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The Family Lifestyles, Actions and Risk Education (FLARE) Study: Protocol for a randomized controlled trial of a sun protection intervention for children of melanoma survivors

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abstract

Background: Children of parents who had melanoma are more likely to develop skin cancer themselves owing to shared familial risks. The prevention of sunburns and promotion of sun-protective behaviors are essential to control cancer among these children. The *Family Lifestyles, Actions and Risk Education* (FLARE) intervention will be delivered as part of a randomized controlled trial to support parent-child collaboration to improve sun safety outcomes among children of melanoma survivors.

Methods: FLARE is a two-arm randomized controlled trial design that will recruit dyads comprised of a parent who is a melanoma survivor and their child (aged 8-17 years). Dyads will be randomized to receive FLARE or standard skin cancer prevention education, which both entail 3 telehealth sessions with an interventionist. FLARE is guided by Social-Cognitive and Protection Motivation theories to target child sun protection behaviors through parent and child perceived risk for melanoma, problem-solving skills, and development of a family skin protection action plan to promote positive modeling of sun protection behaviors. At multiple assessments through one-year post-baseline, parents and children complete surveys to assess frequency of reported child sunburns, child sun protection behaviors and melanin-induced surface skin color change, and potential mediators of intervention effects (e.g., parent-child modeling).

Conclusion: The FLARE trial addresses the need for melanoma preventive interventions for children with familial risk for the disease. If efficacious, FLARE could help to mitigate familial risk for melanoma among these children by teaching practices which, if enacted, decrease sunburn occurrence and improve children's use of well-established sun protection strategies.

Keywords

children; family; intervention; melanoma; prevention; telehealth

Background

In the United States, melanoma is the fifth most common type of cancer. [1] It is the also the most lethal form of skin cancer, [2, 3] with substantial costs linked to morbidity and mortality, as well as treatment costs totaling more than $3.3 billion per year. [4-6] Children who have a biological parent with melanoma are twice as likely to develop the disease compared to the general population, which has a 2.3% lifetime risk. [2, 7] Based on current incidence, more than 42,000 children per year will have a parent diagnosed with melanoma [2, 8, 9] and the number of parents with a history of melanoma is also expected to grow. [10-13] Racial/ethnic and socioeconomic disparities in melanoma detection, incidence, and survival among both children and adults and among rural populations have been well-documented. [14-17] The only risk-mitigating factor for melanoma prevention is

avoidance of sunburn through behavior change, particularly during childhood, and there are no clinically-recommended biological interventions to mitigate risk for melanoma. [18-22] Reductions in the number of severe sunburns in childhood decreases melanoma risk by 33-50%. [23, 24] As a result, efficacious behavioral interventions are critically needed in order to change clinically relevant targets of skin cancer reduction, such as sunburn occurrence. [25]

Unfortunately, studies have shown that children in families with a history of melanoma, similar to children without a family history of the disease, use sun protection inconsistently and experience sunburns. [26-30] Use of sun protection strategies among children of melanoma survivors is variable, with sunscreen use the most commonly used strategy (79%). [28] Only 20% of at-risk children reportedly re-apply sunscreen, 30% wear hats, 28% wear long-sleeved shirts, 23% stay in the shade when outdoors, and 8% wear sunglasses. [28, 29, 31-36] As a result, sunburn occurrence in this population is common, with 49% of melanoma survivors reporting that their children experienced sunburn in the preceding 12 months. [28] These findings signify a need for efficacious melanoma prevention programs for at-risk pediatric populations.

To date, there have been two programs targeting sun exposure among children with a family history of melanoma that have been rigorously evaluated using randomized clinical trials (RCTs). [37, 38] Through parent-focused materials, including mailed information on sun protection, videos and booklets on sun protection, and melanoma risk feedback, these interventions produced short-term improvements to sun-protection behaviors, such as sunscreen application/re-application, and wearing hats and other protective clothing among parents and children in the first months post-intervention. [37, 38] However, these outcomes were assessed at limited follow-up periods (i.e. one or two follow-ups 4 to 12 weeks post-intervention) and prior programs did not include booster content which may be important for sustaining of outcomes. Importantly, no interventions produced decreases in sunburn occurrence. [37, 38]

