C.A.R.E.S. A Mobile Health Program for Alcohol Risk Reduction

1R42 AA026788-01A1

NCT03927482
12/17/2020

1. SPECIFIC AIMS

Excessive alcohol use is the third-leading preventable cause of death in the U.S.[1] Younger adults aged 18-29 show the highest rates of hazardous alcohol use.[2-5] Community colleges serve over 12 million students,[6] comprising 45% of all U.S. college students.[6-8] Community college students (CCS) show rates of heavy alcohol use similar to students at traditional four-year residential (FYR) colleges,[3,9-12] but CCS are at higher risk for negative consequences of heavy drinking, including physical and sexual assault, fatal injuries, and driving under the influence.[9] Despite the large number of CCS and their level of risk, *alcohol interventions for young adults have focused almost exclusively on students at FYR colleges*. CCS differ from those at FYR colleges in several ways; CCS are more likely to have multiple roles and responsibilities (e.g., employment), drive more (to/from campus), live with family, and socialize off campus, and thus require intervention approaches tailored to their life circumstances. Community colleges are less likely to offer health services than FYR institutions[13,14] and typically lack resources needed to implement alcohol interventions that are recommended for traditional college students, such as in-person motivational counseling.[15] Approaches are needed that can reach CCS and provide harm-reducing interventions that fit with the needs and resources of community colleges.

Live Inspired$_{LLC}$ in collaboration with our colleagues at The Miriam Hospital/Brown University and local community colleges, conducted an initial evaluation of a text message (TxM)-delivered alcohol intervention,[16-18] developed for, and in collaboration with, CCS. We obtained strong initial results from our pilot trial (section 4.2) following the 6-week intervention.

In Phase I of this FastTrack STTR we will develop and iteratively test an application (app) that will incorporate the TxM messages as an app-resident personal coach ("*CARES coach*"), with additional features and functionality requested by students in our pilot trial. After obtaining user feedback (2 rounds) we will complete programming in both iOS and Android languages (4.2.e for benchmarks). **To ensure that the College Alcohol Risk Education System (CARES) is well positioned to get into the community college marketplace, it is critical to demonstrate efficacy**.

In Phase II, we will conduct an efficacy trial of CARES compared to an alcohol education program that would be feasible for most community colleges to adopt, thus providing a real-world comparison with data suitable to support our efforts in future commercialization. We also seek to identify the types of individuals for whom CARES is more or less effective (Aim 2.2), and identify areas where it might be improved (Aims 2.3).

Phase I Aims for the 12 month period are:

Aim 1.1. Develop wireframes, design and adapt the program to an Android platform app with added features (section 4.4.c). The app's personal coach ("*CARES coach*") will deliver messages designed to encourage responsible alcohol use, provide motivational messages tailored to the participant, and push notifications at times when risky alcohol consumption is most likely to occur. Other app features will include drink logging and tracking, providing transportation locators, calculating cost-savings from reduced use, encourage peer support, and monitor progress based on a participant's goals (3 months).

Aim 1.2. Conduct two one-month iterative tests of the CARES app, each with 20 users. Qualitative interviews will be conducted with all users after 30 days of use. Co-investigators will meet in person after each test for a 'hackathon' where pilot test data and qualitative feedback from interviews with users will be reviewed to guide any needed app changes (6 months).

Aim 1.3. After any needed final programming adjustment and debugging of the CARES app and programming, a parallel app will be built for the iOS platform. Project staff will pilot test the iOS app to ensure proper functioning on that platform. (3 months).

Phase II Aims for the 24 month period are:

Aim 2.1. Conduct a rigorous randomized trial of the CARES program compared to a brief alcohol education intervention (AE) with follow up assessments at 3 and 6 months. **H1)** CARES will result in significantly greater reductions in heavy episodic drinking and alcohol-related problems at end of treatment and follow-up compared to AE (analyses in section 4.4.h.).

Aim 2.2. Identify sub-populations for whom CARES is more or less effective. We will examine differences in relevant biological, social/demographic, and alcohol use variables as potential moderators of intervention efficacy. These include age (e.g., over/under age 21), gender, race/ethnicity, marital status, parental status, employment and level of heavy drinking at program enrollment (section 4.4.h.).

Aim 2.3. Investigate participant reactions to the CARES system, including text ratings, response latency, sharing of texts, and text content (by theme). These data will be used to predict alcohol use outcomes within the CARES group during intervention (using week-level observations) and at follow-up, to determine promising directions for future research (section 4.4.e).

Future Commercialization: With over 1,400 community college systems across the U.S. this seems an opportune moment to be targeting this market for health promotion products such as the CARES app. With an increasing number of states offering free community college to state residents, the demand for services is likely to increase rapidly in coming years.

2. SIGNIFICANCE

2.1 Alcohol Use among Community College Students: Community college students (CCS), nearly half of all college students nationwide,[6-8] and the population of CCS is likely to increase dramatically in the next few years, as an increasing number of state governments are passing legislation to make community college free to state residents.[19,20] CCS are at greater risk for binge drinking,[21] and have higher rates of driving under the influence than students at traditional 4-year/residential (FYR) colleges.[9] CCS differ from FYR students in many ways. They are more: (1) racially diverse, (2) likely to be part-time students, (3) likely to come from lower income families, (4) likely to be concurrently employed, and (5) likely to have children at home.[22,23] Therefore, approaches to addressing problematic alcohol use among CCS must be sufficiently flexible to be relevant for an array of individual characteristics and life circumstances. Importantly, heavy drinking is related to lower academic performance[24,25] and college dropout,[26] making hazardous drinking essential for community colleges to address. But community colleges typically have far fewer resources for risk prevention interventions and while all have alcohol policies in place, many have no alcohol risk prevention programs offered to students.[14,15,27-29] Also, since CCS are commuters they spend less time on campus, they have less exposure to any on-campus risk reduction approaches compared to traditional college students. **Approaches that can deliver effective alcohol harm reduction messages to CCS using a modality that is flexible, accessible, and tailored to their specific needs are urgently needed.**

2.2 Computer-Delivered Interventions: Computer Delivered interventions (CDIs) for behavior change can be administered at home or at school, and are promising given their wider reach and lower administrative burden than face-to-face interventions.[30] CDIs are increasingly used to address problem drinking.[31-33] The two CDIs most widely used and that have the most extensive evaluation with college populations are AlcoholEdu[34] and e-Checkup To Go (e-CHUG).[35] AlcoholEdu contains online text, streaming videos, and interactive web pages delivered over 3 hours. Some RCTs have shown AlcoholEdu to reduce alcohol use and alcohol-related problems compared to no intervention at short-term follow-ups,[36-39] while other trials have shown no differences relative to controls.[40] e-CHUG is a 1-session online alcohol intervention that provides normative feedback about one's risks related to the amount of alcohol consumed, estimates of blood alcohol concentration, and alcohol-related consequences, and takes 20-30 minutes to complete. Of the seven studies comparing e-CHUG to an assessment only control (AO),[36,41-46] five showed greater reductions in alcohol use in the e-CHUG condition vs. AO.[36,41-44] e-CHUG has been recommended as an alcohol prevention strategy by the NIAAA Alcohol Intervention Matrix.[47] However, neither e-CHUG nor AlcoholEdu are designed with the limited resources of community colleges in mind. For example, AlcoholEdu refers users with identified alcohol problems to on-campus health services, which are frequently not available on community college campuses. Moreover, neither program has been tested for effectiveness among CCS. Current commercially available programs have not been developed for the community college population. They are not being used with or tested in this population, and are typically too expensive or are inappropriate for community colleges (see Commercialization Plan for comparisons).

A likely alternative for community colleges seeking to institute alcohol programs is Check-Your-Drinking (www.CheckYourDrinking.net). Check-Your-Drinking (CYD) provides normative feedback on the user's drinking habits relative to peers. Alcohol interventions such as CYD that provide normative feedback are rated by the NIAAA Alcohol Intervention Matrix as effective and low cost, and with few administrative or structural barriers to implementation, thus making it suitable for community colleges.[48] Although there are many apps on the market related to alcohol, most target party and drink planning and are not focused on reducing drinking or associated risks. The few that do target drinking reduction and/or risk reduction, tend to be non-evidence based, of poor quality,[49] and none have been tested among college populations.[50]

2.3 Why an App? The number of alcohol-related apps is proliferating, none of them to date are based on a solid psychological framework and supported by empirical evidence.[51] A content analysis of behavior change techniques in alcohol apps found that most could be perceived as *encouraging* alcohol use.[50] A common feature of commercially available apps – a calculator for estimating blood alcohol content (eBAC), may even be ill-advised, as recent studies have shown that apps with eBAC calculators tend to be inaccurate, ineffective, and often actually *increased* college student drinking.[52,53] A review of 58 existing apps that provide BAC estimates aimed at reducing drunk driving showed lower engagement compared to apps aimed at managing alcohol consumption,[54] but none of these apps had been evaluated to determine their efficacy.[54,55] Mobile apps that provide personalized risk estimations and feedback have received positive reviews from potential users.[56] Apps that help record drinking episodes and provide periodic feedback are more likely to be used than other methods (e.g., IVR, Internet) and have been shown to improve user engagement and reduce heavy drinking.[57] A recent review of user preferences showed that personalized feedback and alcohol consumption monitoring were the most highly rated features in a review of alcohol reduction apps.[58] *Approximately 94% of Americans aged 18-29 currently own smartphones,[59] thus making smartphone apps a convenient way to read a very broad segment of the college-age population.*

2.4 Why Use Text Messaging Within an App?: Mobile phones can integrate interventions into students' everyday lives. Over 95% of U.S. adults (100% of those ages 18-29) use mobile phones.[59] Text messaging (TxM) is nearly ubiquitous among young adults, crossing all income levels and ethnic groups.[60] Among CCS, TxM is an appealing, widely used medium. A recent survey among CCS showed that TxM was used more frequently than voice calls and the internet.[61] Most students in our pilot study (87%) had phone plans that allow unlimited texting.[61,62] Internet-based text services and apps also make texting a very low-cost modality for intervention approaches. Also of importance, TxM have an extremely high read rate, with 95% being read within 3 minutes of being sent.[59] Given the near-market saturation of TxM as a preferred method of communication among young adults, wide availability of an effective alcohol risk-reduction intervention could exert a powerful, sustained impact on public health.

Effective text and app-delivered interventions have been developed in diverse areas such as diabetes and nicotine dependence.[63-65] This intervention delivery approach is feasible to use with adolescents[66,67] and college students.[68,69] Qualitative data show that users enjoy the familiarity of the medium, experience automated messages as personal, and prefer mobile intervention platforms because they can be integrated into their everyday routines.[17,70] Relevant for this proposal, messages received several times a week act as "small pushes" reinforcing thought processes about making behavioral change.[70] The CARES program is designed to send messages at targeted times (i.e., weekends & evenings) that may assist with preparatory cognitions and behaviors associated with managing risk in alcohol use situations. A recent systematic search (April, 2017) found 3 RCTs evaluating TxM interventions for alcohol use among young adults, all showing significant improvement in alcohol reduction.[71-72] Our pilot[16-18] also showed positive results on drinking behaviors (section 4.2.).

2.5 Mechanisms: The development of our initial text message delivered intervention (section 4.2.) was guided by Social Cognitive Theory (SCT) and the Stages of Change (SOC). Interventions using SCT and SOC have shown predictive relationships for alcohol reduction.[73,74] The SOC approach established the importance of **motivational readiness**, which is the degree to which individuals are concerned about and motivated to modify their behavior. Interventions that provide information about alcohol-related risks, including those designed to inform participants of the discrepancy between their perception of their risk level and their actual level may facilitate motivation to change.[75] The CARES program targets motivational readiness by providing caring supportive micro-intervention, employing feedback from the individual regarding their level of motivation to change and using that to assist with **goal-setting**.[47,76,77] One of the most robust predictors of behavior change in SCT is **self-efficacy**.[78] Bandura[79] postulated that enhanced self-efficacy influences behavior change by increasing attempts to perform particular tasks, persistence despite encountering difficulties, and degree of success. For example, lower drink refusal self-efficacy predicts higher alcohol consumption in college student samples.[80] CARES text messages target self-efficacy for reducing drinking and for using harm-reduction strategies, and may lead to increased persistence in efforts to reduce drinking despite encountering temptations. In our pilot work all three of these constructs showed evidence of change (section 4.2.).

Protective Behavioral Strategies (PBS) are skills and behaviors employed during drinking situations that are expected to attenuate heavy drinking and related consequences (e.g., alternating alcoholic & non-alcoholic drinks) and are associated with lower rates of alcohol use and related consequences.[81-86] PBS are central to the most common FYR college alcohol interventions,[81-87] and have been shown to mediate alcohol intervention outcomes.[88,89] *Examples of CARES messages and how they draw from theory are noted in Table 2*.

2.6 Moderators of Intervention Efficacy: Identifying for whom the program is most effective, and perhaps more importantly, for whom the program needs to be improved, is important for finalizing development and/or designing new versions for future marketing. We will investigate possible moderators including age,[90] gender,[76,90] and level of heavy drinking[91] because these have been related to outcomes in other studies of young adult drinkers. We will also examine possible moderators specifically relevant for our population, including marital, parental, and employment status.

2.7 Mobile Health (mHealth) Specific Processes: The interaction between individuals and the technology may be especially relevant to understanding how, and for whom the program is effective.[92-97] mHealth modalities allow the observation of engagement and response at the level of the micro-intervention (i.e., each message). Objective data on latency to response and subjective data on participant's appraisal of messages (for example) may inform our product evaluation. Furthermore, program content, like text messages may be shared with others (via screenshots, message forwarding, etc.); and such sharing is a likely indicator of engagement. We will use responses to individual text messages, weekly texted surveys, and outcome surveys to examine the association between engagement with CARES and alcohol outcomes. We believe this approach to investigating the interaction of the participant with an mHealth intervention is novel and should give us insight into user acceptance of the CARES program.

