Going Protocol title **Pilot randomized control trial of smartphone-enabled breath alcohol monitoring on perceived fitness to drive a vehicle among intoxicated adults**

Short Title BrAC monitoring and Perceived Fitness to Drive Among Intoxicated Adults

Brief description of the protocol Please provide, in 500 characters or less, a description of the purpose of the study, the targeted population and the procedures/interactions/interventions necessary for participation.

The **goal of this study** is to conduct a laboratory-based pilot randomized control trial of smartphone-enabled breath alcohol monitoring on perceived fitness to drive a vehicle among intoxicated adults. We will enroll up to 30 adults aged ≥ 21-44 who are frequent drinkers without dependence who drive more than four times per week to complete a standardized alcohol drinking protocol in a monitored setting collecting breathalyzer measurements. The protocol involves consuming three weight-based doses of alcohol with a target BAC of 0.10 and completing breathalyzer measurements every 20 minutes until a BAC of 0.03 is reached. The control group would complete a visual analog scale on their perceived fitness to drive and be blinded to their breath alcohol readings with the BACtrack Mobile Pro device, while the intervention group would do the same, but be shown their breath alcohol readings on the paired BACtrack smartphone application. Our previous research has validated the accuracy of the BACtrack Mobile Pro device to measure BAC within +/- 0.001 of police-grade breathalyzer and estimate BAC within +/- 0.01 of a blood test.

Submission type

Social and Behavioral Sciences

Is this a response to an already submitted Initial Review? 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

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? YES

Pathology and Laboratory Medicine Resources*

Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System? NO

Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components? NO

Research involving blood transfusion or drug infusions* NO

Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes? NO

Trial in Radiation Oncology. Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee? NO

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? (UPHS includes all Penn hospitals and clinical practices, including the Clinical Care Associates network of community practices). Examples of UPHS services/tests/procedures includes the Clinical Translational Research Center (CTRC), laboratory tests, use of the pathology lab, cardiovascular imaging tests or radiology imaging tests (whether being billed via the Service Center or through UPHS), other diagnostic tests & procedures and associated professional services, etc.

YES

Primary Focus The primary focus of your research is best described by which of the following (single best answer):

- Tissue/biospecimen
- Research on human data sets (e.g. medical records, clinical registries, existing research data sets, medical administrative data, etc.)
- Epidemiological research
- Survey research (the main focus of the research is administration of a survey to research subjects)
- Sociobehavioral (i.e. observational or interventional)
- Mechanistic or physiologic study in human subjects (T1 Translational research in humans or Phase I drug research)
- Clinical Trial (prospectively assigning subjects to health-related interventions to evaluate outcomes)
- Quality Improvement research (assessment of clinical care practices to enhance patient care)
- Other

Protocol Interventions: Does your protocol require any of the following interventions? Check all that apply.

- 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
- Survey
- None of the above

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Department budget code

Funding Sponsors: (internal pilot) University of Pennsylvania Injury Science Center

Project Funding

Is this project funded by or associated with a grant or contract? Yes

Study Instruments:

1. Intake Survey (attached to the protocol)

a) Driving History and Experience Questionnaire DHEQ (Harrison & Fillmore, 2005)This self-report questionnaire gathered 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 gathered 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).

2. Decision making survey (attached to the protocol)

a). the Delayed discounting questionnaire (Senecal et al 2012).

b). 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 (score range 30120).

3. Self-Reported intoxication Survey (attached to the protocol): Includes visual analogue scales which measure self reports of

a) Perceived Driver Fitness (Van Dyke and Fillmore 2014)

b) Perceived intoxication and BAC estimation.(Harrison and Fillmore 2005; Harrison et al 2007)

4. Smartphone Breathalyzer (BACTrack Mobile Pro). Our previous research (IRB protocol # XXX) has validated the accuracy of the BACtrack Mobile Pro device to measure BAC within +/- 0.001 of police-grade breathalyzer and estimate BAC within +/- 0.01 of a blood test. This work has been submitted as an abstract to a national meeting on injury prevention and will be submitted in next two months for peer-reviewed publication. (https://www.bactrack.com/products/bactrack-mobile-smartphone-breathalyzer?gclid=CNi555bygNMCFZyPswodb7sNOg&mkwid=&pcrid=104045623957&pdv=m&pkw=&pmt=&ring-central=google-ppc).

5. Bactrack Skyn: Bactrack skyn is a wearable device that tracks breath alcohol content. A portion of participants will be selected to wear these devices in order to validate their ability to measure and estimate blood alcohol content. (https://www.bactrack.com/pages/bactrack-skyn-wearable-alcohol-monitor).

