Abstract

Skin cancer is a growing epidemic, with almost five million US diagnoses annually, in contrast with most cancers, which are decreasing in incidence. Although largely preventable, skin cancers can be deadly, debilitating, damaging, and disfiguring. US adolescents have the lowest skin protection rates of all age groups and also engage in increased ultraviolet radiation (UV) exposure as they move into adulthood. Thus, young adults are in need of intervention to reduce their skin cancer risk. Prior interventions to increase skin protection and/or decrease UV exposure among young adults have been limited in their dissemination and longitudinal assessment, and no prior interventions targeted to this population have been internet-based besides our own. Our research team developed a web-based intervention that was found to significantly decrease UV exposure and increase skin protection behaviors among young adults in a randomized controlled trial (RCT) of nearly 1000 participants recruited from a consumer research panel. The intervention (UV4.me) is individually-tailored, interactive, and multimedia in nature, and based on the Integrative Model of Behavioral Prediction. Similar to other online trials, 73% of eligible individuals completed the baseline questionnaire, 70% who were randomized to the intervention accessed it, and 68% accessed it and completed at least one module. However, we have an opportunity to increase the engagement, implementation, and ultimately, the impact of UV4.me. We will do this by adding several key interactive features/strategies suggested by participants, our data, and supported by the literature (i.e., by creating a mobile version, adding incentives embedded in the intervention, a behavior tracking and feedback feature, peer interaction component, and ongoing news updates). This Hybrid Type 2 dissemination-effectiveness project's purpose is to implement the enhanced UV4.me2 with adults aged 18-25 years at moderate to high risk of developing skin cancer and evaluate the intervention's effectiveness in a sample recruited online through national dissemination to the general population. This project will use the RE-AIM framework to determine the reach, effectiveness, implementation, maintenance, and cost of UV4.me2. The team will recruit individuals from several general online sources (e.g., nonprofits, social media, commercial). Our team has already recruited three non-profit organizations to promote uptake of UV4.me2 and a commercial skincare company to offer incentives to encourage participation of young adults from across the US. In order to evaluate intervention effectiveness, young adults who enroll in the study will be randomized to either receive the enhanced UV4.me2, the original UV4.me, or a skin cancer e-pamphlet from the American Cancer Society. In summary, this project proposes a novel approach to address an issue of growing public health significance. The uniquely well-suited multidisciplinary and multi-institution research team is comprised of junior, mid-level, and senior investigators who have previously worked together successfully on skin cancer prevention interventions.

2. Specific Aims

In a 2014 call to action, the US Surgeon General noted skin cancer as a growing and costly epidemic, with almost five million US annual diagnoses (19), in contrast with most cancers that are decreasing in incidence. Though largely preventable, skin cancers can be deadly, debilitating, damaging to tissues and organs, and disfiguring. US adolescents have the lowest skin protection rates of all age groups (20) and engage in increased ultraviolet radiation (UV) exposure as they move into adulthood (21). Thus, young adults are in need of intervention to reduce their skin cancer risk. Prior interventions to increase skin protection and/or decrease UV exposure among young adults (8, 22, 23) have been limited in their dissemination and longitudinal assessment, and no prior intervention targeted to this group has been web-based besides ours.

Given the potential of web-based approaches to address such issues, we developed an individually-tailored, interactive, multimedia, and theoretically-grounded web intervention targeted to young adults (UV4.me). With NCI R01 funding, we evaluated the intervention in almost 1000 18-25 years olds at moderate to high risk of developing skin cancer from a consumer research panel in a randomized controlled efficacy trial. Behavioral risk factors for melanoma were significantly improved. Intervention effect sizes (Cohen's *d*) were 0.53 for skin protection and 0.43 for UV exposure behaviors at three-month follow-up. Sunburns were also significantly reduced. However, similar to other online trials, 27% of eligible individuals did not complete the baseline survey, 30% who were randomized to the intervention did not access it, and 32% accessed it but did not complete any of the modules. **The next step in this research program is to enhance the intervention and implementation strategies and conduct a Hybrid Type 2 Dissemination-Effectiveness trial (24),** which has the goal of increasing efficiency of moving novel evidence-based interventions to the community through mass access and reach. As our conceptual framework, we have selected RE-AIM (25), which refers to intervention Reach (access by individuals), Effectiveness (on individual behavioral outcomes), Adoption (by professionals - not the main focus of the current project), Implementation (individual use), and Maintenance (sustainability of effects). We believe this framework is the most appropriate to investigate the dissemination, implementation, and effectiveness of a self-administered and automated online intervention. Participants will be randomized to either the original UV4.me, the enhanced UV4.me2 (described below), or a readily-available free electronic skin cancer prevention pamphlet (e-pamphlet) from the American Cancer Society. **We hypothesize that effectiveness, implementation, and maintenance outcomes will be best for UV4.me2, next best for UV4.me, and least for the e-pamphlet group. Primary Specific Aims are as follows:**

1. Reach: To enhance and determine intervention reach (i.e., enrollment, representativeness). For the efficacy trial, we recruited solely from an online consumer research panel, and some eligible individuals did not enroll. Therefore, we will recruit more broadly using several types of online sources (i.e., nonprofits, social media, commercial) and also allow participants to access the intervention(s) using a mobile version. We will work with young adults and experts at PatientRecruitmentOnline.com to refine our keywords, ads, recruitment campaign, homepage, and enrollment process. We expect that the study enrollment rate will be greater than in the efficacy study. We hypothesize that our sample will be representative of national demographics of young adults other than race/ethnicity (associated with skin cancer risk), indicating potential generalizability.

2. Effectiveness: Some participants in the efficacy trial did not access or complete the intervention. One strategy to improve effectiveness, consistent with RE-AIM (26), is to increase implementation by increasing intervention interactivity (5). Thus, we will add several key interactive features in UV4.me2 based on participant feedback, our data, and approaches found to increase implementation, satisfaction, and effectiveness in prior reviews of online interventions (4, 5, 9, 10) (i.e., incentives embedded in the intervention, a behavior tracking and feedback feature, peer interaction component, and ongoing news updates). **This aim is to determine the enhanced intervention's effectiveness** in a sample of 18-25 year olds recruited from across the internet at moderate to high risk of skin cancer based on the Brief Skin Cancer Risk Assessment Tool (27). Behavioral outcomes are outdoor and indoor UV exposure and higher skin protection at 3-month follow-up.

Secondary Aims are as follows:

3. Maintenance: To determine maintenance, effectiveness of the interventions will be evaluated at 6 and 12-month follow-up. 4. Implementation: To determine intervention implementation by young adults. We hypothesize that greater intervention utilization (e.g., logins, module completion) and satisfaction will be associated with better behavioral outcomes. **5. Cost: To determine the costs of the interventions.** We hypothesize that UV4.me2 and UV4.me will have higher incremental costs than the e-pamphlet. However, because UV4.me2 and UV4.me are also expected to result in better behavioral outcomes, we will assess cost-effectiveness to address whether these interventions are worth the additional costs.

3. Research Strategy

SIGNIFICANCE
The Skin Cancer Problem

Skin cancer is the most common cancer and can be deadly, debilitating, damaging, and disfiguring, yet is highly preventable. In 2014, the US Surgeon General made a call to action about the "major public health problem" of skin cancer, noting potential contributions of behavioral science and education, and a need for investments in such efforts (19). Almost five million Americans are treated for skin cancer annually, and incidence is rising (19, 28-31). If current trends continue, melanoma will be the only Healthy People 2020 cancer objective to not meet death reduction goals (19). Additionally, non-melanoma skin cancer (NMSC) can be a chronic disease for some, requiring ongoing costly treatments and decreases of quality of life similar to some other cancers (32). Risk factors for melanoma and NMSC include personal or family history of melanoma or NMSC, certain phenotypic (e.g., fair skin) and other physical characteristics (e.g., numerous moles) (33-45), as well as excessive ultraviolet (UV) radiation exposure (44, 46-51).