2.8 Summary of Significance and Overall Impact: The proposed study will greatly enhance programs available to community college students, who comprise nearly half of all U.S. college students. In Phase II we will greatly expand the availability of CARES by programming an iOS version in addition to the Android version developed in Phase I. Efficacy data will provide crucial assistance to commercialization efforts. In addition,

data on moderators and mediating variables will identify areas of weakness in the program and help guide additional efforts to improve the product.

Evidence Base: The extant scientific literature shows that individual-level strategies that include personalized normative feedback (PNF; i.e., personalized feedback about the individual's quantity and frequency of alcohol use, risks, and alcohol-related problems; comparing their own alcohol use to actual use by their peers), skills-training (e.g., approaches to limit alcohol use such as alternating alcohol with water, self-monitoring drinking behaviors), and goal-setting are the most effective strategies to reduce drinking and its harmful consequences.[47,76,77] The text messages delivered in our pilot study and features of the planned CARES app incorporate these evidence based strategies (section 4.2.b-c). **Ultimately, we hope to produce a product that draws its evidence base from three sources: 1) the scientific literature (e.g., text messages focusing on protective behavioral strategies, personalized feedback and building self-efficacy, see section 2.5); 2) Data from our pilot and both Phase I and Phase II trials showing that our planned app features are desired by the target audience (section 4.2.b); and 3) successful results of our planned phase II RCT showing that the CARES app is effective for reducing heavy episodic drinking and alcohol-related problems.**

CARES is custom designed for the community college student population, in that it is delivered entirely through mobile phones, making it accessible to CCS who are more likely to have multiple competing responsibilities compared to traditional college students. CARES also has the potential for high impact by using delivery methods (TxM and smartphone app) that are very familiar to the target population and eliminate barriers to access. Moreover, we have targeted product price to be low-cost (see Commercialization Plan) as it requires no in-person counselors, and requires only online access to set up, making it easy to disseminate and thus, more likely to be adopted by community colleges. The CARES product will have high public health significance, because reducing heavy drinking lowers morbidity, and it targets a large, diverse, under-served group that has significant health benefit to gain by reducing their drinking.

3. INNOVATION

The proposed research represents a unique evaluation of a promising and unique alcohol intervention. There are several innovations in this study:

1. This will be the first investigation to evaluate the efficacy of a smartphone app targeting hazardous drinking among community college students, a neglected and under-served population for alcohol prevention programs.
2. This is the first study that we know of targeting alcohol that will compare a stand-alone mobile phone-delivered program to an active comparison condition.
3. This study will examine the user's interaction with the app as a potentially important characteristic that may influence efficacy.
4. The CARES content is uniquely suited to the target population in that it addresses issues pertinent to CCS and was developed in collaboration with the target population (section 4.2) and messages are delivered on a default schedule recommended by CCS, but which can be tailored to the individual.[16-18]
5. The CARES content is delivered in circumstances that are ecologically valid because it is accessible at any time or location and concentrates on high-risk days.
6. Data obtained from the participants' responses to questions that CARES sends by TxM will allow for extensive process exploration of response patterns and how they relate to intervention outcomes.

4. APPROACH

4.1 Preliminary Studies/Previous Work: Our research & development team has a history of collaboration in the development, revision, and evaluation of web-based and mobile phone technologies to promote behavior change, and collaborated on the initial development work (R21AA021014).[16-18] Christopher **Deutsch** (PI), and Robert **Foster** (Co-I) co-founded Live Inspired$_{LLC}$ and developed its initial website and text message service. Both Mr. Deutsch and Mr. Foster worked with William **Flanagan** (Co-I/Chief Technical Director) to develop the programming architecture for our piloted TxM program. Mr. Flanagan also has extensive experience in app development. Dr. **Bock** is a health psychologist with over 20 years' experience developing and testing preventive health interventions (exercise, smoking cessation, alcohol reduction) delivered through print, in-person, Internet and mobile platforms, and was the PI of the initial pilot project (R21AA021014) that developed the message contents for CARES.[16-18] Dr. **Traficante** (Consultant) is an Associate Professor at the Community College of RI who worked with us on our pilot and will assist with organizing the advisory panel. Dr. **Scott-Sheldon** has worked with Dr. Bock on studies assessing TxM-delivered interventions to reduce alcohol consumption, behavioral interventions to reduce alcohol use among college students, and on meta-analyses on alcohol interventions and text message interventions. She brings expertise in alcohol intervention development, refinement, and assessment as well as sophisticated data analyses including moderators of alcohol use in young adults.[32,64,76,77,91] Dr. **Rosen** is a medical anthropologist trained in behavioral medicine

with extensive experience in the collection and analysis of qualitative data for mHealth[16,64,98-102] and other behavioral intervention designs;[103-106] she has experience on 5 NIH funded mHealth projects—two of them with Dr. Bock—which use qualitative data for app and text message delivery of health information. Our expertise in the development and evaluation of mHealth technologies, behavioral health and alcohol interventions[16-18,62] makes us uniquely qualified to carry out this research (also see Biosketches).

4.1.b Needs Assessment for Alcohol Risk Reduction in Community College Students: Drs. Bock & Traficante conducted a needs assessment to examine alcohol use, negative consequences of drinking, and technology use among CCS (*N* = 141; 58% female; 78% white, 13% Hispanic; Age *M* = 20.9).[61] Past 2-week heavy drinking was reported by 44% of participants, over 70% had experienced negative consequences of drinking in the past year, and 29% reported driving under the influence. TxM was far more commonly used than either voice calls or accessing the Internet via mobile phone (*p*s < .001). This study provides evidence of a need for alcohol interventions in our target population.

4.2. Developing a Text Messaging Program for Reducing Alcohol Risk for CCS:

4.2.a. Overview of Pilot: Our goal was to assist CCS to identify high-risk situations and barriers to alcohol reduction and to help them identify personal motivators and strategies that will move them toward reducing the harm associated with alcohol use. Work was conducted in four phases: (1) initial focus groups with the target population to refine the intervention design; (2) a series of meetings with an advisory board consisting of individuals from the target population who both drafted and rated message contents for the program; and (3) design of the program for text-message delivery, and (4) a pilot randomized controlled trial. Note that the pilot program was TxM-only (no app) and was then called "*TMAP*" for "Text Message Alcohol Intervention."

4.2.b. Formative Research: Inclusion criteria for these focus group participants were: (1) age 18-29 years, (2) current CCS, (3) at least 1 episode of heavy drinking (HD= 4+ drinks for females, 5+ for males on a single occasion) in the past 2 weeks, and (4) use TxM. Of 40 individuals screened, 26 were eligible and enrolled. We conducted 5 focus groups.[62] Participants provided feedback on the desired length of the program (most preferred 12 weeks) and proposed features. Features requested by participants included (1) ability to easily record drinks consumed [self-monitoring], (2) cost calculators, and (3) easy links to safe transportation. They also gave feedback on themes related to drinking that were important to them including: drinking wisely, accessing transportation and ensuring sexual safety. Participants reported that messages should apply to specific drinking contexts, including "pre-game" and "post-game" messages. Importantly, participants strongly endorsed the idea that the texts should deliver a message of caring (e.g., "Drink responsibly, someone at home loves you"). Many specifically stated that messages containing instructions to avoid or stop drinking altogether were not acceptable. This idea (i.e., "Don't tell me not to drink, tell me you care how I drink") was strongly endorsed by all participants. In sum, feedback from focus groups indicated that the program should use a harm-reduction rather than abstinence-based approach, and that messages should consist of educational texts to inform and motivate safe drinking.

4.2.c. Developing Message Content: It became evident during focus groups that CCS did not like texts written by programmers and researchers: They stated that texts needed to be written by and for their peers. We convened an advisory panel of heavy drinking CCS to help construct the program messages. Panelists actively composed intervention texts using their mobile phones during panel meetings and during the week between meetings and sent these texts to the study phone line for data collection. Each week the investigative team asked participants to prepare texts on a subject that had emerged from the focus groups (e.g., caring, planning, pre-gaming, safety). **Study investigators created a library of text messages promoting the use of protective behavioral strategies, encouraging goal-setting and providing personalized normative feedback, strategies which have been shown to reduce alcohol consumption in research trials**.[81-86,89] Other texts that were generated by the advisory panel were independently reviewed by study investigators for inclusion in the final version of the program. This approach was informed by sociolinguist John McWhorter, who describes texting as "fingered speech" with its own structure and specific rules.[107] Importantly, this new linguistic form is not as easily or as effectively "spoken" by older adults - like most people learning a new language, when researchers write texts they sound like "non-native speakers." *This developmental work reflects our ability to respond to the needs of the target population with innovative and engaging methods*.[17,18]

4.2.d. Pilot Trial: We used flyers, Internet ads and classroom presentations to recruit participants who met the same inclusion criteria used in the formative research above. Enrollment was conducted through the study website which provided a description of the research, informed consent with electronic signature, the baseline assessment, and randomization to either the TxM intervention or an attention control (CTL). Randomization was stratified on gender and heavy drinking (lower risk <3, high risk ≥3 HD episodes in the past 2 weeks). The TMAP intervention consisted of 6 weeks of two text messages sent in the evenings Thursday through Sunday. TMAP participants could also text Keywords to the program and receive automated reply texts that provided the number for local cab companies (keyword: Cab), online drink cost calculators (keyword: Cost), and additional tips on reducing drinking in specific situations (keywords: Party, Club). Those in the CTL group received general motivational, non-alcohol-related texts on the same schedule as the TMAP arm. Assessments conducted at baseline, end of intervention (week 6) and 12-week follow-up included a Timeline

Follow-back for alcohol use,[108,109] and measures of alcohol problems, protective behavioral strategies to limit drinking,[110] and self-efficacy in being able to limit/control drinking.[111]

The first generation TMAP program used a hybrid web/SMS application implemented with the *Live Inspired* System Architecture using Java Enterprise Edition 5 (JEE) and Debian GNU/Linux. JEE is an industry-standard framework for development of server applications; among other services, JEE provides web request processing (with the Servlet API and Java Server Pages), data management (with the Java Persistence API), and distributed queuing (with the Java Message Service). Debian is an operating-system distributor, which packages, tests, distributes, and patches a wide-range of robust system and network tools.

Results: Feasibility: Our targeted enrollment of 40 participants was *easily met and exceeded*, with 62 individuals enrolled in 1 month. Of participants, 39% were men, 44% were under 21 years of age, and 36% were high-risk heavy drinkers. All text messages were sent as programmed. Acceptability: Each text message was followed by a reminder text asking participants to reply with a rating from 1-10 indicating how much they liked the message (we use "Liking" because it is a familiar concept to young adults who tend to have experience with Facebook and similar social media websites). This procedure acted as an intervention fidelity check to ensure the message had been received, and provided evaluative feedback about message content. Most (96%) respondents rated all texts received. Average ratings of TMAP and CTL messages were high (M = 7.1, SD = 1.5) and did not differ significantly, indicating good liking of program content for both arms. Of participants, 97% (n = 60) completed the 6-week (end-of-intervention) assessment, and 92% (n = 57) completed the final (week 12) follow-up assessment, with no differential attrition between conditions.

Changes in Alcohol Consumption and Consequences: Compared to controls, participants in the TMAP condition reported significantly fewer heavy drinking episodes at post-intervention (M_{TMAP} = 2.39, SD = 2.35 vs. M_{CTRL} = 4.07, SD = 4.29; Cohen's d = 0.48) and 12-week follow-up (M_{TMAP} = 2.06, SD = 2.10 vs. M_{CTRL} = 4.66, SD = 5.30; Cohen's d = 0.64). Participants also consumed less alcohol (drinks/week) at 12-weeks in the TMAP (M = 9.77, SD = 7.91) vs. control group (M = 10.83, SD = 8.42; Cohen's d = 0.13), and had fewer alcohol-related problems than controls at post-intervention (M_{TMAP} = 3.29, SD = 3.98 vs. M_{CTRL} = 4.81, SD = 4.83; Cohen's d = 0.34) and 12-week follow-up: (M_{TMAP} = 4.03, SD = 5.23 vs. M_{CTRL} = 5.21, SD = 5.85; Cohen's d = 0.21). While many of these changes are not statistically significant, this pilot study *was not powered for significance*. Its primary aims were to assess feasibility, acceptability and to obtain estimates of effect size. It is important to note that **the magnitudes of the changes in the TMAP effect sizes are consistent with those reported in meta-analyses of alcohol interventions among traditional college students.[32,76] Further, the frequency of heavy drinking was significantly reduced among participants in the TMAP condition (vs. control: d = 0.64, 95% CI = 0.13, 1.16). These findings are highly encouraging and indicate the need for a larger, rigorous trial to determine the robustness of this effect.**

***Changes in Targeted Factors*:** The TMAP group showed significant increases in self-efficacy in their ability to limit drinking (M = 58.4, SD = 25.6) at baseline to (M=71.8, SD=24.4) at post-intervention (p=0.002). This increase was sustained through week 12. No changes in self-efficacy were observed in CTL participants. Use of protective strategies increased for TMAP participants from baseline (M=1.6, SD=0.7) to (M=1.9, SD=0.8) at post-intervention (p=0.05; Cohen's d=0.39), there was also a *decrease* in number of strategies used by CTL from baseline to week 12 (p=0.05). Finally, there was a significant increase from baseline to post-intervention in TMAP participants' motivation to reduce drinking (p=0.049).[16]

4.2.e. Summary: These results demonstrate that the proposed program is feasible and highly acceptable, as indicated by high enrollment and low attrition rates. The program message content was designed with and by CCS and was well liked by participants in the pilot. Between-group comparisons on heavy drinking and alcohol-related negative consequences approached significance or were significant with medium effect sizes. We also found effects of small-to-medium magnitude for increases in motivation to change, self-efficacy, and use of protective strategies - all mechanisms targeted by our program and proposed as mediators in this application. The initial program therefore, shows clear indications of success at modifying those behaviors and cognitions central to behavior change, and showed improved behavior change as well, even in this small trial. Some features requested by our participants such as drink tracking systems, cannot be done by text messaging alone and will require the development of a phone-resident app.

