

## **Skills in Navigating College Life (SINC)**

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## PROTOCOL TEMPLATE: INTERVENTIONAL STUDY

**Complete Title:** Skills in Navigating College Life (SINC).

**Short Title:** Skills in Navigating College Life (SINC).

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**Sponsor:**

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**Amendment 3 Date:**

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Short Title: XXXXX

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Protocol Version: XX.XX

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I confirm that I have read this protocol and understand it.

Principal Investigator Name: \_\_\_\_\_

Principal Investigator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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## Abbreviations and Definitions of Terms

Abbreviation	Definition
ABD	Adolescent Binge Drinker
CG	Control group
CRP	C-reactive protein
KM	Koru Mindfulness
MINI	Mini-International Neuropsychiatric Interview
NG	Navigating College
PHI	Protected health information
Co-PI	Co-Principle Investigator
Reward-AB	Reward Attentional Bias
UNC-CH	University of North Carolina at Chapel Hill

## PROTOCOL SYNOPSIS

<b>Study Title</b>	Mindfulness training effects on behavioral flexibility in emerging adults with a history of adolescent binge drinking.
<b>Funder</b>	UNC-CH TraCS pilot grant and Psychology & Neuroscience Departmental King Excellence Award
<b>Clinical Phase</b>	N/A
<b>Study Rationale</b>	Adolescent alcohol exposure is associated with heightened automatic responses to stimuli that impede execution of goal-directed actions, and such behavioral inflexibility is a risk factor for alcohol and other substance use disorders. In this pilot study, we aim to determine the feasibility of delivering a 4-week online training of Koru mindfulness to freshman college students, in addition to a pre- and post-visit. Mindfulness meditation is known to reduce automatic responses to stimuli; however, it's unknown whether mindfulness training can increase behavioral flexibility in emerging adults with adolescent alcohol exposure. Young college adults experience demanding academic and social schedules that challenge maintenance of healthy behaviors while learning to adapt to emerging adulthood. Mindfulness training is one strategy to support healthy outcomes that persist despite inevitable stressors.
<b>Study Objective(s)</b>	<p>Primary</p> <ul style="list-style-type: none"> <li>To determine the feasibility of subject recruitment, participant retention, visit attendance, and study design among freshman college students.</li> </ul> <p>Secondary</p> <ul style="list-style-type: none"> <li>To assess participant satisfaction with study procedures.</li> </ul>
<b>Test Article(s)</b> (If Applicable)	Koru Mindfulness Training
<b>Study Design</b>	This is a parallel assignment randomized controlled trial feasibility study. The two-armed study has the mindfulness meditation intervention and the control groups running parallel to one another. Participants are blinded to condition.
<b>Subject Population</b> <b>key criteria for Inclusion and Exclusion:</b>	<p>Inclusion Criteria</p> <ul style="list-style-type: none"> <li>College enrolled first-year students aged 18-19 years old</li> <li>Internet access to enable online training</li> <li>Fluent English speaker (<math>\leq</math> age 7)</li> <li><math>\geq 4</math> lifetime binge drinking episodes</li> <li>Meditation-naïve</li> </ul> <p>Exclusion Criteria</p> <ul style="list-style-type: none"> <li>Subjects with known neurological, psychiatric, or systemic disease</li> <li>Subjects with any type of motor or visual disturbance that may interfere with performing the cognitive task</li> <li>Subjects using psychoactive drugs (aside from moderate caffeine or alcohol) or medications</li> <li>Subjects with a known history of any substance use disorder (not including alcohol or nicotine) or desire to seek treatment for excess substance use</li> </ul>
<b>Number Of Subjects</b>	18

