

SSW Works: A Virtual Learning Environment for
Occupational Skin Cancer Prevention Ph II

NCT05774600

Study Protocol and Statistical Analysis Plan

August 15, 2025

Study Protocol

3C. Approach

We have already developed a) the effective SSW intervention that uses in-person meetings and training and b) research methods for evaluating occupational sun safety interventions. So, potential feasibility of *SSW Works* is high. We propose to achieve Phase I milestones of culturally adapting content for Hispanic and African American workers, automating the algorithm for tailoring intervention to employers' readiness to innovate, creating the VLE technology platform, and confirming it is usable, feasible, and acceptable for full-production and evaluation in Phase II.

3C.1. SSW Works: Virtual Learning Environment for Occupational Skin Cancer Prevention

The innovative product, *SSW Works*, is a virtual learning environment (VLE) for automated, comprehensive, on-demand, tailored distribution of the SSW program to private and public employers with outdoor workers. Most of the SSW materials that will be adapted and integrated into *SSW Works* were developed in our prior trials, including a) introductory video, b) sun safety checklist, c) SSW Report template, d) manager briefs, e) policy writing tool, f) 30-minute online employee training, g) employee communication to inform and motivate on-the-job sun safety (articles, brochures, posters, tip cards, and stickers), and h) sun safety environmental audit. It will provide guidance and resources to managers for implementing workplace policy and employee education and communications through a combination of three custom-built technology platforms: database platform (registration, staging inputs, and algorithm), content management platform (interactive toolbox with report and resources), and media platform (employee training and videos for managers and employees). The user interface will organize the advice and resources into two sections:

- **Manager Interactive Toolbox:** Tailored support for managers in policy adoption and program implementation for employee sun safety. Features: 2.5-minute introductory video; forms to input workplace policy, actions, and characteristics; tailored, real-time SSW Report based on these inputs; manager briefs (e.g., topical white papers) and videos; policy writing tool; and workplace audit tool.
- **Employee Training:** Library of resources to promote personal sun protection by employees. Resources include: a 30-minute online employee training and assessment compatible with different LMS and employee communications (articles; brochures; signage; tip cards; skills videos). *SSW Works* will also reflect findings from formative research and prototype testing. Specifically, it will address facilitators/barriers to sun protection among Hispanics and African Americans, be culturally-representative (e.g., images will be selected from KB's *Real Health Photos* stock art library), and be available in English and Spanish (using KB's translation-back-translation procedures). The SSW training will conform with various LMS technology to ensure it can easily be part of regular training for employees.

3C.1.1. Staging Algorithm and SSW Report: Using our staging grid that tailors advice on occupational sun safety based on DIT61 principles, investigators and media developers will create an algorithm to automatically perform tailoring of SSW to managers readiness to innovate, previously done by intervention staff. It will use three inputs on employers' current policies and actions:

1. **Policy Checklist** – users report content of workplace policy directly or indirectly on sun safety, based upon the 15 policy categories in our current SSW policy coding protocol.
2. **Manager Survey** – users report opinions about occupational sun safety (risk of skin cancer; support for policy), existing sun safety policy and standard operating procedures (awareness, support, and enforcement), and existing sun safety actions, training, and messages.
3. **Sun Safety Checklist** – users report willingness to implement actions for a model sun safety policy (whether the workplace is already doing, might do, or would not do each action).

Using input forms, staging algorithm, and report template, *SSW Works* will generate a customized SSW Report and Action Plan for the workplace. It will describe gaps in sun safety policy/education and support for/resistance to them, and provide resources on sun safety (e.g., briefs/videos) and plans for implementing sun safety through policy changes, employee training, and workplace actions. Guidance will be matched to DIT stages of managers' readiness to innovate:

- **Agenda Setting** – Convincing managers that UV exposure increases risk for skin cancer and policy/actions in SSW will reduce this risk before addressing program fit and implementation.
- **Matching** – Describe ways policy, education and actions fit in work processes/environments before addressing implementation.
- **Structuring** – Focus on developing plans for implementing policy, education, and actions.
- **Clarifying** – Reinforce implementation and anticipate, monitor, and reduce opposition to implemented sun safety practices by employees, managers, and clients.

3C.1.2. Managers Briefs and Videos: Manager briefs (1-2 pages on individual topics in more detail) will aid decision-making and implementation. We will produce five 5-minute “YouTube” style videos to accompany briefs. Tentatively, we plan briefs/videos on: UV risk in outdoor work, sun safety workplace audit; selecting/sourcing PPE (e.g., wide-brimmed hats; bulk sunscreen), workplace policy, and planning implementation. Videos will contain slides, voiceovers, and animated/live actor demonstrations.

