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Randomized controlled trial of the mySmartSkin web-based intervention to promote skin self-examination and sun protection behaviors among individuals diagnosed with melanoma: study design and baseline characteristics

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ABSTRACT

> 1.2 million people in the United States have a personal history of melanoma skin cancer and are at increased risk for disease recurrence and second primary melanomas. Many of these individuals do not follow recommendations to conduct regular, thorough skin self-examinations that facilitate early disease detection and do not sufficiently engage in sun protection behaviors. In this project, we are conducting a randomized controlled trial of an innovative, tailored, theory-driven Internet intervention—called mySmartSkin—to promote these behaviors among melanoma patients. This paper outlines the study design and characteristics of the study sample. A total of 441 patients were recruited (40.9% response rate) and randomized to the mySmartSkin or a Usual Care condition. Participants complete surveys at baseline and 8 weeks, 24 weeks, and 48 weeks later. The primary aim of the project is to examine the impact of mySmartSkin versus Usual Care on skin self-examination and sun protection behaviors. The secondary aim focuses on identifying mediators of the intervention's effects. In an exploratory aim, we will examine potential moderators of the impact of the intervention. At baseline, the recruited participants had a mean age of 61 years, 49% were female, 7.5% met criteria for having conducted a recent, thorough skin self-examination, and the mean score on the index of sun protection behaviors was 3.3 (on a scale from 1 to 5). The results of the project will determine whether the mySmartSkin intervention is efficacious in promoting skin self-examination and sun protection behaviors among individuals diagnosed with melanoma.

Trial registration: ClinicalTrials.gov NCT03028948

1. Introduction

An estimated 96,280 cases of invasive cutaneous malignant melanoma will be diagnosed in the United States in 2019, making it the fifth most commonly diagnosed cancer [1]. Additionally, 95,830 cases of melanoma in situ will be diagnosed [1]. Currently, > 1.2 million individuals in the United States are living with a personal history of melanoma [2]. Unlike the vast majority of cancers, the incidence of

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melanoma has steadily increased over the past several decades (from 7.9 new cases per 100,000 individuals in 1975 to 25.8 cases per 100,000 in 2015) [2], which is only partly attributable to improvements in disease detection and reporting [3].

Individuals diagnosed with melanoma remain at risk for disease recurrence, second primary melanomas, and keratinocyte carcinomas (basal cell carcinoma and squamous cell carcinoma). Among individuals diagnosed with localized or regional stage disease, estimated rates of recurrence for thin melanomas vary from 3 to 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) [4–6]. After being diagnosed with melanoma, patients are at 10-fold increased risk for being diagnosed with another melanoma and 3- to 5-fold increased risk for keratinocyte carcinomas [7]. Detection and treatment of recurrent disease and new primary melanomas at earlier stages leads to improved survival, which is not accounted for by lead-time bias [8].

Follow-up guidelines for melanoma recommend that patients receive a periodic total cutaneous examination (TCE) from a physician and conduct a regular, thorough skin self-examination (SSE) [9,10], 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 [11]. Although most melanoma patients receive a periodic TCE from a physician [12–15], they do not engage in regular, thorough SSE [16–20]. More than half of all recurrences and new primary melanomas are detected by patients themselves [21,22]. This provides a rationale that promotion of engagement in SSE will further enhance early disease detection by identifying suspicious lesions during the time period between regularly scheduled physician TCEs. It is also recommended that patients engage in a variety of sun protection behaviors that limit their exposure to ultraviolet (UV) light [9], 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. However, many melanoma patients do not sufficiently engage in such behaviors [20,23], which may have contributed to the development of their initial melanoma. Relatively few interventions have been developed and tested to promote SSE and sun protection behaviors among individuals diagnosed with melanoma [24,25]. Several studies have shown promise with regard to improving melanoma patients' engagement in SSE [20,26–30] and sun protection behaviors [29]. The goal of the current project is to develop and test the impact of a novel, interactive web-based intervention, called *mySmartSkin*, on SSE and sun protection behaviors among individuals diagnosed with melanoma.

2. Materials and methods

2.1. Project overview

The project is being conducted in two phases. Phase 1 focused on development and refinement of the mySmartSkin intervention. Phase 2 is a randomized controlled trial (RCT) of the mySmartSkin intervention versus Usual Care.

2.2. Project phase 1: development and refinement of the mySmartSkin intervention

Our overall approach to the design, content, and features of the online intervention was guided by best practices in instructional and user-centered design methods [31,32], health communications and website design [33–35], and by Ritterband and colleagues' Internet Intervention Model [36], which offers guidelines regarding website characteristics and features that improve users' experience and facilitate behavior change. Our goal was to develop a web-based intervention that utilized an intuitive and engaging interface. We first laid the groundwork and established the overall goals of the mySmartSkin intervention. This included developing prototypes of potential intervention functionality and interactive components that were reviewed and refined by the research team members in an iterative manner. As elements of the draft intervention were available, they were presented to participants to review in user testing sessions.

2.2.1. Eligibility criteria

Individuals were eligible to take part in the user testing if they met the following criteria: (a) diagnosis of primary pathologic stage 0–III cutaneous malignant melanoma; (b) from 3 to 36 months post-surgical treatment; (c) ≥ 18 years old; (d) access to a computer connected to the Internet; (e) able to speak and read English; and (f) able to provide informed consent.

