BRIEF INTERVENTION TO PREVENT ALCOHOL SOCIALIZATION (BIPAS ALCOHOL)

Support provided by: National Institute of Alcohol Abuse and Alcoholism (NIAAA)

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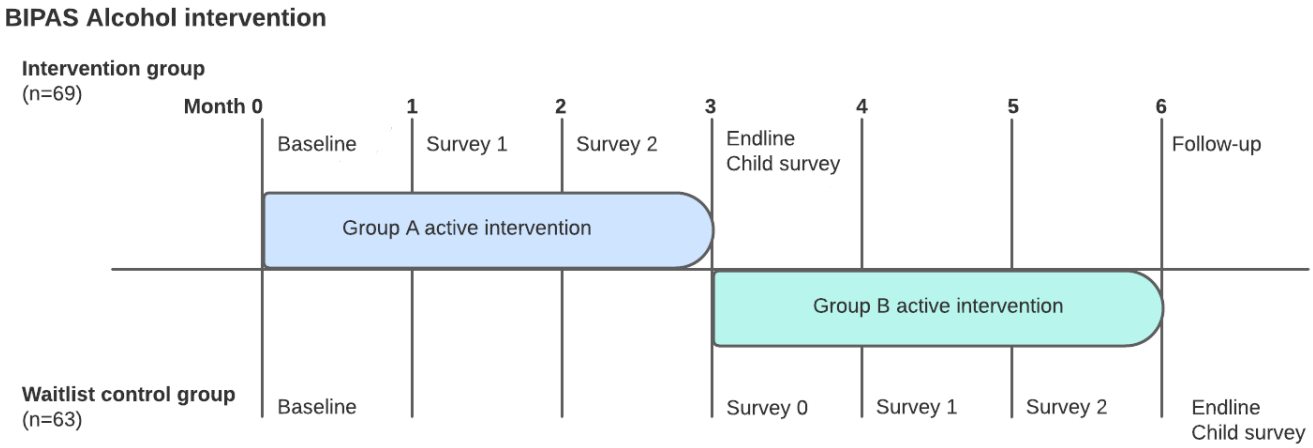
PROTOCOL SUMMARY

Title:	Brief Intervention to Prevent Alcohol Socialization / Better Informed Parents Keeping Adolescents Safe from Alcohol (BIPAS Alcohol)
Summary:	Early alcohol socialization occurs within the family. Our multi-level, high-reach, low-intensity intervention to prevent early alcohol use capitalizes on the influence of providers, immunization timing, and pediatric guidelines that advise healthcare providers to give anticipatory guidance about early alcohol use. In conjunction, the intervention capitalizes on the power of technology to reinforce and expand upon pediatrician messages. Our study seeks to understand the feasibility and effectiveness of a pilot intervention designed to prevent alcohol socialization through education of parents of rising 6th grade students.
Objectives:	To evaluate the feasibility and preliminary effectiveness of an intervention aiming to improve parents' attitudes about child alcohol use. Primary outcome measure: The change in parents' score from an 8-item scale of pro-sipping beliefs from baseline to post-intervention (6 months).
Sample:	Parents of rising 6th grade students.
Phase:	Phase 0/1 (Intervention development)
Participant duration:	Parents will participate in a text-based intervention for three months and complete surveys for up to 6 months after study enrollment. Children will complete one survey 3 months after study enrollment.
Description of intervention:	BIPAS Alcohol is an intervention intended to prevent early onset alcohol use by educating parents of rising middle schoolers. Parents will receive information delivered via text message for three months.
Estimated time to complete	

enrollment:	6 months

Schematic of study design:



1 KEY ROLES

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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 2.1 Background information

Early initiation of alcohol use is a uniquely predictive risk for problematic alcohol involvement during late adolescence and adulthood. Prospective longitudinal studies show that children who have sips of alcohol during early adolescence, typically in the family context, are at higher risk for alcohol misuse, binge drinking and development of alcohol-related problems. Youth whose family context makes them more susceptible to drinking are also more likely to select into pro-alcohol peer groups that reinforce drinking attitudes and behavior. Alcohol misuse is the primary contributor to death by injury and is the leading cause of death for those under age 21. Alcohol use negatively alters brain development and is implicated in risky sexual behavior, aggressive and violent behavior, depression and social isolation, poor economic outcomes, smoking and other drug use, academic problems, and suicidality. Given the variety and magnitude of these negative consequences, early initiation of alcohol use is a major public health problem in need of public health interventions that have the potential for wide reach and high impact across the life course.