<b>Study Duration</b>	<ul style="list-style-type: none"> <li>• Each subject will undergo 4 weeks of intervention or control group training, a pre- and post-training visit, and a 1-month follow-up.</li> <li>• The entire study is expected to last 3 months.</li> </ul>
<b>Study Phases</b> <b>Screening</b> <b>Study Treatment</b> <b>Follow-Up</b>	<ul style="list-style-type: none"> <li>(1) Subjects screened for eligibility and obtaining consent;</li> <li>(2) Cognitive task performance, blood sample collection, surveys;</li> <li>(3) Four weeks of virtual training in Koru mindfulness or an age- and time-matched comparison group;</li> <li>(4) One-month follow up online surveys</li> </ul>
<b>Efficacy Evaluations</b>	<ul style="list-style-type: none"> <li>• Mean number of visits attended by participants and total number of journal entries.</li> </ul>
<b>Pharmacokinetic Evaluations</b>	N/A
<b>Safety Evaluations</b>	Self-report measures of anxiety, depression, and stress will be evaluated at the beginning of each visit to determine any changes that could be in result of the intervention.
<b>Statistical And Analytic Plan</b>	<ul style="list-style-type: none"> <li>• To assess the primary objective (feasibility) of the study, the primary outcome will be the count of participants in each of the 6 visits, and the number of surveys that are completed at the 1-month follow-up contact.</li> <li>• To assess the secondary objective (participant compliance), the secondary outcome will be measured by total journal entries submitted during the 4 weeks of intervention training.</li> </ul>
<b>DATA AND SAFETY MONITORING PLAN</b>	The Co-Investigators will review participants' experiences with study procedures on a weekly basis. Meditation practice may elicit discomfort if traumatic memories resurface or the participant is experiencing high stress. The Koru teacher is trained in trauma-sensitive mindfulness and has implemented this awareness in the design of the visits. Nonetheless, the teacher will regularly check in with students to address any concerns.

## BACKGROUND AND RATIONALE

### 1.1 Introduction

Lifetime risk for developing an alcohol use disorder increases with earlier onset of alcohol consumption [1-3]. This risk may reflect a tendency for escalated alcohol intake among youth due to immature executive control, leading to more frequent binge drinking, which is associated with more alcohol-related problems [4, 5]. Binge drinking is associated with deficits in behavioral flexibility [6, 7], which may suggest impaired control networks that contribute to automatic behavior [8]. Individuals with an alcohol or substance use disorder (A/SUD) exhibit attentional bias toward drug- or alcohol-related stimuli that have attained salience through consistent use [9-13]. Reward history increases attention towards non-drug stimuli, even among individuals with no lifetime A/SUD [14, 15]. Our preliminary data, from a nationally representative US adult sample using data collected via Prolific, found that a questionnaire measure of mindfulness moderates the relationship between alcohol misuse and attention to reward. Given evidence that heavy alcohol drinking impairs behavioral flexibility [6, 16], which in turn promotes escalating intake [17], insight into the relationship between mindfulness and behavioral flexibility could inspire new strategies to prevent alcohol and substance use disorders in people at elevated risk.

### 1.2 Name and Description of Investigational Product or Intervention

#### Koru Mindfulness (KM) Intervention Training

The Koru Basic curriculum [18] will consist of four weekly interactive 75-minute classes delivered online through Zoom. Each class will consist of an overview of 2-3 skills, group practice of the skills, and group reflection. Class size will be limited to 9 participants. Participants will have their video off and will have their own unique identifier (instead of identification by name). Participants will be instructed to practice a skill for 10 minutes/day and log their reflection on that practice using the Koru phone application.

#### Navigating College (NC) Control Group Training

The control group will consist of four weekly 75-minute classes delivered online through Zoom. Each class will consist of lecture and group discussions on topics related to navigating college [19]. Participants will be instructed to journal about learned information and skills for 10 minutes/day.

### 1.3 Non-Clinical and Clinical Study Findings

Potential benefits of this study include learning skills that may help the participant navigate their college experience with more ease. Additionally, participants in the KM intervention may experience decreased stress, anxiety, and sleep problems [18].

Answering the surveys may make the subjects uncomfortable and could cause emotional distress or embarrassment. Completing questionnaires and participating in computerized tasks may make subjects anxious or uncomfortable. Participants will be asked questions regarding use of illegal alcohol consumption ( $\leq$  age 21), use of illegal substances, and involvement in activities such as driving while under the influence of drugs and/or alcohol. To minimize this risk, participants may choose not to answer any question and they may terminate participation at any time during all tasks. Participant's data will only be identified using an ID assigned to them at the beginning of the study. Any paperwork that includes participants' names or other personal information will be kept separate from study documents with their ID number and will be stored in a locked file cabinet in the locked lab. All data will be archived without personal identifiers, using only ID numbers.