Most skin cancers are preventable with skin protection such as minimizing UV exposure and wearing protective clothing and sunscreen (52, 53). US adolescents have the lowest skin protection rates of all age groups (20) and also <u>increase</u> exposure to natural and artificial UV radiation as they progress into adulthood (21). Though childhood is a particularly high-risk period for UV exposure and skin damage, research suggests that only 25% of lifetime UV is accumulated by age 18 (54). Our work shows that skin cancer risk behaviors, including sunburns, indoor tanning, and lack of protection peak at age 25 (55, 56). Thus, **young adulthood is an important window for skin cancer risk reduction interventions.** However, young adults tend to be resistant to public health recommendations because, as a group, they perceive themselves as having more immediate priorities than disease prevention, that the consequences of their current health behaviors are in the distant future, and they also tend to be experimenters and risk-takers highly influenced by peers (57-59).

Interventions to Modify Skin Cancer-Related Behaviors

Large skin cancer prevention campaigns have the potential to reduce incidence, mortality, and morbidity as well as be cost-effective. For example, a long-term comprehensive multi-modality skin cancer prevention campaign in Australia returned US$3.27 per dollar invested in terms of life-years saved and disability-adjusted life-years (60). A recent study reported that **a comprehensive US skin cancer prevention program similar to Australia's would be estimated to prevent 20% of US melanomas,** or 21,000 melanoma cases annually, with an average annual reduction of $250 million spent on new melanomas (3). The US spends several hundred thousand dollars more per year than Australia on skin cancer (61), and the annual cost of treating new melanomas in the US is projected to increase threefold from 2011 to 2030 (3). US and Australian (one randomized controlled trial) studies have found that NMSC can also be reduced by 14-40% with regular sunscreen use (62-64). A few prior interventions targeted to US young adults have shown increased skin protection and/or decreased UV exposure in research settings; however, their reach and sustainability have been limited because most have been conducted in person and had brief follow-ups (65-71). **Innovative, age-appropriate interventions are important to reduce skin cancer risk among young adults.**

Ninety-three percent of US young adults use the web (72), and web interventions can be disseminated widely and be cost-effective to maintain (73, 74). Often websites are designed to provide information rather than as interventions to improve health behaviors and/or disease risk. Despite this purpose, a review of existing melanoma websites found that the majority failed to include complete information on important topics such as risk factors, diagnosis, and prevention, with a significant minority containing inaccuracies (75). However, web interventions designed to improve health behaviors (e.g., exercise and weight loss) have been found to produce medium effect sizes and consistently outperform similar non-web interventions (74).

Our Internet Intervention (UV4.me) and its Enhancement

We developed a web intervention that included many of the components found in successful internet interventions. We found significantly improved skin cancer risk behaviors among young adults in a randomized controlled trial (RCT) that enrolled almost 1000 participants from a consumer research panel (see **Preliminary Studies**) (76). To our knowledge, this is the only empirically-tested internet intervention focused on skin cancer risk behaviors targeting young adults. The intervention (UV4.me) is individually-tailored, interactive, and multimedia based on Ritterband and colleagues' (6) model for online behavior change interventions and the Integrative Model of Behavioral Prediction (77), which includes background variables such as demographics; cognitive variables such as beliefs, attitudes, norms, and self-efficacy; intentions; and behavior. We also emphasized appearance concerns, which is a major factor associated with young adult tanning (78-80).

In addition to successful outcomes, approximately two thirds of eligible participants enrolled in the study and completed the baseline survey, two thirds randomized to UV4.me accessed the intervention, and two thirds completed the 3-month follow-up. **Yet, we still have an opportunity to increase UV4.me implementation and impact.** We propose to do this by enhancing recruitment and enrollment strategies as well as incorporating additional interactive features into the intervention (i.e., creating a mobile version, embedding incentives into the intervention, adding a behavior tracking and feedback feature, peer interaction component, and ongoing news updates). Features/strategies were chosen based on participant feedback, our data (e.g., attempted use of mobile devices), and reviews/models of effective e-Health interventions including for tobacco cessation, physical activity, weight loss, and nutrition (4-8) and online implementation strategies (9-12). Several enhancements are expected to improve reach, implementation, and behavioral outcomes simultaneously. See **Approach: Intervention Enhancement** for more information. The enhanced version of UV4.me will be referred to as UV4.me2. The proposed project is aimed at disseminating UV4.me2 nationally via the internet with the help of non-profit and commercial organizations interested in skin protection. It will also evaluate the intervention's implementation and effectiveness in improving skin cancer risk behaviors among young adults at moderate to high risk of developing skin cancer. The framework to be used for the proposed project is RE-AIM. The proposed interactive features are consistent with RE-AIM (26).

RE-AIM Framework. One of the major problems with health behavior research is that many interventions that demonstrate initial effects are never tested in effectiveness or dissemination trials, nor are they distributed to populations who most need them, thus, having little impact on population health (81). To address these concerns, the RE-AIM Framework was developed by Glasgow and colleagues (25). "RE-AIM" refers to Reach, Effectiveness, Adoption, Implementation, and Maintenance. **Reach** refers to the number, proportion, and representativeness of individuals willing to participate in a given initiative, indicating potential generalizabiity (82). **Effectiveness** refers to the impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes. **Adoption** refers to the absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program (not a main focus of the proposed project given the self-administered and automated intervention). **Implementation** refers to the individual's use of the intervention. **Maintenance** refers to the long-term effects of a program on outcomes. Although widely used since 1999, most reviews have found that the components of the RE-AIM framework are not assessed and/or reported comprehensively or well (83-87). Additionally, most D&I studies focus on dissemination of guidelines, policies, practices, or interventions to healthcare agencies or practitioners rather than D&I of online self-administered interventions directly to consumers. We selected the RE-AIM framework over many others because we believe it is the most appropriate to investigate the dissemination, implementation, and effectiveness of an innovative self-administered and automated online intervention. We could identify no relevant studies that addressed D&I issues related to self-administered materials online.

Significance Summary: 1) Skin cancers are common, costly, and can be deadly or devastating to health, functioning, and appearance. **2)** Most skin cancers are preventable with skin protection. **3)** Young adults have unique barriers to preventive healthcare, and their UV exposure is high and skin protection is low. **4)** The reach and sustainability of skin cancer prevention interventions for young adults have been limited. **5)** Our web intervention performed as well as if not better than more traditional behavioral health interventions. **6)** The use of the web can cost-efficiently facilitate wide dissemination and sustainability. However, our study would be one of the few that will assess cost and longer-term maintenance of skin cancer risk reduction interventions. **7)** Melanoma risk factors were impacted significantly by our intervention in a randomized efficacy trial. **8)** A comprehensive US skin cancer prevention program could prevent up to 20% of melanoma cases (3). **9)** The RE-AIM Framework offers a guide for the planning, conduct, evaluation, and reporting of intervention D&I research. **10)** We have formulated several strategies for enhancing the reach, implementation, and ultimately effectiveness of our intervention. **11)** The overall approach and findings would likely be relevant to web interventions for young adults for other behavioral health issues (e.g., diet, physical activity).

