RUTGERS
Cancer Institute
of New Jersey

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

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Internet Intervention for Sun Protection and Skin Self-Check Behaviors

Principal Investigator: Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903
Telephone: (732) 235-6759, FAX: (732) 235-6225
Email: mannesl@cinj.rutgers.edu

Subinvestigators:

Jerod L. Stapleton, PhD
Rutgers CINJ Co-Investigator

Janice Mehnert, MD
Rutgers CINJ Co-Investigator

Lee Ritterband, PhD
University of Virginia Co-Investigator

Paola Chamorro, MD
Rutgers RWJMS Co-Investigator

Rutgers Cancer Institute of New Jersey Operations Center
Office of Human Research Services
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903
Telephone: (732) 235-8675
FAX: (732) 235-7690

Rutgers Cancer Institute of New Jersey Biostatistical Center
Biometrics Division
Rutgers Cancer Institute of New Jersey
120 Albany Street, 5th Floor
New Brunswick, NJ 08903
Telephone: (732) 235-6791
FAX: (732) 235-7350

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NCI CCC
A Comprehensive Cancer Center Designated by the National Cancer Institute

LIST OF ABBREVIATIONS

CINJ, Cancer Institute of New Jersey

ITW, interactive tailored website

RCT, randomized controlled trial

RWJMS, Robert Wood Johnson Medical School

SSE, skin self-examination

SPF, sun protection factor

TCE, total cutaneous examination

UV, ultraviolet

NJSCR, New Jersey State Cancer Registry

1. Purpose/Specific Aims

The overall purpose of this project is to develop and test a web-based intervention to promote skin self-examination (SSE) and sun protection behaviors among individuals diagnosed with melanoma.

Individuals diagnosed with melanoma are at increased risk for second primary melanoma and disease recurrence, and it is recommended that they periodically receive a total cutaneous examination (TCE) from a physician, perform a regular SSE, and routinely engage in sun protection behaviors (NCCN, 2011). Although patients typically have a periodic TCE, our previous research suggests that more than two-thirds of them do not perform a thorough, full-body SSE on a sufficiently regular basis (Manne & Lessin, 2006). We have also found that many patients fail to engage in one or more sun protection behaviors (Coups & Ostroff, 2005). There is a critical need to develop effective interventions to promote SSE and sun protection behaviors among melanoma patients. In this research, we will develop and test an innovative web-based intervention to promote skin surveillance and sun protection behaviors among melanoma patients.

The project will be conducted in three phases. Phase 1 focuses on intervention development, usability testing, and refinement. In Phase 2, we will conduct a randomized controlled trial (RCT) comparing the efficacy of an interactive tailored website (ITW) versus Usual Care in promoting SSE and sun protection behaviors among melanoma patients who completed surgical treatment from 3–24 months previously. In Phase 3, we will conduct qualitative interviews in order to obtain feedback on the ITW.

Aim 1 (primary aim): To evaluate the impact of the ITW versus Usual Care on SSE and sun protection behaviors among individuals diagnosed with melanoma. Hypothesis. Individuals assigned to the ITW will be more likely to engage in SSE and sun protection behaviors than those assigned to Usual Care.

Aim 2 (secondary aim): To examine mediators of the impact of the intervention. Hypothesis. The effects of the intervention on SSE and sun protection behaviors will be mediated by melanoma knowledge, self-efficacy for SSE and sun protection behaviors, perceived benefits of SSE and sun protection behaviors, perceived barriers to SSE and sun protection behaviors, and perceived controllability of melanoma.

Aim 3 (exploratory aim): To examine moderators of the impact of the intervention. Research Question. To evaluate whether ITW effects are moderated by the following factors: time since diagnosis, disease stage, age, sex, income, education, Internet experience, distress about melanoma, worry about recurrence, and evaluation and usage of the ITW.

2. Background and Significance

2.1. Melanoma Incidence, Recurrence, Second Primaries, and Survival

Currently, more than 920,000 individuals in the U.S. are living with a personal history of melanoma (Howlader et al., 2013). Unlike the vast majority of cancers, the incidence of melanoma has increased over the past several decades (e.g., 2.8% increase per year since 1992), which is only partly attributable to improvements in disease detection and reporting (Linos et al., 2009). In 1960, the lifetime risk of melanoma in the U.S. was 1 in 800 (Lens & Dawes, 2004) and it is currently 1 in 37 for men and 1 in 55 for women (American Cancer Society, 2011). Melanoma incidence rates have increased most notably among men over the age of 65 years (Erickson & Driscoll, 2010). The incidence of melanoma is highest among non-Hispanic white individuals and those with a higher socioeconomic status (Little & Eide, 2012; Russak & Rigel, 2012; Singh et al., 2011).

Individuals diagnosed with melanoma remain at risk for disease recurrence, second primary melanomas, and non-melanoma skin cancer. Among individuals diagnosed with localized or regional stage disease, estimated rates of recurrence for thin melanomas vary from 3–24%, with recurrence rates for thicker melanomas or tumors with lymph node involvement being substantially higher (e.g., 51% among those with stage III disease) (Francken et al., 2005; Francken et al., 2008; Leiter et al., 2012). An estimated 4–11% of melanoma patients will be diagnosed with one or more second primary melanomas (Bradford et al., 2010; Freedman et al., 2006; Ferrone et al., 2005). Recurrent or new primary melanomas occur most commonly during the first five years after diagnosis, but can also arise many years later (Christianson & Anderson, 2003; NCCN, 2011). Recurrent melanoma is highly amenable to early detection by patients or via clinical examination. Most melanoma patients receive a periodic TCE from a physician (Barzilia et al., 2004; Coups et al., 2010; Federman et al., 2004; Federman et al., 2006), but do not engage in regular SSE (Manne & Lessin, 2006; Loescher et al., 2006; Mujumdar et al., 2009). More than half of all recurrences and new primary melanomas are detected by patients themselves (Francken et al., 2007; Moore Dalal et al., 2008), which provides optimism that promoting patients' engagement in SSE will further enhance early detection of recurrences and new primaries. Detection and treatment of recurrent disease and new primary melanomas at earlier stages leads to improved survival (Leiter et al., 2010).

