Basic Info

Protocol Number: 827345

Principal Investigator: DELGADO, MUCIO C

Protocol Title: Pilot trial leveraging smartphone-paired breathalyzers and loss- and gain-framed text notifications for reducing drinking driving

Short Title: BE SAFE

Protocol Description: This project aims to demonstrate the feasibility of a scalable behavioral intervention using smartphone-paired breathalyzers and text messages aimed at reducing drinking and driving among individuals who report heavy drinking. Participants receive a smartphone breathalyzer to provide feedback on their estimated blood alcohol level. The intervention compares loss- and gain-framed messages that make the consequences of drinking and driving more salient to standard messages not to drink and drive.

Submission Type: Social and Biological Sciences

Application Type: FULL

Study Instruments

Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.

1. Intake Survey (attached to the protocol) a) Driving History and Experience Questionnaire DHEQ (Harrison & Fillmore, 2005): This self-report questionnaire gathers information on driving history and behaviors. Included in the questionnaire are measures of driving experience such as length of time holding a driver's license and number of days and miles driven per week. The questionnaire also gathers information about participants driving behaviors, such as license revocations, presence and number of DUI citations and punishments, traffic accidents, traffic tickets, typical driving environment (rural, urban, and interstate), and the type of vehicle transmission (manual, automatic, or both). b) Drinking and driving questionnaire (McCarthy et al): This self-report questionnaire gathered information on individuals drinking and driving history. The questionnaire asked participants to respond to questions about drinking and driving history on 4 or 5 point Likert scales. The questionnaire included a measure of frequency of drinking and driving and typical quantity of alcohol consumed before driving. The items were obtained from a scale reported by McCarthy et al. (2012). c) Delayed discounting questionnaire (Senecal, Kable et al 2012). Time discounting (known interchangeably as present-biased preferences or delay discounting) is a measure of impulsivity that reflects people's tendencies to discount the value of a

reward as a function of how far in the future it would be received. It has been established that people who engage in maladaptive behavior such as drinking and using other drugs have steeper delayed discounting functions, meaning they have stronger present biased preferences.

This is expected because engagement in unhealthy behaviors entails immediate gratifications in exchange for future health problems. It is not known whether a similar pattern of behavior is present in those engaging in drinking and driving. Consistent with prior work, we will use the 51-item monetary choice questionnaire developed by Seneca; and colleagues (2012) that defines 10 ranges of delayed discounting by fitting a hyperbolic function to participants expressed preferences for smaller immediate versus larger delayed rewards. d) Barratt Impulsiveness Scale BIS-11 (Patton et al., 1995) This 30-item self- report questionnaire is designed to measure the personality dimension of impulsivity. Participants rated 30 different statements on a 4-point Likert-type scale ranging from Rarely/Never to Almost Always/Always. Higher total scores indicate higher levels of self-reported impulsiveness. e) Self reported drinking. We will collect self-reported drinking days and drinks per day using a timeline follow-back method. This method has been used by multiple researchers in the Substance abuse literature since its development by Sobell and colleagues (1996). We will cover the previous month in this assessment. f) Basic demographics such a race, age, and education. g) Self-report of drinking and driving instances (Sloan et al. 2014). This survey is a validated instrument that asks participants to report on their general drinking behavior and its relation to driving.

2. End of Baseline survey (attached to protocol) a) Driving History and Experience Questionnaire DHEQ (Harrison & Fillmore, 2005): This self-report questionnaire gathers information on driving history and behaviors. This will be modified to cover the length of time since this was previously asked (4 weeks), all questions that were used in the intake and are no longer relevant will be removed. b) Drinking and driving questionnaire (McCarthy et al): This self-report questionnaire gathered information on individuals drinking and driving history. The questionnaire asked participants to respond to questions about drinking and driving history on 4 or 5 point Likert scales. The questionnaire included a measure of frequency of drinking and driving and typical quantity of alcohol consumed before driving. The items were obtained from a scale reported by McCarthy et al. (2012). This survey will be modified to cover the previous 4 weeks of the baseline period. c) Self-reported drinking. We will collect self-reported drinking days and drinks per day using a timeline follow-back method. This method has been used by multiple researchers in the Substance abuse literature since its development by Sobell and colleagues (1996). We will cover the previous month in this assessment.

3. End of Study Survey (attached to protocol) a) Driving History and Experience Questionnaire DHEQ (Harrison & Fillmore, 2005): This self-report questionnaire gathers information on driving history and behaviors. This will be modified to cover the length of time since this was previously asked (4 weeks), all questions that were used in the intake and are no longer relevant will be removed. b) Drinking and driving questionnaire (McCarthy et al): This self-report questionnaire gathered information on individuals drinking and driving history. The questionnaire asked participants to respond to questions about drinking and driving history on 4 or 5 point Likert scales. The questionnaire included a measure of frequency of drinking and driving and typical quantity of alcohol consumed before driving. The items were obtained from a scale reported by McCarthy et al. (2012).

This survey will be modified to cover the previous 4 weeks of the intervention period. c) Self-reported drinking. We will collect self-reported drinking days and drinks per day using a timeline follow-back method. This method has been used by multiple researchers in the Substance abuse literature since its development by Sobell and colleagues (1996). We will cover the previous month in this assessment.

4. End of study interview (attached to protocol) This interview will ask about the experience in the trial and help determine if this intervention is acceptable and liked by the participants. We will also use this interview to inquire about ways it can improve and things that were not liked by each participant.

5. Smartphone Breathalyzer (BacTrack Mobile Pro) This device was chosen as one of the most popular currently commercially available breathalyzers that pair with smartphones, which has received growing attention in the national media. (A smartphone breathalyzer, 2015; Jolly, 2015). In a recently completed study conducted by our team, this was the most accurate smartphone paired breathalyzer available on the market and it was actually better than a current police grade breathalyzer at predicting blood alcohol levels.

This study was accepted for presentation at the 2017 Society for the Advancement of Violence and Injury Research annual meeting. The device pairs with the BACtrack app available for Android and iPhone, which enables the export of data to the study team. The currently collected data fields available in this free, publically available consumer application include: guessed BAC, actual BAC, was it themselves or friend, GPS coordinates of where BAC was taken, and timestamp of the BAC.