2.2.2. User testing procedures and results

Potentially eligible participants were identified by reviewing patients scheduled for follow-up appointments at Rutgers Cancer Institute of New Jersey (a National Cancer-Institute designated comprehensive cancer center), New Brunswick, NJ. A member of the research staff approached patients in person immediately before or after their clinic appointment. Eligible and interested individuals provided informed consent and were scheduled to attend an in-person individual user testing session in a private office at the Cancer Institute. A total of 26 user testing sessions were completed with 15 participants. Prior to starting their first user testing session, participants completed a brief paper and pencil survey that included questions about demographic factors and their level of experience using the Internet. The characteristics of the participants were as follows: female, $n = 8$ (53.3%); M age = 59.7 years ($SD = 11.7$, range = 37–80); non-Hispanic white, $n = 15$ (100.0%); married/partnered, $n = 13$ (86.7%); college graduate, $n = 12$ (80.0%); use the Internet at least daily, $n = 13$ (86.7%); at least moderately comfortable using the Internet, $n = 11$ (73.3%). Each user testing session lasted approximately 60–90 min and participants were invited to return for subsequent sessions to review different material if they wished. Participants received a $20 gift card for each hour of user testing in which they participated. During each user testing session, one member of the research team guided the participant to review the draft intervention content on a laptop while another member of the research team unobtrusively observed, took notes, and asked the participant for feedback after he/she had viewed each section of content. After several (typically 3 to 4) participants had provided feedback on each draft section, their feedback was summarized, discussed by the research team, and changes to the intervention were made accordingly. Subsequent rounds of user testing were conducted on the revised intervention content until all identified issues were resolved. The main issues that were addressed as a result of the user testing were as follows: reduced the amount of text on each screen of the intervention; improved the readability of the text (e.g., by increasing the text size and contrast); reworded unclear or confusing instructions and content; resolved programming bugs for interactive content; improved the overall usability of the online body mole map; improved intervention navigation (e.g., by reducing the need to scroll up and down and using consistent and clearly identified navigation buttons); and increased the number of patient vignettes (peer role models), which participants found to be relatable and engaging.

2.3. Project phase 2: randomized controlled trial of the mySmartSkin intervention

2.3.1. Primary aim

The primary aim is to evaluate the impact of mySmartSkin versus Usual Care on SSE and sun protection behaviors among individuals diagnosed with melanoma. *Hypothesis 1*: Individuals assigned to mySmartSkin will be more likely to engage in SSE and sun protection behaviors than those assigned to Usual Care.

2.3.2. Secondary aim

The secondary aim is to examine mediators of the impact of the intervention. *Hypothesis 2:* The effects of the intervention on SSE behaviors will be mediated by increased melanoma knowledge, increased self-efficacy for SSE, increased perceived benefits of SSE, decreased perceived barriers to SSE, and increased perceived controllability of melanoma. *Hypothesis 3:* The effects of the intervention on sun protection behaviors will be mediated by increased melanoma knowledge, increased self-efficacy for sun protection behaviors, increased perceived benefits of sun protection behaviors, decreased perceived barriers to sun protection behaviors, and increased perceived controllability of melanoma.

2.3.3. Exploratory aim

The exploratory aim of the project is to examine moderators of the impact of the intervention. *Research Question 1:* To evaluate whether the effects of the intervention are moderated by the following factors: time since treatment, disease stage, age, sex, income, education, Internet experience, distress about melanoma, worry about recurrence, and evaluation and usage of the mySmartSkin intervention.

2.3.4. Conceptual framework

The conceptual framework for the project is guided by several considerations: prior empirical findings regarding factors associated with skin cancer surveillance and sun protection behaviors [37], including our own research testing a skin cancer risk reduction intervention for family members of melanoma patients [38], and the Preventive Health Model (PHM) [39]. These perspectives informed our selection of the a priori mediators noted for the secondary aim: knowledge, self-efficacy; perceived benefits and barriers; and perceived controllability of melanoma. They also guided our selection of the a priori moderators noted for the exploratory aim: time since treatment, disease stage, age, sex, income, education, Internet experience, distress about melanoma, worry about recurrence, and evaluation and usage of the mySmartSkin intervention. We addressed other potentially relevant factors in the content of the mySmartSkin intervention and in our survey measures, but they were not specified as a priori mediators or moderators. These factors will be examined in exploratory analyses and include: social normative influences from family/friends and healthcare providers; perceived risk of a melanoma recurrence; perceived severity of melanoma; SSE planning; and automaticity of engaging in sun protection behaviors.

2.3.5. mySmartSkin web-based intervention

After completing the baseline survey, participants randomly assigned to the mySmartSkin condition receive an email with their unique username and password to the intervention. An overview of the mySmartSkin intervention content and the mediator variables targeted is shown in Table 1, and screenshots are shown in Supplement A. In brief, the intervention included the following sections: How to Use Tutorial; Core 1: Introduction; Core 2: Getting Ready To Do a Skin Self-Check; Monthly Skin Self-Check (Online Body Mole Map); Core 3: Sun-Safe Behaviors; Sun-Safe Action Plan; myStuff. Cores are chunks of thematically organized content that have been optimized for intervention users. After completing the brief How to Use Tutorial, participants gain access to the first main section of the intervention, Core 1: Introduction. Immediately after completing Core 1, participants receive access to Core 2, Getting Ready To Do a Skin Self-Check. This core includes educational content, skills-building activities, and practice with immediate feedback to help patients gain confidence in identifying suspicious skin lesions based on the ABCDEFs of melanoma (Asymmetrical; Border irregularity; Color variation; Diameter > 6 mm; Evolving; Funny looking) [40]. It also included content on getting help from a partner (such as a family member or friend) to conduct a thorough SSE of all areas of the body. Partner-assisted SSE is important because melanoma commonly appears on areas of the body that are hard to see, including the back among men and the lower extremities among women [41–43]. After completing Core 2, mySmartSkin guides participants to perform a SSE using its online body mole map. Throughout the mySmartSkin intervention, we use the term "skin self-check" as opposed to "skin self-examination", as we felt it was a more accessible term for patients. The online body mole map guides the user to examine each area of the body and to add skin lesions that meet one or more of the ABCDEF criteria. For each skin lesion added, the user evaluates it based on the ABCDEF criteria. Based on the criteria, an automated algorithm provides a status for each lesion (See Your Doctor; Watch; Low Concern). The online body mole map also prompts users to schedule their next monthly skin self-check. In Core 2 and the online body mole map, users are instructed to follow-up with a physician as soon as possible if they identify any suspicious skin lesions. Users gain access to Core 3, Sun-Safe Behaviors, one week after completing Core 2. A key component of Core 3 is to guide users to create a sun-safe behaviors action plan that includes their target behaviors to improve as well as the associated strategies and steps to follow. mySmartSkin includes numerous elements and features to promote user engagement and interest, including: automated email reminders; extensive personalized tailoring of content (see Table 1 for details); brief physician videos to reinforce content; quizzes; and interactive game-like activities.

