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Original Papers

Original Paper

Acceptability and Feasibility of a Trial Testing Allocation to Sunscreen and a Smartphone App for Sun Protection: Discontinued Randomized Controlled Trial

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Abstract

Background: Recreational sun exposure has been associated with melanoma prevalence, and tourism settings are of particular interest for skin cancer prevention. Effective, affordable, and geographically flexible interventions to promote sun protection are needed.

Objective: The aim of this study was to describe the protocol for a definitive randomized controlled trial (RCT) evaluating a smartphone mobile intervention (mISkin app) promoting sun protection in holidaymakers and to assess the acceptability and feasibility of the mISkin app and associated trial procedures in an internal pilot study.

Methods: Participants were recruited from the general community. Holidaymakers traveling abroad and owning a smartphone were enrolled in the internal pilot of a 2 (mISkin vs control) x 2 (sun protection factor [SPF] 15 vs SPF 30) RCT with a postholiday follow-up. The smartphone app is fully automated and entails a behavioral intervention to promote sun protection. It consisted of five components: skin assessment, educational videos, ultraviolet (UV) photos, gamification, and prompts for sun protection. Participants were also randomly allocated to receive sunscreen SPF 15 or SPF 30. Primary outcomes for the internal pilot study were acceptability and feasibility of trial procedures and intervention features. Secondary outcomes were collected at baseline and after holidays through face-to-face-assessments and included skin sun damage, sunscreen use (residual weight and application events), and sun protection practices (Web-based questionnaire).

Results: From 142 registers of interest, 42 participants were randomized (76% [32/42] female; mean age 35.5 years). Outcome assessments were completed by all participants. Random allocation to SPF 15 versus SPF 30 was found not to be feasible in a definitive trial protocol. Of the 21 people allocated to the mISkin intervention, 19 (91%) installed the mISkin on their phones, and 18 (86%) used it at least once. Participants were satisfied with the mISkin app and made suggestions for further improvements. Due to difficulties with the random allocation to SPF and slow uptake, the trial was discontinued.

Conclusions: The internal pilot study concluded that randomization to SPF was not feasible and that recruitment rate was slower than expected because of difficulties with gatekeeper engagement. Possible solutions to the problems identified are discussed. Further refinements to the mISkin app are needed before a definitive trial.

Trial Registration: International Standard Randomized Controlled Trial Number ISRCTN63943558; http://www.isrctn.com/ISRCTN63943558 (Archived by WebCite at http://www.webcitation.org/6xOLvbab8)

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KEYWORDS

sunscreening agents; sun protection factor; smartphone; mobile applications; feasibility studies; randomized controlled trial; skin neoplasms; melanoma; skin aging; holidays; health promotion; health behavior

Introduction

Skin cancer is the most common form of all types of cancer diagnosed in the United Kingdom [1]. In 2014, about 15,400 new melanoma skin cancer and 132,000 new nonmelanoma cases were registered [2]. Melanoma incidence rates have increased by almost a half (45%) over the last decade in the United Kingdom [2]. Intermittent sun exposure, in particular, (eg, summer holidays in sunny destinations) has been shown to increase melanoma risk considerably [3]. Epidemiologic studies suggest that implementation of sun protection behaviors would decrease intermittent sun exposure and would reduce skin cancer incidence [4,5]. Although applying sunscreen has been widely promoted, there is some discrepancy regarding the recommended sunscreen protection factor. The National Institute for Health and Care Excellence (NICE) recommends using a sun protection factor (SPF) of 15, whereas the British Association of Dermatologists, Cancer Research UK, and the British Skin Foundation suggest the use of at least SPF 30 [6].

Tourism settings are of particular interest for skin cancer prevention [3]. Sunburn is a common experience [7,8], and sun-related behaviors such as intentional sun seeking associated with lifestyle changes (eg, holidays in sunny destinations and fashion trends) are increasingly high [9]. Holidaymakers are a volatile population present at different locations, which may make them difficult to reach. A scalable and geographically flexible mobile phone intervention might be an effective way of reaching this population. Mobile phone interventions have been shown to improve sun protection behaviors either by using SMS text messaging (short message service, SMS) interventions or mobile phone apps [10-12]. A novel mobile phone intervention (mISkin app) to promote sun protection among holidaymakers has recently been developed based on evidence [13,14], experts' knowledge and experience, and user involvement [15].

The starting point for this research was to address the main challenges identified by a recent systematic review of sun protection interventions, including (1) poor reporting of intervention development, design, and contents; (2) poor outcome measurement; and (3) poor study methodology [13]. In line with this, this study describes an internal pilot study evaluating an evidence-based behavior change intervention to promote sun protection among holidaymakers, using both objective and self-reported outcome measures. The study also provides evidence to inform guidelines regarding the recommended sunscreen SPF. The specific study objectives are to:

1. Test the acceptability of recruitment, allocation, measurement, and intervention procedures.
2. Assess the feasibility of a mobile phone intervention to promote sun protection (feasibility).
3. Collect feedback regarding satisfaction with the intervention (acceptability).
4. Explore users' engagement with the app and its active ingredients (fidelity).

Methods

Full details of the research protocol have been registered: ISRCTN3943558 [16]. Ethical approval was obtained from the Faculty of Medical Sciences at Newcastle University.

Trial Design

The study was initially designed as a single center assessor-blinded parallel group, individually randomized controlled trial (RCT), using a 2 (mISkin app intervention vs no intervention) x 2 (sunscreen provision: SPF 15 vs SPF 30) factorial design. This study sought to explore the independent main effects of both sunscreen SPF and mobile app that would result in consistent differences between the levels (SPF 15 vs SPF 30; app vs no app), rather than an interaction effect.

The intended number of participants to be recruited for the definitive trial was 200, with the first 30 comprising the internal pilot phase. The internal pilot was conducted from September 2012 to October 2013. A schedule of events is presented in Multimedia Appendix 1 (schedule of events for the trial, including enrollment, interventions, and outcome assessments).

