Study Protocol and Statistical Analysis Plan

Study Title: Feasibility of a mobile parent-based intervention to reduce alcohol use by high school seniors

Clinical Trial registration: NCT03932097

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Background

Underage drinking continues to be a significant public health concern in the U.S. (CDC, 2015; NIAAA, 2015). Recent data indicate that among youth ages 12-20, about 23% report past month use and nearly 14% report at least one binge episode (5+ drinks) within that same time frame (Center for Behavioral Health Statistics and Quality, 2015). Results from national epidemiologic studies suggest that use escalates in later adolescence (ages 17- 20) (SAMHSA, 2014). This is concerning as alcohol use, particularly risky use, has myriad consequences for adolescents, the people around them, and society as a whole (CDC, 2015; Miller et al., 2007; NCES, 2016). Individual-level consequences are physical, emotional, and social in nature including death from injuries, engagement in risky sexual behavior, increased risk of sexual and physical assault, academic failure, and changes in brain functioning, which may last into young adulthood (Hingson & Kenkel, 2004; Cooper & Orcutt, 1997; Hingson et al., 2005; Grunbaum et al., 2005; Brown et al., 2000; White & Swartzwelder, 2005; Risher et al., 2015).

Research has shown that parents have a potentially powerful role to play in reducing the scope of these problems (Testa et al., 2010; Turrisi et al., 2000; Turrisi et al., 2001; Turrisi et al., 2009; Turrisi et al., 2013; Wood et al., 2010; Wood et al., 2004). However, parenting interventions, such as Strengthening Families, while impactful, require a great investment in delivery (i.e., implementer, space) and participation (i.e., time). In contrast, the evidence-based, *A Parent Handbook for Talking with College Students about Alcohol*, developed by Dr. Turrisi, is a brief guide for parents derived from his research on both college student decision-making about alcohol use and parent-child communication. The curriculum spans several conceptual domains. The first domain introduces the problem of underage drinking and related harm to help motivate parents to talk with their teen. The next domain focuses on relationship building and specific strategies that parents can use to improve communication channels with their teen. The final domain is an in-depth discussion of the risks of underage drinking alcohol-related consequences (whom is most at risk, decision making, peer influences, positive and negative reasons why some teens drink, alternatives to drinking, driving under the influence, and riding with an impaired driver). Ultimately, the Parent Handbook provides parents with: 1) skills to improve parenting, reducing barriers to communication; 2) skills to guide teens on choosing friends, peer pressure, and decision making; and 3) information for specific topics to discuss about drinking, DUI, and riding with drinking drivers.

The data show that the Parent Handbook not only prevents non-drinking teens' onset of use when they come to college campuses, but it also reduces the drinking of those students who come to college with established high-risk drinking habits (Turrisi et al., 2013). However, the current format has limited efficiency and engagement in that it is accessible only in hard-copy handbook/PDF in a technology-driven age.

Additionally, there is a need to extend the reach of Parent Handbook to a larger population of high-school students that include non-college bound youth. The Parent Handbook research has been limited to parents of teens who are college-bound. However, research suggests that those who do not attend college are at higher risk for alcohol problems later in life (Johnston et al., 2015; Torres-Thomas & Norris, 2012). Further, non-college bound youth are a large group, with recent data indicating that 34% of high school students do not enroll in college immediately following graduation (NCES, 2016). Focusing prevention efforts specifically on college-bound or recently college-enrolled youth leaves a substantial portion of the late adolescent population vulnerable to hazardous drinking tendencies and associated harm.

REAL Prevention LLC (RP) adapted the Parent Handbook to digital format, REAL Parenting (RP), and established its feasibility for a broader audience through a successful Phase I SBIR to address these limitations. In Phase II, our team will refine and complete PN based on our Phase I findings examining parents' preferences. These refinements include: 1) RP will have core modules that cover essential topics (e.g., why it is important for parents to talk with their students, improving communication, parent permissiveness toward adolescent drinking, how alcohol works in the body, and the difficulty of making accurate judgments of impairment); 2) Customization, user-initiated tailoring, is accomplished through offering a menu of optional topics that parents can choose to acquire content specific to their interests (e.g., other commonly used substances that adolescents combine with alcohol use, parents' drinking and drug history, and the importance of being committed to a healthy lifestyle); and 3) Personalization, system-initiated tailoring, is accomplished through adapting content to the parent's communication style.

Objectives
Three specific aims for the research: 1) Evaluate RP's effects on youth alcohol use and other substance use; 2) Examine the process of how RP influences parents' behaviors and how these in turn influence students' behaviors; and 3) Prepare RP for market dissemination. Three objectives for Phase II research are: 1) Refine and complete development of RP based on Phase I findings; 2) Conduct a group randomized trial to evaluate outcomes of the RP curriculum; and 3) Finalize RP programming (if needed) and prepare support materials for the market.

Study Design
A randomized 2-arm intervention (REAL Parenting; Active Control) with 2 waves of online survey data collection for parents (baseline, 3-month) and 5 waves for teens (baseline, 3-month, 6-month, 9-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, teen must be in the 10^{th}, 11, or 12^{th} grade of high school, 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, teen reported not being in the 10-12^{th} grade, 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 with 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 RP, we aimed to have

final dyad sample N of 400. This translates into our two groups (RP/Active Control) each having n's of ~200 at the follow-ups. 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 or marijuana for similar parent-based interventions 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.