2.3.6. Usual care

Participants assigned to the Usual Care condition receive no additional intervention aside from their usual non-study clinical care. At the end of their participation in the study, participants in the Usual Care condition are offered access to the mySmartSkin intervention (outside of the context of the research study).

2.3.7. Eligibility criteria

Individuals were eligible to take part in the RCT if they met the following criteria: (a) diagnosis of primary pathologic stage 0–III cutaneous malignant melanoma; (b) from 3 to 24 months post-surgical treatment; (c) not adherent to thorough SSE (i.e., they did not report checking each of 15 areas of the body at least once during the past 2 months) [11] *and/or* not adherent to sun protection recommendations (i.e., a mean score of < 4.0 on a sun protection behavior index that assessed the frequency of engaging in four behaviors, each assessed on a 5-point scale from 1 = *never* to 5 = *always* [44] [see Measures section for more details]); (d) ≥ 18 years old; (e) access to a computer connected to the Internet; (f) able to speak and read English; and (g) able to provide informed consent.

2.3.8. Recruitment process

Participants were recruited from the following sources: Rutgers Cancer Institute of New Jersey (a National Cancer Institute-designated comprehensive cancer center), New Brunswick, NJ; Department of Dermatology, Rutgers Robert Wood Johnson Medical School (RWJMS), Somerset, NJ; Saint Barnabas Medical Center, Livingston, NJ; and the New Jersey State Cancer Registry (NJSCR). There were slight variations in recruitment methods across sites. Potentially eligible patients treated at Rutgers Cancer Institute of New Jersey, the Department of Dermatology at Rutgers RWJMS, and Saint Barnabas Medical Center were identified and mailed a study information letter and consent form. A member of the research team then attempted to reach each patient via telephone to ascertain their study interest and eligibility. As necessary, a second mailing of the information letter and consent form was distributed to potentially eligible patients. Potentially eligible patients were also identified through records held at the NJSCR. An information letter was mailed to each patient's treating physician requesting that the physician contact the NJSCR within 2 weeks if there was any reason (e.g., death, cognitive impairment) that the patient should not be contacted regarding the study. A research team member at the NJSCR then mailed a study information package to each patient

Table 1
Overview of mySmartSkin intervention.

mySmartSkin Section	Content	Mediator variables addressed
How to Use Tutorial	• Overview of mySmartSkin navigation • Overview of mySmartSkin sections, features, and timing of their availability • Summary page	
Core 1: Introduction	• Goals of mySmartSkin • Relevance of mySmartSkin to the user[a] • Melanoma facts and figures • Learn about skin cancer • Risk of getting another melanoma[a] • Melanoma risk factors • Introduction to vignette characters (5 melanoma patients) • Physician skin examinations • Reasons for doing monthly skin self-checks[a] • Rated importance of doing monthly skin self-checks[a] • Overview of sun-safe behaviors • Reasons for doing sun-safe behaviors[a] • Rated importance of doing sun-safe behaviors[a] • Risks of ultraviolet (UV) radiation exposure • Summary page	• Melanoma knowledge • Perceived controllability of melanoma • Skin self-examination benefits • Sun protection benefits
Core 2: Getting Ready To Do a Skin Self-Check	• Prior experience doing skin self-checks[a] • Importance of doing thorough skin self-checks[a] • Confidence identifying suspicious moles and skin growths[a] • Education about moles • The ABCDEFs of melanoma • Revisiting confidence identifying suspicious moles and skin growths[a] • Getting help with skin self-checks[a] • What to do if you identify a suspicious skin growth • Strategies for doing monthly skin self-checks[a] • Creating a skin self-check action plan[a] • Physician recommendation for doing monthly skin self-checks • Summary page	• Melanoma knowledge • Perceived controllability of melanoma • Skin self-examination self-efficacy • Skin self-examination benefits • Skin self-examination barriers
Monthly Skin Self-Check (Online Body Mole Map)	• Preparing for your skin self-check (gathering helpful tools) • Summary of the ABCDEFs of melanoma • User is guided to examine each area of the body in turn and to add (and review on subsequent occasions) skin growths that meet one or more of the ABCDEFs to the online body mole map[a] • For each skin growth added, the user evaluates it based on the ABCDEF criteria; based on the criteria, an automated algorithm provides a status for each growth (See Your Doctor; Watch; Low Concern)[a] • User is prompted to schedule the next monthly skin self-check[a] • Summary page shows each skin growth and its status[a]	
Core 3: Sun-safe behaviors	• Boosting/keeping motivation high[a] • Sun-safe behaviors scorecard[a] • Recommendations, education, and tips for improving sun-safe behaviors and avoiding sunburns[a] • Setting a good example for family and friends • Selecting sun-safe behaviors to improve (goal setting)[a] • Creating a sun-safe behaviors action plan[a] • Summary page	• Melanoma knowledge • Perceived controllability of melanoma • Sun protection self-efficacy • Sun protection benefits • Sun protection barriers • Sun protection norms
Sun-safe action plan	• User is prompted to review and update the sun-safe behaviors action plan (e.g., to change the target behaviors, goal setting strategies, and/or action steps)[a]	• Sun protection barriers • Sun protection self-efficacy
myStuff	• User has access to printable documents from each core section as well as a summary of the most recent Monthly Skin Self-Check and the current Sun-Safe Action Plan[a]	

[a] Content is tailored to each individual user.

and attempted to reach him/her via telephone. Patients who expressed interest in the study agreed for their contact information to be sent to the research team at Rutgers Cancer Institute of New Jersey, who then attempted to reach them via telephone to determine their eligibility. Regardless of the source through which patients were identified, all recruited participants provided informed consent prior to their enrollment in the study. Throughout study participation, participants were sent birthday and non-denominational holiday cards as a way to maintain their interest and engagement in the study. The study received approval from the Rutgers Health Sciences and the Saint Barnabas Medical Center Institutional Review Boards.

