Evaluation of an Interactive Text-Message Based Brief Intervention to Reduce Substance-Impaired Driving among College Students

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Study Goals:

The overarching goal is to reduce driving after drinking, drug use, and combined drug/alcohol use among college students.

We will conduct a 3-group trial with 150 college students (project 50% female and 20% minority) recruited from a large public university.

Group 1: substance information only

Group 2: substance-impaired driving personalized feedback only

Group 3: substance impaired driving personalized feedback and MI interactive text messages

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

Hypothesis 1: Groups 2 and 3 will report greater reductions in driving after substance use at 3-month follow-up compared to Group 1.

Aim 2: Determine whether interactive text-messages sustain intervention effects over time.

Hypothesis 2: Group 3 will report greater reductions in driving after substance use at 6-month and 12-month follow-up compared to Group 2.

Procedures:

Eligibility Criteria

- **Inclusion Criteria:**
  - Age 18 or older
  - Currently enrolled (full or part-time) in college
  - Ability to speak, read, and write in English
  - Reports driving after drinking two or more drinks prior to driving at least three times in the past three months AND/OR reports driving after using marijuana or any other substance prior to driving at least three times in the past three months
  - Reports having access to a motor vehicle, a valid driver's license, and plans to drive a vehicle in the next 3 months
  - Reports access to a cell phone and willingness to read intervention material and exchange 3 texts post intervention with the study administrator
  - Reports a valid email address
- **Exclusion Criteria:**
  - Currently in treatment for substance use or abuse

Approximately 500 students will be recruited from Western Kentucky University (WKU) through the WKU subject pool, emails sent to undergraduate courses, and flyers posted around the Western Kentucky University campus. We expect 150 students to participate in the clinical trial.

Screening:

Approximately 500 college students (recruited through the Western Kentucky University subject pool, emails sent to undergraduate courses, and flyers posted around the Western Kentucky University campus) will complete a brief (10-15 minute) screening survey via the SONA system or through email to identify those students who might be eligible to participate in this study. Students 18 years or older with current access to a motor vehicle who report driving within two hours of drinking two or more drinks at least three times in the past three months AND/OR driving within two hours of using marijuana or any other substance at least three times in the past three months will be eligible to participate in this trial. If the participant meets eligibility criteria, the researcher will contact the participant, explain the project procedures and confidentiality, and will invite the participant to participate in further phases of the study.

Students who meet inclusion criteria as per the screener completed through the WKU Studyboard System or those who meet inclusion criteria as indicated on screeners emailed to classes will be contacted by a study administrator to confirm eligibility status. Other interested university students will be instructed via flyers to contact the Substance Abuse Intervention Lab by email or text and a study administrator will send them a link to the screener. Determination of eligibility status will include a short questionnaire regarding inclusion and exclusion criteria. For all 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 understand the consent process at this time and review the study consent form, which they will subsequently complete online. Participants will be informed that the study is designed to learn more about college students’ lifestyle and health behaviors, particularly drug and alcohol use and driving attitudes and behaviors, and that the study will involve random assignment to a single mobile-based session, along with three brief mobile-based follow-ups.

After completing all screening procedures, eligible and interested individuals will be sent a baseline questionnaire via text-message to be completed remotely on mobile phone via a secure web survey. All self-report measures will be completed via mobile phone on a secure, web-based survey. Prior to completing baseline measures via mobile phone, participants will be provided with a consent form and will be informed of the study’s purpose, risks, benefits, compensation, and all other pertinent study details. 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 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. This remote, web-based session will last

approximately 1 hour and, following the completion of the online consent form, will include an assessment battery (approximately 30 minutes) and either a) a personalized feedback intervention, b) a personalized feedback intervention + interactive text messaging with an interventionist, or c) a substance information intervention (control group). Participants in the personalized feedback intervention + interactive text messaging condition will receive 3 interactive text messages to facilitate processing of the intervention material and goal setting. Upon completion, participants will be thanked for their participation via text message and a 3-month follow-up assessment will be scheduled. Following completion, students will be awarded 1 hour of credit for participation, which the researcher will grant through the Studyboard System. Alternatively, students may elect to receive a payment of $20 in the form of an Amazon gift card for participation.

Though we will not be able to encrypt text messages, all messages will be sent from a secure mobile phone and we will inform all participants that we cannot guarantee the privacy of these messages prior to signing study consent. The phones and email addresses we use will be password protected and kept in a secure locked room accessible only to research staff.

Three-months, 6-months, and 12-months post intervention, participants will be asked to complete a mobile-based follow-up self-report assessment battery. The follow-up will assess the impact of the interventions on substance-impaired driving attitudes and behaviors. For each follow-up, participants will be sent the link (by mobile phone) to an identical assessment battery. These sessions will last approximately 30 minutes. Upon completion, participants will be thanked for their participation via text message and participants will be awarded 30 minutes of credits for participation, which the researcher will grant through the Studyboard System. Alternatively, students may elect to receive a $15 Amazon gift card for participation.

Interventions.

