Evaluation of an Interactive Mobile Phone-Based Brief Intervention to Reduce Substance-Impaired Driving

NCT05537116

Study Protocol and Statistical Analysis Plan

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A. PROPOSED RESEARCH PROJECT

Rates of substance-impaired driving remain especially high among emerging adults, and substance-related traffic accidents remain the leading cause of substance-related death in this age group.1 Although rates of alcohol-impaired driving (AI-driving) among emerging adults have begun to decrease,2 rates of driving after cannabis use (DACU) continue to rise.3 In addition, many emerging adults report simultaneous use of alcohol and cannabis, a behavior that has been shown to increase the odds of substance-impaired driving and results in substantially greater fatal crash risk.4, 5 Brief Interventions (BIs) have been shown to decrease substance use and related problems.6 BIs attempt to identify and correct faulty normative beliefs and highlight personal consequences of substance use (such as driving after substance use). BIs typically consist of one or two individual therapeutic meetings delivered in motivational interviewing (MI)7 style and include personalized feedback (based on a series of questionnaires completed by the participant prior to their BI session). One reason why BIs have not been widely implemented– despite their demonstrated efficacy – is that it is not economically feasible for universities and community agencies to hire and train staff to deliver in-person BIs to all substance users, and very few emerging adults seek out substance prevention or treatment services available on campus or in the surrounding community.8 Innovative ways of delivering BIs to this at-risk population, in a manner that is both effective and economically feasible, needs to be developed. Text messaging represents a particularly advantageous way to provide BIs as they can be highly personalized to the individual and allows for engagement and interaction between the interventionist and participant. Research indicates that emerging adults prefer text messages to telephone calls and emails and rate this medium positively.9 Given the high prevalence and fatal consequences of substance-impaired driving, highly accessible intervention approaches are imperative for reducing this extremely risky behavior.

In the past few years, a number of interventions using text-messaging to target substance use and problems have been developed and evaluated with reviews and meta-analyses suggesting that the majority of these interventions result in improved outcomes and warrant further large scale studies.10,11 Most of these interventions target overall substance use and problems and do not focus on specific risk behaviors, such as substance-impaired driving. We have developed and evaluated a mobile-based BI focused specifically on decreasing AI-driving among college students in a pilot trial.12 This study indicated that a brief, mobile-based AI-driving intervention including MI text messaging resulted in significantly greater reductions in AI-driving at the 3-month follow-up, compared to alcohol information alone. We modified the intervention to focus on driving after cannabis use (DACU; Teeters, King, & Hubbard, in press) and found that the intervention resulted in significantly greater increases in perceived dangerousness of DACU and significantly greater decreases in DACU compared to an informational control condition. Importantly, several recent studies have demonstrated greater effectiveness of interventions that include personal contact vs. those that are fully automated. The present study provides an important bridge between in-person therapist delivered interventions and fully automated interventions by utilizing interactive text messaging with participants in order to enhance retention of intervention elements and provide tailored, individualized interaction. It is imperative to directly test whether the use of interactive text-messages decreases substance-impaired driving significantly more than personalized feedback alone.

The proposed study will extend the promising pilot results by: (a) increasing power by recruiting 240 emerging adults reporting recent DACU, (b) increasing generalizability by recruiting non-college

emerging adults to make up at least half of the sample, (c) including a 6-month follow-up to determine whether intervention effects persist over time, (d) examining mediators of intervention outcomes (e.g., changes in cannabis-related cognitions), and (e) providing additional intervention content focused on decreasing driving after combined use of alcohol and cannabis. The overarching goal is to use mobile technology to reduce driving after substance use among emerging adult cannabis users.

We will conduct a 3-group trial with 240 emerging adults (ages 18-29; project 50% female; 20% minority) recruited from a community in the Southeastern United States.

Group 1: substance impaired driving personalized feedback

Group 2: substance impaired driving personalized feedback and Motivational Interviewing (MI) interactive text messages

Group 3: substance use information (control) Aim 1: Evaluate a text-based substance-impaired driving intervention in a Randomized Clinical Trial.

Aim 1: Evaluate a text-based substance-impaired driving intervention in a Randomized Clinical Trial.

Hypothesis 1: Group 2 will report greater reductions in driving after cannabis use and driving after simultaneous alcohol and cannabis use 3- and 6-months post-intervention. Aim 2: Evaluate mechanisms of intervention response.

