HRP-591 - Protocol for Human Subject Research

Protocol Title: Efficacy of a Behavioral Intervention to Reduce Skin Cancer Risk Among Patients

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Version Date:

January 23, 2018

Clinicaltrials.gov Registration #: not applicable

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1.0 Objectives

1.1 Study Objectives

The purpose of this study is to extend previous research (R03 CA144435) and conduct a preliminary analysis of the effect of a brief dermatologist-delivered intervention (ABC intervention) on patients' skin cancer related outcomes. The long-term goal with respect to the ABC intervention is to conduct a large-scale randomized controlled trial (RCT) with multiple clinics. Specific research aims of the study include:

The first aim examines the efficacy of the Addressing Behavior Change (ABC) intervention versus treatment as usual (TAU) during a regular dermatological visit on patient reported number of UV protective behaviors (such as use of sunscreen) and UV risk behaviors (such as number of sunburns) using a longitudinal design (3 and 6 month).

The second aim of the study will evaluate moderating factors, such as gender and history of skin cancer, and mediating factors, such as attitudes and self-efficacy, which impact the efficacy

of the intervention. The mediating and moderating variables may help to identify those individuals whom the intervention is more (or less) effective.

1.2 Primary Study Endpoints

Whether or not the ABC intervention was efficacious when delivered by dermatologists during a routine office visit compared to treatment as usual, on a number of UV protective behaviors.

1.3 Secondary Study Endpoints

Whether or not moderating factors such as gender, age, and history of skin cancer, and mediating factors, such as attitudes and self-efficacy, identify individuals for whom the ABC intervention is more or less effective.

2.0 Background

2.1 Scientific Background and Gaps

The diagnosis of melanoma (skin cancer) was estimated to have approximately 80,000 new cases in 2014, with over 10,000 persons dying from melanoma (American Academy of Dermatology, 2014). The main factor leading to skin cancer has been UV exposure (Veierod et al., 2003). Therefore, individuals can reduce their skin cancer risk (as well as its morbidity and mortality) by increasing sun protective behaviors (such as wearing sunscreen and protective clothing) and reducing both intentional and unintentional UV exposure.

Deterrence through expert delivered education approaches has been the major method of attempting to change UV risk behaviors. Effective communication between doctors (MD) and patients has been shown to enhance a variety of outcomes, such as improved health, improved patient management of chronic illness, decreased symptoms, treatment compliance, and overall satisfaction with care.

Using the ABC (Addressing Behavior Change) intervention to change UV risk behaviors is a strategy based on the principles of Motivational Interviewing (MI), which is a client centered approach originally developed in the addictive behaviors field with the intent of promoting and supporting behavior change through empathic communication. The ABC intervention emphasizes a collaborative relationship between health care providers and patients when addressing behavior change rather than MDs dictating change to a patient.

While we have developed and tested the ABC intervention during routine office visits in our R03 study, what is lacking is an examination of using the ABC intervention to address skin protective behaviors.

2.2 Previous Data

This study is a continuation of a research program examining brief dermatologist-delivered intervention on patients' skin cancer related outcomes. We had previously received a grant R03 CA144435, which found that dermatologists were very motivated to deliver the ABC intervention, were able to quickly learn the skills associated with the intervention, were able to deliver the intervention with fidelity, and showed minimal deterioration in knowledge, skills, and motivation over a 6 month period. Based on those findings, we conducted a pilot study, collecting patient data following a dermatologist visit, and found that those patients who received the ABC intervention had much higher intentions to utilize sunscreen and rated the communication with their dermatologist much higher than control patients receiving TAU. These findings together suggest the promise of the ABC intervention, which supports the need of an evaluation of the effectiveness of the ABC intervention on patient outcomes such as UV risk and protective behaviors.

2.3 Study Rationale

To date, it is unclear how effective the ABC intervention will be on patients' UV risk and protective behaviors. While we have found that dermatologists both like the ABC intervention and are able to deliver it with fidelity, and patients in a small pilot had higher intentions to utilize sunscreen and rated their dermatologist communications higher than TAU patients, it is unclear if the ABC dermatologist-delivered intervention will change patient behavior.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Patients must be:

1) Fluent in English
2) Mentally capable of giving consent and free of cognitive impairment (e.g., stroke, dementia, etc.)
3) Age 21-65 years old
4) A patient at Penn State Medical Center Dermatology Clinic in Hershey, PA or State College, PA, scheduled for a skin examination (either annual full body skin check or suspicious lesion) or scheduled for a Mohs surgical procedure.
5) Patients may include anyone who meets inclusion criteria (including previous skin cancer patients, newly diagnosed skin cancer patients, non-skin cancer patients)

Providers must:

1) Provide skin examinations (either annual full body skin check or suspicious lesion) or Mohs surgical procedures directly to patients (rather than supervise residents)
2) Treat patients that meet inclusion criteria for the study

3.2 Exclusion Criteria

Patients will be excluded if they:

1) Do not meet inclusion criteria as stated above
2) Have psoriasis (as a recommended treatment of psoriasis is intentional UV exposure)
3) Have had previous exposure to the ABC intervention during the R03 at Penn State Hershey Medical Center in 2010 or during data collection for this study during Spring 2016

Providers will be excluded if they:

1) Only supervise residents and do not provide skin exams directly to patients
2) Do not treat patients that meet inclusion criteria for the study

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

The only reasons participants will be removed from the study is if they fail to give or withdraw consent for participation.

