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Study Protocol and Statistical Analyses for  
Family Based Prevention of Alcohol and Risky Sex for Older Teens (AA020977)  
(NCT03521115)

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## I. Background Information

Older teens (ages 16-18 ) encounter situations where they need to make decisions about using alcohol, engaging in sexual activity and forming romantic relationships. Parents report that they actively try to assist their older teens in navigating these pathways to young adulthood. Although older teens are becoming increasingly independent of their parents, most teens still seek support and assistance from parents as they negotiate these transitional years to young adulthood. Creating a resource for parents and teens to initiate conversations in a non-threatening and interactive manner is needed. Practicing and developing skills that can be used when encountering situations are also needed. Despite the interest in assisting their teens, families report difficulty in finding time to engage in a prevention program that would be conducted outside the home. For this reason, the program “Smart Choices 4 Teens,” was created as an online program. Allowing the parent and teen to view the program separately and privately engage in the interactive features, was considered important. Bringing the parent and teen together for an offline discussion of scenarios drawn from real teen stories and experiences, allowed them to engage in interactive dialogue and practice skills that could be used when the teen would need to make choices in the real world.

## II. Purpose of Study

Smart Choices 4 Teens was created by adapting materials from two evidence-based prevention programs that are both booklet-based and independently completed by families: Family Matters (Bauman et al., 2001) (designed for parents of younger adolescents) and A Parent Handbook for Talking with College Students about Alcohol (Abar & Turrisi, 2008; Turrisi et al., 2001) (designed for parents to prepare their adolescents for the first year as college students). The intent was to determine whether this online program would improve the teen’s ability to make safe and responsible choices regarding their alcohol use and sexual behaviors as compared to teens not exposed to the program.

## III. Study Design

### Description of the Intervention—Smart Choices for Teens:

The Smart Choices 4 Teens intervention was designed to be sensitive to the transition to young adulthood and increased independent decision-making. The intervention addresses critical needs for families of older adolescents, including the perspectives of adolescents and parents, leveraging the continued influence of parents even later in adolescence, and permitting flexibility to the schedules of families. The intervention was designed to engage parents and teens in an online program that was comprised of three major components: 1) Parent-teen communications—how to improve dialogue between parents and teens on important and sensitive topics like teen alcohol use and sexual behaviors; 2) Teenage alcohol use—addresses important choices that teens make about whether to use or not use alcohol and the skills that can be developed for making “smart choices;” and 3) Teen relationships and decisions about sexual behaviors—addresses important choices that teens make about romantic relationships and decisions about sexual behaviors as well as provides skills for interacting with others. The Communication component provided a foundation for the other components by providing needed communication skills through videos and interactive activities. The Alcohol Prevention component’s goal was to prevent or reduce teen alcohol use. It began with an overview and

statistics about teen alcohol use, information about peer pressure, and consequences of drinking. Interactive activities addressed physical and social consequences of drinking, signs of alcohol poisoning, a BAC calculator activity, myths about sobering up, parental influences important to address teen alcohol use, social host laws in each state, refusal skills, and indicators of problem drinking. The goal of the relationship component was to foster communication around healthy relationships, increase parental monitoring, clarify expectations and values, provide skills for making healthy choices around the decisions related to relationships, and encourage reflection on decision making. Topics included, challenges of parent-teen communication about relationships and sexuality, choosing healthy relationships (considering type of relationship desired, identifying desired partner characteristics, and raising awareness of emotional and verbal abuse); developing awareness of sex expectancies, assessing possible unintended health consequences such as pregnancy and sexually transmitted infections, addressing social media responsibility and influences, developing confident refusal skills; and values and guidelines for smart choices.

The intervention was delivered via video narratives, info-gadgets (activities with a series of tabs on a single topic, containing graphics and text), interactive exercises, and an offline parent-teen discussion centered around real-life teen scenarios that addressed each topic.

