Study protocol and Statistical Analysis Plan for

A behavioral activation intervention administered in a 16-week freshman orientation course

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Study Protocol

The present study will be a cluster-randomized trial testing the efficacy of BA administered in a semester-long (16 week) freshmen orientation course, compared to a standard orientation course (SO) for addressing alcohol use and related clinical outcomes. Thirty-six 36 course sections (18 course sections for BA and 18 for SO) will be conducted in total, with N=540 participants. Mediation analyses will test mechanisms of action and moderation analyses will test the efficacy of the intervention based on key variables of interest.

Randomization

Randomization will occur at the course level. Randomization will employ blocking across morning and afternoon times and will occur within years.

Participant Recruitment and Enrollment

In collaboration with the University Director of Orientations, 36 sections of the existing, semester-long UNIV 101 freshman orientation curriculum will be modified and taught by research study staff. Each section will be randomly assigned to a condition, with 18 sections assigned to BA and 18 assigned to SO. Students will enroll into the offered UNIV 101 course sections *independent of* the research study by registering with the University's standard online course registration system. The 36 sections will be paired such that BA and SO classes will be offered at the same time of day and will be matched for treatment contact time.

Students enrolled into the BA and SO course sections will be offered the opportunity to participate in the research assessment portion of the study during the first week of class. Students aged 18+ will provide written informed consent, and students under age 18 will be required to sign an assent form and to obtain written parental permission to participate.

Assessment Schedule

Participants will be assessed at three times during treatment (weeks 1,7, and 15), all of which will occur during the first semester. At the end of the academic year (April of spring semester), students will complete a final 5-month follow up assessment to test durability of treatment effects. The study will also test longer-term (17-month) efficacy in a random subsample of 20% of participants in Years 2-4, which will occur at the end of participant's sophomore year. While an extended follow up assessment of all N=540 participants is beyond the scope of the project, the longer follow-up on a random subsample of participants will provide an initial indication of longer-term efficacy. The 17-month follow up will yield approximately n=100 participants (n=50 BA condition and n=50 standard orientation condition).

Assessments during the intervention (weeks 1, 7, and 15) will be conducted in the classrooms in which the courses will be run, to facilitate participation. At follow up(s), participants will be contact via text and email and scheduled to attend the follow up assessment(s) at a study lab, which is located centrally on campus. Participants will be provided an escalating incentive schedule to maximize attendance at follow up(s), as described below.

Incentives

Participants will receive extra credit in their UNIV 101 course for participating in Assessments 1-3, and will be compensated $50 for completing Assessment 4, which will occur after the courses have finished. To ensure participation in the research will not be coerced, students will be offered alternative extra credit assignments that will require approximately the same amount of time as participating in the study. The subsample of students participating in Assessment 5 (17-month follow up) will receive $75 for completing the final assessment.

Research Staff

Research assistants who will collect study data will not be affiliated with the courses and will be blinded to study condition. Likewise, clinical staff who lead the course sections will not be

involved in research assessment administration and will be blind to participant responses.

Course and Intervention Content

SO course. The standard orientation course, UNIV 101, is designed to facilitate student adjustment to academics and campus life. UNIV 101 courses meet twice weekly for 50 minutes each. The course content is structured around four main themes: 1) academic and personal wellness; 2) experiential learning; 3) social justice; and 4) skill building. Within these themes, lessons address a variety of subjects, from introductions to academic resources on campus (e.g., the university writing center, library, advising), tours of campus venues, presentations from speakers, and academic success topics such as time management. Students are required to develop an individualized academic plan during the course. Work to be completed outside of class is required and includes development of the academic plan, writing and reflection assignments, projects that facilitate goal setting, and academic projects such as an annotated bibliography assignment to facilitate academic information literacy.

BA course. The BA course will include all major instructional content of the standard orientation course (main themes and assignments), as well as the BA content. The BA content will replace the supplemental topics and sessions from the standard orientation course, thus retaining key SO content while incorporating BA content. The goal of BA for addressing alcohol use is to identify, develop and reinforce healthy behaviors that can serve as alternatives to alcohol use. In addition, BA supports students in identifying areas of importance and concern (e.g., stress after arriving on campus), and guides them to engage in reinforcing behavior that best addresses their concerns and aligns with their goals (e.g., engaging in self-care for stress management, in service of a goal to performing well in classes). The basic components of BA that will be used to achieve these outcomes are 1) facilitating students' engagement in self-

monitoring of daily activities; 2) guiding students to identify values within a variety of life areas; 3) identifying and engaging in reinforcing activities that align with their values; 4) providing support to engage in activities as identified. BA course sessions and content are summarized in Table 1.