In 10 years of testing participants at UNC, including a study that recruited alcoholics (unlike this study), we have experienced a single instance of an acutely intoxicated participant arriving for a study, and no instances of participants in acute withdrawal. Therefore this scenario is highly unlikely. However, in the event that a participant arrives for a session intoxicated, we will help them arrange a ride home. If intoxication or withdrawal symptoms are severe, study personnel will escort participants to the UNC emergency room.

There are no risks for injury expected to occur with virtual discussion and training of mindfulness, meditation or college skills. Potential risks include boredom, fatigue, or discomfort with spending additional time on the computer, aside from schoolwork. Additional discomfort may arise during mindfulness practice for subjects who have previously experienced trauma or are currently experiencing high stress. Participants will be observed for any obvious discomfort and followed up with by the mindfulness teacher with trauma resources if necessary.

Rare: A participant's personal information could be linked with their study data. To minimize this risk, no one outside of the research team will have access to participants' data. Participants' data will only be identified in all computer analyses with their ID numbers. Any paperwork that includes participants' names or other personal information will be stored in a locked file cabinet in the locked lab. All data will be archived without personal identifiers, using only ID numbers.

Potential minor risks and discomforts are associated with cognitive testing. Although it is hoped that subjects will complete the study, subjects may stop participation at any time during the cognitive testing.

## **1.4 Relevant Literature and Data**

Our preliminary data, from a nationally representative US adult sample, found that a questionnaire measure of mindfulness moderates the relationship between alcohol misuse and self-report attention to reward (Figure 2). It is unknown whether increasing mindfulness will show similar effects using a task measure of attentional bias.

The Reward-Attentional Bias (Reward-AB) task will be used to measure attentional bias pre- and post-intervention. The task includes a training and testing portion, each of which are adapted from tasks described elsewhere that measure the influence of reward on visual attention [15, 20, 21].

Although not a primary objective, trait mindfulness will be measured using the Five Facet Mindfulness Questionnaire (FFMQ) and Mindful Attention Awareness Scale (MAAS). The FFMQ contains 5 subscales, with Cronbach  $\alpha$ s for the subscales range from 0.73 to 0.91 [22]. This measure has also been shown to reliably compare mindfulness pre- and post-training. The MAAS has been shown to have good 4-week test-retest reliability [23] and this measure correlates with other common measures of mindfulness, such as the Freiburg Mindfulness Inventory [24].

## **STUDY OBJECTIVES**

The purpose of this pilot study is to explore the feasibility of the study design and compliance of freshman college students with task procedures.

### **2.1 Primary Objective**

The primary objective will be to assess the feasibility of the study design and determine factors crucial to the success of a larger scale study, including those that influence recruitment and retention, consistency of practicing skills learned during training, and adherence to all study procedures.

### **2.2 Secondary Objective**

Secondary objectives include participant satisfaction with study procedures, the expectancy of learning skills in their assigned training group, and satisfaction with skills learned during training.

## **INVESTIGATIONAL PLAN**

### **3.1 Study Design**



This proposed study is a parallel assignment randomized controlled trial. Interested individuals will be initially screened for psychiatric and neurological health, medications, use of psychoactive substances, the presence of study specific contra-indications, and prior experience with meditation. Participants who meet inclusion criteria according to the initial phone-based screening will then be invited to the lab for further screening and possible participation. Upon arrival and consent, subjects will be given a urine test to screen for psychoactive drugs and a breathalyzer test to detect alcohol currently in system. Positive results will exclude participants from further participation.

Interested participants are instructed to first complete an online screening survey (through REDCap). Potential participants are then contacted for a more in-depth phone screen. When the participant comes in for the first visit, they will be screened for any current alcohol intoxication or recent substance use, followed by a mental health assessment with the Mini-International Neuropsychiatric Interview (MINI) [25]. The participant will then have blood collected by finger prick, complete the Reward-AB task, and fill out some paper surveys. During visits 2 through 5, participants will complete virtual training on either mindfulness and meditation skills, or navigating college skills. Each visit will last approximately 90 minutes, starting with the completion of a few online surveys. Visit 6 is similar to visit 1, without the health interview. Participants will be contacted one month following the date of the 6<sup>th</sup> study visit to complete online surveys.