Aim 2: Evaluate mechanisms of intervention response.

Hypothesis 1: Cognitive factors (e.g., changes in perceptions of dangerousness and consequences, peer norms, cannabis expectancies) will mediate intervention outcomes.

B. Inclusion Criteria:

- Ages 18 to 29
- Ability to speak, read, and write in English
- Reports driving after cannabis use at least three times in the past 3 months AND/OR reports driving after simultaneous use of cannabis and alcohol at least three times in the past 3 months
- Reports having access to a motor vehicle, a valid driver's license, and plans to drive a vehicle frequently throughout the next 6 months
- Reports access to a smart phone and willingness to read intervention material and exchange a brief series of text messages via a smartphone app with encryption technology post intervention with the study administrator
- Reports a valid email address

Exclusion Criteria:

- Currently in treatment for substance use

Lab personnel (undergraduate and graduate students and the post-bac research coordinator) will recruit approximately 1000 emerging adults (ages 18-29) from campuses and communities surrounding Western Kentucky University (WKU). Flyers will be strategically placed around WKU's campus and around community locations frequented by emerging adults within 60 miles of campus. Additionally, targeted advertisements will be placed on Facebook and Google. We expect 240 emerging adults to participate in the clinical trial. This number was chosen based off a power analysis suggesting 71 participants per condition to have a power of .3, assuming $\alpha = .05$. In order to achieve this sample size at follow-up, we plan to enroll 80 participants per condition, allowing for some attrition. The approximately 1000 emerging adults will complete a brief (10-15 minute) screening survey (sent through text message or email) to identify emerging adults who might be eligible to participate in this study. Emerging adults ages 18-29 years old with current access to a motor vehicle who report driving within two hours of using cannabis AND/OR driving after using cannabis and alcohol at least three times in the past 3 months will be eligible to participate in this trial. If the research participant meets eligibility criteria, a research assistant will contact the participant by telephone, explain the project procedures and confidentiality, and will invite the participant to participate in further phases of the study. For all research participants, eligibility status and study description will occur via a phone call giving participants the opportunity to ask questions. Furthermore, this phone call will serve as an "instruction" session in which study details are explained and participants have a chance to ask questions about the study. We will also make sure the participants understood the consent process at this time and review the study consent form, which they will subsequently complete online. All ethnic groups and races will be included in all of the proposed protocols.

C. **Informed consent: Describe the consent process and attach all consent documents. (formatted samples are included below)**

We would like to request permission to replace the traditional signed consent with implied consent due to the fact that all participants will be informed that study participation consists of completing mobile-based assessments. The participant will have to click on the "accept" button in order to initiate the online survey questionnaires, indicating that they agree to participate in the research. This method will ensure that identifiable data is not linked to the survey instruments.

Upon clicking the link to the survey measures, each participant will see the informed consent document on the screen. If they wish to participate in the study, they must click the "accept" button to begin completing the survey measures.

D. **Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.**

Lab personnel (undergraduate and graduate students and the post-bac research coordinator) will recruit approximately 1000 emerging adults (ages 18-29) from communities surrounding Western Kentucky University. Flyers will be strategically placed around campus and around community locations frequented by emerging adults within 60 miles of campus. Additionally, targeted advertisements will be placed on Facebook and Google. We expect 240 emerging adults to participate in the clinical trial.

Screening: Approximately 1000 emerging adults ages 18-29 will complete a brief (10-15 minute) screening survey sent through text message or email by an undergraduate research assistant to identify emerging adults who might be eligible to participate in this study. Emerging adults ages 18-29 years old with current access to a motor vehicle who report driving within two hours of using cannabis AND/OR driving after using cannabis and alcohol at least three times in the past 3 months will be eligible to participate in this trial. If the participant meets eligibility criteria, an undergraduate research assistant will contact the participant by telephone, explain the project procedures and confidentiality, and will invite the participant to participate in further phases of the study.