In contrast, melanoma prevention programs that promote collaboration or teamwork between parents and children to manage daily sun protection tasks may be particularly effective at addressing barriers to consistent sun protection use. [39, 40] For a range of health behaviors, such as healthy eating and physical activity, children are likely better at implementing recommended behaviors when their parents are actively involved in supporting those health behaviors. [41, 42] For instance, within parent-child dyads, parents can serve as positive models to their children when they engage in health behaviors, and parents provide the environment and resources that facilitate their children to carry out desired health behaviors (e.g., parent makes healthy food choices available in the home). In the case of melanoma, greater family discussion about preventive behaviors is linked to stronger beliefs that sun protection is beneficial, as well as increased self-efficacy in performing sun-protection behaviors. [43] In addition, previous studies have shown that protective clothing is more frequently worn by children when this behavior is modeled by the parent. [44] As encouraging as these findings are, they have yet to be integrated into lasting behavior change strategies for high-risk families and little is known about the reciprocal influences between parents and children in the context of melanoma prevention.

The *Family Lifestyles, Actions, and Risk Education* (FLARE) intervention uses several well-established behavioral change methods to promote parent-child collaboration for melanoma prevention. [45] Guided by the Social Cognitive Theory [30] and Protection Motivation Theory, [46, 47] components of the intervention include risk communication to enhance perceived risk of melanoma, problem-solving skills training to help families address barriers to child sun protection, and development of a family sun-protection plan to promote positive modeling of sun-protection behaviors. A pilot study of FLARE among 21 parent-child dyads supported the acceptability and feasibility of the intervention. FLARE was linked to statistically significant improvements in protective clothing use (37% improvement), long pants (24% improvement), shade-seeking (27-34% improvement), and avoidance of outdoor tanning (35% improvement), along with a reduction of 1.43 standard erythemal doses (SEDs) per week overall UVR exposure between the pre- and post-intervention visits. [45] The pilot study led to several modifications of the study design for the larger efficacy trial. In order to extend the reach of the study to a larger number of dyads including those living in more disparate geographical areas, ambient UVR readings based on environmental data and a skin tone assessment using a color palette will be used rather than personal dosimeters or reflectance spectroscopy.

Aims

This study will test the efficacy of the FLARE intervention and examine moderators and mediators of its effects. The primary goals of the study are to 1) evaluate the efficacy of the FLARE intervention in decreasing outcomes such as sunburn occurrence in the children of melanoma survivors from pre- to post-intervention during high ambient UVR months of the year and at one-year follow-up, compared to a control intervention that includes review of publicly-available skin cancer prevention resources, and 2) identify child and parent moderators of intervention effects (e.g., child's age). A secondary goal is to examine parent-child reciprocal influences and understand how these influences related to sun protection behaviors differ across dyads receiving FLARE versus a comparison intervention.

Methods

Trial Design

The FLARE study is a two-armed randomized controlled trial that will be coordinated through Huntsman Cancer Institute at The University of Utah. This study is funded through the American Cancer Society (RSG-19-121-01-CPPB). Approval has been obtained from the Institutional Review Board at The University of Utah and the trial has been registered at ClinicalTrials.gov (NCT04201223).

Eligibility Criteria

Parents and children will be enrolled as dyads. Adults are eligible to participate if they: 1) Have been diagnosed with melanoma at any time in their life; and 2) Have at least one biological child between the ages of 8-17 years who is able to participate in the study with them. This age range was selected to increase the potential for children to be engaged participants in the intervention and to allow for children to provide self-report measures. If parents have more than one biological child between the age range of 8-17 years, they

will be asked to select one child to participate in the study with them, by being prompted to identify the child who has the most difficulty implementing sun protection behaviors. If the parent cannot decide based on that criterion, we will select the child who has the birthday closest to March 1. Diagnosis of melanoma will be corroborated by medical documentation through the Utah Cancer Registry (UCR), a SEER cancer registry, or medical record review. Children are eligible to participate if they: 1) Are between the ages of 8-17 years; 2) Had at least 1 sunburn in the last 12 months (which will serve as a marker for insufficient sun-protection use and heightened behavioral risk for melanoma); and 3) Have at least 1 biological parent with a history of melanoma who can participate in the study with them. Adults and children will be excluded from participation if they: 1) Do not speak English; 2) Are unable to participate due to developmental delay; 3) Received testing for a mutation in *CDKN2A*/p16; 4) Enrolled in another intervention study on skin cancer prevention behaviors that recruited through the UCR; or 5) Have only a history of ocular melanoma, based on the lack of evidence that children of ocular melanoma survivors are at higher risk for developing cutaneous melanoma.