4.3. Approach for Phase I: In Phase I, we will design the initial app for an Android platform based on successful features used and identified by participants in our pilot trial. This app will be tested with ~40 users, using two iterative pilots of 20 users each. Participants will complete brief surveys at recruitment and will complete quantitative surveys and an interview at the end of the 30-day testing phase. They will be compensated $25 for completing the baseline survey and $50 for the Day-30 survey and interview. The qualitative feedback and quantitative-use data will be reviewed by co-investigators, and used to guide revisions to the CARES app. After the two pilot tests, a parallel app will be built for iOS and tested by project staff.

4.3.a. Population and setting: We will recruit students from two local community colleges (Bristol Community College [BCC] and the Community College of RI [CCRI]) which together have 10 campuses or

satellite locations in Southern New England and enroll approximately 11,000 students annually. These are the same settings from which participants will be recruited for Phase II, (see sections 4.4.a-b below).

4.3.b. Inclusion/Exclusion Criteria:

(1) age 18-29; (2) current CCS; (3) report ≥ two heavy (episodic) drinking (HEDs) in the past two weeks (This pattern is called Frequent Binge Drinking[112] and should net a group of regular heavy drinkers); (an HED is defined as 5 [4] or more drinks in one sitting for men [women]);[113-115] (4) has a smartphone and uses apps and text messaging; and (5) speaks and reads English comfortably.

Due to safety concerns, we will exclude participants who (1) receive a score >14 on the Alcohol Dependence Scale (indicating psychological to physical dependence),[116,117] or (2) report prior or current alcohol treatment (these individuals will be provided information about local treatment options).

4.3.c. Recruitment Procedures: Participants will be recruited through flyers, classroom presentations, and emails to students at CCRI and BCC. Ads will provide a brief description of the study, a study website and a contact phone number, allowing individuals to access information about the study by phone or internet. These recruitment and enrollment procedures have been used successfully in our previous studies.[16,18] Recruitment materials will emphasize that professors and community college administrators will not have access to information about participants. The website will provide a description of the study and an option to continue to online screening questions. For those calling by phone, study staff will briefly explain the study, answer questions, and direct interested callers to the website to complete screening. At the end of the screening survey, respondents will be asked to provide their community college email address. Our web-based survey system will be programmed to determine the eligibility of respondents, check the provided email address against prior respondents, and send the eligibility information only to valid email addresses (e.g., ccri.edu or bcc.edu) that have not previously been used. These procedures ensure that respondents will not be able to complete the screener more than once. Email addresses will be stored in a separate data table from screening responses (linked by a unique ID), allowing us to maintain confidentiality.

4.3.d. Consent and Baseline Assessment: Ineligible individuals will be provided with a list of local and online resources for alcohol education and treatment. Eligible students will be sent an email containing an authenticated link to the baseline survey, which will include study information and the IRB-approved consent form for electronic signature. As part of the consenting process, individuals will answer true/false questions to ensure they understand the fundamentals of enrolling in the study, including the study purpose and procedures, confidentiality, and freedom to withdraw. On all correspondence, we will provide a study phone number so participants can call study staff with any questions. Consented participants will proceed to the baseline survey. Upon completion of the survey they will be emailed a link to the Live Inspired website to down load the app. Procedures for acquiring and using the app mirror those to be used for Phase II.

4.3.e. Iterative pilot tests: We will enroll ~40 participants in two pilot tests of 20 participants each. Participants will use the CARES app to receive coaching in the form of CARES coach messages and reminders, reply to behavioral inquiries, track and log alcohol consumption, view graphics of their drinking history with normative feedback, seek transportation as needed and use of all app features.

4.3.f. Measures:

Screening: The eligibility screener will assess age, CCS status ("Are you currently registered for classes at a community college?"), recent heavy drinking ("How often in the past two weeks have you had 4 [5] or more drinks in one sitting?"),[114,115] phone use ("Do you have a smartphone?"), texting frequency ("How often do you text messaging?"), and comfort reading English ("How comfortable are you reading English?"). Individuals with a score >14 on the Alcohol Dependence Scale,[116,117] and respondents who answer "Yes" to the question "Have you ever been treated for an alcohol problem?" will be excluded (see section 4.3.b.).

Demographics: Participants will indicate their age and gender, race, ethnicity, education level, weight (for estimating BAC),[118] marital status, parental status (presence and number of minor children, whether living with them), employment (none/part-time/full-time; number of hours/week), and household income.

Alcohol Use: Participants will be provided with a definition of a standard alcohol drink (i.e., 12-ounce beer or wine cooler, a 5-ounce glass of wine, one mixed drink, or 1 shot 1.5 ounces of liquor) for all assessments. The Timeline Follow-back (TLFB)[108,109,119] is a well-validated, calendar-assisted measure that collects participants' retrospective account of drinking behavior.[120,121] Our primary outcome of number of heavy drinking days over the past 3 months will be constructed from the TLFB. The Brief Young Adult Alcohol Consequences Questionnaire (BYAACQ)[122] is a 24-item measure of negative consequences due to alcohol use over the past 3 months; items are summed for a total score. Secondary outcomes: We will use the TLFB to calculate number of drinking days, number of drinks per week, and estimated blood alcohol concentration (eBAC).[118] During the 12-week intervention, we will also use "push" TxM to deliver weekly assessments of drinking to all study participants regardless of randomization. These messages are used to collect single-item weekly assessments of HD episodes (e.g., "Did you drink 4 [5] drinks in a day over the past week? Please text

back 'YES' or 'NO'"), and maximum alcohol use ("What is the highest number of alcohol drinks you had in a day in the past week?"). We had a 94% response rate to this type of assessment in our pilot.

User Satisfaction: At week 12 participants will complete a survey regarding their evaluation of the program including app features and text message content, timing of the messages, program duration, number of messages sent, app features used and perceived helpfulness of each feature. Analysis of these data will provide an indication of which aspects of the overall program are most liked or seen as helpful and those which may need remediation. Overall program evaluation will be quantitatively assessed with user ratings of the grade (A-F) they would give the program and whether they would recommend their college offer this program to students (1-10 scale from "would not recommend" to "would strongly recommend").

User Engagement: We will adapt the Web Analytics Demystified measure of user engagement to assess participant's engagement with CARES. User engagement is a function of the (a) click depth (number of pages viewed), (b) duration of use (length of time using app), (c) Duration of use/ time between uses, (d) loyalty (rate of return to the app), (e) interaction (number of notifications viewed), (f) brand (awareness of brand/logo), and (g) feedback (subjective measure of satisfaction with app [see above]). An overall engagement index will be used as a predictor of alcohol use (controlling for baseline alcohol use) at follow-up.[123]

4.3.g. Qualitative Interviews and analysis: An in-depth qualitative interview will be conducted with each participant after their 30 days of app use. We will use a detailed interview agenda to ensure that the same questions are asked of each participant. Interviews will cover participant reaction to the program, including responses to the alcohol use messages (e.g. did they read them all, why or why not), replying to the messages and behavioral inquiries (willingness to reply, timing and accuracy of replies) and use of each of the app functions (e.g., alcohol consumption logging). We will ask participants to discuss messages and functions that they felt were particularly influential to them and why. We want to know: did the platform work well, what bugs were encountered, and was the content appropriate and well timed? We also will ask how and why (or why not) the app experience influenced their drinking behavior, including planning for social occasions. Qualitative work will also inform future commercialization of CARES, thus will ask if they would be willing to use this app as part of a college sponsored program. Detailed experience descriptions, in participants' own words, also inform marketing messages for commercialization.

Qualitative interviews will be audio recorded. A detailed audio review and interview summary will be written for each interview by Dr. Rosen and reviewed by at least one other project staff member for accuracy. Qualitative interviews will be analyzed using a framework matrix analysis. This qualitative data reduction technique is used to review summarize and classify data; it is particularly appropriate for practice-oriented findings and is often used in health-related research. NVivo 11 qualitative data analysis software includes a framework matrix tool; it will be used to manage data and facilitate this analysis in which participant comments about key content are aggregated and entered into the software for easy review. A written qualitative data report, summarizing the findings or each round of qualitative interviews will be used to represent the perspective of the users during the hackathon meeting/data review.

4.3.h. Finalizing Phase I development: "Hackathon" data review and programming*:* After the qualitative interviews, data from all participants will be used to guide refinements of CARES. A "hackathon" team comprising the Live Inspired$_{LLC}$ leadership, (Deutsch, Foster) programming team (Flanagan), behavioral science and content leadership (Bock, Rosen, Traficante) and project staff will meet for a 3-day conference to identify improvements in the CARES app and its intervention content. Modeled on the hackathons common in the health care technology development arena, we intend to use quantitative data on participant use habits, qualitative data on participant use experiences and preferences, feedback from monitoring staff and programming team along with best practices in behavioral medicine to optimize interactivity, usability and functionality of CARES. The team will meet to review available data and determine what changes need to be made to the app. For example, if we learn that safety in dangerous situations is a concern, we will add features the easily connect users to emergency services (e.g., ambulance, 911, etc).

TABLE 1. Phase I PROJECT TIMELINE

MONTH	1	2	3	4	5	6	7	8	9	10	11	12
A 1.1 Develop app												
Adapt TMAP to build CARES on Android	X	X										
A 1.2 iterative pilot tests												
Recruit and enroll first ~10 users			X									
1 month of use				X								
Follow up interviews & framework matrix					X							
Program revisions					X	X						
Recruit and enroll second ~10 users							X					
Follow up interviews & framework matrix								X				
Hackathon – final revisions Android platform								X	X			
A 1.3 Finalize Program design												
Build iOS platform									X	X		
Project staff test functionality on iOS											X	X

Advisory Board: Dr. Traficante (Consultant) is an Associate Professor at CCRI and was a consultant on the pilot study. She

will work with the PIs and colleagues at CCRI and BCC to assemble an Advisory Board consisting of at least 2 administrators, 2 student services staff, 2 faculty members, and 2 students. The Board will provide advice regarding implementation of the trial, including reviewing the recruitment materials, website and surveys to ensure acceptability to the student audience. The Board will ensure that administrators are informed about the study, and members will serve as embedded information providers to facilitate study enrollment. The Board will meet with investigators twice annually throughout Phase I and Phase II. Participant (student) data will not be shared with the Board.

4.3.i. Milestones for Phase I: The milestones achieved at the end of Phase I will be:

1. Successful development of wireframes design of the CARES app and complete programming in Android.
2. Recruitment of ≥ 40 participants and completion of 2 rounds of iterative pilot testing of the prototype app (N=20 each round of testing).
3. Complete qualitative interviews with participants about the app interface, use patterns, responses to content & features.
4. Demonstrating Feasibility by recruiting 40 participants within the projected timeline and retaining at least 80% through final follow up assessment.
5. Demonstrating Acceptability by achieving an average rating of 6 on program recommendations and a grade of C or better (these scores indicating above the middle ranking and allow for us to make any improvements recommended by participants during interviews or in the user satisfaction survey.)
6. Produce summaries of interview findings and quantitative data on app usage guides iterative design and programming improvements.
7. Final programming of the app (with any needed revisions as determined by the user-feedback from phase-I) in both iOS and Android operating system languages.

4.4. Approach for Phase II: Following successful completion of Phase I, we will conduct a rigorous randomized controlled trial (RCT) of the CARES product using a 2-group design comparing CARES to an active control arm to examine the effects on hazardous alcohol use among students attending community colleges in Rhode Island and southern Massachusetts. Participants will be screened, assessed, and randomly assigned to each condition using internet-based automated methods. The CARES condition will consist of 12 weeks use of the app that includes a push of six text messages per week aimed at reducing hazardous alcohol use. Participants randomized to the control condition will receive online access to CheckYourDrinking.net, a free online alcohol intervention (section 4.4.c below). Assessments will be conducted at baseline, 3 and 6 month follow ups. (*See section 4.4.g for design considerations*).

4.4.a. Population and Setting: This study will be conducted with students from two community college systems: Bristol Community College (BCC), which has four campuses across southern MA, and the Community College of Rhode Island (CCRI), which has six locations across RI. Approximately 11,000 students are enrolled annually across both systems (56% women). About 80% of students (8,800) are ages 18-29 and of these, 48% are ages 18-20, with no differences between systems. We will enroll participants ages 18-29 to be representative of the bulk of CCS population. Restricting the upper age to 29 will exclude older students who may respond differently to an app-delivered program than younger adults. The ethnic and racial distribution is 12% Black, 3% Asian, 1% Native American, 1% Native Hawaiian/Pacific Islander, 75% White and 8% more than one race; 20% are Hispanic. Both colleges maintain a small student services office, but health services are not available on CCRI or BCC campuses which is typical of many community colleges across the U.S.[124] In our discussions with officials at these sites, both Dr. Bensink at BCC and Dr. Schertz at CCRI expressed enthusiasm about offering the CARES intervention at their campuses (see letters of support).

4.4.b. Eligibility and Recruitment:

Recruitment Procedures: Note that **inclusion and exclusion criteria** for the Phase II RCT will be the same as those used in Phase I (see section 4.3 above). For the Phase II RCT, we will enroll 250 participants who will be randomized to each arm (we anticipate at ≥80% retention resulting in *N* = 200 at the 6-month follow-up). To achieve this goal we will enroll ~83 participants each semester (there are 3 semesters per year). With an eligibility rate from our pilot work as a guide, we expect 60% of screened students to be eligible, so we will screen approximately 138 students in each of 3 semesters of the first year of the Phase II project period. Over 8,800 students age 18-29 enroll in the local CCS system every year (BCC and CCRI), thus we will need to screen less than 5% of the enrolled students in each year. Our recruitment strategy includes multiple methods to reach students, with reasonable incentives for participating, and although our pilot was much smaller, we had no difficulty reaching our enrollment goals. We will use benchmarks to ensure that we achieve our targeted enrollment and ensure adequate representation of women and ethnic/racial minorities. Given the number of available students, our recruitment strategies, and our pilot data showing high rates of eligibility and research enrollment, we are confident we will be able to enroll sufficient numbers of eligible students.