Participants

Holidaymakers from the North East of England traveling abroad, older than 18 years, and owning an Android smartphone were recruited. The recruitment strategy involved placing posters in local urban community areas such as universities, travel agency; large companies; and using social media (ie, Twitter and Facebook). Interested individuals contacted the research team by email. Participants were assessed for inclusion criteria by a researcher (AR) and provided informed consent before participation.

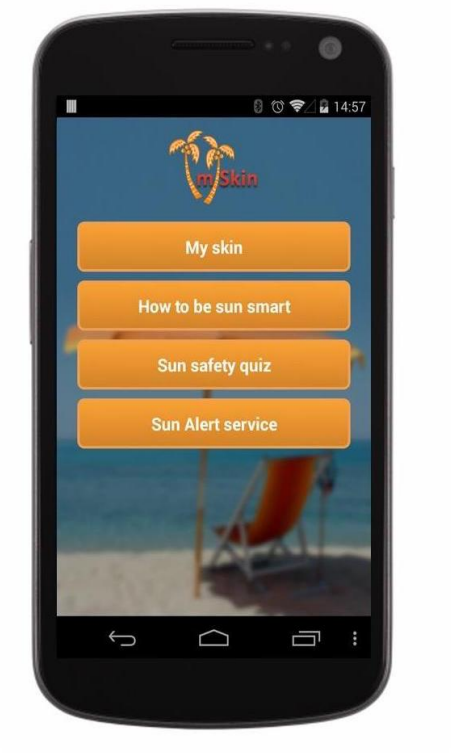
Interventions

mISkin Intervention Group

Participants randomized to the intervention group engaged in a behavioral intervention (mISkin) delivered through a mobile phone (Android smartphone) during their holiday (see Template for Intervention Description and Replication checklist in Multimedia Appendix 2). The mISkin app (Figure 1) is fully automated and was designed to promote holidaymakers' sun protection behavior by providing information, addressing appearance-related concerns (eg, ultraviolet [UV] photo), and prompting sun protection based on location (ie, global positioning system, GPS) [15]. The content of the mISkin app was unchanged during the trial. The mISkin app had four main menus: (1) *My skin*, (2) *How to be sun smart*, (3) *Sun safety quiz*, and (4) *Sun alert service*. First, the *My skin* menu assessed skin sensitivity and provided advice depending on skin type. Second, the *How to be sun smart* menu contained videos on sun protection recommendations, detailed information on how to

apply sunscreen appropriately (quantity, frequency, SPF, when to apply, where to apply, and guidance on costs), and skin damage information depicted in UV photographs. Third, the *Sun safety quiz* component engaged participants by answering questions on general principles of sun protection practices, information on positive consequences of sun protection, tanning, vitamin D, and UV index.

Figure 1. Main screen of the mISkin app.



This involved a gamification component, by which participants received performance-based rewards (ie, positive feedback and a final score message), with immediate feedback on general recommendations for sun protection. Fourth, the *Sun alert service* menu allowed participants to receive sun protection reminders. The default setting for this feature comprised a minimum of two prompts, but participants could customize these to suit their preferences (eg, times and frequency). This menu also included a self-monitoring feature that recorded sun protection from 11 AM to 3 PM.

The development of the app was based on evidence [13,14], experts' knowledge and experience, and user involvement, and the systematic and iterative development process has been detailed elsewhere [15]. The process incorporated both theory and evidence-based approaches outlined by the Medical Research Council framework [17,18], engaging users' perspectives in the development process of the mISkin app [19,20].

No Mobile App Control Group

Participants allocated to the control condition did not receive the mISkin app on their phones.

Sunscreen Sun Protection Factor

All participants received two bottles of sunscreen (Ambre Solaire, 200 mL), and they were randomly allocated to receive either SPF 15 or SPF 30. To reflect the current guidelines for sunscreen use [21], the following instructions for sunscreen use were provided to all participants: (1) participant information sheet defined SPF 15 as medium SPF and SPF 30 as high SPF, stating that there is general agreement for the need of sunscreen use with an SPF of 15 or higher (SPF 15+); (2) the sunscreen bottles provided could not be shared with traveling partners; and (3) participants were asked to use the provided sunscreen.

The sunscreen bottles used in the study had a standard label, providing information on application, other forms of sun protection, dangers of overexposure, and long term prevention of UV-induced skin damage and premature skin ageing.

Protocol Deviations

Participant feedback over the course of the trial indicated that random allocation to the distinct SPF strengths was not acceptable. Although the random allocation to sunscreen SPF continued, the protocol was amended to give participants three options: (1) SPF 15, (2) SPF 30, or (3) both. Records were kept about participant allocation acceptance and any request to change allocation.

Primary Outcomes

Acceptability and Feasibility

The primary outcome of the internal pilot trial was to assess the quality and quantity of the delivery of the trial procedures and the mISkin intervention, including (1) acceptability and feasibility of trial procedures—procedures used to recruit holidaymakers, materials provided, meeting arrangements, outcomes assessment, and group allocation and (2) acceptability and fidelity of the intervention—satisfaction and app usage.

Postholiday, face-to-face interviews were conducted to obtain detailed information regarding acceptability and feasibility of recruitment, allocation, outcome measurement procedures, and intervention components. These interviews were conducted with the first 30 participants involved in the study providing consent to be recruited to the interviews and lasting 8 to 34 min for intervention participants and 3 to 8 min for control. The analyses focused on the general feedback and main issues arising from trial procedures.

Secondary Outcomes

This section describes the variables that would be the main outcomes for the definitive trial.

Mitochondrial Deoxyribonucleic Acid Damage

Skin damage caused by UV exposure was measured objectively using a reliable epithelial skin swab to test for mitochondrial deoxyribonucleic acid (mDNA) before and after holiday. These samples were taken at baseline and follow-up. Cotton swabs were collected from sterilized skin from the nose bridge and forearm and stored in a sterile collection tube until extraction following standard procedures [22].

Sunscreen Use

Participants were given sunscreen bottles with a built-in triaxial accelerometer (AX3; time- and date-stamped) recording sunscreen application. This method has shown to have a sensitivity of 91% and specificity of 98% in detecting sunscreen use events. Due to shortage, sensors were allocated to participants on the basis of availability at baseline (N=28). Sunscreen use (quantity) was also measured by weighing bottles at baseline and posttest. The same scale (Salter, model 1234SSDR) was used for all sunscreen assessments.

