7/21/2020

IRB Protocol

Study Title: Social Media Indoor Tanning Study

NCT03834974

IRB-1 Study Protocol

Protocol Version # and/or Date: 7/14/2020

Study Protocol Title: Social Media and Young Adults Intervention Phase

Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes.

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes.

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes.

Research Plan

Purpose/Introduction: *[State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.]*

Please note that this protocol is for the pilot trial, aim 3, in the grant application SPS 180816 "Using a Narrative-Based Approach to Reducing Indoor Tanning". The development phase, aims 1 and 2, was submitted and approved under protocol # H17-305.

Indoor tanning is a risk factor for the most prevalent cancer in the US. Skin cancer is the most prevalent cancer in the US, and incidence of melanoma, the deadly form, has doubled since 1973.[1] A recent study revealed we now have more cancers related to indoor tanning than tobacco.[2] Indoor tanning increases risk for melanoma,[3,4] which is, as a result, the most common cancer in women aged 25-29.[5,6] A population-based study of US adults

[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

found that 6.5% of women and 1.7% of men have tanned indoors in the past year.[7] However, young women have the highest rates (14%). A recent study revealed that 20% of college students had used a tanning bed in the last year.[8] In 2014, the Surgeon General's Call to Action to Prevent Skin Cancer emphasized the need to reduce harms from indoor tanning with targeted messaging efforts.[9]

Health messaging doesn't work. In a recent study, 99% of indoor tanner surveyed were aware that tanning can cause skin cancer and premature aging, which suggests that educating tanners about the risks is not changing behavior.[8] The majority (83%) of participants agreed that tanning makes them more attractive and 83% said tanning helps them relax.[8] The immediate desirable consequences of tanning seem to override concerns about future consequences to health.[10] Researchers have moved toward messaging related to the appearance-damaging effects of UV exposure (e.g., premature skin aging and wrinkling) in combination with health risk messaging, with modest results.[11,12] Two limitations of previous research are 1) appearance messaging still focuses on long-term consequences (e.g., wrinkles) and 2) researchers pay tanners to review intervention content which lacks real world applicability.[11,12] Interventions that persuasively increase the salience of the negative immediate consequences of tanning and in a way that engages tanners might be more impactful. Our proposal addresses these issues.

Tanners' tweets reveal immediate negative consequences. Our previous research shows that women who tan indoors use social media at higher rates than their peers.[13] We content analyzed 1000 tweets that included the words "tanning bed" or "tanning salon." Most of these tweets (71%) clearly indicated the user engaged in indoor tanning. Many tweets (57%) expressed positive sentiment about tanning, but 31% described negative experiences including unexpected burns, deceptive business practices, injuries (e.g., swollen eyes), bad odors, unsanitary conditions, and peeping Toms. Incorporating narratives about these everyday negative tanning salon experiences in an intervention may more effectively impact tanning than an intervention that focuses on long-term consequences. Negative experience narratives could shift attitudes around the desirability of tanning by associating tanning with real life imagery that generates disgust (i.e., unsanitary conditions), distrust (i.e., deceptive practices), and anxiety (i.e., being spied on while naked). This is consistent with recent laboratory-based research that showed that graphic and loss-framed messages are effective in increasing tanner's motivation to quit.[14]
We recently conducted focus groups of 15 tanners to explore messaging they would find compelling. They urged us against both health and appearance messages but instead to capitalize on content that would make them angry or rebellious, and they specifically mentioned tanning salon deceptive practices. We propose an intervention that uses real negative experience tweets by tanners as conversation starters about the costs vs benefits of tanning. To balance the negative, we will also include tweets that share the positives of quitting tanning and using UV alternatives like spray tans or bronzing makeup in an effort to shift attitudes about these. Tanners who see similar others making the decision to quit or switch to alternatives might be moved to follow suit. Our first aim is to identify search terms with high precision for identifying this content on Twitter so that it can be leveraged in the intervention.