2.3.9. Randomization

Study randomization was conducted in line with standard operating procedures of the Rutgers Cancer Institute of New Jersey Biometrics Shared Resource. Specifically, the study biostatistician generated a single hard copy of the randomization schema that included stratification according to disease stage (0, I, II, III) and time since melanoma surgery (3 months to < 14 months, 14 to 24 months) and block randomization (using blocks of 6 patients) within strata. The hard copy randomization schema was held in a secure location by a staff member who was not involved in any other aspects of the study. After each participant was consented, the consenting research team member emailed the holder of the randomization schedule and provided the participant's unique study identification number, disease stage, and time since melanoma surgery. The staff member holding the randomization schema entered the participant on the schema and emailed the research team member with the resulting assignment (mySmartSkin or Usual Care) for that participant. Due to programming requirements associated with the project management and intervention system, it was necessary to conduct randomization after consenting each participant, as opposed to after completion of the baseline survey. Participants were notified via email of their randomization assignment only after completing the baseline survey. Neither the research team members nor the

Table 2
Measures assessed at each study time point.

	Baseline	8 weeks	24 weeks	48 weeks
Clinical characteristics	✓			
Demographic characteristics	✓			
Internet experience	✓			
Melanoma risk factors	✓			
Receipt of total cutaneous examination	✓	✓	✓	✓
Receipt of biopsy, skin cancer diagnosis		✓	✓	✓
Melanoma knowledge	✓	✓	✓	✓
Distress about melanoma	✓	✓	✓	✓
Worry about melanoma recurrence	✓	✓	✓	✓
Perceived controllability of melanoma	✓	✓	✓	✓
Perceived severity of melanoma	✓	✓	✓	
Perceived risk of melanoma recurrence	✓	✓	✓	
Skin self-examination self-efficacy	✓	✓	✓	
Skin self-examination benefits and barriers	✓	✓	✓	
Skin self-examination norms	✓			
Skin self-examination planning	✓	✓	✓	
Physician recommendations for skin self-examination	✓			✓
Sun protection self-efficacy	✓	✓	✓	
Sun protection benefits and barriers	✓	✓	✓	
Sun protection norms	✓			
Automaticity of sun protection behaviors		✓	✓	✓
Physician sun protection recommendations	✓			✓
SSE behaviors	✓	✓	✓	✓
Sun protection behaviors	✓	✓	✓	✓
Intervention perceived impact, utility, and problems		✓		
Intervention usage		✓	✓	✓

research participants themselves were blinded to the randomization assignment.

2.3.10. Measures

Participants completed online surveys at baseline and then at 8 weeks, 24 weeks, and 48 weeks post-baseline. As an appreciation for their time and effort, participants received a $25 gift card for each completed survey. An overview of the measures assessed at each time point is shown in Table 2. Data on disease stage and the length of time since having melanoma surgery were abstracted from the medical record (when available) and confirmed with the participant. Participants completed questions about their demographic characteristics (age, sex, race/ethnicity, level of education, household income, and marital status), experience using the Internet, and melanoma risk factors [45,46]. At each time point, participants indicated when they had their most recent TCE and the reasons for the examination (e.g., a scheduled check-up, the participant made an appointment because he/she noticed something suspicious and wanted to get it checked). At the 8, 24, and 48 week time points, they also indicated whether a skin biopsy was conducted in the intervening time period and whether they had been diagnosed with skin cancer. Melanoma knowledge was measured using a set of true-false items [17] as well as items regarding knowledge of the ABCDEF guide to melanoma [19,47]. Distress about melanoma, worry about melanoma recurrence, and perceived controllability of melanoma were measured using standard items [17,48,49]. Established scales were also used to assess perceived severity and risk of melanoma, SSE self-efficacy, SSE benefits and barriers, and SSE norms [17,50–53]. SSE planning was assessed with two items adapted from prior research [54–56]. With regard to physician SSE recommendations, a series of yes/no questions asked 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, sun protection benefits and barriers, and sun protection norms were measured using established measures [17,57,58]. Automaticity of sun protection behaviors was assessed using the 4-item Self-Report Behavioral Automaticity Index [59]. Physician sun protection recommendations were assessed using yes/no questions.

With regard to the SSE outcomes, participants indicated 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 who reported checking their skin one or more times indicated the number of times they checked their skin during the corresponding time frame, the last time they checked their body, and the specific areas of the body (out of a maximum of 15) 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 [60,61]. For analytic purposes, the primary SSE outcome is performance of thorough SSE, defined as examining each area of the body during the most recent skin self-check in the past 2 months [61]. We focus on thorough SSE as the primary SSE outcome because greater SSE thoroughness is associated with detection of thinner tumors [62–64], which have a lower mortality rate than thicker tumors [65]. The secondary SSE outcomes 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 also indicated whether, the last time they did SSE, they used a mirror, had someone else help them, or used a body mole map.

Participants rated 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 [44]. The primary sun protection outcome is 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 rated how often they use sunglasses, wear long pants, and spend time in the sun in order to get a tan [44], and the number of sunburns they had. As an exploratory outcome, at the 48 week survey, participants indicate whether, and if so how many times, they indoor tanned in the past year.

At the 8 week survey, participants in the mySmartSkin condition completed multiple measures regarding their perceived impact and utility of the intervention, as well as any problems that they encountered [66,67]. For participants in the mySmartSkin condition, a number of intervention process measures will be examined, including completion of key sections of mySmartSkin and the number of monthly SSEs conducted using the online body mole map.