3C.1.3. Employee Training Compatible with Learning Management System (LMS): Many organizations have adopted LMS, software that manages, tracks, and reports on employee training (i.e., registration, attendance, completion, and assessment). In our recent SSW trial, several state DOTs are using LMS and requested the 30-minute employee training be loaded into their LMS. However, the current training is in HTML5 format, not compatible with all LMS. KB media developers will re-program the employee training to be compatible with popular LMS (e.g., Edmodo, Moodle, Blackboard, SAP SuccessFactors, Thinkific, SkillSoft, Instructure, Saba Software, Cornerstone OnDemand, and Schoology60), based on our prior trial, Phase I interviews, and LMS literature so it can be institutionalized in the workplaces. This will involve formatting files for specific LMS requirements and ensuring SCORM-compliance. A training assessment (i.e., knowledge check) for LMS will measure employee sun safety knowledge and skills.

3C.1.4. Employee Skills Videos: In our SSW trial, managers requested short videos for safety meetings to reinforce employee training. We will produce five 5-minute videos in “YouTube” style on skills acquisition. Tentative topics are using UV Index; assessing personal risk; wearing protective clothing; using shade; and applying sunscreen. Videos will contain slides, voiceovers, and animated/live actor demonstrations.

3C.2. Target Populations, Recruiting, and Inclusion/Exclusion Criteria for Phase I and II

Target populations are employers, outdoor workers, and managers. We will recruit employers from diverse industries (e.g., agriculture, oil and gas exploration, construction, utilities, transportation, landscaping, outdoor recreation, public works/safety). In our SSW trial, employees were 66% age 31-60, 80% male, 93% white, 1% African American, 10% Hispanic, and 12% with Type I or II skin, and 37% had a college/postgraduate degree. Males are least sun protective^{174,175}; non-Hispanic whites are at highest risk for melanoma and skin cancer.¹⁷⁶ Managers included human resources directors, risk managers, safety officers, resident engineers, and managers of facilities, maintenance, fire, and transportation. They were long-term employees (M=19.8 years) and worked some of the time outdoors (66%). Further, 55% were age 20-50 (M=48.9), 43% had a college/ postgraduate degree, and 91% were male. Also, 91% were white (6% Hispanic), 30% had Type I or II skin most susceptible to UV damage¹⁷⁷ and 10% had had skin cancer.

3C.3. Overview of Phase I Research and Timeline

Phase I research will be completed in 9 months. Protocols will be developed and approved by Western IRB in Month 1. Employers and Hispanic and African American outdoor workers will provide input on the tailoring algorithm, LMS, and content for *SSW Works* during Months 2-3. A prototype *SSW Works* VLE will be produced in Months 4-5 and its acceptability, feasibility, and usability evaluated in Months 6-7. Phase I results and feasibility of Phase II research will be evaluated in Month 9.

3C.4. External Advisory Board

An External Advisory Board (EAB) will review plans and provide input on Phase I/II activities. The EAB will be chaired by Barbara Walkosz, PhD. Members will include Robert Dellavalle, MD (dermatology), Cristian Gonzalez, MD (Hispanics & skin cancer), Robert Newton, PhD (African Americans & disease prevention), Patterson McKinlay (risk management), Dena Baldwin (human resources), and Tammy

Wright (Vector Solutions, e-learning product development). In Phase I, EAB will help fill two open positions for expertise such as workers compensation insurance and workplace safety and meet in Month 1 to approve the protocols. In Month 9, it will review Phase I findings and advise on feasibility of the *SSW Works* and its evaluation in Phase II. In Phase II, the EAB will meet in Month 11 to approve Phase II protocols, in Month 17 to review fully-programmed *SSW Works*, and in Month 36 to review findings from the trial evaluation. Meeting notes will be prepared by project staff of each meeting and reviewed by research team.

Milestones & Deliverables: Milestone 1: Approval of Phase I Research Procedures: In Month 1, the EAB will review and approve the Phase I research procedures. *Deliverable 1: Approved Study Protocol.*

3C.5. Formative Research to Develop SSW Works (Month 2-3)

3C.5.1. Training Concept/Content Focus Groups: To refine SSW content for racial/ethnic minority employees in the outdoor workforce, Hispanic and African American outdoor workers recruited in Denver, Colorado will participate in focus groups (n=8) – 4 groups of Hispanics and 4 groups of African Americans (n=8 per group; 64 total) – to identify ethnic differences in their attitudes, barriers, and practices related to sun safety. They will be sent a link to view the SSW training and a set of materials promoting sun safety in the workplace for employees (e.g., fact sheets, posters, newsletter articles, etc.) before arriving at the focus group session. Focus groups aim to describe outdoor workers' knowledge of workplace sun safety, sun protection on the job, perceived susceptibility to solar UV damage, benefits and harms of sun safety on the job, facilitators and barriers to sun safety, and content preferred in the occupational sun protection training and materials. Discussions will examine content/features that promote cultural appropriateness, including images that represent cultural/ethnic diversity from our *Real Health Photos* stock art library, which improved message effectiveness. Focus groups will last approximately two hours and participants will be paid \$50 for their time.