INNOVATION: This project will advance skin cancer prevention D&I research in several innovative ways. **1)** It involves online implementation of a self-administered intervention. **2)** It also utilizes a novel Hybrid Type 2 design. **3)** Few evidence-based skin cancer prevention interventions other than co-investigator Dr. Glanz's have been disseminated widely. **4)** To our knowledge, ours is the only empirically-based internet intervention to address skin cancer risk behaviors targeting young adults. **5)** Our intervention will now be available via a mobile version and will include novel embedded incentives. **6)** In addition to the strategy of direct dissemination/implementation for individuals, non-profit and commercial partner organizations will be used for national dissemination to young adults from the general public as another strategy to increase reach and

generalizability. **7)** Websites and other interventions typically rely on passive dissemination rather than the more active implementation strategies for intervention engagement that we propose (See **Approach**). **8)** <u>Finally, the RE-AIM framework has never been used in the area of skin cancer prevention.</u>

In summary, we have designed a project to assess the reach, effectiveness, implementation, maintenance, and cost of our evidence-based internet intervention. The ultimate goal is to improve the skin cancer protection behaviors (and potentially decrease skin cancer incidence) among a national sample of young adults at moderate to high risk of developing skin cancer. Even with relatively small effect sizes, low-cost and highly disseminable interventions can have a large public health impact. This project proposes a novel and promising approach to address an issue of growing public health significance.

INVESTIGATORS: The uniquely well-suited multidisciplinary team is comprised of junior, mid-level, and senior investigators who have worked together successfully on skin cancer interventions and other projects.

<u>Principal Investigator:</u> **Carolyn Heckman, PhD,** is a tenured Associate Professor at Fox Chase Cancer Center (FCCC). In addition to her UV4.me R01, Dr. Heckman was the PI of several other skin cancer prevention-related studies, all of which recruited young adults online (88-101). Dr. Heckman is currently in her <u>second</u> year of a two-year Mentored Training for D&I Research program funded by NCI.

<u>Co-Investigators:</u> **Karen Glanz, PhD, MPH,** is a Professor at the University of Pennsylvania, Director of Penn's Center for Health Behavior, and Director of its CDC-funded Prevention Research Center. Dr. Glanz is the individual with the most experience conducting skin cancer prevention D&I research and also has experience conducting online research. **Elliot Coups, PhD,** is an Associate Professor and social and health psychologist with expertise in behavioral aspects of skin cancer prevention, detection, and control.

<u>Staff</u>. **Elizabeth Handorf, PhD,** is a biostatistician in the FCCC Biostatistics and Bioinformatics Facility. **The Office of Health Communications and Health Disparities** will assist in ensuring that recruitment materials and the enhanced intervention are understandable and salient to a broad audience. **Stephanie Raivitch, BA,** is the Director of Health Communication Programs and the Research and Education Center at FCCC. A TBD **Postdoctoral Fellow** will serve as a liaison between all project entities, as well as assist with intervention enhancement, participant management, data management/analysis, and manuscript preparation.

Table 1. Consultants/Service Providers	Expertise
BeHealth Solutions	www.behealthsolutions.com, programmers of UV4.me and UV4.me2
Lee Ritterband, PhD	BeHealth's Founder and VP of R&D, Professor of Behavioral Health and Technology, co-founder of the International Society for Research on Internet Interventions
PatientRecruitmentOnline.com	Experts in online marketing for health-related recruitment
Amy Yaroch, PhD	Professor and expert in skin cancer and protection among young people
Amanda Honeycutt, PhD	Experienced senior health economist at **RTI International**
Survey Sampling International (SSI)	Expert hosts of a large national online consumer research panel

APPROACH
Selected Preliminary Studies.

<u>Dr. Heckman's UV4.me, R01CA154928</u>. In a four-year R01, **Dr. Heckman,** with **BeHealth** and other team members, developed a multimedia, tailored, interactive web intervention based on the Integrative Model of Behavioral Prediction (77) to reduce skin cancer risk behaviors among young adults. A paper describing UV4.me's development <u>was published in</u> *Internet Interventions* (102). UV4.me is connected to a data management system created by **BeHealth**. US adults 18-25 years old (n = 964) were recruited April - June of 2014 by **SSI** for the RCT. Demographic characteristics of participants were: 85.7% white, 66% female, 21.8

years of age (SD = 2.2), and 35% family history of skin cancer. Participants were randomized to UV4.me, the Skin Cancer Foundation website, or assessment only. <u>Generalized estimating equation regression models contained intervention condition; time (baseline, 3 week follow-up, 12 week follow-up); and the interaction between intervention and time.</u> The UV4.me group reported a

Figure 1. Change in Outcomes from Baseline to 12 weeks
- Assessment only
- SCF Website
- UV4.me
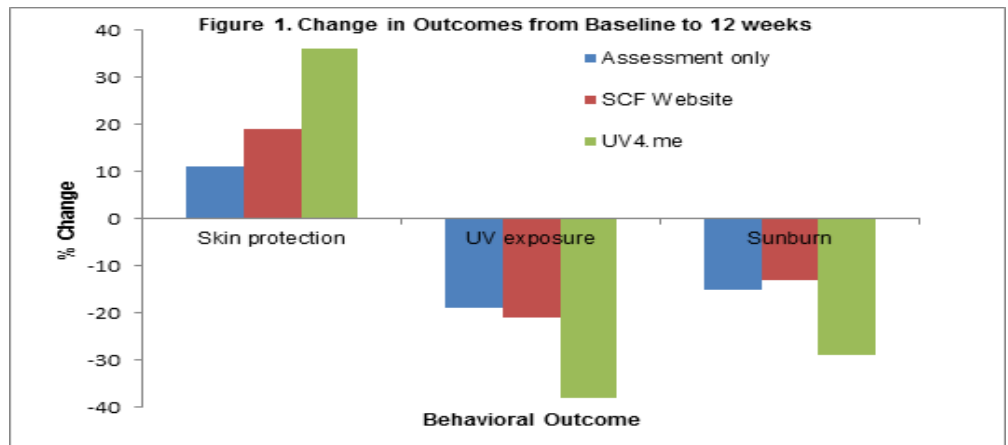
significantly greater decrease in UV exposure and increase in skin protection at three-month follow-up than the other groups (ps < 0.001; See Figure 1) (76) (See **Appendices** for outcomes paper). The intervention effect direction and significance were maintained even when using the more conservative last observation carried forward method for missing data. **Effect sizes (Cohen's *d*) comparing the UV4.me and assessment only arms were 0.53 for protection and 0.43 for exposure behaviors.** The UV4.me group also experienced significantly better outcomes for sunburns, incidental UV exposure, and sunscreen use of SPF 15 or above. Few interventions have used sunburn as an outcome, though it could be considered a biomarker for melanoma prediction since a greater numbers of sunburns is associated with higher risk of melanoma (103). Most effects were stronger at 12- week follow-up (end of summer) than 3-week follow-up. Though UV4.me participants reduced their indoor tanning by about 55%, this effect was not significant, probably because only about 9% of the sample reported indoor tanning at baseline. The intervention had significantly greater effects on high risk groups such as indoor tanners or those with a family history of skin cancer than others. Papers describing the refinement and psychometrics of the measures and the change mechanisms are under review at *Preventive Medicine* and the *American Journal of Preventive Medicine,* respectively.

Regarding study process, 75% of eligible participants consented to participate, 73% of those completed the baseline survey, and 72% completed the three-month follow-up. Seventy percent of those randomized to the intervention accessed it, and 68% accessed it and completed at least one module. Experimental participants completed an average of 5.7 of the 12 modules (only 2.6 were recommended based on tailoring), and most set a behavioral goal at the end of at least one module. Systematic reviews and meta-analyses find the average participant adherence for web-based health interventions (e.g., completed x number of intended modules) is 50-53% (2, 17), and attrition at time-points similar to ours is 24-46% (2, 18). Completing more modules or setting more goals was significantly associated with decreased UV exposure (p < 0.01) but not increased protection at three-months. On average, intervention participants rated aspects of the program at least a 4 on a scale of 1-5 except for avatar helpfulness (3.3). Avatar ratings were bimodally distributed, so we will retain it for those who liked it but not invest in further enhancement. Some participants commented that the intervention was a little dry/boring and/or needed more activities, so several of the enhancements (i.e., social interaction, ongoing new updates, tracking/feedback) will address those concerns.

