

## **Study Protocol and Statistical Analysis Plan**

**Study Title:** Examining an intervention to reduce underage DUI and riding with impaired drivers

**Clinical Trial registration:** NCT03506880

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**Ethical Approval:** Institutional Review Board at Penn State University, University Park, PA, US

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## **Background**

Drunk driving is a major public health problem. The National Highway Traffic Safety Administration reported nearly 10,000 people died from alcohol-related crashes in the U.S. in 2014 (National Center for Statistics and Analysis, 2015). This translates into over 1 DUI related death per hour every day of the year. The problem is further magnified when one considers that each year over 1.3 million drivers in the U.S. are arrested for driving under the influence (DUI) (Department of Justice, 2013). This results in over 3.5 thousand DUI arrests per day. As alarming as these statistics are they pale by comparison to estimates indicating that they only represent 1 percent of the 121 million self-reported episodes of alcohol-impaired driving among U.S. drivers each year (Jewett et al., 2015). Drunk driving also does not only affect the driver. Almost 1 in 5 of all alcohol-related driving fatalities are passengers (NHTSA, 2011). Finally, youth under 21 are significantly over-represented in both alcohol-related driving and alcohol-related passenger fatalities relative to the proportion of all licensed drivers (NHTSA, 2014; Shults et al., 2009; Chen et al., 2008). Together these statistics all underscore the need for immediate action to curb these alarming trends.

There has been a wealth of research dedicated to identifying factors that influence DUI, riding with drinking drivers (RWDD), and under-age drinking to curb these alarming trends. Policies and regulatory actions that focus on maintaining the drinking age at 21, graduated licensing, sobriety check points, server training, and zero tolerance have all been shown to effectively reduce underage drinking and DUI (Hingson et al., 1994; Voas et al., 2000; Hingson et al., 2004; Shults et al., 2001). Despite these efforts, youth continue to engage in DUI, RWDD, and abuse alcohol before they are 21. This indicates a great need to effect change on their motivations and risky behavior through efficacious prevention efforts.

The research proposes to move the field forward by conducting a randomized controlled trial of MADD's parent-based intervention's (PBI) efficacy for all three categories of risky behavioral tendencies (underage drinking, DUI, and RWDD) on a nationally representative sample assessed at 3-waves (baseline, 6 mo., and 12 mo). To the extent that the research is successful, it will provide an easy to implement and low cost alternative that can be widely disseminated to address this important public health problem.

## **Objectives**

Three objectives for the research: 1) Evaluate the efficacy of the PBI (short and long term); 2) examine the mediators of the PBI that directly influence drinking, DUI, and RWDD behaviors; and 3) identify the moderators of intervention efficacy (the subgroups for whom the intervention is more vs less effective).

## **Study Design**

A randomized 3-arm intervention (PBI, Surgeon General, Active Control) with 3 waves of online survey data collection for parents (baseline, 6-month, 12-month), and 4 waves for teens (baseline, 1-month, 6-month, 12-month).

## **Recruitment Strategy**

The participants were recruited by Ipsos using their proprietary KnowledgePanel. Parent-teen dyads who met inclusion criteria were invited to participate in the study via email. Up to 7 email reminders were sent to participants who did not complete the survey initially.

## **Study Population**

The eligibility *inclusion criteria included*: Parent – must have a teenager aged 15-18 years old; Teen – must be 15-18 years old and have a parent/guardian agree to participate in the study. *The exclusion criteria were*: Parent – did not have a teenager aged 15-18; Teen – was not 15-18 years old or did not have a parent/guardian agree to participate in the study.

Participants were required to provide online consent to participate. Parent participants received a description of the research and Ipsos' contact information for questions or to decline participation. Parents were presented a screen describing the research, their consent form, as well as a parental assent statement. Once parents provide consent, they were routed to the baseline survey; after parents provide assent for their teen, teens were also provided with an assent form, and then were routed to their baseline survey.

### **Sample Size, Power, and Attrition**

*Sample Size/Statistical Power*: The sample sizes were chosen based on statistical analytic and theoretical considerations. For example, for Aim 1 examining efficacy of the PBI, we aimed to have final dyad sample Ns of 588 and 532 (and approximately equal n's for our PBIs and control groups of 294 and 266) at the 6 and 12 month follow-ups, respectively. Using power estimation procedures described in Cohen (Cohen & Cohen, 1983) these sample sizes will yield power of greater than 0.80 for small effect sizes (e.g., 5-10%) in the MANCOVA-based analyses (omnibus tests, interactions, and planned comparisons). In our published papers with similar Ns comparing drinking for PBI and controls (Turrisi et al., 2013; Doumas et al., 2013; Ichiyama et al., 2009; Turrisi et al., 2009; Testa et al., 2010; Turrisi et al., 2001; Turrisi et al., 2004) we have detected effect sizes of .05 to .09 for main effects and .05 to .08 for interactions. Thus, with our final Ns we should have sufficient power to evaluate Aim 1.