3C.5.2. Semi-Structured Interviews with Managers: Managers (n=10) in public organizations and private companies with outdoor workers will complete semi-structured interviews on *SSW Works*, culturally relevant content for Hispanic/African American workers, and overall content/features, including tailoring to stages in the diffusion process. Managers will be identified nationwide through professional associations (e.g., Moody Insurance Company, Baldwin HR Consulting, and North American Association of Transportation Safety and Health Officials [NAATSHO]), and employers in our prior research. They will be sent a link to view SSW policy promotion materials for managers toolbox and SSW training and materials for employees (e.g., fact sheets, posters, newsletter articles, etc.). Managers will describe sun safety policies and standard operating procedures, employee sun safety practices, employee susceptibility to solar UV damage, benefits, harms, facilitators and barriers for sun safety on the job, if they would use on-demand VLE, how training will be used (e.g., individually or in groups), current LMS, if they would add SSW training to LMS (and preferred format), need for assessment in LMS, and how helpful SSW would be for their outdoor workers. These 1-hour interviews will be conducted by telephone by the Project Coordinator; participants will be paid \$50 (unless public employees cannot accept financial compensation).

Milestones & Deliverables: Milestone 2: Development of the Specifications Document: Qualitative analysis will rely on constant comparative analysis and methods by Krueger and Casey, assigning codes that categorize themes and opinions. A comprehensive specifications document describing the *SSW Works* will be developed from this analysis. This will include content changes to increase relevance and effectiveness with Hispanic and African American employees. *Deliverable 2: Specifications Document for SSW Works.*

3C.6. Production of the Prototype SSW Works (Months 4-5)

A prototype of *SSW Works* will be produced using agile, iterative production. Training/materials for employees will be revised to address facilitators/barriers identified by Hispanics and African Americans. We will create a staging algorithm on readiness to innovate in DIT, with input forms for managers to report their support for and actions on sun safety and tailored report template. A process for managing missing data will be established. The prototype will generate real-time, customized workplace SSW Report. We will also create a storyboard for one manager brief/video, list of tentative topics for employee skills videos and a storyboard for one of them. KB media developers will re-program the employee training to be compatible with a popular LMS by formatting files for specific requirements and

ensuring SCORM-compliance. We will author a 15-item assessment of employee sun safety knowledge and skills for the LMS. KB media developers will add technical requirements to the specifications document and, along with investigators, determine how robust the prototype will be given budget/timeline to meet Phase I goals (i.e., demonstrate features and test elements users may have trouble using). Outlines, flow charts (i.e., wireframes), storyboards, and screen designs will be prepared as clickable wire-frame prototypes. The prototype will conform to the federal 508 standards for accessible information technology.

Milestones & Deliverables: Milestone 3: Development of SSW Works Prototype: KB programmers will develop a prototype SSW Works in Months 4-5. A clickable wire-frame of tailoring algorithm, training conforming with an LMS, and storyboards of videos will be produced, with other materials in flowcharts. *Deliverable 3: Revised Specifications Document for SSW Works. Deliverable 4: SSWWorks Prototype.*

3C.7. Evaluation of Prototype SSW Works Virtual Learning Environment (Months 6-7)

3C.7.1. Semi-structured Usability Interviews: The prototype SSW Works will be evaluated for feasibility, acceptability, and usability in semi-structured interviews with 10 managers and 20 Hispanic and African American workers (10 each) in Months 6-7 (those participating in prior Phase I research will be ineligible). To identify problems that impact $\geq 10\%$ of users in usability testing with a 90% chance of detection ($\log(1-.90)/\log(1-.10)$), 21 participants are needed. We will create scenarios and tasks for using SSW Works, which will be given to participants who will review and interact with the flowcharts/storyboards/wire-frames, complete the System Usability Scale (SUS), and answer a set of interview questions. For workers, the tasks will focus primarily on completing the training and reading/reacting to the other promotional materials. They will evaluate perceived appropriateness and usefulness of content, if it is feasible to use SSW Works at their workplace, and potential barriers to use. Managers and workers will be paid \$75.

