RISE-UP (Risk Information and Skin-cancer Education for Undergraduate Prevention)

Protocol Summary

IRB Approval Date of Current Version:	3/24/2021
University of Utah IRB #:	IRB_00116807
Sponsor:	DERMATOLOGY
Principal Investigator:	Yelena Wu
Internal Staff and Sub-Investigators:	**Site Name** / **Staff Names** University of Utah Yelena Wu Hannah Brady Helen Lillie Benjamin Haaland Wendy Kohlmann Nic Siniscalchi Kadyn Kimball Ali Palmer Xuechen Wang Jakob Jensen

This document was created using the ERICA Online System at the University of Utah. The document is created from study information approved by the IRB on the date listed above. Any alteration to the original content of this document may not be considered to represent the study as approved by the IRB.

Background and Introduction

Skin cancer is the most commonly diagnosed cancer in the United States.[1] Melanoma is the most deadly form of skin cancer, and the incidence of melanoma in Utah is the highest in the U.S.[2,3] Although skin cancers typically onset in the later adult years, it is becoming increasingly diagnosed among young adults.[4] Efforts to decrease ultraviolet radiation (UVR) exposure, the main risk factor for development of skin cancer, should start early in life.[5]

Prior research indicates that college students are at high risk for engaging in unintentional and intentional tanning behaviors that dramatically increase their UVR exposure and that they use inadequate sun protection strategies when they are outdoors.[6,7] However, few studies have examined novel strategies to improve college students' use of sun protection and decrease their intentional tanning behaviors.[8,9] Prior studies have shown that traditional risk communication strategies do not effectively change college students' health behaviors.[10,11] It is possible that college students require more novel forms of risk information in order to motivate behavior change, and that these new forms of risk information should be grounded in established theoretical models. In the current study, we will test several theoretically-driven risk communication strategies that aim to improve college students' engagement in skin cancer prevention behaviors, including sun protection behaviors (sunscreen, protective clothing, shade, peak UVR hours avoidance) and tanning behaviors (indoor, outdoor, unintentional).

Based on prior literature,[12] we anticipate low levels of distress regarding *MC1R* feedback. In the current study, we will test several theoretically-driven risk communication strategies that aim to improve college students' engagement in skin cancer prevention behaviors, including sun protection behaviors (sunscreen, protective clothing, shade, peak UVR hours avoidance) and tanning behaviors (indoor, outdoor, unintentional).

Purpose and Objectives

The purpose of this study is to test the feasibility of providing young people with skin cancer prevention education and/or personalized feedback on their risk for skin cancer using novel methods of communicating this risk. In addition, we will examine the effects that the education and risk feedback have on individuals' reported sun protection and tanning behaviors.

Study Population

Age of Participants: 18+

Sample Size:
At Utah: 300

All Centers: 300

Inclusion Criteria:

Individual is enrolled in courses at the University of Utah

And

Individual reports having had at least 1 sunburn in past year

And/or

Individual reports having intentionally indoor or outdoor tanned at least 1 time in the past year

And/or

Individual reports using sunscreen plus 1 or more of the following behaviors never/rarely/sometimes in the past month: 1) Protective clothing items, 2) Shade when outdoors

Exclusion Criteria:

Individual does not read/speak English

Individual reports a personal history of skin cancer

Design

Randomized Trial

Study Procedures

Recruitment/Participant Identification Process:

1) Participants will be recruited through courses at the University of Utah (e.g., through Departments of Communication, Biology, Psychology) in which professors have agreed to offer extra credit in exchange for participation in this study. Professors will be contacted prior to recruitment to determine their willingness to offer extra credit. Information about the study may be made available to potential participants in these courses via in person contact, email, canvas, phone or text.

2) Information will be made available in common areas on campus via flyers (e.g., in the student Union, through campus newspapers, email listservs) including study information and the study team's contact information for potential participants to get in touch if they want to participate. Potential participants will have the option to text the study phone number to be

screened, or complete an online screening form. Study staff may contact participants who screen to be eligible via phone, text, or email.

3) Information about this study may be be available on the Huntsman Cancer Institute website and via social media postings (see advertisements attached). Patients who self-refer in response to these advertisements will receive a follow-up from the study team.

Informed Consent:

Description of location(s) where consent will be obtained:

Consent will be obtained from the participant in-person at the University of Utah during visit 1.

Description of the consent process(es), including the timing of consent:

1. Participants will be provided all of the required information about the study via the consent document. 2. We will give participants this information in a language they understand (English). We will use language that is simplified and appropriate for potential participants to understand. Participants that do not speak/read or write in English will be excluded from the study. 3. Participants will be given an opportunity to ask questions before they consent and to ensure that the individual has had enough time to review the consent form to before they sign the consent. The study staff will review the consent form with potential participants and be available to potential participants to ask any questions they may have. 4. Participants will be given time to review the consent and consider being in the study. If the participant wants to take more time to consider whether they want to participate in the study, study staff will schedule another time to complete the consent and visit 1 procedures with them. 5. We will use clear and easy to understand language in the consent document and will not include exculpatory language. 6. Consent will be documented by obtaining a signature from the participant, and study staff will keep the signed document in the research record. 7. Participants will receive a copy of their signed consent documents via email, mail, fax, or in person.