Transportation theory[15] as a framework for persuasion. Transportation theory suggests that one's behavior is governed by stories about one's life,[16-19] and to the extent that a person is transported into a narrative or story, it can affect their beliefs.[20] Young adults convey personal stories to their social media audience every day. These narratives may be more persuasive than conventional messages from organizations/professionals[110] because when individuals identify with characters in a story the narrative shifts their thinking and behavior.[115-122] Research also reveals that the persuasive impact of social media posts in young adults is associated with how similar the user perceives themselves to be to the individual who made the post.[21]

Social marketing theory as a framework for engagement. Social marketing theory is a framework to design, implement, and evaluate social media-delivered content.[22] Social marketing theory suggests that effective campaigns must package information in a manner that will be accessible, digestible, and engaging to a target audience. Social media facilitates audience awareness via repeated messaging, i.e., "saturation." Image advertising is used and involves pairing a "product" with recognizable images and ideas to create a favorable setting for product promotion. Image advertising stimulates audience interest which increases the likelihood that

new information will be consumed. Using this theory as a guide, a Twitter feed will be created that includes content from sources recognizable to the target population (e.g. magazines, fashion blogs).

Real world implementation plan via the Skin Smart Campus Initiative. The PI is co-chair of the *Indoor Tan-Free Skin Smart Campus Initiative*, a program modeled after the *Tobacco Free Campus Initiative*, and commissioned by the National Council for Skin Cancer Prevention in 2016 (See Letter of Support).[23] Our mission is to encourage universities to adopt a policy that prohibits tanning beds on campus, severs relationships with tanning businesses (e.g., as cash card vendors), and provide education to their student bodies. Three universities (total enrollment= 70,775) have already adopted the policy-- East Tennessee State University, University of North Florida, and Temple University (pending). Our team is actively engaging others with a goal of >2-3 campuses/year. We have an opportunity to leverage these relationships to engage their students in a social media feed produced by this line of work. To remain in good standing as a Skin Smart Campus, they must provide education and this feed is how we can help them accomplish that goal. We have a letter of support co-signed by our current campuses showing their support for our mission of eventually using this feasibility work to inform a randomized trial, followed by an implementation plan targeting their campuses.

Preliminary Studies.

Team. Our interdisciplinary team is well-equipped to do this research by including a behavioral scientist with expertise in skin cancer prevention and social media delivered interventions, an epidemiologist/biostatistician with experience analyzing social media data, a computer scientist with experience analyzing social media data, and a dermatologist with media messaging experience.

What messaging strategies do indoor tanners find compelling? Female tanners (N=15; 87% Caucasian; mean age=22) participated in 2 focus groups conducted by Dr. Linos (consultant) with consultation from the PI. Tanners were asked to discuss the credibility of various message sources (e.g., peers, celebrities, public health organizations), to suggest persuasive messaging approaches, and critique a set of messages. Tanners said they have more trust in messages coming from peer or celebrities than from organizations like American Cancer Society. They avoid messaging that makes them sad (e.g., narratives about cancer deaths), or that attempt to exert control over their behavior (e.g., restrictions/laws). They preferred messages that make them feel in control and those that generate anger and defiance such as those focusing on shady industry tactics as long as they are factual.

Do tanners tweet about their tanning? Study 1: We used the Twitter Streaming API to collect in real time all tweets mentioning indoor tanning, tanning bed, tanning booth, tanning salon, sun bed, or sunlamp, over 2 weeks.[24] Over 154K tweets mentioned indoor tanning, or 7.7 tweets per minute, suggesting this is an oft tweeted topic. **Study 2:** All tweets in 2013 containing search terms for both indoor tanning (e.g., tanning bed) and burns (e.g., burn, fried) were extracted by a social media monitoring firm (Olytico; Dublin, Ireland). Each tweet was assessed to determine whether an indoor tanning burn is described. A total of 16,827 described indoor tanning burns. Tweets included descriptions of peeling (n=53), blistering (n=10), skin purpling (n=12), as well as inability to sleep (n=125), sit (n=103), or move (n=85). Findings reveal that reports of tanning bed burns/injuries are plentiful on Twitter. **Study 3.** We used NVivo to extract unique tweets using the terms "tanning bed" or "tanning salon" over a 7-day period (N=4,691) to learn about the full range of experiences tanners report. We randomly selected 1,000 tweets for content analysis. Tweets (n=1,000) were posted by 978 unique accounts. The majority of tweets (71%; N=699) were clearly by tanners. Themes included: tanner expressing positive sentiment about tanning (57%), tanner sharing a negative experience (32%), and tanner reporting sleeping in a tanning bed (9%). Negative experiences included burns/injuries, unsanitary conditions, poor results, being lied to by employees about pricing or likelihood of getting burned, and privacy violations (e.g., being walked in on while unclothed).