### **3.2 Allocation to Treatment Groups and Blinding (if applicable)**

At the end of visit 1, participants will be randomly assigned to either the training group where they will learn mindfulness and meditation skills, or the control group to learn skills in navigating college. An online random number generator will be used to determine which subject IDs will be allocated to each training group (18 people total, 9 in each group).

### **3.3 Study Duration, Enrollment and Number of Subjects**

The entire duration of the study is expected to take no more than 3 months. About 5-6 weeks will elapse from the first visit to the 6<sup>th</sup> visit, and the inclusion of a one-month follow-up survey adds another 4 weeks, totaling a little over 2 months. Eighteen subjects are expected to be enrolled in the study, with 9 participants randomized to each of two training groups (Koru Mindfulness as the intervention training, Navigating College serving as the age- and time-matched comparison group).

### **3.4 Study Population**

#### Inclusion Criteria

- High school educated; college enrolled first-year student
- Medically healthy
- Ages 18-19
- Native-English speaker (or fluent  $\leq 7$  years old)
- Self-report of  $\geq 4$  lifetime binge drinking episodes ( $>4$  drinks/2hours for females,  $>5$  drinks/2 hours for males).

#### Exclusion Criteria

- Psychiatric disease (such as depression or psychosis) using the MINI [25]
- Systemic disease such as cancer, cardiovascular or inflammatory disease which could influence cognitive functioning
- Motor or visual disturbance (e.g., colorblind)

- Current use of psychoactive drugs (aside from moderate caffeine or alcohol), including prescription medications, or individuals with a known history of any substance use disorders (not including alcohol; including nicotine) or desire to seek treatment for excess substance (not including alcohol) use.

## STUDY PROCEDURES

### 4.1 Screening/Baseline Visit procedures

Individuals who show initial interest in the study are contacted via phone or e-mail with a questionnaire containing items related to psychiatric and neurological health, medications, use of psychoactive substances, the presence of study-specific contra-indications, and prior experience with meditation. Evidence of neurological or psychiatric disorders, current use of psychoactive medications or other drugs (excluding alcohol or moderate caffeine), or prior experience with meditation will result in non-inclusion in the study. For the purpose of this study, meditation includes loving kindness, guided imagery or visualization, qi gong, and yoga. Those participants who meet inclusion criteria according to initial phone screening will be invited to the lab for further screening and possible participation. Upon arrival to the initial visit, after reading and signing the informed consent form, subjects are given a urine test to screen for psychoactive drugs (amphetamine/methamphetamine/MDMA (“ecstasy”), cocaine, opiates, THC, and PCP) and a breathalyzer test to detect alcohol currently in system (approx. 5 minutes). Results of these screening tests are not written down, but positive results will exclude participants from further participation.

### 4.2 Intervention procedures (by visits)

See Figure 1 for overview of study visits.

#### Visit 1

- Written consent, MINI interview [25], urine drug screen and breathalyzer alcohol test, C-reactive protein (CRP) assay, Reward-AB task

#### Visits 2-5

- Randomization to either the Koru Mindfulness (KM) intervention or the Navigating College (NC) control group.
- Each training visit will consist of the following:
  - Surveys completed online through REDCap.
  - 75 minutes of instructor-led discussion
  - Breakout sessions for participants to share their thoughts and experiences in response to instructor’s prompt.

#### *Navigating College (NC) Control Group Training*

Topics discussed during each training visit include: habits, roommate issues, homesickness, the internet (week 1); strategies when sinking, study skills, getting involved, habit formation (week 2); HALT, gateway habit (week 3); and academic success tips, taking notes, and procrastination (week 4).

#### *Koru Mindfulness (KM) Intervention Training*

Topics discussed during each training visit include: belly breathing, dynamic breathing, body scan (week 1); walking meditation, gatha (week 2); guided imagery, labeling thoughts (week 3); eating meditation, and labeling feelings (week 4).

#### *Daily Logging of Skills*

Participants in the CG intervention will be asked to journal by hand or via Qualtrics every day for  $\geq 10$  minutes, on anything related to the topics learned during that week’s training visit. Participants in the KM intervention will

be asked to practice every day for  $\geq 10$  minutes any mindfulness or meditation skill previously learned during training visits, in addition to logging their practice and reflection using the Koru application.