Consent, Baseline Assessment, and Condition Assignment: Ineligible individuals will be provided with a list of local and online resources for alcohol education and treatment. Students who are eligible will be

sent an email containing an authenticated link to the baseline survey, which will include study information and the IRB-approved consent form for electronic signature. As part of the consenting process, individuals will answer true/false questions to ensure they understand the fundamentals of enrolling in the study, including the study purpose and procedures, confidentiality, and freedom to withdraw. On all correspondence, we will provide a study phone number so participants can call study staff with any questions.

Consented participants will proceed to the baseline survey. After completing the baseline survey, the online system will randomly assign them to an intervention condition using stratification by age (under/over 21), gender, and Audit-C scores (scores of >4 for men or >3 for women are considered hazardous drinking). Participants will immediately be informed of their condition and will be provided relevant information by email. This email also will contain summary information about the study, the consent form, the schedule of upcoming assessments, and compensation information. All randomized participants will be followed regardless of intervention completion. Our participant tracking system will allow us to track completion of all components, including consent, the baseline survey, and the assigned intervention. Eligible participants who do not complete enrollment or who enroll but do not complete the baseline survey will be contacted by phone.

4.4.c. Conditions:

CARES: Participants randomized to CARES will be texted or emailed a link to their appropriate App Store to download the *Live Inspired* app. *Live Inspired* will send a message containing a code that the participant must enter into the *Live Inspired app* (similar to verification codes used by online vendors) to gain access to the CARES program. Participants will set up an online profile and receive CARES app coaching messages for 12 weeks. The messages developed in our pilot study (section 4.2.) focus on alcohol education, caring messages, and strategies for risk reduction and are designed to increase self-efficacy and motivation to control/reduce drinking and promote the use of protective behavioral strategies and goal-setting. Some messages are targeted to the individual's life circumstances (e.g., having children at home, multiple jobs), or demographics (e.g., gender), while others depend upon user inputting data about their current drinking in order to receive personalized normative feedback. The language of many messages was composed by CCS and uses humor and language that appeal to these students. **Table 2** describes some of the constructs and relevant issues addressed through CARES TxM and other app features.

Table 2.
Constructs and Community College Student-desired Features in CARES Coach Messages

Message Type	CCS Relevant Issue	Example message
Safety messages targeting self-efficacy	CCS identified the need for messages on drinking safely: "Don't tell me not to drink. Tell me you care *how* I drink"	*When out partying, always be aware of your surroundings - and have an exit plan.*
Finding counseling in the community	Community colleges frequently do not have on-campus counseling or health services	*Everyone needs help sometimes. If drinking is giving you problems, local counselors can help* [phone #].
Messages targeting work/school balance (Goal-setting themed)	CCS likely to have full or multiple part-time jobs.	*You work hard and study hard. Set goals for yourself that are Personal, Possible, and Specific. And don't let drinking compromise all that hard work.*
Protective Behavioral Strategies relevant to driving	CCS tend to drive more than residential college students	*Are you prepared for tonight?! Money? ID? Designated driver?*
Messages referencing family and children	CCS more likely to live with family and have children at home.	*Your children depend on you—limit your drinking.*
Messages on "pre-gaming"	CCS identified pre-gaming as a special risk for those under age 21	*Don't let your pre-game ruin the big game. Pace yourself and know your limit.*
Safety messages that are gender-specific	CCS identified need for gender-specific risk management relevant to drinking	*Women absorb alcohol more slowly than men, so we get drunk faster and stay drunk longer. Pace yourself. Go slow. Stay safe.*

TABLE 3: CARES APP FEATURES	
Designed for community college students	✓
Teaches protective behavioral strategies	✓
Encourages goal-setting	✓
Links to safe rides	✓
Promotes self-efficacy	✓
Addresses motivational readiness (SOC)	✓
Helps manage and track drinks	✓+
Helps control spending on alcohol	✓
Provides personalized normative feedback	✓
Focus on harm reduction	✓
Promotes moderate drinking guidelines	✓
Push messages timed for likely drinking events	✓

The CARES app also allows for two-way communication allowing some user-driven content. For example, messages sent to users (bi-weekly) through the text message portion of the program ask for users to answer questions regarding their self-perception of their drinking habits. Based on a users' input, specific messages correcting any misperceptions and providing normative information about drinking are provided (personalized normative feedback). Users can also drive content by texting keywords or clicking corresponding app icons to initiate desired content (e.g., texting "CAB" icon  will return lists with phone numbers of local cab companies and Uber resources for rides that can be accessed by tapping each hotlink). Following the advice of focus groups in our pilot trial, messages are delivered through the app's personal coach twice-daily Thursday through Sunday. This schedule received high satisfaction ratings by CCS in our pilot. However, anytime during the 12-week program individual participants can access the study website to program in hours during which they do not wish to receive messages; CARES will adjust the delivery time. Participants will receive a reminder message a few minutes after being sent each CARES Coach message; the reminder message prompts participants to reply to the message with a rating of liking on a scale from 1 = not at all, to 10 = liked it a lot. While we can verify through the app's back-end (administrative functions that reside at Live Inspired$_{LLC}$) whether the participant opened (i.e. read) the message, having the participant provide message ratings increases their engagement with the CARES app and provides us with ongoing feedback about perceived message quality. Our program messages received high ratings for liking in the pilot and the program was highly acceptable (section 4.2).

Active Control: Those randomized to the control arm will be given access to an online alcohol education intervention; Check Your Drinking (**CYD**: www.CheckYourDrinking.net). CYD provides normative feedback on the user's drinking habits relative to his/her peers. Alcohol interventions that provide normative feedback are rated by the NIAAA Alcohol Intervention Matrix as effective and low cost, and with few administrative or structural barriers to implementation thus making it suitable for community colleges.[48] CYD was chosen as the comparison because we want to provide a rigorous test of CARES and for future marketing efforts, we will need to establish that CARES outperforms a program that college administrators could obtain for free.[48]

4.4.d. Assessment Procedures: The assessment schedule is identical for both conditions. At baseline, we will collect contact information including alternate email addresses, home address, and phone numbers. We will request contact information for two locators and permission to reach out to locators if we are unable to reach the participant. Staff will update contact information at each assessment. Our tracking system will automatically establish each participant's schedule of assessments, reminders, and compensation payments. Participants will complete all follow-up assessments online. Participants will be sent an email containing a unique link to the online survey when assessments are due. Reminder emails, text messages and telephone calls will be used to reach non-respondents. To ensure high retention we will compensate participants $25 at baseline, and $50 at 3- and 6-month follow ups. Dr. Bock's (Co-PI) most recent trials have had follow up completion rates of 97% (R21AT008830) and 84% at 12 months (R01AT006948), and our pilot (R21AA021014) had a completion rate of 92%. Thus, we have a strong record of conducting longitudinal trials and using proven incentives that support our ability to achieve our target follow-up rates.

4.4.e. Measures:

Screening: The eligibility screener will assess age, CCS status ("Are you currently registered for classes at a community college?"), recent heavy drinking ("How often in the past two weeks have you had 4[5] drinks in one sitting?"),[114,115] mobile phone use ("Do you have a smartphone?"), and comfort reading English ("How comfortable are you reading English?"). Individuals with a score >14 on the Alcohol Dependence Scale,[116,117] and respondents who answer "Yes" to the question "Have you ever been treated for an alcohol problem?" will be excluded (see section 4.3. for inclusion/exclusion criteria).

***Demographics*:** Participants will indicate their age and gender, race, ethnicity, education level, weight (for estimating BAC),[118] marital status, parental status (presence and number of minor children, whether living with them), employment (none/part-time/full-time; number of hours/week), and household income.

Alcohol Use (Aim 2.1): The definition of a standard alcohol drink will be provided for all assessments as a 12-ounce beer or wine cooler, a 5-ounce glass of wine, one mixed drink, or 1 shot (1.5 ounces) of liquor. The Timeline Follow-back (TLFB)[108,109,119] a self-administered, well-validated, calendar-assisted measure that collects participants' retrospective account of drinking behavior,[120,121] will be used to construct our primary

outcome of number of heavy drinking days over the past 3 months. The Brief Young Adult Alcohol Consequences Questionnaire (BYAACQ)[122] is a 24-item measure of negative consequences due to alcohol over the past 3 months; items are summed for a total score. Secondary outcomes: We will use the TLFB to calculate the number of drinking days, number of drinks per week, and eBAC.[118] The AUDIT-C[125] will be used to assess hazardous drinking at screening and all follow up assessments.

During the 12-week intervention, we will also use "push" text messaging to deliver weekly assessments of drinking to all study participants (both arms). These messages will be used to collect single-item weekly assessments of HD episodes (e.g., "Did you drink 4 drinks [5 drinks] in a day over the past week? Please text back 'YES' or 'NO'"), and maximum alcohol use ("What is the highest number of alcohol drinks you had in a day over the past week?"). We had a 94% response rate to this type of assessment in our pilot.

Measures for Secondary effects of CARES: In addition to direct effects on alcohol use, other alcohol-related factors will be assessed to strengthen the need for the CARES program and for future marketing efforts. We will assess self-efficacy for resisting drinking using the Brief Situational Confidence Questionnaire (8 items).[111,126] Motivation to reduce alcohol use will be assessed using the Readiness to Change Questionnaire (12 items; 5-point scale ranging from *strongly disagree* to *strongly agree*).[127] Use of protective strategies will be measured with the 15-item Protective Behavioral Strategies Survey,[83,84] that has three subscales: Manner of Drinking, Limiting Drinking, and Harm Reduction that was developed for use among college students (5-point scale ranging from *never* to *always*).[78] Risk perception will be assessed using the Alcohol Effects Questionnaire (AEQ), a 40-item measure used to assess positive and negative alcohol-related expectancies (6-point scale ranging from *strongly agree* to *strongly disagree*).[128]

Moderators (Aim 2.2): Assessments of demographics (e.g., gender, age, race/ethnicity, parental status, employment) and heavy drinking are described above and will be investigated as potential moderators of intervention efficacy.

CARES-Specific Processes (Aim 2.3): To investigate engagement with the CARES app we will ask CARES participants to rate their liking of each text message they receive using a 5-point scale. The app will also calculate the time to respond (i.e., latency) to this rating request. We will also collect information about the sharing of texts through the app and through a survey at week 12 ("Did you share any of the CARES messages with your friends or family?"). The content of the text messages will be coded according to the constructs identified in Table 2, and associations with liking, sharing, and weekly outcomes will be evaluated. We will also assess the same User Engagement analytics described above (section 4.3.f). Analyses are described in section 4.4.h.

4.4.f Methods Used to Achieve Scientific Rigor and Transparency: We will use multiple methods to ensure an unbiased, rigorous clinical trial. Screening for potential participants will be conducted online with programming to ensure unbiased recruitment results. All data collected in online surveys and through the app are entered by participants, avoiding any potential bias by study staff. Structured interview guides will be used to ensure consistency in Phase I. All Phase II study participants will have the same schedule of assessments to avoid bias due to unequal subject burden or priming effects from multiple assessments (e.g., if delivered unequally between groups). Participants will be randomly assigned to condition via computer algorithms. Analyses will follow the plans developed *a priori*. Statistical power is conservatively estimated based on effect sizes from relevant literature and our pilot work, and recruitment goals are set to allow for reasonable attrition. To ensure transparency, terms, our study will be registered on ClinicalTrials.gov in advance of collecting data.

4.4.g. Design Considerations:

Alternative Designs Considered: The issue of greatest importance in designing this study was to rigorously evaluate CARES compared to a control. In this regard, we deemed it important that the comparison condition was ecologically valid (comparable to CARES in accessibility) and provided a reasonable real-world comparison. In particular, for future commercialization efforts, it is important that we compare our CARES app to a program that any community or technical college would see as a viable alternative to purchasing CARES. Thus, an online (or app delivered) format was important, and that it be free or low-cost. That is, why would they purchase CARES if they could get an alternative, easily accessible (i.e., online or app) program free?

We considered a comparison with a 'no-intervention' control (e.g., assessment only or a wait-list) but a no-intervention control seemed to be a bit of a 'straw-man' in that, given our pilot data, CARES is likely to easily outperform nothing. Also, we wanted a more real-world comparison, so we chose a control group using an alcohol program that is free, inexpensive and easily disseminated, and thus, something a community college might consider as an alternative to purchasing CARES.

We considered other web-based college alcohol interventions including AlcoholEdu (everfi.com), College Drinkers Check-up (CDCU; collegedrinkerscheckup.com), and e-Checkup-to-go (eChug). However, the CDCU has only one peer-reviewed publication describing two small randomized trials that support its efficacy.[129] AlcoholEdu has several peer-reviewed evaluations,[36-39] but can cost $10,000 or more per school per year. Neither eChug nor AlcoholEdu were designed for, or tested in, community college students. We could have proposed to compare CARES to another text-messaging-based alcohol intervention program without an app feature, but as with the aforementioned CDIs, these programs were not designed for, and have not been

tested in, CCS[130,131] We also considered comparing to the 'gold standard' of a Brief Motivational Interview, a well-established intervention for college students.[15,76,132] Brief motivational interviews have a low likelihood of being adopted by community colleges, which typically do not have the resources to support in-person counseling,[13,14] and thus, could not be delivered to all CCS who drink. Ecological validity and disseminability were high priorities in the development of CARES and in the consideration of the other conditions.

4.4.h Statistics Procedures and Data Analyses: Dr. Scott-Sheldon will conduct all statistical analyses.

Preliminary Analyses: Prior to conducting the main analyses, the distribution of all outcome variables will be examined. While count-based outcomes are expected to follow Poisson or negative binomial distributions, and the main analyses will be conducted using counts, we also can create dichotomous variables indicating whether participants engaged in any (vs no) HD and/or experienced any (vs no) problems. This will allow us to evaluate the extent to which there is clinically meaningful change in important public health outcomes.[133] Baseline comparisons between CARES and CYD on demographic and alcohol use variables will be assessed using chi-square and t-tests. Any group differences will be statistically controlled for in the main analyses as a subject- (e.g., gender) or time- (e.g., number of HD days) dependent covariates, as appropriate.