Recruitment

The primary recruitment method will involve a linkage between the UCR and two other databases: the Utah Population Database (UPDB), a statewide resource comprising linked medical and family data, [48] and the Family Cancer Assessment Clinic at the Huntsman Cancer Institute. Survivors will be removed from the recruitment pool if: 1) the UPDB's birth certificate and driver's license records indicate that survivors' children are outside the desired age range for this trial, and/or 2) the survivor had *CDKN2A*/p16 testing through the Family Cancer Assessment Clinic and thus already had thorough melanoma risk information and sun protection recommendations provided through this clinical care. After the UPDB sends a list of potentially eligible melanoma survivors to the UCR, UCR will remove individuals known to be deceased, who did not have a reportable cancer, or who were only reported to UCR by other central state registries and are excluded from being included in research due current interstate data sharing agreements. Additionally, for each recruitment year, UCR will remove survivors who are enrolled in another ongoing melanoma prevention intervention study. Trial procedures, including recruitment, interventions, and outcome assessments, are illustrated in Figure 1.

Starting in January of each recruitment year, UCR will implement their established research recruitment protocol and send an introduction letter describing the FLARE study to potentially eligible parent participants requesting permission to release the individual's contact information to the study team. After UCR receives confirmation by phone or return mailer that an individual is willing to be contacted regarding study participation, the name, contact information and cancer characteristics (e.g., stage at diagnosis) will be sent to the research team for further contact. We anticipate that most survivors will be non-Hispanic White (consistent with the general population typically affected by melanoma) [3] and live in urban settings and that the trial will successfully recruit 10-15% of potentially eligible melanoma survivors. In order to increase generalizability of the study findings, we will target recruitment through UCR to underserved populations, specifically Hispanic melanoma survivors and survivors living in rural areas. Specifically, when sampling, we will ensure that

all individuals in UCR's database who are Hispanic and/or live in a rural geographic area will receive an invitation to participate in the study. Our team has previously successfully enrolled individuals who identify as Hispanic as well as individuals living in rural areas into melanoma prevention studies. [49, 50]

A secondary recruitment method will involve recruitment through hospitals in the Western region of the US affiliated with the Huntsman Cancer Institute (e.g., in Colorado and Wyoming). In these locations, potentially eligible patients will be screened by research staff and then approached during scheduled appointments. Patients who are deemed eligible will be asked to provide their contact information which will be shared with the research team.

Consent/Enrollment and Baseline Survey

Enrollment will occur each year from April through July in order to control for seasonality and to ensure that assessments occur in the summer season when ambient UVR is high. [51] Research staff will contact each potential parent participant via text, phone call and/or e-mail and screen potential participants to ensure they meet eligibility criteria. Parents who choose to participate with their child will receive consent and assent forms via e-mail to review prior to a consent call with a study coordinator. Parent participants will provide verbal informed consent for themselves to participate and parental permission for their child to participate. Child participants will provide verbal assent. Enrolled dyads will be invited to complete an online baseline assessment via REDCap. [52]

Randomization

Randomization will be conducted after parent participants complete their baseline assessment. Randomization will be conducted within REDCap [52] and will be stratified based on the child participant's age, parent ethnicity (Hispanic or non-Hispanic), and survivor geographic area (rural versus urban using Rural-Urban Commuting Area (RUCA) codes). [53] After randomization, all dyads will be mailed the printed education materials, skin tone palette printout (for assessment of melanin-induced surface skin color change), and a webcam if needed. They will also receive unique log-in information for a secure study website to review didactic materials prior to each intervention session.