We decided to create a mobile version and utilize the proposed recruitment and incentive strategies for the new study due to data and feedback from the original UV4.me and other support within the literature. Based on our Google Analytics data, approximately 18% of individuals who first landed on the UV4.me study webpage were using a mobile device (smartphone = 14% or tablet = 4%). The percentage of users who did not continue further into the website from the homepage was approximately 23% for desktops/laptops versus 30-34% for mobile devices. Enrolled participants reported that they use the web for personal reasons about 17 hours per week on a laptop/PC, 8 on a smartphone, and 4.5 on a tablet. Participants reported that the search engines/website they were most likely to view and click on ads from were Google and Facebook. Seventy-six percent of participants reported that they had purchased skincare products online at least once in the last year.

Dr. Glanz's skin cancer D&I research. To our knowledge, only 15 papers on dissemination and/or implementation of skin cancer-related interventions exist, and most were authored by Dr. Glanz about her Pool Cool Program, which improved skin cancer risk and protection policies and behaviors among aquatic staff and children at Hawaii and Massachusetts pools (104, 105). The D&I trial assessed effects of an enhanced vs. basic D&I strategy on adoption, implementation, and maintenance of protection promotion policies and practices by aquatic staff at >400 pools across the country based on Diffusion of Innovation theory (106-111). Program adoption was high (86.6%), the enhanced intervention produced greater adoption, implementation was similar across conditions, and core skin protection elements were maintained for two years. Dr. Glanz has published several papers describing the correlates of successful adoption and implementation (112-117). She has also published other D&I papers related to other health behaviors such as dietary choices and intake.

Summary of experience and findings. The team has conducted numerous other skin cancer studies, resulting in many, including some co-authored, publications (**see Biosketches**). **Dr. Heckman** and team are experienced in online recruitment of national samples of young adults, assessing skin cancer risk and protective behaviors online, and conducting skin cancer prevention trials, including one via the internet. **Dr. Glanz** is the researcher most experienced in conducting skin cancer prevention D&I research.

Project Design: This novel internet intervention Hybrid Type 2 dissemination-effectiveness project consists of three major components: 1) intervention and implementation enhancement and user-centered refinement including acceptability and usability testing, 2) organizational adoption and dissemination to young adults, and 3) a longitudinal RCT comparing behavioral outcomes of the original UV4.me, the enhanced

UV4.me2, and an e-pamphlet (all of which will be available via a mobile version) assessed at 3, 6, and 12 months. We will also assess intervention implementation/utilization at 1-month follow-up.
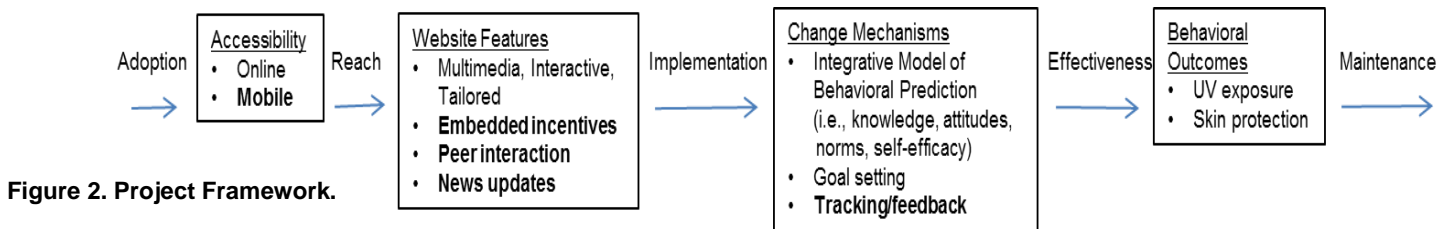
E-Pamphlet Condition: A free non-interactive e-pamphlet ("Skin Cancer Prevention and Early Detection" from the American Cancer Society) will be accessible via our website. We chose to include a pamphlet condition for the following reasons: 1) such pamphlets are widely available to the public and used by dermatologists and primary care providers, 2) to compare the effects of our intervention to a minimal intervention, 3) to compare our effects to prior studies that used pamphlet or minimal interventions, 4) to include a standardized rather than a variable intervention, 5) we also considered using an intervention for another health issue (e.g., nutrition, physical activity, sleep) but anticipated that skin protection organizations would be less likely to participate in that case, and 6) a no-treatment condition could affect adoption and reach and could be considered unethical for those with moderate to high skin cancer risk.

The Original UV4.me: UV4.me is targeted to young adults, personally tailored, and includes interactive, multimedia, and goal-setting components (see **Appendices** for screenshots). It includes 12 modules with content related to a specific topic important in terms of risk or protective behaviors: Why do people tan? To tan or not to tan? Indoor tanning, UV & looks, UV & health, Skin cancer, Skin damage, Sunscreen, Shade, Clothes, Skin exams, and Sunless tanning. Several more general sections (e.g., avatar, MyStuff – a printable summary of tailored goals/recommendations) are also included. Tailoring algorithms were created to direct participants to focus on certain modules based on their responses to a few initial questions (e.g., the indoor tanning module was recommended for indoor tanners). Throughout the program, participants are asked questions and provided with tailored feedback (e.g., "Do you know people who tan? If so, how likely are they to affect your choice to tan or not?"). A number of interactive elements (e.g., videos, games) were created to encourage implementation. For example, at the end of each module, participants could choose to set a goal for the next two weeks or not (e.g., "For the next two weeks, I will not use a tanning bed.").

The Enhanced UV4.me2: We believe UV4.me's reach, implementation, and successful outcomes can be increased by adding key interactive features/strategies. Features/strategies were chosen based on participant feedback (e.g., suggested strategies to make UV4.me more interactive), our data (e.g., number of mobile users who tried to access UV4.me), and reviews/models of effective e-Health interventions (4, 5) and implementation strategies (9, 10, 12). One framework derives from a Critical Interpretive Synthesis review of design/delivery features associated with effective e-Health interventions (n = 52) for health behaviors including tobacco cessation, weight loss, and so on conducted by Morrison and colleagues (5). UV4.me already addressed many constructs within their framework (e.g., targeting, tailoring). The constructs of contacts with the intervention, program exposure duration, and self-management can be enhanced by creating a mobile version, embedding incentives into the intervention, and adding behavior tracking/feedback, respectively. These enhancements are also consistent with a framework for reach/efficacy for online interventions for substance use disorders (4) and five of six implementation strategies identified by Powell and colleagues (minus political context) (12). Reviews and meta-analyses have found that components of effective internet interventions include interactivity, behavior tracking/feedback, and social interaction (5, 7, 8, 11) and that incentives facilitate exposure to online health behavior change interventions aimed at young adults (11). The new interactive features are also consistent with the Integrative Model of Behavioral Prediction (77) on which the original UV4.me is based.

Several enhancements are expected to improve reach, implementation, and behavioral outcomes simultaneously. For example, a mobile version will likely improve reach directly because more people will have access and may improve effectiveness indirectly by facilitating ongoing implementation (dose). On the other hand, tracking and feedback have been widely shown to improve effectiveness, but participants may not be more likely to engage or recruit peers (reach) for this reason; whereas, participants may promote the website to peers based on other enhancements (e.g., coupons and free samples). Most evidence-based web interventions are designed to be utilized at least weekly for several weeks, but one problem has been that many participants only access the interventions once, if at all (17, 118-121). An expert panel noted factors important to the D&I of online interventions in terms of a first visit (promotion via multiple sources, appealing interface, perceived personal salience), extended visit (tailored feedback, easy navigation, interactive technology), and revisits (ongoing updates, monitoring progress) (9, 10). Our approach is also consistent with recent trends in commercial marketing for successful startups, referred to as "growth hacking" in which a product and its creative and inexpensive online marketing strategy is developed and tested simultaneously based on consumer feedback/data in order to build an initial user base for sustained word of mouth marketing (122). **Figure 2** shows how the RE-AIM, IM, and online intervention frameworks (4-6, 9, 10, 25, 77) fit together and how we envision our intervention enhancements (**bold font**) affecting reach, implementation, and effectiveness. Essentially, we

hypothesize that the more young adults we can reach and motivate to implement the intervention, the greater the effectiveness and ongoing (denoted by the final arrow) maintenance.