Assessment and Intervention. After completing all screening procedures, participants will be provided with an online consent form and an undergraduate research assistant will inform them of the study's purpose, risks, benefits, compensation, and all other pertinent study details. Research participants will be provided with a phone number and email address should they have questions and will also be informed in the consent that they can discontinue the study at any time. If research participants do not choose to "accept" the conditions of the consent form or decide not to participate in the study at any time, they will be provided with an informational document containing details about driving under the influence and a list of mental health resources in the community. Those who accept will be sent a baseline questionnaire via text-message (by an undergraduate research assistant) to be completed remotely on mobile phone via a secure web survey. The remote, web-based assessment battery will take about 30 minutes to complete. Randomization will occur immediately after the participant completes the baseline assessment. We will use an urn procedure to ensure baseline treatment group equivalence on past-month frequency of driving after cannabis use. Following completion of the assessment battery and a 90-day, phone-based Timeline Followback interview, participants will receive either: a) a personalized feedback intervention + interactive text messaging with an interventionist (approximately 10-15 minutes), or b) personalized feedback only (approximately 10-15 minutes; control group). Participants in the personalized feedback + interactive text messaging condition will receive a series of interactive motivational interviewing-style text messages (delivered by a trained graduate student in the lab) to facilitate processing of the intervention material and to complete goal setting. Participants will receive a payment of $25 in the form of a gift card for completing the baseline survey and intervention session.

At 3- and 6-months post-intervention, participants will be asked to complete a mobile-based follow-up self-report assessment battery in addition to the TLFB interview. The follow-ups will assess the impact of the interventions on substance-impaired driving cognitions and behaviors. For each follow-up, participants will be sent the link (by an undergraduate research assistant via encrypted text message) to an identical assessment battery. Completing the assessment battery will take approximately 30 minutes. Participants will be awarded an additional $20 gift card for participation in each of these follow-ups.

All text messaging will take place through a secure, encrypted instant messaging platform. The mobile application that will be utilized uses cryptographic algorithms to encrypt and protect all communications. Phone numbers and email addresses will be kept in a password protected document on a computer kept in a secure locked room accessible only to research staff.

Intervention Groups

Substance Impaired-Driving Personalized Feedback. Immediately after completing the baseline questionnaire, research participants will be sent a link via encrypted text message to a secure website

containing personalized feedback (which is programmed to populate automatically and immediately based on questionnaire responses). Feedback will include the following elements (proposed mechanism targeted is named in parentheses): a personalized substance-impaired driving profile, information on social norms related to substance use and substance-impaired driving (targets perceived peer approval), personalized information on impairment due to drug use prior to driving (targets perceived safety), costs associated with a DUI citation in Kentucky (targets perceived legal consequences), and information on simultaneous drug and alcohol impaired driving risk (if endorsed; targets perceived dangerousness of driving after combined use). Participants who endorse driving after the combination of alcohol and cannabis use will see an additional page of feedback with information on factors that impact BAC, their BAC prior to driving and predictable effects of driving at that BAC, crash risk based on BAC, and increased driving risk when combining alcohol and cannabis with a graphical representation of risk. The goals of this session are to raise concern about potential consequences relating to driving after substance use and to correct faulty normative perceptions of substance use and substance-impaired driving. Research participants will be instructed to view the personalized feedback document and to respond to a number of questions embedded in the feedback document as a comprehension and fidelity check.

Substance Impaired-Driving Personalized Feedback plus Interactive Text Messaging Intervention. Procedures for the personalized feedback portion of this intervention will be identical to the procedure described in the Substance Impaired-Driving Personalized Feedback condition above. After viewing the personalized feedback document and responding to embedded questions, research participants will be asked to send an encrypted text message back to the study administrator (a trained research assistant). After confirming receipt and processing of the feedback document, a graduate student in the lab will then send the participant four text messages containing the following open-ended questions: 1) Of the information you just viewed, what was most interesting?, 2) How would receiving a DUI impact your future career goals?, 3) What is your plan for driving after substance use in the future?, and 4) What specific goals (if any) related to driving after substance use would you be willing to set? Based on participant responses to these open-ended questions, the graduate student will send follow-up text messages to provide appropriate reflection/encouragement in Motivational Interviewing (MI) style (See section C. of table 1 for example text-messaging exchange). All interventionists will be trained in MI and a licensed clinical psychologist with expertise in MI will supervise the text messaging interactions. The interactive texts are expected to enhance intervention retention/processing and to provide an interpersonal/interactive element that may enhance efficacy.61

Information Control. Emerging adults randomized to the educational control condition will receive standard information about substance use via a link to a website delivered through text message. The control condition format will mimic the intervention format visually (participants in all conditions will see the same amount of graphics on the same number of pages; however, the information in the control condition will not be personalized and will not include goal setting). Just as in the intervention conditions, participants will be instructed to respond to a number of questions embedded in the informational document as an attention and comprehension check. The information provided during this session is similar to traditional drug and alcohol education programs commonly found on college campuses, which provide information about the risks of alcohol and drug use via lectures and websites.