2.2. Skin Surveillance and Sun Protection Behaviors among Individuals with Melanoma

Follow-up guidelines for melanoma recommend that patients receive a periodic TCE from a physician and conduct a monthly thorough SSE (NCCN, 2011), which entails a deliberate, systematic inspection of all areas of the body, using a mirror or the assistance of another person to examine hard to view areas (Weinstock et al., 2004). It is also recommended that patients engage in a variety of sun protection behaviors that limit their exposure to ultraviolet (UV) light (NCCN, 2011), such as wearing clothing that covers or shades exposed skin, using sunscreen with a sun protection factor (SPF) of 30 or higher, and seeking shade when outside on a sunny day.

Although most patients receive a periodic physician TCE (Barzilia et al., 2004; Coups et al., 2010; Federman et al., 2004; Federman et al., 2006), the majority do not perform a regular, thorough SSE and do not sufficiently engage in recommend sun protection behaviors (Manne & Lessin, 2006; Loescher et al., 2006; Mujumdar et al., 2009). Only 12–33% of melanoma patients report performing a thorough SSE at least every two months (Bowen et al., 2012; Loescher et al., 2006; Mujumdar et al., 2009). Manne and Lessin (2006) found that 39% of melanoma patients reported conducting a SSE every month, but only 14% of them conducted a thorough examination. In a recent needs assessment survey, we found that 72% of melanoma patients reported doing a SSE in the past 2 months, but only 12% performed a thorough examination (defined as examining all body parts at least once). Performing a thorough SSE is important because it has been shown to lead to the detection of thinner, early stage melanomas (Pollitt et al., 2009) and is associated with longer disease survival (Moore Dalal et al., 2008). In one study, 23% of melanoma patients met criteria for engaging in regular sun protection behaviors (Mujumdar et al., 2009). Coups and Ostroff (2005) found that 10% of melanoma patients reported always engaging in each of four sun protection behaviors (wearing a hat, wearing a long-sleeved shirt, using sunscreen, and staying in the shade). These studies demonstrate the need to develop and disseminate effective interventions to promote skin surveillance and sun protection behaviors among melanoma patients.

2.3. Web-Based Health Behavior Interventions

There is considerable evidence that the Internet can be used to deliver tailored (i.e., personalized) interventions that promote changes in various health behaviors across diverse groups, including medical populations (Bennett & Glasgow, 2009; Portnoy et al., 2007; Webb & Sheeran, 2006). Compared to other delivery channels (such as in person, telephone, print, or mass media), the Internet provides an ideal channel for delivering tailored health behavior interventions, as it has the capability to manage the key elements needed for tailored communications: collecting each individual's unique attitudes, beliefs, and behaviors; storing a database of tailored messages; storing and applying a set of algorithms to guide the tailoring; and delivering the tailored information to each individual (Kreuter et al., 2000). Additional advantages of delivering health behavior interventions via the Internet as opposed to other channels include: high convenience for patients; ability to use highly interactive content and engaging multi-media materials; ease of updating intervention content; cost-effectiveness, particularly with regard to the marginal costs of providing the intervention to additional patients; high treatment fidelity; ability to reach patients across geographical locations; and high potential for widespread adoption and dissemination of efficacious interventions (Bennett & Glasgow, 2009).

2.4. Internet Penetration and Health Information Seeking

Currently, 85% of adults in the U.S. report using the Internet (Pew Internet & American Life Project), as do 88% of adults in New Jersey (Internet World Stats). While Internet use is almost ubiquitous among young adults (98% of 18–29 year olds), an increasing number of older adults are also using the Internet (83% of 50–64 year olds and 56% of those ≥ 65 years) (Pew Internet & American Life Project). More than

80% of Internet users have high-speed broadband connection at home. With the aging of the baby boomer generation, it is expected that older adults will continue to be one of the fastest growing groups of Internet users.

The Internet is an increasing source of health information for healthy adults as well as patients with a variety of medical conditions. Among Internet users, 83% report having looked online for health information (Pew Internet & American Life Project). More than two-thirds of individuals diagnosed with cancer report looking for cancer information and the most common source of information is the Internet (Mayer et al., 2007). Relatively little research has examined Internet use among melanoma patients. A study conducted from 2001–2003 of 1,613 melanoma patients treated at a single institution found that 39% had researched their disease on the Internet, 94% of whom found the Internet to provide useful information (Sabel et al., 2005). Rates of Internet usage have increased considerably since 2003, particularly among older adults. A recent study of 55 melanoma patients found that 84% used the Internet at least on a weekly basis (Marble et al., 2010). Almost three-quarters (73%) preferred to receive melanoma health education via computer-based as opposed to other types of technology (e.g., DVD, MP3, videotape). In our own recent survey of 176 melanoma patients at Rutgers Cancer Institute of New Jersey (Rutgers CINJ), 84% reported using the Internet. Among the Internet users, 78% reported ever looking for information about melanoma on the Internet and 93% had ever looked for information about any health topic. In sum, the increasing penetration of the Internet, particularly among older adults, and the fact that many melanoma patients have Internet access and seek information online, suggest that a web-based intervention is a viable approach for promoting health behavior change among these patients.

3. Research Design and Methods

In this project, we will develop and test a web-based intervention to promote SSE and sun protection behaviors among melanoma patients. The project will be conducted in two phases: Phase 1 – intervention development, usability testing, and refinement; Phase 2 – RCT of the efficacy of an ITW versus Usual Care in promoting SSE and sun protection behaviors. Phase 3 – obtain feedback on the acceptability and usability of the ITW through phone interviews with study participants who have completed the intervention.