#### Visit 6

- Similar to visit 1, without repeating the MINI interview.

### **4.3 Follow-up procedures (by visits)**

One month after the conclusion of visit 6, participants will be recontacted via email with a link to REDCap to complete several surveys.

### **4.4 Subject Completion/ Withdrawal procedures**

Participants will be screened for drug and alcohol use upon arrival to visits 1 and 6. If the test results from a urine sample and breathalyzer are positive, subjects will be withdrawn from the study. If participants in the KM group are experiencing extreme discomfort during weeks when visits 2-6 take place, due to resurfacing of traumatic experiences, subjects will be withdrawn from the study and given resources (see attachments) to alleviate distress. Investigators may also terminate an individual's participation if the subject is uncooperative or otherwise behaves in a way that makes study personnel feel uncomfortable or unsafe.

### **4.5 Screen failure procedures**

All study personnel will review study materials required for screening and will be trained in phone screening, including conducting interviews with the MINI. Personnel will also be trained in blood collection by finger prick so that any safety concerns can be addressed. Voicemails and emails left by interested participants will be checked daily.

## **STUDY EVALUATIONS AND MEASUREMENTS**

Surveys, a CRP assay, and the Reward-AB task will be administered pre- and post-training of skills learned in the intervention or control group. Surveys will be administered at the beginning of each training visit.

### **5.1 Surveys**

To identify factors that may contribute to individual or group differences, participants will complete several questionnaires via REDCap [26] or in person. These include the Credibility/Expectancy Questionnaire (CEQ; [27]) to measure expectancy/credibility of the intervention and control groups, self-report measures of substance use and consequences: the Alcohol Use Disorder Identification Test (AUDIT; [28]), an Alcohol-Related Blackouts Questionnaire (ARBQ; see appendix); the Carolina Alcohol Use Patterns Questionnaire [CAUPQ], which is a modified version of the Alcohol Use Questionnaire [29], the Daily Drinking Questionnaire (DDQ; [30]), the Rutgers Alcohol Problem Index (RAPI; [31]), the Brief Young Adult Alcohol Consequences Questionnaire (B-YAACQ; [32]), and the Drinking Motives Questionnaire-Revised (DMQ-R; [33]); measures of familial alcohol misuse [34], adult resilience (ARM-R; [35]), depression, anxiety and stress (DASS-21; [36]); and personality measures with the Barratt Impulsiveness Scale (BIS-11; [37]). We will also collect two questionnaire measures of behavioral flexibility: Value-Driven Attention Questionnaire (VDAQ; [38]) and the Creature of Habit Scale (COHS; [39]). Finally, we will administer two indices of mindfulness: the Five Facet Mindfulness Questionnaire (FFMQ; [22]) and the Mindful Attention Awareness Scale (MAAS; [23]).

### **5.2 C-Reactive Protein (CRP) Assay**

Using aseptic technique, we will use a contact-activated lancet to collect a small blood sample from the finger to generate a dried blood spot (Approximately 1 cm diameter on Cytiva Watman 903 cards) for use in CRP quantification assays. Blood will be collected on the indicated cards designed for this purpose, marked with the participant's ID code which will then be airdried, sealed in a freezer bag with silica gel packs, and placed in a designated area within a freezer. Commercially available Simple Plex microfluidic cartridge immunoassays (Bio-

Techne, <https://www.proteinsimple.com/ella.html>) will be used. In all cases, every sample is run in triplicate, and the cartridge will include positive and negative controls.

### 5.3 Reward-Driven Attention Bias (Reward-AB) Task

The Reward-AB task is a modified version of tasks measuring the influence of reward on visual attention [15, 20, 21]. Participants will complete the reward-conditioning phase (training) followed by the testing phase of the task. In brief, participants are instructed to indicate the orientation (vertical/horizontal) of a line inside a target circle (blue/yellow) among an array of circles. One color is associated with probabilistic (80%) monetary reward for correct responses; the other target color does not yield a monetary reward for a correct response. The training phase consists of two 60 trial runs. The testing phase of the Reward-AB task measures attentional control in the presence of a reward-conditioned distractor [21]. In this component, two colored circles appear on either side of a fixation cross. Inside each circle is a letter, either a target letter ('S' or 'P'), or a neutral letter ('E' or 'H'). Participants are instructed to pick the target letter, with correct answers not associated with any monetary reward. There are 3 runs of the testing phase, with each run consisting of 120 trials. The total duration of the task is ~30 minutes.