3.3.2 Follow-up for withdrawn subjects

N/A – withdrawn subjects are simply dropped from the participant pool, and no further contact will be made.

4.0 Recruitment Methods

4.1 Identification of subjects

The first step in identifying potential patient participants will be to have the PSHMC Dermatology research nurse coordinator review appointment schedules at both sites (Hershey – intervention; State College – control) to see which patients are scheduled to receive skin checks (either annual full body skin check or suspicious lesion) or Mohs surgical procedures at upcoming appointments. The PSHMC Dermatology research coordinator at the clinics will either: 1) call potential patient participants and invite them to participate via the phone, or 2) send a letter to these patients approximately 2-4 weeks prior to their scheduled appointment, explaining the research and inviting them to call the research team to obtain more information or to email/call the PSHMC research team within approximately 2 weeks if they are not interested in learning more about the study.

Providers interested in participating at Penn State Hershey Medical Center (PSHMC) and State College will be randomly selected from the departments (up to n=10 per site).

4.2 Recruitment process

Recruitment of Patients:

1) The PSHMC Dermatology research nurse coordinator will either: 1) call potential participants and invite them to participate via the phone, or 2) send a pre-notification letter to these patients approximately 2-4 weeks prior to their scheduled appointment, explaining the research and inviting them to call the research team to obtain more information or call/email within approximately 2 weeks if they are not interested in learning more about the study.
2) For those receiving the pre-notification letter, after approximately 2 weeks, the patients who did not indicate disinterest in the study or contact PSHMC for more information, will be called by a PSHMC research assistant and will be formally invited to participate in the study. For both individuals who contact the research team directly and those who are contacted due to not declining, will follow the same procedures: If they are interested, the research assistant will obtain verbal consent to screen patients to see if they qualify for the study based on the inclusion/exclusion criteria. If they are eligible, they will then be formally invited. Potential participants interested in the study will be asked to arrive 25 minutes early for their appointment so that the consent form may be reviewed with them in its entirety and signed informed consent can be obtained in a private area of the clinic prior to the completion of the brief baseline survey. A log will be kept of all *de-identified* patients contacted via phone who declined participation, with the reasons for declining participation as well as those who decline to participate when approached in the clinic (example: adult male #1 refused study due to time commitment).
3) For those who are called and invited to participate over the phone by a PSHMC research assistant, the research assistant will explain the study, and if the patient is interested, the research assistant will obtain verbal consent to screen patients to see if they qualify for the study based on the inclusion/exclusion criteria. If they are eligible, they will then be formally invited. Potential participants interested in the study will be asked to arrive 25 minutes early for their appointment so that the consent form may be reviewed with them in its entirety and signed informed consent can be obtained in a private area of the clinic prior to the completion of the brief baseline survey. A log will be kept of all de-identified patients contacted via phone who declined participation, with reasons for declining participation as well as those who decline to participate when approached in the clinic (example: adult male #1 refused study due to time commitment).

4) In the first cohort in Spring 2016, we enrolled 27 participants who qualified after completing the screening. For the second cohort in Spring 2017, we plan to enroll an additional sample of 200 (100 per site). Based on the response rate of the first cohort in Spring 2016, we will invite up to 770 participants in Spring 2017. Once the target enrollment of 200 total (about 100 per site) is obtained, we will discontinue recruiting. The study will be split into 2 cohorts

– one taking place in Spring 2016 (n=27) and the other taking place in Spring 2017 (target n=200).

5) Participants who are interested and who qualify to participate will either: 1) be asked on the phone for their email address in order to send a copy of the consent form and reminder to arrive at their scheduled appointment 25 minutes prior to their scheduled time, or 2) receive a copy of the informed consent and a letter by mail reminding them to arrive at their scheduled appointment 25 minutes before their scheduled time to perform the written informed consent process and to complete the baseline survey. Participants will also be called 1-3 days before their scheduled appointment to remind them to arrive 25 minutes early (see reminder phone script).
6) 1-month and 3-month follow-up surveys will be conducted online to reduce burden and allow participants to complete them from home. Participants can request mailed, paper-based surveys if they do not want to complete the online version of the survey. Paper-based cover letter and surveys will be mailed to participants' homes along with prepaid return envelopes. Both the online version of the follow-up surveys as well as the hardcopy surveys (which will include identical questions/prompts as the REDCap survey), will include the text at the beginning of the survey that states "By completing the following survey you are agreeing to take part in this research study. If you have any questions about the survey or your participation, please contact project coordinator, Sarah Ackerman, at 814-865-4222 or sdf5013@psu.edu". Participants will receive an invitation email, up to 5 reminder emails, and up to 3 reminder phone call attempts to complete each survey. During the baseline survey, participants will also be asked if they would like to receive SMS text message reminders to participate in the follow-up surveys. If participants opt into receiving SMS text message reminders, they will receive 2 text message reminders for each survey along with all other contact methods.
   Subjects will be informed in the consent process:
   "You should be aware that it is illegal in the Commonwealth of Pennsylvania to text while driving. It is also dangerous to pay attention to your cellular phone while driving, walking, or doing any activity that requires your attention. You should continue to exercise good judgment on this while participating in this study."