Aim: We will conduct a pilot randomized feasibility trial (N=60) comparing a 1 month sun safety social media intervention to a healthy lifestyle social media intervention. Our outcomes include recruitment, retention, acceptability, participation, message engagement (likes, replies), and message dissemination (retweets, shares, impressions). We will describe changes in outdoor tanning, unprotected sun exposure, sun protection (sunscreen, protective clothing), burns, tanning intentions, and desirability of a tan during the one month intervention period as exploratory outcomes.

For EACH Participant Population State the Number of Participants to be Enrolled and Screened and/or the number of participant records reviewed (including, HIPAA covered health records and FERPA covered school records)*, if applicable: [State the total number of participants/records to be enrolled and, if enrolling more than one participant population, describe the total enrollment for each. Tip: consider attrition and the number of participants who may fail screening. Use of a range may provide flexibility. Note that the range must be justified in the* ***Justification of Sample Size section below****.]*

We plan on enrolling 60 indoor tanners to complete the pilot trial. Since we are recruiting online, we anticipate screening a total of 1000 participants to achieve this goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants.

Justification of Sample Size*: [For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.]*

The purpose of this pilot is to assess intervention feasibility. Leon, Davis, & Kraemer (2011) state "power analyses should not be presented in an application for a pilot study that does not propose inferential results".[25] As they and others recommend,[25,26] we based a sample size of 30 per group on necessities for examining feasibility.

For EACH Participant Population State Describe the Study Population(s)*: [Describe the participant population(s) including gender, ethnicity, income, level of education and age range.]*

We are recruiting women and men in the United States who are ages 18-30, report to have used tanning beds at least once in the past year, are likely to tan outdoors this summer, and who is a regular user of any social media platform (on most days of the week).

Enrollment of UConn Students and/or Employees*: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees report to any key personnel. For each group, explain why this population is necessary to the study. Tip: convenience is not sufficient justification.]*

We will be recruiting women and men 18 and 30 from states in the US that have an averages temperature of ≥75 degrees in May. UConn students and employees may be enrolled if they meet eligibility requirements and are interested in completing the study. Since it is not essential that we recruit students and employees directly reporting to key personnel on this project, we will exclude them from participation.

Enrollment of Key Personnel, Spouses or Dependents/Relatives*: Will study key personnel, spouses of key personnel, or dependents/relatives of any key personnel be enrolled in the study? If so, describe and provide justification.*

No.

For EACH Participant Population Describe Recruitment Methods: *[Specify each method and describe specific procedures for how participants will be identified and recruited. Attach copies of all advertisement/recruitment materials for IRB review. Describe how UConn Students/Staff and Key Personnel/Spouses/Dependents/Relatives will be identified and recruited, if applicable.]*

We will focus our recruitment in locations that have an average temperature > 75 in May. These states include: California, Arizona, Oklahoma, Texas, Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Kansas, Missouri, Delaware, and Hawaii. A survey link will be included with our recruitment materials. Participants will be instructed to complete the survey to be considered for the study and will be recruited using the following online strategies:

- Google ads that appear when users search the words related to tanning;
- Social media posts on Facebook, Instagram, and Twitter;
- Connect with large businesses to get our ad and/or flyer emailed to their staff and students;
- Posts on Craigslist
- Other online sources as appropriate
- Having participants refer their friends and/or family in the study

Recruitment ads will describe the study based on the topic of interest (e.g. beauty) and will employ strategies for attracting tanners as suggested by focus groups.

A portion of our participants will be recruited from Qualtrics, a recruitment panel company. These participants will also complete the initial survey required for eligibility. Emails of eligible participants will be given to our staff from Qualtrics along with their initial survey data.