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

Eligible participants will be randomized into one of two arms:

Arm 1 (Control): Participants randomized to this arm will consume three weight-based doses of alcohol with a target BAC of 0.10 and comple breathalyzer measurements every 20 minutes until a BAC of 0.03 is reached. They will complete a visual analog scale (the Self-Reported intoxication Survey) on their perceived fitness to drive and be blinded to their breath alcohol readings with the BACtrack Mobile Pro device.

Arm 2 (Intervention): Participants randomized to this arm will consume three weight-based doses of alcohol with a target BAC of 0.10 and comple breathalyzer measurements every 20 minutes until a BAC of 0.03 is reached. They will be shown their breath alcohol readings with the BACtrack Mobile Pro device before completing a visual analog scale (the Self-Reported intoxication Survey) on their perceived fitness to drive.

Because of the limited availability of the Bactrack Skyn measurement tool in our previous trial (please reference IRB #825273, “Reducing Risky Drinking using Smartphone Paired Breathalyzer”), we will continue to test the validity of this device with the BacTrack Mobile Pro breathalyzer throughout this protocol.

Method for Assigning Subjects to Groups: Describe how subjects will be randomized to groups.

All participants who meet eligibility criteria and provide written consent will then be randomized at the time of study enrollment using block randomization.

Administration of Surveys and/or Process*: Describe the approximate time and frequency for administering surveys 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 and/or evaluations.

We are planning to recruit and enroll up to 30 participants through recruitment material that will be sent out through email and posted on fliers (see recruitment material attached). Inclusion criteria will be: (a) age 21-39 years old, (b) less than 4 drinking days and less than 12 drinks per week on average in the past 2 months, (c) have consumed at least 4(women) or 5 (men) drinks on one occasion, in the past year without experiencing adverse effects (c) a valid photo ID (d) willing and able to use a rideshare credit or septa token as transportation home from the study visit. Exclusion criteria will be (a) desire alcohol treatment now or received it in the past 6 months, (b) alcohol use disorder with withdrawal 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. Individuals, who are interested in the study, will be contacted and screened over the telephone using our Alcohol Study Screener (attached to this protocol). All participants who meet inclusion criteria will be invited to consent to the study.

Interested participants will call the study hotline where an IRB-approved research assistant or project manager, will answer any questions, administer the study screening and go over the written informed consent. There will be an optional in person study visit for the participant to come in and review study procedures, and sign written informed consent, in person. At the study visit, which occurs at a predetermined time, the participant will first sign written informed consent to participate. They will then take an initial survey, with questions related to their past alcohol use and habits including Driving History and Experience Questionnaire DHEQ1, Drinking and Driving Questionnaire. Participants will also take the Decision making survey, which includes The Barratt Impulsiveness Scale, and the Delayed discounting questionnaire.

Some participants will wear the BACtrack Skyn wrist device, which will start collecting alcohol measurements after the first dose of alcohol. Participants will then receive three doses of vodka mixed with juice based on their gender and weight designed to reach a peak blood alcohol level of .10 g/dL. After each dose, their Breath Alcohol Content (BrAC) will be measured using the BacTrack Mobile device. After each breathalyzer measurement, participants will receive the Self-Report of Intoxication Survey, which will include Perceived Driver Fitness and Perceived intoxication and BAC estimation, which are measured using a visual analogue scale.

For the control group, participants will remain blinded to the BrAC readings on the BacTrack mobile app. For the intervention group, the participants will be shown their BrAC readings on the BacTrack mobile app before completing their Self-Report of Intoxication Survey.

Besides a preliminary study visit for participants to consent to the study and complete the eligibility survey, all research activities will take place in one of the four CTRC study sites and will occur in a study session of approximately six hours in length with up to four participants at each session. Participants will be separated into different research rooms at the CTRC.
Data collection will include contact information, medical history, and history of alcohol use, various measurements of Breath Alcohol Content (BrAC), as well as survey data from the self-reported

intoxication survey. The informed consent process during study enrollment will describe all of these aspects of data collection.

Attached to this protocol are the following study instruments for data collection and recruitment:

1. Written Informed Consent
2. Screening Survey
3. Eligibility Survey
4. Intake Survey
5. Decision making survey
6. Self-Reported intoxication Survey

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.

Paper forms will be used to collect data and a research assistant will create and maintain the research database. 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.