3C.7.2. Algorithm Testing: We will evaluate the tailoring algorithm in the following 4 steps, using the SSW Reports prepared for 21 state DOTs in our previous trial:

1. Policy coding, manager survey, sun safety checklist, and SSW Report for 5 DOTs selected at random will be used to create the initial algorithm flowchart.
2. Next, 5 DOTs will be selected at random and the algorithm will be trained by using policy coding, manager survey, and sun safety checklist to prepare a SSW Report using the algorithm flowchart. The report will be compared to the one created for DOTs and algorithm adjusted to resolve discrepancies.
3. Refined algorithm flowchart will then create SSW Reports for another 5 DOTs selected at random and further refined to resolve remaining discrepancies with the original report.
4. Finally, to measure feasibility and accuracy, the final algorithm flowchart will create the SSW Report for the last 6 DOTs and the number of discrepancies with the original reports will be recorded.

3C.7.3. LMS Testing: We will identify 5 employers (compensation=\$500) that use LMS for which training is programmed. KB media developers will work with employers' IT staff to load the training into the LMS and confirm that it operates (e.g., collects registration; tracks completion; conducts assessment).

Milestones & Deliverables: Milestone 4: Evaluation of the Prototype: Data will be stored in KB's secure servers, with data management and analysis supervised by Dr. Cutter, Project Biostatistician and KB's Biostatistical Manager, using quality assurance protocols and SAS software. Analyses of the SUS will include descriptive statistics; answers to interviews will rely on qualitative methods to code and categorize themes. In Month 9, reports will summarize findings from interviews and SUS on usability/acceptability, discrepancies in algorithm-generated report, compatibility with LMS, and suggestions to improve it in Phase II research. Media developers will update specifications document for the full SSW Works in Phase II. *Deliverable 5: Evaluation Reports. Deliverable 6: Further Revised Specifications Document.*

3C.8. Evaluation of Feasibility of SSW Works Virtual Learning Environment (Month 9)

In Month 9, EAB will review Phase I findings and advise on feasibility of SSW Works, how to meet preferences of managers and workers, and methods for implementing and evaluating it in Phase II. Feasibility metrics include a) tailoring algorithm and training content being acceptable to $\geq 75\%$ of

managers and workers, b) specifications and prototype of MedTend being successfully developed, c) prototype being acceptable/usable to at least 75% of manager and workers (minimum score of 68 out of 100 on SUS), c) algorithm-generated report have <20% discrepancies, and d) training operating within LMS environment. If these feasibility metrics are not achieved, we will continue to iteratively refine *SSW Works* based on Phase I results, EAB input, and testing with more managers, employees, and employers until prototype is acceptable, receives a SUS score of ≥ 68 , produces reports with <20% discrepancies, and operates on LMS. Given *SSW* was acceptable/effective in past research, likelihood of not achieving Phase I feasibility metrics is low.

Milestones and Deliverables: Milestone 5: Feasibility Assessment: The EAB will review Phase I outcomes, advise on feasibility of full *SSW Works*, and provide input on final specifications document to guide Phase II production, if deemed feasible. Findings will be formalized into a final report on Phase I, including decision on feasibility of *SSW Works* and plans for Phase II development and research. *Deliverable 8: Phase II Plan and Final Specifications Document. Deliverable 9: Final Report.*

3C.9. Scientific Rigor, Limitations, and Alternatives in Phase I Research

State-of-the-art, pre-defined protocols, diverse samples, and established measures (e.g., SUS) will ensure scientific rigor of Phase I, which focuses on feasibility of *SSW Works*. The small samples in Phase I are typical for formative qualitative research. If recruitment of Hispanics and African Americans lags, we will also recruit them through KB's staff in New Mexico and our professional networks in other states.

3C.10. Overview of Phase II Research and Timeline

SBIR Phase II research will include full production of *SSW Works* (Months 10-18) and a randomized controlled field trial testing its effectiveness (Months 15-36), in a 27-month timeline. The target population is employees and managers at employers with outdoor workforces. Media developers at Klein Buendel (KB) will produce the *SSW Works*, using Phase I specifications and prototype. The EAB will meet in Month 11 to approve protocols, in Month 17 to review fully-produced *SSW Works*, and in Month 36 to review trial outcomes. All Phase II procedures will be approved by the Western IRB. Employers participating in Phase I research will be ineligible for Phase II.

