate models were conducted for the baseline vs 2-month follow-up comparison and for the baseline vs 1-year follow-up comparison for the sunless tanning outcome. Fixed effects included the time effect, the main effect of group, and the time × group interaction to examine whether the intervention group resulted in greater change than the control group at 2-month and 1-year follow-ups. Age and beach were included as covariates in the analyses.

Missing values were treated as missing in the analysis. At 2-month follow-up, 71% of control participants and 82% and 81% of intervention participants had complete data for sunbathing and sunless tanning, respectively. For sunburns, sunscreen use, and protective clothing use, 61% of controls and 77% of intervention participants had complete data. The sunbathing and sunless tanning variables had more complete data because participants who did not complete follow-up surveys after 6 attempts were asked to complete at least these 2 items. All other missing data occurred due to participants skipping items or not returning surveys.

At 1-year follow-up, 62% of control participants and 69% and 70% of intervention participants had complete data for sunbathing and sunless tanning, respectively. For sunburns, sunscreen use, and sun protection use, 60% to 62% of control participants and 68% to 69% of intervention participants had complete data. At 1-year follow-up, participants who did not complete the follow-up surveys after 6 attempts were asked to complete the sunbathing and sunless variables.

RESULTS

Participants had a mean (SD) age of 31.21 (12.36) years. Most participants were white (88.7%), and many (35.3%) completed some college (Table 1).

SUNBATHING

Analyses revealed a significant time × group interaction on sunbathing at 2 months ($t = -2.13, P = .03$) such that participants in the intervention group reported a 33% decrease in sunbathing ($t = -5.12, P < .001$) compared with 10% decrease in the control group ($t = -2.28, P = .02; Cohen d = 0.32$) (Table 2 and Table 3). At 1 year, the time × group interaction was also significant ($t = -2.32, P = .02$). Intervention participants reported a greater decrease in

<table>
<thead>
<tr>
<th>Table 1. Demographics of the 250 Study Participants by Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variable</strong></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
</tr>
<tr>
<td>Ethnicity, No. (%)</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>American Indian</td>
</tr>
<tr>
<td>Multiracial</td>
</tr>
<tr>
<td>Education, No. (%)</td>
</tr>
<tr>
<td>Less than a college degree</td>
</tr>
<tr>
<td>College degree</td>
</tr>
<tr>
<td>Graduate degree</td>
</tr>
<tr>
<td>Skin type, No. (%)</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>Family history of skin cancer, No. (%)</td>
</tr>
<tr>
<td>Personal history of skin cancer, No. (%)</td>
</tr>
</tbody>
</table>

a P < .05.
b Twelve participants (4.8%) were missing ethnicity data.
c Six participants (2.4%) were missing education data.
d Skin type is classified using the Fitzpatrick phototyping scale where 1 indicates never tans, always burns; 2, sometimes tans, usually burns; 3, usually tans, sometimes burns; and 4, always tans, never burns.
sunbathing ($t = -5.07, P < .001$) compared with control participants ($t = -2.47, P = .01; \text{Cohen} d = 0.32$).

### SUNBURNs

The time $\times$ group interaction was significant for sunburns at 2 months ($t = -2.01; P = .04$). Sunburn scores in the intervention group reduced by 73% across time ($t = -5.51; P < .001$) compared with 37% in the control group ($t = -2.48; P = .01; \text{Cohen} d = 0.31$) (Tables 2 and 3). At 1 year, the interaction was not significant ($t = -0.24; P = .81$), but participants in both groups reported fewer burns at 1 year relative to baseline ($t = -2.57, P < .01$).

### PROTECTIVE CLOTHING USE

The time $\times$ group interaction was significant for protective clothing use at 2 months ($t = 2.15, P = .03$) such that the intervention group reported a 32% increase in protective clothing use ($t = 2.39; P = 0.02$) relative to a 2% increase in the control group ($t = -0.69, P = .49; \text{Cohen} d = 0.37$) (Tables 2 and 3). At 1 year, the interaction was not significant ($t = -0.50; P = .61$), but protective clothing use increased across time for all the participants ($t = 2.13; P = .03$).

### SUNSCREEN USE

The time $\times$ group interaction did not significantly predict sunscreen use at 2 months ($t = 1.18; P = .24$) or at 1 year ($t = 0.88; P = .38$). However, sunscreen use decreased across time in the groups at 2 months ($t = -2.32; P = .02$) but did not change at 1 year ($t = 0.94, P = .35$).

### SUNLESS TANNING

The time $\times$ group interaction was not significant for sunless tanning at 2 months ($t = -1.08, P = .28$) but was significant at 1 year ($t = 5.31, P < .001$) such that participants in the intervention group significantly increased their total annual use of sunless tanning by an average of 8.40 uses ($t = 14.26, P < .001$) compared with the control group, which increased their total annual use by 3.56 uses ($t = 2.92, P = .005$).