Smart Choices 4 Teens required that parents and teens complete the activities online separately. Following completion of the component, teens and parents discussed scenarios reflecting teen choices regarding alcohol use and relationships as an offline activity. Families had to indicate that they had completed the discussion to move on to the next component. In addition, as the program is family based, families could only progress to the next component if their other participating family member had also completed that component. For example, if a teen had completed the Communication component, but their parent had not, the teen would not be able to begin the Alcohol component until their parent had also completed the Communication component. On average, the Communication component took families 20.29 min to complete (21.83 minutes for parents, 18.75 minutes for teens). The Alcohol component took 15.94 min (16.34 minutes for parents, 15.53 minutes for teens), and the Relationship component took 19.75 min (19.79 minutes for parents, 19.71 minutes for teens). The amount of time spent in family discussions of the scenarios is not included in these averages.

**Description of the Control Condition:** Families in both the control and intervention condition received links to resources, including hotline numbers and websites to provide information about teen alcohol and drug use, sexual behavior, suicide, and other health issues. The websites provided contact information for crises, as well as information about the specific health issue (e.g., the Mothers Against Drunk Driving website provided information about rates and consequences of impaired driving). All families also had access to an 800 number throughout the duration of the project to contact with the research team.

**Selection and Exclusion of Subjects:** Participants were recruited from November 2014 to November 2015 from two online panel vendors to provide a sample that would reflect the national population (Wang-Schweig et al., 2019). Panel members provided demographic characteristics when joining the panel, which were used to determine eligibility for the trial. Panel vendors provided contact information for 1,531 adult panelists via a secure shared website. Among these, 559 were found to be eligible, that is, parent with a teen aged 16–17; English speaking; and a device (tablet or computer) compatible with viewing the online intervention. The research team performed a second level of verification, which entailed calling

and speaking to both parent and teen to verify their eligibility via phone after passing the screener. We were unable to contact 607 panelists to complete this second level of verification, another 365 were not eligible, and 148 declined to participate. Among the 559 eligible panelists, 411 (73.5% of eligible adults) completed baseline online surveys (and their teens completed separate online surveys) and enrolled in the study. Parents were consented for their own and their teen's participation in the program and the surveys. Assent forms were completed by teens prior to engaging in any exposure to treatment or surveys. Each participant received US \$30 for baseline surveys, US \$40 for 6-month follow-up surveys, and US \$50 each for 12-month and 18-month follow-up surveys via a mailed check.

*Survey and Randomization Procedures:* Separate surveys were conducted for parents and teens at baseline (at time of enrollment), and at 6, 12 and 18 months later. After both parent and teen completed the baseline survey, families were randomly assigned to either the intervention or control condition using a computer-generated program. Automated e-mails and texts were sent to invite families to complete the follow-up surveys. One week after follow-up survey invitations were sent, reminder e-mails and texts were sent to families who had not completed the surveys, with the e-mails/texts repeated after another week of nonresponse. One week later, separate phone calls were made to parents and teens if they had still not completed. Participants could complete the surveys up to 2 months after surveys were initiated. Of the 411 enrolled dyads, 315 teens (76.6%) and 364 parents (88.6%) completed the 6-month follow-up surveys, and 311 teens (75.7%) and 354 parents (86.1%) completed the 12-month follow-up surveys and 309 teens (75.2%) and 357 parents (86.9%) completed the 18-month follow-up surveys.

*Measures:* Measurement of assignment to condition (experimental vs. control) was based upon the original randomized assignment. Program dosage (no exposure, exposure to alcohol component, exposure to relationship component) was based upon tracking progress through the program, automated in the online delivery.

*Teen alcohol use.* Alcohol items were adapted from the National Longitudinal Study of Adolescent Health (Harris et al., 2008) and asked in surveys. Teens first reported whether they had consumed alcohol over the past 6 months and past 30 days (1 = Yes, 0 = No).

*Quantity and frequency of alcohol use.* Teens reported their frequency of drinking over the past 30 days and past 6 months (0 = Never, 1 = once a month, 2 = 2–3 times a month, 3 = once a week, 4 = 2–3 times a week, and 5 = daily or almost daily). The variable was recoded to more closely approximate the actual number of times used over the time period. For example, 2–3 times a month in the last 30 days was recoded to 2.5, whereas 2–3 times a month over the past 6 months was recoded to 15 (2.5 = 6 months). Teens also reported the usual amount they drank on drinking days (0 = less than one to 7 = more than six).