Data Analyses.

The primary study analyses will examine whether or not there is a statistically significant difference between treatment groups in change in self-reported substance impaired driving. Repeated measures mixed modeling analyses will be conducted to compare the brief intervention groups and the informational control group on each of the primary outcome variables at 3-month and 6-month follow ups. Mixed modeling examines data similarly to repeated measures ANOVA; however, mixed modeling provides increased flexibility in handling missing data by utilizing all available data for each participant and provides ease of adaptation for multiple research designs (Hox, 2010; West, Welch, and Galecki, 2007).

E. How will confidentiality of the data be maintained? (Note: Data must be securely kept for a minimum of three years on campus, and describe how participants will be protected)

Participants' data will be assigned a number, which will be used to identify all study records. Participants' names will not be associated with any subsequent publication or representation of the data. Risk of disclosure of sensitive information will be minimized by removing personal identifying information from the files, and by using the data only to develop statistical tables for group data in which no individual can be identified. The web-based surveys used in the present study are password protected and do not ask for or record any identifying information. All data collected from these surveys are identified by ID numbers rather than names.

All data received will be stripped of personal identifiers. Measures will be identified with a study ID number not based on a personal identifier. A cross-index of names and ID numbers will be stored in a separate locked location from all data. Additional precautions include: (1) data will be entered in coded form, (2) data will be stored in computer files protected from unauthorized access by passwords, (3) information that might potentially allow an individual participant to be identified will not be allowed in any publications or reports sent to individuals outside the study, and (4) all employees who are to handle data will be trained in confidentiality policies and procedures. Raw data will be retained for 6 years.

F. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc. Describe how any potential conflict of interest or problem of undue influence that may be encountered through the protocol will be handled.

The risks in this study include subject discomfort (e.g., psychological discomfort due to discussing personal and/or sensitive information related to participant substance use or substance-related problems) and risk of breach of confidentiality. The likelihood of experiencing subjective discomfort from completing the present assessment batteries is low. The questions used in this study are standard research instruments that have been used without observed discomfort in numerous studies with similar populations. The risk of breach of confidentiality is also judged to be low based on the safeguarding procedures in place, including removing identifiers from data, storing identifiers and data in separate locked file cabinets, password-protecting all data files, and limiting access to project data to project personnel. Only the study administrator and study research assistants will have access to any identifying information. Any identifying information will be destroyed after completion of last follow-up or if the participant does not complete the last follow up, within six-months of study enrollment. We will use an encrypted texting app for all text-messages used in the study.

Planned procedures for protecting against risk. For the possibility of subjective discomfort from answering questions, any distress will be minimized by assurances that participants can refuse to answer

any particular question that they do not feel comfortable addressing and may withdraw at any time without penalty. Participants will also be advised to talk to a research assistant following the assessment batteries should any psychological distress persist, and referrals will be provided accordingly. The risk of breach of confidentiality will be handled by numerically coding all data, by separating all identifying information from study data, and by ensuring that all data is collected via secure web server. No participant names or identifying information will be used in presenting data in lectures, presentations, or publications. All feedback and text messages will be framed in a manner that is as objective and nonjudgmental as possible, consistent with MI theory and the empirical literature on effective brief intervention approaches.

Plans for ensuring necessary professional intervention in the event of an adverse event. Participants who express concern about their substance use will be provided with referrals to appropriate university and community resources for addressing these issues. If any participant reports suicidal ideation, the study administrator (who will all be graduate-level students) will immediately notify Dr. Teeters, who is a licensed clinical psychologist. The study administrator will immediately attempt to reach the participant via phone and Dr. Teeters will subsequently conduct a thorough suicide risk assessment. If necessary, Dr. Teeters will arrange for the participant to be transported to an emergency room or the Counseling Center for further crisis intervention services. All participants will be informed that they can contact Dr. Teeters if they would like more information on obtaining substance use services. Dr. Teeters has over 8 years of clinical and research experience with college student substance users and is well prepared to address any clinical concerns that may arise in the context of this research.