6. TrueMotion Driving app: TrueMotion.is a leading provider of smartphone applications aimed at measuring and improving driving behavior. They are the vendor for Progressive Insurances usage-based insurance application. The app uses native phone sensors to detect driving and passenger vs. driver status. The app is also able to log passenger episodes in which user is using Uber or Lyft. The TrueMotion app will be installed on participants' phones to track driving exposure. Once installed it will run continuously in the background without any user interaction. TrueMotion collects the following information for each trip level data set (each will be coded with user ID and trip ID): , 1. Start/stop time, location, and intensity of detected braking and acceleration events 2. Start/stop time, location, and intensity of speeding events (excess speed relative to an absolute threshold or relative to local speed limits) 3. OS-level events like screen on, screen unlock, call state 4. Start/stop time and location of detected distraction events using our sensor-based algorithms: phone calls (with a detection of in-hand versus hands-free) and general non-call usage like tapping, typing. As far as the time-series sensor data which can be linked with a user ID and trip ID, TrueMotion will provide: 1. GPS points (lat/lon position, speed, accuracy, etc) at 1 Hz IMU sensor data (3-axis accelerometer, gyroscope, and magnetometer) at 9 Hz. The standard data fields collected and that will be exported include trip start/ stop time, location, and mileage The data will be securely transferred to the University of Pennsylvania on a weekly basis.

References

A smartphone breathalyzer. (2015). Retrieved January 4, 2016, from http://www.usatoday.com/videos/tech/2013/05/19/2216497/ BACtrack Mobile Pro. (n.d.). Retrieved December 24, 2015, from https://www.bactrack.com/products/bactrack-mobile-smartphonebreathalyzer
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A. Artificial sweeteners versus regular mixers increase breath alcohol concentrations in male and female social drinkers. Alcohol Clin Exp Res. 2013;37(4):696-702. McCarthy DM, Niculete ME, Treloar HR, Morris DH, Bartholow BD. Acute alcohol effects on impulsivity: associations with drinking and driving behavior. Addiction. 2012;107(12):2109-2114. doi:10.1111/j.1360-0443.2012.03974.x. Patton JH, Stanford MS, Barratt ES. Factor structure of the Barratt impulsiveness scale. J Clin Psychol. 1995;51 (6):768-774. Senecal N, Wang T, Thompson E, Kable JW. Normative arguments from experts and peers reduce delay discounting. Judgm Decis Mak. 2012;7(5):568-589. Sloan FA, Eldred LE, Xu Y. The Behavioral Economics of Drunk Driving. Journal of Health Economics. Duke University. 2014. Vol 35, pp 64-81. Sobell LC, Sobell MB, Buchan G, Cleland PA, Fedoroff I, Leo GI (1996). The reliability of the Timeline Followback method applied to drug, cigarette, and cannabis use. Paper presented at the 30th Annual Meeting of the Association for Advancement of Behavior Therapy, New York, NY, November 1996.

Group Modifications

Describe necessary changes that will or have been made to the study instruments for different groups.

During all phases study staff will collect data from 3 sources:

1) The BACtrack device and app will require the participant to initiate use during all phases of the trial. Researchers will instruct participants to use this device during the study when drinking to help inform them of their level of impairment and ability to operate a vehicle. See section attached screenshots for more information on this app and what it tells users. As part of the BACtrack app each participant will be asked to guess what their BAC is prior to submitting a sample. Once a sample is submitted and processed the app will display both the actual BAC measure as well as the participants guess. They will also be able to indicate of the sample was provided by them or someone else. Data collected using this app and device includes guessed BAC, actual BAC, person submitting the sample, GPS coordinates, and timestamps.

2) The TrueMotion app will collect participant driving data without any additional initiation by the participant. Data collected from this app will include GPS coordinates, driving speed, trip length, time of drive, and cellphone use while driving. During a drive or after its completion participants will be able to indicate if they are a passenger or a driver.

3) Self-report in the form of a TLFB and additional questions about drinking and driving over the past 7 days will be collected once a week for all participants. Each week participants will be asked to complete a brief survey on the Way to Health site that asks them about drinking events, drinking and driving events, and BACtrack use for the previous week. At enrollment, the research coordinator will confirm that the participant has an active Uber and/or Lyft app installed and active account. This will be done to encourage participants to not drink and drive.

Baseline Phase: All participants will receive an identical baseline phase lasting 4 weeks. This phase will serve as a way of capturing observed and self-reported incidents of alcohol use and driving episodes after drinking. During this phase participants will be asked to install and use the TrueMotion app and will receive a BACtrack device. Once both apps are installed and working the baseline phase will begin.

After the baseline phase, participants will be randomized into one of three arms for the remaining 4 weeks of the trial:

1. *Control arm:* Participants assigned to this arm will continue to use the TrueMotion app and BACtrack device as in the baseline phase. They will also be asked to complete the same weekly self-report survey each week.
2. *Loss-framed messaging arm:* Participants assigned to this arm will continue to use the TrueMotion app and BACtrack device as in the baseline phase. They will also be asked to complete the same weekly self-report survey. During this phase participants will receive a text message on Thursday, Friday, and Saturday before 6:00 PM that are framed as a loss (financially or personal). On each of these days, a text message will be selected from a bank of messages (attached) that utilizes loss aversion as it reminds participants to use the BACtrack app and to not drink and drive (for example, "A BAC >0.04 significantly impairs driving and can lead to a failed sobriety test. A DUI can land you in jail with $10,000-15,000 in fines and increased insurance costs. Don't ruin your life: plan a ride and commit to not drinking and driving tonight. #BESAFE").
3. *Gain-framed messaging arm:* Participants assigned to this arm will continue to use the TrueMotion app and BACtrack device as in the baseline phase. They will also be asked to complete the same weekly self-report survey. During this phase participants will receive a text message (Thursday, Friday, and Saturday before 6:00 PM) that are framed as a gain (financially or personal). On each of these days, a message will be selected from a bank of messages (attached) that utilizes a gain as it reminds participants to use the BACtrack app and to not drink and drive (for example, "A BAC >0.04 significantly impairs driving and can lead to a failed sobriety test. *Save a life*: plan a ride and commit to not drinking and driving tonight. #BESAFE").