Substance Impaired-Driving Personalized Feedback Intervention. Following the baseline assessment, participants will be sent a link via text message to a secure website containing substance-impaired driving specific personalized feedback. Feedback will include the following elements: a personalized substance use profile and substance-impaired driving profile, information on social norms related to substance use and substance-impaired driving, personalized information on BAC (or level of impairment due to drug use) prior to driving, costs associated with a DUI citation in Kentucky, and information on combined drug and alcohol impaired driving risk (if endorsed). 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. 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. Following the baseline assessment, participants will be sent a link via text message to a secure website containing substance-impaired driving specific personalized feedback (described above). Participants will be asked to send a text

message back to the study administrator after viewing the feedback document. After confirming receipt and processing of the document, the study administrator will then send the participant three 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?, and 3) What is your plan for driving after substance use in the future? Based on participant responses to these open-ended questions, the interventionist will send follow-up text messages to provide appropriate reflection/encouragement in Motivational Interviewing (MI) style. All interventionists will be trained in MI and a 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 (Walters et al., 2009).

Information Condition. Students randomized to the information condition will receive standard information about alcohol and other drugs and substance-impaired driving via a link to a website delivered through text message. The informational document provided will detail information about how alcohol, drugs, and combining alcohol and other drugs affects the brain and nervous system, memory, and driving performance, and is similar to substance education programs commonly found on college campuses. The substance-related information will not be personalized. Students will be provided the opportunity to ask any questions related to the information provided via interactive text message.

Research Measures

We will apply for a Certificate of Confidentiality and inform participants during recruitment that their data will remain confidential in order to enhance the accuracy of participants' self-reports. We will also ensure that study administrators receive training on conveying a nonjudgmental attitude toward reports of substance use. All assessment measures will be collected via a secure web-based survey that will be given at baseline, and 3, 6, and 12 months post-intervention.

Demographics Form. These questions will ask about participant gender, age, ethnicity, past and present academic status and grade point average, and fraternity/sorority affiliation.

Drug Use Questionnaire (DUQ; Hien, & First, 1991). This measure will be used to assess the frequency of past month illicit and prescription drug use.

Daily Drinking Questionnaire (DDQ; Collins, Parks, & Marlatt, 1985). The DDQ will be used to assess information regarding past month typical drinking frequency and quantity, as well as the number of heavy drinking episodes (5 or more drinks for a male participant, 4 or more drinks for a female participant) in the past month. Heavy drinking episodes among college students are related to numerous public health concerns including risky sexual behavior, accidents, injury, and death.

Impaired Driving Questions: Participants will be asked 10 questions related to driving after consuming alcohol and/or other drugs.

Brief Young Adult Alcohol Consequences Questionnaire (BYAACQ; Kahler et al., 2008). The B-YAACQ is a 24-item self-report measure that assesses whether or not participants have experienced items on a list of 24 potential alcohol-related problems. Participants indicate whether they have experienced each alcohol-related problem by circling 'yes' or 'no' for each item. The items are then summed for a total score. The BYAACQ has demonstrated high internal consistency with college students as well as good reliability and validity (Kahler et al., 2008).

Marijuana Problems Scale (MPS; Stephens, Roffman, & Curtin, 2000). The MPS assesses different types of problems experienced as a result of smoking marijuana or using other drugs in the past year. Individuals respond to 20 items on a three-point scale (0=No Problem, 1=Minor Problem, 2=Serious Problem). Higher MPS scores indicated greater drug-related problem severity.

Data Analyses.

Power. A power analysis for a design with three conditions being measured on four occasions was run using the G-Power software (Buchner et al., 1997). Based on a previous Murphy et al. (2010) study examining AI driving outcomes among students receiving a BI or education control intervention and the review of behavior change interventions delivered by mobile telephone short-message service (Fjeldsoe, 2009), we chose to utilize an anticipated between-groups effect of .58, which was the mean of the effect size found with alcohol-impaired driving outcomes (*d*=.42) and mobile delivered behavior change interventions (*d*=.73). This would require 44 participants per condition total to have a power of .80, assuming $\alpha = .05$. In order to achieve this sample size at follow-up, we plan to enroll 50 participants per condition, allowing for some attrition.

Overall Evaluation of the Aims. The primary study analyses will examine whether 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, 6-month, and 12-month follow up. 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). 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: Groups 2 and 3 will report greater reductions in driving after substance use at 3-month follow-up compared to Group 1.

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 drinking, using drugs, and/or combining alcohol and drugs). For each model tested, one of the primary outcome variables (number of times driving after drinking, using drugs, and combined use of alcohol and drugs) as the dependent variable with gender, ethnicity, and age included as covariates.

Aim 2: Determine whether interactive text-messages sustain intervention effects over time.

> **Hypothesis 2:** Group 3 will report greater reductions in driving after substance use at 6-month and 12-month follow-up compared to Group 2.

Aim 2 analytic plan. To evaluate hypothesis 2, generalized linear mixed models (GLMM), which represent an extension of linear mixed models to non-normal data, will be utilized. 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 drinking, using drugs, and/or combining alcohol and drugs). For each model tested, one of the primary outcome variables (number of times driving after drinking, using drugs, and combined use of alcohol and drugs) as the dependent variable with gender, ethnicity, and age included as covariates.