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Title: FLARE: Family Lifestyle Actions and Risk Education

4. Study Information

1. **Design of Study (select all that apply):**
   Survey/Questionnaire Research
   Interviews and Focus Groups
   Prospective Clinical Research
   Other
   If Other, describe:
   Pilot study of a behavioral intervention

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:** 3 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   In-person contact (e.g., patients, students, etc.)

   Referrals

   Written or electronic record review

   Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   From a database or participant pool for which participants have given prior permission to be contacted for research studies

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

We will recruit study participants in the following ways and from the following sources:

1. A study flyer (see enclosed) will be made available in medical clinics serving individuals with a personal or family history of melanoma. We will also implement targeted clinic recruitment for individuals with a history of melanoma or who have a family member diagnosed with melanoma who are seen at the University of Utah or Huntsman Cancer Institute: The study staff will review the medical records of patients scheduled to be seen in clinics at the University of Utah or HCI. The study staff member will confirm with patient's healthcare providers that he/she can approach the patient during the clinic appointment to briefly present the study. Healthcare providers or clinic staff will also be able to refer patients to the study staff, and the study staff will contact the patient using their preferred contact information.

2. Participants from prior studies (IRB protocols 46387, 41211, 13816) who agreed to recontacted about other research opportunities: A letter introducing the study and study flyer will be sent to these prior participants (see "FLARE letter to previous study participants", attached). Contact information for the study staff will be provided so that interested participants can express interest in hearing more about the current study. If we do not receive a response from these individuals, we will send one follow-up letter and the study staff of the original study the person participated in will make follow-up phone calls.

3. Individuals who respond to advertisements and postings (e.g., flyer, email, social media; see enclosed) to schools in Utah, and community organizations serving melanoma survivors and their families (Huntsman Cancer Institute, SolSurvivors, Aim at Melanoma, Richard David Kann Melanoma Foundation, Melanoma Education Foundation, Melanoma Research Foundation, The Susan Fazio Foundation For Melanoma Research, Shade Foundation of America, Only Skin Deep, Skin Cancer Foundation, The Melissa K Bambino Melanoma Foundation, Utah Cancer Action Network).

4. The study staff will provide information on the research study at patient education days related to melanoma and skin cancer (e.g., HCI Skin Cancer Screening day). Interested individuals will have the option of providing their contact information so that the study staff can follow-up to provide additional information.

5. We will use family expansion methods to identify other family members who may be eligible to participate in the current study. We will ask individuals whether they have other family members who may be eligible for the current study. If they do, we will collect those extended family member's contact information. We will mail a letter explaining the study (see enclosed "FLARE family" and "Noncontact" letters modified from approved letters through IRB protocols 46387 and 72947) and make follow-up phone calls to determine their interest and eligibility. If we do not receive a response from these

individuals, we will send one follow-up letter. For extended family members with a history of melanoma, we will obtain medical records to confirm a diagnosis of melanoma.

6. We will use the University of Utah's Clinical Cancer Research (CCR) database to identify people with a personal or family history of melanoma. A letter introducing the study and study flyer will be sent to these individuals (see Recruitment Letter for CCR). Contact information for the study staff will be provided so that interested participants can express interest in hearing more about the current study. If we do not receive a response from these individuals, we will make up to two follow-up phone calls.

7. We would like to use a brief screening form in the HCI clinics (see "Referral for family melanoma risk research", attached) serving patients with a history of melanoma or who are at risk for melanoma. This screening form will be given to patients who are being seen in the HCI melanoma clinics and will be made available in the clinic facilities. The information that patients provide will be retained for research study recruitment. Patients who may be eligible for the current study will be contacted by our study team after their clinic visit, or if patients prefer, a study coordinator will meet with them to discuss the study.

8. For individuals with a personal history of melanoma, we will check to see if they are in the CCR database. If they are, we will consider that a confirmation of diagnosis. For those not in the CCR database, we will ask individuals to fill out the appropriate medical release form based on the clinic where they were treated (see "Medical records release form", attached). We will ask that they return it to us so that we can request records confirming a melanoma diagnosis. For individuals with only a family history of melanoma, regardless of whether they are in the CCR database, we will ask that the individual give the medical release to their family member to fill out and send back to us so that we can request the relevant records. For individuals treated at the University of Utah, we may access the electronic medical record to determine diagnosis.

