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# A Randomized Controlled Trial of a Mobile Medical App for Kidney Transplant Recipients: Effect on Use of Sun Protection

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**Background.** Perception of skin cancer risk, belief that sun protection prevents skin cancer, and having sun protection choices enhance sun protection behaviors by kidney transplant recipients, who are at greater risk of developing skin cancer than the general population. **Methods.** A randomized controlled trial used stratified recruitment of non-Hispanic white, non-Hispanic black, and Hispanic/Latino kidney transplant recipients, who received a transplant 2 to 24 months before the study. The same culturally sensitive SunProtect program was delivered to all recipients with tablet personal computers in 2 urban ambulatory offices. Text messages reminders were provided at 2-week intervals. Self-reported surveys and skin pigmentation measured before the intervention and 6 weeks later were analyzed. **Results.** Among 552 eligible participants, 170 participated (62 non-Hispanic whites, 60 blacks, and 48 Hispanics). Among participants receiving the intervention with skin that burns after sun exposure and becomes tan or becomes irritated and gets darker, there was a statistically significant increase in self-reported knowledge, recognition of personal skin cancer risk, confidence in sun protection preventing skin cancer, and sun protection behaviors in participants compared with those receiving usual education ( $P < 0.05$ ). At the 6-week follow-up, participants in the intervention group with skin that burns or becomes irritated had significantly less darkening of the sun-exposed forearm than control participants ( $P < 0.05$ ). **Conclusions.** Providing sun protection education with SunProtect in the spring with reminders during the summer facilitated adoption of sun protection behaviors among kidney transplant recipients with skin that burns or becomes irritated.

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More than 180 000 extant kidney transplant recipients (KTRs) in the United States are at risk to develop skin cancer, especially squamous cell carcinoma (SCC).<sup>1,2</sup> In KTRs, the risk of developing SCC is 100 times, and risk in melanoma is 2.4 times that of the general population.<sup>3</sup> Kidney transplant recipients with skin that easily sunburns have the greatest risk of developing SCC with 19% developing SCC in 4 to 9 years posttransplant; however, SCC also occurs in 5% of patients with darker skin tones which becomes irritated after sun exposure.<sup>4,5</sup>

Education concerning the importance of protection from ultraviolet radiation (UVR) for all KTRs is necessary to prevent skin cancer. Sun protection counseling offers the following choices: (a) restricting outdoor exposure between 10 AM and 4 PM whenever possible, (b) seeking shade when outdoors from 10 AM to 4 PM, (c) wearing protective clothing (hats, long sleeved shirts, long pants, and sunglasses), and/or (d) applying broad-spectrum sunscreen with a sun protection factor of at least 30 on exposed skin.<sup>6</sup> The risk of developing skin cancer can be ameliorated by effective sun protection. Organ transplant recipients randomized to receive sunscreen for daily application to sun-exposed areas demonstrated marked reduction in the development of SCC over 2 years ( $P < 0.01$ ).<sup>7</sup>

In our previous formative research, KTRs read about sun protection in a print workbook at the time of the visit with the doctor and took it home to serve as a reference.<sup>8</sup> The core

workbook content was elaborated upon and developed into an interactive English or Spanish culturally sensitive, mobile medical app sun protection educational program, SunProtect, delivered with a tablet personal computer (tablet) with audio narration of text and videos that extends sun protection education across the health literacy spectrum of participants.<sup>9,10</sup> The primary aim was to assess the effect of the intervention by comparing change in KTRs' sun protection behaviors over the course of the summer in those receiving the educational intervention with those receiving customary sun protection education. A secondary aim was examining the influence of the participants' skin type, for example, ease of burning and tanning or getting irritated and darker after sun exposure, on adoption of sun protection behaviors.