One quarter of 8th grade students and half of 10th grade students have already consumed alcohol. A significant minority of youth begin drinking even younger, and alcohol use rates double as children transition from elementary to middle school. Whereas only 10% of fourth graders have ever tried alcohol, more than 20% of sixth graders report ever drinking. Given this, and our finding that school transitions promote risk for onset of substance use, the transition to middle school is a critical period for prevention of alcohol initiation.

2.2 2.2 Rationale

Parents are the essential target of early intervention to prevent underage alcohol use initiation. A substantial body of evidence shows that permissive parental beliefs about alcohol, and concomitant permissive behaviors (e.g., permitted sipping of alcohol at home), are strongly associated with children's self-reported alcohol use. While peers become increasingly influential during adolescence, parents are more influential than peers for children and young adolescents. Additionally, parental attitudes shape how they monitor adolescent interactions with peers, so intervening with parents during early adolescence may also buffer negative peer influence. Our prospective analysis showed that, even in the context of other protective factors, adolescents whose parents had permissive beliefs about alcohol use exhibited quicker escalations in alcohol involvement across adolescence than those whose parents were less permissive about their children's alcohol use. Indeed, permissive parenting practices were more strongly predictive of growth in adolescent alcohol misuse than whether the parents themselves used alcohol heavily.

Text message-based interventions have been shown to be both acceptable and very effective across a variety of behaviors, including with parents. A meta-analysis of 19 RCTs of text message-based interventions found that tailored text messages are even more powerful for

promoting behavior change than un-tailored messages. Mobile phone ownership is near-universal in the United States (96% in 2019, including 99% of individuals aged 18-49). Importantly, mobile phone ownership rates are in the high-90%s for Black, White, and Hispanic/Latino individuals.

2.3 2.3 Potential Risks and Benefits

2.3.1 2.3.1 Potential risks

Potential risks associated with participation for parents include loss of time and slight risk of embarrassment or discomfort in answering questions about their family practices around alcohol. However, because text message viewing is discretionary for parents, we expect loss of time to be minimal. All answers to survey questions and data received from text message usage will be kept confidential. Thus, the risk of embarrassment is anticipated to be very slight. Parents could become distressed about their own drinking behavior. We minimize these risks by tailoring the message content to parenting-related behaviors and offering resources on our website for parents seeking information about alcohol misuse.

We do not anticipate immediate or long-range risks associated with participation.

2.3.2 2.3.2 Known potential benefits

By participating in this study, parents will receive actionable information about incorporating alcohol discussions in their family life. This study will also help inform a future larger randomized control trial of the BIPAS Alcohol intervention.

3 OBJECTIVES

3.1 3.1 Study objectives

The purpose of this study is to evaluate the feasibility and preliminary effectiveness of BIPAS Alcohol, an intervention aiming to reduce pro-sipping beliefs, to encourage creation of clear, alcohol-specific rules, and to limit their provision of sips of alcohol to young adolescents.

3.2 3.2 Study outcome measures

Our primary outcome measure is changes in parents' self-reporting pro-sipping beliefs, attitudes, and practices at the end of the intervention period.

3.2.1 3.2.1 Primary outcome measures

For each participating parent, we will assess the change in composite score on an 8-item scale of self-reported pro-sipping beliefs, attitudes, and practices from baseline to 6 months (length of intervention). A four-point scale ranging from "strongly disagree" to "strongly agree" will be used, with higher values on the scale indicating a more pro-sipping belief system.

3.2.2 3.2.2 Other measures

No *a priori* secondary outcome measures.

4 STUDY DESIGN

This study will evaluate the BIPAS Alcohol intervention with approximately 100 families. Parents will be randomized after enrollment into two groups: an intervention group and a waitlist-control group. Parents in the intervention group will begin receiving the intervention after enrollment, while parents in the waitlist-control group will receive the intervention three months after enrollment.

During the intervention period, all parents will receive text messages 2-3 times/week and online resources for three months about alcohol use and negative consequences in children, focusing on ways that they can create rules within the family environment to prevent alcohol use in children.

Parents in both groups will complete monthly surveys, and their child will complete one survey after three months. The parents in the intervention group will also receive a follow-up survey at 6 months. Parents in both groups will be asked if they would like to participate in an optional, follow-up qualitative interview about their experiences participating in the intervention.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject inclusion criteria

In order to be eligible to participate in this study, parents must:

- Be aged 18 or older;
- Be a parent or guardian of a child aged 10-12 years old;
- Cohabitate part-time (2 days/week) or more with enrolled child;
- Be able to complete study activities in English;
- Be able to give informed consent;
- Own a phone with text messaging capabilities and access to internet.