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

We will use block randomization where participants and will be to assigned their study arms

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

We are planning to recruit and enroll approximately 60 individuals through recruitment material that will be sent out through emails and fliers (see recruitment material attached). Participants will also be recruited through posted flyers, postcards, email blasts, social media, and by word-of-mouth/colleague referrals at Penn. The flyers will be posted in a variety of public and private locations. Research assistants will recruit participants by handing out information in crowded places, such as on the street or near bars. No one will be approached to participant who appears intoxicated. And No recruitment will occur at public or private places without first obtaining permission. The Penn Social Media & Health

Innovation Lab will assist with recruitment through a variety of social media outlets including Facebook and Craigslist. Language for these postings have been included with the application. All recruitment materials will direct potential participants to either visit the Way to Health portal for more information and to sign up or to call research staff for more information.

When a participant is ready to register for this study they will be directed to the Way to Health platform. A participant will create an account and review an Eligibility screening consent. This brief consent will grant us access to administer a brief eligibility survey. We have decided to use this process to reduce the time needed to read the full consent for those who may not qualify. Once eligibility has been determined eligible participants will be instructed to review and sign the full consent for participation.

We are also planning to recruit through the Emergency Department (ED). Through ED recruitment, we will have an opportunity to encounter potential participants who may benefit from this injury prevention intervention. The Emergency Departments at the Hospital at the University of Pennsylvania (HUP) and Penn Presbyterian Medical Center (PPMC) are staffed with Academic Associates (AA). The AAs are a cadre of staff who are trained, provided appropriate access to patient information, and employed for the express purpose of screening patients for eligibility upon admission and recruiting patients as research participants at clinically appropriate times. The recruitment of research subjects is an ongoing procedure in the ED of HUP and PPMC and their systems for subject recruitment are well established. The AAs at all locations participate in training seminars throughout the year to stay current with protocol updates and to orient to upcoming studies. Approximately 2-4 weeks prior to the recruitment phase, our research team will initiate training seminars with ED staff at HUP and PPMC to discuss the purpose of the proposed study, to familiarize ED staff with the intake protocol and to ensure human subjects research requirements are met. The AA program staff at the HUP and PPMC will evaluate patients in the ED for eligibility to be screened. Our research team members who have completed appropriate trainings and have access to EPIC/PennChart may also participate in these seminars and recruit in the ED.

Eligibility for screening will be determined via the ED tracking system using EPIC. AAs and trained research staff in the ED will review the tracking boards to identify patients age 21-39. This review is for screening purposes only. AAs and research staff will not review medical records for any patient. When an eligible patient is identified (age 21-39), they will check the tracking board and/or confirm with the treating physician or resident physician that the patient is fit to be approached for research (no altered mental status, no active intoxication, not too uncomfortable from pain, no unstable vital signs, no Emergency Severity Index (ESI) level 1 or 2). If the timing is clinically appropriate, the AA or research staff member will confirm with the treating physician that the interviewer will not interrupt the flow of care. Once confirmed, the interviewer will approach the patient to provide information about the study including the inclusion/exclusion criteria. If the timing is suitable and the patient is interested, the interviewer will proceed through the eligibility screening process and the informed consent procedure via electronic device (UPHS-approved tablet or laptop, or patients personal device) used to enroll the patient as a participant via Way to Health. The interview may be conducted with patients in a private room in the ED as they await discharge. For patients on the ward, the interview would also be conducted in a private room. For patients who are discharged before being enrolled, the enrollment process will continue electronically via the Way to Health platform. If its clinically appropriate to approach, but not enroll, the AA or research staff member may approach the patient to provide information about the study including the inclusion/exclusion criteria and obtain contact information for the study team to follow up at a later time. For patients who are discharged before completing the onboarding portion of the enrollment process (downloading apps, providing a photo of their ID,

receiving a breathalyzer) the AA or research staff member may take the patient to a private area in the HUP or PPMC lobby to complete this process.

Following this, a member of the research team will contact the participant to answer any questions and send text message and email links to download the TrueMotion and BACtrack apps and mail the BACtrack device. If enrolled in the ED, the study staff member will set up an appointment with the participant to go through all of the enrollment steps. Staff will ensure full comprehension of study procedures and requirements during this call. Participants will also be asked to complete the intake survey to continue in the trial. The trial timeline will not begin until the intake has been completed, all apps have been installed and activated, and the BACtrack device has been received.

Participants will be asked to complete 2 surveys outside of the weekly self-report survey using the Way to Health portal. They will be prompted via way to health to complete an intake survey and end of study survey at predetermined time points (following eligibility and consent and study completion respectively).

Attached to this protocol are the following study instruments for data collection and recruitment: 1) Written Informed Consent 2) Eligibility Survey 3) Intake Survey 4) End of Study Survey 5) Weekly self-report survey

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

Way to Health (Survey data): All personal information that the participant is asked to provide will be collected via Penn's Way To Health study platform. Way To Health collects subjects names, dates of birth, addresses, email addresses, phone numbers, and the last four digits of their social security number. They also request the name and phone number of an alternate contact. To assure that participant confidentiality is preserved, individual identifiers are stored in a single password protected system that is accessible only to study research, analysis and IT staff. The last four digits of participant's social security numbers will be stored in a locked cabinet to be destroyed at a later date. An investigator or statistician who logs in will be able to access only non-identifiable data. The Way To Health administrative group and research coordinators responsible for contacting participants for follow-up study visits or responding to questions about the study are able to view participant names and contact information. The WTH web development team and Project Director currently have administrative access to PHI. All of these personnel will have completed Human Subjects Protection and HIPAA privacy training. The system automatically generates logs of all data queries which can be reviewed by research staff to ensure that no unauthorized persons have gained access to identifiable information.

