PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Title: Behavioral Intervention in Reducing Indoor Tanning

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Study Protocol

Background

The use of indoor tanning beds that emit artificial ultraviolet radiation (UVR) is estimated to cause 400,000 cases of skin cancer in the United States each year and contribute to 1 in 10 of all new melanoma cases (Wehner et al., 2012; Wehner et al., 2014). Melanoma has become the 5th most common cancer in the U.S and the 3rd most common cancer among young adult women, who are the most frequent users of tanning beds (Barr et al., 2016). Although past year rates of indoor tanning among U.S. adults have declined in the past decade from 1 in 7 in 2007 to 1 in 25 in 2018 (Geller, 2018), the rate of frequent use has increased with 24% of tanners reporting tanning 25 or more times in the past year in 2018 compared to 13% in 2007 (Bowers et al., 2020). Compelling evidence from biological and psychological studies has shown that UVR exposure can have physically reinforcing effects and leads to the concern that excessive tanning may be a result of sensitivity to these addictive properties (Heckman et al., 2016; Noar et al., 2014; Stapleton et al., 2017a). Tanners who exhibit tanning addiction symptoms report more tanning-related problems (e.g., neglected responsibilities due to tanning, felt physically or psychologically dependent on tanning) compared to other tanners (Ashrafioun and Bonar, 2014; Stapleton et al., 2016), are more likely to continue to tan after skin cancer diagnosis (Cartmel et al., 2013) and report a younger age of tanning onset (Harrington et al., 2011) compared to tanners without symptoms. Despite the increasing public health importance of frequent tanning, there is a dearth of interventions designed to target this group, which is an important gap in the skin cancer intervention literature (Stapleton et al., 2017a).

Our theoretical intervention is grounded in Motivational Interviewing (MI) principles designed to motivate individuals to make changes in addictive behaviors (Miller and Rollnick, 2012). A fundamental MI principle is that individuals who engage in risky behavior like tanning experience a natural state of behavioral ambivalence, which is defined as holding both positive and negative views of the behavior. Traditionally, MI has been used to inform the way that trained counselors deliver in-person therapy

sessions related to reducing risk behaviors among clients. Such sessions are designed to promote self-exploration of ambivalence by encouraging individuals to reflect on both the positive and problematic aspects of behaviors. This exploration is intended to make the negative aspects of behavior more salient and produce an increased openness to changing behavior, the first step in the behavior change process. Among individual who are open to changing, the MI approach increases the commitment to make a change and provides behavior change strategies to boost self-efficacy and likelihood of making a successful change (Miller and Rollnick, 2012). Although MI-based interventions have not been thoroughly tested in the context of changing tanning behavior, studies show tanners perceive aspects of their tanning to be problematic, perceive advantages to reducing their tanning, and are receptive or actively trying to change their tanning (Banerjee et al., 2014; Glanz et al., 2018; Harrington et al., 2011; Mosher and Danoff-Burg, 2010). This evidence that some tanners experience behavioral ambivalence and report an openness to changing their tanning behavior suggests adopting an MI approach to tanning interventions may be appropriate.

One of the more successful applications of MI with young adults can be found among brief interventions developed to reduce high-risk alcohol use. Traditionally, these interventions adopt an in-person counseling approach to engage participants in discussions about their alcohol use, beliefs, and related problems and help participants identify strategies for behavior change and reducing harm (e.g., moderate drinking/drinking less) (Carey et al., 2007; Carey et al., 2009; Carey et al., 2012; Cronce and Larimer, 2011; Foxcroft et al., 2014; Huh et al., 2015; Larimer and Cronce, 2007; Miller et al., 2013; Murphy et al., 2010; Scott-Sheldon et al., 2014). More recently, researchers have begun to test alternative intervention delivery modalities to eliminate the need for resource-intensive counselors. Personalized feedback interventions (PFIs) are web-delivered interventions that utilize one-time assessments to gather data regarding users' alcohol use and beliefs which is used to subsequently produce tailored feedback about an individual's own drinking patterns, alcohol-related concerns, and strategies to reduce harm (Leeman et al., 2015; Miller et al., 2013; Paulus et al., 2020; Ray et al., 2014; Walters and Neighbors,

2005). To the extent that such feedback elicits reflection on an individuals' problems stemming from their alcohol use, they may increase their openness to changing their drinking by enacting the provided change strategies.