3.1. Phase 1: Intervention Development, Usability Testing, and Refinement

During this phase, we will develop, test, and finalize the ITW to be used in the RCT to be conducted in Phase 2. Our overall approach to the design, content, and features of the website will be guided by best practices in health communications and website design (Centers for Disease Control and Prevention, 2009; National Institutes of Health, 2008; U.S. Department of Health and Human Services, 2006) and by Ritterband and colleagues' (2009) Internet Intervention Model, which offers guidelines regarding website characteristics and features that improve users' experience and facilitate behavior change. The Internet intervention will utilize an intuitive and engaging interface that will provide the look, feel, and navigation similar to that of an application or "app" that one might use on a tablet (e.g., iPad) or smartphone, rather than a traditional website.

The ITW will utilize a computerized tailoring algorithm to provide specific messages and content to each participant based on his/her beliefs and behaviors. Sections of the website include: Introduction – purpose, outline of content, features, instructions, and frequently asked questions, overview of melanoma information and risk factors etc.; Getting Ready to Do a Skin Self Check – includes sections on when and how to do a thorough SSE, asking for assistance, what to look for, overcoming barriers, gaining confidence, what to do if you see something suspicious; Monthly Skin Self-Check – guides the user through conducting a SSE and recording moles on a body mole map; Practice Sun-Safe Behaviors – overview of sun-safe behaviors, risks of tanning, overcoming barriers, sun-safety during outdoor activities, gaining confidence;

Sun-Safe Action Plan – allows the user to create and review an action plan for engaging in sun-safe behaviors and avoiding risky UV behaviors (e.g., sunbathing, indoor tanning).

Up to 30 melanoma patients will provide input and feedback on an iterative basis throughout the development and usability testing process. After providing informed consent, participants will complete a brief survey (in person at Rutgers CINJ/RWJMS, via telephone, secure website) described in Section 4.1. In order to minimize participant burden, we will use multiple, flexible methods for obtaining input and feedback from patients (e.g., telephone, in-person interviews, and focus groups). Draft website content materials will be presented to participants in a semi-structured format and their feedback will be elicited. Initially, design and learning activities for the ITW will be evaluated by participants using paper prototypes. Subsequent prototypes will be web-based. Participants will be reimbursed for their valued time and participation with gift cards (at a rate of $25 per hour up to a maximum of 5 hours).

We expect that Phase 1 of the project will yield a set of understandable, acceptable, and appealing web features that are customized to the needs, capabilities, and preferences of melanoma patients.

3.2. Phase 2: RCT of the Efficacy of the Intervention

Consented patients will be provided with a link to a secure, password-protected website to complete a baseline survey. After completing the survey online, patients will automatically be randomized to the ITW or Usual Care condition. Patients will be stratified according to disease stage and time since diagnosis (3–<14 months vs. 14–24 months) and then, within strata, block randomized using blocks of four or six patients. The study biostatistician, Dr. Ohman-Strickland, was responsible for creating the randomization schedule and overseeing the randomization process, following standard operating procedures of the Rutgers CINJ Biometrics Shared Resource. After 8 weeks, study participants will be prompted (via email, as well as by telephone, text message [with their permission] and mail, as necessary) to complete an online survey (follow-up 1), followed by additional online surveys 24 weeks (follow-up 2) and 48 weeks post-baseline (follow-up 3). The estimated time to complete each online survey varies from 40 minutes for the baseline to 20 minutes for the follow-up 3 survey.

Participants randomized to the ITW condition will be provided with a link to the intervention website, which they will be free to access any time throughout their study participation. To promote usage of the website, the modules of the ITW will be available to participants on a staggered basis using event- and time-based triggers. Specifically, an initial set of modules will be available to participants immediately. Once those modules have been completed (which we anticipate will take participants no longer than 2 weeks), a final module will be introduced after one week. This approach of introducing website intervention content in a staggered manner has been shown to facilitate greater use of, and exposure to, health promotion websites (Brouwer et al., 2011). We anticipate that each module will take from 30–40 minutes to complete, although participants will be encouraged to review each module regularly. Key elements of the ITW will be available (for example, as fully formatted .pdf documents) for participants to download and print.

Participants randomized to the Usual Care condition will receive no additional intervention aside from their usual non-study care. At the end of their participation in the study, participants in the Usual Care group will be offered the ITW intervention.

All participants will receive a $25 gift card for completing each survey.

3.3 Phase 3: Qualitative Interviews:

Up to 50 study participants who have completed at least the How to Use Tutorial of the ITW will be randomly selected to participate in a qualitative interview lasting up to 45 minutes (for which they will receive a $25 gift card). The interviews will consist of a semi-structured discussion to explore the participants' thoughts and experiences with regard to the ITW.

All of the telephone interviews will be digitally recorded and subsequently transcribed, which will allow them to be reviewed by the full research team. In line with our prior research studies, the telephone interviews will be transcribed under a fee-for-service agreement by trained personnel at the University of Pittsburgh Qualitative Data Analysis Program (QDAP). The interview recordings will be sent to the QDAP using a secure Internet file transfer protocol (FTP). After the transcription and translation has been completed for each interview, the QDAP will delete the respective recording. If any names or other potentially identifying information are mentioned during the interview, the relevant information will be removed from the audio recording prior to transcription. The research team will meet regularly to discuss the interview transcripts and to refine survey items, as necessary. We have used a similar approach in several prior skin cancer-related studies, and the qualitative interviews provided a rich source of relevant information that directly informed subsequent studies that have been conducted.

3.4. Duration of Study

Phase 1 of the project will last approximately 18 months. In Phase 2 of the project, participants will take part in the study for 12 months. Phase 3 of the project will last for approximately 6 months.