## MATERIALS AND METHODS

### Educational Sun Protection App

The theoretical framework guiding development of the educational tablet program was the Theory of Reasoned Action and Planned Behavior.<sup>11</sup> The mobile app content of SunProtect, in both English and Spanish, was modeled directly after the print workbook.<sup>8</sup> The 39 screens of SunProtect were displayed on a touch screen Samsung Galaxy Tab 2 10.1. At the beginning of the app, participants selected the program in English or Spanish with or without audio narration. The educational content was presented in easily understood terms through multiple interactive media, including audio, video, pictorial, and textual information written below a sixth grade reading level. Eight chapters presented the following topics: Why protect against the sun? What is skin cancer? What is the chance of a KTR getting skin cancer? How do people get sun exposure? ABC rule for sun protection, frequently asked questions about sunscreen, and personal recommendations for you from the doctor. Each screen had graphics or images, for example, skin cancer occurring in non-Hispanic white (white), non-Hispanic black (black), and Hispanic/Latino (Hispanic) KTRs.<sup>10</sup> Audio testimonials from KTRs recounted their experiences in the sun, and videos demonstrated effective sun protection strategies. Recipients engaged in 2 interactive quizzes with answers provided to reinforce recognition of skin cancer and the amount of sunscreen needed to cover the body. Recipients selected their usual activities with daily sun exposure and their customary sun protective behaviors. Recipient responses were incorporated in a tailored sun protection message that was given to the user at the end of the program. SunProtect was created in collaboration with the Center for Behavioral Intervention Technologies at Northwestern University.

### KTR Sample and Recruitment

Recipients were eligible to participate if they: (1) had a history of kidney transplantation within the past 2 to 24 months; (2) spoke and read English or Spanish; (3) were between the ages of 18 and 85 years old; (4) could see to read a newspaper; (5) lived in the greater Chicago area; and (6) self-identified as white, black, or Hispanic. Recipients were excluded from the study if they had a previous history of skin cancer as self-reported or noted in their medical record, received education about sun protection or participated in our previous educational sun protection study, experienced kidney rejection, if

they were visually impaired, or comorbid diseases prevented participation.

Recruitment for the randomized control trial was performed at Northwestern Medicine (NM) and the University of Illinois Hospital and Health Sciences System (UIC). At NM, a list of adult KTRs was created from a database of patients who had received a kidney transplant within the past 2 to 24 months. At NM, 3 letters were mailed to potentially eligible subjects explaining the research study and inquiring about their interest in participation. Two weeks after mailing each letter, research coordinators called recipients to inquire about their interest in the study. At UIC, the research coordinator identified potential participants from nephrology appointments in the previous year. The potential UIC recipients were called to inquire about their interest in the study. Accrual was purposefully stratified to obtain representation of all 3 ethnic/racial groups in both arms of the study (control vs intervention).

### Design

From May 30 to July 15, 2014, participants were randomized either to receive SunProtect, the educational intervention, or usual education (control). Customary sun protection education consisted of 2 to 3 sentences in the binder provided at the time of transplant surgery, and during the summer, some clinicians gave verbal reminders to wear sunscreen. During the participant's baseline visit, 1 of 4 research coordinators—1 Hispanic woman, 1 Hispanic man, 1 white woman, and 1 black woman—reviewed the informed consent with the participant. The research coordinators gave participants a brief tutorial about operating the tablet, which was used to obtain baseline measures before randomization. Randomization was performed using stratified random blocks using R Core Team<sup>12</sup> to assure equal allocation to groups over the accrual period, in total, as well as within ethnic/racial groups. The research assistants were available to assist if the program failed to launch and to observe the participants as they used the tablet in the doctor's office. The duration of program use was recorded by the program, which made it possible to assess compliance with use of the program.<sup>10</sup>

During the next 5 weeks, 2 reminders were provided to intervention group participants as telephone calls, text messages, or email messages depending on the participant's preference. Control and intervention participants received reminders about the upcoming visit.

The follow-up visit was scheduled 6 weeks after the baseline visit. Participants received US \$30 gift cards after completing the baseline visit and US \$50 gift cards after the follow-up visit in appreciation of their time. The Institutional Review Boards of Northwestern University and UIC approved the study, and written informed consent was provided by all participants.