*Drunkenness:* To assess drunkenness, teens reported the number of times they had gotten “drunk or very, very high” on alcohol over the time period (e.g., past 6 months, past 30 days).

*Communication regarding teen alcohol use.* Both parents and teens responded to items regarding their alcohol communication at each time period (baseline, 6 months, 12 months). All parent–teen alcohol communication items were adapted from Turrise, Mastroleo, Mallett, Larimer, and Kilmer (2007)(Turrise et al., 2007) and Reimuller, Hussong, and Ennett (2011)(Reimuller et al., 2011). Three constructs were assessed: (a) Consequences and

Expectations: alcohol communication regarding consequences and parental expectations about teen alcohol use (12 items, e.g., how drinking could get the teen in trouble with a parent or the law; drunk driving consequences), 1 = never to 5 = very often. Items were averaged to create separate parent and teen scales (parent report:  $\alpha = .95$  at baseline,  $.97$  at 6 months,  $.97$  at 12 months; teen report:  $\alpha = .96$  at baseline,  $.96$  at 6 months, and  $.97$  at 12 months). (b) Safe drinking strategies: two items that consisted of teen drinking was acceptable in moderation, and teen drinking was acceptable under supervision, 1 = never to 5 = very often. Items were averaged to create separate parent and teen scales at each time point (parent report:  $r = .72$ ,  $p = .001$  at baseline,  $r = .72$ ,  $p = .001$  at 6 months,  $.74$ ,  $p = .001$ . at 12 months; teen report:  $r = .73$ ,  $p = .001$  at baseline,  $r = .72$ ,  $p = .001$  at 6 months, and  $r = .78$ ,  $p = .001$  at 12 months); and (c) Both parents and teens responded to one question as to how often parents had discussed social host laws with them (1 = never to 5 = very often).

*Overall frequency of communication about sex:* The overall frequency of sex communication was assessed with a single item adapted from the evaluation of the program Parent Handbook for Talking with College Students about Alcohol (Turrissi et al., 2010) — “Overall, how often have you talked to your parent about sex”—with response options ranging from (1) never through (5) very often.

*Topics of conversation about sex:* Adolescents were asked to report whether their parents had talked about specific topics with them, adapted from the evaluation of Family Matters (Reimuller et al., 2011).

*Conversations regarding delaying sex until older:* Three items asked whether a parent had cautioned the adolescent not to have sex, not to have a serious relationship in high school, and not to have sex specifically because their religion or values forbid sex outside of marriage. A sum of the three items was taken, and reliability was adequate (T0:  $\alpha = .62$ ; T1:  $\alpha = .64$ ; T2:  $\alpha = .68$ ; T3:  $\alpha = .70$ ).

*Health risks associated with sex:* Two items were summed for discussions of health risks: “sex can result in pregnancy” and “sex can result in a sexually transmitted infection.” The two items were significantly correlated for all four waves (T0:  $r^2 = 0.58$ ;  $P < .001$ ; T1:  $r^2 = 0.71$ ;  $P < .001$ ; T2:  $r^2 = 0.74$ ;  $P < .001$ ; T3:  $r^2 = 0.77$ ;  $P < .001$ ).

*Parental monitoring and dating rules:* Adolescents were each asked about the expectations for behavior in romantic relationships that they had decided upon (Madsen, 2008). They were asked to respond no (0) or yes (1) to a list of 15 possible rules, for example, “no dates on school nights,” “come home at an agreed-upon time (curfew),” “use good judgment,” and “be a gentleman/lady.” Responses were summed. Internal consistency was good (T0:  $\alpha = .83$ ; T1:  $\alpha = .87$ ; T2:  $\alpha = .86$ ; T3:  $\alpha = .89$ ).

*Sexual activity:* Teens were asked whether they had had sex at baseline (ever), and at 6, 12, 18 month follow-up surveys (during the past 6 months) with answers of Yes/No.