3.5. Study Sites

Recruitment of participants and human subjects interactions will take place at Rutgers, The State University of New Jersey,Saint Barnabas Medical Center (see IRB approval letter for Saint Barnabas Medical Center), and the New Jersey State Cancer Registry. The online survey and the Internet intervention will be developed, hosted, and maintained at the University of Virginia (site PI: Lee Ritterband, PhD). The role of the research team at the University of Virginia includes providing input, feedback, and advice concerning web program creation and implementation, and study design and recruitment procedures, as well as full survey and web intervention development, hosting, and maintenance. Specifically, the team at the University of Virginia will work to create the intervention and help to identify and determine the structural and functional features of the web program. In Phase 1 of the project, Dr. Ritterband and his team will consult with the study team at Rutgers University regarding intervention design and content, create functional documentation for the intervention, provide design services for the intervention website, implement the study team's content into the technology framework, complete programming of the client side of the intervention, and integrate and optimize the backend database needed to employ the randomized controlled trial, which will be implemented in Phase 2 of the project. Continued support and maintenance of the intervention will be provided throughout Phase 2. At the end of the randomized controlled trial, the team at the University of Virginia will retrieve and clean all of the data captured by the Internet intervention for analysis. The research team at the University of Virginia will have access to protected health information of recruited patients. Specifically, the eligibility criteria require that patients have a personal history of melanoma; additionally, the University of Virginia research team will know the name and email address of recruited participants, as this information is needed to send out automated emails as part of the study protocol.

3.6. Sample Size

Up to 30 individuals will take part in Phase 1 of the project. For Phase 2 of the project, we will recruit 420 participants. For Phase 3 of the project, we will recruit up to 50 participants. For the Phase 2 RCT study,

we conducted power calculations for the primary and secondary aims. (We did not conduct power calculations for Aim 3 because it is an exploratory aim.) For the primary aim (intervention efficacy), there are two primary outcomes: engagement in thorough SSE (binary outcome) and sun protection behavior index (continuous score) at 24 weeks post-baseline. At baseline, we anticipate that 9% of participants will be adherent to thorough SSE. Based on our own and others' prior research (Glanz et al., 2010; Janda et al., 2011; Manne et al., 2010; Weinstock et al., 2007), we anticipate that the rate of adherence to thorough SSE at 24 weeks post-baseline will be ≥35% in the ITW group and this will be at least 15 percentage points higher than the adherence rate in the Usual Care group. An increase in SSE of this magnitude would be considered a successful rate. We assume proportions of individuals completing SSEs are compared between treatments using a z-test. Allowing for 10% dropout at 24 weeks (a rate comparable to that experienced in our prior research; Manne et al., 2010) and an adherence rate to thorough SSE of up to 20% in the Usual Care group at 24 weeks post-baseline (which is at the upper end of what might be expected), 153 individuals would need to be recruited in each group to obtain 80% power. Power calculations for the sun protection behaviors outcome are based on results of prior tailored interventions, including our own (Glanz et al., 2010; Manne et al., 2010). In our prior RCT, sun protection scores at baseline were 2.8 for both groups and increased to 3.2 and 3.4 for the generic and tailored interventions, respectively. Given that the Usual Care control group in the current RCT is not an active control (the generic intervention in the prior study was an active control), we assume that the sun protection scores in that group would increase to a maximum of 3.0. Standard deviations were, on average, 0.66 at baseline and 0.76 at follow-up. We assume a correlation between baseline and follow-up measures of 0.60. Under these assumptions, recruiting 153 individuals to each group would provide more than 80% power to detect differences in changes in sun protection scores from baseline to 24 weeks post-baseline. For the secondary aim (intervention mediators), we utilized sample size tables for mediated effects based on simulation studies that model the two pieces of the mediating path (from intervention group assignment to mediating variable and from mediating variable to outcome) (Fritz & Mackinnon, 2007). Based on the results of relevant prior research, we conservatively assume that one of the two paths will have a regression coefficient of at least .14 (a small effect, according to Cohen's [1998] criteria) and the other will have a regression coefficient of at least .26 (a small-to-moderate effect). Under those assumptions, and allowing for 10% dropout at 24 weeks, recruiting 210 individuals to each group would provide 80% power to detect mediational effects (Fritz & Mackinnon, 2007). Overall, based on a consideration of the aforementioned factors, we will recruit 210 individuals to each of the ITW and Usual Care groups, for a total sample size of N = 420, which will provide at least 80% power for the primary and secondary aims. We anticipate that at least 378 of the 420 patients (i.e., 90%) will complete the 24 weeks post-baseline assessment and 357 (85%) will complete the 48 weeks post-baseline assessment.

3.7. Inclusion Criteria

Phase 1

1. Diagnosis of primary pathologic stage 0–III cutaneous malignant melanoma;
2. From 3–36 months post-surgical treatment;
3. ≥ 18 years old;
4. Access to the Internet;
5. Able to speak and read English;
6. Able to provide informed consent.

Phase 2

1. Diagnosis of primary pathologic stage 0–III cutaneous malignant melanoma;
2. From 3–24 months post-surgical treatment;
3. Not adherent to thorough SSE (i.e., did not check every area of the body at least once during the past 2 months) (Weinstock et al., 2004) or not adherent to sun protection recommendations (i.e., mean score < 4 [which corresponds to "often"] on a 5-point scale [from 1 = "never" to 5 = "always"] that assesses the frequency of engaging in four sun protection behaviors);
4. ≥ 18 years old;
5. Access to a computer connected to the Internet;
6. Able to speak and read English;
7. Able to provide informed consent.

Phase 3: Qualitative Interviews

1. Diagnosis of primary pathologic stage 0-III cutaneous malignant melanoma
2. Completed at least the How to Use Tutorial of the ITW
3. ≥ 18 years old
4. Able to speak and read English;
5. Able to provide informed consent.