This system is hosted on site at The University of Pennsylvania and is protected by a secure firewall and several layers of operational security. Once a participant has been entered into this system, they are given a unique study identification number (ID). Any datasets and computer files that leave the firewall are stripped of all identifiers and individuals are referred to by their study ID. The study ID is also used on all analytical files. The Penn Medicine Academic Computing Services (PMACS) is the hub for the

hardware and database infrastructure that supports the project and the Way To Health web portal is built on this infrastructure. The data collected for Way To Health based studies is stored in mySQL databases on a PMACS-operated blade server environment devoted specifically to Way To Health. The data center is housed in Information Systems and Computing at 3401 Walnut Street. All data are stored in a single relational database, allowing researchers to correct mistakes. Every SQL transaction, including accessing and changing data, is logged for auditing purposes. Data are entered into the database through several different mechanisms. Participants enter their own personal information and respond to surveys through a PHP-based web interface. Researchers have a separate interface that allows them to manually enter data if needed. Datasets are stripped of all personally identifiable information when exported for analysis. The web application automatically removes all identifiers when a researcher requests an analytic dataset. The only people with access to identifiable participant information are pre-specified Research Coordinators responsible for contacting participants for follow-up. Personal information and research data will be stored in separate SQL tables and will be linked by a computer-generated ID number. Additionally, any information that leaves this system to communicate with third party data sources (i.e. survey software) is stripped of any identifiers and transmitted in encrypted format.

The same unique study ID is used to link these outside data to the participants. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by UPenn system managers. Way To Health uses highly secure methods of data encryption for all transactions involving participant's financial information using a level of security comparable to what is used in commercial financial transactions. This multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. All communications between users and our site will be encrypted with SSL/HTTPs technology.

TrueMotion (Driving data): TrueMotion requires users to enter in basic information to set up the account policy. This includes: Username Password Name Phone number Email The TrueMotion app currently tabulates the following data which are uploaded securely to the TrueMotion server: The following raw data fields organized at the timestamp level (clustered within drives, clustered within participants) will be transferred in CSV files in a way that can be securely downloaded in bulk by the University of Pennsylvania: Trip level data set with user ID and trip ID: 5. Start/stop time, location, and intensity of detected braking and acceleration events 6. Start/stop time, location, and intensity of speeding events (excess speed relative to an absolute threshold or relative to local speed limits) 7. OS-level events like screen on, screen unlock, call state 8. Start/stop time and location of detected distraction events using our sensor-based algorithms: phone calls (with a detection of in-hand versus hands-free) and general non-call usage like tapping, typing. As far as the time-series sensor data which can be linked with a user ID and trip ID, TrueMotion will provide: 2. GPS points (lat/ lon position, speed, accuracy, etc) at 1 Hz 3. IMU sensor data (3-axis accelerometer, gyroscope, and magnetometer) at 9 Hz Using an established secure data transfer, data collected by the TrueMotion app will be posted on a secure FTP server managed by TrueMotion. Our study team has been granted password access to pull these data onto PMACS server in one week increments. Data will not be tracked or analyzed in real time.

BACTtrack (Breathalyzer Data) We collect time-stamped and geocoded data on breath alcohol content using the BACTrack App which pairs with the FDA approved BACtrack Mobile Pro. Each participant will be instructed to download the BACTrack View app from the Apple App store and register a uniquely assigned, de-identified study email (e.g. besafe24@waytosafety.org) to create a BACTrack account. Participants will need to accept the BACTrack privacy policy and accept the option to share data with BACtrack. No identifying HIPAA sensitive information will be entered into BACTrack app registration portal by study participants. BACtrack will provide the University of Pennsylvania a weekly download of all data collected from designated user accounts (prefix besafe) via access to BACtracks secure Box folder. These password protected CSV files will be downloaded from the BACtracks Box folder by the UPenn research coordinator on a weekly basis and be inputted into Way to Health. This includes the de-identified user ID (e.g. besafe24), timestamped and geocoded guessed and actual BAC measurements. In addition to the BACTrack privacy policy outlines that personally identifiable information (account names) will not be shared with outside parties, we will also obtain an NIH Certificate of Confidentiality that will protect the University of Pennsylvania from disclosing this potentially sensitive information to any third parties.

Radiation Exposure*

Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?

No

Human Source Material*

Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?

No

CACTIS and CT Studies*

Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?

No

CAMRIS and MRI Studies*

Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?

No

Cancer Related research not being conducted by an NCI cooperative group*

Does this protocol involve cancer-related studies in any of the following categories?

No

Medical Information Disclosure*

Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?

No

CTRC Resources*

Does the research involve CTRC resources?

No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*

Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?

No

Primary Focus*

Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x Sociobehavioral (i.e. cognitive or behavioral therapy)
Drug
Device - therapeutic
Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
Surgical
Diagnostic test/procedure (research-related diagnostic test or procedure)
Obtaining human tissue for basic research or biospecimen bank
x Survey instrument
None of the above

Sponsors

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Funding Sponsors

Name: **UNIVERSITY OF PENNSYLVANIA**
Type: **UPENN Internal**

Funding sponsors billing address

If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

University of Pennsylvania Transdisciplinary Awards Program in Translational Medicine and Therapeutics (TAPITMAT) Program in Incentive Based Translational Science (IBTS) 2016

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor
None

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Industry Sponsor
None

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?
Status of contract

Multi-Site Research

Other Sites
No other sites

Protocol

Abstract

Nearly 88,000 people die annually from alcohol-related causes, making it the third leading cause of preventable death in the US.1 Excessive alcohol consumption is a major risk factor for injury, assault, and suicide. Framed messaging, whether through leveraging health gains or loss aversion, has been found to be effective in motivating people to complete certain activities such as quitting smoking,to purchasing select items, and preventative behaviors like using sunscreen. [10,36,37] However, theymay not be as effective in other areas such as food choice.[14] The next logical step, which is the goal of this project, is to demonstrate the feasibility of a scalable intervention using loss- or gain-framed messaging to reduce drinking and driving, compare the effectiveness of each type of messaging, and to increase the use of a personal BAC monitor. Our long-term objective is to secure federal funding for research that leverages insights from behavioral economics supported by smartphone technology to reduce risky drinking, drinking and driving, and to increase self-monitoring and understanding of how alcohol affects us. This long-term objective is consistent with the recently released FY 2016-20 NIH Strategic Vision that strives to deliver effective mobile health (mHealth) technologies for health promotion and disease

prevention and monitoring blood-alcohol levels in real time to prevent alcohol-related injury and disease.