Table 1. Behavioral Activation in UNIV 101: Course Content Overview

Week	BA Content	BA Work Outside of Class
Week 1	Introduction of treatment rationale: focus on engaging in reinforcing activities to promote a rewarding college lifestyle; Introduction to daily monitoring	Daily monitoring of activities, ratings of activity enjoyment
Week 2	Life areas and values: students will be guided in identifying their values within various life domains	Daily monitoring of activities, ratings of activity enjoyment and importance
Week 3	Identification of activities that align with values; Planning activities using the daily monitoring form	Daily monitoring, ratings of activity enjoyment and importance, planning activities using the daily monitoring form
Week 4	Engaging support to complete planned activities	Daily monitoring, ratings of activity enjoyment and importance, planning activities using the daily monitoring form
Weeks 5-14	Periodic BA review sessions	Daily monitoring, ratings of activity enjoyment and importance, planning activities using the daily monitoring form

Note. BA= behavioral activation

Materials for BA course. College students are technologically-savvy and mobile phone use in this population is extensive; 95% of college students own smartphones[15]. Thus, to facilitate use and engagement with BA materials (e.g., daily monitoring), all materials will be provided through a web-based platform that students will be able to access via any computer-based device (smartphones, computers, tablet devices). However, alternatives to the web-based platform will be offered to students who prefer to complete forms using paper.

Instructor training and supervision. The instructors will undergo extensive training before delivering treatment and will be supervised by the study's Clinical Supervisor. In addition,

weekly supervision will be provided. Manuals will be used at all times to ensure standardization of treatment. All course sessions will be audiotaped and participant confidentiality will be protected by storing all recorded data on a HIPAA-secured server.

Measures

Assessment will focus on three domains: (1) alcohol use and alcohol-related problems, (2) reinforcement processes (3) clinical health outcomes and moderators. Measures of treatment compliance and fidelity are also described below.

Alcohol Use and Problems

Alcohol use and problems in the past month will be assessed using two measures:

The *Alcohol Use Disorder Identification Test (AUDIT*)[16] is a 10-item questionnaire designed to assess hazardous drinking and related problems. The AUDIT provides a total score, with 8+ indicating hazardous use[17,18]. The AUDIT has also been examined as two subscales: alcohol consumption (items 1-3 focused on frequency and quantity) and alcohol problems (items 4-10 that assess consequences)[19–21]. The percent of participants above the clinical cutoff for the total score will be used in analyses, as well as both subscale scores. While the AUDIT was originally designed to assess a time interval of the past 12 months, researchers have assessed change in alcohol use and related problems in shorter time intervals of 1, 3, and 6 months[14,22]. The present study will use the past month as the reference point for the AUDIT.

The computerized Time Line Follow Back (TLFB-C) will be used to assess daily alcohol use in standard drinks during the past month[23–25]. The TLFB-C has good test-retest reliability and evidence of convergent validity with the TLFB administered in-person among college

student samples [26,27]. Heavy drinking occasions will be defined as 4+ drinks for females, or 5+ for males in one episode, in excess of the low risk drinking guidelines from the National Institute on Alcohol Use and Alcoholism[28]. High-intensity drinking occasions will be defined as double the heavy drinking occasion criteria, or 8+ for females and 10+ for males.

Reinforcement Processes

Environmental reinforcement. The Adolescent Reinforcement Survey Schedule - Alcohol Use Version (ARSS-AUV) assesses the frequency of past-month engagement in and enjoyment derived from 45 activities[29]. Each question is posed twice - once to assess the frequency and enjoyment of the activity while using alcohol and the once to assess the frequency and enjoyment of the activity while not using alcohol. Frequency and enjoyment items are summed to form respective scores and then multiplied to form subscales for alcohol-related reinforcement and alcohol-free reinforcement. The two subscales are used to calculate the outcome, the total reinforcement ratio (TRR) between alcohol-related and alcohol-free reinforcement.