3.8. Participant Recruitment and Consent Procedures

At Rutgers CINJ/RWJMS, potentially eligible individuals will be identified through electronic chart review (by research team members), from registrars at the tumor registry, clinical records (such as pharmacy and billing), scheduling, and from treating physicians/nurses/social workers. Potentially eligible individuals will also be identified by referral from Saint Barnabas Medical Center (see IRB approval letter from Saint Barnabas). Potentially eligible individuals at Saint Barnabas Medical Center will be identified by a member of their research team, who will send them a study information letter and medical release form (as well as a pre-paid return envelope to return the completed medical release form). For individuals at Saint Barnabas Medical Center who are mailed a study information letter (and do not call to decline further contact), a member of their study team will attempt to reach the individual by telephone to confirm they received the letter and answer any questions they may have. Another copy of the information letter along with the medical release form (and a pre-paid envelope) will be mailed a second time to individuals who have not responded. When the research staff at Saint Barnabas Medical Center receive a completed medical release form from a potentially eligible individual, the form will be sent via fax or secure email to the Rutgers research team, who will handle all subsequent study-related interactions with the individual (including determination of eligibility and consenting of eligible/interested individuals). Potentially eligible individuals will also be identified through electronic chart review at the NJSCR. Potentially eligible individuals at the NJSCR will be identified by a research NJSCR team member who will contact the physician of record for each patient. An information letter will be mailed to the physician describing the study and that the NJSCR team member will be contacting their patient for participation. The physician is requested to notify the NJSCR team member within two weeks if there is any reason that the individual should not be contacted, such as death, mental illness, or severe illness. The NJSCR team member will then mail a recruitment packet to individuals who have been identified, which includes a cover letter, study information sheet, NJSCR brochure, consent form, and postage-paid return envelope (see attachments). The NJSCR staff will conduct follow-up calls 1 week after recruitment packet mailing to confirm receipt of the packet and to answer questions about the study. As necessary, a second copy of the recruitment packet will be sent. Individuals will be called 1-2 times per week up to 8 attempts before being considered a passive refuser. An individual could participate in the study by providing verbal consent at the time of phone contact or by returning a signed consent form. If verbal consent is provided, NJSCR staff will screen the individual

using the Rutgers CINJ eligibility screening questionnaire previously discussed. Team members at NJSCR will provide contact information of consented participants as well as de-identified data including, refuser ID, full surgery date (mm/dd/yyyy), melanoma stage, age, gender and refusal reason for non-respondents securely through email to the Rutgers CINJ research team. After this step, all contact will be made to individuals by the research team at Rutgers CINJ. Team members at NJSCR will also develop and maintain a database to track patient study status, and physician and patient contact. Rutgers CINJ staff will be sending a list of individuals through encrypted and secure email who have already been recruited as well as any new lists received in order to eliminate the possibility of double-approaching or consenting. Participants may also be recruited via self-referral (e.g., from individuals who learn about the study at www.clinicaltrials.gov). Regardless of the method with which potentially eligible individuals are identified, they will be emailed/mailed an introductory letter and consent form (or receive the documents in person if they are approached in person by the Rutgers research staff during a clinic visit). The letter includes a telephone number to call if the individual has any questions or does not wish to be contacted further regarding the study. For individuals who are sent a study invitation letter (and do not call to decline further contact), a member of the study team will attempt to reach the individual by telephone to ascertain their interest and eligibility. As necessary, a second copy of the introductory letter and consent form will be sent, and a member of the research team will again try to reach the person via telephone. For eligible and interested participants, a research team member will complete the informed consent process and answer any questions that arise. In Phase 2 of the project, participants will provide verbal consent during a telephone call. We have successfully used this approach in similar prior minimal risk studies. Thus, we are requesting that the IRB provide a waiver of written/signed consent for participants who provide verbal consent. Our procedure for obtaining verbal consent and documentation of that consent has been developed based on materials from the James Madison University Office of Sponsored Programs (http://www.jmu.edu/sponsprog/allforms.html) and the Office of Human Research Protection Program at UCLA (http://ohrpp.research.ucla.edu/pages/biomedical-informed-consent). Specifically, following the "Phase 2 Consent Guide and Documentation" document, the person obtaining consent will go through each section of the consent form with the participant over the telephone. Participants will be encouraged to ask any questions regarding the consent form and the study. The person obtaining consent will check off to indicate that each section of the consent form was discussed with the participant. Additionally, the person obtaining consent will sign and date the document to attest that the consent was orally presented to the participant and that the participant provided oral assurance of his/her willingness to participate in the research.

In Phase 3, we will use the same recruitment methods and study procedures as for Phase 2. Participants will provide verbal consent during a telephone call. We will be using a "Phase 3 Consent Guide and Documentation" document to obtain consent for each of the participants who take part in the study as described above.

4. Study Variables

4.1. Phase 1 Measures

After providing informed consent, participants will complete a brief survey, including demographic information and questions about their experience doing skin self-examinations and engaging in sun protection behaviors. Draft website content materials will be presented to participants in a semi-structured format and their feedback will be elicited using open- and closed-ended questions adapted from measures developed by Ritterband and colleagues (2008).

4.2. Phase 2 Measures

An overview of the study measures is shown in Table 1. We will utilize concise, psychometrically valid measures used in our prior research or that of other research groups.