G. Describe the anticipated benefits/incentives to subjects, and the importance of the knowledge that may reasonably be expected to result. All Participant incentives MUST be approved prior to data collection and incentive distribution. Changes must be approved prior to participant recruitment into the study. NO EXCEPTIONS.

We are unaware of any direct benefits for participation in this study. One potential benefit of this study is the development of a potentially efficacious intervention to lower substance-impaired driving behaviors. The findings from this study may also inform future prevention and intervention efforts.

Importance of the Knowledge to be Gained. Substance-impaired driving among college students is a major a public health problem that requires substantial attention from researchers. Despite years of prevention efforts, rates of alcohol and drug impaired driving among college students remain high. There is a need to implement targeted (but brief) theoretically derived treatment elements with the potential to decrease incidence of driving after using substance. This proposed research would evaluate a novel substance-impaired driving personalized feedback intervention with emerging adults. The proposed project will be the first to specifically target substance impaired driving through a brief intervention with college student substance users.

Participants will be granted 4 credits on the Study Board system (or a $25 Amazon gift card) for their participation in the baseline portion of this study. They will be granted another 2 credits (or another $20 Amazon gift card) for each subsequent follow-up completed.

H. List of references (if applicable):

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Statistical Analysis Plan.

Power. We calculated the power and sample size using the simr package from R version 4.0.3 for the Poisson mixed-effects model with random intercepts. We used our pilot data from 117 substance users reporting recent driving after substance use (69 participants randomized to the intervention condition and 48 randomized to the informational control condition) and an effect size of 0.31 for the interaction term between treatment and time as an estimate of the effect size we will observe in a new study. Results are summarized in Figure 1. We would need to have a total sample size of 142 to have 97.5% confidence of having at least 80% power. In order to achieve this sample size at follow-up, we plan to enroll 80 participants per group.

General analysis. Statistical analyses will be performed using SPSS version 27 and R version 4.0.3. Outliers greater than 3.29 SDs above the mean on a given variable will be Winsorized to one unit greater than the greatest nonoutlier value. Distributions of continuous variables including impaired driving outcomes, mediators, and covariates will be examined. Missing data will be carefully examined and models will be run with intervention completers and non-completers in order to determine any systematic differences between groups. Intention-to-treat (ITT) analyses will be used for intervention outcomes.

Overall Evaluation of the Aims. The primary analyses will examine whether there are statistically significant differences between the three treatment conditions in changes in self-reported substance-impaired driving over time. Repeated measures mixed modeling analyses will be conducted to evaluate the effects of group (PF, PF + MI text, IC), time (baseline, 3-month, 6-month), and the group × time interaction on each primary outcome. Mixed modeling examines data similarly to repeated measures ANOVA; however, mixed modeling provides increased flexibility in handling missing data by utilizing all available data for each participant and provides ease of adaptation for multiple research designs.69 For each model tested, one of the primary outcome variables will serve as the dependent variable with gender, age, and ethnicity included as covariates.

Hypotheses and Specific Data Analysis Plan

Aim 1: Evaluate a text-based substance-impaired driving intervention in a Randomized Clinical Trial.

Hypothesis 1: Participants in the PF + MI text intervention condition will report greater reductions in driving after cannabis use and driving after simultaneous alcohol and cannabis use at 3- and 6-month follow-ups compared to both the PF-only and informational control conditions. We also expect the PF-only condition to demonstrate greater reductions than the informational control condition.

Aim 1 analytic plan. To evaluate hypothesis 1, generalized linear mixed models (GLMM) will be utilized, which represent an extension of linear mixed models to non-normal data. GLMM with a negative binomial distribution, which allows for over-dispersion in count outcomes, will be utilized for outcomes of non-normally distributed count data (i.e., total number of times driving after cannabis use and/or total number of times driving after simultaneous alcohol/cannabis use). For each model tested, one of the primary outcome variables (total number of times driving after cannabis use and/or total number of times driving after simultaneous alcohol/cannabis use) will serve as the dependent variable with gender, ethnicity, and age included as covariates due to their association with substance use levels and the possibility of differential intervention response.