9. Participants in our pre-established registry of individuals who have expressed interest in participating in melanoma-related studies, and who have participated in our prior studies and provided permission for us to re-contact them about future research (IRB protocols 72947, 86073) will be contacted through their preferred method (e.g., phone, mail). Study staff will provide a brief description of the current study and provide individuals with the option of hearing about the study more and/or discussing their potential participation.

5. How will consent be obtained?

Informed Consent Process (with or without a document)

6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

The study staff will screen each potential participant to ensure that they meet the eligibility criteria. If, during participant recruitment efforts, we encounter individuals who are not eligible for the study, we will request these individual's permission to record their information so that we can contact them about future studies that they may be eligible for. Individuals who are eligible for the current study and who are interested in participating will be able to choose when they want to provide informed consent and complete the study activities. They can choose to do this immediately with the study staff, or schedule a separate time to do this. If participants live farther than 40 miles from the University of Utah, they will be eligible to receive travel compensation.

Participants who provide informed consent and/or assent to participate will be asked to participate in up to 6 study visits (described below). Visits 1-5 will be scheduled approximately 2 weeks apart, and there will be approximately 4 weeks between Visits 5 and 6. We will ask participants to attend visits in-person; however, some sessions (e.g., Visits 2, 3 and 4) could occur electronically (e.g., by phone, Skype) to decrease participant burden. For those who participate in Skype sessions, if participants do not have a device with a camera (e.g., computer, SmartPhone) we may provide them a webcam to use during the study. They will not be financially responsible for this webcam if it is lost or broken during the study.We may have one test Skype session prior to visit 2 with participating famlies to make sure Skype is working and to work out any technical issues. If families are unable to participate by Skype, they will have the option of participating in all 6 study visits in-person or by phone.

Participants will be asked to wear a wristwatch style dosimeter between study visits. Participants will be instructed in the use and care of the dosimeter (e.g., that it cannot be immersed in water, and that participants who are swimming should try to place the dosimeter upright near the pool or lake area so that it records the amount of UV exposure they will receive on their person). Participants will also receive a handout reiterating these precautions. Participants will be instructed to bring the dosimeter with them to each in-person study visit, so that the data may be downloaded and the device checked for whether it needs a new battery and is functioning properly. Participants will return the dosimeter to study staff during Visit 6. Participants will not be responsible for paying us for the device if it gets broken, lost, damaged, etc. We will provide replacement units if any are broken and participants will not be withdrawn if the device is broken. Participants will also be asked to complete diaries of sunburn occurrence and skin checks using diary pages/books that the study team will provide.

Participants will be asked to be 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). Molecular evaluation will be performed at the genetic, enzymatic (protein and RNA), and cellular response levels to identify melanoma and other predisposition genes.

Visit 1: All participating parents/caregivers and children from each family will be asked to complete questionnaires (children to participate if the child is at least age 8). Study questionnaires will assess domains including: demographic information, melanoma beliefs, beliefs about efficacy of melanoma preventive behaviors, self-efficacy in implementing preventive behaviors, worry about developing melanoma, parent's and children's current adherence to melanoma preventive behaviors, and barriers to implementing melanoma preventive behaviors (see Primary Questionnaire documents for examples of types of items participants will be asked to complete). We will assess each participant's degree of tan using reflectance spectroscopy. Saliva collection will typically happen during visit 1, unless a participant is unable to attend visit 1. In that case, their saliva sample will be collected at a later visit.

Visit 2: The primary caregiver and at least one child (if the child is at least age 8) from each family will attend session 1 of the behavioral intervention, which will consist of a review and/or assessment of the family's barriers and facilitators to melanoma preventive behaviors, education on the child's risk for melanoma, melanoma preventive behaviors, creation of a family skin protection plan that details allocation of responsibility for preventive behavior implementation and logistics for implementing the preventive behaviors, and learning a structured problem-solving strategy to address barriers to adherence to melanoma preventive behaviors. The problem-solving content will be adapted from an existing evidence-based intervention (49). Participants will also be asked to complete questionnaires (see Primary Questionnaire documents for examples of types of items participants will be asked to complete).

Visit 3: The primary caregiver and at least one child (if the child is at least age 8) from each family will attend session 2 of the behavioral intervention, which will consist of reviewing implementation of the skin protection plan, discussing behavioral and organizational strategies for implementing preventive behaviors, and applying problem-solving strategies to a barrier to preventive behavior adherence. In addition to revising the skin protection plan if needed, families will review educational material on the importance of adhering to the skin protection plan to mitigate children's risk for melanoma.