- On the first page of the survey, they will read a brief introduction about this project and if they complete the survey, they will receive Qualtrics incentives regardless of participation in this trial.
- If they decide to hear more, they will click forward to the next page, which will be our information sheet.
- If they would like to participate in the trial after reading that sheet, they will click forward to the next page and start the survey.
- Participants who provide their email will be contacted by the study team for the telephone screening.

For EACH Participant Population Describe Screening Procedures, if applicable: *[Describe when participants will be screened and how this will occur. Include copies of all screening forms and related documents. Describe procedures to notify participants of the screening result, if applicable. Provide a copy of the screening instrument.]*

Participants will complete screening procedures online and over the phone since they will be non-local to UConn. . We will focus our recruitment in locations that have an average temperature > 75 in May. These states include: California, Arizona, Oklahoma, Texas, Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Kansas, Missouri, Delaware, and Hawaii.

We will post online recruitment ads which will contain a link to an online 5-minute survey containing the initial screening questions. The survey will first have a description of the study and will then have the eligibility questions. The participants recruited by Qualtrics will also complete this initial survey. If they are eligible to proceed they will be contacted by the study team to book a 10-minute telephone screening call to review the consent. Afterwards they will be emailed a 15-minute online baseline surveys including tanning behavior, sun protection behavior, and social networking use. Participants will be randomized into two conditions, one will be assigned to a sun safety challenge and the other will be assigned to a healthy lifestyle through technology challenge.

Anticipated Study Time Frame*: [Describe the estimated time frame of the study from anticipated start to anticipated finish. If the study will occur in more than phase include these in the time frame. Use of a table is often helpful.]*

This study will take approximately 2 hours of time for participants to complete according to the breakdown below:

Visit	Time (in minutes)
Initial Survey	5 min
Telephone Screening	10 min
Baseline survey	15 min
Webinar	30 min

Intervention Approx. 10-15 min/week for 4 weeks	60 min
Follow-up survey	30 min
Total	2.5 hours

Design, Procedures, Materials and Methods: *[Describe the study design, including the sequence ll study procedures. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, clearly describe what participation will be like for each of the groups or study arms. Tip: describe procedures in the order conducted, where they will be conducted and how long they will take to complete. The IRB strongly suggests that investigators incorporate flexibility into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. Use of a table is often helpful here.*

Study design:

Overview: Participation starts with an initial survey, telephone screening, and baseline survey. Eligible participants will then be randomized to one of two conditions, complete a webinar, 4-week intervention, and an end-of-study follow-up survey.

About the intervention: During the 4-week intervention, participants will be asked to create social media posts (related to the topic of the condition). These posts will be sent to the study team who will post them in our study-lead Twitter and Facebook feeds. The sun safety challenge posts will be posted in the Skin Smart Campus Initiative feed and the healthy lifestyle through technology challenge posts will be posted in the @UConnmHealth Feed.

Randomization:

Randomization will take place after eligibility is determined and screening procedures are complete. Using the pre-programmed randomization feature in REDCap, participants will be randomized to the sun safety challenge condition or the healthy lifestyle through technology challenge stratified by gender and US region (West, Southwest, Southeast, Midwest, and Northeast). The program director will tell the research assistants who will reach out to participants to inform them of the condition assignment.

Webinar:

After randomization, participants will complete a 30-minute orientation webinar to learn how to participate. The purpose of the webinar is to educate participants about what research is, review study procedures, review importance of participation of enrolled participants, and to allow participants another opportunity to evaluate if joining this study is the right choice for them. This webinar is being conducted to improve study retention and help inform participants about the study procedures.

In the sun safety condition, they will learn about the Skin Smart Campus Initiative and its audience, how to create effective social media posts, and the type of content that would disqualify a post (e.g., one that promotes tanning or depicts the tanned appearance as desirable since these would undermine a sun safety message). We will inform them that they do not have to reveal their identity in the post, but they may use pics of themselves engaging in sun safety if they so choose. They will be informed that if other people are depicted in their post, they will need to get written permission from those people. We will show them examples of appropriate posts. Participants can choose to either have staff pick a time for their post to go out or they can pick the time themselves. We will give them the timeframe that they can choose from if they wish to do so.. If two participants select the same day and time, we will notify the second participant selecting that time slot that another post is scheduled for that time and she/he will be asked to pick a new time slot. Releasing two posts at the same time can result in both posts getting less engagement.