3C.11. Full Production of *SSW Works* Virtual Learning Environment (Months 10-18)

3C.11.1. Iterative Production: *SSW Works* will be produced by KB's Creative Team of a graphic designer and multimedia programmers, using KB's agile, iterative development approach. Based on formative research, specifications document, and prototype from Phase I, we will finalize content, with cyclical review and feedback. All materials will be in both English and Spanish; Dr. Gonzalez (EAB) will review Spanish materials and Dr. Newton (EAB) the African American materials for cultural accuracy. The 30-minute online training can be viewed within the *SSW Works* or downloaded compatible with common LMS technologies. Interface design ideas with "timeless" language, graphics, and video depictions will be created and combined with scripts, flowcharts, and storyboards. Overall look and feel is consistent with Phase I prototype. Each component will be tested for platform stability/code errors prior to being exported to the Web server. After usability testing, *SSW Works* will be published to KB's secure web server in Month 19. It will run on common web browsers for Mac OS X and Windows personal computers and on iOS and Android tablet computers and smartphones. It will be authored in a Responsive Web Design approach that optimizes user experience across platforms/screen sizes, using Angular, HTML5, CSS, JavaScript, and Microsoft dotNet platform (using C# language). Microsoft SQL databases will track use. KB's media developers will maintain *SSW Works*, monitor usage, and provide technical support to users by email and toll-free phone number.

3C.11.2. Iterative Usability Testing: *SSW Works* will be usability tested in Month 16-17 with procedures from Phase I. Managers (n=10) meeting eligibility criteria will be recruited and consented (10 usability testers will identify 95% of problems; compensation=\$75). Using protocol analysis, participants will talk aloud while navigating *SSW Works*, saying what they are thinking. Staff will record navigation and problems. Participants will complete SUS, and interview on usefulness/ appropriateness of content, feasibility at workplace (including in their LMS), and barriers to its use. Project staff will summarize results for investigators and KB media developers. Participants will be run in two rounds of

5 participants, with revisions made between rounds to improve usability and produce the final *SSW Works*.

Milestones and Deliverables: Milestone 6: Production of the *SSW Works*. *Deliverable 10: Fully-produced *SSW Works*.*

3C.11.3. Limitations and Alternatives of the *SSW Works* VLE Development: We will use our experience with technology interventions and Phase I findings to design a usable, effective *SSW Works* meeting needs of employers and outdoor workers. KB developers will use up-to-date, cost-effective production software. Usability testing will ensure *SSW Works* is maximally user-friendly.

3C.12. Randomized Trial (Months 15-36)

A randomized trial will evaluate *SSW Works* on outdoor workers' sun protection (primary outcome). Employers (n=20) will be recruited nationally and enrolled in a randomized, pretest-posttest controlled field trial. After baseline assessment of employees (n=50; compensation: \$20) and managers (n=6; compensation: \$25) in Months 15-18, employers will be stratified by expected probability of implementation based on a propensity score including size (number of employees), solar intensity (proxy for climate and UV), and urbanicity, and randomized to receive the *SSW Works* (n=10 employers) or minimal information only (n=10 employers) by Dr. Cutter. These 3 variables were significant covariates in our past research⁴⁴ or predicted baseline policy. We will then randomize within blocks of similar propensity scores to achieve comparable groups. A minimal information treatment, not the original *SSW*, will be the control condition because we do not expect *SSW Works* to be superior to *SSW* in effectiveness (our primary outcome) but rather more feasible and lower in cost. Intervention period will last 12-months – Months 19-30. Posttesting will be completed in Months 31-33 and data analysis by Month 36. Primary outcome will be assessed by surveying employees who work outdoors pre and post on sun protection practices. Workplace sun safety policy, education, and actions will be assessed pre and post by coding written policies (coders blind to condition) and surveying managers. Analyses will test the following hypotheses:

H1: Compared to employers in the minimal information control group, employers assigned to receive *SSW Works* will have employees that practice more sun protection at posttest.

H2: Improvements in employee sun safety will be mediated by workplaces adopting occupational sun safety policies and implementing education and actions on sun safety for employees.

We will test a research question of whether use of the *SSW Works* improves employees' sun protection.

