Title: Communicating multiple disease risks: A translation of risk prediction science

Short title: Comm multi disease risk Aim 2

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Background and Rationale

RISK CALCULATOR (Parent grant)

Epidemiology seeks to improve public health by identifying risk factors for cancer and other diseases and conveying that information to relevant audiences (e.g., physicians, the public). The audience is presumed to understand and use that information to make appropriate decisions about lifestyle behaviors and medical treatments. Yet, even though a single risk factor can affect the risk of multiple health outcomes, this information is seldom communicated to people in a way that optimizes their understanding of the importance of engaging in a single healthy behavior.[1] Providing individuals with the ability to understand how a single behavior (obtaining sufficient physical activity) could affect their risk of developing multiple diseases could foster a more coherent and meaningful picture of the behavior's importance in reducing health risks, and increase motivation and intentions to engage in the behavior.

We will test the effectiveness of a risk calculator that conveys individualized risk estimates for colon cancer, heart disease, diabetes, stroke, and breast cancer (women) to socio-demographically diverse laypeople who do not get 150 minutes of moderate intensity physical activity per day. Estimates of how the participant's risk would change if they were to engage in at least 3 hours of moderate intensity activity per week will also be provided.

MENTAL IMAGERY (Supplement)

Although risk calculators can improve comprehension and produce favorable changes in health cognitions that lead to behavior change (e.g., accuracy of perceived risk, response efficacy, intentions), the effect of calculators on behavior itself is modest.[2-4] However, the gap between intentions and behavior can be bridged via interventions that help people develop self-regulatory skills, such as developing action plans for how to achieve each step of the behavior.[5-8] Mental imagery may be particularly useful in the development and realization of these plans.[5, 9, 10]

We will adapt an existing and effective mental imagery-based self-regulation physical activity intervention[5] for incorporation into the working risk calculator and compare its effectiveness in increasing physical activity behavior to an active control that addresses sleep hygiene.

RISK CALCULATOR AND MENTAL IMAGERY (Conceptual Model)

The conceptual model was adapted from the Health Action Process Approach (HAPA).[8] It asserts that behavior change occurs in two phases. The **motivation phase** is most relevant for people who do not engage in the recommended behavior. The goal of interventions that target the motivation phase – such as the risk calculator – is to increase intentions to engage in the behavior. Risk perceptions are important in this phase because they raise awareness of the consequences of not engaging in the behavior. Together with outcome expectancies (e.g., the expected consequences of engaging in the behavior, operationalized here as response efficacy), perceived severity of the health outcome, and action self-efficacy (i.e., confidence in one's ability to initiate a new behavior), risk perceptions influence intentions to start the behavior change process. Note that the risk calculator is not expected to increase action self-efficacy or perceived severity because it was not designed with a component to target those constructs.

We enhanced the motivation phase of the conceptual model with additional components drawn from risk perception and communication research. Comprehension of information was added because perceptions and comprehension are slightly different constructs that each have an important role in influencing health behavior and decisions.[11] Worry, affective reaction to the information, affective attitudes to exercise, and anticipated regret were added because a growing body of research demonstrates that affect and emotion are integral to the formation of risk perceptions, in increasing motivation to change behavior, and in changing behavior itself.[12-17] Demographics, numeracy, health literacy, and graph literacy were added because they are associated with the ability to understand and use health risk information.[18-20]

According to HAPA, progression to the **action phase** is dependent upon factors not included in the motivation phase. These new factors include developing action plans for engaging in the behavior, coping plans for overcoming barriers to action, maintenance self-efficacy (i.e., confidence in the ability to overcome barriers to acting), and recovery self-efficacy (i.e., confidence in the ability to recover from a relapse).

Objectives

RISK CALCULATOR

To compare the effectiveness of communicating personalized risk estimates via text, table, or risk ladder.

Primary outcomes hypotheses and exploratory research questions

H1: Comprehension of risk information and intentions to increase physical activity will be higher among individuals who see multiple disease risks presented as a risk ladder than as text.

RQ1: Prior research has shown that tables can be effective in communicating risk information.[21] Compared to the table, will the risk ladder elicit higher comprehension and intentions?