Objectives

Overall objectives

The overall objective of this project is to leverage smartphone-paired breathalyzers to implement cost-effective and scalable behavioral interventions to reduce risky drinking behaviors such as drinking and driving. Prospect theory proposes that messages framed in different ways can elicit different responses from individuals.[36] Loss aversion refers to people's tendency to prefer avoiding losses to acquiring equivalent gains: it's better to not lose $5 than to find $5. People are more motivated to avoid losing something than they are to win something. Studies have found that delivering messaging framed as a loss are also effective in motivating certain behaviors. On the other hand, gain-framed messages have been shown to have a positive effect on preventative healthcare.[37] By using automated remote monitoring, innovative loss aversion and gain-framed messaging strategies incorporating insights from behavioral economics could be more easily implemented by delivering effective messaging prior to a risky behavior taking place. We hope that the use of loss aversive and/or gain-framed messaging will lead to individuals improving planning behavior around drinking, especially in regards to drinking and driving. The objective of this project is to demonstrate the feasibility of a scalable intervention using loss- gain-framed messaging to reduce drinking and driving, compare the effectiveness of each type of messaging, and to increase the use of BAC monitors as a way to plan safer strategies when drinking. Our long-term objective is to secure federal funding for research that leverages insights from behavioral economics supported by smartphone technology to reduce risky drinking. This long-term objective is consistent with the recently released FY 2016-20 NIH Strategic Vision that strives to deliver effective mobile health (mHealth) technologies for health promotion and disease prevention and monitoring blood-alcohol levels in real time to prevent alcohol-related injury and disease.

Primary outcome variable(s)

The primary outcome will be: Change in proportion of breathalyzer measurements submitted with self-reported drinking episodes across groups.

Secondary outcome variable(s)

Secondary outcomes will be: 1) Change in frequency of BACtrack monitoring within each intervention group from baseline; 2) Drinking and driving episodes in which their BAC via self-report or BAC measure is expected to be positive; 3) Changes in accuracy of BAC guess vs actual BAC measure with continued use (Does a participant become more accurate overtime in predicting what their BAC will be prior to measuring). Lack of previous research prevents us from calculating the power to detect the drinking and driving outcomes, which is why this pilot trial is critical for securing future funding.

Background

Nearly 88,000 people die annually from alcohol-related causes, making it the third leading cause of preventable death in the US.[1] Excessive alcohol consumption is a major risk factor for injury, assault, and suicide. In 2013, 10,076 people were killed in drinking and driving-related motor vehicle crashes, accounting for one-third of all driving-related deaths.[5] Individuals who engage in drinking and driving, compared to those do not, have similar cognitive abilities, actually understand legal consequences

better, but are poorer planners and more present-biased, heavily weighing immediate costs and benefits relative to future ones when making decisions.[6] This suggests that strategies such as planning a designated driver and providing immediate reinforcement of the benefit of moderating alcohol consumption are particularly promising approaches to reduce drinking and driving and binge drinking. Nationally, 17% of individuals aged 18 and older report binge drinking in the past month.[7,8] Importantly, binge drinkers are 14 times more likely to report alcohol-impaired driving than non-binge drinkers.[9] Prospect theory proposes that messages framed in different ways can elicit different responses from individuals.[36] Loss aversion refers to people's tendency to prefer avoiding losses to acquiring equivalent gains: it's better to not lose $5 than to find $5. People are more motivated to avoid losing something than they are to win something. Studies have found that delivering messaging framed as a loss are also effective in motivating certain behaviors. On the other hand, gain-framed messages have been shown to have a positive effect on preventative healthcare.[37] By using automated remote monitoring, innovative loss aversion and gain-framed messaging strategies incorporating insights from behavioral economics could be more easily implemented by delivering effective messaging prior to a risky behavior taking place. The effectiveness of this messaging relies on being able to deliver a well-designed, motivating messaging prior to the risky behavior occurring and to have an easy to measure behavior as an indicator of success. As alcohol is metabolized more quickly than most drugs, making it difficult to monitor in the community and self-report of drinking and driving incidents can be underestimated these are not desirable metrics to use alone. A recent trial demonstrated the feasibility of sending text message videos of personalized breathalyzer readings in non-dependent frequent drinkers.[12] However, this process is difficult to scale up as study staff had to confirm breathalyzer readings manually in videos sent by participants. In the last two years, breathalyzers that pair with smartphones have come on the market,[17,19] allowing individuals to monitor and more easily track their own breath alcohol concentration (BrAC). Given the popularity of these devices,[20,21] booming sales (an $816 million dollar market),22 and the ability to share the data they generate in a secure and automated fashion, the devices could be used to as a way to measure the effectiveness of interventions aimed at reducing risky drinking on a much broader scale.

Real time knowledge of your level of intoxication could help educate the population and lead to better planning behavior, reducing incidents of drinking and driving. One difficulty in using these devices to this end is that users may not be inclined to measure their BAC when it matters most. The information provided by BAC monitors is only effective if it is being used. Combining these devices with innovative strategies that incorporate insights from behavioral economics to deliver loss averse messaging prior to a risky behavior taking place could not only increase self-monitoring but could have a significant impact on planning behavior as well.[23,24] Communication and framing are important in health care, how messages are framed can impact behavior.[35] A nutritional study on children found educational messages paired with loss framed messages, gain framed messaged, and a small incentive positively impact behavior change.[34] To date, there are no published studies testing the use of messaging to increase the use of smartphone-paired breathalyzers. Our cross-disciplinary research group at Penn recently obtained funding to conduct what will be the first peer-reviewed study to validate the test accuracy of the leading smartphone-paired breathalyzers on the market against a policy grade breathalyzer. The next logical step, which is the goal of this project, is to demonstrate the feasibility of a scalable intervention using messaging to increase the use of the monitors.

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Study Design

Phase*

Not applicable

Design

Study population: We will recruit 60 participants for this trial. Participants must be (a) over 21 years of age, (b), Reports an average of one heavy drinking day (men more than five drinks, women more than four drinks) per week over the preceding 8 weeks. (d) a valid photo ID (e) willing and able to use an Uber or Lyft or septa as transportation home (f) drives four or more trips per week (g) and owns an Apple iPhone or Android smartphone. Participants will be excluded if they (a) desire alcohol treatment now or received it in the past 6 months, (b) alcohol use disorder per DSM-V criteria and (c) non-English-speaking, and (d) women who are pregnant (e) individuals who should not consume alcohol due to a medical condition.

Procedures: Participants will be provided with a smartphone-paired breathalyzer (BACtrack) and a smartphone app that tracks (TrueMotion) driving behavior. The drive tracking app has been modified for research purposes to run completely in the background with special privacy protections for research participants with an approved NIH Certificate of Confidentiality.