The current study describes the formative testing of a web-based indoor tanning intervention that adapts the general PFI approach of assessment and tailored feedback related to users' tanning beliefs and behavior. This novel tanning intervention approach is designed to better address the unique psychological motivations for tanning among frequent indoor tanners and utilizes a behavior change framework that has been shown to be successful in changing addictive behaviors. Our study also introduces some innovations to the typical PFI approach. Rather than deliver feedback after the initial assessment, our intervention provides feedback in real-time as users progress through the assessment. This approach is intended to produce more meaningful reflection of intervention content. We also supplemented the web intervention, designed primarily to motivate openness to change, with a series of four weekly booster interventions designed to encourage change planning, behavior monitoring, and building self-efficacy, all critical skills in successful behavior change. These modifications were designed to offer an experience that more closely aligns with a traditional, in-person delivery approach.

In this study, we report results from a randomized control trial of the intervention among a sample of young adult women engaged in frequent indoor tanning. Our study was designed to examine intervention acceptability and engagement. We also assess the preliminary impact of the intervention by comparing the tanning bed behaviors of intervention recipients compared to a waitlist control condition. Finally, we explore putative mediators of the intervention by evaluating intermediate intervention outcomes consistent with PFI behavior change principles including readiness to change and self-efficacy.

METHODS

Participants and Recruitment

Study eligibility criteria included women between 18 - 25 years of age engaged in frequent tanning bed use, which was defined as at least 25 indoor tanning sessions in the past 12 months. Participants were recruited using multiple approaches. Qualtrics Sample Providers emailed study advertisements with links to a brief online eligibility screening survey to members of internet panels and posted online advertisements. The screening survey was programmed to present eligible participants with a brief description of the intervention trial and a question to indicate their interest in receiving an email study invitation. Second, recruitment flyers with study personnel contact information were posted on campus and in classrooms at a large Northeastern University and on internet ads on social media and Craigslist. Most participants (96%) were recruited by Qualtrics.

Study Design and Procedure

The study was a 2-arm randomized controlled trial with planned 1:1 allocation. A study coordinator enrolled participants, administered all procedures, and monitored trial progress. Following screening, the study coordinator sent an invitation email with a link to the online baseline survey, programmed using Qualtrics survey software, and a unique study personal identification number (PIN) for accessing the survey. Each PIN was assigned to a study condition, and we used a random number generator to randomly order the PINs in our study tracking spreadsheet. PINs were assigned to participants in order of our receipt of their screening survey and prior to sending the baseline survey invitation. Participants were asked to provide online informed consent prior to beginning the baseline survey and those who did not were not provided access to the survey. Up to three email reminders were sent to individuals who agreed to participate. Links to the web-based intervention were sent to participants two weeks after completing the baseline survey. A brief intervention evaluation survey was presented immediately after participants completed viewing the intervention. All participants who completed the baseline were invited to complete the follow-up assessment 12 weeks later. Participants assigned to the waitlist control were invited to access the intervention after the follow-up surveys concluded. Participants received a gift card for completing the baseline survey, the intervention

evaluation, and the follow-up survey. Baseline assessments were completed between April 2018 and November 2018, and follow-up assessments were completed between July 2018 and February 2019.

Intervention

The intervention was programmed with Snap survey software (SNAP Surveys Ltd, 2012). Each page was designed to be completed in a pre-determined order and the intervention was designed to take 30 minutes or less to complete. Following the web intervention, participants received 4 weekly boosters designed to be completed in 5-minutes. Booster content engaged participants in monitoring their recent tanning behavior and provided additional skills-based behavior change content.