Abstract*

In the last two years, personal breathalyzers that pair with smartphones have appeared on the market, allowing individuals to monitor and track their own Breath Alcohol Content (BrAC). We are in the midst of completing a laboratory based validation study of the test accuracy of six of these devices relative to a police-grade breathalyzer and blood alcohol content (BAC) levels. Our preliminary data from our first 10 participants indicate that at least 2 of the 6 devices (Alcohoot and BACtrack Mobile Pro) are highly accurate within +/- 0.01 of police grade breathalyzers and BAC levels. The next logical step in determining how these devices can be leveraged to reduce drinking and driving is to determine whether knowing one's breath alcohol content in real-time affects the likelihood of driving among intoxicated individuals. In the U.S., it is illegal to drive with a BAC of 0.08 or higher. However, driving is impaired at BACs of 0.04 or higher and some countries impose a stricter illegal BAC limits (e.g. 0.05 or higher). Therefore, while it is hoped that the use of personal breathalyzers may reduce the risk of driving impaired by taking the guesswork out of estimating one's BAC, there is the possibility that some individuals may be more likely to drive if their measured BrAC is less than 0.08 even if they feel intoxicated.

Overall objectives:

Given the popularity of these devices and the ability to share these data in a secure and automated fashion, if reliable, these devices could be used for implementing strategies to reduce risky drinking on a much broader scale than previously possible. Contingency management is the systematic use of behavioral rewards or disincentives to reinforce desired behaviors, and shows promise as one of the most effective means of prevention of drug and alcohol abuse. By using automated remote monitoring, innovative contingency management strategies incorporating insights from behavioral economics could be more easily implemented by providing immediate rewards and feedback and by taking advantage of group-based incentives and norms. Our preliminary data from our first 10 participants indicate that at least 2 of the 6 devices are highly accurate within +/- 0.01 of police grade breathalyzers and BAC levels. Because our long-term objective is to leverage smartphone-paired breathalyzers to implement cost-effective and scalable behavioral interventions to reduce risky drinking behaviors such as drinking and driving, the next logical step is to determine whether knowing one's breath alcohol content in real-time affects the likelihood of driving among intoxicated individuals.

Primary outcome variable:

Perceived fitness to drive on a visual analog scale, repeated every 20 minutes. We will test the hypothesis that those shown the BraC reading vs. those blinded to the BraC reading have lowered perceived fitness to drive for BACs > 0.05.

Secondary outcome variables:

Secondary outcomes: We will conduct descriptive analyses of the association between self-reported measures of intoxication, predicted blood alcohol content, driving fitness, and willingness to drive with measured breath alcohol content by device. We will also explore the effect modification of these by self-reported measures of impulsivity and delayed discounting.

Background: Describe succinctly and clearly the past findings which justify the plan for this project. A summary of the relevant literature in the area of interest and reports of previous studies should be included.

Nearly 88,000 people die annually from alcohol-related causes, making it the third leading cause of preventable death in the US.(National Institute on Alcohol Abuse and Alcoholism, 2015) Excessive alcohol consumption is a major risk factor for injury, assault, and suicide.(Easton, C.J., Swan, S., & Sinha, 2000; McNeill, Sherwood, Starck, & Thompson, 1998; White & Hingson, 2014) In 2013, 10,076 people were killed in drinking and driving-related motor vehicle crashes, accounting for one-third of all driving-related deaths.(National Highway Traffic Safety Administration, 2015) 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.(Sloan, Eldred, & Xu, 2014) 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.(Centers for Disease Control and Prevention, 2015; Substance Abuse and Mental Health Services Administration, 2015) Importantly, binge drinkers are 14 times more likely to report alcohol-impaired driving than non-binge drinkers.(Naimi et al., 2003)

Contingency management, the systematic use of behavioral rewards or disincentives to reinforce desired behaviors, is one of the most effective approaches to reduce drug use,(Alessi & Petry, 2013; Kosten & O'Connor, 2003; N. M. Petry, 2000; Prendergast, Podus, Finney, Greenwell, & Roll, 2006; Roll et al., 2006) likely because heavy substance abusers are consistently more present biased.(MacKillop et al., 2011) Our prior work demonstrates the effectiveness of contingency management among dependent drinkers using daily visits to a treatment center.(Nancy M Petry, Martin, Cooney, & Kranzler, 2000) The effectiveness of contingency management relies on readily being able to detect substance use. However, alcohol is metabolized more quickly than most drugs, making it difficult to monitor in the community. In the last two years, breathalyzers that pair with smartphones have come on the market,("Alcohoot Smartphone Breathalyzer," n.d., "BACtrack Mobile Pro," n.d.; Drivesafe Evoc, n.d. "Floome: Smartphone Breathalyzer," n.d; "DrinkMate," n.d; "BACtrack Ultra-Portable Personal Keychain Breathalyzer," n.d) allowing individuals to monitor and more easily track their own breath alcohol concentration (BrAC). Given the popularity of these devices,("A smartphone breathalyzer," 2015; Jolly, 2015) booming sales (an $816 million dollar market),(Wintergreen Research, 2016) and the ability to share the data they generate in a secure and automated fashion, the devices could be used to implement contingency management strategies to reduce risky drinking on a much broader scale. These could be combined with contingency management strategies that incorporate insights from *behavioral economics* to provide immediate rewards and feedback and take advantage of group-based incentives and norms.(Loewenstein et al., 2007; MS et al., 2015)