### Sample Characteristics:

Among enrolled families at baseline, parents were on average 43.7 years of age ( $SD = 6.7$ ) and their teens were 16 or 17 years of age ( $M = 16.4$ ,  $SD = 0.5$ ). Mothers comprised 84.7% of the parents and slightly more than half (55.3%) of the teens were females. Household size ranged from two to 12 ( $M = 4.5$ ,  $SD = 1.6$ ). About one-tenth (9.5%) of the teens were Hispanic/Latino.

Teens reported the following race/ethnicities: 72.5% White, 1.9% Asian, 11.7% African American, 1.0% Native American, 8.3% Multiracial, 2.7% some other race, and 1.9% unreported. No significant differences were found between the experimental and control conditions on demographic characteristics at baseline.

### **Exposure to Treatment**

Concerns about Recruitment: Because the intervention is available online, families could complete the intervention in their own homes, at a time convenient for them. Thus, some of the typical barriers to participation were removed. Despite these barrier reductions, only half (49.5%) of the families assigned to the intervention condition completed the program materials on teen alcohol use and less than half (42.7%) completed the materials on romantic/sexual relationships.

There are many reasons for prevention strategies to fall short of this total “inoculation” of the general population. First, families whose teens are perceived as “doing fine” or “not in need of any prevention” are difficult to engage in prevention. Second, parents sometimes believe that it is important not to prevent risky behaviors of teens like drinking and sexual activity but rather to teach teens how to engage in these behaviors while minimizing risks; they may not view a prevention program as aligned with their parental values. Third, families with teens who are already engaged in heavy alcohol consumption and/or engaged in risky sexual behaviors need a more intensive treatment intervention. Fortunately, there does not need to be total saturation of the general population for community-level perspectives to change. Nonetheless, an efficacious intervention that reaches even a sizeable proportion of the general population does potentially provide a resource to a sizeable number of families. Furthermore, parents of older teens do express a desire for some support and help in managing these “adult” behaviors.

### **Analyses:**

Descriptive analyses were conducted first to describe rates and mean scores of outcomes overall and by condition across three assessments to check the randomization.

Selection model: Because families chose how much of the intervention to which they were exposed, we conducted a probit analysis predicting whether or not a family completed the alcohol or relationship component from baseline measures. Based on this analysis, an instrumental variable, inverse Mills’ ratio (IMR) representing the underlying selection processes was included as a covariate in our primary dosage analyses (Heckman, 1979). The IMR (non-selection hazard) was calculated in Stata using the two-step procedure described in Heckman (1979). When the IMR is significant in a model, this indicates that the predicted probability of completing the component is associated with the outcome. That is, the same factors that predispose families to complete (or not complete) the component are related to the outcomes. In models where dosage is significant, this indicates that even accounting for factors that are related to completing the program, that dosage is still related to outcomes.

Conducting analyses in SPSS 21, dichotomous outcomes were examined using multiple logistic regression, while continuous outcomes were examined using multiple linear regression. Listwise deletion was used for missing cases. For all regression analyses, the baseline value of the outcome variable, teen gender, teen age, and teen ethnicity, an inverse Mills’ ratio and intervention condition, were covariates to determine whether dosage predicted the outcome for a specific follow-up period (i.e., 6, 12 18 months).

### **Assessment of Efficacy-Overview:**

Results from the Smart Choices 4 Teens program indicate efficacy for prevention of alcohol use and alcohol-related problem behaviors for older teens when parents and teens, with greater exposure to the program content producing better outcomes, when controlling for baseline rates and selection bias. The intervention also showed efficacy for parent–teen communication, especially around conversations related to social host laws. Further parents and teens engaged in the program were less likely to discuss ways that teens could drink “safely,” and thus not providing a message that teens could drink if they drank safely. Of particular importance is that the dosage effects were noted across different alcohol involvement indicators and some of these impacts persisted at the 12-month follow-up period, showing that the program may have sustained effects.

For the relationships/sexual behaviors component of the intervention, the data support the efficacy of the Smart Choices 4 Teens intervention in increasing adolescent and parent communications about sexual relationships (eg, frequency) and to increase parental guidance (eg, dating rules) when controlling for baseline rates and selection bias. There was some support that the intervention had a main effect on frequency of communication and dating rules set for the adolescents, even after controlling for other adolescent characteristics that were also significant predictors of adolescents’ reports of sexual communication with their parents, including developmental changes over time, as well as adolescent gender, sexual minority status, and sexual experience.