In the healthy lifestyle through technology condition, they will receive the same information except they will learn about the @UConnmHealth feed and its audience. We will inform them that posts should promote the use of technology to engage in healthy lifestyle behaviors including healthy diet, exercise, sleep, meditation, stress reduction, and any topic relating to physical or mental health.

Intervention: Participants will be given the name of the feed where their posts will appear. The feeds will be public which means others may follow and content can be shared by other users not in the study.
Every Monday participants will be reminded via text message to create their post for the following week and send it to the study team by Friday. They will be given access to a shared calendar to indicate their preferred day/time to for their post to appear. When a post does not meet the guidelines, we will reply to the participant with feedback and encourage them to resubmit an edited version. Participants will receive $10 Amazon gift card per post for a maximum of 6 posts. Additionally, the participant whose post receives the most engagement, defined as likes, retweets, and replies within the first 48 hours of posting each week will receive $50 Amazon gift card. The majority of engagement on a social media post occurs within 48 hours. The 48 hour time limit also allows all posts put up by Friday to have a 48 hour period of engagement before the week is over. Winners will be announced via email every Monday.

Follow-Up Assessment: Following the intervention period, participants will receive an email (in week 5) with a link to the follow-up survey which will assess indoor tanning, outdoor tanning, intention to tan indoors and outdoors, desirability of tanning and tanning alternatives, exercise and diet quality, social media use, use of health technologies, and acceptability.

[Describe study procedures for use of interviews or focus groups if applicable. Include details such as how long each procedure will take to complete, who will be asked to participate in these procedures and where these procedures will be conducted. Provide copies of interview and focus group questions/topic areas.]

[If the study includes measures, survey instruments and questionnaires (including the collection of demographic data), identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study and attach a copy for IRB review.]

Measures:

Data collected	List of Measures	Baseline	Intervention	Follow-up	Method
Demographics	Age, gender, sexual orientation, income, employment, marital status, race/ethnicity, household composition, location	X			REDCap
Tanning behavior and sun protection	Tanning behavior and sun protection	X		X	REDCap
Intentions to Tan	Intentions to Tan	X		X	REDCap
Use of tan alternatives	Use of tan alternatives	X		X	REDCap
Exercise and dietary quality*	Block 2005 Food Frequency Questionnaire	X		X	

Social media use (by platform)	Survey questions	X		X	
Use of health technologies	Health Wearable and Health App Usage Questions	X		X	
Recruitment and Retention	Number of responses, eligible, consented participants, % participants who unfollow, % who complete follow-up	X		X	REDCap
Acceptability	Survey questions			X	REDCap
Persuasive impact for each message	Transportation Scale Short Form			X	REDCap
Engagement and dissemination of intervention messages	Engagement in feeds (likes/reactions, comments/replies)		X	X	Twitter and Facebook

** Will be added to the measures attachment when it is purchased.*

[If applicable, describe the use of audiotape and/or videotape, provide justification for use and indicate if this is a requirement of participation.]

[If the study involves use of deception or incomplete disclosure, explain the reason why this is necessary to answer the research question(s). Complete the alteration of consent section below]

[Describe opportunities provided to participants to ask questions in order for them to make an informed decision regarding participation.]

Participants will review an informational page before completing the initial survey screener. The participants have the option to end the survey at any time. At the beginning of the telephone screening, staff will review the informational page and ample time will be allowed for discussion or questions.

***Data Analysis**: [For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.]*

We will use information on recruitment yield, rates, and retention to inform the recruitment strategies and timeline for the subsequent large efficacy trial. Using t-tests, we will compare the two conditions on acceptability, persuasive impact, engagement, and content dissemination. We will also describe changes from baseline to follow-up in desirability of tanning and alternatives, outdoor tanning, intentional tanning outside, sunburns, and sun protection in the two conditions.