### Measures

Participants completed the same self-reported survey in either English or Spanish at the baseline survey and 6 weeks later. At baseline, participants also responded to demographic questions and health literacy items. At both baseline and follow-up, the validated self-reported measures<sup>8</sup> assessed: (a) knowledge of skin cancer and sun protection (10 items; range, 1-10), (b) concern about developing skin cancer (2 items; range, 1-10), (c) recognizing personal skin cancer risk (1 item;

range, 1-5), (d) confidence in sun protection preventing skin cancer (2 items; range, 2-10), importance of and confidence in using regular sun protection behavior (10 items; range, 10-50), (e) willingness to change use of sun protection (20 items; range, 20-100), (f) use of sun protection (sunscreen, shirt, sunglasses, and shade) (20 items; range, 20-100), (g) painful sunburn or skin irritation from the sun in the prior week (2 items; range, 1-10), and (h) daily hours outdoors (1 item; range, 0.5-6 hours). The higher score in knowledge, attitudes, and behavior items (items a-f) indicated better knowledge, attitudes, and sun protection behavior. For the number of sunburns or skin irritation and daily hours outdoors (items g and h), the lower number indicated better protection.

At baseline, the following demographic information was obtained: race/ethnicity, sex, age, marital status, skin type (ease of sunburn/skin irritation and tanning/getting darker after sun exposure, which are grouped into categories I, II-IV, V-VI), education, annual household income, months since transplant, and history of sun-related work.

At each visit (preintervention and postintervention), the melanin index, a measure of skin pigmentation, was obtained in the following locations: (1) right forearm in sun exposed skin; (2) right midcheek below the cheekbone in sun exposed skin; and (3) right upper inner arm in sun protected skin, which was the natural or constitutive skin tone. Noninvasive skin pigmentation measurements were taken using a spectrophotometer, using the area under the intensity curve along the 450- to 615-nm wavelength interval of reflected light having a range of 1 to 1000 with the lower range associated with light skin color and higher range with dark skin color. (Mexameter MX18 probe, Corage + Khazaka Electronic GmbH, Koln, Germany). In addition, a clinical dermatologist trained 2 research coordinators, who were blinded to the participants' study group, to assess the chronic sun damage on each participant's left forearm by comparing it with clinical images of chronic sun damage (range, 1-10) (inter-rater agreement,  $\kappa$ , 0.76) and select a score for the sun damage.<sup>13</sup> The 2 biologic measures provided an objective assessment of sun protection.

### Ambient Sunlight

The daily ultraviolet index (UVI) for Chicago, IL, was obtained from the National Weather Service Climate Prediction Center's archived database.<sup>14</sup> The UVI was based on a scale from 0 to 11, according to increasing levels of ultraviolet radiation exposure from the sun. Ultraviolet radiation is measured as low (UVI  $\leq$  2), moderate (UVI = 3-4), high (UVI = 6-7), very high (UVI = 8-10), and extreme (UVI = 11-12).

### Statistical Analysis and Sample Size

The power analysis was based on the use of sun protection, our primary outcome. The sample size required to sensitively detect a 30% difference in using sun protection between the 3 ethnic/racial groups was 180 (60 in each group completing the study), assuming an  $\alpha < 0.05$  and power  $> 0.8$  in a 2-tailed test. Attrition was estimated at 20% with  $N = 60$  per group, the effect size was 20 with 95% confidence of  $\pm 1\%$  to 39%.

Demographics, baseline outcome measures, and change in outcomes were compared between groups using  $\chi^2$  tests of association and Wilcoxon Rank Sum tests. Because a

biological outcome measure was pigment darkening as measured by spectrophotometer, participants with similar constitutive ability to have their skin get darker in response to sunlight were grouped together.<sup>15</sup> Summary statistics are presented as counts and percentages, or median (25th percentile, 75th percentile) and (minimum, maximum) as appropriate. All analyses were run at a nominal type I error rate of 5% and performed in SASv9.2 (Cary, NC).