Self-Reported Sun Protection Behaviors

A web-based self-reported questionnaire with seven items on sun protection was also completed by all participants. This questionnaire assessed exposure times; sunscreen, hat, t-shirt, and sunglasses usage; seeking shade; and experience of sunburn [23].

Process Variables Assessment

Participants completed a Web-based questionnaire at baseline and posttest, adapted from previous studies [24-30], assessing knowledge, intentions, attitudes, self-efficacy, social influences, and time perspective (see Multimedia Appendix 3).

Sample Size

This study was originally intended to be a full-scale definitive trial. The period until the first 30 participants to enter the study was defined as the internal pilot study.

Stopping Guidelines

The following stop rules were defined:

- If more than 10 out of the first 30 participants do not accept the group allocation, measurement procedures, or other aspects of the trial procedures or if the postholiday interviews identify any significant problems with the acceptability of the trial protocol, the protocol will either be modified to enhance acceptability and feasibility based on the insights gained, or the trial will be discontinued.
- If during this period no significant problems with acceptability and feasibility are detected, the data from the internal pilot will become part of the main dataset and analyzed as part of the definitive trial.
- If any major modifications to the protocol needed to be implemented, the data from the internal pilot will not be analyzed alongside the definitive trial.

Randomization

A simple randomization was used with a 1:1:1:1 allocation ratio to assign participants to the experimental conditions. This was performed using a telephone-based randomization service provided by a staff member independent and blinded to the identity of individuals. An independent researcher generated and administered the randomization list. Only after baseline assessment were participants assigned to experimental groups.

Blinding

At baseline assessment, the outcome assessor was blinded to allocation. At follow-up, assessors were aware of the allocation, and it was hypothesized that outcome assessors could not influence outcome measurements as these were mainly objective. Researchers conducting the lab analyses for skin damage were blinded to allocation, and samples were given a code unrelated to the trial ID. This coding was performed by an independent lab researcher.

Analytical Methods

The analyses focused on descriptive data regarding recruitment rates and attrition, as well as acceptability and participants' satisfaction with the intervention. The main aim was to test whether the proposed protocol was viable for a definitive trial.

For the secondary outcomes, the focus of the analysis was on data yield and quality. Descriptive statistics are provided for participants' characteristics and trial outcomes at baseline and follow-up.

Results

Participants

A total of 42 participants were recruited from December 2012 to October 2013. Figure 2 shows the flow of participants through the feasibility study. As seen on the flow diagram, there were six protocol deviations.

Participants' characteristics and demographics can be found in Table 1. The mean age of the participants was 35.5 years (SD 9.7; N=42), with more women participating (76% [32/42]). The majority of participants reported that they usually burn and tan minimally (35% [15/42]). The most frequent holiday destination was Spain (N=12) and lasting more than 14 days (N=15).

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) diagram for the trial.

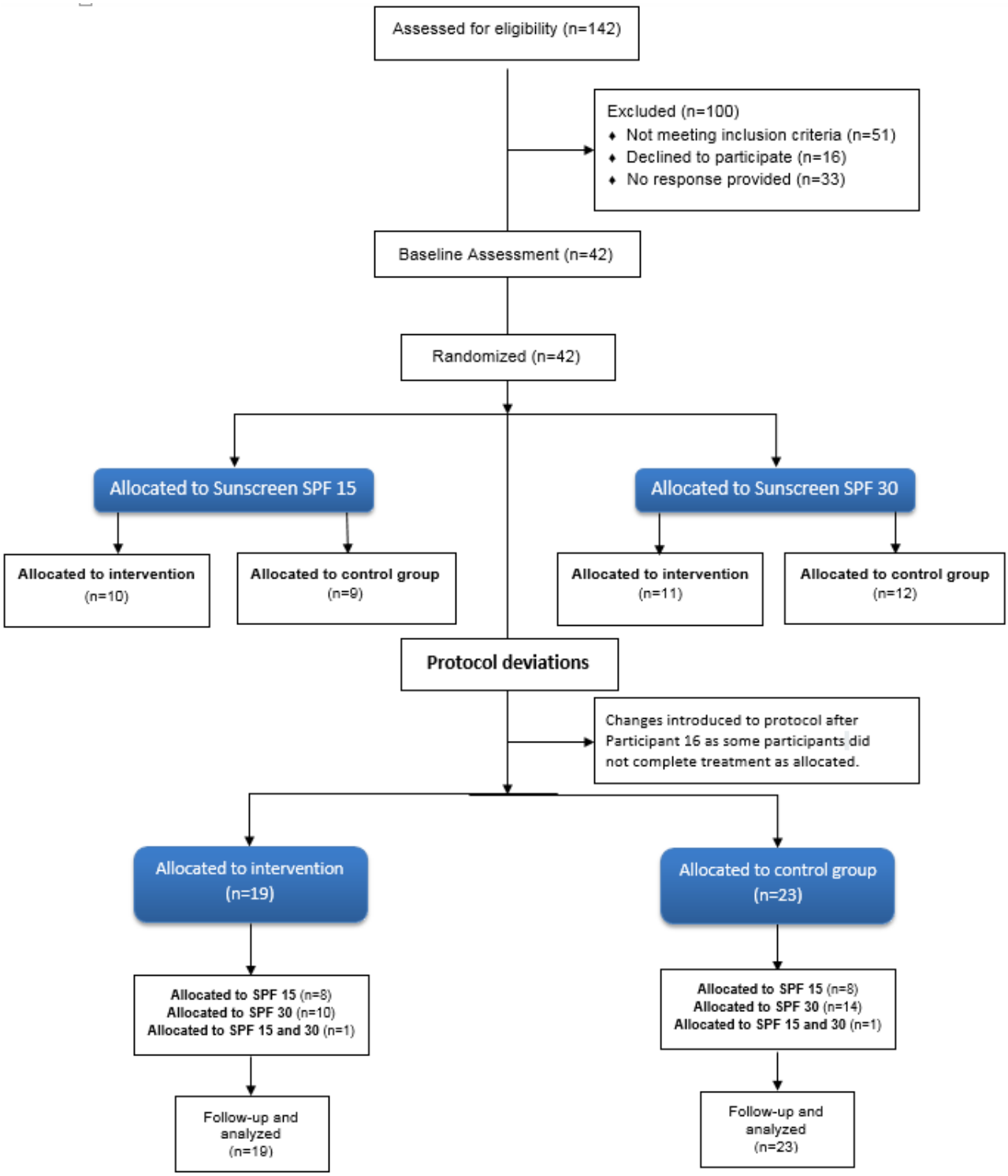


Table 1. Demographics of study participants by group (N=42).

