Clinical Trial registry name and registration number: Alcohol Screening in an Ethnically Diverse Sample of Adolescents in Primary Care; NCT01797835

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Study protocol and analysis plan

This proposal focuses on screening and treatment referral specifically among adolescents. In the proposed study, we will train PC clinicians (e.g., nurses) in four clinics across two states to use the new two-question NIAAA screening guide (NIAAA SG)[1] to determine the prevalence of at-risk alcohol use among an ethnically and racially diverse group of youth age 12-18, and to test the feasibility and practicality of this brief screener for predicting subsequent alcohol use, alcohol risk and problems among this population. In addition, we will examine how well the NIAAA SG questions identify other behavioral health problems, including cigarette and marijuana use, sexual risk behavior, delinquency and conduct disorder.

Youth identified as at-risk according to the NIAAA SG will receive a brief motivational interviewing (MI) intervention as recommended by the guide.[2]

Our specific aims are:

Aim 1: Use the NIAAA SG[1] to screen 2000 ethnically and racially diverse adolescents age 12-18 in four PC clinics and assess the prevalence of youth who screen positive for at-risk alcohol use in this setting. We will compare prevalence across the NIAAA screening guide, and other highly used screening measures, such as the Problem Severity Scale (PS) on the PESQ[5], the AUDIT[6] and the CRAFFT.[7]

Aim 2a: Compare the NIAAA SG and the PESQ-PS, AUDIT and CRAFFT against a gold standard of DSM diagnosis of abuse or dependence to determine each screener's utility, sensitivity and specificity as a predictor of alcohol risk, use, and problems in this population at baseline and at six months.

Aim2b: Compare the NIAAA SG to the PESQ-PS, AUDIT and CRAFFT to determine each screener's utility, sensitivity and specificity as an initial screen for other behavioral health problems, including marijuana use, cigarette smoking, sexual risk behavior, delinquency, and conduct disorder at baseline and at six months.

Aim 3a: Use the NIAAA SG to identify youth who are at moderate and high risk. Provide a brief MI intervention in the PC setting to adolescents who screen in at moderate or high risk based on the guide and examine whether alcohol use and problems decrease over a one year period for these youth compared to youth at moderate or high risk who receive enhanced usual care.

Aim 3b: Explore whether there is differential effectiveness of the intervention depending upon risk level.

Recruitment protocol

All adolescents who have appointments at the clinic and are between the age of 12 and 18 will be screened by clinic staff using the NIAAA screening guide. We expect to screen approximately 2000 youth. After completion of the screener and their PC appointment, clinic staff will ask youth to be part of a study to complete a web-based baseline and six month survey. Those who agree will complete additional surveys. Teens must have parental consent if they are under 18 and must also assent. Based on our previous experiences in survey studies with youth, we expect 90% of youth to agree to complete the surveys. If a teen would like to participate, but the parent is not present, we will follow-up with that teen to obtain parental consent and then schedule a time for him or her to return to the clinic. At the 6 month follow up we will survey all individuals who were screened as high risk (estimated 25%). We will follow-up with a randomly selected 40% of individuals screened as low risk (assuming that 75% were low risk); we will therefore follow up

810 individuals, which still provides us with ample power to test our hypotheses (see Power section) and keeps project costs down. Youth who screen in at moderate or high risk on the NIAAA SG will be told that they are eligible to participate in additional surveys at three months and 12 months, and that they have an opportunity to obtain additional information on AOD use if they are interested. They will then complete an additional section of the consent/assent form that details the additional surveys and randomization to CHAT (our brief motivational interviewing intervention) or enhanced usual care (EUC) (if under 18, they must also have parental consent). As noted above, all youth will complete a web-based baseline survey on site and a six month follow up web survey. Youth who are part of the randomized trial will also complete follow-up web-based surveys at 3 months and 12 months. Half of the youth will receive the CHAT MI session, which is delivered in 15-20 minutes and is reinforced with a 5-10 minute MI booster phone call one month later that follows up on information discussed during the session. EUC: Since usual care may differ slightly across the sites, similar to other work in this area, we will provide an EUC condition for the other youth. EUC will be designed to replicate current practice, which generally consists of teens getting screened for AOD use and 'yes' responses being queried further and followed by some brief discussion (personal communication from clinic directors). EUC participants will also be provided with a brochure from our staff, similar to the brochure for the MI intervention, and they will be asked to review it. Given the extra burden of the two additional surveys and staying to receive EUC or CHAT, we conservatively estimate that of those who are eligible for Aim 3, 70% will agree to participate and will have parental consent.

Statistics

Analyses for Aim 1 are primarily descriptive. We will calculate prevalence scores for each level of each of the four measures (NIAAA SG, PESQ-PS, AUDIT, CRAFFT), and calculate confidence intervals of those rates of prevalence. We will explore prevalence differences across location, gender, age and race/ethnicity using each measure in a logistic regression.

Overview of follow up for Aims 2 and 3

At the 6 month follow up, we will follow-up with all at-risk youth and 40% of individuals screened as low risk and expect 85% to complete the six-month follow up.

Aim 2a: Compare the NIAAA SG and the PESQ-PS, AUDIT and CRAFFT against a gold standard of DSM diagnosis of abuse or dependence to determine each screener's utility, sensitivity and specificity as a predictor of alcohol risk, use, and problems in this population at baseline and at six months.

Aim 2a involves comparing four screening tests (NIAAA SG, PESQ-PS, AUDIT, and CRAFFT) to the gold standard of the DSM diagnosis using the DISC. For each test we will calculate the sensitivity, specificity, positive predictive value and negative predictive value, along with their 95% confidence intervals for each potential cutoff for each of the tests. We will calculate age and gender specific sensitivity and specificity, and compare sensitivity and specificity across age and gender. Because of the confounding of race/ethnicity and location we will calculate sensitivity and specificity separately for each racial/ethnic group in each location.

Aim 2b: Compare the NIAAA SG to the PESQ-PS, AUDIT and CRAFFT to determine each screener's utility, sensitivity and specificity as an initial screen for other behavioral health problems, including marijuana use, cigarette smoking, sexual risk behavior, delinquency and conduct disorder at baseline and at six months.

For each test we will calculate the sensitivity, specificity, positive predictive value and negative predictive value, along with their 95% confidence intervals for each potential cutoff for each of the tests. We will determine an appropriate cutoff to maximize specificity (while maintaining sensitivity, as is desirable in a screening program). We will calculate odds ratios and their confidence interval, and interpret the c-statistic (the area under the ROC curve).

Aim 3a: Examine whether alcohol use and problems decrease over a one year period for the youth at moderate or high risk youth who receive CHAT compared to those who receive usual care.

We will examine differences in outcomes between the two groups at 3-, 6-, and 12-months follow-up. We will also examine rates of change over time using a growth modeling procedure.[8] This procedure will allow us to examine overall trajectories of differences in cognitions or behaviors, We will use appropriate modeling techniques for continuous outcome variables and categorical outcome variables. We will employ facilitator as a fixed factor (i.e. dummy coded), as facilitators are involved in both CHAT and EUC conditions. Controlling for facilitator also has the effect of controlling for location. We will use full information maximum likelihood (FIML) estimation to account for attrition.

Aim 3b: Explore whether there is differential effectiveness of the intervention depending upon risk level.

We will also examine heterogeneity of treatment effects, testing the assumption that there are no interactions between baseline measures of initial severity and the effectiveness of the intervention. We will use a slopes as outcomes model[9] within a structural equation modeling framework to determine whether there is a relationship between the rate of improvement of an individual and their initial severity - essentially this is an interaction between severity and intervention group.

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