Secondary outcomes hypotheses and exploratory research questions

H2: Any significant effect of the risk ladder on intentions will be mediated by comprehension, risk perceptions, response efficacy, worry, affective reactions to information, affective attitudes to exercise, and anticipated regret.

H3: Engagement in physical activity will increase from baseline to 90 day follow-up to a greater extent for individuals who see the risk ladder than those who see text only.

H4: Intentions will mediate any significant effect of the risk ladder on physical activity.

RQ2: Compared to the table, will the risk ladder elicit higher risk perceptions, response efficacy, worry, affective reactions to information, affective attitudes to exercise, and anticipated regret?

Sociodemographic exploratory research questions

RQ3: Will education, race/ethnicity, numeracy, health literacy, and/or graph literacy moderate the effect of risk communication strategy on primary outcomes?

MENTAL IMAGERY

To test whether supplementing the risk calculator with a mental imagery-based self-regulation intervention will increase actual engagement in physical activity over time, and to explore several possible mechanisms.

Primary outcome and exploratory research questions

H5: Engagement in physical activity will increase from baseline to 90-day follow-up only among individuals in the physical activity mental imagery intervention,[5, 7-9] not in the sleep hygiene imagery active control condition.

RQ5: Will education, race/ethnicity, numeracy, health literacy, and/or graph literacy moderate the effect of mental imagery condition on behavior?

Secondary outcomes and exploratory research questions

H6: Within the physical activity mental imagery condition, increases in activity from pre-intervention baseline to 90-day follow-up will be preceded by the following measures assessed at the week 4 follow-up: action planning, coping planning, action self-efficacy, maintenance self-efficacy, recovery self-efficacy, affective attitudes to exercise, and perceived vividness of imagery.[5, 7-9, 16]

RQ6: Within the physical activity mental imagery condition, the direction and magnitude of change in activity from pre-intervention baseline to week 1 follow-up will be preceded by the following measures assessed at the survey assessed immediately post-intervention: action planning, coping planning, action self-efficacy, maintenance self-efficacy, recovery self-efficacy, affective attitudes to exercise, and perceived vividness of imagery.[5, 7-9, 16] Similarly, measures assessed at week 1 will predict change in behavior from week 1 to week 2; measures assessed at week 2 will predict behavior change from week 2 to week 3; and measures assessed at week 3 will predict behavior change from week 3 to week 4.

Eligibility Criteria

RISK CALCULATOR AND MENTAL IMAGERY

Inclusion criteria are: 30-64 years of age, less than three relevant comorbidities (diabetes, heart disease, stroke and cancer, where cancer counts as 2 comorbidities for women but 1 for men due to the statistical properties of the risk calculator), having a SMS/text capable mobile phone that is not shared with anyone else, text messaging more than once a month, and not meeting national guidelines for aerobic physical activity (i.e., at least 150 minutes per week of moderate intensity aerobic physical activity).[22]

Registration Procedure

RISK CALCULATOR AND MENTAL IMAGERY

Participants will be recruited from the Recruitment Enhancement Core (REC), reasearchmatch.org, the Health Communication Research Lab's FReDa database, word of mouth, newspaper advertisements, and a database maintained by the Waters Lab. REC will follow their established standard procedures by posting information about the study in BJC today (Appendix P: Aim 2, BJC Ad), on the REC website (Appendix T: Aim 2, Website posting), Facebook (Appendix R: Aim 2, Facebook Posting), Centerwatch (Appendix Q: Aim 2, Centerwatch Ad), and newspaper advertisements (Appendix CC, Newspaper Advertisement). REC will forward interested participants' contact information to the study team, who will make outbound calls to potential participants. Researchmatch.org will email registry members with information about the study (Appendix U: Aim 2, Researchmatch.org email), and offer participants a chance to contact the study team if they are interested in participating. The study team will make outbound calls and emails to members of the HCRL FReDa database and Waters Lab database (Appendix N: Aim 2, Screening Call Script; Appendix O: Aim 2, Recruitment Email Script).