   Please note: Mailed hardcopy surveys/letters will only be offered to individuals who indicate that they do not have access to the internet, not as an option for all participants. With the timeframe between the 1-month survey and the 3-month survey being shorter, we do not want there to be any overlap of surveys if participants are slow to mail back their responses.

Recruitment of Physician Interventionists:

1) The dermatologists from the intervention site will undergo 1 session of training to deliver the ABC intervention, following the same protocol developed and used in the R03 study. A weekly scheduled journal club meeting will be cancelled and this training will take the place of it in the evening (instead of morning) and will require no additional time commitment from the dermatologists to participate in the training or study.
    a. The first component of training will involve learning to deliver each of the 6 components of the intervention. Patient interactions will be demonstrated by the study staff.
    b. The second component will involve role plays. The physicians will practice implementing the intervention on research assistants who will pose as mock patients.
    c. The third component will involve supervision and feedback. Drs. Mallett and Turrisi will observe the physicians while they deliver the ABC intervention to patients. They will then provide feedback privately.
        i. For Spring 2017, a training booster will take place. This will include component C (supervision) in order to ensure there is consistency in intervention delivery.
2) Up to 10 providers from the intervention site and up to 10 providers from the control site will be randomly selected to participate. If they agree, intervention dermatologists will give

verbal consent after reviewing the Summary Explanation of Research provided by a member of the research team during the scheduled Dermatology Department meeting, and control site dermatologists will give verbal consent prior to the recruitment of patients.

3) The dermatologists at the control site will deliver treatment as usual (TAU) to their patients, and will not undergo the training and supervision.

4.3 Recruitment materials

See details of procedure in section 4.2

1) Options Pre-Note Initial Recruitment Letter
2) Options Phone Script Baseline Invite
3) Options Reminder Email for Baseline Participation
4) Options Phone Script for Baseline Survey
5) Options Reminder Letter for Baseline Participation
6) Options Phone Reminder Script for Baseline Survey
7) Options 1 Month Followup Survey Email Mail Invite
8) Options 1 Month Followup Survey Reminder Email
9) Options 3 Month Followup Survey Email Mail Invite
10) Options 3 Month Followup Survey Reminder Email
11) Options Followup Reminder Call Script
12) Options Followup Survey Text Message Reminder
13) Options Thank You Letter for Study
14) Options Collateral Contact Call Script
15) Options Collateral Contact Email Mailed Letter

4.4 Eligibility/screening of subjects

Patients will be pre-screened following the inclusion and exclusion criteria listed in sections 3.1 and 3.2 of this protocol by the PSHMC Dermatology Research Nurse Coordinator who has clinical access to this patient population. Subjects will then give verbal consent to be screened over the phone for eligibility for this research study for items not able to be determined from clinical access.

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

If a patient expresses interest in participating when they are called to be invited over the phone (or when they contact us), they will be verbally consented to be screened for the research study (see phone scripts for consenting language).

Research assistants will then approach participants to obtain informed consent when they arrive in the dermatology clinics at PSHMC and State College after they check in for their appointment. The research assistant will escort the patient to a private area where the informed consent process will take place. The consent form will be read and reviewed in its entirety, all questions will be answered prior to the subject signing for participation. If patients agree to participate, they will then sign the informed consent form and provided a copy.

Additionally, at the beginning of every online survey (as well as paper-based copies), it will include the text that states “By completing the following survey you are agreeing to take part in this research study. If you have any questions about the

survey or your participation, please contact project coordinator, Sarah Ackerman, at 814-865-4222 or sdf5013@psu.edu".

For participating physicians: Those physicians who agree to participate in the research will give verbal consent after reviewing the Summary Explanation of Research provided by a member of the research team during the scheduled training (intervention) or prior to patients being recruited (control).

5.1.1.2 Coercion or Undue Influence during Consent

Study procedures will be fully explained, all critical study information will be disclosed, voluntariness will be emphasized as well as the fact that no care will be denied regardless of the subject's decision. Subjects will be told they do not have to participate in the research. They will be told that whether or not they agree to participate in the study, their current or future care at the PSHMC will not be affected by their decision.

For physician subjects, they will be told they do not have to take part in the research and that their educational and employment status will not be affected in any way by their decision.

5.1.2 Waiver or alteration of the informed consent requirement

We are requesting a waiver of informed consent so that the Hershey coordinator/team can review clinic schedules for recruitment purposes. This waiver will minimize the possibility of subjects being contacted who do not qualify for the research based on information available in their medical record.

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

Written informed consent will be obtained from all participants in a private area of the clinic prior to their scheduled appointment. The consent form will be read and reviewed in its entirety with the subject, all questions will be answered prior to the potential subject signing for participation. Both the subject and the investigator obtaining informed consent will sign, date and time the consent document.