Figure 2. Project Framework.

Adoption → Accessibility (• Online • **Mobile**) → Reach → Website Features (• Multimedia, Interactive, Tailored • **Embedded incentives** • **Peer interaction** • News updates) → Implementation → Change Mechanisms (• Integrative Model of Behavioral Prediction (i.e., knowledge, attitudes, norms, self-efficacy) • Goal setting • **Tracking/feedback**) → Effectiveness → Behavioral Outcomes (• UV exposure • Skin protection) → Maintenance

Mobile Version. Approximately 79% of 18-24 year olds own smartphones (123). Among 18-29 year old cell-phone owners, 45% are "cell-mostly" web users (124), 42% look for health information online (125), and 24% have a health app on their phone (125). Though only 18% of individuals interested in UV4.me tried to access it via a mobile device, they were less likely to enroll, and enrollees may have preferred mobile access but were informed upon enrollment that the website was not designed for mobile use. We will design the mobile platform for use with Android and Apple devices, which accounts for almost all individuals who tried to access UV4.me. Our programmers/developers will begin with the program structure from our existing intervention platform/structure. Developers will test all functionalities across a variety of browsers and versions using responsive design to ensure the program works well across devices. Instructional designers will ensure the content is optimized for learning. The only prior mobile skin cancer prevention intervention not solely SMS-based was an RCT of smartphone owners 18 and older that found improved use of hats and shade but a *decrease* in sunscreen use and no change in sunburns at 7-12 weeks (126, 127). However, the intervention was narrowly focused on delivering real-time advice about protection based on the user's UV index.

Incentives will be provided via clickable coupons and links to order free samples (e.g., sunscreen) throughout the intervention. Appropriately selected incentives generally reinforce behavioral implementation, retention, and health behavior change, including in online trials, especially among those initially least motivated and/or for behaviors that are not intrinsically enjoyable (e.g., applying sunscreen) (11, 13-16, 128-131). They will also help facilitate sustainability of dissemination after grant funding ends because they will be provided by for-profit companies as a marketing strategy. However, there is risk for some to be "turned off" by marketing, perceived privacy concerns, or their behavior not being sustained after reinforcement ends. Note that ads will only be included if they offer discounts or free samples, not other types of ads. Incentives embedded within the intervention would be a unique approach. Only one prior study used "deals" (modeled after Groupon) similar to those envisioned here in an online tobacco cessation program for college students (132). 91% of participants recommended keeping the deals in the program, and many reported some influence on implementation, health behaviors, and favorable attitudes toward the businesses involved.

The behavioral tracking and feedback feature will allow users to set goals and enter relevant behavioral events (e.g., sunbathing, indoor tanning, sunburns, sunscreen use) over time and see them summarized graphically on the homepage and receive motivating feedback (e.g., "Great job, your tanning is going down over time!"). Behavior tracking and feedback are well-established empirically-supported behavior change techniques including for internet interventions (133, 134). Participants will be able to set "alerts" to notify them (e.g., email, SMS texting) to remind them to work on their behavioral goals. We will also explore the acceptability and feasibility of sharing goal progress with others with permission. Goal-setting and email reminder alerts were part of the original UV4.me, but tracking over time and graphic feedback was not.

The peer interaction component will involve an interactive open-text component within the UV4.me2 website to encourage social support and implementation. Peer, normative, and social factors have a powerful influence on individual behavior, especially among adolescents and young adults, and social context was a factor identified in the review/model of effective eHealth interventions by Morrison and colleagues (5), has been shown to increase intervention implementation (135, 136), and is consistent with other reviews of online interventions (4, 9, 10) and Bandura's Social Cognitive Theory (137). The open-text component will encourage participants to think, write, and communicate about relevant topics. There will be several spaces within the UV4.me2 website in which participants will be able to enter open-text comments and upload images (e.g., "Tell us about someone you know who has had skin cancer."). We will initially populate some feedback from participants from the original RCT into these areas (e.g., "The avatar was fun."). These areas will have some functions similar to Facebook in which participants can post text or images, like, comment, or share. These open-text areas within the website will also all be linked to and organized in one central "bulletin board" on the homepage so that users can find them easily without searching through the entire website. Participants will be able to choose to submit material

privately (for themselves only) or publicly (for staff and all UV4.me2 users). We will be able to monitor and control this material such that what is submitted for online "publication" will initially be reviewed by study staff before public posting to ensure that material is appropriate (e.g., not profane, abusive, or irrelevant) and not un-helpful (e.g., does not recommend tanning). If most submissions are appropriate for a period of time, we will then move to an immediate posting procedure without staff pre-review with users being permitted to "flag" inappropriate content to alert staff to remove it.

Ongoing news updates will occur by adding new material (e.g., news/media stories, new research, events such as runs for melanoma charities) to UV4.me2 at least weekly with biweekly notifications to interested users (e.g., email, SMS texting). Updated information was a factor identified in a review/model of effective eHealth interventions (5), is important for dissemination of online interventions (9, 10), and has been shown to increase intervention implementation (135, 136).

User Testing. After each of the rounds of testing below, data will be summarized and reviewed by the team to direct modifications for the next version of the intervention, followed by another round of team review.

Acceptability Testing. Once the enhancements are fully developed, acceptability testing modeled after an NCI online design project will be conducted (138) as was done for the original UV4.me (102). We will focus on the new features added to UV4.me for UV4.me2 (e.g., the mobile version), a prototype study Facebook page, and the recruitment ads/strategies. Testing will involve consulting users about attractiveness, comprehension, salience, and persuasion. Questions and structured guides will be prepared in advance relating to the elements to be evaluated is in the original UV4.me. Acceptability testing will be conducted using focused interviews with approximately 20-25 participants eligible for and recruited using methods similar to the RCT. The first 10 or so sessions will be conducted in person, and the latter 10 will be conducted remotely via the web and telephone. Participants will use a device (computer, tablet, or smartphone) with access to the web intervention. The iterative process will involve discussion of an intervention element, followed by interaction with that part of the intervention, followed by discussion reacting to the part, etc. The sessions will be video- or audio-recorded and transcribed, and the moderator will take notes.

In usability testing, users do typical tasks with a product or explore it freely while their behaviors are observed and recorded to identify design flaws that cause user errors/difficulties (139). As in the original UV4.me (102), we will follow the NCI usability guidelines (140) on planning, analyzing, developing, testing, and refining online interventions. We will conduct usability testing with 12-15 participants as recommended by Bastien (139). The evaluator notes the frequency/duration of behaviors that can indicate user problems/difficulties as well as measures such as time to finish a task, time recovering from errors, number of wrong choices, observations of frustrations, confusion, satisfaction, etc. Morae software video-records the session and provides descriptive statistics on behaviors observed (frequencies, duration, etc.) and behavior patterns (139). We will conduct half of the usability sessions via the web using similar software without video.