Data and information will be collected in 3 ways throughout this study:
1) The BACtrack device and app will require the participant to initiate use during all phases of the trial. Researchers will instruct participants to use this device during the study when drinking to help inform them of their level of impairment and ability to operate a vehicle. As part of the BACtrack app each participant will be asked to guess what their BAC is prior to submitting a sample. Once a sample is submitted and processed the app will display both the actual BAC measure as well as the participants guess. They will also be able to indicate of the sample was provided by them or someone else. Data collected using this app and device includes guessed BAC, actual BAC, person submitting the sample, GPS coordinates, and timestamps.

2) The TrueMotion app will collect participant driving data without any additional initiation by the participant. Data collected from this app will include GPS coordinates, driving speed, trip length, time of drive, and cellphone use while driving. During a drive or after its completion participants will be able to indicate if they are a passenger or a driver.

3) Self-report in the form of a TLFB will be collected once a week for all participants. Each week participants will be asked to complete a brief survey on the Way to Health site that asks them about drinking events, drinking and driving events, and BACtrack use for the previous week

Participants will be given educational information on the risks of drinking and will be randomized, using block randomization, to a control or one of two intervention groups for 8 weeks. Participants will be blinded as to their group assignment. Participants in the intervention groups will receive messages on Thursday, Friday, and Saturday before 6:00 PM and will be informed of this random selection in the consent. For the intervention groups, the context of these messages will differ across each group and participants will not be alerted to this difference. Specifically, the consent will state that researchers will

test the effect of different messaging strategies on the use of self-monitoring. Text messages will be delivered 3 days a week—Thursday, Friday, and Saturday—through the Way to Health platform and Twilio, a texting service that is contracted through Way to Health.

This program does not encourage drinking and driving, in fact it is designed in hopes that participants will be more informed about their level of intoxication and their ability to drive. Additionally, messages delivered following a positive BAC reading highlights the dangers and risks of a DUI. Attached to this protocol are examples of these messages.

Measures and Data Analysis. Participants will complete a baselineand end of study survey via Way to Health with standard measures of drinking and driving behavior, measures of planning ability, a delay discounting task, and demographic variables. Time-stamped and geocoded drive trip data will be obtained from the TrueMotion app. Self-reported drinking behavior will be recorded weekly using the timeline follow back method.

The ***primary*** outcome measure will be the change in proportion of breathalyzer measurements submitted with self-reported drinking episodes across groups.

Secondary outcomes will be: 1) Change in frequency of BACtrack monitoring within each intervention group from baseline; 2) Drinking and driving episodes in which their BAC via self-report or BAC measure is expected to be positive; 3) Changes in accuracy of BAC guess vs actual BAC measure with continued use (Does a participant become more accurate overtime in predicting what their BAC will be prior to measuring). Lack of previous research prevents us from calculating the power to detect outcome #3, which is why this pilot trial is critical for securing future funding.

We will use logistic regression as our primary analytic model to assess effectiveness, between and within the interventions. Although longitudinal models such as generalized estimating equations might be considered in light of the repeated measures among individual participants, logistic regression is preferred in this case because the primary outcome collapses most time points into a single dichotomous measure. Approach to missing data: As our main outcome in this trial is the proportion of measures conducted overtime, missing data will be scored as not completing a measurement.

Participants missing weekly self-report surveys will be reminded to complete a TLFB for any missing weeks regularly. If a participant fails to complete 75% of the self-report surveys under baseline conditions they will not be allowed to continue to the intervention phase. If participants who have moved to the intervention phase fail to complete self-report data during the intervention phase estimates on drinking behavior can be derived from their baseline data.

Study duration

Participants will be enrolled for eight weeks in the study. The projected start date of the study is September 1, 2017 and the date of completion is March 1, 2018.

Resources necessary for human research protection

Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the

researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

The project manager will oversee all study operations and research assistants will be trained in the protocol and present at the study sessions. All research staff will be fully trained in the pilot protocol and their role in the study, will be supervised by the PI, Dr. Mucio (Kit) Delgado, MD (Assistant Professor of Emergency Medicine), and will be trained to refer patients to the appropriate provider (emergency department, outpatient doctor/clinic, social worker) as warranted.

Characteristics of the Study Population

Target population

We will recruit 60 participants for this trial. Participants must be (a) over 21 years of age, (b), Reports an average of one heavy drinking day (men more than five drinks, women more than four drinks) per week over the preceding 8 weeks. (d) a valid photo ID (e) willing and able to use an Uber or Lyft or septa as transportation home (f) drives four or more trips per week (g) and owns an Apple iPhone or Android smartphone. Participants will be excluded if they (a) desire alcohol treatment now or received it in the past 6 months, (b) alcohol use disorder per DSM-V criteria and (c) non-English-speaking, and (d) women who are pregnant (e) individuals who should not consume alcohol due to a medical condition.

Subjects enrolled by Penn Researchers

60

Subjects enrolled by Collaborating Researchers

0

Accrual

It is expected that the majority of subjects will volunteer to participate after responding to IRB approved advertisements on mass transit and broadcast email messages at institutions (including the University of Pennsylvania Health System) that offer such a service; and by posting/distributing recruitment materials in community settings with public posting areas or other means of providing community access to materials (such as hospitals, town halls, public libraries, YMCAs, health fairs/ organizations). Research assistants will hand out fliers for the study in approved public and private locations. Research assistants will recruit participants by handing out information in crowded places, such as on the street or near bars. No one will be approached to participate who appears intoxicated.

Participants recruited at the hospital will be introduced to the study by a dedicated member of the study team and provided with a link to the Way to Health website. The academic associates or research assistant will introduce the study to eligible patients and provide them with an iPad to administer a brief eligibility screening (if applicable). If eligible for the study participants will be instructed to review and sign the full consent for participation, if willing.

And No recruitment will occur at public or private places without first obtaining permission. Recruitment materials may also be posted on social media and in newsletters and postings. Social media can include Facebook, Twitter, Snapchat, Craigslist, and other outlets as they become available.

Newsletters can include internal UPenn postings and newsletters sent by organizations who agree to share our recruitment information.