In addition, we will also recruit participants in person at various locations around St. Louis. The locations will be determined by the REC and will include publicly available places with private space available, like laundromats, libraries, and community centers. In this case, research assistants will speak with potential participants in person to assess interest in the study. If potential participants are interested in participating in the study, research assistants will go through appendix H, the eligibility screener. If the participant is eligible, the study team member will record the participant's contact information on Appendix I, the Contact Info Sheet. If the participant is able to conduct the data collection session immediately, the research assistant will continue on to begin the data collection session following Appendix W (Aim 2 Data collection session 1 guide). If the participant is not able to conduct the data collection session immediately, we will schedule a time for the session at a later date, or offer times for walk-in sessions. Study coordinators will schedule sessions to take place either at the Taylor Avenue Building (Wash U) or at a mutually agreed upon public place with adequate private space to conduct the interview (e.g. a meeting room at a library). When the participant arrives for the session, the research assistant will explain the study procedures, obtain written consent, and begin data collection.

We will enroll 500 participants. Recruitment will be stratified based on race (at least 50% racial/ethnic minority) and education (at least 50% will have no college experience) to ensure adequate representation of populations that experience health disparities and, consequently, to increase relevance of the intervention to those groups.

Research Plan

RISK CALCULATOR AND MENTAL IMAGERY

Design

This study will use a 3 (risk presentation condition: text vs. table vs. risk ladder) x 2 (mental imagery condition: physical activity vs. sleep hygiene) experimental design. Participants will be block randomized to ensure that each of the 6 experimental conditions has equal numbers of participants at the end of the study. Randomization will occur by the computer program after eligibility screening and consent, but prior to engaging in any study activities.

Blinding

The research staff will be blinded to participants' risk presentation conditions, but they will unblinded to mental imagery condition. This unblinding was the result of a combination of the block randomization (which prevented us from preparing packets of study materials ahead of time and assigning participants to condition in order of completion (e.g., A, B, C, D, E, F)), and the need for the goal cards and Baseline Survey 2 to include information specific to the mental imagery condition the participant was assigned to (see below).

Procedure

The procedures for the study will occur in 3 parts. Part 1 is an initial 45 minute data collection session in person, followed by (Part 2) reminders and surveys conducted by Short Message Service (SMS) text messaging over the subsequent 4 weeks, and (Part 3) a final mailed survey on paper. The last half of Part 1 and all of Part 2 are adapted from prior research conducted by Linda Cameron for use with University of Auckland employees.[5, 9] We worked closely with Dr. Cameron to adapt the interventions so they would be acceptable to our St. Louis community sample (e.g., minimize burden, reduce the need for Internet access, to accommodate cell phone plans that do not have unlimited text and/or data, etc). This adaptation was performed in Spring 2017 and involved 3 sets of cognitive interviews, each set including 6-7 participants (Aim 2, Part 1).

Part 1, Baseline Intervention Administration and Data Collection. Participants will complete all baseline activities in person with a research assistant. After completing eligibility screening and informed consent processes, participants will use a smartphone provided by research staff to complete the risk calculator portion of the study. The research assistant will enter the participant ID into the responsive website, and then the participant will provide information about their demographics, health behaviors, and personal and family health history (Appendix A Aim 2, Risk Display App Screens, pg. 2-34). The website then provides participants with personalized risk results for their current activity level and how it would change if they began exercising regularly. Results are displayed either as alphanumeric text, table, or risk ladder (Appendix A Aim 2, Risk Display App Screens, pg. 35-38). Afterwards, the participant will complete Baseline Survey 1 independently on paper (Appendix C, Instructions Appendix HH).

Immediately after completing Baseline Survey 1, participants will begin the mental imagery component of the study. The research assistant will enter the participant's personal phone number into the website so they can receive text messages for the next 4 weeks. Then, participants will use the smartphone and headphones provided by the research team to listen to an audiorecording that walks the participant through how to set a physical activity or sleep goal and asks them to imagine themselves exercising or improving their sleep hygiene (Appendix A Aim 2, Risk Display App Screens, pg. 39-42; Appendices D and E, Mental Imagery audio recording scripts). Participants will be asked to practice this mental imagery twice a day for 5 minutes each day the subsequent weeks. The audio recording also instructs the participant to write down an exercise or sleep-related goal on a pamphlet provided by the research assistant (Appendix F, Pamphlet). Participants will then complete Baseline Survey 2 independently on paper (Appendices L and M). Based on the cognitive interviews conducted in Spring, 2017, Part 1 will take approximately 45 minutes. Participants will receive a $20 gift card to Schnucks for their time and effort.