Procedures:

Arm 1: Skin Cancer Education Only

Screening: Participants will have the option to complete and online or text based screening form. Study staff may contact participants who screen to be eligible via phone, text, or email. Study staff will screen potential participants who do not complete the screening form on their own for eligibility. Participants will be contacted by phone, text, or email (starting with the method they indicated would be best to reach them) to schedule their first study visit.

Enrollment

Visit 1: All participants who consent to participate will be asked to participate in up to 3 study visits approximately 4 weeks apart. At visit 1, all participants will be asked to complete informed consent procedures and a baseline questionnaire via computer (e.g., using

Qualtrics) or paper. Participants will be randomized to receive education only, or varying combinations of the intervention components.

Visit 2: At visit 2 participants will receive education on the importance of skin cancer prevention behaviors (e.g., sunscreen, protective clothing) and avoiding tanning and sunburns. All education will be delivered at this visit on a computer screen and additionally given to participants as a handout they can take home to review. When participants view the information on the computer screen, eye tracking will be used to assess participant response. Prior to viewing results, eye tracking equipment set up at the computer station will be calibrated. We will then put up their results on the screen and the imotion system will then track their pupillary movement, facial expression, and galvanic skin response (physiological arousal). Participants will be allowed as much time as they would like to review their results. Following this, participants will complete a post assessment. Participants will receive paper copies of all of the relevant information to take home with them.

Visit 3: Visit 3 may be conducted remotely. At visit 3, participants will complete a follow-up assessment.

Follow-up interview: A random sample of the participant population with be contacted to participate in a follow-up interview with study staff to answer questions about their experience participating in the RISE-UP study.

Arm 2: Skin Cancer Education + UV Photo

Screening: Participants will have the option to complete and online or text based screening form. Study staff may contact participants who screen to be eligible via phone, text, or email.Study staff will screen potential participants who do not complete the screening form on their own for eligibility. Participants will be contacted by phone, text, or email (starting with the method they indicated would be best to reach them) to schedule their first study visit.

Enrollment

Visit 1: All participants who consent to participate will be asked to participate in up to 3 study visits approximately 4 weeks apart. At visit 1, all participants will be asked to complete informed consent procedures and a baseline questionnaire via computer (e.g., using Qualtrics) or paper. Participants will be randomized to receive education only, or varying combinations of the intervention components. Participants randomized to the education + UV photo arm will have their UV light photo taken of their face to show UV damage in the skin that is invisible to the naked eye. Photos will be taken with the VISIA Facial Complexion Analysis System, which captures high resolution imagery at the far spectrum of UVA or long wave UV.

Visit 2: At visit 2 participants will receive education on the importance of skin cancer prevention behaviors (e.g., sunscreen, protective clothing) and avoiding tanning and sunburns. Participants will be provided with their personalized risk feedback based on their personalized photo showing their skin's existing UVR damage from UVR exposure. All information will be delivered at this visit on a computer screen and additionally given to participants as a handout they can take home to review. When participants view their results on the computer screen,

eye tracking will be used to assess participant response. Prior to viewing results, eye tracking equipment set up at the computer station will be calibrated. We will then put up their results on the screen and the imotion system will then track their pupillary movement, facial expression, and galvanic skin response (physiological arousal). Participants will be allowed as much time as they would like to review their results. Following this, participants will complete a post assessment. The imagery resulting will be kept on file in a password protected computer. Participants will receive paper copies of all of the relevant information to take home with them.

Visit 3: Visit 3 may be conducted remotely. At visit 3, participants will complete a follow-up assessment.

Follow-up interview: A random sample of the participant population with be contacted to participate in a follow-up interview with study staff to answer questions about their experience participating in the RISE-UP study.

Arm 3: Skin Cancer Education + MC1R Testing

Screening: Participants will have the option to complete and online or text based screening form. Study staff may contact participants who screen to be eligible via phone, text, or email.Study staff will screen potential participants who do not complete the screening form on their own for eligibility. Participants will be contacted by phone, text, or email (starting with the method they indicated would be best to reach them) to schedule their first study visit.