***Inclusion/Exclusion Criteria:** [List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion.]*

Inclusion criteria: 1) Ages 18-30, 2) tanned indoors or outdoors ≥1 in the past year, 3) likelihood of indoor or outdoor tanning this summer>4 on a scale from 0-10), 4) regular user of any social media platform.

Participants will be excluded if they:

1. Do not have a smartphone;

2. Do not use a social media platform daily;
3. Did not tan indoors or outdoors at least 1 time in the past year
4. Likelihood of indoor or outdoor tanning this summer is 4 or less on the scale of 0-10
5. Older than 30
6. Younger than 18
7. Does not live in a state with an averages temperature >75 degrees in May (Must live in one of these states: California, Arizona, Oklahoma, Texas, Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Kansas, Missouri, Delaware, Hawaii);
8. Did not complete the screening procedures;
9. Are unable to provide consent due to mental illness or a cognitive impairment;
10. Does not speak English; or
11. Are a prisoner

[Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]

Participants will be withdrawn from the study if: they drop from participation or do not complete all screening procedures. Participants reporting that they would like to withdraw from the study will be given the option to withdraw from the study completely with no additional study contact.

Potential Harms/Risks and Inconveniences: *[Describe the potential risks to participants (and secondary participants, if applicable) and* ***steps taken to minimize risks*** *for each participant population. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include, but are not limited to: physical, psychological, social, legal, employment, and financial.*

Possible risks for being in this study includes release of confidential information. Tracking data will be stored electronically in REDcap, a network secure data entry program; any data on paper will be stored in a locked file cabinet; and participants will be informed that they may withdraw from the study at any time if they feel discomfort with any of the study procedures. All text messages that was sent and received between staff and participants will be deleted off of the phone at the end of the intervention. All participant phone numbers will also be removed from the study phone after the intervention ends. Any privacy-related problems will be brought to the attention of the PI immediately.

The Twitter and Facebook feeds will be public, which means others may follow it and content can be shared by any Twitter user. Status as a study participant will not be made known on the feeds. Engagement on the intervention posts will be continuously collected, stored for analysis, and monitored using computer programming and will address any issues related to privacy. A staff member will read and assess each interaction with the study feed on a daily basis. Any privacy-related problems will be brought to the attention of the PI and Co-I's immediately.

[Describe any anticipated inconveniences the participants may experience (such as: their time, abstention from food, etc.).]

Benefits: *[Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Do not include compensation or earned course credits in this section.]*

Participants may experience a benefit of reduced skin cancer risk and a healthier lifestyle

[Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children).]

Societal benefits include providing evidence to support an intervention delivery modality to help reduce indoor tanning rates and skin cancer.

Risk/Benefit Analysis: *[Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.]*

The possible risks of the study are minimal and are outweighed by the possible benefits to participants. Societal benefits include providing evidence to support an intervention delivery modality to help reduce indoor tanning rates and skin cancer.

Economic Considerations: *[Describe any costs to the participants or amount and method of compensation provided. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.]*

Economic burden to subjects includes the time needed for screening and study participation. There is no cost to participants for participating in the study. Depending on smartphone data usage plan for each participant, usage charges may incur due to increased use of texting as well as Twitter and Facebook mobile apps.

Participants will receive $10 in compensation per post for up to 6 posts. They will also have a chance of receiving $50/week for the post that receives the most amount of engagement. Participants will receive $50 for completing the follow-up survey. Additionally, we will provide participants $25 at the end of the study if they referred friends and/or family members who ended up being eligible and/or completing the study. All compensation will be in the form of an emailed Amazon gift card.

Data Safety Monitoring: *[This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies reviewed under the Exempt Criteria. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring before completing this section - http://research.uconn.edu/policies-procedures.*

Issues that should be addressed in the DSMP include the following:

1. *Frequency of the monitoring.*
2. *Who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures?)*
3. *What data will be monitored (include compliance with approved IRB protocol?*
4. *How the data will be evaluated for problems?*
5. *What actions will be taken upon the occurrence of specific events or end points?*
6. *Who will communicate to the IRB and how will communication will occur?*
7. *Describe procedures to inform the sponsor.*

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

A DSMP will be set up for this study and will convene after it is completed. DSMP reports will be produced by the program director and data manager. Reports will be reviewed by the principal investigator and a statistician then will be sent to the safety officers on the board.