Part 2, SMS/Text Message Intervention and Data Collection. Beginning at 7:00pm on the day the participant completes the Baseline/Part 1 activities, the participant will begin receiving text messages related to the study. The first texts will welcome them to the study and provide information about how to contact the Lab, how to stop the texts from being sent, and how to access the audiorecording to which they were assigned (physical activity vs. sleep). At noon on Mondays, Wednesdays, and Fridays, they will be sent 1 of 3 texts that remind them to practice the imagery presented in the audio recording twice daily for five minutes each time. These reminders will continue for 3 weeks. Each week after the 3rd reminder they will receive a text message based survey. A final text message based survey will be sent one week after the third text message based survey. The content and schedule for the text messages and text surveys are found in Appendices X and Y (Text Message Reminders and Survey- Exercise, Sleep). Each text message length is no more than 160 characters, including spaces, to fit within the universal constraints of SMS messaging protocols. This was done to avoid having 1 intended message being sent in multiple pieces. The total participation time per week is estimated to be approximately 10 minutes. Participants will earn a $10 gift card to Schnucks for each text message survey they complete. This amount is intended to help offset the cost of text messages for participants who may not have unlimited text messaging.

Part 3, Mailed 90-Day Follow-Up Survey. Ninety days after Baseline/Part 1, participants will receive a final follow-up study survey (Appendix BB) in the mail along with a written survey invitation (Appendix AA). If participants do not complete the first mailed survey, we will follow-up with one reminder call (Appendix Z) and one additional mailed survey. The survey is expected to take approximate 15 minutes. Participants will receive a $20 gift card for Schnucks for completing the follow-up survey.

Part 4, Follow-Up Phone Call. Within one year of the final follow up period, we may contact up to 20 participants by phone and ask them questions about their experience and thoughts on the study process (Appendix II). If this occurs, the phone call will take approximately 10 to 15 minutes.

Measures

To reduce participant burden, we limit the number of survey questions by adapting single item measures used in nationally representative surveys and in published empirical research. Many items are identical or very similar to the items in Aim 1 and Aim 2, Part 1 of the study. All items for the proposed research, including items that were adapted or developed specifically for Aim 2, Part 2, underwent cognitive testing in either Aim 2, Part 1 or in prior research studies conducted by the Waters Lab. Adaptations to the items intended for use in the text messaging surveys (160-character limit) were made in close collaboration with Linda Cameron, who was the initial developer of the interventions. Table 1 below provides each of the measures that will be assessed in each part of the survey.

Table 1. Summary of Study Measures, in Order of Completion

Questionnaire Name	Timing	Content
Part 1: Baseline		
Eligibility Screener (Appendix H)	Pre-randomization	Age;[23] race/ethnicity;[23] education;[23] personal diagnosis of the target diseases;[24, 25] physical activity behavior;[26, 27] and cell phone access (developed in-house)
Risk Assessment (Appendix A)	Immediately following randomization to 1 of 6 conditions in a 3 (risk presentation: text vs. table vs. risk ladder) x 2 (mental imagery: physical activity vs. sleep hygiene) design	Demographic, biological, and behavioral characteristics needed for the risk algorithm[28-30]
Baseline Survey 1 (Appendix C)	Immediately following provision of personalized risk information	Comprehension;[31] cognitive and affective perceived risk;[32] perceived severity[33] worry;[32] response efficacy;[34] action self-efficacy;[35] affective reaction to the information;[36] affective attitude about exercise;[16] anticipated regret;[17] intentions to engage in physical activity in the next 90 days;[34] numeracy[37]; graph literacy;[20] health literacy.[38] self-reported health status;[24] work schedule;[39] sleep behavior.[9] Other items intended to be used as preliminary data in future studies examining possible defensive processing of personalized health risk information include: perceived accuracy of information;[4, 40] message acceptance;[41] defensive processing[42] time orientation,[43] and spontaneous self-affirmation.[32]