The participant will receive a signed/dated copy of the consent documentation for their records.

A copy of the signed consent form will not be added to the subject's medical record.

5.2.2 Waiver of Documentation of Consent

Verbal consent will be obtained to screen potential participants for eligibility. This waiver will minimize the possibility of subjects being approached in the clinic who do not qualify for the research based on information available in their medical record or able to be screened for via the telephone.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

Not Applicable – Participants will not be non-English speaking

5.3.2 Cognitively Impaired Adults

5.3.2.1 Capability of Providing Consent
Not Applicable – Participants will not be cognitively impaired

5.3.2.2 Adults Unable To Consent
Not Applicable

5.3.2.3 Assent
Not Applicable

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission
Not Applicable – Inclusions criteria states that participants must be at least 21 years of age.

5.3.3.2 Assent
Not Applicable

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ Authorization will be obtained and documented as part of the consent process.

☒ Partial waiver is requested for recruitment purposes only *(Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained)*

☐ Full waiver is requested for entire research study *(e.g., medical record review studies)*

☒ Alteration is requested to waive requirement for written documentation of authorization

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure
Information is included in Section 10 of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers
The patient permission for the use, storage, and sharing of their health information will expire upon completion of the research study. At that time, the identifying research information will be destroyed.

6.2.2 Explanation for why the research could not be practicably be conducted without access to and use of PHI
We will be conducting the study in dermatology clinics and will be contacting participants via mail, email, and/or phone for recruitment purposes. We will need the names of participants in order to know who was deemed eligible by clinic nurses, and as age is an inclusion criteria, we will need access to age. However, until the patients agree to participate in the study via the phone screening or contact PSU researchers directly, the

PSHMC Dermatology Research Nurse Coordinator/Hershey team will be the only ones with access to this information.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

The waiver of authorization is required to screen for eligibility.

6.3 Waiver or alteration of authorization statements of agreement

Not Applicable

7.0 Study Design and Procedures

7.1 Study Design

This study will use a longitudinal design to compare the effect of the ABC intervention on the intervention group versus the control group receiving TAU. Participants will not be randomized to a group. Instead, patients who meet eligibility criteria at PSHMC will be invited to participate at the intervention site, and current patients who meet eligibility criteria at the clinic in State College will be invited to participate at the control site.

7.2 Study Procedures

Subjects will be recruited from two sites: 1) Penn State Hershey Medical Center Clinic in Hershey (PSHMC), which will serve as the intervention site where patient participants will receive the ABC interventions, and 2) Penn State Medical Group in State College (State College), which will serve as the control site where patient participants will receive TAU.

1) Participation will begin when participants are screened for eligibility over the phone.
2) Participation will continue for subjects when they arrive at either PSHMC or State College for an appointment with a participating physician that will include a skin check (either annual full body skin check or suspicious lesion) or Mohs surgical procedure (please see the recruitment section for a step-by-step process of how eligible participants will be obtained). A skin check involves the physician checking the patients' skin for any growth or mark that could potentially become cancerous. Patients at the control site will be receiving TAU for their skin check; patients at the intervention site will receive a normal skin-check, combined with the ABC-intervention (see uploaded information sheet). The audio recordings which will be done at both the control and intervention sites for all participants will be used to compare the information patients receive from their doctor during the course of a skin check.
3) Participants will be asked to arrive 25 minutes prior to their appointment so the informed consent process may take place prior to any study related procedures being conducted. After they check in, they will be greeted by a research assistant in the waiting room and directed to a private area within the clinic. The research assistant will be accessible while the participant completes the survey to answer questions that may arise. The baseline survey will assess demographic information, history of skin cancer, UV risk behaviors, perceived risk of skin cancer, dermatologist communication, attitudes about sun protection behavior, self-efficacy about sun protective behaviors, etc. (Please refer to Measures document for full questionnaire).
4) As part of the surveys, participants will be asked to provide the contact information of a friend or relative that we could contact in the event that we are unable to locate the individual for the 1-month and 3-month follow-up surveys. Phone and email/letter scripts are included in the recruitment documents. We will attempt to call the "collateral contact" up to 2 times, and then will send a letter or email if we cannot reach them by phone. Participants will be reminded of the following when they log on to the survey: "By completing the following survey you are agreeing to take part in this research study. If you have any questions about

the survey or your participation, please contact project coordinator, Sarah Ackerman, at 814-865-4222 or sdf5013@psu.edu".