Enrollment

Visit 1: All participants who consent to participate will be asked to participate in up to 3 study visits approximately 4 weeks apart. At visit 1, all participants will be asked to complete informed consent procedures and a baseline questionnaire via computer (e.g., using Qualtrics) or paper. Participants will be randomized to receive education only, or varying combinations of the intervention components. Participants randomized to the education + MC1R testing arm will be asked to provide a saliva sample. Saliva will be collected by study staff using a system for the collection, stabilization and transportation of DNA from saliva (e.g., Oragene DNA collection kits). Participants will be genotyped for SNPs in MC1R that have been associated with melanoma risk. Genotyping will be done through U of U core facilities

Visit 2: At visit 2 participants will receive education on the importance of skin cancer prevention behaviors (e.g., sunscreen, protective clothing) and avoiding tanning and sunburns. Participants will be provided with their personalized risk feedback based on a summary of their MC1R genetic testing results. All information will be delivered at this visit on a computer screen and additionally given to participants as a handout they can take home to review. When participants view their results on the computer screen, eye tracking will be used to assess participant response. Prior to viewing results, eye tracking equipment set up at the computer station will be calibrated. We will then put up their results on the screen and the imotion system will then track their pupillary movement, facial expression, and galvanic skin response (physiological arousal). Participants will be allowed as much time as they would like

to review their results. Following this, participants will complete a post assessment. Participants will receive paper copies of all of the relevant information to take home with them.

Visit 3: Visit 3 may be conducted remotely. At visit 3, participants will complete a follow-up assessment. Participants who have clinical questions about melanoma or concerns about their family history will be referred to speak with a genetic counselor or be referred to HCI's Family Cancer Assessment Clinic (FCAC) for further information and information on CLIA testing.

Follow-up interview: A random sample of the participant population with be contacted to participate in a follow-up interview with study staff to answer questions about their experience participating in the RISE-UP study.

Arm 4: Skin Cancer Education + UV Photo + MC1R Testing

Screening: Participants will have the option to complete and online or text based screening form. Study staff may contact participants who screen to be eligible via phone, text, or email.Study staff will screen potential participants who do not complete the screening form on their own for eligibility. Participants will be contacted by phone, text, or email (starting with the method they indicated would be best to reach them) to schedule their first study visit.

Enrollment

Visit 1: All participants who consent to participate will be asked to participate in up to 3 study visits approximately 4 weeks apart. At visit 1, all participants will be asked to complete informed consent procedures and a baseline questionnaire via computer (e.g., using Qualtrics) or paper. Participants will be randomized to receive education only, or varying combinations of the intervention components. Participants randomized to the education + UV photo + MC1R testing arm will have a UV light photo taken of their face to show UV damage in the skin that is invisible to the naked eye and will be asked to provide a saliva sample. Photos will be taken with the VISIA Facial Complexion Analysis System, which captures high resolution imagery at the far spectrum of UVA or long wave UV. Saliva will be collected by study staff using a system for the collection, stabilization and transportation of DNA from saliva (e.g., Oragene DNA collection kits). Participants will be genotyped for SNPs in MC1R that have been associated with melanoma risk. Genotyping will be done through U of U core facilities

Visit 2: At visit 2 participants will receive education on the importance of skin cancer prevention behaviors (e.g., sunscreen, protective clothing) and avoiding tanning and sunburns. Participants will be provided with their personalized risk feedback based on a summary of their personalize UV photo and a summary of their MC1R genetic testing results. All information will be delivered at this visit on a computer screen and additionally given to participants as a handout they can take home to review. When participants view their results on the computer screen, eye tracking will be used to assess participant response. Prior to viewing results, eye tracking equipment set up at the computer station will be calibrated. We will then put up their results on the screen and the imotion system will then track their

pupillary movement, facial expression, and galvanic skin response (physiological arousal). Participants will be allowed as much time as they would like to review their results. Following this, participants will complete a post assessment. The imagery resulting will be kept on file in a password protected computer. Participants will receive paper copies of all of the relevant information to take home with them.

Visit 3: Visit 3 may be conducted remotely. At visit 3, participants will complete a follow-up assessment. Participants who have clinical questions about melanoma or concerns about their family history will be referred to speak with a genetic counselor or be referred to HCI's Family Cancer Assessment Clinic (FCAC) for further information and information on CLIA testing.

Follow-up interview: A random sample of the participant population with be contacted to participate in a follow-up interview with study staff to answer questions about their experience participating in the RISE-UP study.

Procedures performed for research purposes only:

Statistical Methods, Data Analysis and Interpretation

Descriptive statistics (number, percent for categorical variables and mean, standard deviation for quantitative variables) were calculated for demographic characteristics and participant's sun protection and tanning outcomes. For inferential statistical analyses, missing data was handled via multiple imputation, which ensures valid inference under missingness-at-random (data values independent of missingness pattern, conditional on the observed data), the most general data-centered missing data assumption. Twenty complete data sets were generated and all statistical analyses were based on these, with pooling via Rubin's rules. The primary outcomes of interest include sun protection and tanning. In order to estimate changes in outcomes over time overall and compare changes over time between the four intervention groups, generalized estimating equations (GEE) were used to account for repeated measures within individuals. Season of participation (fall versus spring) was considered an important factor for the primary outcomes, so it was included as an adjustment factor in all models and outcomes were also examined within each season separately.