2.3.11. Sample size considerations

We conducted power calculations for the primary and secondary aims. 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, it was estimated that fewer than 10% of participants would be adherent to thorough SSE. Based on our own and others' prior research [38,68–70], we anticipate that the rate of adherence to thorough SSE at 24 weeks post-baseline will be $\geq$30% for participants in the mySmartSkin condition and this will be at least 15 percentage points higher than the adherence rate among those in the Usual Care condition. 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 [38]) and an adherence rate to thorough SSE of up to 15% in the Usual Care group at 24 weeks post-baseline, 134 individuals would need to be

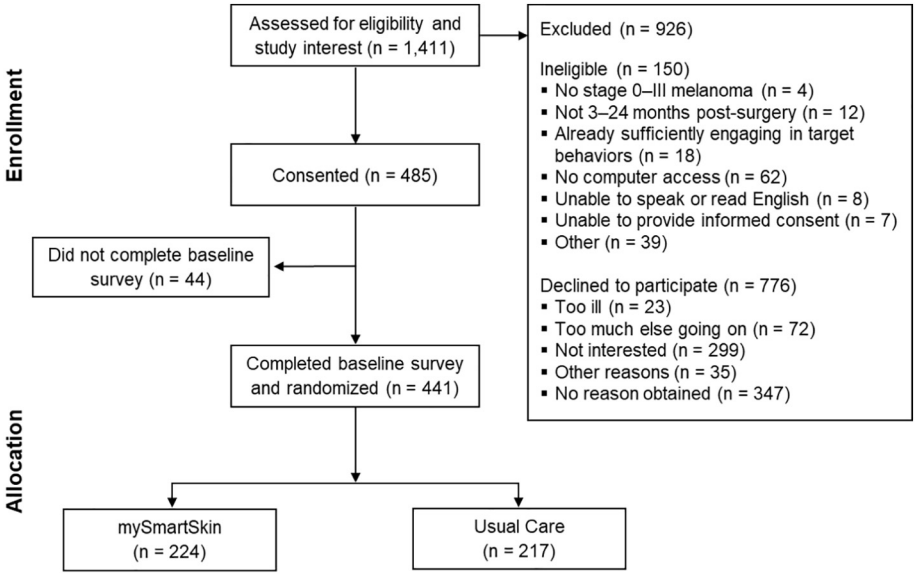

Fig. 1. CONSORT diagram of study enrollment and allocation.

enrolled in each condition to obtain 80% power. Power calculations for the sun protection behavior index outcome are based on results of prior tailored interventions [38,68]. In our prior RCT comparing a generic to a tailored intervention for individuals at increased risk for melanoma, sun protection scores at baseline were 2.8 for both conditions and increased to 3.2 and 3.4 for the generic and tailored interventions, respectively [38]. 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 134 individuals to each group would provide > 90% 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) [71]. We conservatively assume that one of the two paths will have a regression coefficient of at least 0.14 (a small effect, according to Cohen's criteria [72]) and the other will have a regression coefficient of at least 0.26 (a small-to-moderate effect [72]). Under those assumptions, and allowing for 10% dropout at 24 weeks, recruiting 210 individuals to each condition would provide 80% power to detect mediational effects [71]. Overall, based on a consideration of the aforementioned factors, we planned to recruit 210 individuals to each of the mySmartSkin and Usual Care conditions, for a total sample size of $N = 420$, which will provide at least 80% power for the primary and secondary aims. We anticipated that at least 90% (378) of the recruited patients would complete the 24 week post-baseline assessment and 85% (357) would complete the 48 week post-baseline assessment.

2.3.12. Statistical analyses

In this paper, we use descriptive statistics to provide the enrollment and allocation results of the RCT, describe participants' background characteristics at baseline, and to report on baseline values of the study outcomes. We also use *t*-tests and chi-square tests to examine potential differences in demographic and clinical characteristics between recruited participants and individuals who declined to participate. Below we provide the planned statistical analyses for the study aims.

2.3.12.1. Primary aim. The primary aim is to evaluate the impact of mySmartSkin versus Usual Care on SSE and sun protection behaviors among individuals diagnosed with melanoma. *Hypothesis 1*: Individuals assigned to mySmartSkin 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 mySmartSkin versus Usual Care, with the outcomes at 24 weeks as the primary focus (and controlling for the randomization stratification variables of disease stage and time since melanoma surgery). To handle missing data due to participant dropout, weighted generalized estimating equations [73–75], 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 [76–79]. Additional multilevel models [80] will examine the effect of the intervention on changes in thorough SSE and sun protection behaviors over time, comparing changes across 8 weeks, 24 weeks, and 48 weeks. Specifically, generalized estimating equations [81,82] will be used for estimation and testing. Additional analyses will focus on the effect of the intervention on the a priori specified secondary SSE and sun protection outcomes.

2.3.12.2. Secondary aim. The secondary aim is to examine mediators of the impact of the intervention. *Hypothesis 2:* The effects of the intervention on SSE behaviors will be mediated by increased melanoma knowledge, increased self-efficacy for SSE, increased

Table 3
Participant background characteristics.

