Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard (Project GUARD)

Protocol

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Objectives

The proposed project, Project GUARD, is a fully-powered randomized controlled trial of a smartphone app which includes an alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking in the previous 4 months.

The specific aims are to compare SP-BI and EUC in:

1. Reducing the frequency and intensity of at-risk drinking at 4 -, 8- and 12-months;
2. Decreasing binge drinking at 4-, 8- and 12 months.

The secondary aims are to:

1. Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 4-, 8- and 12-months;
2. Examine if deployment status moderates the effect of intervention assignment (SP-BI or EUC) on post-intervention drinking, depressed feelings, and other substance use.

Design

After tailoring the content of the SP-BI intervention for NG soldiers, the proposed study will screen ~3,100 individuals over the three year enrollment period to identify 750 participants with at-risk drinking across the 2 sites. Participants in this study will be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed at 4, 8 and 12 months post-enrollment. The study is intended to address the primary and secondary aims and corresponding hypotheses listed below.

Methods

Participants who are randomized to the SP-BI condition will receive an informational brochure with resources available to members of the military related to mental health and alcohol use and will download a free app on to their smartphones. The app will be developed to be used on both Android and iPhone platforms and will be used over 12 weeks to deliver the study intervention. They will be contacted to complete 4-, 8-, and 12-month follow-up assessments.

Those assigned to the control condition will receive an informational brochure with resources available to members of the military related to mental health and alcohol use. They will be contacted to complete 4-, 8-, and 12-month follow-up assessments.

Randomization:

After the baseline assessment is completed, participants will be assigned to one of the two study conditions (SP-BI or EUC) using a computerized randomization system. Random assignment will be stratified based on gender and an AUDIT-= score > 19.

Intervention

Brief Intervention

Smart Phone (SP-BI) Content. Participants in the SP-BI condition will receive a 20-30 minute intervention session through an app program. The intervention will be based on the FRAMES

format: providing personalized Feedback (regarding substance use, risk factors), emphasis on Responsibility for change, Advice, Menu of options, Empathic clinical behaviors, and support of Self-efficacy regarding making changes. The intervention is designed to address the primary target behavior of alcohol use, and will include a tailored review of participants' goals/values, feedback regarding their present alcohol use patterns and consequences (either actual experiences or potential based on risk behaviors), developing a discrepancy between their alcohol use and ability to meet goals and values through a decisional balance exercise, and formulation of a "change plan" tailored for each participant.

Measures

Background Characteristics. The Substance Abuse Outcomes Module (SAOM) will be used to measure background characteristics including basic demographics (i.e., gender, age, race, ethnicity, marital status) and other background variables (e.g., education, employment, income, legal history). The SAOM has undergone extensive reliability and validity examinations (Smith et al., 2006).

Alcohol Use. As recommended by (Babor, 2007; Babor & Hall, 2007; Babor et al, 2007) and the IOM Report (Institute of Medicine, 2012) we will administer the full AUDIT which includes the AUDIT-C (Bush et al., 1998; Saunders et al., 1993) assessing alcohol consumption using 3-items: average quantity, average alcohol use frequency, and binge drinking (5 or more drinks/day for men; 4 or more drinks/day for women) over the past 4-months, and the 7 consequence questions. In addition to the standard item responses (which are categorical groupings such as 5-6 drinks), we will probe for exact numbers. Thus, for data analyses purposes, we will assess these alcohol consumption variables using counts and continuous response scales. Recent literature, including a review paper (Reinert & Allen, 2007) and population-based study (Dawson et al., 2005a, 2005b) support the internal consistency, test-retest reliability, and accuracy of the AUDIT-C in identifying at-risk alcohol use (hazardous use).

Revised Injury Behavior Checklist (RIBC). The original injury behavior checklist was developed for adolescent (Starfield, 1991) and revised for adults (Longabaugh et al., 2001). Participants indicate in the past year how often each of 18 injuries occurred, if they were treated by a doctor for the injury, and if alcohol was consumed within 2 hours of the injury. Prior research demonstrates the RIBC is related to outcomes following a brief intervention (Longabaugh et al., 2001). The RIBC has been modified to include two collapsed questions for intentional and unintentional injury.