Aim 2.1. Main Analyses: All analyses will be conducted in SAS 9.4 We will use mixed effects regression models to estimate the effects of CARES vs. CYD on heavy (episodic) drinking and alcohol-related problems at the 3- and 6-month assessments. Mixed effects regression models can readily handle outcomes with normal distributions, but also (via use of generalized linear mixed modeling) dichotomous outcomes, count data (Poisson distribution), and over-dispersed (negative binomial models) or zero-inflated count data. Models will include a subject-specific intercept to estimate and adjust for repeated measurement within participant over time. The models are conducted using a likelihood-based approach and thus makes use of all available data without directly imputing missing outcomes to produce consistent estimated of the regression parameters. These analyses will control for the baseline value of the respective outcome measures and the linear effect of time. We will also examine interactions between intervention group and time to determine whether group differences in HD and problems differ across follow-ups.

User Satisfaction and evaluations of app features and overall program evaluation will be examined. Analysis of these data will indicate which aspects of the overall program are most liked or seen as helpful and those which may need remediation. User Engagement will be examined using the adapted Web Analytics Demystified measure to assess participant's engagement with CARES (section 4.3.f). The overall engagement index will be used as a predictor of alcohol use (controlling for baseline alcohol use) at follow-up.[123]

Aim 2.2. Moderation Effects: There has been limited exploration of individual- and intervention-related factors that may moderate the efficacy of mHealth interventions. We will examine demographic factors (e.g., gender, age) as moderators of the intervention. The extent to which demographics that tend to be different from traditional 4-year college students, including race/ethnicity, marital and parental status, employment (full/part-time, hours worked/week), and level of heavy drinking at baseline (defined as 5 [4] drinks on a single occasion for men [women] in the past 30 days) will also be examined as moderators of the intervention. Moderation analyses will be conducted by adding these variables to the mixed effects regression models; the main effect of each potential moderator and the interactions between that moderator and intervention condition will be assessed (group × moderator × time).

Aim 2.3 Predictors of CARES outcomes (Exploratory Aim): Among those receiving CARES, additional analyses will examine trends over time in the weekly (12 weeks) TxM responses to questions asking: (1) whether the participant had engaged HD that week (yes/no) and (2) the highest number of alcohol drinks in a day over the past week. Analyses will examine participant ratings of received texts, latency of response and self-reports of any sharing of texts (section 4.4.e), to examine whether individual responses to each message or type of message (thematic content) are predictive of alcohol use. Analyses of these data will use mixed effects regression modeling approaches to evaluate the effect of time on each outcome, estimating a binomial model for the dichotomous outcome of HD and a Poisson model for the count variable of maximum number of drinks, each of which uses a logit link function.

Additional Analyses: Across all aims, we will extend the examination of intervention comparisons to additional alcohol outcomes *(e.g., number of drinking days, number of drinks per week).* Data on alcohol use collected at the weekly level (any heavy drinking and maximum number of drinks on a single day over the past week) will be used in ancillary analyses to investigate trajectories in heavy and peak drinking episodes. Analyses will use mixed effects regression modeling approaches to evaluate the effect of time on each outcome, estimating a binomial model for the dichotomous outcome of HD and a Poisson model for the count variable of peak drinks, each of which uses a logit link function.

Missing Data: All analyses will be based on an intent-to-treat approach meaning that all participants will be included in the analyses regardless of completeness of data. Our proposed sample size allows for up to 20% attrition at 6-months (see Power Analysis). We will test for systematic differences between participants who do and do not complete assessments to determine the nature of any potential bias due to attrition. Full-information maximum likelihood (FIML) methods will be used in our analyses and we will supplement with multiple imputation (MI) as needed.[134,135] To support missing-at-random assumptions required for unbiased

interpretation of FIML and MI estimates in mixed effects regression models (e.g., Proc MIXED) we will run sensitivity analyses. If the results of the sensitivity analyses are similar with and without missing data substitution, confidence in the findings increases.

Power Analysis: The proposed study is fully powered for our **primary outcomes** of heavy (episodic) drinking and alcohol-related problems. Results from our pilot study (section 4.2) indicated a *d* of 0.64 (95% CI = 0.13, 1.16) for heavy (episodic) drinking and 0.21 (95% CI = -0.32, 0.75) favoring the intervention at the 12-week assessment (6-weeks post-intervention). When we assessed the presence (any) or absence (none) of alcohol-related problems at the 12-week assessment, we found a *d* of 0.66 (95% CI = 0.14, 1.18) favoring the intervention. Findings from a related pilot trial evaluating an extended internet-based intervention that included text messages (AHC; AlcoholHelpCenter.net) compared to CYD indicated a *d* of 0.41 (95% CI = 0.11, 0.72) on the Alcohol Use Disorders Identification Test for Consumption (AUDIT-C)[125] at the 6-month follow-up. (The AUDIT-C is a brief screening measure used to assess hazardous drinking, including heavy drinking, and higher scores would indicate that the individual would likely be experiencing alcohol-related problems.) **Therefore, we conservatively chose to power on a *d* of 0.41 across the 3- and 6-month assessments.** This effect size is considered to be small to medium using Cohen's criteria.[136] It is important to note that our power analysis is based on our ability to detect differences in at-risk drinking between our two active conditions, CARES and CYD, across a 6-month follow-up. Given the aforementioned findings, and an alpha level of 0.05 and power of 0.80, a power analysis was conducted using GPower 3.0.[137] This analysis revealed that 190 participants (95 per condition) would be required. Assuming an estimated attrition of 20% by the 6-month follow-up, approximately 238 participants (119 per condition) are needed. Thus, our proposed sample size of **250** (125 participants per group) will be sufficient to detect even small between-group effects on the hypothesized outcomes as well as controlling for covariates.

5. PROTECTION OF HUMAN SUBJECTS

5.1. Risks to Human Subjects:

5.1.a. Human Subjects Involvement and Characteristics: Subjects will include male and female students (N=40 for Phase I and N=250 for Phase II) attending community college who are age 18-29 and who report at least two heavy drinking episodes in the past two weeks (5 or more drinks for men, 4 or more for women). Subjects will be recruited through flyers, classroom presentations and campus internet advertisements targeted to the student population at the Community College of Rhode Island (CCRI) and Bristol Community College (BCC: see letters of support). Based on our prior experience recruiting participants for college drinking interventions and interview studies,[16,17,61] our very successful recruitment in the pilot trial, and the student pool at both CCRI and BCC, we anticipate that we will be able to recruit all participants needed for this study within the proposed timeline. Our project staff will solicit feedback from professionals who work with community college students and students themselves. This advisory board will be chaired by Dr. Traficante (Consultant) who is a member of the faculty at CCRI. The advisory board will consist of at least 2 persons in each category: Administrators, teachers, students and student services workers. These advisory board members will meet twice annually and review our program as content experts and are not considered research subjects.

5.1.b. Population and Setting: This study will be conducted with students at two college systems serving the region: Bristol Community College (BCC) located in Fall River, MA (with four locations across southeastern Massachusetts), and the Community College of Rhode Island (CCRI), which has six locations throughout RI. Student populations at both colleges are comparable, with approximately 11,000 students enrolled annually, about 35-40% of whom are heavy drinkers.[9,11] Approximately 80% of students are between ages 18 and 29 (the age group of interest in this study), and of these, 48% are ages 18-20. Thus, we are confident that there will be sufficient numbers of eligible students who will be available to enroll in the study. We were able to over-recruit for our pilot trial (section 4.2) using the same eligibility criteria as we will use for both Phase I and II of the proposed STTR project.

Approximately 56% of the students at BCC and CCRI are women. The current ethnic and racial distribution of the student population at CCRI and BCC are similar. Approximately 12% are Black/African American, 3% Asian, 1% Native American, 1% Native Hawaiian or Other Pacific Islander, 75% White and 8% more than one race. Approximately 20% of students are Hispanic. However, nationally enrollment at community colleges and similar 2-year institutions is approximately 50% ethnic and/or racial minority. Therefore we will over-recruit to ensure that approximately 50% of our study participants will be ethnic and/or racial minorities. This is similar to the overall population in the greater Providence, RI area. Both colleges maintain a small student services office, but health services are not available on campus.

5.1.c. Recruitment Procedures: Participants will be recruited through flyers, classroom presentations and emails to students meeting age criteria at CCRI and BCC. Ads will provide a brief description of the study, a study website and a contact phone number, allowing individuals to access information about the study by phone or internet. Recruitment materials will emphasize that community college professors and administrators will not have access to information about participants. The website will provide a description of the study and an option to continue to online screening questions. For those calling by phone, project research staff will briefly explain the study and answer any questions, then will direct interested callers to the website to complete the screening. At the end of the screening survey, respondents will be asked to provide their community college email address. Our web-based survey system will be programmed to determine the eligibility of respondents, check the provided email address against prior respondents, and send the eligibility information only to valid email addresses (e.g., ccri.edu or bcc.edu) that have not previously been used. These procedures will ensure that respondents will not be able to complete the screener more than once. Email addresses will be stored in a separate data table from screening responses (linked by a unique ID), allowing us to maintain confidentiality.

Those not eligible will see a message informing them that they are ineligible because they do not meet the criteria for the study (the specific criteria will not be provided to avoid individuals sharing this information with others). Ineligible individuals will also be provided with a list of local and online resources for alcohol education and treatment.

Eligible individuals will be sent a link to their college email address. By clicking the link embedded in that email, the individuals will access the next set of web pages that explain the study in detail and present the IRB approved consent form for electronic signature. As part of the consenting process individuals will answer a series of true/false questions to ensure they understand the fundamentals of enrolling in a research study (e.g., this is a research study, your information is confidential, you may withdraw at any time, etc.). A phone number is also provided on the website so that individuals can call our study staff with any questions regarding the study or the consent.

After providing an electronic signature for consent, participants will complete a contact information form (name, address, email, phone, locator contact). Contact information is stored in a secure database separate from survey data to protect participant privacy and the confidentiality of their data. The participant will then have a 24-hour window in which to complete the baseline survey. When the survey is complete, the tracking system (used for assessment reminders and compensation payments) will be automatically updated. Eligible participants who do not complete enrollment or who enroll but do not complete the baseline survey will be contacted by telephone.

The online enrollment system will be programmed to follow the randomization scheme (stratified by age over/under 21, gender, and heavy drinking frequency) developed by Dr. Scott-Sheldon (Co-I). At the completion of the baseline survey participants will be informed about their assignment and given instructions. This information will also be sent via email. Participants assigned to the control condition will be routed to www.checkyourdrinking.net and will be instructed to complete the Check Your Drinking assessment within 7 days. Participants randomized to receive CARES will receive instructions on how to download the CARES app by first sending a text message to the dedicated phone number at *Live Inspired.* This phone number will reply with a link that will open in the appropriate App Store to download the Live Inspired application. In addition, the system will then send a message containing a code number that the participant must enter into the Live Inspired application (similar to verification codes used by online vendors) to connect them to the study.

CARES will push text messages twice daily on Thursday, Friday, Saturday and Sunday weekly for 12 weeks, following the schedule recommended by our focus groups of community college students and tested in our pilot study. Message content focuses on alcohol education, motivation, building self-efficacy, caring messages, and strategies for risk reduction (section 4.4.c). Information provided about CARES will include key functions participants can use with the system as desired (e.g., clicking a button labeled “CAB” will return a list of contact phone numbers for local cab companies and a link to Uber). Following each content related text message sent by CARES, the system will send a follow up message asking the participant to rate the message they received on a scale of 1-10 to indicate how well they liked that specific message.

All participants regardless of randomization assignment will receive information about the assessment schedule and associated compensation. Assessments will be conducted at baseline/enrollment, weekly through text messages, and at 3- and 6-month follow-up.

Data from all surveys will be linked with the individual’s study ID. For those receiving CARES, use of the app will also be linked to the individual’s study ID. We used this online recruitment method very successfully in our previous studies. All direct human subjects involvement for this study and analysis of data will be performed at The Miriam Hospital site.

5.1.d. Inclusion/Exclusion Criteria: (1) age 18-29; (2) current CCS; (3) report $\geq$ two heavy drinking episodes (HDEs) in the past two weeks (This pattern is called Frequent Binge Drinking[112] and should net a group of regular heavy drinkers); (an HDE is defined as 5 [4] or more drinks in one sitting for men [women]);[113-

[115] (4) has a smartphone and uses apps and text messaging; and (5) speaks and reads English comfortably. Due to safety concerns, we will exclude participants who (1) receive a score >14 on the Alcohol Dependence Scale (indicating substantial dependence),[116,117] or (2) report prior or current alcohol treatment (these individuals will be provided information about local treatment options).

5.2. Sources of Research and Clinical Material: The research and clinical material for the proposed study will consist of questionnaires collected as electronic survey instruments concerning the following areas: sociodemographic characteristics (age, gender, ethnicity, household income, employment, parental status [that is, being the parent of minor children and whether those children live with the participant]); drinking habits and substance use history (current levels of drinking and/or substance use, any prior treatment history); a series of assessments relevant to examining posited mediators and moderators of intervention efficacy (e.g., motivation, self-efficacy); and items concerning current drinking behaviors. Weekly text messages will be sent to all participants regardless of randomization assignment to assess current drinking (see section 4.4.e for detailed descriptions of the assessment instruments and schedule of assessments).

5.3. Potential Risks: The risks in this study are considered minimal. The primary risk to participants in all phases of this study is loss of confidentiality of information shared via the questionnaires or materials provided to researchers. Participants may experience some emotional discomfort responding to questions about their alcohol use and beliefs but we do not consider this potential risk to be either common or serious.