### 5.4 Safety Evaluations

The DASS-21 will be used to measure depression, anxiety and stress and will be administered at the beginning of each visit. Scores will be used to evaluate any within-subject changes that may prompt further review. The KM instructor will read logs daily and determine if any participant should be followed up with.

## STATISTICAL CONSIDERATIONS

### 6.1 Primary Endpoint

1. Feasibility assessment [Time Frame: every week]
  - a. The feasibility of the study design will be measured using the total number of eligible participants, and retention rate for each visit, in addition to the one-month follow-up survey of enrolled participants. Compliance with individual training will be determined by the mean number of journal entries submitted per week in each group, due to previous evidence demonstrating an association between amount of homework completed and positive outcomes [40].

### 6.2 Secondary Endpoint

1. Participant satisfaction [Time Frame: 4 weeks]
  - a. Feedback will be collected the same day as each training visit, using a simple survey designed on Qualtrics.
2. Depression, Anxiety, and Stress Scale (DASS-21) [Time Frame: 8 weeks]
  - a. The DASS-21 consists of three self-report scales used to measure depression, anxiety and stress. This is a shortened form of the original DASS [36], which contains 42-items but shows no improvement over the 3-factor model for the 21-item scale [41]. The DASS-21 has been validated in non-clinical samples, and may even be used to measure an overall level of psychological distress [42]. In a non-clinical sample of Greek adults 18 years of age and older, the DASS-21 showed satisfactory reliability, with Cronbach alphas of 0.85, 0.84, and 0.84 for the depression, anxiety and stress scales, respectively [43]. There was also high convergent and discriminant validity of the three scales in this same sample.
3. Credibility/Expectancy Questionnaire (CEQ) [Time Frame: 1 week]
  - a. Questions on the CEQ are used to measure the credibility of an intervention and treatment expectancy in clinical studies [27]. However, due to methodological limitations of comparison groups for mindfulness meditation (e.g., waitlist control group doesn't match intervention in any

way), evaluating the credibility of the control group intervention and the expectation of benefit to participants in both groups will facilitate the design of better comparison groups than those that currently exist.

### **6.3 Statistical Methods**

The total number of eligible participants will be used as a measure of successful recruitment strategies and feasibility of enrollment criteria. The mean number of self-report training or journaling days recorded by participants and the total number of visits attended by each participant will be used as measures of compliance with study procedures. The number of times discomfort is reported by participants with any training procedure will be used as a measure of safety. A within-subjects ANOVA will be used to analyze the change in DASS-21 scores across the training visit weeks, including the total score and scores for all 3 subscales. A 1-Sided t-Test will be used to analyze the mean difference in CEQ score between the intervention and control group.

### **6.4 Sample Size and Power**

A power analysis is not applicable for this pilot study due to the small number of subjects intended to be recruited solely for the purpose of determining the feasibility of conducting described study procedures.

### **6.5 Interim Analysis**

The study will be stopped for any individual participant if the reported level of discomfort described by the participant in their journal entries or meditation logs is considered to be more than minimal by a trained clinical psychologist (Co-PI), if their DASS-21 scores increase significantly from one visit to the next, or if they report that the study procedures themselves have contributed to any discomfort/distress.

## **STUDY INTERVENTION**

### **7.1 Koru Mindfulness (KM) Intervention Group**

Koru Mindfulness is a 4-week mindfulness meditation training initially designed for the emerging adult population (considered  $\leq 29$  years). The skills are intended to help young adults manage stress, and thus can be advertised as an opportunity to learn skills in navigating college without having to mention mindfulness training anywhere in recruitment materials. The intervention will be delivered online through Zoom by a certified Koru instructor, with the goal of assessing the feasibility of an accessible intervention for college students. Koru is delivered with a mix of PowerPoint slides, group training of mindfulness and meditation skills and discussion, and daily logging of practice with an application or journal. The training is accompanied by the book *The Mindful Twenty-Something* [44].