Study Procedures

Parent-child dyad participants in both conditions will receive: 1) access to a website with didactic content, 2) three remotely-delivered live education sessions between a study interventionist and the parent-child dyad, and 3) three text message booster intervention messages to reinforce intervention content (sent to the parent). Study sessions will be recorded and archived for fidelity assessments. Both conditions will follow the same schedule for study assessments delivered via REDCap and standardized booster messages that review session content. Session content for each arm is described in Table 1. The key differences between the FLARE and control interventions are that the FLARE intervention covers the child's elevated risk for melanoma, behavioral and organizational strategies for sun protection, and teaches parent-child dyads how to work together to improve use of child sun protection practices. Dyads will be reminded to log in to the website for reviewing educational material before each intervention session. In the case that dyadic participants

do not attend scheduled intervention sessions, the research assistant will attempt at least 3 times to reach the parent (e.g., by text message or phone call). If parent and/or child participants do not complete questionnaires in the desired time frame, the research assistant will provide at least one reminder to the parent through their preferred contact method (e.g., text message) and through another method (e.g., email or phone call).

Pre-Intervention Orientation Session and Web-Based Educational Modules.— To ensure that dyads are familiar with procedures for using the telehealth system, they will be asked to sign on for a brief technology check session before intervention sessions begin. During this session, the dyad will receive an orientation to the website (Canvas Learning Management System) for educational modules. The online educational modules will be designed to provide dyads with foundational knowledge for each intervention session, and to maximize time spent during the live intervention sessions on interactive activities. The educational modules for the FLARE intervention arm focus on: 1) melanoma risk factors (e.g., family inheritance), sun-protection behaviors, and monitoring a child's UVR exposure; 2) behavioral and family organizational strategies to improve sun protection behaviors; and 3) communicating with family and peers about skin cancer prevention. The modules for the control arm focus on accessing reputable health information and navigating credible skin cancer information websites (Centers for Disease Control and Prevention [CDC], American Academy of Dermatology [AAD]).

FLARE Arm.—During these sessions (30-40 minutes each), parents and children will receive information from the study interventionist on melanoma prevention and the child's elevated risk for melanoma, learn strategies to address barriers to sun protection, work together to create a Family Skin Protection Plan and practice a structured problem-solving approach to overcome their specific barriers to child sun protection adapted from a prior intervention used in pediatric oncology (see Table 1). [54] Information will be presented using a combination of illustrations, videos, risk communication materials, and interactive activities, such as a 'risk slider' (a visual depiction of low to high risk for melanoma) to demonstrate how sun protection lowers melanoma risk and how failure to protect oneself increases risk. Parent participants will also receive booster messages with reminders about sun protection principles that were described during the study sessions.

Control Arm (Standard Education).—Dyads randomized to standard education will receive the same general melanoma prevention information reviewed in FLARE. During standard education sessions (20-30 minutes), interventionists will help dyads navigate the CDC and AAD websites on skin cancer which include information on skin cancer and its symptoms, risk factors for skin cancer, data and statistics related to skin cancer, skin cancer prevention recommendations, and personal testimonials from skin cancer survivors. In addition, families will receive information on finding credible health information online. Those in the standard education condition will receive booster messages with reminders about sun protection practices that were described during the study sessions.

Interventionist Training/Fidelity Assessment.—The interventionist (Master's and/or Bachelor's-level individuals) will receive training on delivering FLARE and standard

education from the study PI. The interventionist will be certified to deliver the conditions when he/she demonstrates adequate fidelity (>90% of core components delivered as intended per PI review). To promote and assess fidelity throughout the trial and to minimize potential contamination in intervention delivery across study arms, scripted intervention manuals for both conditions will be utilized, and the interventionist and a trained research assistant will complete post-session fidelity checklists. All intervention sessions will be recorded. Supervision and corrective feedback related to intervention sessions will be provided to the interventionist on a weekly basis throughout the trial.