Baseline Survey 2 (Appendices L and M)	Immediately following completion of the mental imagery activity. The specific item wording is tailored based on which mental imagery condition is assigned (i.e., mental imagery vs. sleep), but the constructs assessed are the same for both conditions.	Message acceptance,[41] perceived clarity and vividness of images;[5, 9] and the following items obtained, developed, or adapted from:[5, 6, 9, 34] action plan; coping plan; action self-efficacy; recovery self-efficacy; and maintenance self-efficacy.
Part 2: Text Messaging		
Mid-Intervention Text Message Surveys (Appendices X and Y)	1, 2, 3, and 4 weeks after Part 1	Perceived clarity and vividness of images;[5, 9] and the following items obtained, developed, or adapted from:[5, 6, 9, 34] action plan; coping plan; action self-efficacy; recovery self-efficacy; and maintenance self-efficacy.
Part 3: 90-Day Follow-Up		
Follow-Up (Appendix BB)	90 days after Part 1	Comprehension;[31] physical activity behavior,[26, 27] sleep behavior,[9] tobacco use,[27] and the same items as in Baseline Survey 2 assessing intentions, action self-efficacy, cognitive and affective perceived risk, response efficacy, anticipated regret, and affective attitudes.

Note: Race and education will be assessed during eligibility for recruitment stratification purposes only. Baseline Survey 1 excludes characteristics that will be assessed in the Risk Assessment questionnaire.

Statistical Considerations

Preliminary Analyses

We will begin by using descriptive statistics to understand the frequency and distributional properties of all items. For variables with non-normal distributions, data transformations or non-parametric tests will be used for subsequent analyses.

Cronbach α will be used to test the internal consistency of multi-item constructs in Baseline Survey 1 (i.e., cognitive and affective perceived risk; response efficacy; action self-efficacy; affective reaction to the information; affective attitude about exercise; anticipated regret; intentions to engage in physical activity, message acceptance), Baseline Survey 2 (i.e., message acceptance, perceived clarity and vividness of images), and the Follow-Up Survey (i.e., intentions, action self-efficacy, cognitive and affective perceived risk, response efficacy, anticipated regret, affective attitude about exercise). Where $\alpha \geq .70$ we will create a scale by averaging responses to a given construct across diseases. That average score will be used in subsequent analyses. Comprehension, numeracy, and graph literacy will each be operationalized as continuous variables comprised of the number of items answered correctly.

Next, we will verify that participant characteristics (i.e., demographics, personal diagnosis of one of the target

diseases, self-reported health status, numeracy, health literacy, graph literacy, pre-intervention minutes of physical activity per week) are equivalent across experimental conditions by conducting t-tests, one-way ANOVAs, chi-square tests, or other tests, as appropriate. If any differences are found, these variables will be included in subsequent analyses as potential covariates. Personal characteristics will also be explored to determine if they are related to the outcomes of interest. Any characteristic that has a significant association with the outcomes will be included in subsequent analyses as potential covariates.

Main Analyses

All hypotheses and research questions will be examined using separate analyses for each outcome variable. Assumptions of each type of test will be checked (e.g., assumptions of normality and homogeneity of variance for ANOVAs). If there are violations, non-parametric tests will be used instead. Sex will be a covariate because there are no valid prediction models for male breast cancer, so men will not be shown a breast cancer risk estimate. The inclusion of other personal characteristics as covariates will be determined by the results of the preliminary analyses. Tests of moderation will be conducted by creating interaction terms between the risk presentation condition or mental imagery condition variables, as appropriate, and the variable assessing the moderator of interest. All statistical tests will be based on list-wise deletion except structural equation models, which can accommodate missing data.

Mediation analyses will be conducted using structural equation modeling (SEM). Full Information Maximum Likelihood estimation (FIML)[44] will be used to allow the inclusion of missing data. Standardized estimates will be calculated and bias-corrected bootstrapping will be used to obtain the 95% confidence intervals.[45-48] Criteria assessing model fit will also be examined (e.g., Standardized Root Mean Square Residual ≤.08, comparative fit index ≥.95, root mean square error of approximation ≤.06).[49, 50] Mediational analyses will examine each construct as an individual mediator first, and then as a multiple mediator model.

Table 2 below describes the analyses that will be conducted for each hypothesis or research question.