Characteristic	Total (N = 441)	mySmartSkin intervention (n = 224)	Usual care (n = 217)
Age, mean (SD)	61.4 (13.3)	62.0 (12.9)	60.8 (13.7)
Sex, % (n)			
Female	49.0 (216)	46.0 (103)	52.1 (113)
Male	51.0 (225)	54.0 (121)	47.9 (104)
Race/ethnicity, % (n)			
Non-Hispanic White	98.0 (432)	97.3 (218)	98.6 (214)
Non-Hispanic Black	0.2 (1)	0.5 (1)	0.0 (0)
Non-Hispanic other	0.5 (2)	0.9 (2)	0.0 (0)
Hispanic	1.4 (6)	1.3 (3)	1.4 (3)
Level of education, % (n)			
≤ High school graduate	12.2 (54)	14.3 (32)	10.1 (22)
Some college	19.7 (87)	18.8 (42)	20.7 (45)
College graduate	30.2 (133)	31.3 (70)	29.0 (63)
Graduate degree	37.9 (167)	35.7 (80)	40.1 (87)
Annual household income,[a] % (n)			
≤ $59,999	16.1 (63)	18.0 (37)	14.0 (26)
$60,000 to $99,999	27.8 (109)	27.2 (56)	28.5 (53)
$100,000 to $149,999	21.4 (84)	21.8 (45)	21.0 (39)
≥ $150,000	34.7 (136)	33.0 (68)	36.6 (68)
Marital status, % (n)			
Married/partnered	79.6 (351)	79.9 (179)	79.3 (172)
Not married/partnered	20.4 (90)	20.1 (45)	20.7 (45)
Frequency of using the Internet,[b] % (n)			
2 or fewer days/week	6.0 (26)	6.0 (13)	6.1 (13)
3 to 5 days/week	5.8 (25)	6.0 (13)	5.6 (12)
Once a day	14.6 (63)	18.4 (40)	10.8 (23)
2 to 3 times/day	27.4 (118)	24.4 (53)	30.4 (65)
4 or more times/day	46.2 (199)	45.2 (98)	47.2 (101)
Level of comfort using the Internet,[b] % (n)			
Very uncomfortable	4.4 (19)	4.6 (10)	4.2 (9)
Somewhat uncomfortable	5.3 (23)	6.9 (15)	3.7 (8)
Neither comfortable nor uncomfortable	6.3 (27)	7.4 (16)	5.1 (11)
Somewhat comfortable	23.0 (99)	23.0 (50)	22.9 (49)
Very comfortable	61.0 (263)	58.1 (126)	64.0 (137)
Number of melanoma risk factors (range 0–8), mean (SD)	4.4 (1.6)	4.3 (1.7)	4.4 (1.6)
Time since melanoma surgery, % (n)			
3 to < 14 months	50.8 (224)	48.2 (108)	53.5 (116)
14 to 24 months	49.2 (217)	51.8 (116)	46.5 (101)
Disease stage, % (n)			
0	30.8 (136)	29.9 (67)	31.8 (69)
I	55.6 (245)	56.3 (126)	54.8 (119)
II	7.7 (34)	8.0 (18)	7.4 (16)
III	5.9	5.8 (13)	6.0 (13)

[a] N = 392 (data were missing for 49 participants).
[b] N = 431 (data were missing for 10 participants).

perceived benefits of SSE, decreased perceived barriers to SSE, and increased perceived controllability of melanoma. *Hypothesis 3:* The effects of the intervention on sun protection behaviors will be mediated by increased melanoma knowledge, increased self-efficacy for sun protection behaviors, increased perceived benefits of sun protection behaviors, decreased perceived barriers to sun protection behaviors, and increased perceived controllability of melanoma.

Potential mediators for the effect of treatment on outcomes will be examined using counterfactual models with binary regression models (for the SSE outcome) and standard linear regression models (for the sun protection behavior index outcome) [83]. Because at least one of our outcomes is binary with expected modest to high rate of success, traditional mediation analyses may provide estimates of treatment effects that are not comparable across models [83]. In the counterfactual models, baseline values of the potential mediating variables and outcomes will be considered as potential confounders for the mediators (for example, see [84]). Bootstrap procedures will be used to estimate reliable estimates of the standard errors. Confidence intervals for the direct effect of treatment as well as indirect effects with each mediator will be presented. Imputation will be used to evaluate the robustness of the results to missing data, assuming dropouts are MAR as well as MNAR.

2.3.12.3. Exploratory aim. The exploratory aim of the project is to examine moderators of the impact of the intervention. *Research Question 1:* To evaluate whether the effects of the intervention are moderated by the following factors: time since treatment, disease stage, age, sex, income, education, Internet experience, distress about melanoma, worry about recurrence, and evaluation and usage of the mySmartSkin intervention.

To examine this aim, we will incorporate interactions between the effect of intervention and potential moderators into the multilevel models described for the primary aim, with the outcomes at 24 weeks as the primary focus (and 8 week and 48 week outcomes examined secondarily). In order to minimize the type I error rate due to multiple testing, variables with low variability in the sample will be eliminated from consideration, and Holm'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 with regard to missing data, assuming dropouts are MAR as well as MNAR.

2.3.12.4. Additional analyses. Using the same analytic approach as for the primary aim, we will examine the impact of mySmartSkin versus Usual Care on additional outcomes, including: distress about melanoma, worry about recurrence, and perceived risk of melanoma recurrence. We will examine having non-routine visits for a TCE (i.e., because the patient noticed a suspicious lesion), receipt of biopsies, and diagnoses of skin cancer as exploratory outcomes. Using the same analytic approach as for the secondary and exploratory aims, we will examine additional potential intervention mediators (e.g., perceived risk of melanoma recurrence; SSE planning; automaticity of engaging in sun protection behaviors) and moderators (e.g., recruitment site; marital status; perceived severity of melanoma; SSE norms; sun protection norms).

3. Results

3.1. Enrollment and allocation

A CONSORT diagram of the study enrollment and allocation is shown in Fig. 1. A total of 1411 individuals were invited to participate in the study and assessed for their eligibility and interest: 1027 from Rutgers Cancer Institute of New Jersey and the Department of Dermatology at Rutgers RWJMS; 50 from Saint Barnabas Medical Center; 333 from the NJSCR; and 1 individual who contacted the research team after learning about the study from the registered protocol at www.clinicaltrials.gov. The primary reason for ineligibility was not having access to a computer connected to the Internet (n = 62). Of the 429 individuals who provided a reason for not wishing to participate, 299 (69.7%) indicated that this was due to a lack of interest in the study. Of the 485 individuals who were consented to the study, 441 (90.9%) completed the baseline survey and were assigned to the mySmartSkin (n = 224) or Usual Care condition (n = 217). Following established guidelines for estimating the proportion of individuals of unknown eligibility status who were in fact eligible for the study, the participant response rate for the study was 40.9% (American Association of Public Opinion Research [AAPOR] response rate 3) [85].