## RESULTS

### Demographics

Among the 552 eligible KTRs, 170 participants were accrued to the study (32% participation rate). Stratified recruitment had an 86% (62/72) participation rate among whites, 34% (60/177) participation rate among blacks, and 26% (48/185) participation rate among Hispanics. The most common reason for nonparticipation was travel was too far or difficult (32%, 113/352) (Figure 1). Refusal to participate for lack of interest (52 blacks, 47 Hispanics, 10 whites), the study location being too far away or travel too difficult (65 blacks, 48 Hispanics), or time constraints (27 blacks, 40 Hispanics) was more common among minorities. Participants failing to complete the 6-week follow-up visit ( $n = 9$ , 5.2% attrition) were excluded from the analyses.

There were no significant demographic differences between the educational intervention and standard of care groups in terms of race/ethnicity, sex, age, marital status, education, household income, time since transplantation, skin type, and work-related sun exposure (Table 1).

### Program Use

All participants were observed using the program. The mean duration of program use recorded on the program counter was 27.5 minutes. Whites had the shortest use at 23 minutes, and Hispanic/Latinos had the longest at 42 minutes. Chapters with at least 1 repetition of content in descending order of frequency were: frequently asked questions (86%), skin cancer (85%), risks of developing skin cancer in KTRs versus the general population (84%), video of sunscreen application (52%), and pictures of sunburn/skin irritation from the sun (47%).