Table 2. Overview of Statistical Analyses

	Priority	Statistical test(s)	Outcomes	Predictors/Mediators/Moderators
Risk Calculator				
H1; RQ1	Primary	3 arm ANOVA, 2 planned contrasts (risk ladder vs. text; risk ladder vs. table)	Comprehension, intentions	Predictor: Risk presentation condition
H2	Secondary	SEM	Intentions	Predictor: Risk presentation condition (risk ladder vs. text) Mediators: comprehension, risk perceptions, response efficacy, worry, affective reactions to information, affective attitudes to exercise, anticipated regret
H3	Secondary	3 arm ANOVA, planned contrast (risk ladder vs. text)	Change in physical activity (mins/week at 90 days – mins/week at baseline)	Predictor: Risk presentation condition
H4	Secondary	SEM	Change in physical activity (mins/week at 90 days – mins/week at baseline)	Predictor: Risk presentation condition (risk ladder vs. text) Mediator: Intentions
RQ2	Secondary	3 arm ANOVA, planned contrast (risk ladder vs.	Risk perceptions, response efficacy, worry, affective reactions to information, affective attitudes	Predictor: Risk presentation condition

		table)	to exercise, anticipated regret	
RQ3	Secondary	3 arm ANOVA	Comprehension, intentions	Predictor: Risk presentation condition Moderators: Education, race/ethnicity, numeracy, health and graph literacy
Mental Imagery				
H5	Primary	T-test	Change in physical activity (mins/week at 90 days – mins/week at baseline)	Predictor: Mental imagery condition
RQ5	Primary	ANOVA	Change in physical activity (mins/week at 90 days – mins/week at baseline)	Predictor: Mental imagery condition Moderators: Education, race/ethnicity, numeracy, health and graph literacy
H6	Secondary	Regression (physical activity mental imagery condition only)	Change in physical activity (mins/week at 90 days – mins/week at baseline)	Predictors: Week 4 action planning, coping planning, action self-efficacy, maintenance self-efficacy, recovery self-efficacy, affective attitudes to exercise, perceived vividness
RQ6	Secondary	Regression (physical activity mental imagery condition only)	Weekly change in minutes of physical activity, assessed by 4 difference scores: Week1-Baseline; Week2-Week1; Week3-Week2; and Week4-Week3	Predictors: For each weekly behavioral assessment, use the previous week's measures of the following constructs: action planning, coping planning, action self-efficacy, maintenance self-efficacy, recovery self-efficacy, affective attitudes to exercise, perceived vividness.

Sample Size Calculations

We will enroll 500 participants at baseline. This will enable us to test the primary hypothesis for each of the components of the study. This calculation was based on the information below.

RISK CALCULATOR

Sample size was calculated to be able to detect an effect of risk presentation strategy on the primary outcome variables comprehension and intentions (Risk Calculator Hypothesis 1 and RQ1). Based on a 2-sided test of means for 3 groups (ANOVA) at 80% power, α=.05, *df*=2, and Cohen's *f* effect size of 0.15 (approximately equivalent to Cohen's *d* of 0.3),[51, 52] we anticipate needing 432 participants. The effect size estimate was based on a study of personalized breast cancer risk and risk reduction communication that found an effect on intentions to increase physical activity of approximately *f*=0.25 and an effect on response efficacy of approximately *f*=0.20.[4] However, most of those participants were white, highly educated, had high health literacy, and recruited from a breast health center. Thus, we can expect the findings in our more diverse sample to be somewhat lower. We chose *f*=.15 as a reasonable compromise because it represents slightly more than a minimal effect,[53] but is also logistically feasible. To account for the possibility of 10% missing data in Baseline Survey 1, which assesses the constructs for the Risk Calculator Hypothesis 1, we would need to enroll 480 participants to obtain 432 completed surveys.