Delay discounting. A computerized binary choice procedure will assess DD. On each DD trial, two hypothetical money rewards will be presented on the screen. One outcome will be an amount of money available immediately; the other outcome will be a larger amount of money ($25, $100) available after a specified delay (1 day, 1 week, 1 month, 6 months, 1 year, 5 years). Participants will indicate the preferred alternative with a click and the computerized algorithm will adjust the immediate reward over 6 trials to determine an indifference point for each amount/delay pairing. Indifference points will be used to calculate a delay discount rate. Subjects will be told to indicate preference on the task as if the outcomes were for real money; research has indicated the statistical equivalence of DD tasks for hypothetical and real rewards[30].

Clinical Outcomes and Moderators

Stress and depression. The Depression Anxiety Stress Scale-21 (DASS-21)[31] is a 21-item measure that has subscales for stress, depression, and anxiety. The DASS-21 measures stress, anxiety, and depression on a dimensional scale and is appropriate for use in a non-clinical, college sample. Studies reported strong internal consistency reliability in clinical and nonclinical samples[31,32], including college students[33].

Binge eating. The Eating Pathology Symptoms Inventory (EPSI)[34] will be used to assess binge eating. The EPSI conceptualizes eating behavior on a dimensional scale and is appropriate for use in samples with and without eating disorders. The binge eating subscale will be used in the study, which includes items on overeating and loss of control eating. The EPSI has evidence for excellent discriminant and convergent validity in female and male college students[34,35].

Coping-motivated drinking. The Drinking Motives Questionnaire-Revised (DMQ-R), a measure designed to measure motives for drinking alcohol, will be used to assess coping-motivated drinking[36,37]. In a variety of young adult and college samples, the DMQ-R has demonstrated high subscale internal consistencies and four factor structure stability[38–40]. The coping scale has been reliably associated with alcohol problems among young adult and college samples[38].

Treatment Compliance and Fidelity

Treatment compliance. Adherence to treatment will be measured by determining participants' completion of daily monitoring forms, and with course attendance (where students will receive the intervention content).

Treatment fidelity. Audio recordings of treatment will be rated by independent raters (e.g., raters not otherwise associated with the treatment delivery) to assess instructor adherence to and competence with the treatment protocol, using separate rating checklists and scales developed for the SO and BA protocols. Two senior research assistants will be trained in BA components to perform therapist adherence checks. They will review 20% of all audiotapes and perform competency checks, ratings-based adherence checks, and address any issues with instructors. Their feedback will be implemented in later sessions. Instructors will be required to complete a fidelity checklist for every class session they conduct.

Statistical Power

Power analysis. A target course section N of 36 (N=18 BA and N=18 SO), with N=432 participants total, will be required to detect medium effect sizes (*d*=.43) for main outcomes. Each class is expected to contain 18-20 students and power analyses were conducted assuming an 85% consent rate and a 20% attrition at follow up. An 85% consent rate will yield 15 participants per class, or N=540 total. With a 20% attrition rate, we will achieve the N=432 participants (12 per course section cluster) necessary to detect our outcomes of interest. For mediation analyses, will have sufficient power to detect a correlation between a drinking outcome and BA at a given time point >.20.

Data Analysis Plan

We will use SAS PROC Mixed with full information Maximum Likelihood estimation to evaluate outcomes using general linear mixed models for continuous outcomes and SAS PROC GLIMMIX for binary outcomes. Assignment to treatment condition will occur at the class section level (level 3). Student observations (level 1), will be nested in students (level 2), which will be nested within class sections. Fixed effects for intervention condition (BA or SO), instructor, and

cohort will be included at the class section level. Sex will also be added as a fixed effect at level 2. This approach will result in models with appropriate standard errors for the clustered sample.

For aim 1 we will compare differences between BA vs control in likelihood of exceeding the clinical cut-off for risky drinking as a binary outcome, and alcohol consumption (AUDIT consumption questions) and alcohol-related problems (AUDIT problem questions) as continuous outcomes. In addition, we will test differences across conditions in high-intensity drinking. Separate models will be developed for each outcome. Of primary interest are the main effects of treatment condition on both the intercepts and slopes for each of the outcomes. For aim 3 exploratory analyses on stress, depression, and binge eating, outcomes will be modeled separately for each outcome using general linear mixed models.

Analyses will be conducted to determine whether changes in environmental reinforcement and delay discounting mediate the association between intervention condition and alcohol outcomes. Moderation analyses will be conducted to determine whether intervention efficacy depends on coping-motivated drinking at baseline, sex, or race/ethnicity.

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