5) The patient will then proceed to their appointment with a dermatologist. At the intervention site, the provider who has been trained to deliver the ABC intervention will do so during the skin exam. During the appointment at the intervention site, providers will provide their patients with a handout (as a small card and/or magnet) which summarizes what they discussed during the appointment regarding sun protection (CURE Method Tips – see uploaded document). At the control site, patients will receive TAU, with no ABC intervention. All patient participant appointments are to be audio recorded and by consenting to the study, patients are consenting to be audio recorded. A research assistant will accompany the patient into the exam room to audio record the visit. Only providers who have taken the appropriate training will have patients identified to participate in this study (intervention). Providers at both the intervention and control sites will be consented prior to any audio recordings being done, as explained in section 5.1.1. Research assistants will later listen to and code the data to determine if the components of the ABC intervention were delivered with fidelity. Control sessions will be recorded and coded using the same criteria to document those patients who did not receive elements of the ABC intervention. The recordings will be coded with the patient's study number and will be destroyed per PSHMC IT Security Group policy as soon as data is coded from their analysis. The participant and the provider will be reminded prior to the recording to not use names or other identifying information during the recording.
6) At 1-months and 3-months following this appointment, the first (1 month) and second (3 months) follow-up surveys will be sent out, via email to complete online to allow participants to complete at home. Participants can request mailed, paper-based surveys if they do not want to complete the online version of the survey. A cover letter and paper-based surveys will be mailed to participants' homes along with prepaid return envelopes. In an email, participants will be instructed to complete the survey online (or, if the participant requested a mailed paper-based survey, they will be instructed via mailed letter to mail back the paper-based survey to the investigator's office in the enclosed pre-paid envelopes). The 1-month and 3-month follow-up surveys will be almost identical to the baseline survey (minus the screening items, background item, and physician communication item, as indicated in the measures document), and each should take about 5-10 minutes to complete. Participants will receive a $25 Walmart gift card, Target gift card, or Amazon electronic gift card for completing each survey, totaling $75 if they complete all 3 surveys. Participants will be paid for the baseline survey after completion of the visit, and the two follow-up surveys will be paid at the end of the study (that is, after the 3-month follow-up survey). If they do not complete all surveys they will be compensated for the ones they do complete. Participants will be asked during the screening call which payment option they would like, so that we can have the appropriate option in clinic, and if they do not complete one of the follow-up surveys, we will have their payment option on file.

Note: Dermatologists from the intervention site will undergo 1 session of training to deliver the ABC intervention. This will take place during the rescheduled weekly journal club meeting, which will take place in the evening and will require no additional time. 1) The first component of training will involve learning to deliver each of the 6 components of the intervention. Patient interactions will be demonstrated by the study staff. 2) The second component will involve role plays. The physicians will practice implementing the intervention on research assistants who will pose as mock patients. 3) The third component will involve supervision and feedback. Drs. Mallett and Turrisi will observe the physicians while they deliver the ABC intervention to patients. They will then provide feedback privately. Up to 10 providers from the departments of dermatology at each site will be selected to perform the skin exams, based on their availability.

Physicians at the control site will deliver TAU to their patients, and will not undergo the training and supervision.

7.3 Duration of Participation

Patient participants will be involved in the study for up to 4 months. The baseline visit in clinic will take approximately 25 minutes longer than their scheduled appointment, which lasts on average 15 minutes (they are asked to arrive 25 minutes early to complete the consent and baseline survey). Each post- survey will take 5-10 minutes to complete. Participants will complete a baseline assessment, and subsequent 1-month and 3-month post-surveys.

Their participation will last up to 60 minutes (inclusive of their scheduled dermatologist appointment) over a 4 month period.

Dermatologists at the intervention site will be involved from the beginning of their training through the end of baseline data collection, approximately 8-10 weeks (April-May 2016 & 2017). Dermatologists at the control site will be involved only during baseline data collection, approximately 8-10 weeks (April-May 2016 & 2017).

8.0 Data and Specimen Banking For Future Undetermined Research

8.1 Data and/or specimens being stored

Not Applicable

8.2 Location of storage

Not Applicable

8.3 Duration of storage

Not Applicable

8.4 Access to data and/or specimens

Not Applicable

8.5 Procedures to release data or specimens

Not Applicable

8.6 Process for returning results

Not Applicable

9.0 Statistical Plan

9.1 Sample size determination

874 is the maximum number of patient participants to be enrolled.
The number of participants that will be contacted (874) is much larger than the number we intend to enroll (227). Based on the response rate of the first cohort in Spring 2016, we are confident that the recruitment process explained above will yield the required number of participants within the proposed period.

27 participants were enrolled during the first cohort in 2016.

9.2 Statistical methods

We will utilize a number of statistical methods. For example, basic t-tests and regression will be used for preliminary analyses. The majority of the analyses will center on two types: 1) moderated multiple linear regression (SEM models) for Aim 2 and 2) Mixed ANOVA for Aims 1 and 2.

10.0 Confidentiality, Privacy and Data Management

10.1 Confidentiality

The collected research data will be kept completely confidential. All hard copies of completed questionnaires will be labeled with a code number only (PIN) and stored in locked filing cabinets in locked offices. Survey responses will be entered into a secure research database: REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. REDCap is maintained by the REDCap Consortium which is comprised of over 600 institutional partners including Penn State University, on a password protected computer in a locked office and/or the PRO Health Lab's departmental Penn State PASS drive, only accessible by the team members listed on this application.