MENTAL IMAGERY

Dr. Cameron's prior self-regulatory intervention accounted for approximately 20% of the unique variance in physical activity at 4-week follow-up.[5] This is approximately equivalent to a Cohen's *d* effect size of 1.0, which is considered a large effect.[53] Because our follow-up is 90 days, we can expect that our effect size will be somewhat lower. Other self-regulation interventions yielded smaller effects over varying timeframes (e.g., *d*=0.28-0.78).[7] Thus, powering the study to detect an effect of *d*=0.30 of the intervention on behavior (Mental

Imagery Hypothesis 5) would be conservative and reasonable. Based on a 2-sided test of means for 2 groups (t-test) at 80% power, α=.05, and Cohen's *d* effect size of 0.30,[51, 52] we anticipate needing 352 participants at 90-day follow-up. To account for the possibility of 30% attrition rate due to our underserved sample (unpublished data), we expect needing to enroll 500 participants at baseline to achieve this goal.

Study Procedure Calendar

Table 3. Study Timeline

	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Startup (hiring, IRB amendments)	X	X	X	X					X							
Biweekly research team meetings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Aim 1, Part 1: modify and refine stimulus (includes cognitive interviews)	X	X	X													
Aim 1, Part 2: refine, program, pilot test, and finalize questionnaires	X	X	X													
Aim 1, Part 2: collect data (GfK)				X												
Aim 1, Part 2: analyze and interpret data					X	X	X									
Aim 1, Part 2: disseminate results							X	X	X	X						
Aim 2, Part 1: convert relative risk estimates to absolute risk estimates	X	X	X	X												
Aim 2, Part 1: disseminate results				X	X	X										
Aim 2, Part 1: write and verify the accuracy of the computer code used to calculate risk estimates and show the risk results displays (includes interviews)					X	X	X	X								
Aim 2, Part 2: Recruit participants and implement risk calculator and mental imagery interventions									X	X	X	X				
Aim 2, Part 2: 90-day follow-up										X	X	X	X			
Aim 2, Part 2: analyze data												X	X	X		
Aim 2, Part 2: disseminate results															X	X

Drug Formulation and Procurement

Not applicable.

Data and Safety Monitoring Plan

RISK CALCULATOR AND MENTAL IMAGERY

Voluntary participation

We will protect against emotional discomfort by emphasizing that participation is voluntary. Participants will provide informed consent. They will be informed that participation is voluntary and that they can elect not to answer any question that makes them uncomfortable or withdraw at any time during the study without any penalty. Additionally, participants will be informed that all study data will be kept confidential and that all personal identifiers will be destroyed when the study is completed.

Confidentiality and Data Security

There are several layers of protection regarding confidentiality and data security.

First, the study is undergoing a Washington University Information Security Office IRB Study Security review. A detailed description of our study's confidentiality and data security features is described in that document. (see Appendix JJ).

Second, the websites that host the data (i.e., Amazon Web Services and Twilio) have extensive security precautions. These precautions are being reviewed by the Information Security Office (see Appendices JJ, KK, and LL).

Third, the study team will be alert for any potential breaches to prevent inadvertent release of confidential information. If a potential breach in confidentiality occurs, the PI will work with the Institutional Review Board, HIPAA, and the Information Security Office according to their rules and regulations for such a situation.

Fourth, all study data will be downloaded to WUSM servers on a daily basis. Access to data will be password protected to restrict use by non-study personnel. All data will be stored using ID numbers, not names. Participants' responses to study questions will be coded to protect their confidentiality, and names will be kept separate from survey data. Any data that is transported on portable storage devices will be encrypted. Hard copies collected at the in person recruitment locations will be transferred to storage by an RA in a closed envelope and will not leave sight of the RA until securely stored. All paper copies will be will be stored in a locked filing cabinet in a locked suite in an entry controlled building. No personally identifying information will appear in any presentations or publications that results from this study; only aggregated data will be disseminated.

Record Keeping

RISK CALCULATOR AND MENTAL IMAGERY

Records will be maintained by the study coordinator and supervised by the PI. All information will be recorded in password-protected databases and held on WUSM servers, which are encrypted and backed up nightly. The study coordinator will record the following pieces of information:

- Participants' contact information, which is needed for the text messaging and follow up activities (i.e., Parts 2 and 3).
- Survey responses, which are linked to participants via an individual identifier but are not linked to names or contact information.

Paper copies of study materials will be kept in a locked filing cabinet located within a locked office suite. For additional information, see *Data Safety and Monitoring Plan*.

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Special Considerations

Not applicable.

List of Appendices

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