There were indications that the intervention had impact on sexual communication over time, irrespective of the gender of the adolescent. When accounting for the possible interaction between the time of administration, gender of the adolescent, and exposure to the intervention, demonstrated an impact on the parent-teen sexual communication outcome. The intervention increased parent-teen communications regarding increased dating rules, indicating greater parental monitoring of teen relationships. There was no indication of an interaction effect between gender and intervention exposure on dating rules. Participating in the intervention increased the dating rules for all participants and was durable across time.

Further details for the efficacy of the intervention are detailed in the online report of findings and publications.

### **Assessment of Safety (Adverse events, ethics)**

All study procedures were approved by the Institutional Review Board of the Pacific Institute for Research and Evaluation.

Families had access to an 800 number throughout the duration of the project for live contact with the research team for both experimental and control families. A registration and profile page were required to be completed to gain entry to the website. Separate passwords were established for teen and parent to provide protection from parent or teen reviewing responses by anyone else. Throughout the study, no parent or teen contacted us or gave us information that warranted concerns about adverse or serious adverse events.

**Citations:**

- Abar, C., & Turrisi, R. (2008). How important are parents during the college years? A longitudinal perspective of indirect influences parents yield on their college teens' alcohol use. *Addictive Behaviors, 33*(10), 1360-1368. <https://doi.org/doi:10.1016/j.addbeh.2008.06.010>
- Bauman, K. E., Foshee, V. A., Ennett, S. T., Hicks, K., & Pemberton, M. (2001). Family Matters: A family-directed program designed to prevent adolescent alcohol and tobacco use. *Health Promotion Practice, 2*(1), 81-96.
- Harris, K. M., Halpern, C. T., Entzel, P., Tabor, J., Bearman, P. S., & Udry, J. R. (2008). *The National Longitudinal Study of Adolescent Health: Adolescent In-Home Interview*. URL: <http://www.cpc.unc.edu/projects/addhealth/codebooks/wave1>
- Heckman, J. J. (1979). Sample selection bias as a specification error. *Econometrica, 47*(1), 153-161.
- Madsen, S. D. (2008). Parents' management of adolescents' romantic relationships through dating rules: Gender variations and correlates of relationship qualities. *Journal of Youth and Adolescence, 37*(9), 1044-1058. <https://doi.org/10.1007/s10964-008-9313-8>
- Reimuller, A., Hussong, A., & Ennett, S. T. (2011). The influence of alcohol-specific communication on adolescent alcohol use and alcohol-related consequences. *Prev Sci, 12*(4), 389-400. <https://doi.org/10.1007/s11121-011-0227-4>
- Turrisi, R., Abar, C., Mallett, K. A., & Jaccard, J. (2010). An Examination of the Mediation Effects of Cognitive and Attitudinal Factors of a Parent Intervention to Reduce College Drinking. *J Appl Soc Psychol, 40*(10), 2500-2526. <https://doi.org/10.1111/j.1559-1816.2010.00668.x>
- Turrisi, R., Jaccard, J., Taki, R., Dunnam, H., & Grimes, J. (2001). Examination of the short-term efficacy of a parent intervention to reduce college student drinking tendencies. *Psychol Addict Behav, 15*(4), 366-372. <https://www.ncbi.nlm.nih.gov/pubmed/11767270> (Understanding binge drinking)
- Turrisi, R., Mastroleo, N. R., Mallett, K. A., Larimer, M. E., & Kilmer, J. R. (2007). Examination of the mediational influences of peer norms, environmental influences, and parent communications on heavy drinking in athletes and nonathletes. *Psychol Addict Behav, 21*(4), 453-461. <https://doi.org/10.1037/0893-164X.21.4.453>
- Wang-Schweig, M., Miller, B. A., Buller, D. B., Byrnes, H. F., Bourdeau, B., & Rogers, V. (2019). Using Panel Vendors for Recruitment Into a Web-Based Family Prevention Program: Methodological Considerations. *Evaluation & the Health Professions, 42*(1), 24-40. <https://doi.org/10.1177/0163278717742189>