Organizational Adoption: Passive diffusion of interventions ("If you build it, they will come") tends to result in limited adoption and reach or generalizability (141-148). Moreover, sustaining interest after grant-funding ends is often challenging (149). In addition to offering an appealing and effective intervention, our innovative strategies to help increase the likelihood of reach and ongoing sustainability include the utilization of: 1) minimal effort to post/promote UV4.me2 by non-profit organizations who are committed to the mission of skin cancer prevention and have an existing base of users/members and 2) for-profit companies who have the resources to offer discounts and free products while benefitting from project participation via free marketing. As evidence of feasibility, the team has created partnerships with three non-profit organizations (e.g., the Melanoma Research Foundation) interested in skin cancer prevention to promote UV4.me2 on their websites and garnered corporate sponsorship from a for-profit company (Blue Lizard Sunscreen) who will offer discounts and free skincare products to encourage participation of young adults (see **Letters of Support**). The project can be completed with these organizations alone. However, we have created a list of an additional 22 non-profit and 60 for-profit companies concerned with skincare that we will also attempt to enlist (see **Appendices**). The non-profit organizations are members of the National Council on Skin Cancer Prevention and additional organizations we identified (e.g., SunAWARE). The for-profit companies are those with sun protection products given the Seal of Recommendation by the Skin Cancer Foundation, based on data reviewed by independent photobiology experts. Individuals who go to such organizational websites would tend to be more interested in skin cancer than others. Such individuals would also likely be more similar to potential end users (e.g., those with a melanoma family history) than those representative of the general population (e.g., minorities). Although we also hope that our social media efforts will encourage initial viewers to recommend our website to family/friends who may exhibit higher risk behaviors and be less interested in change than initial viewers. Additionally, we will use a "snowball"

method and ask each organization for recommendations for their partner organizations that might be interested in collaborating. Specifically, in addition to skin protection groups, we will seek to create a list of organizations and companies most relevant to young adults at moderate to high risk of skin cancer (e.g., spring break vendors, outdoor sporting groups, swimwear companies). We have also begun the review process for the intervention to be included as a Research-Tested Intervention Program (RTIP) on the NCI website. At minimum, in order to participate in the project, we will require non-profit organizations to post a link to UV4.me2 on their website and for-profit companies to provide discounts and/or free products (that are not associated with harm to the skin) to UV4.me2 users. However, we will encourage/facilitate additional promotion via social and traditional media. We will offer: 1) promotion of organizations within UV4.me2, 2) ongoing data/reports on web users and study progress, 3) creation of a network for similar organizations, and 4) opportunity for collaboration with expert investigators on research/publication. We will assess the nature and timing of interaction that would be of most interest to them (e.g., email, conference call, web meeting). For-profit companies could also receive: free marketing, tax write-offs, positive public relations, and participation in a charitable effort.

Reaching Young Adults: Five types of online sources will be used to reach young adults: 1) national non-profit and for-profit skincare organizations (e.g., the Melanoma Research Foundation and Blue Lizard Sunscreen), 2) Google Adwords, 3) paid Facebook ads, 4) a consumer research panel - SSI, and 5) word of mouth (e.g., unpaid study Facebook page, earned news media [free publicity from a third party]). Google Adwords and Facebook are common online recruitment sources for young adults that can produce cost-effective, representative, and quality samples/data (150-158). Facebook is the largest social networking website and the second most popular website in the US after Google (159). Because some participants may know one another (e.g., from Facebook), we will inquire about/control for contamination between intervention conditions. Consumer research panels possess the qualities of Google Adwords and Facebook and can also produce guaranteed enrollment/data collection within a specified time-frame and budget (160-166), as occurred in the original UV4.me study with SSI. The team will refine web banner ads and create a Facebook study webpage to recruit individuals from the five online sources. Enrolled participants will be informed about the Facebook page, and non-enrolled individuals will be able to find the publicly available page organically by being referred by friends or searching Facebook or the web for related topics. To facilitate recruitment via Google and Facebook (also Bing and Yahoo), we will work with young adults and www.PatientRecruitmentOnline.com (PRO, see **Budget Justification**) to help develop our keywords, ads, and recruitment plans. We will also consider Twitter, but this was not particularly popular with our original sample. Several recruitment messages, images, and formats will be tested for acceptability and piloted for effectiveness prior to the RCT (see **Appendices** for samples). To have our final sample composed of participants distributed across the sources, we will employ the following strategy. We will aim to recruit >25% of the sample from national non-profit and for-profit skincare organizations, the unpaid study Facebook page, and word of mouth. In an ideal world, these would be the only sources used for recruitment since they are essentially free and therefore most sustainable. However, in order to guarantee an adequate sample size to assess the effects of the enhancements and to compare several common recruitment methods for representativeness and efficiency, we will also use paid strategies. We will budget for what we believe will produce 25% of the proposed sample size each for Google Adwords and Facebook ads and stop recruitment from these sources when either the maximum budget or sample size is reached, whichever comes first. We will budget for and recruit $\leq$25% of the proposed sample from the consumer research panel. We will attempt to recruit most participants during spring/summer when skin cancer risk behaviors are highest in much of the US.

Randomized Controlled Trial (RCT): Compared to the original UV4.me trial, the key differences for the UV4.me2 trial include: 1) recruitment from organizations and online sources rather than solely a consumer research panel, 2) the addition of several enhanced recruitment strategies and intervention features (e.g., embedded incentives), 3) assessment of dissemination, implementation, and effectiveness rather than solely efficacy, 4) a final follow-up of one year instead of three-months, and 5) assessment of maintenance and cost. These characteristics will enhance intervention implementation and effectiveness among a more representative sample and provide data to inform decision-making for ongoing program utilization.

Based on our analyses of adult NHIS data, skin cancer risk behaviors (e.g., sunburns, indoor tanning,) peak around age 25 (55, 56). To minimize risk behaviors in early adulthood, we will recruit adults ages 18-25. Individuals will be screened with the Brief Skin Cancer Risk Assessment Tool by Dr. Glanz (**see Measures**) (27). Items include sun sensitivity, sunburn history, latitude of childhood residence, and so on. A cut-off of $\geq$27 out of 78 denotes moderate-high skin cancer risk. Only those at moderate-high risk of developing skin cancer will be enrolled. Individuals with a history of skin cancer will be excluded. Interested and eligible participants will sign

an electronic informed consent form using their mouse/cursor to draw their signature and then complete a baseline survey focusing on exposure and protection behaviors that takes approximately 15 minutes. The study statistician will create a randomization scheme to randomize enrolled participants on a 2:2:1 basis to UV4.me2, UV4.me, or the e-pamphlet condition, respectively. Participants will not be informed of the differences in the intervention conditions beyond that they will all be online skin cancer risk reduction interventions. In addition to discounts and free samples, participants will be eligible to earn Amazon e-giftcards for completing study assessments for a possible total of $100 throughout the year, plus a chance in a raffle for $100 at each time-point. We chose this level of incentives to balance two issues: 1) we wanted to encourage young adults to complete the longitudinal study assessments, but 2) when the research phase is complete, individuals will not be paid for using the program (other than the discounts and free products). Adult participants who are not eligible but are willing to consent will still be given access to UV4.me2 in order to promote good will with organizations and individuals and to gather preliminary data regarding additional dissemination and effects of UV4.me2 for older individuals and those at population-level risk for skin cancer.

Most of the intervention and procedures have been tested previously, but the new recruitment strategies and enhanced intervention and implementation strategies have not. We will pilot the procedures for the recruitment process, screening, eligibility, consenting, randomization, the interventions, reminders, assessment, data management and reporting, incentives, etc. Participants will provide feedback about any problems they experience. Once these issues have been resolved, we will begin the full RCT. Such a pilot was fruitful for the original UV4.me study (102). The basic nature of the interventions would not change after the pilot, but procedural details of the participation process could still be enhanced. For example, we could correct bugs in the programming, clarify instructions, or send additional task reminders.

Measures. Dr. Heckman and team have used most measures below with young adults online (See **Appendices**), except for the cost measures, which will be administered by Dr. Honeycutt and the RTI team.

Adoption. Though not the focus of the proposed project, we will monitor the level of adoption of non-profits (e.g., whether a champion is identified, level of participation with research staff, how/where/when the study URL is posted on the organizational website, etc.) and for-profits (e.g., the value/number of discounts and free products provided over what period of time, whether the study URL is on the company website, etc.).