Report type
Recruitment;
Baseline characteristics of the participants;
Completeness of data (visits completed, % of expected forms submitted, % of submitted forms passing edit);
Missing data;
Summary of adverse events (including duration, severity, seriousness, relatedness, action taken, resolution);
Descriptive information for each endpoint without statistical testing;
Participant retention; and
Quality control analyses for primary outcome.

Recruitment rates and adherence inclusion/exclusion criteria, and ethnic diversity goals:
Recruitment progress, inclusion/exclusion criteria, and diversity goals will be reviewed at each meeting. This review will ensure that project deadlines are being met, that participants meet eligibility criteria, and that the ethnic diversity goals outlined in the grant proposal are being met.

Adherence to study protocols:
The principal investigator will: direct creation of all study protocols and will be involved in trainings and supervision of all study staff. Quality control will be conducted in all phases of the project.

Adverse events:
Participants who report conditions during the screening phase that could create a safety concern while receiving the intervention will be excluded. Adverse events that occur during the intervention will be assessed, recorded, and followed up until resolved. Safety monitoring procedures will be documented in a standard protocol and overseen by the PI and program director. Any adverse events will be immediately reviewed by the program director. The safety officers will be informed during monthly reports for all adverse events. Serious adverse events will be communicated immediately to the safety officers. The NIH and UConn IRB be notified immediately in the event of serious adverse event. Any death of a study participant will be reported to the NIH and UConn IRB whether or not it appears to be related to the study.

The adverse event report will include a listing of adverse events including duration, severity, seriousness, relatedness, action taken, and resolution. This information will be presented unblinded. A significant increase in the rate of adverse events in one treatment group would be cause for concern for the safety of participants in the study.

Participant retention
Engagement will be recorded throughout the study. Engagement data will be provided in a report to the safety officers.

Data Security:
The databases will be maintained on UConn servers where security will be maintained through access controls. The program director will control the database and surveys and will allow access to necessary staff. Staff wanting access to identifiable data will need to: have prior IRB approval to be on the project, apply for a REDCap account, be approved by the program director, and utilize a password for login.

Data review (completeness/outliers):
Data reports will be reviewed by the data manager, project director, statistician, and PI. Reports will include completeness of data (visits completed, online engagement, % of expected forms submitted, % of submitted forms passing edit); missed visits and missing information within visits; descriptive information for each endpoint (change in weight and physical activity) without statistical testing; and quality control analyses for primary outcome (change in weight).

Privacy/Confidentiality Part 1: *[Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. Explian how long data will be kept in an identifiable format and how long de-identified data will be retained. Explain how long the master key or audio or video recordings obtained, will be kept. Consider whether keeping de-identified data will be retained indefinitely and whether participants may be contacted for a follow-up study (explain procedures to retain identifiable contact data is kept.]*

REDCap will be used for data entry and NVivo, SPSS, and SAS will be used for the data extraction. The database will be maintained on UConn servers where security will be maintained through access controls. Files will be managed by the data manager and project director, who will control user access and rights. For each user, REDCap will require a REDCap profile, username and password to enter the program. Staff will only have access to the database if the data manager has given them access. To protect research staff privacy, they will each use Google Voice to send the reminder text messages to participants. Google Voice is a free app that provides you with a phone number that is not the same as your personal number. The research assistants that have Google Voice on their phone will ensure that their phone is password protected. Also, they will not save any contact information into the Google Voice app. UConn IRB and their representatives, and study personnel will have access to the research data, as will the study sponsor if requested. When discussing the referral process to participants, we will not disclose names to either the referred person or to the person who referred others to the study. If someone is compensated for their referral, we will not tell them who it was that referred them. Participants will be assigned an ID number, which will link them to their study data. The ID number will be 3-4 numerical characters representing the number of participants in the study. PHI fields will be stored in a separate form from other data collection forms. Data will be completely de-identified once the study is complete and extraction data has been analyzed. At this time the link between participant identity and study data will be destroyed. Study data in the form of hard copies will be stored in a locked file cabinet managed by the program director and will be destroyed 3 years after completion of the study.