Variables	SPF[a]15		SPF 30		Total
	mISkin app (N=10)	Control (N=9)	mISkin app (N=11)	Control (N=12)	
Age in years, mean (SD)	37.2 (11.2)	34.2 (9.1)	36.6 (9.3)	34.0 (10.1)	35.5 (9.7)
Gender (female), n (%)	5 (50)	7 (78)	9 (81)	11 (92)	32 (76)
Skin type, n (%)					
I—Burns easily, never tans	0 (0)	0 (0)	0 (0)	1 (8)	1 (3)
II—Burns easily, tans minimally	3 (30)	1 (14)	3 (33)	3 (25)	10 (26)
III—Burns and tans moderately	2 (20)	1 (14)	6 (67)	5 (42)	14 (37)
IV—Burns minimally, tans easily	4 (40)	4 (57)	0 (0)	2 (17)	10 (26)
V—Rarely burns, tans profusely	1 (10)	1 (14)	0 (0)	0 (0)	2 (5)
VI—Never burns, tans profusely	0 (0)	0 (0)	0 (0)	1 (8)	1 (3)

[a]SPF: sun protection factor.

Primary Outcomes for the Internal Pilot Study: Acceptability and Feasibility

Feasibility of Trial Procedures

Recruitment

Out of the 142 participants that registered interest, 42 (29.6%) met the inclusion criteria and provided consent to participate in this study. The main reasons for exclusion were as follows: (1) ineligible smartphone (eg, iPhone; 21.8% [31/142]) and (2) unwillingness to be randomized to SPF 15 or SPF 30 (3.5% [5/142]).

Randomization

Two breaches in the trial protocol occurred, as 2 participants were allocated to receive the mISkin app but were unable to install it because of smartphone technical issues.

Outcome Assessment

All participants consenting to participate in the study completed baseline and follow-up assessments.

Mitochondrial Deoxyribonucleic Acid Skin Damage

The skin swabs were obtained for all participants at both time points. Data on mDNA skin damage for the nose was retrieved from 34 (81% [34/42]) samples at baseline and 33 (79% [33/42]) at follow-up. Data were available for 31 (74% [31/42]) samples at baseline and 36 (86% [36/42]) at follow-up for the arm. Two reasons explain these missing data: (1) polymerase chain reaction analyses could not be computed (4.2% [7/168]; the total number of mDNA samples was 168, as a total of four samples were taken from each participant [nose and arm; before and after holiday]) and (2) samples were mislabeled during analyses and therefore lost when decoding (16.1% [27/168]).

Residual Sunscreen Weight

Sunscreen weight was available for 41 out of 42 participants at both baseline and follow-up. For one participant, a value could not be obtained because of a fault in the scale used.

Sunscreen Use Patterns (Accelerometry)

AX3 sensors measuring sunscreen-use events were allocated to only 28 participants out of 42 participants because of a lack of sensors at baseline. Reliable data detecting sunscreen use was extracted from 28 participants. Due to battery issues, data were missed at the end of the holiday period for 14 participants. Battery life lasts approximately 14 days, but sometimes the time between the initial assessment and the postholiday assessment was longer.

Self-Reported Sunburn and Sun Protection Practices

The survey was completed at baseline by 38 participants (90% [38/42]) and at follow-up by 41 participants (98% [41/42]).

Acceptability of Trial Procedures

A total of 30 interviews were conducted (mISkin app: N=13, no app: N=17), and data were collected about three main areas: consent, allocation to interventions, and assessment.

Consent

All participants stated that information received before or during enrollment was easy to understand and clear. All participants were also very positive about the arrangements made for the assessment meetings.

Allocation to Interventions

Participants were satisfied with being randomized to the mISkin app or control group. App installation was not possible because of technical difficulties in two cases. The randomized group allocation to SPF 15 versus SPF 30 was not acceptable to many participants. A total of 11 participants raised concerns about the random allocation to sunscreen SPF. From this, 10 were unwilling to be randomly allocated to SPF 15, as it was considered to be too low. Only one participant raised concerns about SPF 30 being too high. Overall, 7 people declined participation based on the random allocation to SPF.

Taking into account this information, after the initial 16 participants, the trial procedures were changed to give participants the option to choose from three options: (1) SPF 15, (2) SPF 30, or (3) both. With the introduction of this change, 6 participants chose a different SPF to what they had been

allocated to: 3 participants asked to change allocation to SPF 30 instead of SPF 15, 1 participant asked to change allocation to SPF 15 instead of SPF 30, and 2 participants asked for one bottle of each.

Outcome Assessment

The main findings for secondary outcomes with descriptive data for the total sample at baseline and follow-up can be seen in Multimedia Appendix 4.

Mitochondrial Deoxyribonucleic Acid Skin Damage

The skin swabs procedure was described as painless and made easy by the provision of information detailing the procedure. Some participants reported that it might be helpful to mention that the swabs would remove makeup.

Sunscreen Use Patterns (Accelerometry)

Participants indicated that they did not experience problems carrying the AX3 sensors attached to the sunscreen bottle. A total of 5 participants (18% [5/28]) mentioned, though, that their silicone band snapped, which in some cases led to problems in calculating data events. To overcome this, when possible, participants were given an extra silicone band and were instructed on how to fit it.

Self-Reported Sun Protection Behaviors and Psychological Variables

Questionnaires were described as being straightforward, easy to understand, and the length was considered acceptable. One participant mentioned that some questions were difficult to understand, in particular questions about social norms and skin color.