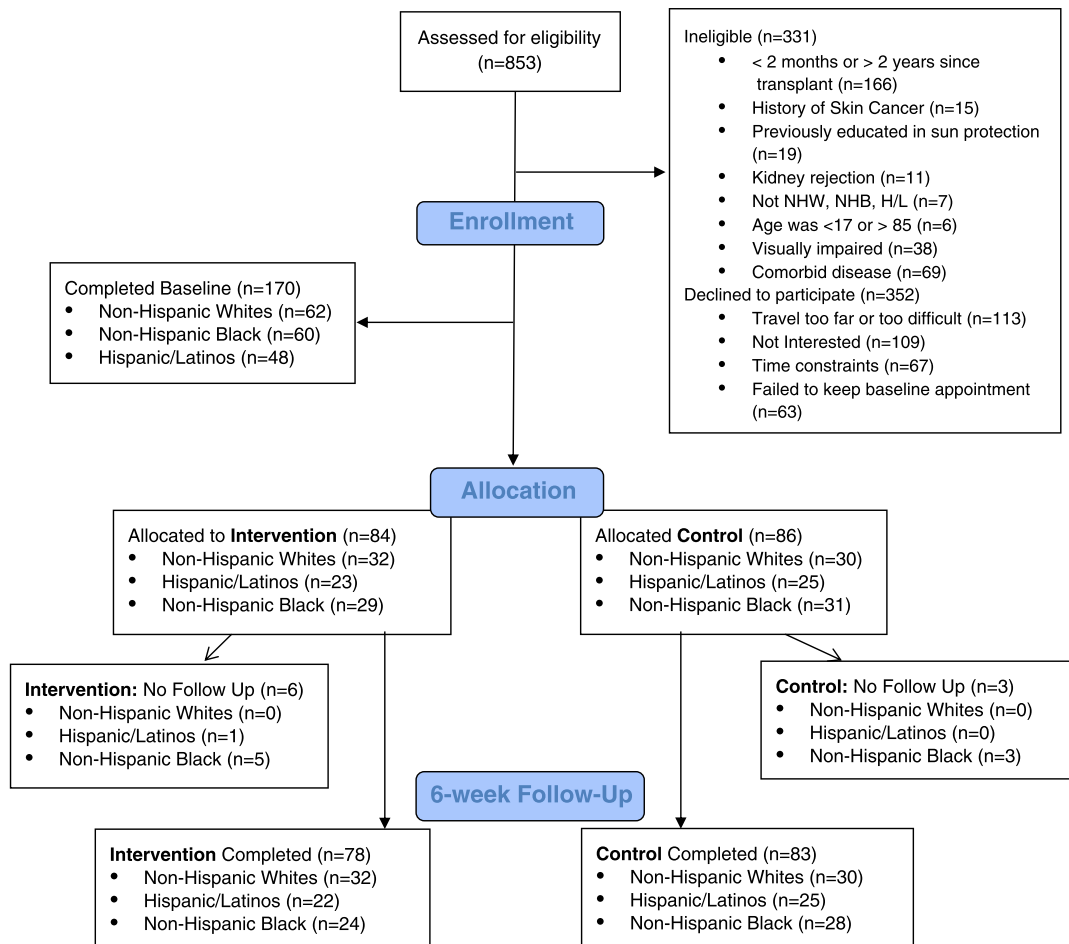
### Ambient Sunlight

The median daily UVI for May was 5.9; June, 7.4; July, 7.5; and August, 7.0. Days in a month with UVI 3 or less (not able to burn the skin) were 3 days in May, 1 day in June, 1 day in July, and none in August.

### Knowledge, Attitudes, and Sun Protection Behavior

At baseline, there were no significant differences between the educational intervention and standard of care groups in self-reported measures of knowledge about skin cancer, concern about getting skin cancer, confidence in engaging in sun protection behavior to prevent skin cancer, willingness to change sun protective behaviors, and sun protection behavior (Table 2). Sunburn (29%) or skin irritation (17%) from sun exposure occurred without significant differences between the groups (Table 2). There was no difference in the biologic measures of pigmentation and sun damage of the forearm between the 2 groups.

From baseline to the 6-week follow-up, there were statistically significant increases in knowledge, concern about



**FIGURE 1.** Consolidated Standards of Reporting Trials diagram of enrollment, randomization and completion.

developing skin cancer, recognition of personal risk of developing skin cancer, confidence in sun protection preventing skin cancer, and willingness to change behavior in the intervention group compared with the standard of care group ( $P < 0.05$ , Wilcoxon rank sum test) (Table 3). The increase in knowledge by KTRs with skin types II to IV (skin with some sunburn/skin irritation and the ability to tan or get darker after sun exposure) was significantly greater than the increase in knowledge by those with skin types I and V to VI ( $P < 0.05$ ).

Sun protection behaviors were statistically significantly increased in the intervention group compared with controls ( $P < 0.001$ , Wilcoxon rank sum test) (Table 3). The preferred method of sun protection differed by racial/ethnic group with Hispanic and Black KTRs wearing protective clothing, especially long sleeved shirts, and White KTRs using sunscreen ( $P = 0.05$ , Wilcoxon rank sum test, data not shown). From baseline to 6 weeks later, the number of sunburns or skin irritation from the sun reported in the previous week in the intervention group decreased; however, statistical significance was only achieved in those with skin types II to IV.

Intervention group participants with skin types I to IV reported significant reductions in their average daily sun exposure compared with the control group and those with skin types II to IV reduced sun exposure from 3.7 hours a day to 2.4 hours a day ( $P < 0.001$ , Wilcoxon rank sum tests). By contrast, during the 6 weeks of the study, control group

participants with the equivalent skin types increased their average daily sun exposure. Hispanic/Latino intervention group participants reduced the hours of outdoor activities and black intervention group participants sought shade ( $P = 0.05$ , Wilcoxon rank sum test, data not shown).

### Biologic Measures of Sun Protection

From baseline to the 6-week follow-up, the KTRs with skin types II to IV in the control group had significantly greater darkening of the sun exposed right forearm skin by spectrophotometry than the intervention group ( $P \leq 0.01$ ) (Table 3). There was also a significant difference between the 2 groups among those with skin types II to IV in pigmentation change in the midcheek, which may have been sun protected by wearing a broad brimmed hat or sunscreen. There was no significant difference in the chronic sun damage assessment of the forearm.