Assessment and Intervention Schedule (see Figure 1).—Prior to randomization, parent participants will complete a baseline questionnaire assessing demographic information, sun protection behaviors, and potential mediators related to sun protection (e.g., parent-child modeling of sun protection behaviors). Children will also be sent a baseline questionnaire, but it is not required to be answered in full to move forward with the intervention. The parent-child dyad will then attend three intervention sessions, scheduled at 2-week intervals. They will be asked to complete a mid-intervention questionnaire between the second and third telehealth sessions (approximately 6 weeks post baseline), post-intervention surveys at four and eight weeks post-Session 3, followed by a long-term follow-up survey one year post-baseline. Dyadic participants will also be sent one monthly sunburn survey question each to the parent's e-mail (one e-mail addressed to the parent in the e-mail body, one e-mail addressed to the child) for thirteen months following the second post-intervention assessment. Parent and child participants will be sent all assessments, regardless of their completion (or not) of prior assessments. The timepoints of assessment for all measures are summarized in Table 2.

Outcome Measures.—*Sunburn* (defined as "red and painful") occurrence will be assessed on a scale of 0 to 5+ sunburns that month, using an item from the Sun Habits Survey. [55]

Sun protection behaviors over the past month and tanning (indoor, outdoor, unintentional) behaviors over the past 12 months will be assessed by items based on or modified from the Sun Habits Survey, which has been shown to be valid, reliable (alphas .45 to .85; test-retest reliability ICC=0.87), and sensitive to change [38, 55, 56]. Melanin-induced surface skin color change will be assessed for the child (through parent-report and child self-report) by comparing skin tone on both the dorsal and inner arm with a skin tone palette. [57] Dyads will be mailed a hard copy of the palette and will also be provided with the palette on-screen when they complete electronic assessments.

Other Measures.

Parent-child reciprocal influences (potential mediators).: Parent-child modeling will be assessed using parent self-report, parent report on child, and child self-report on the Sun Habits Survey sun protection behavior items described earlier. [38, 55, 56] Children and parents will also complete measures of perceived risk for the child to develop melanoma later in life (e.g., "What do you think your child's chances are of getting melanoma sometime in their life?" with response options on a 5-point likert-type scale ranging from

"Very unlikely" to "Very likely") adapted based on the investigator's prior work with adults at increased risk for melanoma and their children as well as the broader literature on perceived health risks [30, 58]. Children and parents will complete investigator-designed items on sun protection-related problem-solving skills (e.g., "My child and I come up with ways to make it easier for them to use sun protection" and "My child and I work together to make sure that they use sun protection" answered on a 5-point likert-type scale from "Never" to "Always").

Demographic factors (potential moderators).: Child and parent demographic characteristics will be assessed at baseline, including potential moderators of the intervention effect such as child age and parent sex. In addition, UCR will provide information related to the parent's melanoma diagnosis such as the parent's age at and date of diagnosis.

Ambient UVR.: Monthly ambient UVR will be calculated based on daily reports pulled from a public database [59] based on zip code.

Analytic Approach

The primary goals of the study are to 1) evaluate the efficacy of the FLARE intervention in decreasing outcomes such as sunburn occurrence in the children, and 2) identify child and parent moderators of intervention effects This trial makes use of repeated measures to increase the power for detecting intervention differences, as the rate of occurrence of sunburn, for example, at any one time can be low. [26, 35, 36] Structural equation modeling will be used to model the repeated observations of sunburns and protective behaviors. Individual-specific intercepts and slopes across time will be estimated as latent variables through the use of latent growth curve modeling. [60-62] Difference in both the level and change of sunburn occurrence and protective behaviors will be examined. The regressions of *sunburn change* and *behavior change* onto FLARE vs standard education will address whether longitudinal trajectories for the two groups differ. Moderation of the effects of FLARE vs standard education will be examined, and models will control for the time-covariate of monthly ambient UVR levels. Additional outcomes include examination of sun protective behavior intercept and change on changes in occurrence of sunburns and child skin tone. It is expected that in the 1-year follow-up period, effects of the intervention will be more stable rather than changing as in the initial year. For this later period, a latent growth curve similar to that described above will be fit, but with only the intercept latent variable for the occurrence of sunburns; in such a model, under the constraint of homogenous error variances, the latent intercepts can be understood as equivalent to the random effects of a mixed model. [63] FLARE vs standard education will be regressed onto the latent intercept, and the models will control for monthly UVR levels, and test for moderators of the effect.