Data from ineligible participants:
Contact information will be stored in a file with an indication that they are not eligible. However the data collected from the screening, including reason ineligible, will be stored in a separate de-identified file.

If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained.

Be sure to state whether any limits to confidentiality exist (e.g. mandated reporting) and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data.

If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

***Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form**: [**This form IS REQUIRED for ALL studies**. The form is available here - http://research.uconn.edu/irb/irb-forms-infoed/. This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best Practices. Review the document proving tips to complete the form located at http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.*

Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent/permission Setting: *[Describe the consent/permission process including who will obtain it, where and when will it be obtained, and how much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process.*

A signed consent waiver is being requested for this study. Participants will review an informational page before completing the initial survey screener. They will have as much time as needed to review the information sheet and email/call staff with questions. They may also decide not to proceed with the survey. Consent will be reviewed during the telephone screening by research assistants/coordinators trained in the consent process.

State whether an assessment of consent/permission materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).]

Capacity to Consent: [Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]

To be able to actively participate in the study, participants must be adults without impaired decision making ability that are able to speak and read English. The consent process will include a discussion of the participants understanding of what participating in research means including their rights as a research participant, the protocol, as well as risks and potential benefits to participating in the study. If research personnel obtaining consent believes there is a concern regarding a participant understanding participation will be discussed with the program director who will determine whether to exclude the participants on this basis.

Parent/Guardian Permission and Assent: *[If enrolling children, state how many parents/guardians will provide permission, when the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained. For longitudinal studies, assent may happen at several points during the study.]*

N/A

Documentation of Consent: *[Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, parental permission sheet. child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).]*

An online information sheet will be used for the study participants. Participants will select an item on the survey after reviewing the online consent if they choose to participant or not.

Waiver or Alteration of Consent: *[The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a* ***waiver of consent*** *(i.e., participants will not be asked to give consent), an* ***alteration of consent*** *(e.g., deception) or a* ***waiver of signed consent*** *(i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]*

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception/incomplete disclosure in research):

- *Why is the study considered to be minimal risk?*
- *How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.*
- *Explain why the research could not be practicably carried out without the waiver. For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.*
- Since we are recruiting nationally, an electronic consent process is most efficient for participants and study staff. *Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens.*
- *How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.*
- *Indicate if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study.*

*Waiver of **signed** consent (i.e. , no signature, participants give consent only after reading an information sheet). Tip: if the investigator will obtain information through oral or written communication with the prospective participant or if the investigator will obtain private identifiable information or identifiable biospecimens by accessing records, then a waiver of signed consent is NOT required.,:*

We are requesting a waiver of signed consent to recruit participants across the US for an online study.

- Why is the study considered to be minimal risk?

  The study is minimal risk because it includes three brief surveys and following a social media feed. The probability of harm or discomfort from three surveys and following a social media feed is no greater than ordinarily encountered in daily life.

- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.

  No. There would not be harm to participants if identification of participants or their responses would place them at risk of liability or be damaging to financial standing, employability, insurability, reputation, or be stigmatizing. The participants are informed that they do not have to answer any questions or interact with any portion of the Twitter or Facebook feeds if it makes them feel uncomfortable in any way is free to stop participating at any time. Participants will be invited to follow the study Twitter and Facebook feeds. They will also be asked questions in the surveys regarding demographics, tanning, impact of the messages, and their acceptability of the Twitter feed, as can be seen in the measures section. None of these measures would negatively impact their financial standing, reputation, employability, or insurability. They are also informed they do not have to respond any survey questions if they do not wish to answer. The ability to review the consent online prior to the survey limits any risks of travelling to the study site for in-person consent. During the telephone screening, we ask for permission to ask questions and indicate that they may choose not to answer.

- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.

  No. We will use approved institutional data security procedures to protect this information.

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

  No.

- Describe if the participants or their legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. Not applicable to FDA Regulated Studies.

  N/A

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