### DISCUSSION

This study assessed the effectiveness of a culturally sensitive, mobile medical app to increase knowledge of skin cancer and sun protection, attitudes about the importance of skin cancer and sun protection, recognition of personal risk of developing skin cancer, willingness to change sun protection behavior, and use of sun protection. The primary finding was that KTRs, who used SunProtect, improved their knowledge, concern about getting skin cancer, recognition

**TABLE 1.**  
**Participant demographics (n = 170)**

Characteristics	Intervention: n (n = 84)	Standard of care: n (n = 86)	P <sup>a</sup>
Non-Hispanic white	32 (38%)	30 (35%)	0.183
Hispanic/Latino	23 (27%)	25 (29%)	
Non-Hispanic black	29 (35%)	31 (36%)	
Male	45 (56%)	56 (62%)	0.376
Age: mean (SD), y	51.0 (12.5)	49.0 (14.2)	0.334
Married	49 (60%)	41 (46%)	0.060
Skin type (ease of sun burn/skin irritation)			0.145
I—always sunburn	3 (3%)	2 (2%)	
II, III, IV—some sunburn/skin irritation V, VI—rarely/never	56 (66%)	58 (67%)	
Sunburn/skin irritation	25 (30%)	26 (30%)	
College education or higher	37 (46%)	30 (33%)	0.099
Annual household income			0.648
<10 000	16 (20%)	14 (16%)	
10 000-19 999	12 (14%)	13 (15%)	
20 000-34 999	14 (16%)	13 (15%)	
35 000-50 999	18 (22%)	14 (16%)	
51 000-100 000	13 (15%)	22 (26%)	
>100 000	11 (13%)	10 (12%)	
Months since transplant: mean (SD)	17.3 (15.1)	18.0 (15.3)	0.733
Work-related sun exposure	35 (43%)	38 (42%)	0.896

of the personal risk of getting skin cancer, confidence in sun protection preventing skin cancer, and willingness to change sun protection. A secondary finding was that KTRs

with skin types that have sunburn/skin irritation from the sun and can tan or get darker after sun exposure (II-IV) changed their use of sun protection after receiving the educational program and reduced the number of sunburns/skin irritation in the prior week and the daily number of hours outdoors.

A threshold UVI of 3 or more was exceeded on 118 of 123 days of this study; therefore, there was sufficient ambient sunlight to darken skin.<sup>16</sup> Forearm skin pigmentation was significantly reduced in the intervention group with skin types II-IV, which confirms the self-reported increase in participants' use of sun protection. Forearm pigmentation did not achieve a significant difference between the intervention and control groups for those with skin types V to VI. Sun exposure was restricted in this low income urban group of black KTRs, who had less than 1 hour of daily sun exposure. In comparison, in the general US adult population the norm for outdoor exposure is 2.4 hours per day.<sup>17</sup> At baseline, 24% of KTRs in this study reported sunburn and an additional 17% reported irritation of the skin after sun exposure. Thus, the 41% of KTRs in this study with skin reacting to the sun was comparable to the general US population in which 42% of white adults, with a subset of the white adults who self-identify as Hispanic (20%), sustaining at least 1 sunburn annually.<sup>18</sup> Although black and Hispanic KTRs have greater photoprotection due to their increased epidermal melanin, there are individuals in these groups who have sun sensitivity which is a risk factor for skin cancer.

Sun sensitivity, which in whites is expressed as sunburn with the skin becoming pink or red after exposure to 1 hour of noonday sun without using sunscreen may be expressed in people with skin of color (Hispanics and blacks) as skin irritation after sun exposure.<sup>19,20</sup> Race/ethnicity is a