The secondary goal of this trial is to examine parent-child reciprocal influences to understand how dyadic interactions differ for FLARE versus standard education participants. At least three intervention mechanisms will be analyzed in separate models: perceived child risk for melanoma, parent modeling of sun protection, and problem-solving skills. For each

mechanism, a cross-lagged panel model will be fit to the data using a 2-group structural equation model, with group membership defined by FLARE vs Standard Education. Use of a two-group model will allow for testing whether the cross-lags (parent-child, child-parent effects) differ on average for the FLARE and standard education groups, providing insight into the hypothesized intervention mechanisms.

Statistical Power and Missing Data

Planned enrollment for the study based on initial power analyses and expected attrition consists of 375 parent-child dyads Power analyses were conducted using Monte Carlo simulations and assumed 10% full-case missingness to take into account attrition. The minimum required effect size for 80% power for the effect of FLARE vs standard education on either the sunburn intercept or change was r=0.2; this suggests the intervention would require at least a small to moderate effect to be adequately powered with the planned sample. The minimum required effect size for 80% power for the moderators was r=0.15, also suggesting the moderators would require a small to medium effect in the population to be adequately powered. Monte Carlo simulations were used to evaluate the power of the cross-lagged panel models. The standardized effect of parent on child was varied from 0.1 to 0.3 for the standard education Group, with an increase included for the FLARE group corresponding to greater coupling; these simulations indicated 80% power or greater will occur if the FLARE standardized cross-lagged path increases by at least 0.125. Planned analyses will make use of modern methods for addressing missing data to avoid costly reductions in power and potential biasing of effects. [64] Full Information Maximum Likelihood or Multiple Imputation will be used to address missing observations, as appropriate to different analyses or different estimators, with auxiliary variables related to theorized or observed missing data patterns to support a missing-completely-at-random or missing-at-random assumption.

Conclusion

The *Family Lifestyles, Actions*, and *Risk Education* (FLARE) is a theoretically-guided intervention aimed at promoting child sun protection and decreasing sunburn occurrence by enhancing perceived risk of melanoma, problem-solving skills, and parent-child collaboration for sun protection. This RCT will test the effects of the intervention as well as evaluate moderators of intervention effects. Additionally, this study will evaluate the reciprocal relationships between parent-child melanoma-related perceptions and behavior. Findings from this study will inform the broader literature on how parents and children collaborate to manage health and how these processes are influenced by behavioral interventions.

Strengths

First, the FLARE intervention was co-developed and piloted by a team with substantial prior experience working with the target population. [30, 45, 65] The past work of our team and others has identified important barriers to child sun protection, such as forgetting to use sun-protection, lack of awareness or education about melanoma risk, and time spent under another adult’s supervision. [66-70] The theory-guided intervention components included in

the FLARE intervention provide methods for addressing these and other barriers and have undergone extensive pilot testing, supporting their acceptability and preliminary efficacy. [45] Second, in contrast to past intervention studies with children of melanoma survivors, the FLARE study will include seasonally-timed evaluation of outcomes over a longer time period which will allow for examination of sustainability of intervention effects. Sunburn will be assessed on a monthly basis which will be informative concerning the times of the year that have the highest sunburn risk. Third, the recruitment strategy used by FLARE provides an efficient method to identify at-risk children of survivors and inviting them to the study through linkages between clinical, population, and registry resources. [71-74] Fourth, the FLARE study aims to enroll Hispanic survivors and survivors living in rural geographic regions, which could increase applicability of the findings to populations who experience disparities in melanoma detection, incidence, and survival. [14-17]

Limitations

This study has several limitations that may impact generalizability of study findings, including that the study will be restricted to a single geographic area in the Western area of the US (although is expected to include survivors and their children from both urban and rural areas), will likely include a low percentage of non-White individuals (although efforts will be made to oversample Hispanic survivors), and excludes those who do not speak English. We start with English only given that over 90% of US residents speak English, either as native speakers or as English proficient speakers. [75] If FLARE is shown to be efficacious, we will pursue the detailed linguistic and culture adaptations necessary to bring comprehensible and acceptable versions of FLARE to Low English Proficient populations for future research. In trials of melanoma prevention interventions among high-risk individuals, it is common for samples to be predominantly White because melanoma incidence much higher among Whites compared to non-Whites. [76] Nevertheless, in future studies among larger and more diverse samples, it will be important to evaluate whether the intervention is equally effective among populations of various races and ethnicities. Furthermore, future studies could use other methods, beyond oversampling, to increase the diversity of samples and inclusion of individuals from underrepresented groups, such as collaborating with community groups and tailoring recruitment materials to specific populations. Interventions to prevent or facilitate early detection of melanoma likely need to be modified for certain populations, including those at risk for developing acral lentiginous melanoma, which is not UVR-induced. Another limitation is that most assessments, with the exception of the skin tone rating, will be based on self-report measures, rather than on objective measures, such as individually assessed UVR exposure or reflectance spectroscopy. Also, some measures that will be used to assess potential mediators (e.g., for problem-solving skills) have not been previously validated.