*Attrition*: We will first examine if the attrition is random by forming a dummy variable that indicates completion or drop-out at each assessment. The dummy variable will be correlated with key variables in the study (e.g., Group, drinking/DUI/RWDD outcomes). In the past, we have observed nonsignificant correlations suggesting that the attrition has been random and then used the most advanced multiple imputation techniques to impute missing data. We then analyze all cases with the imputed data (Turrisi et al., 2009). Although we have not observed differential attrition by condition in our previous work, we recognize the potential. We will reduce this possibility by providing the controls with an online link to the intervention at the completion of the 12-month assessment. Thus, all conditions will be identical except for the timing of intervention. However, if we should observe non-trivial correlations (e.g., > .2) between the dummy variable reflecting completers vs. drop-outs, we will include the dummy coded variable as a covariate in subsequent analyses and attempt to interpret significant effects.

### **Randomization**

Participants meeting the inclusion criteria were randomly assigned to one of the three groups following eligibility screening.

### **Intervention**

The study included two interventions (Turrisi's PBI adapted for MADD; Surgeon General materials) and an active control (HPV materials). *The PBI*: The first section provides an introduction to the problem of underage drinking, DUI, and RWDD. It provides parents with an overview of the problems, various basic facts, instructions on how to use the materials, and comments from parents about the consequences associated with underage drinking. It also helps motivate parents to talk with their teen by emphasizing that such discussions could make a difference in both improving their relationship and reducing their teen's risk. The next two sections focus on developmental changes, relationship building, specific strategies that parents

can use to improve communication channels with their teen, and parenting types. The final section is an in-depth discussion of the risks of underage drinking, DUI, RWDD, and all of the major variables in the proposed theoretical network. Parental reluctance to engage in discussions is also considered. Discussion is provided of whom is most at risk, making agreements, specific strategies for talking so that teens listen, decision making, peer influences, and positive and negative reasons why some teens drink. This section also addresses the issues of alternatives to drinking, DUI, and RWDD, issues for discussion, and additional resources. Parents who were randomized to this group, received a link following the baseline assessment to access the materials. *The Surgeon General*: These materials provided parents information on how to prevent and reduce underage drinking, with sections defining what a drink is, why underage drinking is a problem, the results of underage drinking, what families can do about underage alcohol use, etc. *The Active Control (HPV materials)* provided information regarding the HPV vaccination.

### **Measures**

Data were collected online at baseline, 6-month, and 12-month for both parents and teens. Teens also had a 1-month follow-up. Ipsos provided demographic information on the parents based on panel demographics. Other measures included: DUI, riding with drinking drivers; alcohol use; intentions/willingness/attitudes/beliefs/norms to drink/DUI/RWDD; parental monitoring, permissiveness, modeling; intervention fidelity (Chen et al., 2008; Hultgren et al., 2015; Kann et al., 2014; Poulin et al., 2007; Abar et al., 2014; Mallett et al., 2011; Cartwright & Asbridge, 2011; Dhami et al., 2011; Collins et al., 1985; Dimeff et al., 1999; Marlatt et al., 1998; Turrisi & Jaccard, 1992; Grube & Voas, 1996; Beck & Treiman, 1996; Abar et al., 2009).

### **Primary Outcome Measure**

The primary outcome measures were typical weekend drinking, and declining to ride with impaired drivers.

### **Secondary Outcome Measures**

The secondary outcome measure was willingness to ride in a car with an impaired driver.

### **Intervention Variables**

Parents in the MADD and SG groups received a fidelity questionnaire to measure the useful, interesting, readable the sections of the intervention were.

### **Statistical Analysis Plan**

Statistical analyses were performed using IBM SPSS Statistics version 28. Each primary and secondary outcome was examined using Tukey's critical difference value to compare the means following Wilkinson et al., (1999) recommendations. This approach has been shown to have the most power and least Type I error rates with varying sample sizes to compare mean differences between conditions.

### **Sample Characteristics**

Of those invited, 1,176 (28.5%) met the study eligibility criteria of being a parent or legal guardian to a 15-18 year old adolescent-teen and consented for both themselves and their teen to participate in the study. There were 562 (13.6%) participants who responded to the study invitation but did not meet the study eligibility criteria. Eligible dyads were randomly assigned to one of three conditions: Active Control (AC; n=390, 33.1%), Surgeon General (SG; n=393, 33.4%), or Mothers Against Drunk Drinking Parent-Based Intervention (MADD PBI; n=393, 33.4%).

At the T1 baseline survey, the average age of the teens was 16.33 (SD=1.09). About half of teens identified as female (49%) and most parents identified as female (54%). The majority of participants identified as White (78.2%), Black (8.7%), Asian (2.9%), Native Hawaiian or Pacific Islander (0.2%), American Indian or Alaska Native (1.2%), Multiracial (4.1%), Other (4%), and Hispanic (26.9%).

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