In the last two years, three companies have begun to sell breathalyzers that pair with smartphones, allowing individuals to monitor and track their own Breath Alcohol Content (BrAC). Given the popularity of these devices, and the ability to share these data in a secure and automated fashion, if reliable, these devices could be used for implementing contingency management strategies to reduce risky drinking on a much broader scale than previously possible. Furthermore, by using automated remote monitoring, innovative contingency management strategies incorporating insights from behavioral economics could be more easily implemented by providing immediate rewards and feedback and by taking advantage of group-based incentives and norms. However the validity of smartphone-paired breathalyzer measurements has not been independently confirmed in the peer-reviewed literature, impeding further research application and funding. Informal assessments by the national media suggest that commercial smartphone paired breathalyzers may vary in reliability. Our preliminary data from our first 10 participants indicate that at least 2 of the 6 devices are highly accurate within +/- 0.01 of police grade breathalyzers and BAC levels. Now that we have an understanding of the reliability of these technologies in measuring breath alcohol content, it's important to determine whether knowing one's breath alcohol content in real-time affects the likelihood of driving among intoxicated individuals to further so we can more effectively develop behavioral intervention strategies..

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Study Design: Include design issues such as randomized, blinding (double, single, etc), placebo-controlled, parallel group or cross-over, telephone survey, internet research, focus group, etc.

In a controlled setting, up to 30 participants, aged 21-39, will attend a session where they receive 3 doses of a standard amount of alcohol, based on weight and gender(Watson, Watson, & Batt, 1981), designed to raise Blood Alcohol Content to 1.02g/dL. Participants will receive their first dose of alcohol. After 30 minutes, breath alcohol content (BrAC) will be measured with the BacTrack Pro (BACtrack Mobile Pro, n.d.). To continue assessing the validity of the BacTrack Skyn device, some participants will be instructed to wear the Bactrack skyn at the beginning of the study.

For participants in the control group, they will remain blinded to their BrAC reading and complete the Self-Report of Intoxication Survey. For participants in the intervention group, they will be shown their BrAC reading on the BacTrack mobile app and then instructed to complete the Self-Report of Intoxication Survey.

A second dose and third dose will be given and this process will be repeated at 40 minutes and 80 minutes after the first dose. A study smartphone will be used to collect smartphone-paired breathalyzer readings. We will also measure self-reported intoxication rating using measures subjective intoxication: Personal Drinking Habits Questionnaire (PDHQ)(Vogel-Sprott, 1992), Perceived Driver Fitness(Van Dyke & Fillmore, 2014)and Perceived intoxication and BAC estimation(Harrison & Fillmore, 2005; Harrison, Marczinski, & Fillmore, 2007) administered by the study staff.

All research activities will be conducted in the CTRC and alcohol will be provided from Investigational Drug Service. 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. A nurse, trained in the protocol, will be onsite at all times and able to assist if any adverse effects occur.

Study duration. List projected overall duration of the study including: 1. Estimated length of time to enroll all subjects and complete the study; 2. Length of a subject's participation time in study; 3. Project date of the proposed study.

Recruitment will take place for one month before the first study date, in order to enroll up to 30 participants in the study. Each subject will participate in one 5-6 hour study session. There will one to

two study sessions per week. The estimated duration of the study is 10 weeks. The projected start date of the proposed study is April 1, 2017.

Resources necessary for human protection

All research activities will be conducted in the CTRC and alcohol will be provided from Investigational Drug Service. The project manager will oversee all study operations and two 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. A nurse, trained in the protocol, will be onsite at all times and able to assist if any adverse effects occur.

Target population. State the clinical condition, disease state, or population characteristics of primary interest, eg: "Adult subjects with a diagnosis of Type II diabetes for greater than two years."