5.2 Subject exclusion criteria

Individuals will be excluded from participation if they do not meet study inclusion criteria. Additional exclusion criteria include: families in which the 10- to- 12- year-old child is actively receiving treatment for alcohol use disorder.

5.3 Strategies for recruitment and retention

Parents will primarily be recruited through flyers placed in elementary school electronic newsletters.

The risk of this research is minimal risk to participants. We affirm this study will be conducted in accordance with sound ethical principles. Potential participants will be fully informed about the details of the study and encouraged to ask questions or stop at any time.

5.4 Treatment assignment procedures

5.4.1 Randomization procedures

We will use a coin flip to determine which group parents will randomly be assigned to after enrollment.

5.4.2 Masking procedures

None.

5.4.3 Reasons for withdrawal

Participants who request to withdraw will be given the option to discontinue participation in the intervention. Participants who request to completely withdraw from the study will no longer be contacted.

5.4.4 Handling of withdrawals

See above.

5.4.5 Termination of study

Given the low-risk nature of this study, we do not anticipate grounds for premature termination.

6 STUDY INTERVENTION

6.1 Study intervention description

The BIPAS Alcohol intervention offers education and tools to parents of children ages 10-12 about preventing early onset alcohol use through information delivered via text message. Parents will receive text messages on early onset alcohol use, negative effects, and evidence-based recommendations about encouraging discussion and rules with their child about alcohol. Text messages will be delivered 2-3 times/week for three months.

Parents will complete a baseline survey as well as monthly surveys about alcohol-related beliefs, knowledge, and behaviors. Parents in the intervention group will also complete a follow-up survey six months after enrollment.

6.2 Dosage, preparation, and administration of study intervention

Each parent will receive text messages up to three times weekly and monthly surveys from our study team for a period of up to six months.

6.3 Modification of study intervention for a subject

Not applicable.

6.4 Accountability procedures for the study intervention

Not applicable.

6.5 Assessment of subject compliance with study intervention

Not applicable.

6.6 Concomitant medications/treatments

Not applicable.

7 STUDY SCHEDULE

7.1 Screening

Parents who are interested in participating will complete an online pre-screening questionnaire. Eligible families will be contacted by a member of the study team and confirm eligibility over the phone. Screening of interested families will be conducted prior to informed consent. After enrollment, study participants will be given a baseline survey and provided with additional study instructions. Successful completion of the baseline questionnaire will demonstrate a willingness and ability to participate.

7.2 Enrollment/baseline

Enrollment and data collection will occur in 2023-2024.

7.3 Follow-up

Not applicable.

7.4 Final study visit

Not applicable.

7.5 Early termination visit

Not applicable.

7.6 Unscheduled visit

Not applicable.

8 STATISTICAL CONSIDERATIONS

8.1 Study hypotheses

This is a feasibility trial designed to evaluate implementation outcomes and to obtain pilot data on efficacy of the intervention with a group of 100 parent-child dyads. We hypothesize that the BIPAS Alcohol intervention will increase parents' knowledge and decrease their pro-sipping behaviors around adolescent alcohol.

8.2 Sample size considerations

We will test our hypothesis that the BIPAS Alcohol intervention will increase parents' knowledge and decrease pro-sipping behaviors with 100 parents of 10-to-12-year-old children. We acknowledge that our trial is underpowered to detect small differences or control for multiple testing. One purpose of this feasibility study is to estimate effect sizes for powering a large-scale RCT. By piloting our intervention in two clinics, our study is designed to provide the data needed to lay this groundwork.

8.3 Planned interim analyses (if applicable)

Not applicable.

8.4 Final analyses plan

We will use generalized linear mixed models to model change in parent attitudes and behaviors over time as a function of treatment arm and baseline characteristics. We will handle missing data on survey outcomes using multilevel multiple imputation. Parameter estimates generated from these secondary analyses will be used for refining the intervention and for power analyses in a subsequent grant proposal.

9 ETHICS/PROTECTION OF HUMAN SUBJECTS

9.1 Ethical standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 62 Federal Regulations 25691 (1997).

9.2 Institutional Review Board

Study procedures have been approved by the University of North Carolina Institutional Review Board.

9.3 Informed consent process

Informed consent will be obtained from all participating families prior to participation in baseline data collection.

9.4 Exclusion of women, minorities, and children (special populations)

Not applicable.

9.5 Subject confidentiality

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. The study team will take precautions to ensure that subject confidentiality is maintained. All data will be stripped of patient-level identifiers and stored on a password-protected server accessible only to UNC study staff. Data will be reported in aggregate and will not identify participating parents or children by name.

9.6 Study discontinuation

Not applicable.

9.7 Future use of stored specimens

Not applicable.