Key inclusion criteria

Inclusion criteria will be: (a) over 21 years of age, (b), Reports an average of one heavy drinking day (men more than five drinks, women more than four drinks) per week over the preceding 8 weeks. (d) a valid photo ID (e) willing and able to use an Uber or Lyft or septa as transportation home (f) drives four or more trips per week (g) and owns an Apple iPhone or Android smartphone. Participants will be excluded if they (a) desire alcohol treatment now or received it in the past 6 months, (b) severe alcohol use disorder (AUD) per DSM-V criteria (6 or more AUD symptoms reported)and (c) non-English-speaking, and (d) women who are pregnant (e) individuals who should not consume alcohol due to a medical condition such as liver disease, cancer, and seizure disorders. Participants will be asked to answer yes if they have any disorder that their doctor has suggested that they should not drink alcohol. If they are unsure or say I dont know we will ask them to speak with their doctor prior to participation.

Key exclusion criteria

Exclusion criteria will be (a) desire alcohol treatment now or received it in the past 6 months, (b) severe alcohol use disorder per DSM-V criteria (6 or more AUD symptoms reported) and (c) non-English-speaking, and (d) women who are pregnant (e) individuals who should not consume alcohol due to a medical condition.

Vulnerable Populations

Children Form
Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
Fetuses and/or Neonates Form
Prisoners Form
Other
x None of the above populations are included in the research study

Populations vulnerable to undue influence or coercion

This study may enroll employees or students of Penn. These participants will not be recruited directly or incentivized differently than other subjects in the study. During informed consent study staff will review the voluntary nature of their participation and reminded that they are able to leave the study at any time during the study procedures.

Subject recruitment

Subjects for this study will be recruited primarily from individuals who present themselves for evaluation for study inclusion by calling our research facility. It is expected that the majority of subjects will volunteer to participate after responding to IRB-approved advertisements on mass transit; and broadcast email messages at institutions (including the University of Pennsylvania Health System) that offer such a service; and by posting/distributing recruitment materials in community settings with public posting areas or other means of providing community access to materials (such as hospitals, town halls, public libraries, YMCAs, health fairs/organizations). Research assistants will hand out fliers for the study

in approved public and private locations. We will obtain permission before distributing or posting the approved recruitment materials.

For participants recruited at the hospital, those who are eligible will be introduced to the study by a dedicated member of the study team and provided with a link to the Way to Health website. The academic associates or research assistant will introduce the study to eligible patients and provide them with an iPad to administer a brief eligibility screening (if applicable). If eligible for the study participants will be instructed to review and sign the full consent for participation, if willing. They will then schedule an appointment to review the enrollment procedures over the phone with a study team member. This can also be done in person if the participant requests. If enrollment is completed in person, the participant will be provided their BACtrack breathalyzer and Clincard.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
Yes

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.*
We plan to use Facebook and Twitter to post recruitment messages. These messages are severely limited in terms of the length they can be. Our message will be "Help Upenn researchers reduce drinking and driving while earning money" and will include a link to the WTH study portal that will contain more information such as that listed on our recruitment flyer. We also plan to post our recruitment flyer on Craigslist.

Study Procedures

Suicidal Ideation and Behavior

Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures

Enrollment: Potential participants will be directed to the Way to Health platform. A participant will create an account and review an Eligibility screening consent. This brief consent will grant us access to administer a brief eligibility survey. We have decided to use this process to reduce the time needed to read the full consent for those who may not qualify. Once eligibility has been determined eligible participants will be instructed to review and sign the full consent for participation. Following this, a member of the research team will contact the participant to answer any questions and to mail out the BACtrack device. Participants will also be asked to complete the intake survey to continue in the trial. The trial timeline will not begin until the intake has been completed and all devices and apps have been received and activated.

Randomization: Once participants have received and activated their devices they will be placed into the baseline phase of the trial for 4 weeks. Following baseline, if the participants have completed 75% of their self-report measures they will be randomized to one of three groups: a) control, b) loss-framed messaging group, or c) gain-framed messaging group.

Baseline Measurement: During the baseline period, the TrueMotion app will passively track driving behavior and participants. Participants will not receive any information on whether to use their BACtrack device. At the end of the baseline measurement period participants will complete an end of Baseline survey via way to health.

Intervention Period: After four weeks, participants will be randomized into one of three arms: control, loss-framed messaging group, or gain-framed messaging group.

Weekly Surveys: Each week, under both phases, participant will be prompted to complete a self-report survey and TLFB.

Deception

Does your project use deception?

No

Analysis Plan

Measures and Data Analysis. Participants will complete a baseline, end of baseline period, and end of study survey via Way to Health with standard measures of drinking and driving behavior, measures of planning ability, a delay discounting task, and demographic variables. Time-stamped and geocoded drive trip data will be obtained from the TrueMotion app. Self-reported drinking behavior will be recorded weekly using the timeline follow back method.

Primary outcome: The primary outcome measure will be the change in proportion of breathalyzer measurements submitted with self-reported drinking episodes across groups.

Secondary outcome measures include: 1) Change in frequency of BACtrack monitoring within each intervention group from baseline; 2) Drinking and driving episodes in which their BAC via self-report or BAC measure is expected to be positive; 3) Changes in accuracy of BAC guess vs actual BAC measure with continued use (Does a participant become more accurate overtime in predicting what their BAC will be prior to measuring). Lack of previous research prevents us from calculating the power to detect the drinking and driving outcomes, which is why this pilot trial is critical for securing future funding.

To measure the primary outcome, we will employ a logistic regression using the participants baseline as a predictor and the intervention vs. control and vs each other as the primary predictors. Although longitudinal models such as generalized estimating equations might be considered in light of the repeated measures among individual participants, logistic regression is preferred in this case because the primary outcome collapses most time points into a single dichotomous measure.

Approach to missing data: As our main outcome in this trial is the proportion of measures conducted overtime, missing data will be scored as not completing a measurement. Participants missing weekly self-report surveys will be reminded to complete a TLFB for any missing weeks regularly. If a participant fails to complete 75% of the self-report surveys under baseline conditions they will not be allowed to continue to the intervention phase. If participants who have moved to the intervention phase fail to complete self-report data during the intervention phase estimates on drinking behavior can be derived from their baseline data.