Visit 4: The primary caregiver and at least one child (if the child is at least age 8) from each family will attend session 3 of the behavioral intervention, which will consist of reviewing the skin protection plan implementation, applying the problem-solving strategy to a barrier, discussing communication skills and tools related to preventive behaviors, and revising the skin protection plan as needed. Families will also review educational material on the importance of adhering to the skin protection plan to mitigate children's risk for melanoma.

Visit 5: All participating caregivers/children from the family will be asked to complete questionnaires (see Primary Questionnaire documents for examples of types of items participants will be asked to complete). This visit will be the 'post-intervention' visit to assess outcomes. We will assess each participant's degree of tan using reflectance spectroscopy.

Visit 6: All caregivers and participating children will be asked to complete questionnaires (see Primary Questionnaire documents for examples of types of items participants will be asked to complete) as a follow-up visit. We will assess each participant's degree of tan using reflectance spectroscopy.

Throughout the intervention, participants will be asked to provide feedback on the feasibility of attending study sessions, acceptability of the study procedures, perceptions of their melanoma preventive behaviors, and general feedback for the study team (see interview questions attachment for examples of types of questions that will be asked).

In appreciation for their time, each participant will receive separate $25 gift card cards for completing Visits 1, 5 and 6. To thank participants for filling out online questionnaires, each participant will receive via email a $10 gift card for completing questionnaires for Visit 2, 3 and 4. Thus, each participant could receive up to $105 in gift cards for completing study visits.

Questionnaires will be administered by one of the following methods: paper, in person, by mail, or electronically (e.g., via REDCap). We may also administer items verbally if needed or requested by participants. At each study visit, participants may be asked open-ended interview questions to assess the acceptability and feasibility of the intervention (see example Interview Questions). The study staff will record barriers to study/intervention participation as another measure of feasibility. Participants will be asked to complete sunburn and skin self-exam calendars and checkbooks (see checkbook attachments), which will serve as additional measures of adherence to preventive behavior recommendations.

Intervention sessions will be audio-recorded so that they can be reviewed for fidelity. We will record sessions using handheld audio recorders. Only the research study staff will have access to the audio files. The audio files will be kept on secure, password-protected computers and servers. Audio files will be kept confidential and will not be used in public presentation of research results.

For participants who have been enrolled in our team's prior studies (IRB protocols: 46387, 41211, 72947, 86073), we may link participant's data generated from the current protocol with their data from prior studies they were enrolled in. This information is disclosed to participants in the consent they will sign (FLARE Consent form).

7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?

● **Yes** ○ No

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. Is there a safety monitoring plan for this study?

○ Yes ● **No**

9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

Descriptive statistics (i.e., mean, SD, frequencies) will be used to summarize feasibility (e.g., percent of visits/sessions completed, barriers to visit/session completion) and acceptability. In order to examine changes in behavioral outcomes (e.g., changes in sunscreen use, objective measures of UVR exposure), we will conduct several different analyses:

1) We will use paired Wilcoxon tests to examine changes in outcomes from Visit 1 (pre-intervention) to Visit 5 (post-intervention) and from Visit 1 to Visit 6 (follow-up) for the children who participated in the FLARE intervention (i.e., one child per family).

2) We will calculate descriptive statistics to examine changes in outcomes among siblings who did not participate in FLARE.

3) We will use a multilevel modeling (MLM) framework to describe changes in outcomes across all children assessed within each family. The MLM framework will enable us to account for the fact that siblings are clustered within families, and thus would be expected to have more similar changes in their behavioral outcomes.

Simulation-based power analyses were conducted in R based on our team's pilot data with children from families at high risk for melanoma. Assuming a 0.5 correlation between pre- and post-intervention measurements and an average improvement in 1 point on primary outcomes (e.g., from "sometimes" applying sunscreen to "often" applying sunscreen), a sample size of 15 child-parent pairs would have 79% power to detect a significant change in sunscreen use and 99% power to detect a significant change in SSE frequency (alpha=.05). Preliminary estimates of the average effect of FLARE will be determined using the mean and standard deviation of the primary outcomes (i.e., photoprotection implementation, SSE frequency) from Visits 1 to 5 and from Visits 1 to 6. Exploratory analyses will be conducted to examine potential predictors of intervention outcomes.