Up to 30 men and women, ages 21-39, will be enrolled who self-report as moderate drinkers, who are not seeking treatment for alcohol abuse (i.e. no treatment in the past year and current verbal report of not wanting treatment) do not have alcohol use disorder, as defined by the DSM-V, and do not have any medical conditions that limit or prevent alcohol consumption. Because there are well known risks of alcohol to the unborn fetus, women will be screened with a urine pregnancy test and must confirm a negative result before alcohol is administered. Children will not be recruited for this protocol because alcohol will be administered and the legal drinking age is 21 years. Due to the risks involved with drinking and driving, participants will only be enrolled in the study if they are willing to take public transportation or a rideshare home from the study visit.

Subjects will be healthy volunteers, 21-39 years old. They will be non-treatment seeking community drinkers. Subjects will be included if they drink socially and have reported consuming (4 or more drinks for women, 5 or more drinks for men) during one occasion without problems. However, they will be excluded if they drink 4 or more days per week on average or consume on average 12 or more drinks per week. They will be excluded if they have met criteria for DSM-V (American Psychiatric Association 2013) alcohol use disorder (lifetime) or substance use disorder (within the past 12 months), or a psychiatric disorder that required hospitalization, are using psychotropic medications or are pregnant or nursing. Subjects will undergo a brief medical screening, female subjects will confirm that they are not pregnant using a urine screening.

Accrual

We plan to enroll up to 30 adults aged 21-39 who are moderate drinkers without dependence to complete this standardized drinking protocol. This is a pilot study aimed at collecting data to understand perceived fitness to drive a vehicle among intoxicated aimed to inform future research. 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).

Key Inclusion Criteria

Inclusion criteria will be: (a) age 21-39 old, (b) Less than 4 drinking days and less than 12 drinks per week on average in the past 2 months, (c) have previously consumed four (women) or five (men) or more standard drinks without problems (d) a valid photo ID (e) willing to take public transportation home, via septa or a rideshare credit.

Key Exclusion Criteria

Exclusion criteria will be: (a) a desire for alcohol treatment now or received it in the past 6 months, (b) alcohol use disorder per DSM-V criteria and (c) substance use disorder within the past 12 months per DSM-V criteria (d) a prior psychiatric condition requiring hospitalization (e) non-English-speaking (f) individuals who have a medical condition or who are taking medication which limits or prevents the consumption of alcohol (g) suicidal ideation. We are excluding non-English speaking individuals due to the fact that we do not have translated materials so they will be unable to consent to participate in the study activities. We are also excluding individuals who are under 21 years in age due to legal restrictions of consuming alcohol. We are excluding individuals who have psychological or medical conditions, or are taking medication, that limit or prevent the consumption of alcohol.

Vulnerable Populations: Specify if the study intentionally includes any of the following populations:

Populations vulnerable to undue influence

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: Overview the approach to subject identification and recruitment, including referrals from physician offices, clinics...

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). We will obtain permission before distributing or posting the approved recruitment materials.

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?*

NO

Subject compensation: Will subjects be financially compensated for their participation?

Yes

Summarize any financial compensation that will be offered to subjects, e.g. cash payments, gift card, reimbursement for travel. The amount of compensation may not constitute an undue inducement to participate in the research. A prorated system of financial compensation is required in most circumstances. Provide the schedule for compensation per study visit or session and total amount for entire participation.

Each subject will receive a $100 gift card or online gift code as an incentive for completing the 6 hour study session. If provided a cashcard, we will work through the Greenphire clincard system (SOP attached to this submission). Information about the greenphire system will be provided during the consent process for the participant. Information, including social security number, will be collected from the participant at the intake phone call in order to set up an online account that the participant will be able to access. Participants will be reimbursed for travel and ensured a ride home by receiving either a septa token or up to $30 in rideshare credits.

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)?

YES

During the intake survey participants will be assessed for suicidal ideation and behavior using the Columbia-Suicide Severity Rating Scale. Participants who exhibit suicidal ideation or behavior will be withdrawn from the study and provided resources.

Central nervous system (CNS) effect: the ability of a test article to enter into and potentially interact with the central nervous system (brain and spinal cord).

YES

Clinical Investigation: Any experiment that involves a test article and one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Adminstration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but, the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

NO

Procedures: Describe study procedures. Include a table or flow chart, if necessary, showing the schedule of the procedures and interactions. It is important to distinguish between inventions that are experimental and carried out for research purposes versus those that are considered standard of care. In addition, routine procedures that are performed solely for research purposes should also be identified.