Other Drug Use. The Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST 3.0) is an 6-item questionnaire developed as a brief screen for at-risk use of psychoactive substances (WHO Assist Working Group, 2002) including: tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulants, sedatives, hallucinogens, inhalants, opioids, and other drugs. We will use the item that measures how often each substance was used in the past 4 months.

Depressive Symptoms. The PHQ-9 (Kroenke et al., 2001) will further assess symptoms of depression; it has 94% specificity and 99% sensitivity for current major depressive disorder. The total score ranges from 0-27, with severity defined as: none (0-5), mild (6-10), moderate (11-15), major (16-20), severe (21+). Recent suicidal ideation will be assessed with one question: "Have

you thought that you would be better off dead or that you wanted to hurt yourself in some way?" from the PHQ-9, and the four additional questions, “Did you have a period of time where you thought about death a lot?”, “ Did you feel so low you thought a lot about committing suicide?”, “Did you make a plan as how you might do it?”, “Did you attempt suicide?” A positive response to any of these question will create a “flag” in the computer that will prompt staff (regardless of study condition) to implement a protocol for further assessment for harm to self.

Self-efficacy. A revised, version of the Modified Drinking Motives Questionnaire (DMQ-R) (Grant et al., 2007) will be used to assess self-efficacy across a variety of high-risk situations. Greater self-efficacy predicts positive outcomes following alcohol treatment (Annis & Graham, 1998; Breslin et al., 2000; LaBrie et al., 2005a, 2005b, 2005c) conceptually is a key component of MI,[100] and is related to less alcohol use among at-risk drinkers (Walton, 2007a, 2007b)
Psychological Distress. The Generalized Anxiety Disorder 7 (GAD-7) questionnaire is used for screening and severity measuring of generalized anxiety disorder and will be used as a measure of perceived anxiety (Lowe et al., 2008).

The Post-Traumatic Disorder Checklist-Military Version (PCL-5) will be used to measure DSM-V PTSD symptoms (Weathers et al., 2013). We will also include items from the Mini-International Neuropsychiatric Interview (MINI) to assess PTSD symptoms (Sheehan et al., 1998).

Unit Risk Inventory. Items from the Unit Risk Inventory (Army Center for Substance Abuse Program, 2011), developed by the Army Substance Abuse Program are included to assess financial situation, suicidality and drinking attitudes in the military.

Healthcare Service Use. We will use the Treatment Services Review to measure health services use. It has adequate reliability and validity (French, 2000; Kaminer et al., 1998; McLellan et al., 1992). We will focus on services for the following problem areas: prescription opioid and sedative use, alcohol use, and psychiatric treatment. The timeframe will be modified to measure past 4 months service utilization.

Readiness to Change. We will also have additional questions related to the importance and confidence to change as separate components of readiness to change. We will measure with the use of visual analog rulers; these rulers have been shown to correlate with longer surveys, and to predict outcomes in alcohol intervention studies (Daeppen et al., 2007; Hesse, 2006; LaBrie et al., 2005).

Social Support. Social support will be assessed using the Deployment Risk and Resilience Inventory (DRRI) (King et al., 2006). The DRRI survey instrument is used to assess the key deployment-related factors implicated in the health and well-being of military veterans. With the nature of military deployment changing, with a larger proportion of women, National Guard and Reserves being deployed for more contemporary conflicts, the DRRI was developed to provide a more comprehensive assessment of the current combat-related experiences.

Alcohol-related consequences. The Young Adult Alcohol Consequences Questionnaire (Barry et al., 2012; Kahler et al., 2005; Tripp et al., 2015) will be used to measure consequences of alcohol

use. This measure has been used in the National Guard population.

Barrett Impulsiveness scale. Measures impulsive behaviors including behaviors related to motor control, non-planning, attention, internal stimulation, & external motivation (Patten et al., 1995).