Acceptability of the mISkin App Intervention

A total of 13 participants were interviewed to collect data on acceptability of the mISkin app. However, one interview was lost because of recording problems.

Data collected showed that 6 out of the 12 holidaymakers were very satisfied with the app, 4 were somehow satisfied, and 2 were dissatisfied. All participants commented and made suggestions to improve the app (Multimedia Appendix 5).

Participants were highly satisfied with the initial skin type identification, the videos, and the *Sun safety quiz.* Participants suggested that the *Sun alert service* could be improved by having a system that is able to learn from participants' sun protection habits, preferences, personal risk, and personalize prompts according to these (eg, time until sunburn risk). A few technical problems regarding the GPS functionality to detect indoor or outdoor location were also reported. Participants also recommended that the UV level forecast should be integrated with the *Sun alert service* to create a parsimonious system. Another reported issue was the disturbance created by keeping the phone on British time (Greenwich Mean Time) so that the sensor data could be synchronized with the app log usage data. This was described as disruptive, as time shown on the phones was incorrect and led to prompts not being received appropriately.

Acceptability of the Sunscreen Sun Protection Factor

One participant allocated to SPF 15 reported being slightly sunburnt at the beginning of the holiday. Some participants allocated to SPF 30 mentioned that using this SPF prevented them from being sunburnt. Others also reported the lack of a tan after their holidays as a consequence of using SPF 30. Participants felt that they used more sunscreen than they would normally (n=7). Two participants reported using sunscreens other than the ones provided.

Fidelity: mISkin App Usage

Data about the usage of the app can be seen in Table 2. A total of 19 participants (91% [19/21]) installed the mISkin on their phones, and 18 (86% [18/21]) used it at least once during holidays (ie, logging and utilized of the app features). Rates of usage were high, with a median of 60 log-in events. The median number of cues acknowledged by participants was 9 (range: 0-43). The *Sun safety quiz* was completed by 17 participants (81%). The median number of ecological momentary assessments completed was 2 (range: 0-11).

Optimization of the Trial Procedures

The problems identified and potential changes to the trial protocol are presented in Table 3. The main change introduced was the possibility of participants choosing their SPF: (1) SPF 15, (2) SPF 30, or (3) both.

Reasons for Stopped Trial

Modification and potential improvements have been recorded in Table 3, following guidelines to produce an informed decision on the internal pilot trial [31]. Evidence gathered during the internal pilot study identified significant problems influencing acceptability and feasibility of the internal pilot that led to stop the trial early, namely the SPF allocation and improvements to the app. The trial was stopped in October 2013, and a definitive trial on the mISkin app has not been conducted. The study was part of a PhD thesis [32], and funding ran out to relaunch the new protocol.

Table 2. Descriptive statistics about the mISkin app usage.

mISkin app features	Descriptive statistics				
	Frequencies	Median	Interquartile range	Maximum	Minimum
Log-in events	—	60	63	181	3
Ecological Momentary Assessments	—	2	4	11	0
Cues received	—	17	12	47	0
Cues acknowledged	—	9	7	43	0
Videos watched	—	0	5	7	0
Videos (any), n (%)	9 (47)	—	—	—	—
Video “Protecting sensitive skin,” n (%)	6 (32)	—	—	—	—
Video “Sun protection tips,” n (%)	5 (26)	—	—	—	—
Video “Choosing a good sunscreen,” n (%)	7 (37)	—	—	—	—
Video “How to apply sunscreen,” n (%)	8 (42)	—	—	—	—
Video “Preventing damage,” n (%)	7 (37)	—	—	—	—
Video “Protecting children,” n (%)	6 (32)	—	—	—	—
Video “Other’s use of sun protection,” n (%)	3 (16)	—	—	—	—
Sun safety quiz, n (%)	17 (81)	—	—	—	—

Table 3. Main problems and changes introduced to the trial protocol.

Trial procedures and problems	Changes introduced during pilot study	Suggestions for definitive trial
Recruitment		
Initial low recruitment rate	Recruitment was scaled up (eg, by involving local councils), and holiday duration was enlarged to 3 weeks.	Alternative pathways for recruitment, such as pharmacies where people buy their holiday medicines. mISkin app to be available in different platforms (ie, iPhone operating system)
mISkin app installation problems	Standard operating procedure (SOP) was changed to fully check participants' smartphone suitability for the mISkin app installation before the randomization procedure.	—
Measurement		
Samples lost during blinding procedure	Skin swabs blinding SOP was changed to ensure that trial number can be fully retrieved by keeping the original skin swab package where both trial number and new labeling is written.	—
Samples lost because of incorrect labeling during analyses	Skin swabs samples labeling SOP during lab analyses was changed to ensure samples have a more meaningful label (ie, date plus numbers from labeling procedure will not conducted more than 24 samples per day). SOP also now recommends that lab analyses are conducted in sets of 24 samples to prevent tiredness of the researcher and potential mistakes.	—
Loss of accelerometer data on final days of holiday	—	Important to keep the time between baseline and follow-up assessments constant as battery life of accelerometers only lasts up to 14 days.
Randomization		
Random allocation to SPF 15 or SPF 30 reported as problematic	SOP and materials were changed to give participants the possibility to choose form three options: (1) two bottles of SPF 15, (2) two bottles of SPF 30, or (3) one bottle of SPF 15 and one bottle of SPF 30.	A preference design trial might be appropriate. Alternatively participants could be given the possibility of buying their own sunscreen (eg, voucher for high-street retailer).
Intervention		
The need to keep phone time on British time (Greenwich Mean time) reported as problematic	SOP was changed to allow participants to keep their time preference on their smartphone. Data from sensors will be analyzed taking into account details provided by participants on the holiday location and local time.	—
Suggested changes to mISkin app (interviews)	—	Improve *Sun alert service* by having a system that is able to learn participants' sun protection habits and preferences. Ultraviolet levels forecast information should be integrated with the *Sun alert service.*

Discussion

Principal Findings

This study described an internal pilot study aimed at testing acceptability and feasibility of the trial procedures and the mISkin app. The internal pilot study revealed potential issues on participant recruitment, acceptability of the randomization to participants, and features of the intervention. A list of possible solutions to the problems identified within pilot and feasibility RCT was mapped (Table 3) following the algorithm for *decision making* after pilot and feasibility trials guidelines [33].