Participants will be encouraged to practice daily any of the mindfulness and meditation skills that were previously learned. To incentivize compliance with training, monetary incentives will be given to individuals who practice  $\geq 3$  days/week and those who practice  $\geq 5$  days/week.

### **7.1 Navigating College (NC) Control Group**

The NC training is designed to match the KM training in at least the total duration of the training, the duration of each individual visit, the practice of daily training of a skill, class structure, and instructor. The skills taught are directly related to the topics discussed in the *Freshman Survival Guide: Soulful Advice for Studying, Socializing, and Everything In Between* [19].

Participants will be encouraged to write in their paper journal or online (via Qualtrics) for about 10 minutes every day. Prompts with suggested topics for reflection will be provided.

## **STUDY INTERVENTION ADMINISTRATION**

### **8.1 Administration for Training Groups**

After Visit 1, participants will be randomized to either the intervention or control group using a randomized number computer generator (e.g., 01-18 assigned to mindfulness meditation group). The NC and KM training instructor will be blinded to the group each participant is randomly assigned to, and participants will be assigned a unique ID to put as their name for their Zoom profile and on questionnaires. This number will be given (and recorded) by a research assistant. During training visits, all videos (except the instructor's) will be turned off.

## **SAFETY MANAGEMENT**

We do not anticipate participant safety to be an issue in this study. Proposed procedures do pose a risk of harm if safety protocols are not followed carefully. To ensure participant safety, all participants will be thoroughly screened by trained personnel for the presence of conditions that could pose a threat to the subject. All research personnel will be trained in blood collection by finger prick. Daily practice logs will give participants a safe space to share any discomfort experienced during training. If participants in the KM group are experiencing extreme discomfort during weeks when visits 2-6 take place, due to resurfacing of traumatic experiences, subjects will be withdrawn from the study and given resources to alleviate distress. Logs will be checked daily. Any adverse event related to the training or blood collection will be immediately reported to the Principal and Co-Investigators.

## **DATA COLLECTION AND MANAGEMENT**

We will obtain a certificate of confidentiality for this study. A participant's personal information could be linked with their study data. To minimize this risk, no one outside of the research team will have access to participants' data. Participants' data will only be identified in all computer analyses with their ID numbers. Any paperwork that includes participants' names or other personal information will be stored in a locked file cabinet in the locked lab. All data will be archived without personal identifiers, using only ID numbers. Emails to participants will be encrypted.

## **RECRUITMENT STRATEGY**

Participants will be recruited through IRB-approved flyers distributed within the University of North Carolina at Chapel Hill community, and through first-year Psychology courses that give class credit in exchange for participation in research studies. No Protected Health Information (PHI) will be accessed prior to contacting participants. Potential subjects who respond to these advertisements will be contacted initially via telephone or encrypted email. If contacted via email, subjects will be scheduled for an initial telephone screening to determine eligibility status. Those meeting inclusion criteria based on the phone interview will be scheduled for all study visits.

## **CONSENT PROCESS**

Individuals who show initial interest in the study are contacted via phone or e-mail by study personnel and once consent is verbalized, the individual is asked about psychiatric and neurological health, medications, use of psychoactive substances, the presence of study-specific contra-indications, and prior experience with meditation. Participants will be emailed the consent form to review before the first study visit. Upon arrival to the first study visit, the research assistant will review the consent form with participants, ask whether the risks



and benefits of the study are understood, and answer any questions. Participants will then read and sign the informed consent form.

## PLANS FOR PUBLICATION

The data collected from this pilot study may be included in papers based on full scale follow-up studies.