5.4. Adequacy of Protection Against Risks:

5.4.a. Recruitment and Informed Consent: Subjects will include male and female community college students (N=40 for Phase I and N=250 for Phase II) ages 18-29 who are current alcohol users and who report at least two heavy drinking (HD) episodes in the past two weeks (in one sitting: 5 or more drinks for men, 4 or more for women), who have a smartphone and use TxM. We will advertise for study participants using campus media outlets, in-class presentations, flyers, email and Internet sources we have used successfully in previous studies.[16,17,61] Before being posted, all flyers and advertisements will be reviewed by The Miriam Hospital Institutional Review Board (will serve as the IRB of record for the overall study) to ensure that descriptions of the study are clear and not misleading. All advertisements and presentations will include both the study phone number and website URL.

Interested persons responding to these ads will access the study's initial description on our website or speak with our research staff who are trained in the conduct of research and protections of human subjects' confidentiality and privacy. The study staff will explain the nature and purpose of the study, answer any questions, and will send the caller the link to our website if they are interested in enrolling. Individuals accessing the website will view a brief description of the study requirements, and be asked to click through to the study screener, if interested. If eligible, they will read and sign the online consent form using an electronic signature by clicking a button indicating consent. Electronic consent for the screening questions is obtained prior to initiating the screener survey and prior to collecting baseline data. As part of the consenting process individuals will answer a series of true/false questions to ensure they understand the fundamentals of enrolling in a research study (e.g., this is a research study, your information is confidential, you may withdraw at any time, etc.). A phone number is also provided on the website so that individuals can call our study staff with any questions regarding the study or the consent.

All screening data will be collected anonymously until eligibility is determined and informed consent is signed. Eligible individuals who are interested in participating and who have provided signed consent will be asked to provide identifiers (e.g., name), contact information (e.g., phone number, email), and locator contact number (1-2 additional individuals who can be contacted if we are unable to reach the participant). Participants will be emailed a copy of the consent document. Data collected at screening for individuals who are determined to be ineligible will be retained as anonymous data (no identifiers). This will be explained to participants at the start of the screening process.

5.4.b. Risk Minimization: All study staff will be trained and certified in handling human subject information to maintain privacy and confidentiality. No survey data will be labeled with the participant's name or other identifying information, but will instead be linked to a study ID number. Documents linking study ID numbers to identifying information (e.g., name, address) will be stored electronically in an encrypted password-protected file. All paper-data (hard copies) with identifying information will be stored in locked file drawers, separate from any coded data. Documents with identifying information and documents linking study ID numbers to identifying information will be destroyed at the end of the study. All electronic data including data entered on through websites will be secured and encrypted. Subject information will be accessible only to research staff, who are pledged to confidentiality. Identifying information will not be reported.

Any emotional distress will be minimized by assurances that participants can refuse to answer any particular question they do not feel comfortable addressing and can withdraw from the study at any time without penalty. If any significant mental health problems are reported appropriate referrals will be arranged.

Any participants who are screened ineligible due to a high alcohol dependence score will be referred to local community health centers.

The Advisory Board will provide advice regarding implementation of the trial, including reviewing the recruitment materials, website and surveys to ensure acceptability to the student audience. Although the Advisory Board will help with recruitment, participant (student) data will not be shared with them. This will be clarified during recruitment/advertising so that students are not hesitant to join the study. Moreover, a Certificate of Confidentiality will be obtained from the Office of Human Research Protections (OHRP) to ensure the security and privacy of participants.

5.5. Potential Benefits of the Proposed Research to the Subjects and Others: Participating in this study may heighten participant's motivation to stop or reduce drinking, and participants may benefit by having the opportunity to consider how alcohol is affecting their lives. Moreover, for those receiving the CARES or CYD programs, intervention content is designed to encourage reduced and responsible drinking and constitutes an active intervention that may result in reduced drinking among participants.

5.6. Importance of Knowledge to be Gained: The anticipated gains obtained through this study are substantial. Excessive alcohol use is the third-leading preventable cause of death in the U.S.[1] Young adults show the highest rates of hazardous alcohol use.[2-5] In the U.S. community colleges serve over 12 million students,[6] comprising 45% of all college students nationwide.[6-8] Community college students (CCS) show rates of heavy alcohol use similar to students at traditional four-year residential colleges,[3,9-12] but CCS are at higher risk for negative consequences of heavy drinking, including physical and sexual assault, fatal injuries, and driving under the influence.[9] Despite the large number of CCS and their level of risk, *alcohol interventions for young adults have focused almost exclusively on students at traditional four-year residential colleges*.

The information derived from this study will be used to produce an effective, low-cost, easily disseminated intervention to help community colleges address student drinking - which could have significant impact on public health. Given how common and problematic student drinking problems are, we believe that the minimal risks described above are reasonable.

Younger adults tend to under-utilize alcohol treatment services delivered through traditional methods (e.g., in-person clinics, telephone hotlines). Dissemination of an evidence-based program designed this population that can be delivered as a smartphone app has the potential to reach a nationwide audience of young adults who might not otherwise receive intervention.

6. DATA AND SAFTEY MONITORING PLAN

6.1. Participant Safety: Monitoring Plan for Adverse Events: Participation of subjects in the Phase I trial will consist of using the prototype CARES app for alcohol risk reduction for 30 days, then participating in a qualitative interview with Dr. Rosen (Co-I). Participants will also complete surveys at program enrollment and at day 30. For Phase II, participants will provide survey data at baseline and complete follow-up assessments at months 3 and 6. For both Phase I and II we will be clear during the enrollment process and in other communications with participants that we will not monitor the CARES text message feature in real time (i.e., that there is not an individual sending and responding to texts), as we do not want participants to assume that any potential expressions of distress will be seen immediately. The CARES system is designed as an alcohol educational tool and risk reduction tool, not as a medical monitoring device. However, during the intervention period we will review our study participant's CARES text messages daily for descriptions of dangerous alcohol-related events or emotional distress. We will contact participants whose welfare we are concerned about and Dr. Bock will determine whether a referral or additional action is necessary.

In addition, at the start of the study (both Phase I and Phase II), all participants will be given the study phone number to program into their cell phones. Participants will be instructed to call the phone number if they are experiencing problems related to the study or to alcohol-related issues. Staff will route these calls to Dr. Bock. Contact numbers and email will remain available to all participants in the study through month 6. Finally, baseline and follow-up web-based survey responses will be viewed following each assessment.

6.1.a. Adverse Events: Throughout the intervention and follow-up phases, Dr. Bock (MPI) will report serious adverse events to The Miriam Hospital IRB immediately by telephone and by written report within 48 hours of our receipt of information regarding the event. The report will include information on the date of the event, what occurred, actions taken by the project staff, planned follow-up (if any), the intervention condition of the affected participant, whether the event appears to be related to the intervention, and whether the event affects future participation (i.e., will the participant continue in the study). Dr. Bock will provide a DSM report to the IRB and to the NIH Project Officer on an annual basis as part of the progress report. The DSM report will include a summary of all adverse events and serious adverse events, and all actions or changes that occurred as a result of these events.

6.2. Data:

6.2.a. Procedure for Collection of Data: Data will be collected through audio recorded interviews that will be transcribed then recordings deleted (Phase I) and online forms (both Phases), and response ratings to text messages hosted on our secure website as dictated by the study protocol. Only the participant's study identification number will appear on data forms or transcripts. Only the Principal Investigators, Co-Investigators and research staff will have access to the completed data forms and electronically stored data. All data are considered part of the subject's confidential record. Data collected from research participants will be stored in a secured, password protected computer file that is separate from other network systems. **All data will remain confidential.** An electronic file will be maintained that associates the subject name with that subject's study identification number. This file will be kept in a secured server that is accessible only by designated study staff, and kept separate from the actual study data.

The CARES application is hosted in an Amazon Web Service (AWS) Data Center. AWS manages dozens of compliance programs in its infrastructure regarding security--and is built to support HIPAA. Our database layer is also hosted in the AWS infrastructure, and is secured by the same standards. Our web configuration interface is protected with an encrypted, user-generated username password combination, following standards of the industry. Data stored on the phone is minimal and protected by the phones security.

6.2.b. Storage of Collected Data: All electronic data are stored in password protected, secured computer systems. Any paper data will be stored in a locked file cabinet. Data will only be removed when coded, entered, or audited.

6.2.c. Requirements for Accessing Data: The web-based data collection system will require a login identification and password in order to gain access to the data. Only the Principal Investigators and Co-Investigators will be able to view the data in its raw state.

6.2.d. Data Management and Analysis: Our research team has substantial experience in the design and implementation of data management procedures that provide accurate recording and storage of data, participant confidentiality, and timely analysis. Based on our past experience, we believe that our major data management and analysis needs for the proposed project can be met by using a high-end PC equipped with the latest version of SAS for Windows and appropriate spreadsheet programs. All data files are automatically backed-up daily.

6.2.e. Data Collection, Storage, and Quality Control: All staff involved in data collection are trained and certified regarding their competence, and re-certified periodically throughout the study as we have done in similar trials. Digital audio recorders are downloaded to our secure project files and removed from recorders immediately following the interviews. Audio files will be deleted at the end of the study. Written summaries of the audios, identified only by participant ID, will be retained.

Survey data will be collected and numerically coded using pre-tested electronic entry forms. Every effort will be made to ensure that missing data are kept to a minimum. Under supervision from Dr. Bock (MPI), the Project Director (Mr. Lantini) will conduct error checking procedures and preliminary analyses on all data to ensure their accuracy. The data collection program will be programmed to avoid accidental skipping of question items. We believe that the quality control system to be used will ensure a complete and accurate database and maximize the likelihood that the intervention will be delivered correctly and efficiently. As we have done in prior studies, a manual of procedures will be developed during the initial study start-up period that explicitly describes the specific procedures related to recruitment, enrollment, data collection, intervention delivery, and quality assurance.

6.2.f. Final Storage of Paper Data: Any paper data that may be collected in this study is minimal. However, all paper data will be housed at a facility that specializes in the storage of medical/ research information. The destruction date of these files will be at least 7 years from the termination of the study and will be authorized by the Principal Investigators of the research study.

6.2.g. Access to Cleaned Computer Data: Once the study is complete, and all data have been collected, entered and passed the audit process, the data will be available to the Principal Investigators and their designates for analysis. Only the Principal Investigators can give permission for the release of aggregated study data. No confidential information may be released without the express written consent of the study participants. Only copies of the finalized data will be released. The original data file will remain in its pristine state.

6.3. Educational Training: Dr. Scott-Sheldon (Co-Investigator) is a standing member of the The Miriam Hospital IRB (which will be the IRB of Record for this project) and will ensure that all key personnel, consultants, and research staff receive appropriate human subjects training. The Miriam Hospital requires all behavioral and social science investigators and their key personnel to receive educational training in human

subjects protection. To meet this training requirement, the Office of Research Administration offers an online training program through the Collaborative IRB Training Initiative (CITI; https://www.citiprogram.org/). The CITI program offers both an initial certification in Basic Human Subject Protection and a three year re-certification program (“refresher course”) as required by Lifespan. Certification in the Health Insurance Portability and Accountability Act of 1996 (HIPPA) is included in the basic human subjects program and requires annual re-certification. All key personnel (Bock, Rosen, Scott-Sheldon, Deutsch, Foster, Flannagan), and Consultant Traficante are in compliance with this policy and have up-to-date basic human subjects and HIPPA certifications. All investigators (and research staff) will be required to comply with this policy throughout the duration of the proposed education training program.

References

1. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA.* Mar 10 2004; 291(10):1238-1245.

2. Grucza RA, Norberg KE, Bierut LJ. Binge drinking among youths and young adults in the United States: 1979-2006. *J Am Acad Child Adolesc Psychiatry.* Jul 2009; 48(7):692-702.

3. Hingson RW, Zha W, Weitzman ER. Magnitude of and trends in alcohol-related mortality and morbidity among U.S. college students ages 18-24, 1998-2005. *J Stud Alcohol Drugs Suppl.* Jul 2009; (16):12-20.

4. Nelson TF, Xuan Z, Lee H, Weitzman ER, Wechsler H. Persistence of heavy drinking and ensuing consequences at heavy drinking colleges. *J Stud Alcohol Drugs.* Sep 2009; 70(5):726-734.

5. Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2013.

6. American Association of Community Colleges. Fast Facts. Feb 2016. http://www.aacc.nche.edu/AboutCC/Documents/AACCFactSheetsR2.pdf. Accessed May 10, 2016.

7. Juszkiewicz J. *Recent national community college enrollment and award completion data.* Washington, DC: American Association of Community Colleges; 2014.

8. Knapp LG, Kelly-Reid JE, Ginder SA. Enrollment in Postsecondary Institutions, Fall 2010; Financial Statistics, Fiscal Year 2010; and Graduation Rates, Selected Cohorts, 2002-07 (NCES 2012-280). Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2012.

9. Blowers J. Common issues and collaborative solutions: A comparison of student alcohol use behaviors at the community college and four-year institutional levels. *J Alcohol Drug Educ.* 2009; 53(3):65.

10. Johnston L, O'Malley PM, Bachman JG, Schulenberg JE. *Monitoring the Future National Survey Results on Drug Use, 1975–2012: College students and adults ages 19-50.* Ann Arbor, MI: Institue for Social Research, The University of Michigan; 2013.

11. Sheffield FD, Darkes J, Del Boca FK, Goldman MS. Binge drinking and alcohol-related problems among community college students: implications for prevention policy. *J Am Coll Health.* 2005; 54(3):137-141.

12. Wechsler H, Lee JE, Nelson TF, Kuo M. Underage college students' drinking behavior, access to alcohol, and the influence of deterrence policies: Findings from the Harvard School of Public Health College Alcohol Study. *J Am Coll Health.* 2002; 50(5):223-236.

13. Seigers DK, Carey KB. Screening and brief interventions for alcohol use in college health centers: a review. *J Am Coll Health.* 2010; 59(3):151-158.

14. Chiauzzi E, Donovan E, Black R, Cooney E, Buechner A, Wood M. A survey of 100 community colleges on student substance use, programming, and collaborations. *J Am Coll Health.* 2011; 59(6):563-573.