Data confidentiality

x Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

x Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x Wherever feasible, identifiers will be removed from study-related information.

x A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

x Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

x Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies on subject privacy and the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. The safeguards described above will be implemented to ensure subject confidentiality. No identifiable data will be used for future studies without first obtaining IRB approval. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes). We will be collecting licenses through the secure Way to Health portal to verify that all participants are licensed to drive. We will destroy these images when the participant study participation is complete, no more than 1 week after their final survey completion

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?

No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

Privacy is of the utmost concern for us. In this trial every participant will be assigned a participant number, this will link their study related data. We will not release any names or information to anyone outside of this study. Participants will complete all surveys online and will not be required to attend any in person sessions. We will allow for participants to be placed on teams with unknown others if they chose and will never release their names to team members. We will include all risks associated with participating such as the potential risk of personal information being obtained in the consent for each participant to consider.

Data Disclosure

Will the data be disclosed to anyone who is not listed under Personnel?

No. Participant BrAC measurements and survey responses from participants will not be linked to participant identifying information, and data will be available only for study personnel. However, all potential subjects will be informed that the information they provide will be held in confidence to the extent that the law allows, but that the exception to this confidentiality is any disclosure of potential for immediate harm of themselves or others, such as active suicidal or homicidal ideation or child abuse. The participants will be notified prior to participation that if any of these issues are raised, the researchers will take whatever steps are necessary to protect the subject or others, including bringing risk of harm to the attention of the proper authorities. As an emergency physician, Dr. Delgado is experienced with assessing this type of risk and committing patients or notifying child protective services or law enforcement when necessary.

*Data Protection**

x Name
x Street address, city, county, precinct, zip code, and equivalent geocodes
All elements of dates (except year) for dates directly related to an individual and all ages over 89
x Telephone and fax number
x Electronic mail addresses
x Social security numbers
Medical record numbers
Health plan ID numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
x Device identifiers/serial numbers
Web addresses (URLs)
Internet IP addresses
Biometric identifiers, incl. finger and voice prints
Full face photographic images and any comparable images
Any other unique identifying number, characteristic, or code
None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable

Consent

1. Consent Process

Overview
Participant consent will be completed via the Way to Health Platform. Participants will be instructed to create a username and password through the WTH platform and then review and sign a brief consent allowing us to assess eligibility. Following this they will be screened with an eligibility survey presented

on the WTH platform. Once eligibility has been determined eligible participants will be instructed to review and sign the full consent for participation. Once complete they will be asked to complete the intake survey immediately. Questions will cover demographics, opinions, perceptions and experiences with alcohol consumption and driving. They will then continue on with their trial participation.

If they are not eligible, the participant will be informed that they are ineligible for the current study and will not complete any study procedures.

A member of the study team will then contact the participant to schedule an in person meeting or a phone meeting. If the participant completed consent in the hospital, they will move forward with the enrollment procedures or set up a time with a research team member to complete enrollment procedures at a later date and time over the phone. During this meeting the study team will answer any questions pertaining to the consent or the study. Participants will receive an email or a text message reminder regarding incomplete steps in WTH depending on their preference selection for communication. A member of the study team will contact all enrolled participants to ensure understanding of study procedures. Electronic signatures will be obtained.

Children and Adolescents
not applicable

Adult Subjects Not Competent to Give Consent
Participants will be excluded from the study if they are not competent to consent to the study.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Minimal Risk*
Impact on Subject Rights and Welfare*
Waiver Essential to Research*
Additional Information to Subjects

Written Statement of Research*
Yes

Risk / Benefit

Potential Study Risks
This is a minimal risk, behavioral intervention study. Physical risk is no more than the risks already caused by risky driving behavior. Participants will not have to interact with the TrueMotion app after installation and will be instructed to only use the BACtrack device in a safe setting. There are no expected serious adverse events related to the intervention or participation in this study. This program does not encourage drinking and driving, in fact, it is designed in hopes that participants will be more

informed about their level of intoxication and their ability to drive. Additionally, messages delivered following a positive BAC reading highlights the dangers and risks of a DUI. Attached to this protocol are examples of these messages.

There is some risk that subjects will be identified as participants in the study and that the confidential information provided regarding psychiatric and substance use history will be inadvertently disclosed without the subjects permission. To help protect against this we will be using assigned participant IDs that will be tied to the data derived in this trial. These IDs will be used by our partners (TrueMotion and BACtrack) as the key identifier and data labeling. We will not disclose participants names as part of this trial.

Rating Scales and Questionnaires. To avoid breach of confidentiality, subjects' names will appear only on a consent form, a telephone screening form and a "key" form kept in a locked cabinet. All forms that contain identifying information will be kept double locked (i.e., in a locked cabinet, in a locked room) to maintain their security. All study data forms will contain only the subject's unique study identification number, using a reference system maintained by the study staff. Completed study forms will be kept in a locked cabinet, the key to which will be available only to the PI and staff working on this study. Subject visits will be scheduled and no information about the subject will be provided to anyone (except in emergencies as defined above) in person or by telephone. All paper research records will be stored in locked cabinets and only the investigators and only IRB approved study will have access to those records.

Potential Study Benefits

All participants will benefit by receiving a text message to promote the use of a BAC monitor to help plan less risky driving incidents. Participants are contributing to preparation of a larger study, which in turn may have benefits to society in general. Understanding the potential of using breathalyzers to reduce risky drinking has the potential to benefit society in general.

Alternatives to Participation (optional)

Data and Safety Monitoring

All source documents will be identified by study identification (ID) number, and the key to that ID number will be kept in a locked file cabinet. All personally identifiable information also will be kept separately in a locked file cabinet. No results will be reported in a personally identifiable manner. All tracking system data and research database information will be password-protected with several levels of protection: first, a password will be required to access the computer of the user who has access to the database; second, a password will be required to access the database. The principal investigator, Dr. Delgado, and the project manager, Jessie Hemmons, will monitor and maintain confidentiality of data.

Risk / Benefit Assessment

In general the benefits outweigh the risks in this study. Participants will receive information on alcohol consumption and health. Participants are also contributing to preparation of a larger study, which in turn may have benefits to society in general. Although there are some risks involved in participating in this study, as mentioned above, these can be minimized to ensure that the potential benefits exceed the potential risks, so that the risk/benefit ratio is favorable.