Table 1. Measures Assessed at Each Time Point

	Baseline	FU 1	FU 2	FU 3
Background Variables and Correlates				
Clinical characteristics	✓			
Internet experience	✓			
Sociodemographic factors	✓			
Melanoma risk factors	✓			
Receipt of TCE	✓	✓	✓	✓
Receipt of biopsy, skin cancer diagnosis		✓	✓	✓
Distress about melanoma	✓	✓	✓	✓
Worry about melanoma recurrence	✓	✓	✓	✓
Perceived controllability of melanoma	✓	✓	✓	✓
Melanoma knowledge	✓	✓	✓	
Perceived severity of melanoma	✓	✓	✓	
Perceived risk of melanoma recurrence	✓	✓	✓	
SSE self-efficacy	✓	✓	✓	
SSE benefits and barriers	✓	✓	✓	
SSE norms	✓			
Physician SSE recommendations	✓			✓
Sun protection self-efficacy	✓	✓	✓	
Sun protection benefits and barriers	✓	✓	✓	
Sun protection norms	✓			
Automaticity of sun protection behaviors		✓	✓	✓
Physician sun protection recommendations	✓			✓
Outcome Variables				
SSE	✓	✓	✓	✓
Sun protection behaviors	✓	✓	✓	✓
Healthcare provider visits		✓	✓	✓
Intervention Evaluation and Usage				
Impact and effectiveness of the intervention		✓		
Evaluation and utility of the intervention		✓		
Website usage		✓	✓	✓

Note. TCE = total cutaneous examination; SSE = skin self-examination; FU = follow-up; FU 1 = 8 weeks post-baseline; FU 2 = 24 weeks post-baseline; FU 3 = 48 weeks post-baseline.

4.2.1. Background Variables and Correlates. Clinical characteristics that will be abstracted from the medical record include: diagnosis, time since diagnosis, disease stage, tumor thickness, tumor ulceration, mitotic index, tumor anatomic site, histologic subtype, sentinel node status, and treatment received. Patients' Internet experience will be assessed based on how often they use the Internet and their level of comfort using the Internet. Sociodemographic factors that will be assessed include the patient's age (obtained from the medical record), sex (obtained from the medical record), race/ethnicity, income, level of education, and marital/partnered status. A number of melanoma risk factors will be assessed, including eye color, natural hair color, skin color, skin reactivity to the sun, presence of freckling, number of moles, history of sunburns, indoor UV tanning, and family history of melanoma (Glanz et al., 2008; Lazovich et al., 2008). Patients will also be asked to indicate when they last had a TCE performed by a physician and the reason for the examination (e.g., routine check-up, because the patient noticed something suspicious on his/her skin). In the 8, 24, and 48 week surveys, participants will be asked whether they had all or part of a mole or growth removed in the intervening time period and whether they were diagnosed with a new or recurrent skin cancer. Distress about melanoma, worry about melanoma recurrence, and perceived controllability of melanoma will be measured using standard items (Manne & Lessin, 2006; Moss-Morris et al., 2002; Vickberg, 2003).

Melanoma knowledge will be measured using a set of true-false items that assess knowledge about the disease and its risk factors (Manne & Lessin, 2006), as well as items regarding knowledge of the ABCDEF guide to melanoma (Coups et al., 2016; Gillen et al., 2011). Established scales will be used to assess perceived severity and risk of melanoma, SSE self-efficacy (i.e., patient's confidence in being able to perform SSE), SSE benefits and barriers, and SSE norms (Coups et al., 2011; Manne & Lessin, 2006; Mullens et al., 2004; Robinson et al., 2008; Weinstein et al., 2007). With regard to physician SSE recommendations, a series of yes/no questions will ask whether a doctor suggested the participant perform SSE, had shown the participant how to do a SSE, and had shown the patient what a melanoma lesion looks like. Sun protection self-efficacy (i.e., confidence in being able to engage in various sun protection behaviors), sun protection benefits and barriers, and sun protection norms will be measured using established measures (Azzarello & Jacobsen, 2007; Bränström et al., 2010; Manne & Lessin, 2006). Automaticity of sun protection behaviors will be assessed using the 4-item Self-Report Behavioral Automaticity Index (Gardner et al., 2012). Physician sun protection recommendations will be assessed using yes/no questions.

4.2.2. Outcome Variables. Participants will indicate whether they checked any part of their body for early signs of skin cancer in the last 12 months (for the baseline survey), 2 months (for the 8 week survey), 4 months (for the 24 week survey), or 6 months (for the 48 week survey). Individuals reporting checking their skin one or more times will indicate the number of times they checked their skin during the corresponding time frame, the last time they checked their body, and the body parts that they thoroughly examined (i.e., systematically and deliberately examined the skin) during their most recent check. This measurement approach has been shown to have excellent reliability and validity in prior research (Weinstock et al., 1999; Weinstock et al., 2004). For analytic purposes, the primary SSE outcome will be performance of thorough SSE, defined as thoroughly examining each area of the body during the most recent skin self-check in the past 2 months (Weinstock et al., 2004). We focus on thorough SSE as the primary SSE outcome, as greater SSE thoroughness is associated with detection of thinner tumors (Pollitt et al., 2009) and improved prognosis (Moore Dalal et al., 2008). The secondary SSE outcomes we will examine include thoroughly examining each area of the body during the most recent skin self-check in the past 1 month, the number of SSEs performed (regardless of their thoroughness) and the number of body areas examined. Participants will also indicate whether, the last time they did SSE, they used a mirror, had someone else help them, or used a body mole map. Participants will rate how often they engage in each of four sun protection behaviors when outside on a sunny day: wearing sunscreen with an SPF $\geq$ 30, wearing a long-sleeved shirt, wearing a wide-brimmed hat, and staying in the shade (Glanz et al., 2008). The primary sun protection outcome will be the mean rating of the four items (sun protection behavior index). The frequency of engaging in each individual sun protection behavior will be examined as secondary outcomes. Additionally, as secondary outcomes, participants will rate how often they use sunglasses, wear long pants, and spend time in the sun in order to get a tan (Glanz et al., 2008), and the number of sunburns they had. As an exploratory outcome, at the 48 week survey, participants will indicate whether, and if so how many times, they indoor tanned in the past year. Participants will also be asked to report any visits to healthcare providers related to skin surveillance, which will be examined as an exploratory outcome. They will also be asked to report any biopsies conducted and diagnosis of new or recurrent skin cancers. Data from the medical record will be abstracted to identify patients' visits to their Rutgers CINJ, Rutgers RWJMS, or Saint Barnabas Medical Center healthcare provider.