There will be 4 phases of the study:

1. Recruitment: We will use broad-based and cost-effective recruitment strategies including: a) advertisements in UPHS and CHOP employee weekly emails; and b) posting of flyers. Individuals, who are interested in the study, will be contacted and screened over the telephone.
2. Phone Screening: General information will be provided to the prospective subject. Study screening form (attached) will be administered, eligibility confirmed, and research staff will go over informed consent with participant. Participants will have the option to have the informed consent form emailed to them prior to the study visit. Columbia suicide severity rating scale will be administered. Inclusion criteria will be: (a) age 21-39 old, (b) Less than 4 drinking days and 12 drinks per week on average in the past 2 months, (c) have consumed either 4 (women)or 5 (men) or more standard drinks on a single occasion without problems (d) a valid photo ID (e) willing to take public transportation home, via septa or a rideshare credit. Exclusion criteria will be (a) desire alcohol treatment now or received it in the past 6 months, (b) alcohol dependence with withdrawal per DSM-V criteria (c) non-English-speaking, and (d) individuals who have a medical condition or who are taking medication which limits or prevents the consumption of alcohol. Interested and eligible participants will schedule their study visit.

3. Study Visit: On a predetermined study date, eligible subjects will come to the study site for a bar-lab session (timeline below), which will be conducted in the Center for Human Phenomic Science. Participants will be taken to a private room to review and sign the informed consent form. Before reviewing the consent, the research assistant will verify the participant is over 21 by checking their photo ID. After their age is confirmed and they are deemed eligible, the participant will review and sign the informed consent form. If the participant cannot produce a photo ID or their photo ID shows they are under 21 years old or over the age of 39, the CHPS appointment will be cancelled. Each study session will comprise of up to 4 participants, one per bed, and last about 5-6 hours. Prior to the test sessions they will be instructed to eat a small meal before fasting for 2 hours, abstain from caffeine for 8 hours and alcohol for 24 hours. Upon arrival, subjects will sign written informed consent. After which the subjects will undergo BrAC measurement, confirming a breath sample of 0 BrAC, using the BackTrack mobile device and complete a screening and medical history. At the CTRC participants will undergo a brief medical screening which will include measuring their blood pressure, heart rate, a urine pregnancy test for female participants. This screening will be performed by a CTRC nurse, who will be trained in the protocol.

Intake Survey: After which an intake survey will be administered by study staff, which Includes a) Driving History and Experience Questionnaire DHEQ(Harrison & Fillmore, 2005), b) Drinking and Driving Questionnaire(McCarthy, Niculete, Treloar, Morris, & Bartholow, 2012), c) , this survey measures participants drinking habits during a single week, frequency of drinking, typical duration of drinking events, and number of months an individual has been drinking on a regular basis. Participants will then complete the Decision Making Survey, which has questions related to their Delayed discounting and measures of impulsivity (Senecal, Wang, Thompson, & Kable, 2012).

Dose Administration: Before dose administration a portion of participants will be instructed to wear the Bactrack skyn wearable device. All subjects will first be given a priming dose of alcohol containing vodka in fruit juice designed to raise the BrAC to 0.03-0.04 g/dL based on weight and gender (Watson et al., 1981). Subjective ratings of alcohols effects and BrAC will be obtained after each dose. Each dose will be consumed within a standard 10-minute block to minimize inter-subject variability in the consumption rate. After each drink, participants will wait 20 minutes, and be instructed to rinse their mouth with a nonalcoholic mouthwash or water to ensure proper results. Breath alcohol content (BrAC) will be measured with BacTrack Pro commercial smartphone-paired breathalyzer (BACtrack Mobile Pro, n.d.) and recorded on a study smartphone using the BacTrack mobile app.
For participants in the control group, they will be blinded to the BrAC readings recorded on the BacTrack mobile app throughout the course of the study. For participants in the intervention group, they will be shown their BrAC readings on the BacTrack mobile app as they are measured.

This process will be repeated two times at minute 40 and minute 80. After each BrAC measurement has been obtained, we will also measure self-reported intoxication rating using: Self-Reported intoxication Survey, which includes: a) Perceived DriverFitness (Van Dyke & Fillmore, 2014) and b) Perceived intoxication and BAC estimation. (Harrison & Fillmore, 2005; Harrison et al., 2007) (survey attached).

After 150 minutes if participants BrAC does not measure .03 or below, participants will be tested at intervals of 20 minutes until their blood alcohol content has reached a level of .03 or below at which time they will be provided with transportation home. Midway through the study participants will receive a small meal provided by the CTRC.