15. US Department of Health & Human Services. A call to action: Changing the culture of drinking at US colleges. *Task Force of the National Advisory Council on Alcohol Abuse and Alcoholism, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.* 2002:(NIH Publication No. 02-5010).

16. Bock BC BN, Thind H, Rosen R, Walaska K, Traficante R, Foster R, Deutsch C, Fava JL. A Text Message Intervention for Alcohol Risk Reduction among Community College Students: TMAP. *Addict Behav.* 2016; 63:107-113. PMID: 27450909.

17. Bock BC, Rosen RK, Barnett N, et al. Translating Behavioral Interventions Onto mHealth Platforms: Developing Text Message Interventions for Smoking and Alcohol. *JMIR mHealth uHealth.* 2015; 3(1):e22. PMCID: PMC4376101.

18. Bock B, Rosen R, Thind H, Barnett N, Walaska K, Cobb V. Building an Evidence Base Using Qualitative Data for mHealth Development. Proceedings of the 47th Annual Hawaii International Conference on System Sciences (HICSS); January 6-9, 2014, IEEE & Computer Society Press. doi: 10.1109/HICSS.2014.335, 2014.

19. Lobosco K. Tuition-free college is getting bigger. Here's where it's offered. *CNN Money*; Published Aug 4 2017. Accessed July 24, 2017 at: http://money.cnn.com/2017/05/16/pf/college/states-tuition-free-college/index.html.

20. Powell F. NY may join other states offering tuition-free college. *U.S. News and World Report*; Published Jan 4 2017. Accessed July 24, 2017 at: https://www.usnews.com/education/best-colleges/paying-for-college/articles/2017-01-04/ny-joins-other-states-in-offering-tuition-free-college.

21. Naimi TS, Nelson DE, Brewer RD. The intensity of binge alcohol consumption among US adults. *Am J Prev Med.* 2010; 38(2):201-207.

22. Provasnik S, Planty M. Community Colleges: Special Supplement to The Condition of Education 2008 (NCES 2008-033). U.S. Department of Education. Washington, DC: National Center for Education Statistics, Institute of Education Sciences; 2008.

23. Horn L, & Nevill, S.,. Profile of undergraduates in U.S. postsecondary education institutions: 2003-2004: With a Special Analysis of Community College Students (NCES 2006-184). U.S. Department of Education. Washington, DC: National Center for Education Statistics; 2006.

24. Paschall MJ, Freisthler B. Does heavy drinking affect academic performance in college? Findings from a prospective study of high achievers. *J Stud Alcohol.* Jul 2003; 64(4):515-519.

25. Paschall MJ, Kypri K, Saltz RF. Friday class and heavy alcohol use in a sample of New Zealand college students. *J Stud Alcohol.* Sep 2006; 67(5):764-769.

26. Jennison KM. The short-term effects and unintended long-term consequences of binge drinking in college: a 10-year follow-up study. *Am J Drug Alcohol Abuse.* Aug 2004; 30(3):659-684.

27. Chamberlin J. Mental health services remain scarce at community colleges. *Monitor on Psychology.* 2012; 43(11):11.

28. McBride PE. Addressing the Lack of Mental Health Services for At-Risk Students at a Two-Year Community College: A Contemporary Review. *Community College Journal of Research and Practice.* 2017:1-3.

29. Eren C, Keeton A. Invisibility, Difference, and Disparity: Alcohol and Substance Abuse on Two-Year College Campuses. *Community College Journal of Research and Practice.* 2015/12/02 2015; 39(12):1125-1136.

30. Zisserson RN, Palfai T, Saitz R. 'No-contact' interventions for unhealthy college drinking: Efficacy of alternatives to person-delivered intervention approaches. *Subst Abus.* 2007; 28(4):119-131.

31. Hester RK, Squires DD, Delaney HD. The Drinker's Check-up: 12-month outcomes of a controlled clinical trial of a stand-alone software program for problem drinkers. *J Subst Abuse Treat.* Mar 2005; 28(2):159-169.

32. Carey KB, Scott-Sheldon LA, Elliott JC, Bolles JR, Carey MP. Computer-delivered interventions to reduce college student drinking: a meta-analysis. *Addiction.* Nov 2009; 104(11):1807-1819.

33. Saitz R, Palfai TP, Freedner N, et al. Screening and brief intervention online for college students: The ihealth study. *Alcohol and Alcoholism.* Jan-Feb 2007; 42(1):28-36.

34. EverFi. Online Programs for Alcohol & Other Drug Education. Accessed October 1, 2015 at: http://everfi.com/higher-education/alcoholedu/.

35. San Diego State University Research Foundation. eCheckup To Go. Accessed August 1, 2017 at: http://www.echeckuptogo.com.

36. Hustad JT, Barnett NP, Borsari B, Jackson KM. Web-based alcohol prevention for incoming college students: A randomized controlled trial. *Addict Behav.* Mar 2010; 35(3):183-189.

37. Lovecchio CP, Wyatt TM, DeJong W. Reductions in drinking and alcohol-related harms reported by first-year college students taking an online alcohol education course: a randomized trial. *J Health Commun.* Oct 2010; 15(7):805-819.

38. Paschall MJ, Antin T, Ringwalt CL, Saltz RF. Evaluation of an Internet-based alcohol misuse prevention course for college freshmen: findings of a randomized multi-campus trial. *Am J Prev Med.* Sep 2011; 41(3):300-308.

39. Paschall MJ, Antin T, Ringwalt CL, Saltz RF. Effects of AlcoholEdu for college on alcohol-related problems among freshmen: a randomized multicampus trial. *J Stud Alcohol Drugs.* Jul 2011; 72(4):642-650.

40. Croom K, Lewis D, Marchell T, et al. Impact of an online alcohol education course on behavior and harm for incoming first-year college students: Short-term evaluation of a randomized trial. *J Am Coll Health.* Jan-Feb 2009; 57(4):445-454.

41. Doumas DM, Andersen LL. Reducing alcohol use in first-year university students: Evaluation of a Web-based personalized feedback program. *J Coll Couns.* Spr 2009; 12(1):18-32.

42. Doumas DM, Kane CM, Navarro B, Roman J. Decreasing heavy drinking in first-year students: Evaluation of a web-based personalized feedback program administered during orientation. *J Coll Couns.* Spr 2011; 14(1):5-20.

43. Murphy JG, Dennhardt AA, Skidmore JR, Martens MP, McDevitt-Murphy ME. Computerized versus motivational interviewing alcohol interventions: impact on discrepancy, motivation, and drinking. *Psychol Addict Behav.* Dec 2010; 24(4):628-639.

44. Walters ST, Vader AM, Harris TR. A controlled trial of web-based feedback for heavy drinking college students. *Prev Sci.* Mar 2007; 8(1):83-88.

45. Walters ST, Vader AM, Harris TR, Field CA, Jouriles EN. Dismantling motivational interviewing and feedback for college drinkers: a randomized clinical trial. *J Consult Clin Psychol.* 2009; 77(1):64-73.

46. Tahaney KD, Palfai TP. Text messaging as an adjunct to a web-based intervention for college student alcohol use: A preliminary study. *Addict Behav.* 2017; 73:63-66.

47. College AIM: Alcohol Intervention Matrix. Accessed August 1, 2017 at: www.collegedrinkingprevention.gov/CollegeAIM.

48. National Institute of Alcohol Abuse and Alcoholism. Planning alcohol interventions using NIAAA's CollegAIM alcohol intervention matrix. Bethesda, MD: National Institute of Alcohol Abuse and Alcoholism; 2015.

49. Penzenstadler L, Chatton A, Van Singer M, Khazaal Y. Quality of Smartphone Apps Related to Alcohol Use Disorder. *Eur Addict Res.* 2016; 22(6):329-338.

50. Crane D, Garnett C, Brown J, West R, Michie S. Behavior change techniques in popular alcohol reduction apps: content analysis. *J Med Internet Res.* May 14 2015; 17(5):e118.

51. Mellentin AI, Stenager E, Nielsen B, Nielsen AS, Yu F. A Smarter Pathway for Delivering Cue Exposure Therapy? The Design and Development of a Smartphone App Targeting Alcohol Use Disorder. *JMIR mHealth uHealth.* 2017; 5(1):e5.

52. Gajecki M, Berman AH, Sinadinovic K, Rosendahl I, Andersson C. Mobile phone brief intervention applications for risky alcohol use among university students: a randomized controlled study. *Addict Sci Clin Pract.* 2014; 9(1):11.

53. Weaver ER, Horyniak DR, Jenkinson R, Dietze P, Lim MS. "Let's get Wasted!" and Other Apps: Characteristics, Acceptability, and Use of Alcohol-Related Smartphone Applications. *JMIR mHealth uHealth.* Jun 25 2013; 1(1):e9.

54. Wilson H, Stoyanov SR, Gandabhai S, Baldwin A. The Quality and Accuracy of Mobile Apps to Prevent Driving After Drinking Alcohol. *JMIR mHealth uHealth.* 2016; 4(3):e98.

55. Cohn AM, Hunter-Reel D, Hagman BT, Mitchell J. Promoting behavior change from alcohol use through mobile technology: the future of ecological momentary assessment. *Alcohol Clin Exp Res.* Dec 2011; 35(12):2209-2215.

56. Carra G, Crocamo C, Schivalocchi A, et al. Risk Estimation Modeling and Feasibility Testing for a Mobile eHealth Intervention for Binge Drinking Among Young People: The D-ARIANNA (Digital-Alcohol RIsk Alertness Notifying Network for Adolescents and young adults) Project. *Subst Abus.* 2015; 36(4):445-452.

57. Hasin DS, Aharonovich E, O'Leary A, et al. Reducing heavy drinking in HIV primary care: a randomized trial of brief intervention, with and without technological enhancement. *Addiction.* Jul 2013; 108(7):1230-1240.

58. Milward J, Khadjesari Z, Fincham-Campbell S, Deluca P, Watson R, Drummond C. User Preferences for Content, Features, and Style for an App to Reduce Harmful Drinking in Young Adults: Analysis of User Feedback in App Stores and Focus Group Interviews. *JMIR mHealth uHealth.* May 24 2016; 4(2):e47.

59. Pew Research Center. Mobile Fact Sheet. 2017; Accessed May 14, 2017 at: http://www.pewinternet.org/fact-sheet/mobile/.

60. Duggan M. Cell Phone Activities. 2013. http://pewinternet.org/Reports/2013/Cell-Activities.aspx. Accessed January 28, 2015.

61. Magee JC, Traficante, R., Barnett, N. P., Bock, B. Examining the potential for using mobile technology to intervene on substance abuse among community college students. Presented at the 2011 meeting of the Association of Psychologists in Academic Health Centers, 2011; Boston, MA.

62. Bock BC, Heron KE, Jennings EG, Magee JC, Morrow KM. User preferences for a text message-based smoking cessation intervention. *Health Educ Behav.* Apr 2013; 40(2):152-159. PMID 23086555.

63. Head KJ, Noar SM, Iannarino NT, Grant Harrington N. Efficacy of text messaging-based interventions for health promotion: A meta-analysis. *Soc Sci Med.* 2013; 97:41-48.

64. Scott-Sheldon LA, Lantini R, Jennings EG, et al. Text Messaging-Based Interventions for Smoking Cessation: A Systematic Review and Meta-Analysis. *JMIR mHealth uHealth.* May 20 2016; 4(2):e49. PMCID: PMC4893152.

65. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. *Cochrane Database Syst Rev.* Apr 2016; (4):CD006611.

66. Ríos-Bedoya CF, Hay C. Feasibility of using text messaging for unhealthy behaviors screening in a clinical setting: a case study on adolescent hazardous alcohol use. *J Am Med Inform Assoc.* 2013; 20(2):373-376.

67. Renner KA, Walker N, Parag V, McCormick R. Harm reduction text messages delivered during alcohol drinking: feasibility study protocol. *JMIR Res Protoc.* 2012; 1(1):e4.

68. Moore SC, Crompton K, van Goozen S, Van Den Bree M, Bunney J, Lydall E. A feasibility study of short message service text messaging as a surveillance tool for alcohol consumption and vehicle for interventions in university students. *BMC Public Health.* 2013; 13(1):1011.

69. Weitzel JA, Bernhardt JM, Usdan S, Mays D, Glanz K. Using wireless handheld computers and tailored text messaging to reduce negative consequences of drinking alcohol. *J Stud Alcohol Drugs.* 2007; 68(4):534-537.

70. Laursen D. Counseling young cannabis users by text message. *J Comput Mediat Commun.* 2010; 15(4):646-665.

71. Suffoletto B, Kristan J, Chung T, et al. An Interactive Text Message Intervention to Reduce Binge Drinking in Young Adults: A Randomized Controlled Trial with 9-Month Outcomes. *PLoS One.* 2015; 10(11):e0142877.

72. Riordan BC, Conner TS, Flett JA, Scarf D. A text message intervention to reduce first year university students' alcohol use: A pilot experimental study. *Digit Health.* 2017; 3:1-10.

73. Gilles DM, Turk CL, Fresco DM. Social anxiety, alcohol expectancies, and self-efficacy as predictors of heavy drinking in college students. *Addict Behav.* 2006; 31(3):388-398.

74. Oei TP, Morawska A. A cognitive model of binge drinking: The influence of alcohol expectancies and drinking refusal self-efficacy. *Addict Behav.* 2004; 29(1):159-179.

75. Miller WR. Why do people change addictive behavior? The 1996 H. David Archibald Lecture. *Addiction.* Feb 1998; 93(2):163-172.

76. Carey KB, Scott-Sheldon LA, Carey MP, DeMartini KS. Individual-level interventions to reduce college student drinking: A meta-analytic review. *Addict Behav.* 2007; 32(11):2469-2494.

77. Scott-Sheldon LA, Carey KB, Elliott JC, Garey L, Carey MP. Efficacy of alcohol interventions for first-year college students: a meta-analytic review of randomized controlled trials. *J Consult Clin Psychol.* Apr 2014; 82(2):177-188.