4.2.3. Intervention Evaluation and Usage. A set of measures developed by Ritterband and colleagues (2008) will be used to evaluate the intervention and will include all aspects of the ITW. These include the Perceived Internet Impact and Effectiveness Questionnaire, the Internet Evaluation and Perceived Utility Questionnaire, and the Internet Intervention Adherence Questionnaire. Participants will also complete a series of questions that will ask them whether they viewed or shared the website information with anyone else (e.g., family members or friends). Objective information about each participant's use of the ITW be collected automatically and unobtrusively on the study web server. Website usage factors that will be

examined include the number of visits to the website, the number of monthly skin self-checks completed, the number of updates to the sun-safe action plan, and starting/completing the remaining sections of the website (Introduction; Getting Ready to Do a Skin Self-Check; Practice Sun-Safe Behaviors) (Danaher et al., 2008; Danaher & Seeley, 2009).

4.3. Phase 3 Semi-Structured Interview

We will follow a semi-structured interview guide to conduct telephone interviews with participants who completed at least the How to Use tutorial of the ITW (see "Phase 3 Interview Guide"). In the interviews, participants will be asked to provide feedback on their use of the ITW and will also provide input on potential future adaptations or applications of the ITW. Each interview will last up to 45 minutes.

4.4. Risk of Harm

This study involves research that presents very little risk. There are no physical risks or side effects associated with the study. Potential emotional risks of study participation include possible discomfort or distress associated with answering questions about melanoma, including the potential for disease recurrence. Based on our prior experience conducting research with cancer patients, the likelihood that participants in this study will experience such discomfort or distress is low.

It is possible that a participant may feel upset or distress if, while conducting a SSE, he/she identifies a suspicious lesion. During the course of the study, patients will remain under the clinical care of their physician at Rutgers CINJ, the Department of Dermatology at Rutgers RWJMS,Saint Barnabas Medical Center, and their respective physician from the NJSCR. As part of the informed consent process, patients will be encouraged to seek medical care with their physician if at any time they identify a suspicious lesion.

As with all research that collects protected health information, there is a risk that participants' confidentiality could be compromised during the study.

4.5. Protections Against Risks

Participants will be encouraged to contact the research team if they experience emotional discomfort or distress at any time during the study. All research staff will receive training to appropriately identify and handle instances when a patient would benefit from a referral (e.g., to a clinical social worker at Rutgers CINJ or Rutgers RWJMS) for follow-up of emotional discomfort or distress. If at any time during the study, a patient indicates concern about a suspicious lesion to a member of the research team, he/she will be advised to contact his/her treating physician to receive appropriate medical care.

In order to preserve privacy and protect the confidentiality of participants, a series of security procedures will be undertaken. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. All study personnel receive training and certification in human subjects protection and HIPAA regulations. Each study participant will be given a unique numeric identifier upon study entry. Names and other protected health information will not be stored in the same database as survey and medical information. All computers used for research purposes adhere to the institution's requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications will be encrypted. This includes transfer of electronic data between Rutgers University and the University of Virginia. All hard copy study-related materials and data will be stored in locked file cabinets in secure locations. The research teams at Rutgers University and the University of Virginia have never previously experienced a breach of participant confidentiality in a research study.

4.6. Potential for Benefit

This research has potential benefits for the study participants as well as for future patients diagnosed with melanoma. Participants who are eligible to take part in the study have a personal history of melanoma and do not currently engage in thorough SSE or sun protection behaviors. This study utilizes an Internet-based approach to promote patients' engagement in thorough SSE and sun protection behaviors. Thus, it is possible that for some study participants, a recurrence of their melanoma or new primary melanoma (or non-melanoma skin cancer) might be identified at an earlier time than would otherwise have been the case. If the intervention is found to promote skin surveillance and sun protection behaviors among melanoma patients, it has the potential to be utilized with broader populations of melanoma patients. Currently, more than 920,000 individuals in the U.S. are living with a personal history of melanoma. There is a critical need to develop effective interventions to promote thorough SSE and sun protection behaviors among melanoma patients. The current research addresses this important issue. By developing and testing an Internet-based intervention, this project has the potential to identify an efficacious, cost-effective, and disseminable approach for promoting skin surveillance and sun protection behaviors among melanoma patients across the country.

5. Data Handling and Statistical Analysis

5.1. Primary Aim

Aim 1. To evaluate the impact of the ITW versus Usual Care on SSE and sun protection behaviors among individuals diagnosed with melanoma. Hypothesis. Individuals assigned to the ITW will be more likely to engage in SSE and sun protection behaviors than those assigned to Usual Care.

Using intent-to-treat analyses, we will compare engagement in thorough SSE and the sun protection behavior index for individuals in the ITW versus Usual Care, with the outcomes at 24 weeks as the primary focus. To handle missing data due to participant dropout, weighted generalized estimating equations (Little & Rubin, 2002; Preisser et al., 2002; Robins et al., 1995), with a logit link for SSE (a binary variable) and an identity link for the sun protection behavior index, will be used to estimate the treatment effect with weights proportional to the inverse of the estimated probability of dropout. Score tests and estimates of regression coefficients for the treatment indicator variable will assess the effect of the intervention. Sensitivity analyses will examine the effect of intervention at follow-up controlling for any demographic information that differs significantly by intervention group at baseline. These analyses are appropriate under the assumption that dropout is missing at random (MAR). Secondary analyses will use multiple imputation to examine the estimated treatment effect under different scenarios assuming the dropout is missing not at random (MNAR). In particular, for the sun protection behavior index, the mean for treated dropouts will be assumed equal to the estimated mean for Usual Care non-dropouts plus a sensitivity parameter, set at values of 25%, 50%, 75% and 100% of the estimated treatment effect (representing scenarios ranging from dropouts experiencing almost all to none of the estimated treatment effect). These analyses provide a picture of potential bias due to informative dropout (Little, 1994; Minini & Chavance, 2004a, 2004b; National Research Council, 2010). Additional multilevel models (Raudenbush, 2003) will examine the effect of the intervention on changes in thorough SSE and sun protection behaviors over time, comparing changes across 8, 24 and 48 weeks. Specifically, generalized estimating equations will be used for estimation and testing (Liang & Zeger, 1986; Ukoumunne & Thompson, 2001). Additional analyses will focus on the effect of the intervention on the number of SSEs performed, the number of body areas examined, and the individual sun protection behaviors (wearing sunscreen with an SPF $\geq$ 30, wearing a long-sleeved shirt, wearing a wide-brimmed hat, and staying in the shade). Analyses will also focus on the effect of the intervention on use of sunglasses, wearing long pants, spending time in the sun in order to get a tan, and the number of sunburns.