3C.13. Recruitment of Employers, Managers, and Employees

Dr. Walkosz will lead recruitment using successful protocols from prior projects and approved by the Western IRB. We will identify eligible employers, working with industry professional associations and employers from GSS and *SSW* trials. Innovations such as *SSW* disseminate in societal sectors and professional associations create loose networks and intra-sector communication on emerging issues. We will recruit employers from diverse industries with outdoor workers (e.g., agriculture, oil/gas exploration, construction, utilities, transportation, outdoor recreation, public works, and public safety), from which we have recruited in the past. We obtained commitment from industry groups such as Moody Insurance Company, Baldwin HR Consulting, and NAATSHO to help us recruit employers, as well as from individual employers such as Eagle River Water and Sanitation. We do not want to bias our sample toward "compliant" employers who may already implement sun safety. Many employers are contending with the COVID-19 emergency as we finalized this application; requests for letters would have interfered with emergency responses. We are confident based on our 20 years of experience recruiting over 220 employers that these industry groups will help us recruit the needed employers. Employers with diverse employees (i.e., non-Hispanic white, Hispanic, and African American) will be recruited from the 4 U.S. Census regions to achieve diverse geography/climates that affects UV (UV is highest in low latitudes, high elevations, and dry climates), population density, and melanoma incidence. If recruitment lags, we will partner with additional industry associations. Employers will be stratified on size, solar intensity and urbanicity, randomly ordered within strata by Dr. Cutter, and contacted by project staff, from the top of list, by sending an invitation letter to the senior-most

managers and following-up by email/telephone and replacing refusals with the next eligible organization. Employers will provide email, mail, and telephone contact information for eligible managers who will be invited to read a consent statement and complete a pretest. Managers will provide a list of eligible employees who work outdoors, and Dr. Cutter will select a random sample. We will send surveys with consent statement to employers to be distributed to the selected employees. Employees can complete the survey and return it in pre-paid envelopes or complete it online. At least 6 managers and 50 employees need to complete the pretest for the employer to be eligible and randomized, so at least 5 managers and 35 employees will posttest.

We will track and posttest all participants, including those who leave the workplaces, using our successful retention methods. At pretest, participants will give name, address, home, work and mobile phone numbers, and email address of a person who can locate them. For managers, persons in the positions sampled at pretest will be posttested (new position holders will be posttested; we will attempt to posttest original person). Invitations will be issued by email. Subsequent contact attempts will be adjusted to maximize completion by non-responders and key ethnic minority groups (e.g., frequency, mode [email, U.S. mail, and telephone], and location). To reach persistent non-responders, staff will visit workplaces and complete survey in person and/or send non-respondents printed and PDF copies of posttests by mail (with a stamped return envelope) and email. We have recruited and retained large manager/employee samples using similar methods.

3C.14. Implementation of the SSW Works

SSW Works will be launched in Month 18 on KB's state-of-the-art web server. Extensive usability testing/refinement and tailoring to employer will increase user engagement (fidelity). We will send email invitations and monthly reminders to use *SSW Works*, tailored for season and UV levels and stressing partnerships with industry groups.

3C.15. Minimal Information Control Condition

As in our *SSW* trial, workplaces randomized to the control condition will receive a set of printed materials on occupational sun safety (1 mailing per year) as an attention control. These will include posters on personal protection and skin cancer incidence, risk assessment brochure, American Academy of Dermatology SPOT bookmark showing the ABCDEs of melanoma and skin self-examination, and a sun safety tip card from OSHA.

3C.16. Measures

3C.16.1. Primary Outcome Measure: Employees Sun Protection Practices: Employees will report a) frequency of sun protection at work (i.e., sunscreen with SPF 30+, long-sleeved shirts, long pants, hat with wide-brim, sunglasses, shade use, limit midday sun exposure, and have sunscreen, hat and eye protection at all times [1=never, 5=always]) and b) prevalence of sunburn in past 3 months on the job (yes/no; number). SPF 30+ is advised in *SSW* to account for typical under-application that reduces effective SPF. The measures are standard, validated, and reliable and were used in our *GSS* and *SSW* trials.

3C.16.2. Intervention Process Measures: With its automation, fidelity is indicated by use of *SSW Works*, recorded with process measures. Managers will log on to *SSW Works*, using project-supplied IDs; database will record use of features (i.e., sessions, pages viewed, and time spent) and b) use of sun safety training recorded on LMS. Mailing of printed materials will be recorded in minimal information control.

3C.16.3. Measures of Policy, Education, and Sun Safety Actions: We will assess implementation of sun protection policy, education, and sun safety actions by coding written workplace policies and surveying managers. A composite score will assess presence, strength, intent, and responsibility in sun protection policies using a protocol developed in the *SSW* trial assessing 15 policy categories: engineering controls (physical environment of the workplace), administrative controls (workplace procedures), and employee education (workers' sun safety). Each category receives a point (0, 1) for presence (total score=15) and a 3-level strength score (0=not allow/specify, 1=allow/recommend, 2=require; total score=30). Policies on engineering controls (scheduling/shade) and sun safety practices (hats/protective clothing) could exist for other reasons (e.g., to prevent injury), so those categories receive a point (0,1) when sun protection is cited. A 3-level responsibility score is

assigned for who provides protection equipment (0=not specified, 1=employee, 2=employer). Ordinal composite scores are continuous and summed across categories. Human resources and safety documents will be excerpted and coded by trained research assistants (blind to condition). Inter-coder reliability will be checked at the beginning, middle and end to ensure it remains high (>0.70). There is no basis for the minimum number of components that must be changed to improve workplace sun safety, so we will assess both presence and extent of change, which can detect expansion of existing policies.