We have taken the following steps to protect individuals' identities as research participants: 1) PSU research team will not have access to potential participants until they are pre-screened by Hershey staff and agree to participate or contact us directly via phone or email, and only the PSHMC Dermatology research nurse coordinator and Hershey team, who has access to this population, will be involved in the initial recruitment; 2) Responses to surveys will be identified only by a unique personal identifier (PIN), which is a number randomly generated for each participant in this study; 3) Hershey will keep a master list of names, addresses, phone numbers, and PINs so that they can mail recruitment letters, and PSU will create a master list based on the participants who agree to participate when pre-screened (and verbally consented) over the phone or contact us directly, to send reminder letters, 1-month and 3-month follow-up surveys and compensation. The master list of consented participants will be stored separately from the survey responses on a password protected computer in a locked office and/or the PRO Health Lab's departmental Penn State PASS drive, only accessible by the team members listed on this application; and all audio recordings will be destroyed once they are scored and coded.

Considering that participants will be sent a link and PIN number to access the 1-month, and 3-month follow-up surveys, they can complete it in any location they wish (e.g., home). The level of privacy they receive is limited to the location they choose to complete it at.

10.1.1 Identifiers associated with data and/or specimens

The data is de-identified as we use a PIN number to identify the data. Any identifiable information is used only to invite participants for follow-up surveys (and is marked as an identifier within REDCap) and to compensate them for participating in the study, and is stored in a file separate from the survey data.

10.1.1.1 Use of Codes, Master List

A master list containing a code number (PIN) and participants' identity will be stored in a separate password protected computer file within the REDCap database, only accessible by the study staff listed on this document. The overall list of ALL participants invited to the study will be maintained by the Hershey team; the Penn State team will keep a separate list as participants complete phone screening. This file will be kept separate from any collected data. The list will be saved on a password protected computer in a locked office and/or the PRO Health Lab's departmental Penn State PASS drive, only accessible by the team members listed on this application

10.1.2 Storage of Data and/or Specimens

All data will be stored in the REDCap database on locked, password protected computers in the PSHMC Dermatology Research office and PRO Health Lab (320 BBH) and/or on the PRO Health Lab's departmental Penn State PASS drive, only accessible by the team members listed

on this application. The data files may also be stored on a Penn State Project Box account accessible only by the individuals listed on this document. All data files will be void of any participant information, and data will be organized by randomly assigned ID numbers.

This study has been issued a Certificate of Confidentiality. Researchers will not disclose or provide any identifiable information without the subject's prior consent or where permitted according to NIH's Policy on Issuing Certificates of Confidentiality.

10.1.3 Access to Data and/or Specimens

Only the study staff listed on this application will have access to the list.

10.1.4 Transferring Data and/or Specimens

Data will be physically transported from the Penn State Hershey Medical Center clinic sites to PSU at University Park. Signed informed consents, baseline surveys, and audio recordings will be transported via vehicle from Penn State Hershey Medical Center clinic sites to PSU at University Park. The items will be transported in a locked file box in a locked car trunk.

10.2 Privacy

All data and other information in this study will be maintained confidentially, and will be identified only by a unique personal identifier (PIN), which is a number randomly generated for each participant. Data will be entered into an electronic, password protected file, only accessible by the study staff listed on this document. Considering that participants will be sent a link and PIN number to access the 1-month and 3-month follow-up surveys, they can complete it in any location they wish (e.g., home). The level of privacy they receive is limited to the location they choose to complete it.

11.0 Data and Safety Monitoring Plan

11.1 Periodic evaluation of data

Not Applicable

11.2 Data that are reviewed

Not Applicable

11.3 Method of collection of safety information

Not Applicable

11.4 Frequency of data collection

Not applicable

11.5 Individual's reviewing the data

Not Applicable

11.6 Frequency of review of cumulative data

Not Applicable

11.7 Statistical tests

Not Applicable

11.8 Suspension of research

Not Applicable

12.0 Risks

Psychological risks posed by the research are primarily related to the sensitivity of some of the measures. Items include thoughts, feelings, and personal difficulties that may be private, and personal behavior such as thinking about their likelihood of developing skin cancer. These questions may make participants uncomfortable, or be perceived as an intrusion on their privacy. Although it is our responsibility to point out the potential for these risks, we must emphasize that we have not observed any indications of these risks materializing in any of our previous research using the same procedures we will employ in this study. Participants will be assured of their voluntary participation in the study, their choice to answer or not answer any question, and of our protocol for maintaining confidentiality.

We have taken steps to protect participants against potential risks posed by their participation in this research. Psychological risks of invasion of privacy or increased awareness or concern about one's behavior as a result of completing the assessments will be addressed as a risk in the consent form. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Drs. Mallett (PI) and Turrisi (Co-Investigator) are qualified to provide referrals and address concerns related to psychological distress arising through participation.

Additionally, we have a Certificate of Confidentiality from NIH.

13.0 Potential Benefits to Subjects and Others

13.1 Potential Benefits to Subjects

Through completing this questionnaire, participants may become more aware of their skin protective behaviors and risk factors, which may prompt some behavior change. However, there may be no direct benefit to participants.