Timeline: Study activities at Site Visit

Time	**Procedures ***
00 - 10 minutes	• Participant is given a priming dose of alcohol containing vodka in fruit juice designed to raise the BrAC to 0.03-0.04 g/dL based on calculations based on weight and gender
10-30 minutes	• Participant rinses with alcohol free mouthwash or water
30-40 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Survey
40-50 minutes	• Second dose of alcohol designed to raise BrAC to 0.07-.08’
50-70 minutes	• Participant rinses with alcohol free mouthwash or water
70-80 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Survey
80-90 minutes	• Participant receives third dose of alcohol containing vodka in fruit juice designed to raise the BrAC to 1.01-1.02 g/dL

90-110 minutes	• Participant rinses with alcohol free mouthwash or water
110-120 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Survey
135 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Rating Survey:
150 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Rating Survey:
175 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Rating Survey:
190 minutes	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Rating Survey:
205 minutes until study completion	• Measurement of BrAC with BacTrack mobile breathalyzer • Control: Blinded to BrAC reading. Intervention: Shown BrAC reading on BacTrack mobile app • Self Report of Intoxication Rating Survey: • Breathalyzer measurements will be obtained until participant is at .03 or lower

Deception: Does your project use deception?

NO

Deception could be considered any direct misinformation presented to the subject or omission of key information pertaining to the design or nature of the project.

NO

Are you conducting research outside of the United States? *

NO

Analysis Plan: Describe briefly the statistical methods used to analyze the data

Data analysis will be led by Wensheng Guo, PhD, Professor of Biostatistics.

Primary outcome:

We will test for differences in perceived fitness to drive according intervention arm and BraAC level accounting for clustering of measurements within participants and time from the first drink using a generalized linear model with a logit link. We will then explore the mediating effects of baseline demographic and psychological variables with inclusion of these variables in the model.

Secondary outcomes: We will conduct descriptive analyses exploring the effect modification of baseline demographic and psychological measures on these differences including: age, sex, BMI, past level of alcohol consumption, delay discounting rate, and the Barrat's impulsivity scale.

Subject Confidentiality: Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data. When developing strategies for the protection of subjects' confidentiality, consideration will be given as to:

Participants who have seen recruitment material will call a study line in order to sign up for the study. At this pre-screening phone call, the research project manager will briefly go over study procedures. If the participant is interested, they will be complete a brief (less than ten minute) screening over the phone to determine eligibility. Participants may be asked to meet with the study staff prior to scheduling their study visit to determine eligibility. At the study visit, eligible participants will sign written informed consent, and be administered the study protocol; all study documents will be de-identified after all contact has been made. Participant information will be stored in a locked filing cabinet only accessible by the research assistants, PI, and project manager. Personal information will not be stored with study data and will be destroyed after data collection.

Sensitive Research Information: Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record? [NOTE: This does not apply to: 1) research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]

NO

Data Disclosure: Will the data be disclosed to anyone who is not listed under Personnel? If so, identify disclosures.

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.

Protected Health Information/Data Protection: Describe if data to be used or collected involves any protected health information (PHI) and specify which PHI is to be used/collected. Health information is determined to be PHI if it contains any of the following identifiers:

Name

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

Telephone and fax number

Electronic mail addresses

Social security numbers

Medical record numbers

Health plan ID numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

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

Consent Process: Overview*Summarize how informed consent will be obtained, including how, when, where, and by whom it will be obtained. Describe any waiting period between informing the prospective participant and obtaining the consent. Describe any steps taken to minimize the possibility of coercion or undue influence. Describe the language used by those obtaining consent. Describe the language understood by the prospective participant or the legally authorized representative.

Participants will respond to recruitment material by calling the study hotline. After calling the study hotline, participants will be screened for eligibility and will schedule a visit. At the study visit, participants will sign written informed consent. Consent will be obtained by explaining the study

objectives, procedures, and potential risks to subjects verbally and in writing at a pre-screening and / or screening visit. Subjects will be given an opportunity to ask questions and will be provided with complete and accurate answers to any questions they may have. Written documentation of this process will be obtained using the IRB-approved consent form. Subjects are given a signed copy of the consent form for his or her reference.

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.