The Conflict Tactics Scales (CTS). The Conflict Tactic Scales (Straus, 1990) is the most widely used measure of domestic violence. We will use a collapsed version of the CTS to measure partner and non-partner violence.

Dimensions of Anger Reactions. The DAR measures anger disposition directed towards others primarily measures Trait Anger. The DAR is a psychometrically strong measure, potentially useful for the evaluation of anger in PTSD (Forbes et al., 2004; Novaco & Chemtob, 2002).

Post-app assessment. The post-intervention assessment will include questions regarding importance and usefulness of the app will occur following the 12 week SP-BI.

Statistical Analysis Plan (SAP)

To minimize the likelihood of chance associations (i.e., protect against Type I errors) which can occur when multiple, unplanned analyses are conducted with large data sets, analyses for testing the main study hypotheses will be planned a priori, and will be limited to the examination of specific outcomes. In addition, analyses that are central to the purpose of the study will be clearly identified as confirmatory hypotheses, and will be clearly identified as separate from exploratory analyses. This plan of analyses is intended to outline the primary data analytic approaches that will be used to test the hypotheses for the specific aims. We will utilize an "intent-to-treat" approach in all analyses to be conservative in our estimate of intervention effects.

It is our standard practice to begin with descriptive data analyses to determine distributions of key variables, calculate transformations or collapse categories, if necessary, and review data for outliers and anomalies. Tests for linearity, independence, missingness, and distributional assumptions (e.g., normality) will also be performed. Normalizing transformations of the dependent variables will be utilized when appropriate. We will validate the randomization scheme by comparing the initial groups on key variables that could be associated with the outcomes, such as age, race, initial alcohol use severity, comorbidity, self-efficacy and stage of change. Stratified randomization should equalize the intervention groups on the key variables of gender and diagnosis of alcohol use disorder. Where we identify significant differences between groups, we will either adjust for these variables in analysis.

In general, for longitudinal analysis we will use repeated measures regression mixed effects models for continuous and non-normally distributed variables. We will use procedures SAS PROC MIXED for continuous variables and PROC GLIMMIX for dichotomous and count data (either Poisson or negative binomial), both of which allow for subject-specific inference (e.g., allows for the estimation of subject-specific effects of interventions). The selection of the covariance matrix in the PROC MIXED procedure will be determined by the distribution of the data (e.g., normally) and covariance structure. The random parameter specified will be the subject effect and we will test for random slopes and intercepts. One of the advantages of these analytic approaches is that all available data are used in the analysis, rather than case-wise

deletion if a follow-up interview is missing (see below for more detail). All analyses of the intervention and EUC condition will adjust for the two randomization stratification variables, gender and diagnosis of alcohol use disorder.

Missing data. To minimize missing data, we will make every effort to gather follow-up information for all participants. Specific strategies to retain participants that have proven successful in our prior research are described above. The use of mixed effects regression to model individual trajectories will allow the use of data from all participants (including those with incomplete follow-up data) and provides unbiased parameter estimates that account for missing data under the missing-at-random assumption.148 If our examination of the pattern of missingness suggests that the missing-at-random assumption is untenable, we will handle missing data with a pattern mixture model.149 Where we have missing data on individual variables that are necessary for analysis, we will impute using SAS PROC MI to perform multiple imputation of missing data and PROC MIANALYZE to combine the results of PROC MI. We have found that sometimes 5 imputations are not enough to achieve optimum results and we increase number of imputations until we see each variable having 100 degrees of freedom or more.

Power Analyses. We propose to enroll a relatively large N at baseline (750, or 375/baseline group) in order to have sufficient power to: (1) detect potentially smaller differences in outcomes of SP-BI compared to EUC as SP-BI has potential for successful implementation even if effect sizes are smaller because of the relatively low cost to maintain this technology-based intervention, and (2) have sufficient power for tests of moderators of the interventions. Longitudinal mixed effects models for binomial, count, and continuous dependent variables will be used to test the aims. We estimate power for an anticipated reduced sample size at 12 months assuming a conservative 80% follow-up (achieved in our previous studies with this population), even though our proposed mixed models use all available follow-up data.