Intervention content development was informed by principles of MI and designed to retain features of web-based PFIs applied to other content areas (e.g., Ray et al., 2014). Content was designed with three main goals (Table 1, end of document). First, intervention content was designed to enhance readiness to change by exploring the natural state of ambivalence of risk behaviors, defined as holding both positive and negative views of the behavior (Miller and Rollnick, 2012). The assessment of tanning behavior and experiences combined with the provision of personalized feedback is designed to encourage self-reflection of risk and risky behaviors and foster exploration of tanning ambivalence. Users answered questions about their individual patterns of indoor tanning bed use, phenotypic skin features (e.g., skin color, freckles) and other skin cancer risk factors, consequences they experienced related to tanning (e.g., getting into disagreements about tanning, neglecting responsibilities to go tanning), and tanning-related problems that represent symptoms of behavioral addiction to tanning (e.g., feeling guilty about tanning, urges to tan, attempts to control tanning). Responses were used to create personalized feedback on their annual amount of tanning behavior, including: the number of standard erythemal doses (i.e., a measure of the typical amount of sun exposure individuals receive in a year) they received from tanning beds in the prior year, risk of developing skin cancer and related problems, a comparison of the participant's level of tanning-related consequences as compared with other tanners based on data from a national survey of tanners (Stapleton et al., 2017b), and a summary of the disruptiveness of tanning in their daily life.

The second goal was to bolster participants' commitment to change by identifying perceived discrepancies with current tanning behavior and important external or internal standards (Neal and Carey, 2004). External standards were addressed with a personalized normative feedback approach designed to correct normative misperceptions about tanning that result from the tendency of frequent tanners to overestimate the prevalence of tanning behaviors of peers (Carcioppolo et al., 2019). Intervention users were asked to provide estimates of the percentage of young women who used any indoor tanning in the past year, tanned 10 or more times, and tanned 25 or more times and subsequent feedback showed how these estimates compared to the actual percent of young adult women who engaged in tanning bed use at these levels based on national survey data collected near the time of intervention development (Stapleton et al., 2017b). Providing data to demonstrate these normative discrepancies is consistent with MI principles and has been shown in experimental research to reduce tanning intentions among frequent users (Carcioppolo et al., 2019).

To address discrepancies between tanning and internal values, participants were presented with four key values or life priorities (i.e., health & fitness; relationships; image; self-esteem & well-being) and rated how important each value was to them. Subsequent intervention screens contained several questions about whether participants agreed with statements of various perceived benefits and costs of tanning. These benefits and costs were selected based on existing literature and corresponded to one of the four personal values. For the personalized feedback portion, a subsequent intervention screen displayed a listing of the pros and cons relevant to each value that were endorsed in prior screens by the user. Users were asked to indicate how they viewed the balance between pros and cons for each value. To the extent that reflection on the undesirable aspect of tanning fosters a shift in the balance of pros and cons in tanning expectancies or creates a perceived misalignment with values, commitment to changing tanning should be strengthened (McNally and Palfai, 2003; Neal and Carey, 2004).

The final intervention goal was to encourage change planning and the consideration of alternative ways to obtain the benefits of tanning while reducing the risks. Participants were asked to evaluate how

sunless alternatives (i.e., spray/airbrush tanning and sunless tanning lotions) compared to indoor tanning on several factors (e.g., enhancing physical appearance, possibility of causing health problems). Participants were presented with multiple suggestions for reducing their tanning (e.g., decide to stop tanning entirely; space out the times between tanning sessions) and reducing temptations to use tanning. Strategies for reducing tanning harm were included along with a link to a Facebook page with information about sunless tanning products. The series of four weekly booster interventions following the intervention asked participants to report on their past week tanning behavior, monitor any progress they made on their change goals, and identify new strategies for reducing their tanning.

Measures

Acceptability. Consistent with our prior intervention trials, intervention acceptability was measured using four general intervention evaluation items (Hillhouse et al., 2008; Stapleton et al., 2015; Stapleton et al., 2018). Participants rated the extent to which the intervention was interesting, understandable, useful, and positive with item response options ranging from 0 (*not at all*) to 10 (*extremely*).

Engagement. Intervention engagement was measured in two ways. First, data on intervention completion rates and responses to intervention questions recorded by the intervention software provided program analytic indicators of engagement. Second, self-reported engagement was collected via an online survey following the completion of the intervention. Survey items from the Audience Engagement Scale (AES) (Greene et al., 2015) were used to measure key aspects of engagement with intervention content. Items in the original AES were designed to capture user perceptions to an in-person, curriculum-based intervention so we chose the most relevant items and adapted the wording to match the web-based intervention delivery format (e.g., “the workshop” was adapted to “the program”). The AES scale measures three constructs: active involvement (i.e., participants’ depth of engagement with the program), perceived novelty (i.e., participants’ perceptions of the newness or originality of the intervention), and personal reflection (i.e., the degree to which knowledge acquired is to re-evaluate personal conduct). All items

(shown in Table 3) were measured using a 5-point Likert scale with response options ranging from 1 (*strongly disagree*) to 5 (*strongly agree*).