**TABLE 2.**  
**Knowledge, attitudes, sun protection behavior, melanin index, and sun damage (n = 170)**

Baseline	Intervention Median (25th, 75th percentile) [range]	Standard of care (control) median (25th, 75th percentile) [range]	Wilcoxon rank sum P
Self-reported measures	(n = 84)	(n = 86)	
Knowledge score	6 (4, 7) [1, 10]	6 (3, 7) [1, 10]	0.597
Attitude score	21 (20, 25) [16, 85]	25 (22, 30) [16, 85]	0.307
Concern about skin cancer	2 (1, 3) [1, 10]	3 (2, 5) [1, 10]	0.092
Recognize personal skin cancer risk	2 (1, 3) [1, 5]	3 (2, 5) [1, 5]	0.697
Confidence in sun protection preventing skin cancer	4 (3, 6) [2, 10]	5 (3, 7) [2, 10]	0.580
Confidence in using and importance of regular sun protection behavior	17 (14, 25) [12, 60]	75 (60, 85) [12, 60]	0.569
Willingness to change sun protection	65 (54, 81) [20, 100]	67 (54, 81) [20, 100]	0.775
Sun protection score	50 (40, 60) [20, 100]	51 (39, 62) [20, 100]	0.890
Sunburn			0.339
None	69 (82%)	77 (89%)	
One or more	15 (18%)	9 (11%)	
Skin irritation from sun			0.123
None	77 (92%)	78 (91%)	
One or more	7 (8%)	8 (9%)	
Daily hours outdoors	3.2 (3, 5) [0.5-6 hrs]	2.9 (2, 5) [0.5-6 hrs]	
Biologic measures			
Melanin index			
Right upper inner arm (sun protected)	194 (143, 351) [1, 1000]	220 (165, 505) [1, 1000]	0.076
Right forearm (sun exposed)	360 (260, 514) [1, 1000]	405 (290, 707) [1, 1000]	0.098
Cheek	252 (201, 475) [1, 1000]	300 (219, 743) [1, 1000]	0.062
Sun damage assessment forearm	4 (2, 6) [1, 10]	3 (2, 5) [1, 10]	0.061



Right forearm (sun exposed)									
Pretest	141 (65)	135 (24)	369 (122)	375 (120)	688 (120)	655 (230)	0.01 <sup>a</sup>		
Posttest	145 (69)	138 (46)	345 (101)	489 (210)	667 (116)	670 (275)	(II, III, IV)		
Cheek									
Pretest	139 (32)	137 (29)	354 (112)	362 (128)	694 (158)	704 (255)	0.01 <sup>a</sup>		
Posttest	142 (37)	140 (42)	342 (128)	472 (190)	687 (135)	710 (267)	(II, III, IV)		
Sun damage assessment: right forearm (1-10)									
Pretest	6 (3)	7 (2)	5 (1)	4 (2)	1 (0)	1 (0)			
Posttest	5 (3)	8 (3)	4 (2)	4 (1)	1 (0)	1 (0)	0.6		

<sup>a</sup> Statistically significant Wilcoxon Rank Sum test.

<sup>b</sup> A participant may respond to both sun burn and skin irritation; thus, the total responses on the pretest may be greater than 170 and on the posttest may be greater than 161.

I, intervention; C, control.

poor proxy for sunburn and skin cancer risk because of the range of skin pigmentation in racial/ethnic minority people with skin of color and other individual risk factors for skin cancer (eg, immunosuppression, personal or family history of skin cancer, occupation and recreational sun exposure, and residence in tropical locations). The range of sun sensitivity in Hispanics is similar to the range in whites.<sup>15,20</sup> Hispanics, who have considerable diversity in the amount of pigment in the skin, have a misconception that their skin pigment protects against skin cancer.<sup>21</sup> Although darker skin pigmentation has some protective effect, ultraviolet radiation (sunlight) is linked to DNA damage and skin carcinogenesis across all skin types.<sup>22,23</sup>

This study has strengths in including recipients across the health literacy spectrum and recipients from racial/ethnic minorities, but it also has some limitations. Participation among recipients from racial/ethnic minorities was low. Generalization among KTRs with skin of color will be limited by normative beliefs regarding the relevance of getting a skin cancer and importance of sun protection. Barriers to recruitment of Hispanic and Black KTRs were normative beliefs and transportation to the medical center, which resulted in lower participation than among whites. Some of these urban participants had very limited outdoor exposure, which made sun protection irrelevant to them. Program limitations made it impossible to know if subjects opened the text or email reminders. It was not feasible to offer SunProtect online during the 6 weeks of the study because most minority KTRs lacked home Internet access.

Skin cancer risk among KTRs can be modified by shifting KTRs to lower levels of sun exposure. English and Spanish delivery of SunProtect by tablet with audio narration made it possible for KTRs to access the culturally sensitive program. SunProtect enabled sun protection self-management by KTRs. Future research will provide sun protection education to KTRs with unlimited access to a mobile app, seek ways to enhance the relevance of sun protection behaviors for those with skin of color, and evaluate the sustainability of sun protection by KTRs.

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