Table 4
Participant baseline values of study outcomes.

	Total (N = 441)	mySmartSkin intervention (n = 224)	Usual care (n = 217)
Primary outcomes			
Did thorough SSE in the past 2 months,[a] % (n)	7.5 (33)	5.4 (12)	9.7 (21)
Sun protection behavior index (range 1–5),[b] mean (SD)	3.3 (0.8)	3.2 (0.7)	3.3 (0.8)
Secondary outcomes			
Did thorough SSE in the past 1 month,[c] % (n)	6.8 (30)	5.4 (12)	8.3 (18)
Did SSE in the past 2 months,[d] % (n)	65.5 (287)	62.3 (139)	68.8 (148)
Number of SSEs in the past 12 months,[e] % (n)			
0	30.3 (133)	34.2 (76)	26.3 (57)
1–5	21.9 (96)	22.5 (50)	21.2 (46)
6–10	15.3 (67)	10.4 (23)	20.3 (44)
11–15	14.6 (64)	15.8 (35)	13.4 (29)
16–20	3.2 (14)	4.1 (9)	2.3 (5)
> 20	14.8 (65)	13.1 (29)	16.6 (36)
Number of body areas examined thoroughly during most recent SSE in past 2 months (range 0–15),[f] mean (SD)	10.6 (3.2)	10.6 (3.1)	10.7 (3.3)
Use of tools to facilitate the most recent SSE in the past 2 months,[f] % (n)			
Used a mirror	46.2 (132)	47.5 (66)	44.9 (66)
Had someone else help	39.2 (112)	40.3 (56)	38.1 (56)
Used a body mole map	1.7 (5)	1.4 (2)	2.0 (3)
Wearing sunscreen with SPF ≥ 30 (range 1–5),[g] mean (SD)	3.8 (1.1)	3.8 (1.1)	3.9 (1.0)
Wearing a long-sleeved shirt (range 1–5),[g] mean (SD)	2.8 (1.1)	2.8 (1.1)	2.9 (1.1)
Wearing a wide-brimmed hat (range 1–5),[g] mean (SD)	2.8 (1.3)	2.9 (1.3)	2.8 (1.3)
Staying in the shade (range 1–5),[g] mean (SD)	3.6 (0.9)	3.6 (0.9)	3.6 (1.0)
Wearing long pants (range 1–5),[g] mean (SD)	2.9 (1.1)	2.9 (1.2)	2.9 (1.0)
Wearing sunglasses (range 1–5),[g] mean (SD)	4.1 (1.1)	4.0 (1.1)	4.1 (1.1)
Sunbathing (range 1–5),[g] mean (SD)	1.7 (1.0)	1.8 (1.0)	1.7 (1.0)
Number of sunburns in the past 12 months, % (n)			
0	74.2 (327)	75.9 (170)	72.4 (157)
1	15.7 (69)	12.1 (27)	19.4 (42)
2	5.4 (24)	6.7 (15)	4.2 (9)
3	3.0 (13)	4.5 (10)	1.4 (3)
4	1.1 (5)	0.9 (2)	1.4 (3)
5	0.2 (1)	0.0 (0)	0.5 (1)
6	0.5 (2)	0.0 (0)	0.9 (2)
Other outcomes			
Distress about melanoma (range 1–10), mean (SD)	3.8 (2.3)	3.8 (2.4)	3.7 (2.1)
Worry about melanoma recurrence (range 1–6), mean (SD)	3.4 (1.3)	3.4 (1.3)	3.4 (1.2)
Perceived risk of melanoma recurrence (range 1–5), mean (SD)	3.2 (0.8)	3.2 (0.8)	3.3 (0.8)
Ever engaged in indoor tanning, % (n)	29.0 (128)	27.2 (61)	30.9 (67)
Time of most recent physician TCE, % (n)			
Within the last month	134 (30.4)	63 (28.1)	71 (32.7)
1–6 months ago	267 (60.5)	136 (60.7)	131 (60.4)
7–12 months ago	25 (5.7)	15 (6.7)	10 (4.6)
> 12 months ago	14 (3.2)	9 (4.0)	5 (2.3)
Never	1 (0.2)	1 (0.5)	0 (0.0)

SSE = skin self-examination; SD = standard deviation; SPF = sun protection factor; TCE = total cutaneous examination.

[a] Defined as examining each of 15 areas of body during the most recent SSE in the past 2 months.

[b] Assessed as the mean rating of the frequency of engaging in each of four sun protection behaviors (wearing sunscreen with an SPF ≥ 30; wearing a long-sleeved shirt; wearing a wide-brimmed hat; staying in the shade) when outside on sunny days in the past 12 months (each behavior was assessed on a scale from 1 = *never* to 5 = *always*).

[c] Defined as examining each of 15 areas of body during the most recent SSE in the past 1 month.

[d] N = 438 (data were missing for 3 individuals).

[e] N = 439 (data were missing for 2 individuals).

[f] Among individuals who reported doing a SSE in the past 2 months.

[g] Assessed as the frequency of engaging in the behavior when outside on sunny days in the past 12 months using a scale from 1 = *never* to 5 = *always*.