13.2 Potential Benefits to Others

The knowledge to be gained from this study is of great importance and will benefit others and society as a whole. Findings will help to improve physician-patient communication, to increase the use of sun-protective behaviors, and therefore reduce the chance of developing skin cancer among patients.

14.0 Sharing Results with Subjects

Not Applicable

15.0 Economic Burden to Subjects

15.1 Costs

The participant will not bear any costs.

15.2 Compensation for research-related injury

Not Applicable – the research does not involve more than minimal risk to subjects.

16.0 Number of Subjects

The total maximum number of participants to be enrolled is 894.
The number of patient participants that will be contacted (up to 874) is much larger than the number we intend to enroll (227 – including both Cohort 1 and Cohort 2) (27 enrolled in Cohort 1 between Intervention and Control; 200 intended to enroll in Cohort 2 – 100 intervention, and 100 control). Based on the response rate of the first cohort in Spring 2016, we anticipate a 26% overall response rate, resulting in 200 individuals (for cohort 2) who agree to participate. However, due to uncertainty on the

overall response rate, participants will be invited in chunks and once we hit our target enrollment, we will stop recruiting. Additionally, we will enroll up to 20 providers (up to 10 from the control site and up to 10 from the intervention site).

17.0 Resources Available

17.1 Facilities and locations

1) PRO Health Lab, University Park, PA – Project preparation including grant writing and submission, IRB document preparation, mailing of recruitment materials, initial telephone contact, participant compensation preparation, and data analysis and report writing will take place on the University Park campus. The office space that will be utilized is located in the Prevention Research Center's PRO Health Lab (320 Biobehavioral Health Building), consisting of a suite of 7 offices, a data coding room, and a large conference meeting area. It has 13 workstations, networked computers and fully functioning office equipment (e.g., fax and copy machines, networked printers). It also contains 8 iMac desktops with 4.0GB RAM, along with 4 Dell PCs with sufficient storage and memory for most analytic functions. The lab also contains 2-laser jet and 4-color jet networked printers, as well as networked access to a large format plotter that can print outstanding presentation-quality posters.
2) Penn State Hershey Medical Center (PSHMC) – Our intervention site will be Penn State Hershey's Department of Dermatology, located at University Physician's Center, 500 University Drive, UPC I, Suite 100, Hershey, PA 17033
3) Penn State Medical Group State College (State College) – Our control site will be Penn State Hershey Medical Group Colonnade and Endoscopy Center, located at 32 Colonnade Way, State College, PA 16803

17.2 Feasibility of recruiting the required number of subjects

We have access to all dermatology patients at both the intervention and control sites. We have secured agreement to use both clinics. Out of all of the dermatology patients, we will only be recruiting a portion.

17.3 PI Time devoted to conducting the research

Given the current research load and the quality and size of the research support team, there is no doubt the PI will have sufficient time to conduct the proposed research.

17.4 Availability of medical or psychological resources

Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Drs. Mallett (PI) and Turrisi (Co-Investigator) are qualified to provide referrals and address concerns related to psychological distress arising through participation.

17.5 Process for informing Study Team

All members of the research staff will be sufficiently trained in study procedures, protocol, and timeline. They will be reminded of confidentiality procedures. Each staff member will receive a copy of the original grant proposal and the approved IRB application. We will walk through procedures in person. Study staff who will be on site at the clinics for consenting participants, administering surveys, and audio recording participants, will be trained on the proper procedures.

18.0 Other Approvals

This project is funded by the National Cancer Institute/National Institutes of Health, and we have a Certificate of Confidentiality as well.

19.0 Subject Stipend (Compensation) and/or Travel Reimbursements

All patient participants will be compensated for their participation in the study. Patients will receive $25 for completing each of the 3 surveys (baseline, 1-month, and 3-month follow-up). The compensation for the baseline survey will be dispersed at the clinic after completing the baseline survey. The compensation for the two follow-up surveys will be dispersed at the end of the study (that is, after the 3-month follow-up). Participants may choose to receive either a Walmart gift card, a Target gift card, or an Amazon electronic gift card. The total possible compensation is $75. If a participant does not complete the study in its entirety (that is, they completed some but not all of the surveys), they will be paid for the surveys that they completed.