For Aim 2, we will use structural equation modeling (SEM) to assess paths between the Group (RP vs. Control) and the mediators (parent-child communication, parental monitoring, parental permissiveness) and student factors at follow-ups (e.g., motives, behavioral willingness, norms, expectancies) as described in MacKinnon et al. In terms of determining the proper sample, the use of SEM means that in addition to statistical power, issues of the stability of the covariance matrix, model complexity, and use of asymptotic theory must be taken into account. In terms of power, it is difficult to evaluate the power associated with specific path coefficients in complex SEM models due to the large number of assumptions about population parameters that must be made. A rough approximation can be obtained by applying power analyses for a coefficient in multiple regression analyses in the context of limited information estimation of path models. As an example, for a regression analysis with 5 predictors (e.g., intervention group, parent discussions, student motives, behavioral willingness, sex, and age) where the squared multiple correlation is 0.25 and where one wants to detect a predictor accounting for at least 5% unique variance in the outcome (e.g., alcohol misuse or alcohol-related consequences), the sample size to achieve power of 0.80 is approximately 125. For a logistic regression analysis having a dichotomous outcome (e.g., yes/no to heavy episodic drinking in past 30 days) where the target predictor is a continuous predictor (e.g., motives), with four other predictors in the equation (e.g., group, parent discussions, sex, and age), where the event rate at the mean of all predictors is 0.20 and where the multiple correlation of the predictor with the other predictors is 0.30, the sample size needed to detect an odds ratio of 1.75 expressed in standardized metrics is about 170 and for an odds ratio in standardized metrics of 2.00 is about 110. Our projected completed sample sizes exceed these thresholds. Thus, we should have sufficient power to evaluate Aim 2 for continuous and non-continuous outcomes.

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 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

Dyads meeting the inclusion criteria were randomly assigned to one of two groups after completing the baseline survey.

Intervention
The study included one intervention (REAL Parenting) and an active control (NIAAA materials on underage drinking). *REAL Parenting:* REAL Parenting is a brief intervention designed for parents of high school students delivered via a web-application that is optimized for smartphones, but can be viewed on larger devices (e.g., tablets, computers) and takes approximately 15 minutes to view in its entirety. Content was presented across four modules (screens) that cover the following topics: (1) What should I know about alcohol use and teens?; (2) How can I improve my communication?; (3) How do I start the conversation?; and (4) What should I say when talking about alcohol? Four brief, animated videos accompanied on-screen text and included complementary content designed to motivate parents to talk, model an example of positive parent-teen communication, and provide additional explanatory information related to the topic page where it was placed. To mimic the experience of the original parent handbook, the pages could be freely explored in any order, parents could look at as much or as little content as they wanted, and they could return to the app via the emailed link as often as they wanted. The *Active Control* (NIAAA materials) provided information regarding underage drinking.

Measures
Data were collected online at baseline, 3-month, 6-month, 9-month, and 12-month for teens, and baseline and 3-month for parents. Ipsos provided demographic information on the parents based on panel demographics. Other measures included: frequency of past 3-month drinking, frequency of past 3-month marijuana use, combined use of alcohol and marijuana, consequences of alcohol use, frequency of past 3-month nicotine use, alcohol motives, alcohol expectancies, alcohol willingness, alcohol injunctive norms, and parental alcohol communication.

Primary Outcome Measure
The primary objective measures was frequency of past 3-month drinking.

Secondary Outcome Measures
The secondary outcome measures were frequency of past 3-month marijuana use, frequency of combined use of alcohol and marijuana, consequences of alcohol use, and frequency of past 3-month nicotine use.

Intervention Variables
Parents received prompts within the app to measure acceptability, usefulness, and interestingness of the app sections.

Statistical Analysis Plan
Statistical analyses were performed using IBM SPSS Statistics version 28. Each primary and secondary outcome was examined using analysis of variance (ANOVA) to test mean differences between conditions on each outcome, while controlling for baseline values.

Sample Characteristics
Of those invited, 306 (26.5%) parents met the study eligibility criteria of being a parent or legal guardian to a 15-18 year old teen and consented for both themselves and their teen to participate in the study (N=612 parents and teens eligible and consented to participate in the study). There were 117 (10.1%) parents who responded to the study invitation but did not meet the study eligibility criteria. Eligible parent-teen dyads (N=612) were randomly assigned to one of two conditions: REAL Parenting (RP; n=320 [160 dyads], 52.3%) or Active Control (AC; n=292 [146 dyads], 47.7%).

At the T1 baseline survey, the average age of the teens was 16.36 (SD=.92) and the average age of parents was 45.96 (SD=6.91). There were 159 teens who identified as female (51.96%) and most parents identified as female (58.5%). The majority of parents identified as White, non-Hispanic (61.1%); Black, non-Hispanic (12.75%); Other, non-Hispanic (6.54%); Hispanic (16.67%); and 2+ races non-Hispanic (2.94%). Majority of teen participants identified as White (76.47%), Black 14.71%), American Indian or Alaskan Native (3.92%), Asian (7.52%), or Other (4.25%).

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