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

Waiver or Alteration of Informed Consent: Are you requesting a waiver of, or alteration to, the informed consent process? Please choose one of the following and provide justification where appropriate: YES

Minimal Risk*
The research involves no more than minimal risk to the subject

This research in general involves minimal risks to the participants because the benefits outweigh the risks in this study. Specifically the waiver of consent only applies to administration of the screening survey, and completing this survey involves minimal risk to participants, such as there is some risk that confidential information provided regarding psychiatric and substance use history will be inadvertently disclosed without the subjects' permission. Methods outlined elsewhere in this protocol will be in place to protect participant information to minimize this risk. Also the benefits for allowing participants to take screening over the phone and not having to come in for two study visits outweighs this risk.

Impact on Subject Rights and Welfare*
The waiver or alteration will not adversely impact the rights and welfare of the subjects.

We will require a waiver of consent written consent in order to administer the screening survey over the phone because it is not feasible for each participant to be required to come in, in order to answer questions in the screening survey. Before the screening survey is administered, participants will be prompted to provide verbal consent over the phone, using the verbal consent script that is attached to this protocol. Once a participant is screened, using the screener, and has set up a study session, participants will signed written informed consent at the beginning of their study visit prior to any other activities being completed.

Waiver Essential to Research*
The research could not be practicably carried out without the waiver or alteration

It is not always feasible for participants to schedule a separate study visit to answer a brief screening survey. In order to accommodate participants who cannot schedule a separate study visit, we are requesting a waiver of written informed consent only to administer the screening survey over the phone. Allowing this step in the process to be completed over the phone will make the study more feasible to be completed by participants.

Additional Information to Subjects
Whenever appropriate, the subjects will be provided with additional pertinent information after participation

We will require a waiver of consent written consent in order to administer the screening survey over the phone because it is not feasible for each participant to be required to come in, in order to answer questions in the screening survey. Before the screening survey is administered, participants will be prompted to provide verbal consent (attached to this protocol) over the phone, using the verbal consent script that is attached to this protocol. Once a participant is screened, using the screener, and has set up a study session, participants will review and sign written informed consent at the beginning of their study visit prior to any other activities being completed.

Potential Study Risks Describe and assess any potential risks associated with the research interventions (physical, psychological, social, economic, monetary, legal or other, loss of confidentiality) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

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.

Urine pregnancy testing is performed for all women of reproductive potential, prior to alcohol administration, to avoid the potential for adverse fetal effects of alcohol. These procedures should add no additional risks beyond the minimal risks normally associated with them. Over a period of 120 minutes, participants will be given three doses of alcohol, which will result in a BrAC of 1.01-1.02g/dL. This amount of alcohol is equivalent to 4-5 standard drinks, an amount that these moderate-drinking subjects have ingested previously. Although the amount of alcohol available to them will produce only moderate blood alcohol levels, subjects could feel intoxicated or react negatively to the alcohol, such as nausea or dehydration. Engaging in any dangerous activities during this period would increase risk of self-harm. Precautions to minimize these risks are discussed below.

After consuming alcohol, participants may be unsafe to operate a vehicle. This risk will be mitigated by providing participants transportation home with either a septa token or rideshare credits of up to $30, depending on their location.

Study activities will be performed in a special clinical research room located in a hospital setting in close proximity to an inpatient care. Nursing and medical personnel will be available to assist in the care of the subject if any adverse event occurs. Participants' breath alcohol concentration (BrAC) and their general condition will be monitored during all aspects of the procedure. The bar-lab will be located in a safe and secure area in in a hospital where medically trained staff will be onsite and there will be ready access to emergency care should it be necessary. All subjects will remain in the test area until their BrAC will be below 0.03 g/dL. All study activities will occur in the afternoon, no earlier than 11am, to minimize nausea and vomiting that could occur with morning alcohol consumption. A meal will be provided.

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: Assess the potential benefits to be gained by the individual subject, as well as benefits that may accrue to society in general as a result of the planned work (such as advancement of knowledge). Summary should also state if there are no direct benefits to subjects as a result of their participation in the study.

There are no benefits to participation. Participation may help us understand how smartphone-paired mobile breathalyzer devices impact behavior, which may lead to potential to help individuals better monitor their drinking behavior. In the future, this may help other people to manage their drinking habits and minimize risky drinking behavior.

Data and Safety monitoring

Paper forms will be used to collect data and a research assistant will create and maintain the research database. 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 will monitor and maintain confidentiality of data.

To maintain privacy, all paper records of individuals who were screened but found ineligible to participate will be shredded.

Risk / Benefit Assessment: Assess the ratio of the benefit to be obtained from the study relative to the risks involved. The risks of participation in the research must be balanced by the potential benefits of the research to potential subjects and/or society. Note: "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.

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.