5.2. Secondary Aim

Aim 2. To examine mediators of the impact of the intervention. Hypothesis. The effects of the intervention on SSE and sun protection behaviors will be mediated by melanoma knowledge, self-efficacy for SSE and sun protection behaviors, perceived benefits of SSE and sun protection behaviors, perceived barriers to SSE and sun protection behaviors, and perceived controllability of melanoma. For each potential mediator, the four component steps (Frazier et al., 2004; Mallinckrodt et al. 2006) will be examined via logit models (for the SSE outcome) and linear models (for the sun protection behaviors outcome). Using Krull and colleagues' approach for multilevel models (Krull & Mackinnon, 2001), we will calculate the product of the two pieces of the mediating path (from intervention group assignment to mediating variable and from mediating variable to outcome), with the outcomes at 24 weeks as the primary focus (and 48 weeks outcomes examined secondarily). Bootstrap procedures will be utilized to formally test for significance of the mediating pathway (Mallinckrodt et al. 2006; Shrout & Bulger, 2002). Imputation will be used to evaluate the robustness of the results to missing data, assuming dropouts are MAR as well as MNAR.

5.3. Exploratory Aim

Aim 3. To examine moderators of the impact of the intervention. Research Question. To evaluate whether ITW effects are moderated by the following factors: time since diagnosis; disease stage; age; sex; income; education; Internet experience; distress about melanoma; worry about recurrence; and evaluation and usage of the ITW. To examine this aim, we will incorporate interactions between the effect of intervention and potential moderators into the multilevel models described for Aim 1, with the outcomes at 24 weeks as the primary focus (and 8 week and 48 week outcomes examined secondarily). In order to minimize the significance due to multiple testing, variables with low variability in the sample will be eliminated from consideration, and Hochberg's step-down procedure for multiple testing will be employed for the remaining candidates for moderators. Again, imputation will be used to evaluate robustness of the results to missing data, assuming dropouts are MAR as well as MNAR.

Additional Analyses. Using the same analytic approach as for Aim 1, we will examine the impact of the intervention on the number of health care visits. We will use multilevel models similar to those described in Aim 1 to compare changes from baseline to follow-up in distress about melanoma, worry about melanoma recurrence, and perceived risk of melanoma recurrence for the ITW and Usual Care groups. Descriptive statistics, including means and standard deviations or relative frequencies will be used to summarize the indicators of study feasibility (ineligibility rate/reasons, recruitment rate/reasons for refusal, differences in sociodemographic and medical factors between study decliners and those recruited, dropout rate and reasons, and use of the intervention website). Additionally, we will use chi-square and regression analyses to examine retention rates and usage of the ITW vary according to patient income and education.

6. Data and Safety Monitoring

This is a minimal risk study and thus does not require a formal data and safety monitoring plan. As outlined in Section 4.4., appropriate safeguards are in place to manage the potential risks of the study.
Databases for participant recruitment and tracking, medical records review data, and participant survey data will be developed and maintained by the CINJ Population Science Research Support Core using HIPAA-compliant DatStat software. Approval for use of this software in research studies has been provided by the Rutgers Biomedical and Health Sciences Institutional Review Board (IRB). (The approval process included: obtaining a Technology Professional Service Agreement and a Business Associate Agreement from DatStat; the approval of a Security Questionnaire from the Rutgers Office of Information Technology; and the completion of a Security Risk and Assessment Tool by the Rutgers

CINJ Office of Information Technology.) The software allows for research study personnel to be assigned data access and privileges specific to their role on the study.

DatStat secure servers are registered with site certificates provided by AddTrust that provide for advanced encryption over the wire. As each user moves through the survey form, his/her responses are encrypted while in-transit between the browser and DatStat's server using SSL (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All servers used for data collection are highly fault-tolerant and equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 5 hot-swappable disk storage. All primary servers are plugged into a monitored, uninterruptible power supply (UPS). DatStat servers are stored in a locked server cabinet/rack, which are housed in a state-of-the-art, well-ventilated data center. Physical access to servers and data backup is restricted to a minimal number of information technology professionals. The servers are secured with physical and firewall security.

The study principal investigator and co-investigators will provide oversight with regard to monitoring the study. All adverse/unexpected events will be reported in line with Rutgers Biomedical Health Sciences IRB and Rutgers CINJ Office of Human Research Services (OHRS) guidelines. As part of its internal audit program, the OHRS at Rutgers CINJ will monitor accrual to the study and adherence to the overall protocol, verify the completion of informed consent forms, and ensure that data collection and storage procedures are being followed appropriately.

7. Reporting Results

The policies and procedures of Rutgers University's legal department (see: Investigator's Handbook) will govern publication of the results of this trial. The results of this trial will be submitted for publication in a timely manner following its conclusion. The Rutgers Cancer Institute of New Jersey PI and all co-authors will review any abstract of manuscript prior to its submission.

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