**Very few unhealthy behaviors have healthy desirable alternatives.** Sunless tanning is a risk-free alternative to sunbathing, but it has not been well studied in the context of skin cancer prevention. The present results reveal that an intervention that promoted sunless tanning led to short- and long-term behavior change. Sunbathers exposed to the intervention in the middle of summer reported declines in sunbathing and sunburns and increased use of protective clothing during the rest of the summer compared with their counterparts who only completed questionnaires. One year after the intervention, effects were maintained for sunbathing. Use of sunless tanning during the year after the intervention increased significantly more in the intervention group compared with those in the control group.

Nearly half of the intervention participants (48%) had used sunless tanning at least once before the study. Another 9% of intervention participants newly adopted sunless tanning at 2 months and approximately 6% at 1 year. Of the intervention participants who tried sunless tanning for the first time 2 months and 1 year after the intervention, most (64% and 75%, respectively) used it more than once, suggesting that many who tried sunless tanning as a result of the study adopted it as a habit. Further investigation is merited to determine what aspect or aspects of the intervention generated the observed effects. Sunless tanning was promoted in an intervention that provided skin cancer education and UV imaging. Although education and UV imaging affect knowledge and inten-

### COMMENT

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### Table 2. Unadjusted Baseline, 2-Month, and 1-Year Follow-up Data for the Primary and Secondary Outcomesa

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>2 mo</th>
<th>1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
</tr>
<tr>
<td>Sunbathingb</td>
<td>4.12 (2.57)</td>
<td>4.46 (2.13)</td>
<td>2.77 (2.6)</td>
</tr>
<tr>
<td>Sunburnsc</td>
<td>0.74 (1.06)</td>
<td>0.71 (0.80)</td>
<td>0.20 (0.50)</td>
</tr>
<tr>
<td>Protective clothing used</td>
<td>1.77 (0.87)</td>
<td>1.62 (0.78)</td>
<td>2.34 (1.33)</td>
</tr>
<tr>
<td>Sunscreen used</td>
<td>2.41 (1.34)</td>
<td>2.41 (1.34)</td>
<td>1.94 (0.80)</td>
</tr>
<tr>
<td>Sunless tanning</td>
<td>7.50 (19.23)</td>
<td>4.52 (10.34)</td>
<td>…</td>
</tr>
</tbody>
</table>

*Abbreviation: Ellipsis, no comparable measure for that time point.

a Data are given as mean (SD).

b 0 indicates never; 1, rarely; 2, sometimes; 3, often; and 4, always.

c 0 indicates none; 1, 1; 2, 2; 3, 3; 4, 4; and 5, 5 or more.

d 0 indicates never; 1, once; 2, twice; 3, once a week; 4, twice a week; 5, 3 to 5 times a week; and 6, every day.

### Table 3. Results of the Multivariate Analyses for the Significant Time $\times$ Condition Interactions for the Primary and Secondary Outcomes in 250 Study Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Estimate (SE)</th>
<th>t</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunbathing, 2 mo</td>
<td>-0.22 (0.09)</td>
<td>2.38</td>
<td>.02</td>
</tr>
<tr>
<td>Sunbathing, 1 y</td>
<td>-0.68 (0.34)</td>
<td>-2.00</td>
<td>.04</td>
</tr>
<tr>
<td>Sunburns, 2 mo</td>
<td>-0.29 (0.14)</td>
<td>-2.01</td>
<td>.04</td>
</tr>
<tr>
<td>Protective clothing use, 2 mo</td>
<td>0.22 (0.09)</td>
<td>2.38</td>
<td>.02</td>
</tr>
<tr>
<td>Sunless tanning</td>
<td>0.45 (0.08)</td>
<td>5.31</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

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First adopters of sunless tanning are users of other tanning methods, such as UV tanning booth visits. These data suggest that sunbathing, whereas only 7% reported having increased their UV tanning booth visits since they began sunless tanning, whereas 73% reported that they had decreased their UV tanning booth visits because of concerns that it might inadvertently rein force the misconception that people can tan “safely.” Future research should examine which prevention messages reduce sunbathing and which increase sun protection use.

Results of the present study suggest that sun safety recommendations have the greatest impact during the season in which they are delivered. At 1 year, the intervention effect on sunbathing remained significant but effects on secondary outcomes did not. Participants in both groups significantly reduced their sunburns and increased their use of protective clothing at 1 year, which could suggest a social desirability bias in survey responses, an intervention effect of surveys, or that people in this region are exhibiting a trend toward healthier habits across time. Regardless, recurrent sun safety messages may be necessary to reinforce the effect on behavior. The present study also suggests that health messages received in the environments in which people sunbath can help deter future sunbathing.

