Title of Project: mHealth Delivery of a Motivational Intervention to Address Heavy Drinking Among College Freshmen

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Structured Abstract

Purpose: This innovative two-stage project studied the mHealth delivery of an alcohol intervention to college freshmen, adapting a proven intervention for delivery through mobile technology. Our aims were to develop a Smartphone (SP) application (app) by adapting a brief motivational interviewing (BMI) intervention to create the pBMI+SP using mHealth technology, and 2) to test the pBMI+SP feasibility and initial efficacy among heavy drinking college students.

Scope: Alcohol abuse is a serious health issue facing today's college students. Alarming numbers of underage college students drink heavily, often in binges and with considerable risks. Interventions targeting risky alcohol use among college students have historically been effectively administered in person. In-person interventions face significant barriers such as cost and access. To address these barriers, mHealth interventions are beginning to appear targeting various health behaviors. We created and tested an evidence-based app intervention based on the behavior change techniques of BMI and ecological momentary interventions (EMIs) targeting risky drinking among college students.

Methods: In Stage 1 ($N = 10$), we developed an SP application by adapting a proven In-Person BMI intervention to create the pBMI+SP using mHealth technology. Then we tested pBMI+SP through iterative theater testing, field testing, and focus groups to identify needed modifications. In Stage 2 ($N = 377$), we conducted a randomized controlled trial (RCT) testing the efficacy of pBMI+SP with an evidence-based in-person BMI.

Results: In Stage 1, we found that the pBMI+SP app was acceptable with good usability of pBMI+SP as a feasible intervention targeting risky alcohol use in college students. In Stage 2, we found pBMI+SP is more convenient for participants (mandated & voluntary) and the app-based self-monitoring with personalized feedback features increases compliance with study protocols.

Key Words: mHealth, alcohol abuse, brief motivational interviewing, ecological momentary intervention, college students

1.   PURPOSE (Objectives of Study)

We designed an innovative app intervention to address underage drinking by college students and tested its feasibility and acceptability. We examined this mobile health (mHealth) approach to determine if it had greater reach, adoptability, portability, and sustainability than current in-person approaches. We explored the use of mobile devices as an innovative delivery method that had greater appeal to the target population. To accomplish this, we modified the in-person brief motivational interviewing (BMI) intervention for use with mHealth technology as the method of delivery of a new Health IT intervention (pBMI+SP). We adapted the intervention to make it effective with this method of delivery. Once modifications were complete, we examined the feasibility of pBMI+SP use by conducting theater testing and pilot field testing to determine acceptability with the college population. Our project included a randomized controlled trial to compare delivery of pBMI using a smartphone (SP) application (or "app") with a BMI delivered in person.

Our study aims were to develop a smartphone application by modifying an existing face-to-face BMI intervention (Aim 1, Stage 1). *Aim 1* had three sub-aims which included (a) developing the app, (b) conducting theater testing to obtain feedback on the clarity, usability, and acceptability of the content, and (c) making modifications to the app based on feedback from the theater testing.

Aim 2 was to conduct a pilot randomized controlled trial (RCT) to obtain data on the feasibility and efficacy of a smartphone application and to refine the application based on feedback (Stage 2). Two sub-aims included (a) conducting randomized field testing comparing the smartphone application with the face-to-face (in-person) BMI intervention on alcohol use and outcomes in college students and (b) making final modifications to the smartphone application to prepare for a full-scale efficacy trial.

2.   SCOPE

Background:

Alcohol abuse is a serious health issue facing today's college students. Alarming numbers of underage college students drink heavily, often in binges and with considerable risks (e.g., blackout, rape, HIV-related sexual risk-taking, academic failure, suicide, and violence). Substantial research has demonstrated that in-person BMI interventions reduce the risks of alcohol misuse and its harmful consequences in this population. However, as with many evidence-based interventions in the alcohol field, widespread implementation has been slow, due in part to feasibility issues in training staff and providing ongoing in-person services, but also to the costs associated with sustaining such an intervention on college campuses. Computerized interventions (e.g., through PC, CD-ROM, or web-based) have shown promise, providing participants with personalized feedback. Newer technologies, such as widely-used smartphones, may provide an even more efficient means of healthcare delivery for college students since they are accessed by young people multiple times a day. Little research, however, has addressed innovative programs using mobile technologies and applications (e.g., mHealth) to address alcohol issues in college students; the only existing studies used computer screenings and handheld devices for electronic interviews. Researchers are now investigating alternative delivery modes, such as technology-based interventions[1,2,3]. Technology-based interventions seem to be extremely applicable to college students, as this "Net Generation" has grown up with digital technologies including mobiles apps, text messaging, and online chat[4]. Additionally, young adults from 18-24 spend the most time on smartphone apps compared with

adults 25 and older, as they engage with apps for 66% of their total digital media time[5]. This specific mobile technology represents a prime intervention delivery mode for current college students, with early evidence of app-based interventions' effectiveness at promoting healthy behaviors in young adults[6].