Aim 1. Screener. Participants will be screened with Dr. Glanz's 9-item Brief Skin Cancer Risk Assessment Tool (**see Enrollment section above**) (27). Internal and test-retest reliability compare favorably to those reported in the literature for similar items/scales (27). Participants will be required to understand English and have access to the internet via any modality (e.g., computer, smartphone) at least weekly.

Demographics. Standard demographic items used by the census will assess: sex, age/birthdate, race/ethnicity, region of residence, education, income, and employment. We will include items on web use from the Health Information National Trends Survey (167), and will inquire about family history of skin cancer.

Reach. We will assess eligibility and enrollment overall and by recruitment source (i.e., skin protection organizations, Google Adwords, Facebook ads, consumer research panel, word of mouth) over 12-18 months in order to assess reach/potential generalizability. Sources will be tracked by placing a unique identifying pixel in each of our authorized web ads so that we know when an individual referred from a pre-specified source accesses the study website. Additionally, we will query participants as to how they found out about the study to identify informal word of mouth diffusion (e.g., unpaid study Facebook page, earned media). The number of individuals who click on the web ads, access the study homepage, complete a screening form, are eligible/ineligible, and use the website without enrolling will be assessed. Organizational sources will be monitored and queried as to strategies (i.e., posting the study URL on their website, additional promotion) used to encourage individual participation. As we have previously, we will use Google Analytics to observe user characteristics and behavior in aggregate in terms of internet source including diffusion via word of mouth, geographic location, technology used (i.e., mobile or not), eligibility/enrollment rates, and so on. We will ask organizations to set up or allow us to set up a Google Analytics "goal" to assess such user characteristics and behavior in terms of individuals accessing the study ad from within the organization's website. We will also query organizations about their number of users/members and website views if they are monitoring these.

Aim 2. Effectiveness: Skin Cancer-Related Outcomes. Skin cancer-related behavioral outcomes will initially be assessed at baseline and 3 months later. They will also be assessed within UV4.me2 via behavioral tracking. We will assess sun protection (e.g., sunscreen use, clothing, shade) and UV exposure (e.g., sunburns, intentional/incidental sun exposure, indoor tanning) using items adapted from Glanz and colleagues and Ingledew and colleagues that our team has cognitively tested and assessed psychometrically with young adults (90, 168, 169). Sunburns, indoor tanning, and sunless tanning will be secondary outcomes since engagement

in these activities is less frequent than sun exposure and protection in general. Negative effects will be defined as an increase in sunburns. Several studies have demonstrated the reliability and validity of self-report questionnaires of UV exposure and protection compared to observation and objective measures with no systematic bias identified among various populations (170-174). As indicators of quality of life, we will inquire as to the amount of perceived benefits of and barriers to UV exposure and protection (78, 175-178). We expect that intervention will increase perceived benefits of protection and barriers to exposure and decrease perceived barriers to protection and benefits of exposure as in our prior study (paper under review).

Aim 3. Maintenance. Skin cancer-related behavioral outcomes (described above) will be assessed at 6 and 12 months. We will also assess maintenance of reach, intervention implementation, and cost over time.

Aim 4. Implementation. Using BeHealth's data management system, we will record whether, how frequently, and for how long participants logged into the interventions, how many sections are completed, use of the enhanced features, and whether these variables are associated with behavioral outcomes. Whether individuals click into the pages with discounts/free samples will be noted. Whether and when a user accesses the e-pamphlet will be noted as well. We will ask participants to give Likert ratings of their satisfaction with and perceived helpfulness of the study/intervention and selected components (e.g., the enhanced features) both from within the intervention and a one-month follow-up inquiry. We have experience using Google Analytics "goals" to track how frequently pages within modules are accessed. These implementation variables will also be linked to participant source (i.e., skin protection organizations, Google Adwords, Facebook ads, consumer research panel) when possible so that sources can be compared by participant intervention implementation.

Aim 5. Cost. We will assess total and incremental costs and evaluate the cost-effectiveness of the interventions. We will first estimate costs from a payer perspective, capturing the explicit resources required to deliver the program after all start-up costs (e.g., development/programming costs) have been incurred. We will also estimate costs from a societal perspective, which includes all costs, regardless of who bears them. These will include all explicit costs as well as the implicit program costs related to participant time (i.e., opportunity costs (179). We will also denote whether costs are related to research or intervention delivery. We will collect cost data using a modified version of prior cost surveys developed by RTI (180, 181) and adapted by Dr. Honeycutt for many interventions (182, 183). The surveys capture all relevant labor- and non-labor-related inputs necessary to quantify costs. We will quantify participant time spent on the intervention using data from BeHealth's system and valuing participant time using age- and sex-specific wage rates, netting out research incentive payments to participants. We will quantify labor costs as program staff time (via questionnaires) valued using actual or estimated wages. Non-labor costs will be collected using program billing records and include materials/supplies used to support program activities and costs for facilities and contracted services. To evaluate the cost-effectiveness of UV4.me2 versus UV4.me and the e-pamphlet, we will combine cost estimates with effectiveness outcomes to estimate the cost per incident of UV exposure and sunburn averted.

Data quality. We will employ several recommended strategies to minimize repeat enrollment and enhance data quality (161, 184-192). See **Data Safety and Monitoring Plan** for more detail.

Analyses: 1. Reach. We believe that enhanced recruitment and enrollment strategies, we can increase the rate of enrollment and baseline completion from 55 to 70%. We will use a one-sample test of a binomial proportion (two-sided, α=0.05) to determine whether the fraction of eligible subjects who enroll and complete the baseline is higher in this project than the prior study. The sample size of 1500 enrolled subjects who complete the baseline survey has been selected to address the primary effectiveness analyses described in Aim 2. Assuming that 70% of eligible subjects enroll and complete the baseline, we will need access to 2,143 (i.e., 1500/0.70) eligible subjects. Given this sample size, we will be able to detect an increased enrollment and baseline completion proportion with at least 98% power if the true proportion is 70%. Demographic data from enrolled participants will be compared to census data using chi-square goodness of fit tests (two-sided, α=0.05). We hypothesize that the demographics of our sample will not differ significantly from national demographics. We do not expect race/ethnicity representativeness because non-Hispanic Whites possess more skin cancer risk factors. **Exploratory**: We will also use the same methods to compare enrollment rates and representativeness separately by recruitment source (i.e., skin protection organizations, Google Adwords, paid Facebook ads, consumer research panel, word of mouth [e.g., unpaid Facebook page, earned media]).

2. Effectiveness. We will compare demographics across randomization arms using chi-squares and ANOVAs for categorical and continuous data, respectively. The primary outcomes are baseline to 3-month changes in UV exposure and protection. We will use multivariable linear regression to compare the effectiveness of UV4.me2 with UV4.me, and UV4.me2 with the e-pamphlet. We will not compare UV4.me to the e-pamphlet because UV4.me compared to a control condition was established in the prior study. Covariates in these models

will include study arm, recruitment month/season, US region, and demographic factors identified as significantly imbalanced across arms (confounders). Analyses will be performed separately for the two primary outcomes. Variance stabilizing transformations may be applied as needed. Hypothesis tests will be two-sided with a 1.25% Type I error to account for multiple testing (2 intervention comparisons x 2 outcomes). Based on our data, experience, the enhanced study procedures, and the consumer research panel's experiences with young adults, we anticipate attrition of approximately 20% at each time-point. With 1500 young adults at baseline, we anticipate collecting 3-month follow-up data from 1200 participants, with 240 from the e-pamphlet arm and 480 participants from each of the other arms. The means (SDs) of the baseline to 3-month changes in UV exposure and protection indexes from the prior study control arm were 0.34 (0.74) and -0.37 (0.90), respectively. Given these parameters, we will have 80% power to detect small standardized effect sizes of 0.22 between the UV4.me2 and UV4.me arms, and 0.26 between the UV4.me2 and the e-pamphlet. These correspond to small detectable differences between intervention arms of 0.16 and 0.19 in baseline to 3-month changes in UV exposure and protection indexes, respectively. We will be able to detect slightly larger differences when the UV4.me2 and e-pamphlet arms are compared (detectable differences - UV exposure: 0.20; protection: 0.24). Missing Data. Analyses will assume that missingness depends on observed data (i.e., missing at random; MAR) (193). For drop-outs, the reason for attrition will be analyzed if available to search for evidence of informative missingness. Baseline variables will be compared by whether participants drop out or not. Significant variables will be added to the model to strengthen our MAR assumption. As a sensitivity analysis, we will use a shared parameter model with the assumption of missing not at random (194). If large changes in parameter estimation are found, we will use the results from the shared parameter model.