78. Bandura A. *Self-efficacy: The Exercise of Control.* New York, NY: Worth Publishers; 1997.

79. Bandura A. Social cognitive theory: an agentic perspective. *Annu Rev Psychol.* Feb 2001; 52(1):1-26.

80. Young RM, Hasking PA, Oei TP, Loveday W. Validation of the Drinking Refusal Self-Efficacy Questionnaire--Revised in an Adolescent Sample (DRSEQ-RA). *Addict Behav.* Apr 2007; 32(4):862-868.

81. Lewis MA, Rees M, Logan DE, Kaysen DL, Kilmer JR. Use of drinking protective behavioral strategies in association to sex-related alcohol negative consequences: the mediating role of alcohol consumption. *Psychol Addict Behav.* Jun 2010; 24(2):229-238.

82. Martens MP, Taylor KK, Damann KM, Page JC, Mowry ES, Cimini MD. Protective behavioral strategies when drinking alcohol and their relationship to negative alcohol-related consequences in college students. *Psychol Addict Behav.* 2004; 18(4):390.

83. Martens MP, Ferrier AG, Sheehy MJ, Corbett K, Anderson DA, Simmons A. Development of the Protective Behavioral Strategies Survey. *J Stud Alcohol.* 2005; 66(5):698-705.

84. Martens MP, Pederson ER, LaBrie JW, Ferrier AG, Cimini MD. Measuring alcohol-related protective behavioral strategies among college students: further examination of the Protective Behavioral Strategies Scale. *Psychol Addict Behav.* 2007; 21(3):307.

85. Martens MP, Martin JL, Littlefield AK, Murphy JG, Cimini MD. Changes in protective behavioral strategies and alcohol use among college students. *Drug Alcohol Depend.* 2011; 118(2):504-507.

86. Kenney S, Napper L, LaBrie J, Martens M. Examining the efficacy of a brief group protective behavioral strategies skills training alcohol intervention with college women. *Psychol Addict Behav.* 2014; 28(4):1041-1051.

87. Dimeff LA, Baer JS, Kivlahan DR, Marlatt GA. *Brief alcohol screening and intervention for college students (BASICS): A harm reduction approach.* New York, NY: Guilford Press; 1999.

88. Barnett NP, Murphy JG, Colby SM, Monti PM. Efficacy of counselor vs. computer-delivered intervention with mandated college students. *Addict Behav.* Nov 2007; 32(11):2529-2548.

89. LaBrie JW, Napper LE, Grimaldi EM, Kenney SR, Lac A. The efficacy of a standalone protective behavioral strategies intervention for students accessing mental health services. *Prev Sci.* Jul 2015; 16(5):663-673.

90. Henson JM, Pearson MR, Carey KB. Defining and characterizing differences in college alcohol intervention efficacy: A growth mixture modeling application. *J Consult Clin Psychol.* Apr 2015; 83(2):370-381.

91. Carey KB, Scott-Sheldon LA, Elliott JC, Garey L, Carey MP. Face-to-face versus computer-delivered alcohol interventions for college drinkers: A meta-analytic review, 1998 to 2010. *Clin Psychol Rev.* Dec 2012; 32(8):690-703.

92. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? *Transl Behav Med.* Mar 2011; 1(1):53-71.

93. Billieux J, Van der Linden M, Rochat L. The role of impulsivity in actual and problematic use of the mobile phone. *Appl Cogn Psychol.* 2008; 22(9):1195-1210.

94. Billieux J. Problematic Use of the Mobile Phone: A Literature Review and a Pathways Model. *Curr Psychiatry Rev.* 2012; 8(4):1-9.

95. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Q.* 1989; 13(3):319-340.

96. Walsh SP, White KM, Young RM. Over-connected? A qualitative exploration of the relationship between Australian youth and their mobile phones. *J Adolesc.* 2008; 31(1):77-92.

97. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management *Epidemiol Rev.* 2010; 32(1):56-69.

98. Birnbaum F, Lewis D, Rosen RK, Ranney ML. Patient engagement and the design of digital health. *Acad Emerg Med.* Jun 2015; 22(6):754-756.

99. Rosen RK, Ranney ML, Boyer EW. Formative research for mhealth HIV adherence: the iHAART app. *Proceedings of the 48th Annual Hawaii International Conference on System Sciences, IEEE & Computer Society Press,.* Jan 2015; 2015:2778-2785.

100. Chai PR, Rosen RK, Boyer EW. Ingestible Biosensors for Real-Time Medical Adherence Monitoring: MyTMed. *Proceedings of the 49th Annual Hawaii International Conference on System Sciences, IEEE & Computer Society Press.* Jan 2016:3416-3423.

101. Chai P, Lewis D, Rosen R, Ranney M, Boyer E. Crowd-Sourced Focus Groups on Twitter: 140 Characters of Research Insight. *Proceedings of the Hawaii International Conference on System Sciences.* Jan 2017:3746-3753.

102. McManus DD, Chong JW, Soni A, et al. PULSE-SMART: Pulse-Based Arrhythmia Discrimination Using a Novel Smartphone Application. *J Cardiovasc Electrophysiol.* Jan 2016; 27(1):51-57.

103. Rosen R, Kuo C, Gobin RL, et al. How Qualitative Methods Contribute to Intervention Adaptation: An HIV Risk Reduction Example. *Qual Psychol.* Apr 24 2017; Advance online publication: http://dx.doi.org/10.1037/qup0000093.

104. Rosen RK, van den Berg JJ, Vargas SE, et al. Meaning-making matters in product design: users' sensory perceptions and experience evaluations of long-acting vaginal gels and intravaginal rings. *Contraception.* Dec 2015; 92(6):596-601.

105. Rosen RK, McGarrity LA, Salmoirago-Blotcher E, Rich C, Rana A, Carey MP. Telephone-Delivered Mindfulness Training for People Living with HIV: A Qualitative 360 degrees Inquiry. *AIDS Behav.* Aug 1 2017; [Epub ahead of print].

106. Guthrie KM, Rosen RK, Vargas SE, et al. User input in iterative design for prevention product development: leveraging interdisciplinary methods to optimize effectiveness. *Drug Deliv Transl Res.* Jun 26 2017; [Epub ahead of print].

107. McWhorter J. Txtng is killing language. JK!!! 2013; Accessed August 1, 2017 at: https://www.ted.com/talks/john_mcwhorter_txtng_is_killing_language_jk.

108. Sobell MB, Sobell LC, Klajner F, Pavan D, Basian E. The reliability of a timeline method for assessing normal drinker college students' recent drinking history: utility for alcohol research. *Addict Behav.* 1986; 11(2):149-161.

109. Sobell L, Sobell M. *Alcohol timeline followback users' manual.* Toronto, Canada: Addiction Research Foundation; 1995.

110. Werch CE. Behavioral self-control strategies for deliberately limiting drinking among college students. *Addict Behav.* 1990; 15(2):119-128.

111. Breslin FC, Sobell LC, Sobell MB, Agrawal S. A comparison of a brief and long version of the Situational Confidence Questionnaire. *Behav Res Ther.* 2000; 38(12):1211-1220.

112. Pittman B, Gueorguieva R, Krupitsky E, Rudenko AA, Flannery BA, Krystal JH. Multidimensionality of the Alcohol Withdrawal Symptom Checklist: A Factor Analysis of the Alcohol Withdrawal Symptom Checklist and CIWA-Ar. *Alcohol Clin Exp Res.* 2007; 31(4):612-618.

113. National Institute of Alcohol Abuse and Alcoholism. NIAAA Council approves definition of binge drinking. *NIAAA Newsletter.* 2004; Winter 2004(3):3.

114. Wechsler H, Davenport A, Dowdall G, Moeykens B, Castillo S. Health and behavioral consequences of binge drinking in college: A national survey of students at 140 campuses. *JAMA.* 1994; 272(21):1672-1677.

115. National Institute on Alcohol Abuse and Alcoholism. Drinking Levels Defined. 2014; Accessed February 28, 2017 at: http://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking.

116. Skinner HA, Horn JL. *Alcohol Dependence Scale (ADS) user's guide.* Addiction Research Foundation; 1984.

117. Murphy CM, MacKillop J. Factor structure validation of the Alcohol Dependence Scale in a heavy drinking college sample. *J Psychopathol Behav Assess.* 2011; 33(4):523-530.

118. Matthews DB, Miller WR. Estimating blood alcohol concentration: Two computer programs and their applications in therapy and research. *Addict Behav.* 1979; 4(1):55-60.

119. Sobell LC, Maisto SA, Sobell MB, Cooper AM. Reliability of alcohol abusers' self-reports of drinking behavior. *Behav Res Ther.* 1979; 17(2):157-160.

120. Pedersen ER, Grow J, Duncan S, Neighbors C, Larimer ME. Concurrent validity of an online version of the Timeline Followback assessment. *Psychol Addict Behav.* Sep 2012; 26(3):672-677.

121. Rueger SY, Trela CJ, Palmeri M, King AC. Self-administered web-based timeline followback procedure for drinking and smoking behaviors in young adults. *J Stud Alcohol Drugs.* Sep 2012; 73(5):829-833.

122. Kahler CW, Strong DR, Read JP. Toward efficient and comprehensive measurement of the alcohol problems continuum in college students: The Brief Young Adult Alcohol Consequences Questionnaire. *Alcohol Clin Exp Res.* 2005; 29(7):1180-1189.

123. Peterson ET, Carrabis J. Measuring the Immeasurable: visitor engagement. 2008; Accessed December 1, 2017 at: http://www.verticalstudio.com/hs-fs/hub/74398/file-15425996-pdf/docs/web_analytics_demystified_and_nextstage_global_-_measuring_the_immeasurable_-_visitor_engagement.pdf.

124. McFadden DL. Health and academic success: A look at the challenges of first-generation community college students. *J Am Assoc Nurse Pract.* Apr 2016; 28(4):227-232.

125. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. *Arch Intern Med.* Sep 1998; 158(16):1789-1795.

126. Marlatt GA, Gordon JR. *Determinants of relapse: Implications for the maintenance of behavior change.* Alcoholism & Drug Abuse Institute; 1978.

127. Rollnick S, Heather N, Gold R, Hall W. Development of a short 'readiness to change'questionnaire for use in brief, opportunistic interventions among excessive drinkers. *Br J Addict.* 1992; 87(5):743-754.

128. Rohsenow DJ. Drinking habits and expectancies about alcohol's effects for self versus others. *J Consult Clin Psychol.* Oct 1983; 51(5):752-756.

129. Hester RK, Delaney HD, Campbell W. The college drinker's check-up: outcomes of two randomized clinical trials of a computer-delivered intervention. *Psychol Addict Behav.* Mar 2012; 26(1):1-12.

130. Suffoletto B, Kristan J, Callaway C, et al. A text message alcohol intervention for young adult emergency department patients: a randomized clinical trial. *Ann Emerg Med.* 2014; 64(6):664-672. e664.

131. Suffoletto B, Callaway C, Kristan J, Kraemer K, Clark DB. Text-Message-Based Drinking Assessments and Brief Interventions for Young Adults Discharged from the Emergency Department. *Alcohol Clin Exp Res.* 2012; 36(3):552-560.

132. Larimer ME, Cronce JM. Identification, prevention and treatment: a review of individual-focused strategies to reduce problematic alcohol consumption by college students. *J Stud Alcohol.* 2002; Supplment (14):148-163.

133. Food and Drug Administration Draft Guidance. Alcoholism: Developing Drugs for Treatment Guidance for Industry. Silver Spring, MD: U.S. Department of Health and Human Services, Food and Gruf Administration, Center for Drug Evaluation and Research 2015.

134. Little RJ, Rubin DB. *Statistical analysis with missing data.* 2nd ed. New York, NY: Wiley & Sons; 2002.

135. Shaefer JL, Graham JW. Missing data: Our view of the state of the art. *Psychol Methods.* 2002; 27:147-177.

136. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. Hillsdale, NJ: Lawrence Erlbaum; 1988.

137. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods.* May 2007; 39(2):175-191.

138. Carey KB, Balestrieri SG, Miller MB, Merrill JE, DiBello AM, Benz MB. Efficacy of the College Drinkers Check-Up for Student Drinkers Living Off Campus. *J Stud Alcohol Drugs.* Jul 2017; 78(4):571-579.

139. Eisenberg D, Goldrick-Rab S. Here's another reason why many community college students do not get their degree. 2016; Accessed December 1, 2017 at: https://theconversation.com/heres-another-reason-why-many-community-college-students-do-not-get-their-degree-56053.

140. Cronce JM, Larimer ME. Individual-focused approaches to the prevention of college student drinking. *Alcohol Res Health.* 2011; 34(2):210-221.

141. Localytics Localytics App Stickiness Index. Q2 2014; Accessed August 16, 2017 at: http://www.localytics.com/resources/app-stickiness-index-q2-2014.

142. Bock B, Rosen R. Creating technology interventions that are useful and used. Paper presented in the panel Facilitating cross-talk: How to bridge the interdisciplinary divides in mHealth intervention development. 2013 mHealth Summit; Gaylord National Conference Center, MD.

143. Brigham J, Schooley B, Rosen RK, Bock B. Introduction to Evidence-Based Mobile and Web Health Design and Analysis Minitrack. Proceedings of the 48th Annual Hawaii International Conference on System Sciences (HICSS); January 5-8, 2015, IEEE & Computer Society Press. doi: 10.1109/HICSS.2015.335, 2015.

144. Bock B, Thind H, Fava J, et al. Development of the Mobile Phone Attachment Scale. Proceedings of the 49th Annual Hawaii International Conference on System Sciences (HICSS); January 5-8, 2016, IEEE & Computer Society Press. doi: 10.1109/HICSS.2016.424, 2016.

145. Fox S, Duggan M. Mobile Health 2012. 2012. http://www.pewinternet.org/2012/11/08/mobile-health-2012/. Accessed August 1, 2017.