3.2. Participant background characteristics

The background characteristics of the study sample are shown in Table 3. In brief, the mean age of participants was 61.4 years (SD = 13.3) and the range was from 18 to > 89 years of age, 49.0% were female, and 98.0% were non-Hispanic white. More than two-thirds of participants had at least a college graduate level of education. Almost all of the participants reported using the Internet at least daily, and more than three-quarters indicated that they were at least somewhat comfortable in their use of the Internet. Participants had predominantly been diagnosed with early stage melanoma (stage 0 and I). For the 810 individuals who were denoted as study decliners (including the 44 individuals who consented but did not complete a baseline survey), information regarding their demographic and clinical characteristics was available as follows: age, n = 703; sex, n = 727; disease stage, n = 709; time since surgery, n = 585). Comparisons between the recruited study participants and the study decliners showed no differences with regard to age (t = 1.88, p = .061), disease stage (χ^2 = 4.76, p = .190), or time since surgery (t = 0.49, p = .626). The study decliners were more likely to be male (58.0%) compared to the recruited participants (51.0%) (χ^2 = 5.48, p = .019).

3.3. Participant baseline values of study outcomes

The baseline values for the primary and secondary outcomes are shown in Table 4. Although two-thirds of participants reported having

Table 5
Areas of the body examined during the most recent skin self-examination in the past 2 months.[a]

	Total (N = 287)	mySmartSkin intervention (n = 139)	Usual care (n = 148)
Body areas examined, % (n)			
Scalp	37.9 (108)	39.6 (55)	36.3 (53)
Face	98.3 (282)	99.3 (138)	97.3 (144)
Neck	89.8 (256)	90.7 (126)	89.0 (130)
Shoulders	88.2 (253)	87.8 (122)	88.5 (131)
Front of arms	97.9 (280)	98.6 (137)	97.3 (143)
Back of arms	79.8 (229)	78.4 (109)	81.1 (120)
Chest	93.7 (268)	94.2 (130)	93.2 (138)
Stomach	87.7 (250)	87.7 (121)	87.8 (129)
Upper back	54.9 (157)	55.1 (76)	54.7 (81)
Lower back	48.8 (139)	50.0 (69)	47.6 (70)
Front of legs	94.0 (266)	93.4 (128)	94.5 (138)
Back of legs	72.6 (204)	71.3 (97)	73.8 (107)
Bottom of feet	41.6 (119)	40.6 (56)	42.6 (63)
Buttocks	40.4 (116)	39.6 (55)	41.2 (61)
Genitals	44.4 (127)	42.0 (58)	46.6 (69)

Due to missing data, sample sizes vary from N = 281–287 for the full sample, n = 136–139 for the mySmartSkin Intervention group, and n = 145–148 for the Usual Care group.

[a] Among individuals who reported doing a skin self-examination in the past 2 months.

done a SSE in the past 2 months, only 7.5% met criteria for having conducted a thorough SSE. For their most recent SSE in the past 2 months, participants reported examining 10.6 (out of a maximum of 15) areas of the body on average. Fewer than 2% of participants reported using a body mole map for their most recent SSE, 39.2% had someone else help them, and 46.2% had used a mirror to facilitate the SSE. With regard to the sun protection behavior outcomes, the mean score on the composite index was 3.3 (SD = 0.8, range 1–5). The most frequently engaged in sun protection behaviors were wearing sunglasses and staying in the shade. A quarter (25.8%) of participants reported having at least one sunburn in the past 12 months. A history of indoor tanning was reported by 29.0% of participants.

The areas of the body that participants reported examining during their most recent SSE in the past 2 months are shown in Table 5. Overall, participants reported greater examination of areas of the body that are easier to inspect, including the face, neck, chest, and the front of the arms and legs. Areas of the body that were less commonly examined included the scalp, genitals, bottom of the feet, and the back of the body.

4. Discussion

This project tests an innovative, web-based intervention to promote SSE and sun protection behaviors among individuals diagnosed with melanoma. There are numerous strengths of the project. Few prior intervention studies have targeted both SSE and sun protection behaviors in at-risk populations. The target sample size was successfully accrued, and the 40.9% response rate is encouraging for a behavioral intervention for cancer patients. The study is powered not only to detect the overall impact of the intervention on the outcomes but also to identify intervention mediators, which will provide insight on how the intervention works. Our approach for measuring mediator variables at several time points is in line with methodological guidelines [86]. Additionally, our focus on identifying moderators of the impact of the intervention will highlight patient subgroups that are particularly receptive or resistant to its effects, which will inform future intervention development and targeting. In addition to primary outcomes being assessed at 24 weeks post-baseline, the project includes a follow-up at 48 weeks post-baseline, which will permit examination of the durability of intervention effects. Finally, the fact that mySmartSkin is a web-based intervention provides significant potential for its future dissemination and implementation in clinical and/or public health practice.

A number of potential limitations of the project warrant mention. The intervention requires that individuals have access to the Internet. In screening individuals for the current project, relatively few individuals were excluded because they did not have Internet access. However, Internet access rates likely vary among melanoma patients in different geographic regions and among those of varying sociodemographic backgrounds. Of note, the incidence of melanoma is greatest among groups that have the highest rates of Internet access (i.e., non-Hispanic whites, individuals with a higher socioeconomic status) [87–90]. Recruitment for this project focused on individuals diagnosed with melanoma in the state of New Jersey, which we felt was appropriate for this initial efficacy study. Future research is warranted to target patients from geographically diverse regions. In this project, the SSE and sun protection behavior outcomes are measured via self-report. Prior studies have found such self-report measures to have excellent reliability and validity [11,44,60,68,91–93], and self-report has been recommended as the most appropriate assessment approach for skin cancer risk reduction intervention studies [44,94]. The outcomes are assessed in line with state-of-the-art guidelines, using measures that have been employed in prior efficacious interventions.

In summary, this project rigorously evaluates the impact of the web-based mySmartSkin intervention on SSE and sun protection behaviors among individuals diagnosed with melanoma. If the intervention is found to be efficacious, future efforts will focus on testing its effectiveness on a broader population level.

Trial status

Participant enrollment into the randomized controlled trial began in March 2017 and was completed in August 2018. The follow-up phase is ongoing and final outcomes data will be available in September 2019.

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Appendix A. Supplementary data

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