Despite most trial procedures being considered acceptable and feasible, the random allocation to SPF 15 versus SPF 30 was found not to be feasible in a definitive trial protocol. During the internal pilot, the SPF allocation procedures were modified to improve acceptability of participants' allocation. A preference design trial based on a participant's preference regarding sunscreen SPF could be a possible solution for a definitive trial.

Regarding the feasibility of recruitment, this was limited by the inclusion requirement to own an Android smartphone. Several participants were excluded because they owned other smartphones, showing the need to improve the interoperability of the mISkin app in a definitive trial. The relatively low rate

of recruitment could also be improved by diversifying the pathways of recruitment (eg, pharmacies).

The key issue reported about the mISkin app was the *Sun alert service*, and future revisions of the app should consider improving this feature. The need for more intelligent and interactive systems has been reported previously [34]. The study by Buller and colleagues [35] also shows that participants were interested in a system that would (1) display how long they could be exposed to the sun without burning (including vitamin D synthesis), (2) show daily UV levels, (3) advice on recommended SPF, and (4) send prompts to reapply sunscreen. Nevertheless, such a system would need to tackle some of the uncertainties related to vitamin D synthesis and sunscreen use. The estimation of time needed to synthesize vitamin D is a complex and challenging calculation influenced by various factors, including skin type, age, body fat, genetic factors, lifestyle, sun protection, solar zenith angle, and atmospheric conditions [36,37]. For sunscreen, most calculations rely on the assumption that people apply the recommended amount (2 mg of sunscreen per $cm^2$of skin surface) to achieve the labeled protection [38,39]. However, evidence suggests that individuals tend to apply less than the recommended amount [14,40], dramatically reducing its protective features. In addition, NICE [41] does not recommend any specific amount of sunlight exposure to stimulate vitamin D production, only stating that longer periods of exposure may be needed for those with darker skin [21].

Comparison With Other Studies

Sun protection information delivered via a purpose-designed mobile phone app was feasible, attractive, and convenient, and usage was high with 86% using it at least once during holidays. Users were particularly interested in the *Sun alert service*, highlighting the value of receiving prompts and advice in convenient place (eg, holiday setting). These findings, although preliminary, are very promising and align with those found in other investigations of mobile apps to promote sun protection, in which usage and acceptability have been similarly demonstrated [11,12,35]. The systematic and iterative development of the app [15] and the theory-driven nature of the app [42], including active components shown to be key in interventions promoting sun protection [13], may have led to greater usage. Further research is required to assess whether the mISkin app can successfully change sun protection behaviors and to identify factors that can contribute to the uptake of the app. As it is easy and convenient to receive advice, delivering sun protection information via a mobile phone app is a promising alternative or addition to existing skin cancer prevention interventions.

Overall, sunscreen use was low in this study, with an average daily use of 14.46 g. This is a special concern if the average exposure time of 5.36 hours per day is taken into consideration. The guideline for sunscreen application thickness is 2 mg/cm^2 [43]. According to Diffey [44], a full body application will consist of 35 g of the sunscreen (ie, one-third of a bottle). In line with our findings, a study conducted by Nicol and colleagues [40], with 364 beachgoers, shows that the daily amount of sunscreen used was 7.67 g/day and 9.33 g/day for the intervention groups. Rodrigues and colleagues [14] also showed that participants used less than the recommended sunscreen amount (1.34 mg/cm^2) in an experimental setting. Future preventive strategies should provide more explicit instructions of sunscreen application thickness, possibly relating to practical examples (eg, “as much as a golf ball or a full shot glass” for whole body coverage).

Even though the use of gamification within the mISkin app is original, more efforts could be made to make this feature more engaging. Gamification can be defined as the use of gaming elements in a nongaming context to foster motivation [45]. Two core ingredients of gamification (linked to behavior change techniques) were used in the mISkin app: reinforcement and progress comparison. A key aspect of gamification is the concept of rewards that promote continuous participation, promoting not only engagement, but also behavior change [46]. Gamification applied to digital health has the potential to make the interventions more fun and engaging [45]. Recent findings have shown the potential of health apps to change behavior though gamification [47-49]. The current quiz has a set of questions that, despite allowing participants to go through it several times, does not change. A possible way to make this more attractive and further “gamify” would be to use gaming principles more systematically, such as allowing users to gain points every time they reapply sunscreen; or engage with app features; or by gradually increase the difficulty of the quiz (ie, different levels to increase challenge) [50].

Strengths and Limitations

This paper describes the efforts in addressing the main challenges identified in a previous systematic review on sun protection interventions: (1) poor reporting of intervention development, design, and contents; (2) poor outcome measurement; and (3) poor study methodology [13]. The tested intervention was developed based on the most recent evidence base available [13,14], and the development process followed a systematic approach, with a thorough report of the process and description of intervention [15]. In addition, the use of digital technologies followed the most recent advances in the area of behavioral science, with a close involvement of users in the design and development of the app [51]. The use of a combination of biologic, technological, and self-report outcome measures to understand and assess sun protection also provided a step forward in the field. Finally, the mISkin intervention was subject to intensive pilot testing, following the preregistered methods of a definitive trial. The methodology implemented aims to reduce the risk of bias by using robust procedures of blinding, allocation concealment, and intention to treat.

The process evaluation alongside the internal pilot trial is also a strength, as it provides relevant information on the mISkin intervention acceptability and how the trial procedures could be enhanced. However, the findings should be interpreted in the context of the study limitations given the nature of the study (ie, feasibility study), and some caution should be taken in generalizing these results.

The feedback on the app and trial procedures was collected through face-to-face interviews and could have introduced bias

to the self-reported acceptability of the intervention and trial procedures. The possibility of measurement reactivity was also a concern, especially considering the comprehensive list of self-reported outcomes used. A recent systematic review on the topic [52] did not find any study assessing question-behavior effect on sun protection behavior and concluded that the "question-behavior effect" on health-related behavior is small and was therefore not considered when designing the protocol.