Future Implementation

If the FLARE intervention is proven to be effective, our next step will be to determine how to disseminate this intervention in a manner that maximizes both reach and effectiveness. The current model of implementation using remote-delivered videoconference or telehealth sessions is more scalable than in-person approaches. Yet, the reliance on trained interventionists will be costly and can lead to variations in fidelity that could reduce impact.

[77, 78] Furthermore, the current intervention model requires synchronous sessions, which may be more burdensome for participants than a self-guided program but may also be more effective. [79] Given these considerations, our intervention team is exploring conversion of the program into a self-guided format and plans to conduct interviews with those who complete the intervention to inform this process.

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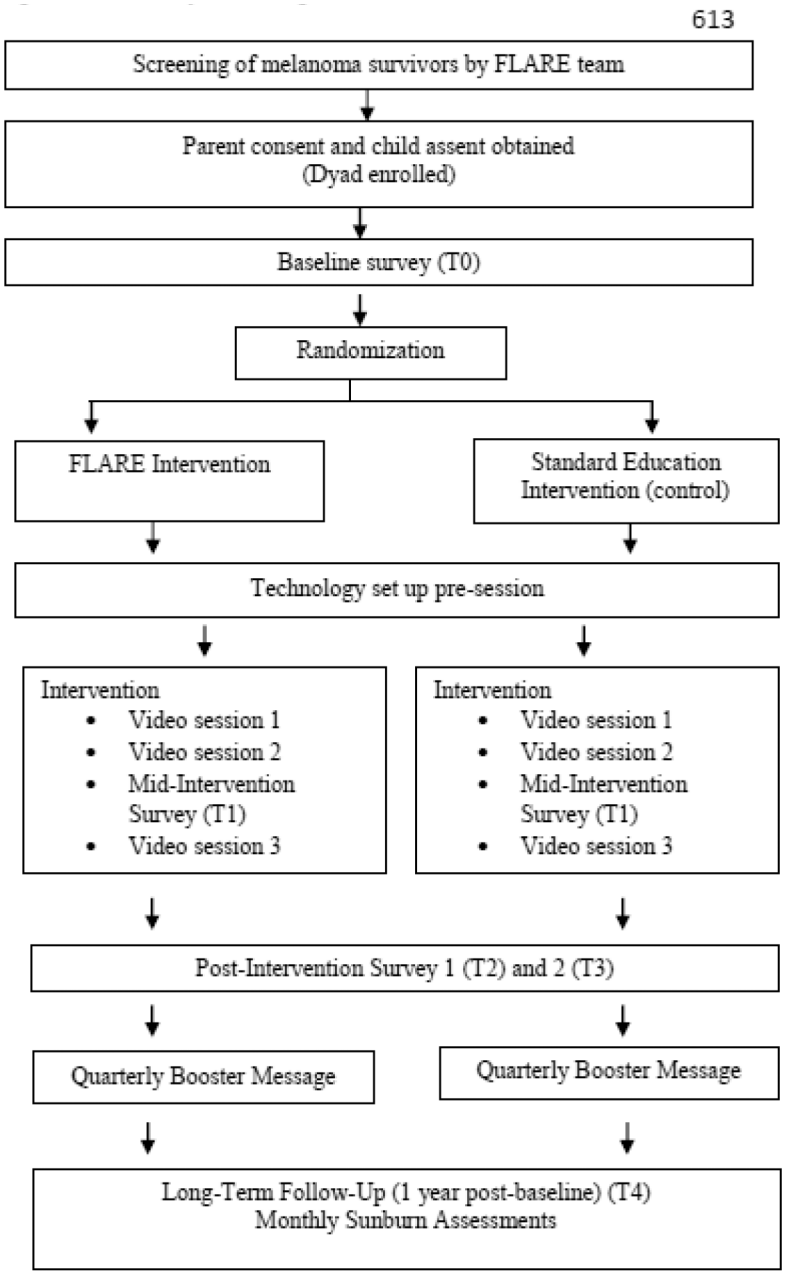