In spite of the promise of app-based interventions, there is a dearth of available apps that have been rigorously tested[7] or are evidence-based[8]. Further, the majority of available apps that are focused on alcohol approach the subject with entertainment in mind (i.e., drinking games)[9,10], with few focusing on alcohol reduction[10], and even fewer containing validated behavior change techniques[7,9]. In attempts to address this lack of alcohol-reduction apps, some researchers are investigating new app-based interventions targeting risky drinking behavior, finding preliminary evidence in favor of their effectiveness[11,12,13,14,15,16].

To contribute to this body of evidence-based mobile app interventions, we created a smartphone application (pBMI+SP) aimed at reducing risky alcohol use among college students. pBMI+SP was informed by the theoretical behavior change techniques of motivational interviewing (MI)[17] and ecological momentary interventions (EMIs)[18]. MI is a therapeutic style aimed at reducing ambivalence and bolstering motivation and commitment to change behavior[17]. EMIs are often used with mobile devices so that they can be administered in real time and in the natural environment[18,19]. Both techniques have been found to be effective in reducing alcohol use and consequences.

After initial development by the research team (Stage 1), the app-based intervention was enhanced through theater testing, field testing, and focus groups. These modifications were then tested on a larger scale through an RCT, comparing the app-based intervention with an in-person BMI control group.

Context:

We developed a suite of mobile features in an app that enabled effective communication and interaction with students enrolled in the pBMI+SP arm of the study. The mobile app was used for a wide variety of purposes, including data collection, intervention, behavior tracking, incentive offering, and education. The original BMI was refined to enhance treatment appeal, improve portability and impact, reach broader audiences, and be more cost effective. We wanted to identify the elements/modalities of smartphone delivery associated with behavior change. This project translated BMI principles and used smartphone delivery to enhance motivation and commitment to changing problematic behavior. By using the electronic devices and applications that are ubiquitous with today's students, our innovative treatment modality represents a shift in the current clinical implementation paradigm by combining an efficacious in-person BMI intervention with enhanced mHealth technology for delivery. Our study was among the first to test the feasibility of delivering BMI interventions using mHealth technologies.

Settings:

The study took place at the University of North Carolina at Charlotte (UNCC), a large public university in the southeastern United States. This project participants were from the population of freshmen enrolled at UNC Charlotte. Total enrollment in fall 2014 was 25,277, including 4,798 freshmen; total enrollment is expected to increase to 35,000 students in 2020. UNC Charlotte students come from 98 NC counties, 44 states and more than 80 countries. UNC Charlotte is the largest institution of higher education in the Charlotte region; 64% of students are Caucasian and 36% are minority (African American, Hispanic, American Indian or Asian).

Participants:

In Stage 1 (AIM 1), participants (*N* = 10) were eligible if they: (a) were enrolled as an undergraduate at the university, (b) owned an iPhone, (c) were able to communicate in English, and (d) had consumed alcohol on at least one occasion in the past month. Ten undergraduate students participated (5 men), with a mean age of 22.7 and of whom the majority were freshmen.

In Stage 2 (AIM 2) of the study, we examined the efficacy of the pBMI+SP intervention with mandated and voluntary college students engaging in risky alcohol use. In both groups, participants were enrolled in classes from the same large, public university in the Southeastern U.S.

Mandated participants (Group 1) were students mandated to a BMI following a campus alcohol policy violation. A total of 141 mandated students including 57 women and 84 men agreed to participate and were randomized to either an in-person BMI condition (*n* = 70; 42 men) or an app-based intervention (*n* = 71; 42 men). The average age was 18.94 (BMI group) and 19.3 (app-based group). The majority of the mandated participants (*N* = 141) were men (59.6%) and Caucasian (63.8%). For Group 1, stratified block randomization[20] with a men to women ratio of 3:2 was used to randomly assign participants to the in-person and pBMI+SP conditions. Randomization was created using R package "blockrand", which is a package for the randomization for block random clinical trials.

Voluntary participants (Group 2) were students recruited from a psychology research pool (SONA). A total of *238* undergraduate students volunteered to participate, including 164 women (69%) and 74 men (31%), and were predominantly Caucasian (41%). Study 2 participants randomly selected to participate in either the app-based intervention (SONA 2; *n* = 81; 32 men) or an assessment-only control group (SONA 1; *n* = 157; 42 men). The mean age for both conditions was 19 years. Both SONA groups completed surveys at baseline and 6-weeks.