Managers will report on sun safety education and workplace actions to support sun safety. Managers will report if training was provided to employees, and to supervisors and managers (yes/no/don't know). They will report on eight sun protection actions in the workplace: 1) Employer monitors UV Index and work scheduled is adjusted for harm associated with UV level; 2) Employees wear PPE (i.e., sun protective clothing, hats, and eyewear; sunscreen with SPF 30 or higher); 3) Employer provides PPE (i.e., gives sunscreen, protective clothing, or eyewear or money to buy them); 4) Employer provides temporary/permanent shade structures in work environment; 5) Employer communicates messages to employees about sun protection; 6) Employer requests contractor/subcontractor employees comply with worksites' sun safety policy; 7) Employees are encouraged to regularly check skin for signs of skin cancer by themselves or physician; 8) Employer conducts a risk assessment of sun exposure and sun protection for employees. This self-report measure was modified from a study on implementation of school sun protection policies.

We will also measure two ancillary policy outcomes in manager surveys with items from past SSW trials: Unwritten informal standard operating procedures on sun safety (i.e., presence and content of procedures) and enforcement of sun protection policies (i.e., how well is policy being implemented and how well are staff complying with policy [very well, well, about average, poorly, or very poorly]).

3C.16.4. Measures of Potential Effect Moderator: Potential effect moderators include those suggested by Diffusion of Innovations Theory and Bingham's model of innovation. Standard published measures will be used (cited below); psychometric analysis will be conducted on new items (reliability>0.60).

- **Organizational factors:** size (i.e., number of employees), employer type, job type, number of female managers, and annual operating budgets (to assess slack resources) (all reported by employers).
- **Community characteristics:** size (population), education, affluence (from the U.S. Census) and mean annual hours of sunshine (from National Weather Service; used to stratify the sample).
- **Manager and employee characteristics:** skin cancer history (doctor told you that you had skin cancer [yes/no; type]); skin sun sensitivity (always burn, unable to tan/usually burn but can tan if try/sometimes mildly burns, tan easily/rarely burn, tans easily); job characteristics (years working in industry, job title, work mostly outside/mostly inside/outside and inside equally) and demographics (age, sex, education, race, Hispanicity, marital status, children in home) from our GSS trials; opinion leadership (validated scale, reliability $\alpha=0.86$; managers only); innovativeness (validated scale; reliability $\alpha=0.94$; managers only)²³⁰; and readership of professional publication (managers only).

3C.16.5. Data Collection and Management Procedures: Surveys of employees and managers will be conducted online and by mail. Managers will receive email invitations, with link to online survey in KB's Qualtrics software on a secure web server (5 email reminders at 7-day intervals). Employees will be sent printed surveys (with postage-paid return envelopes) and a link to online survey and receive a sunscreen lip balm for completing. All answers are confidential and not revealed to co-workers, superiors, or subordinates. Participants will provide name, address, home and mobile phone numbers, and email address of a person who can always locate them. All forms/procedures will be approved by the Western IRB. We had high completion in our SSW trials. Employees will be sampled at pretest from employee rolls; we will track and posttest all employees pretested, including those who leave. Managers will be sampled by position at pretest and persons in same positions will be posttested (new position holders surveyed and original person tracked and posttested). Multiple survey modes have improved retention to eliminate non-response biases. To reduce multi-mode differences, we will follow Dillman a) response options are identical, b) question structure/response labels are invariant, c) skip patterns are same, d) unfolding questions are avoided, and e) response categories are reversed.

Multiple modes introduce very small differences (eliminated by demographic controls) that do not affect relationships between variables. For policy collection, staff will request managers send workplace safety/health policy documents; staff will check employers' websites.