3. Maintenance. We will use the methods described in Aim 2 to compare baseline to 6- and 12-month changes in UV exposure and protection across study arms. Tests will be two-sided with a 5% type I error for these secondary analyses. We anticipate having follow-up data from approximately 960 and 768 participants at 6- and 12-months, respectively. This will allow for 154 participants in the e-pamphlet arm and 307 in each of the other two arms at 12 months. Detectable differences with 80% power are presented in Table 2.

Table 2. Detectable Differences		Baseline to 6-month changes		Baseline to 12-month changes	
Outcome	Comparison	UV4.me2 vs. UV4.me	UV4.me2 vs. pamphlet	UV4.me2 vs. UV4.me	UV4.me2 vs. pamphlet
UV Exposure		0.16	0.19	0.19	0.23
Skin Protection		0.19	0.23	0.23	0.28

4. Implementation. Using BeHealth's Wasabi data management system, we will create a summary index representing how frequently and for how long participants are logged into the interventions and how many sections are completed and determine whether this index is associated with behavioral outcomes. Whether and when a user accesses the e-pamphlet will be noted. We have experience using Google Analytics "goals" to track how frequently individual pages within modules are accessed. We will ask participants about their satisfaction with the study/intervention and selected components (e.g., the enhanced features) both from within the interventions and a one-month follow-up inquiry. These implementation variables will also be linked to participant source (i.e., skin protection organizations, Google Adwords, Facebook ads, consumer research panel) when possible so that sources can be compared in terms of participant intervention implementation. We will use the methods described for Aim 2 to compare these utilization and satisfaction measures across study arms, and Spearman's correlation to measure the level of association between implementation metrics and longitudinal changes in UV exposure and protection indexes within and across study arms. Tests will be two-sided with a 5% type I error for these secondary analyses. We anticipate 1350 participants at 1-month follow-up (e-pamphlet = 270, others = 540). **Exploratory**: Whether individuals click into the pages with discounts and free samples from skincare companies will be noted. We will assess whether accessing more incentives within the interventions is associated with greater intervention utilization and better behavioral outcomes.

5. Cost. We will estimate mean and median costs for each intervention. We will distinguish between development costs (one-time capital investment or "sunk" costs) and implementation costs, or the costs to maintain the interventions. We will also denote whether costs are related to research or intervention delivery. Analyses will distinguish between fixed costs (costs that do not vary with enrollment, e.g., server maintenance, data storage), and variable costs, which increase with additional participants. Because most costs are expected to be fixed, the mean cost per participant will be driven largely by the number enrolled. To explore costs of scale-up, we will conduct sensitivity analyses around additional dissemination efforts and higher take-up rates. We will also estimate the cost-effectiveness of UV4.me2 relative to the other conditions, calculating cost-effectiveness ratios as the difference in estimated costs divided by the difference in estimated effectiveness to determine the incremental cost per sunburn (or incident of UV exposure) averted for each intervention pair (193, 194). We will

also assess and estimate medical cost (e.g., OTC medication use, healthcare visits) offsets resulting from averted sunburns. To estimate longer-term cost-effectiveness, we will develop an Excel-based model to estimate quality-adjusted life year (QALY) gains associated with each sunburn (which increases melanoma risk) averted. For the cost-effectiveness modeling, we will use data from the literature on the probability of developing various forms of skin cancer as a result of sunburns and on QALY losses associated with various cancer outcomes to estimate the cost per QALY gained. Expressing cost-effectiveness as cost per QALY gained will facilitate comparison of the UV4.me2 intervention with other preventive health interventions. For all cost-effectiveness analyses, we will perform one-way (and n-way) sensitivity analyses to examine the impact of varying input values over a plausible range.

Limitations & Alternatives Considered. We reviewed a variety of D&I models and believe that the RE-AIM Framework is the best fit with the proposed project because it involves online implementation of a self-administered intervention. We considered including other organizations for initial adoption (i.e., others relevant to young adults at moderate to high risk of skin cancer such as tanning salons, spring break vendors, outdoor sporting groups, swimwear companies). However, we chose the ones we did initially based on feasibility, internal validity, reportability, and reproducibility concerns in terms of focusing on organizations that are most interested in skin protection and that are members of circumscribed and homogeneous groups (i.e., members of the National Council on Skin Cancer Prevention or those with products with the Seal of Recommendation by the Skin Cancer Foundation). We believe that the enhancements to UV4.me are the ones that will have the greatest impact on reach, implementation, and behavioral outcomes based on the original UV4.me and the literature. We considered other comparison conditions but had several reasons for choosing e-pamphlets (**see e-Pamphlet Section**). We will query participants as to their study-related social media activity and potential contamination and use this as a covariate in analyses if necessary. We anticipate that this could affect study enrollment/attrition somewhat but would be relatively unlikely to have major effects on behavioral outcomes since such behavior change often requires more than minimal intervention. Although objective assessment of behavioral and biological outcomes might be desirable, it would be infeasible for a large national longitudinal trial, and the self-report measures selected have demonstrated adequate psychometric characteristics (**see Measures Section**). Finally, this project focuses on implementation and intervention effects rather than psychological change mechanisms as has been done in prior research and to keep participant burden low.

Table 3. Timeline. The team will meet at least biweekly by phone with ongoing email exchanges.

Aim	Activities	Accomplishments Mo.	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
2	Development/programming	Enhance UV4.me	x									
2	Acceptability/usability	Refine/finalize intervention		x								
1	Develop campaign	Finalize recruitment			x							
1	Initiate sources/recruit	Enroll young adults				x	x	x				
1	Assessment of reach	Determine reach					x	x	x			
2-5	RCT and Follow-ups	Assess implementation, effects, maintenance, cost						x	x	x		
All	Analysis and manuscript preparation	Papers: Reach, Implementation, Effectiveness, Maintenance, Cost						x	x	x	x	x

Conclusions/Future Directions. Few skin cancer prevention interventions have been disseminated widely. Skin cancer implementation research is rare. To our knowledge, ours is the only empirically-based web intervention to address skin cancer risk behavior targeting young adults. This project is likely to demonstrate high impact and efficiency in terms of reach, effect, maintenance, and cost among young adults at risk for skin cancer, the most common cancer. The project is innovative for implementation research because it involves online/mobile implementation of a self-administered intervention. In addition to components previously shown to be effective for (online) behavioral health interventions (e.g., targeting, tailoring), other innovative characteristics are organizational partnerships for adoption, online marketing and recruitment, and the use of discounts and free sample incentives from for-profit companies. In addition to manuscripts, products derived from the project will include a group of committed organizations, an effective online skin cancer risk reduction intervention for young adults, and a framework for future organizational adoption (e.g., healthcare and insurance organizations) and individual dissemination/implementation. Once the UV4.me2 D&I approach is established and assessed, it could be used for other e/mhealth interventions (e.g., nutrition, physical activity) for young adults and other populations. Thus, the project proposes a novel approach to address an issue of growing public health significance with potential application to other health issues and populations.

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