The amount of sunscreen provided might have not been enough, as it is possible that participants inferred (incorrectly) that by giving them 2 bottles (2 x 200 mL) this amount would be sufficient for their whole holiday, and therefore they tried to eke it out. The app highlighted that sunscreen should not be the first line of defense and targeted other forms of sun protection, such as wearing protective clothes and avoiding sun exposure at midday [4].

For practical reasons and resources available at the time of this study, the UV photos shown in the mISkin app were not personalized. Recent evidence suggests the importance of appearance-based beliefs and how interventions should aim at tackling those by showing personalized UV photos that depict damage [13,53,54]. Future studies should explore whether the effects of visualizing nonpersonalized UV photos are equivalent to personalized UV photos.

Unfortunately, this study faced considerable challenges in recruitment. Despite several attempts to involve high-street travel agencies and the local airport, the involvement of a gatekeeper to facilitate the access to holidaymakers was unsuccessful. It took several contacts to reach the relevant decision makers, and many highlighted that the aim of the study to promote sun protection would conflict with their products. This is consistent with other studies that have encountered similar difficulties when involving tourism industries [55,56].

Conclusions

This paper summarizes an internal pilot and feasibility RCT, testing the acceptability and feasibility of the trial procedures and the newly developed mISkin app. The evidence-based intervention was highly acceptable to participants, but the recruitment strategy and allocation to SPF 15 versus 30 were not feasible. This pilot study offers potential solutions to inform the trial procedures of a future trial and to improve the mISkin app, namely the possibility of participants choosing their sunscreen SPF, using alternative pathways to recruit holidaymakers (ie, pharmacies), and upgrading the interoperability of the mISkin app.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Schedule of events for the trial, including enrolment, interventions, and outcome assessments.

[PDF File (Adobe PDF File), 33KB - derma_v1i1e1_app1.pdf]

Multimedia Appendix 2

Template for Intervention Description and Replication checklist.

[PDF File (Adobe PDF File), 36KB - derma_v1i1e1_app2.pdf]

Multimedia Appendix 3

Web-based questionnaire.

[PDF File (Adobe PDF File), 89KB - derma_v1i1e1_app3.pdf]

Multimedia Appendix 4

Main findings for secondary outcomes with descriptive data.

[PDF File (Adobe PDF File), 60KB - derma_v1i1e1_app4.pdf]

Multimedia Appendix 5

Feedback on the mISkin app provided by participants in the internal pilot study.

[PDF File (Adobe PDF File), 63KB - derma_v1i1e1_app5.pdf]

Multimedia Appendix 6

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 525KB - derma_v1i1e1_app6.pdf]

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Abbreviations

AX3: triaxial accelerometer
GPS: global positioning system
mDNA: mitochondrial deoxyribonucleic acid
NICE: National Institute for Health and Care Excellence
RCT: randomized controlled trial
SMS: short message service
SPF: sun protection factor
UV: ultraviolet

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Original Paper

Social Media as a Platform for Information and Support for Melanoma Patients: Analysis of Melanoma Facebook Groups and Pages

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Abstract

Background: Social media is increasingly used as a source of health information and is useful for information exchange and patient support.

Objective: The aim of this study is to describe the Facebook groups and pages that are available for melanoma patients.

Methods: A systematic search of Facebook groups and pages was performed using the word “melanoma.” The first 50 pages found in the search, sorted by most relevant, were analyzed for several characteristics, namely page name, category, verification status, number of likes, number of followers, visitor posts per week, page posts per week, ability to donate, date of inception, and for-profit or nonprofit. The first 50 groups found in the search, sorted by most relevant, were analyzed for name, category, number of members, and privacy setting.

Results: There were 669 pages and 568 groups related to melanoma found on Facebook. The first 50 pages had a combined total of 266,709 likes and 257,183 followers and, of these, 30% (15/50) were verified by Facebook. Within the analyzed Facebook pages, the average number of visitor posts per week was 0.48, the average number of posts by the page per week was 5.6, and the most common page categories were community and nonprofit. Of the 50 groups analyzed, 18 were public and 32 were private (closed). The total number of combined group members in all 50 groups was found to be 23,047 and 52% (26/50) of the groups were categorized as support.

Conclusions: Melanoma pages and groups on Facebook reach a large portion of the population. To provide resources for the population of patients diagnosed with malignant melanoma and ensure that proper information is distributed, physicians and health care organizations may consider using Facebook as a platform to support and educate patients with melanoma.

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KEYWORDS

Facebook; melanoma; online health information; patient education; support; health promotion

Introduction

According to the Centers for Disease Control and Prevention, approximately 61% of US adults have searched for medical information online [1] and due to cost, convenience, and accessibility factors [2], patients search the internet for information regarding medical conditions more often than they communicate with their doctors [3]. In addition, some patients believe that the information on the internet is better than that provided by physicians [4].

In recent years, social media websites have emerged as an easily accessible source of health information [5,6] and social media is used by 39% of US adults to obtain health-related information [6]. Social media allows users to generate and share content with internet users across the world. Social networking sites have become a source of information on awareness, treatment,

and updates regarding medical illnesses [7]. Furthermore, social networking websites allow for the creation of online support communities and create platforms to engage patients in discussion about medical conditions [7]. Facebook is one of the most popular social networking websites with nearly 2 billion active users [8]. Facebook allows users to create, share, post, and react to information. It is reported that Facebook is the fourth most popular source of health information in the United Kingdom [6]. A unique feature of Facebook is the "group" functionality, which has been defined as a space created by users to form a community of people to promote, share, and discuss a topic [9]. Another feature of Facebook is a "page" which is designed for brands, businesses, organizations, and public figures to create a presence on Facebook [10].