Physicians might be reluctant to recommend sunless tanning due to concerns that it might inadvertently reinforce the patient’s desire to be tan. The literature is limited but does not seem to support this contention. Although 1 cross-sectional study found that people who use sunless tanning products report more indoor tanning and sunburns than do nonusers, this is probably because first adopters of sunless tanning are users of other forms of tanning. Several studies in the United States and Australia have found that sunless tanners have higher rates of sunscreen use, which suggests that sunless tanning may cluster with other sun safety behaviors. The extent to which the use of sunless tanning offsets a previously existing tanning habit has been explored in only 1 study. Nearly three-quarters of people receiving a sunless spray tan (73%) reported that they had decreased their UV tanning booth visits since they began sunless tanning, whereas only 7% reported having increased their UV tanning booth visits. These data suggest that sunless tanning might be associated with declining UVR tanning, which is a promising trend on which to capitalize in skin cancer prevention efforts. The present study also suggests that health messages received in the environments in which people sunbath can help deter future sunbathing.

The present study had some limitations. The refusal rate was 46%, which could have contributed to selection bias. Because sunless tanning was not specifically mentioned when participants were invited to participate, refusal would not have been related to attitudes about sunless tanning. Also possibly contributing to selection bias is that randomization occurred by beach instead of by individual. Individual randomization is not feasible in this setting given multiple entrances and the transient nature of beach patrons. Because of the possibility of selection bias, we explored baseline differences in demographic variables. Age was significantly different between groups and was consequently entered as a covariate in all the analyses. Another limitation is that all the measures were self-reported, which may be subject to underreporting due to social desirability bias. Self-report measures are typically used in studies of sun-related behavior because few practical, objective measures exist for large samples and because follow-up could not be conducted in person. Items used in the present study have recently been put forth as the standard in sun exposure and sun protection measurement.

Effect sizes were fairly small. The intervention was a brief, 1-shot, inexpensive approach to behavior change in the very setting in which high-risk behavior occurs. Results of the present study suggest that future studies that increase the intensity and length of the intervention are merited.

Loss to follow-up differed by group. The follow-up rate at 1 year was 66%, which is comparable with the 70% follow-up rate reported in the only other beach-based intervention study to observe participants for 1-year or longer. A systematic review revealed that two-thirds of skin cancer prevention studies observe participants for 6 weeks or less and that more than half observe participants for less than 3 months. The present study extends the literature by examining the maintenance of intervention effects during the following summer. A marginally significant difference between study groups was apparent for missing data on the primary outcome at 2-month follow-up (χ² = 3.75, P = .05) such that more control participants had missing data (28.8%) than did intervention participants (18.4%) but not at 1-year follow-up (χ² = 1.77, P = .18). This transient difference in missing data between groups perhaps resulted from intervention participants receiving more personalized attention than control participants, which may have increased their sense of obligation to follow-up. Finally, although dihydroxyacetone, the active ingredient in sunless tanning products, has been US Food and Drug Administration approved for cosmetic use since 1973 and has received reports of rashes only, studies of the safety of long-term use are lacking. One study in 2004 revealed that dihydroxyacetone led to DNA damage in cultured keratinocytes, but it remains unknown whether dihydroxyacetone induces the same effect in the human epidermis. Sunless tanning is the only safe means of tanning. Encouraging sunbathers to switch to sunless tanning could have an important health impact, but sunless tanning has been considered a cosmetic more so than a health care tool. These findings have implications for public health and clinical efforts to prevent skin cancer.
moting sunless tanning to sunbathers in the context of a skin cancer prevention public health message may be helpful in reducing sunbathing and sunburns and in promoting the use of protective clothing. Future research should determine how to further convince tanners to switch to sunless tanning. Physicians should encourage patients who sunbathe to consider safe alternatives, such as sunless tanning. Finally, reinforcing sun safety messages every season is likely to be necessary to maximize the impact of the message.

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Author Contributions: Dr Pagoto had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Pagoto. Acquisition of data: Pagoto, Oleski, and Bodenlos. Analysis and interpretation of data: Pagoto, Schneider, Bodenlos, and Ma. Drafting of the manuscript: Pagoto, Schneider, Oleski, and Bodenlos. Critical revision of the manuscript for important intellectual content: Pagoto, Schneider, Oleski, Bodenlos, and Ma. Statistical analysis: Pagoto, Schneider, Bodenlos, and Ma. Obtained funding: Pagoto. Administrative, technical, and material support: Pagoto and Bodenlos. Study supervision: Pagoto and Oleski.

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REFERENCES