Fig 1.
FLARE Study Flow Diagram

Table 1:

Content of telehealth-delivered study sessions

Pre-session (10-15 minutes)	• Test of internet connection and troubleshoot Zoom • Connect to Zoom meeting- introduction of interventionist and study participants • Confirm receipt of study binder and provide overview of study materials • Set up Canvas account for learning modules • Schedule study sessions and confirm session 1	
	Intervention Content	**Standard Education (control) Content**
Session 1	*Melanoma Risk and Healthy Skin Habits (60-70 minutes)* • Review highlights of Canvas module (completed before session 1) • Review education on melanoma risk & preventive behaviors • Review the principle of "flexibility" as applied to melanoma preventive behaviors • Address societal norms for tanness • Discuss the importance of modeling • Create family skin protection plan • Introduce problem-solving IDEAS process • Assignments for next session	*Skin Cancer Organizations (15-20 minutes)* • Review highlights of Canvas module (completed before session 1) • Session 1 objectives • Review of major skin cancer organizations • Evaluating health information online: distinguishing between marketing and health information • Questions and preparation for next session
Session 2	*Behavioral and Organizational Strategies to Make Healthy Skin Habits Easier (35-40 minutes)* • Review progress on assignments • Review highlights of Canvas module (completed before session 2) • Discuss behavioral & organizational strategies for implementing healthy skin habits • Apply IDEAS problem-solving process • Update family skin protection plan • Assignments for next session	*The Centers for Disease Control and Prevention (20-25 minutes)* • Review highlights of Canvas module (completed before session 2) • Recap of session 1 • Introduction of CDC organization • Navigation to CDC website • Accessing skin cancer information on the CDC website • Questions and preparation for next session
Session 3	*Communicating about Melanoma Prevention (30-35 minutes)* • Review progress on assignments • Review highlights of Canvas module (completed before session 3) • Discuss communication skills & tools related to healthy skin habits • Apply IDEAS problem-solving skills process • Review skills covered over FLARE sessions • Planning for the future • FLARE program wrap-up and thank you	*The American Academy of Dermatology (15 minutes)* • Review highlights of Canvas module (completed before session 3) • Recap of session 2 • Introduction to AAD organization • Navigation of AAD website • Accessing skin cancer information on the AAD website • Questions and next steps

Table 2:

Outcome measures

	Measure or Construct	T0	T1	T2	T3	T4	Citation
Primary Outcome							
Sunburn	Sun habits survey	✓	✓	✓	✓	✓	Glanz et al.[49]
Secondary Outcomes							
Sun protection & tanning	Sun habits survey	✓	✓	✓	✓	✓	Glanz et al[49]
Skin tone	Adapted from: Garcia, D., & Abascal, M. (2016)	✓	✓	✓	✓	✓	Adapted from: Garcia Abascal[50]
Moderators	Investigator designed with use of the Fitzpatrick scale	✓					Investigator + Fitz[71]
Parent-Child Influences							
Perceived risk	Absolute and relative risk	✓	✓	✓	✓	✓	Aspinwall et al.[72]
Parent-child modeling	Sun habits survey	✓	✓	✓	✓	✓	Glanz et al.[49]
Problem-solving skills	Investigator designed	✓	✓	✓	✓	✓	Investigator designed
Time-varying Covariate							
Monthly ambient UVR assessed daily throughout the intervention							

*T0=baseline survey (4-8 weeks before intervention), T1=mid-intervention, T2=post-intervention 4 weeks, T3=post-intervention eight weeks, T4=one year after baseline survey

**Child sunburn was also assessed monthly between the eight week and one-year assessments and in the months after the one-year assessment.