Skin cancer is the most common malignancy in the US and malignant melanoma is responsible for the most skin cancer related deaths [11]. The incidence of malignant melanoma is increasing worldwide and is associated with increasing health care costs [12]. Previous studies have evaluated the utility of Facebook groups in providing health education for hypertension and diabetes patients [9]; however, to date, there is no literature on the use of Facebook groups and pages by skin cancer patients, specifically those afflicted by melanoma. By gaining a better understanding of the use of Facebook for patient education, physicians, and health care organizations may be able to better utilize Facebook as a platform to support and educate patients diagnosed with malignant melanomas.

Methods

On May 23, 2017, a systematic search of Facebook in the groups and pages categories was performed using the word "melanoma." Groups and pages found in the search but were unrelated to malignant melanoma were excluded from this study. By default, Facebook provides search results by most relevant and the first 50 pages and 50 groups sorted by this method in the search results were selected for analysis in this study. The following information for each page was collected and analyzed: page name, category, verification status, number of likes, number of followers, visitor posts per week, page posts per week, ability to donate, date of inception, and for-profit or nonprofit. For each group, the following information was collected and analyzed: group name, category, number of members, and privacy setting.

Facebook pages and groups have categories identified by the relevant administers that define the main purpose of the page or group. The verification status of a page is determined by Facebook to let users know the page is authentic for a given public figure, organization, or brand. The "like" feature allows users to receive updates about a page and, if a user "likes" a page, this is displayed to their Facebook friends on their home page. The "follow" feature allows users to only receive updates from a page. The visitor posts used in this study were the posts designated under the visitor section on the Facebook pages analyzed between April 19, 2017 and April 26, 2017. The number of page posts defined in this study was the number of posts created by the page in the week of April 19, 2017and April 26, 2017. The "ability to donate" is a feature of a page that allows users to send money to the organization that created the page. The date of inception (defined as the date of inception of the organization if the page is representing an organization, or the date of inception of a page in the absence of an organization) and the type of organization (for-profit vs nonprofit) was determined by the start date and information listed on the pages' "About" sections. For the groups found in the search and analyzed, information about the number of members, privacy setting (either public or closed), and type of group was collected.

Results

Our search returned a total of 669 Facebook pages and 568 Facebook groups related to malignant melanomas. The first 50 pages had a combined total of 266,709 likes and 257,183 followers. Other features of the pages were analyzed, and Table 1 summarizes the general characteristics of the Facebook pages in this study. Of the 50 pages used in the study, 15 were verified by Facebook, 14 pages had the ability to donate feature enabled, and when the organization type was analyzed, it was found that there were 8 for-profit and 23 nonprofit pages, while the remaining 19 did not specify. For each page, the average number of visitor posts per week was 0.48 and the average number of posts by the page per week was 5.6. The categories of the pages (N=50) were classified as follows: personal blogs (n=4), community (n=12), health and wellness (n=3), nonprofit (n=11), charity organizations (n=5), medical research centers (n=2), legal companies (n=2), medical and health (n=2), medical center (n=1), mental health service (n=1), hospital (n=1), event (n=1), public figure (n=1), cause or awareness (n=1), health care administrator (n=1), organization (n=1), and medical company (n=1).

Of the 50 groups analyzed, 18 were public and 32 were private (closed) and the combined number of group members across all 50 groups was 23,047. The groups were classified according to type as follows (N=50): support (n=26), awareness (n=6), fundraising (n=6), personal blog (n=4), advocacy (n=1), and not listed (n=7).

Table 1. Number and Percentage of Characteristics of Melanoma Facebook Pages (N=50).

Characteristic	n (%)
Category	
Personal blog	4 (8%)
Community	12 (24%)
Health and Wellness Website	3 (6%)
Nonprofit	11 (22%)
Charity Organization	5 (10%)
Medical Research Center	2 (4%)
Legal Company	2 (4%)
Medical & Health	2 (4%)
Other	9 (18%)
Verification Status	
Verified	15 (30%)
Not-verified	35 (70%)
For-profit or nonprofit	
For-profit	8 (16%)
Nonprofit	23 (46%)
Unspecified	19 (38%)
Ability to Donate	
Yes	14 (28%)
No	36 (72%)

Discussion

With an increasing proportion of the population relying on social media for health information, it is necessary to understand how social networking websites are used for health information and communication. In this study, we found that there are over 600 pages and 500 groups on Facebook related to melanoma. There were a variety of different categories of Facebook pages, with community and nonprofit organizations being the most common, and these pages have an average of 5.6 posts per week. Since every like on a page suggests a visitor to that page, and since a user's Facebook friends will then see that the page was liked in their own feed, the 266,709 likes observed from the first 50 pages suggests that many people viewed these melanoma pages and that health care providers and organizations can potentially utilize Facebook pages to provide educational materials for a wider audience. The Center for Disease Control and Prevention estimates that comprehensive prevention programs could reduce the number of melanoma cases by nearly 230,000 and cut costs for melanoma treatment by US $ 2.7 billion over a 10-year period [13]. Facebook pages can also serve as a tool for patient empowerment and allow for communication with physicians and other patients. Given the high volume of posts, it is imperative that the information provided is accurate and aligns with the advice of medical professionals. One method to prevent false information could be to have page administrators consult dermatologists or have dermatology departments create Facebook pages to educate patients.

In addition to providing health information, Facebook is a source of support for patients. Online communities have been shown to provide patients with a safe space to discuss sensitive topics [14]. In our study, we found that 52% (26/50) of melanoma Facebook groups were formed primarily for support. Groups not only contribute to social support, but informational, emotional, and esteem support [3]. Melanoma patients can suffer from anxiety, social withdrawal, and denial [15] and online support groups could be therapeutic. Of the groups analyzed, 64% (32/50) were closed (private), allowing users to have a private space to communicate about their health. In addition to emotional support, Facebook groups are also used for awareness, fundraising, and personal blogs. Facebook groups are therefore s another avenue for unregulated health care information to be provided over the internet. The inclusion of dermatologists in Facebook groups may be beneficial to ensure there is no misleading or incorrect information provided within the group. One limitation of our study is the small sample size of groups and pages, selection bias, and lack of information regarding the nature of posts in each page.

Future studies should examine more closely how patients are able to interact in these platforms and their experience with Facebook groups and pages.

Conflicts of Interest

None declared.

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