## REFERENCES

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## APPENDIX

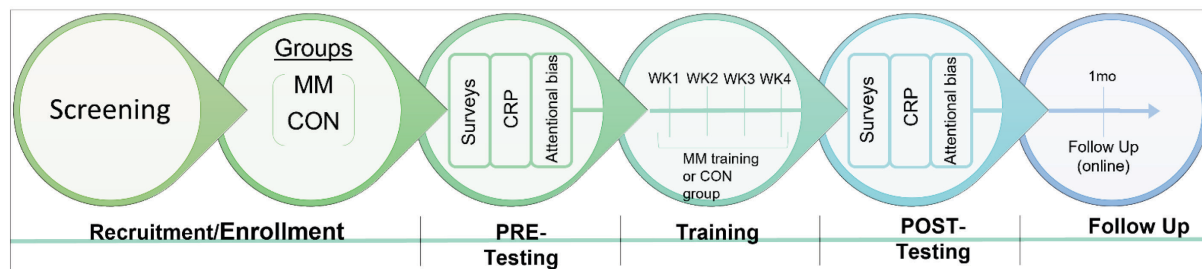
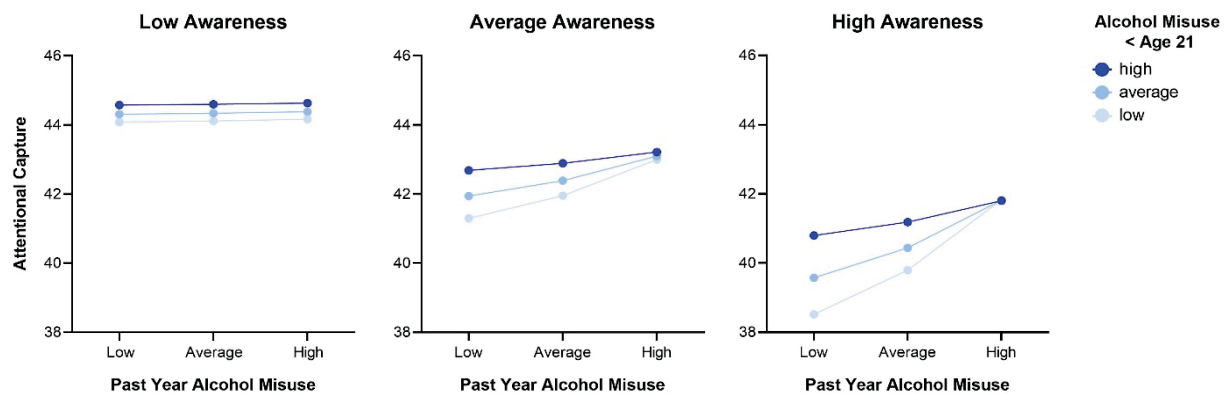


Figure 1. Study design.



**Figure 2. The relationship between alcohol misuse, attentional capture, and acting with awareness.** Among individuals with low or average levels of alcohol misuse in the past year, greater levels of acting with awareness (one facet of the FFMQ) is associated with reduced attentional capture among individuals who misused alcohol before age 21. FFMQ, Five Facet Mindfulness Questionnaire.

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**Blackouts are periods of amnesia during which a person actively engages in behaviors like walking and talking but does not create memories for these events. There are two types of blackouts:**

**TOTAL blackout:** Full and complete memory loss often spanning hours or more.

☐ Yes

☐ No

**IF YES,**

[illegible]

☐ Yes

☐ No

**IF YES,**

[illegible]

How many times BEFORE THE AGE OF 18?      ☐      ☐      ☐      ☐      ☐      ☐      ☐      ☐      ☐

WHILE YOU WERE DRINKING or BECAUSE OF YOUR DRINKING did you EVER suddenly find yourself in a place (physical location) you could not remember getting to?      ☐ Yes  
☐ No

**WHILE YOU WERE DRINKING or BECAUSE OF YOUR DRINKING did you EVER suddenly find yourself in a place (physical location) you could not remember getting to?**

**IF YES,**

	0	1	2	3	4-6	7-11	12-20	21-39	40+
How many times in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times in the PAST YEAR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times between the ages of 18-21?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times BEFORE THE AGE OF 18?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have you EVER awakened the morning after drinking and found that you could not remember something you did or said while drinking?      ☐ Yes  
☐ No

**Have you EVER awakened the morning after drinking and found that you could not remember something you did or said while drinking?**

**IF YES,**

	0	1	2	3	4-6	7-11	12-20	21-39	40+
How many times in your LIFE?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times in the PAST YEAR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times between the ages of 18-21?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many times BEFORE THE AGE OF 18?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For times when you could not remember things you did or said while drinking, were you EVER able to later recall them when reminded by others or cued by the setting?      ☐ Yes  
☐ No

**For times when you could not remember things you did or said while drinking, were you EVER**