20.0 Multi-Site Research

20.1 Communication Plans

Not Applicable

20.2 Data Submission and Security Plan

Not Applicable

20.3 Subject Enrollment

Not Applicable

20.4 Reporting of Adverse Events and New Information

Not Applicable

20.5 Audit and Monitoring Plans

Not Applicable

21.0 Adverse Event Reporting

21.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

21.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

22.0 Study Monitoring, Auditing and Inspecting

22.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

22.2

23.0 References

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24.0 Appendix

25.0 Statistical Analysis Plan

25.1 Power/Sample Sizes

The sample sizes were chosen based on statistical, analytic, and theoretical considerations. For comparisons of the ABC vs. TAU controls on our outcome variables for Aim 1 (e.g., sun protection behaviors), our N should be able to detect effect sizes that correspond to small effects, Cohen's d = .2 or eta squares of 2%. The effect sizes are based on our pilot study examining patients' sunscreen use intentions following exposure to the ABC intervention (see preliminary studies section) and our studies examining group differences using motivational enhanced interventions to reduce tanning intentions and behaviors. Using power estimation procedures described in Cohen, the sample sizes should yield power of greater than 0.90 for the contrasts of interest. A second analysis that we will pursue will be moderated multiple linear regression or SEM models for Aim 2. Turrisi has special expertise in such analyses, where we test for effectiveness of the intervention as a function of a moderator variable at baseline (e.g., gender). With every moderator, our sample sizes for each group are reduced by approximately 50%. With our target N = 300 (at baseline), we will have sufficient samples to explore the potential of 2 moderators simultaneously and still have sample sizes that approximate n = 37 per group. Such Ns will also permit us to detect partial r2 sizes in the .04-.06 range and will have power of .70 or greater for the contrasts of interest.

25.2 General Analytic Issues

Missing Data. We will first test if the data are missing at random by forming a dummy variable that indicates the presence or absence of missing data on a variable. If the data are missing at random, the correlations with other variables should be trivial. We will use the EM method as implemented in SOLAS or FIML in Amos to impute missing data. If the data are not missing at random, then we will include dummy variables that explicitly model the nature of the missing data.

Outlier Analysis and Response Distributions. Throughout all of our statistical analyses, we will be sensitive to the potential influence of outlier cases and possible biases due to ill-behaved (i.e., nonnormal) distributions. Where necessary, we will use robust analytic techniques.

Measurement Error. Many of our variables will be subject to some measurement error that, in turn, can bias our parameter estimates. Where possible, we will pursue analytic strategies that permit us to incorporate an error theory into our parameter estimation methods (structural equation modeling). When multiple indicators of an underlying latent variable are present, the incorporation of an error theory is straightforward. When an error theory cannot be empirically operationalized, we will take care to interpret our data in light of the potential bias that may be present.

Multiple Tests and Evaluation of Study Aims. Some of our analyses will have multiple DVs. We will be sensitive to inflated experiment-wise error and control it with the multivariate F statistic based on Pillais criterion in our MANOVAs or with modified Bonferroni methods based on recommendations of Jaccard, Turrisi, and Kirk.

25.3 Aim 1: Evaluate efficacy of the ABC intervention

Dr. Turrisi (Co-I) will conduct all outcome analyses in order to avoid any bias. First a 2 (Group: ABC vs. Controls) x 3 (Time: baseline, 3 & 6 mo. follow-up) Mixed ANOVA will be conducted to test the intervention on a given outcome variable (e.g., use of sun protection). First, we expect to observe a main effect of Group with the highest reports of sun protection (and lowest reports of UV risk behaviors) occurring in our ABC condition. Second, we anticipate observing a Group x Time interaction with no differences between the groups at baseline but differences (lower risk in the ABC group) at each of the follow-ups. He will also assess the scientific and clinical significance of the effects utilizing the magnitude estimation approach described by Jaccard. Specifically, statistical significance refers to the case when the null hypothesis is rejected, whereas magnitude estimation approaches emphasize the size of the effect. To utilize magnitude

estimation approaches, the researcher must specify an a priori effect size that differentiates a trivial effect from a meaningful effect. If the effect size observed is less than the criterion for meaningfulness, then the result is deemed nonsignificant, even if the null is rejected. We will use Cohen's d statistic to assess clinical significance of the main effects and interactions. We will define an effect as clinically and statistically significant to the extent that the d is greater than or equal to .20.

25.4 Aim 2: Evaluate moderators and mediators

We will also undertake a set of analyses that identify individual differences in intervention efficacy to examine for whom the intervention is more or less effective. Where the moderator variable is qualitative (e.g., gender), it will be included as another factor into the Mixed ANOVA described earlier. For example, a 2 x 3 x 2 (group x time x patient gender) on sun protection may be used to evaluate gender of the patient as a moderator. First, we will explore whether our effect of Group, where the lowest reports of UV risk behaviors occurring in our ABC condition, differs by the gender of the patient (a group x gender interaction). Second, we will explore whether our Group x Time interaction differs by gender (e.g., a significant group x time x gender interaction). These analyses will be repeated for each of the qualitative moderator variables and evaluated for clinical significance. For quantitative (ordinal or interval) moderator variables (e.g., age), we will calculate product terms between the moderator and group and then analyze the data using moderated regression following the logic in Jaccard & Turrisi. For mediation, we will use the joint significance test, which Monte Carlo simulations have shown has the most power and lowest Type I error rates relative to other approaches. We will evaluate model fit using global fit indices (e.g.,CFI, RMSEA), and more focused indices that suggest specific areas of poor fit (modification indices). We will use bootstrapping where necessary to account for non-normal variable distributions. Using Amos 20.0, if both the a and b paths are significant at the .05 level there is evidence for mediation. The mediated effect is the product of a and b and provides an estimate of the strength of the mediated effect. When there is evidence of mediation, 95% confidence intervals using the bootstrap procedures in Amos can be calculated to provide a range of estimates for the mediated effect. If the confidence intervals do not contain zero there is evidence of statistically significant mediation. Figure 1.