- **Data management** will be performed by KB's data managers using well-established procedures. Missing responses will be checked to ensure they were not intentionally skipped. A random sample of 10% of manually-entered forms will be double entered; if error rate exceeds 1%, all forms will be double entered. Sophisticated editing/quality assurance procedures (e.g., manual and computerized audits) will be implemented. SAS software (V9.3 or higher) will be used in analyses. Analyses will be done on data collected (case-wise deletion) and by imputation for missing data. We will estimate effect of missing-ness by assigning all lost individuals to an extreme category, in either direction. We will perform imputation utilizing Markov Chain Monte Carlo – Data Augmentation Method in SAS PROC MI, and use a variety of covariates and propensity scores.

Statistical Analysis Plan

4.3 Statistical Design and Power

4.3.1. Descriptive and Exploratory Analyses: Simple descriptive analyses (e.g., frequencies, means, standard deviations, etc.) on employee and employer characteristics and outcome will be calculated. Propensity scores will be calculated before randomization and distribution examined. Given the sample size of worksites, we do not think inverse probability weighting will be necessary but will look for outliers in propensity score distribution to guide sensitivity analyses. After randomization, descriptive analyses by treatment group will be

conducted, using bivariate analyses (e.g., *t*-tests, χ^2) to identify unexpected differences at baseline. Those with differences exceeding 0.25 SD will be treated as covariates in sensitivity analyses to assess their impact on conclusions. Analyses will use intention-to-treat with sensitivity analyses. All analyses will be performed using SAS 9.4, using a 2-tailed $p=.05$.

4.3.2. Primary Outcome Analysis – H1: Improvement in Employee Sun Protection: Primary analysis will test hypothesis that compared to employers in minimal information control, employers receiving the *SSW Works* will have employees who practice more sun protection at posttest. Employee sun protection (ordinal summed frequency score) and history of sunburn (yes/no; number) will be analyzed using a mixed effects model, a variation of hierarchical linear modeling, in SAS PROC GLIMMIX using a binomial covariate, experimental group (i.e., *SSW Works* v. control) as a fixed effect, and testing period as a repeated factor, adjusting for intraclass correlation (ICC) among employees within worksite to avoid inflating Type I error. Changes at posttest between groups and within intervention group will be examined.

4.3.3. Secondary Analyses of Mediation – RQ: Association of Use of *SSW Works* with Employee Sun Protection: We will explore mediation by program exposure assessed by process measures, using mediational analyses from Judd and Kenny and elaborated by MacKinnon. To satisfy the conclusion of mediation, significance will be determined via interval estimation using a bootstrap estimate. Ratio of indirect to total effect will estimate proportion of effect mediated by engagement.

4.3.4. Secondary Analyses of Mediation – H2: Association of Occupational Sun Protection Policies/Actions with Employee Sun Protection: H2 predicts *SSW Works* will improve employees' sun protection by increasing workplace policies, education, and actions. Separate ordinal scores will be calculated for policy content/strength, education, and actions. Using our nested models to account for differential numbers of respondents by employer, we will test them as mediators of the impact of *SSW Works* on employee sun protection, using regression techniques from Judd and Kenny and MacKinnon, testing significance of mediation via interval estimation using a bootstrap estimate of the variation and estimating proportion of effect mediated with ratio of indirect to total effects, as above

4.3.5. Ancillary Tests of Moderators: Stratifying variables (i.e., size; region; urbanicity) and potential moderators (i.e., organizational factors; community characteristics; *manager and employee race/ethnicity* and other characteristics), including employee sex, will be tested for representativeness of *SSW Works* effects. Added as fixed effects, interactions with experimental condition will be examined at $p=.05$ (2-tailed), unadjusted for multiple comparisons.

4.3.6. Statistical Power: In our previous *SSW* trial, employees in the *SSW* group reported higher composite sun protection on the job than in the control group (mean=3.46 [sd=0.05] v. 3.34 [sd=0.05]). Using these standard deviation (sd) estimates in a cluster randomized trial with $n=20$ employers (10 per group) and assuming the ICC is as much as 0.01, the power is over 99% for detecting differences on this composite score of 0.02 (**H1**) with a sample of 35 employees per worksite evaluated at posttest. Similarly, in the prior trial, sun safety policy, education, and actions predicted higher employee sun safety: The composite score was higher at employers with a policy than without (mean=3.46 v. 3.34, $p=0.006$) and *SSW*'s effect on the composite score was mediated by implementation of more sun

safety training (proportion mediated=37.6%, $p=0.035$) and actions (observed messages and PPE, proportion mediated=26.4, $p=0.041$). With this level of proportion mediated, we will have sufficient power (>90%) to identify a positive level of mediation (**H2**) with 35 employees per worksite at posttest. Adjusting for a retention rate of at least 70% at follow-up, we will sample 50 employees per worksite for the baseline survey, expecting 35 per worksite to complete the posttest.