Primary Outcomes. The primary outcomes of indoor tanning bed use, sunburns, and indoor tanning intentions were assessed at both the baseline and follow-up surveys. Participants were asked to recall the number of indoor tanning sessions they had in the past two months. A similar question format was used to assess the number of sunburns they received in the past two months. Sunburns are a commonly-experienced side-effect of tanning bed use and independent risk factor for skin cancer risk (Stapleton et al., 2013). Our measure did not specify if reported sunburns were a result of indoor tanning so the measure is considered to be a general marker of ultraviolet risk behavior. For tanning intentions, participants indicated how likely they were to use an indoor tanning bed in the next year on a 6-point response scale anchored with 1 = *Extremely unlikely* and 6 = *Extremely likely* (Hillhouse et al., 2008).

Exploratory Outcomes. Interest in changing tanning was assessed using a single item (Would you like to reduce or quit indoor tanning if you could do so easily?) adapted from Sobell and colleagues' (1996) questions about readiness to change drinking behaviors (responses coded as 0 = *no* and 1 = *yes*). Self-efficacy in quitting tanning was assessed using Zeller and colleagues (2006) single item assessing perceived difficultly in quitting tanning (How hard would it be for you to stop using tanning beds/booths? *(Please answer on a scale for 0-10, where 0 is "Not at all hard", 10 is "Extremely hard"*).

Statistical Analyses Plan

Acceptability and engagement metrics are described for all participants who completed the intervention evaluation. We compared intervention and control participants on their baseline responses for the primary study outcomes and found evidence of non-equivalence. Specifically, intervention participants reported disproportionally higher rates of lifetime indoor tanning use ($M_{intervention} = 409.0$, $M_{control} = 158.5$) and 12-month indoor tanning ($M_{intervention} = 72.3$, $M_{control} = 49.0$) compared to control participants. A series of 2 (condition) X 2 (time) mixed-measures analysis of variance (ANOVA) was used to examine differences in study outcomes to control for baseline differences between conditions. Our power calculations indicated that a sample size of 54 participants would allow us to detect a moderately large intervention effect (specifically, 80% power to detect an 8 IT session difference between conditions).

Table 1. Intervention map with the goals and brief descriptions of intervention content.

Goal	Content and Description
Enhance interest and readiness to change	Self-exploration of tanning ambivalence. Participants were encouraged to answer open and close-ended questions in which they described individual patterns of indoor tanning bed use and experiences with tanning. Additional personalized feedback tailored to participant responses encouraged reflection on the balances of pros and cons of indoor tanning.
Bolster commitment to change	Normative beliefs about IT. Participants were asked to estimate the percent of women their age who use IT. Following this exercise, participants were provided with the actual percent of women compared to what they believed to be true.
	Desired motives and values. Tanners were asked questions designed to clarify their most important desired motives or values. Through a series of close-ended questions, participants were then encouraged to think about the good and not-so-good aspects of indoor tanning. Following this exercise, personalized feedback was provided to the participant aligning their personal values with the pros and cons of indoor tanning.
Encourage change planning	Skills necessary for successful behavior change. Information about what other tanners believed to be the benefits of changing their indoor tanning behavior was provided to participants. Two alternatives to indoor tanning were reviewed and the participants evaluated whether or not the alternative could enhance their physical appearance, boost their mood, damage their appearance, or cause health problems.
	Examples of strategies for change. A personalized change plan was shown to the participant offering new procedures for meeting the participants tanning needs in a healthier way. This included a strategy and detailed instructions on how to reduce tanning-related harm. The change planning process concluded with the participant evaluating their own thoughts about changing their tanning. Four weekly boosters designed to assist the participant in monitoring their tanning behavior and adherence to their change goals were emailed to participants.

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