Incidence: Prevalence:

Heavy alcohol use is a major public health concern, resulting in significant costs nationally, causing over 88,000 deaths annually, and contributing to short- and long-term health risks such as injuries and cancer[21]. The consequences for young adults are especially pertinent, as alcohol consumption and alcohol-related risks peak between the ages of 18 to 25[22]. Individuals aged 18 to 25 engage in higher rates of binge drinking (i.e., five or more drinks per drinking occasion for men, four or more for women) and heavy alcohol use (i.e., binge drinking on five or more days in one month) than other age groups[23]. The risk for college students is even more salient, as college students have been found to misuse alcohol, to engage in heavier drinking, and to suffer from alcohol-related problems more than their non-student peers[2,24]. Further, a recent survey from the American College Health Association (ACHA) found that 67% of college students report consuming alcohol[25]. As a result of their drinking, 12% were physically injured, 35% did something that they later regretted, 29% had memory loss, 3% seriously considered suicide, and 22% engaged in unprotected sex[25]. Additionally, more than one third of college students report engaging in heavy episodic drinking (4+/5+ drinks in a single sitting for women/men) at least once in the past two weeks[3(26)], and 8% (women) to 20% (men) consume at least twice on a binge (i.e., 8+/10+ drinks)[4(27)]. High-quantity drinking is accompanied by substantial negative consequences for both drinking and non-drinking students, with annual rates of 646,000 physical assaults, 97,000 sexual assaults, 599,000 unintentional injuries, and even 1,825

deaths[5(28)]. Additional adverse effects experienced by college student drinkers include blackouts, academic underperformance, and social/interpersonal problems[6(29)]. Alcohol use among students also results in secondary effects on the campus environment[7(30)]. Mandated college students are at even higher risk since they are individuals who have received a disciplinary sanction from the university due to their misuse of alcohol (i.e., underage drinking). Mandated college students have been found to differ from a voluntary group of college students, in that they often report heavier drinking and more drinking consequences[31,32,33,34], and are less responsive to interventions and more resistant to change than voluntary students[32,33,34].

3.   METHODS

Study Design:

To address our two main aims, we conducted the study in two stages. First in Stage 1 (Aim 1), we developed a suite of mobile features in an app that enabled effective communication and interaction with students enrolled in the pBMI+SP arm of the study. The mobile app was developed with a wide variety of purposes, including data collection, intervention, behavior tracking, incentive offering, and education. The application used mobile web service features that enabled the application to communicate securely with a remote server. The server stored the users' sensitive data and provided user authentication, management, alerts, and other services. User notifications were provided using in-app alerts that were provided and supported by the web server. The data server was implemented using noSQL databases to provide a secure, scalable approach for managing online data storage and retrieval. The data collected were stored on a secure server that was only accessible to the research team for analysis. Users registered a user name and password to identify them with the mobile application. Multi-factor authentication was required in which users registered an email address that was used to send an authorization token to verify the user identity during registration. The app was developed as a hybrid mobile app that enables its deployment on the Android mobile platform, iOS, and Windows.

In Stage 1 we developed the pBMI+SP application that targeted college students and aimed to reduce risky alcohol use. The app was developed by the research team over the first nine months. The investigators from multiple disciplines developed the pBMI+SP app (e.g., nursing, computer science, mathematics) along with experts in product design and graphics. The app features were designed to be easy to use and have interactive components, including text messages, that incorporate MI and EMIs. After development, we conducted iterative theater testing, field testing, and focus groups to evaluate the acceptability of the app with college students. Participants were assigned to 2 groups (Group 1 [*n* = 4], Group 2 [*n* = 6]). At baseline, participants completed 2 standardized surveys. During theater testing, the facilitator demonstrated the app functionality to participants, downloaded the app on each person's phone, and answered any questions about the app. After theater testing, participants then completed field testing, by using the app for one or two weeks (depending on which group they were in). Participants used the app for a different number of weeks to help identify how long the intervention should take place. After field testing, participants were invited to take part in focus groups to gather more in-depth information about the usability and acceptability of the app. After the participants provided feedback in the focus groups, modifications to the app were made to prepare for the RCT. Information gathered from Stage 1 was used to finalize the pBMI+SP intervention that users received in Stage 2 of the study.

In *Stage 2*, we conducted an RCT to test the efficacy of the app. Participants from Group 1 were mandated (i.e., received a disciplinary sanction from their misuse of alcohol) to receive an

intervention. After an intake meeting determining eligibility, individuals were invited to participate in the study and completed informed consent. Individuals were randomized to participate in either the face-to-face BMI intervention or the app-based intervention. Both the in-person and app groups completed baseline surveys in person and 6-week surveys electronically. The in-person group was administered two hour-long motivational interviewing sessions. The app group used the app every day over two weeks. Additionally, we had a voluntary group (Group 2) that was recruited via the psychology research pool (SONA). Participants could randomly choose to participate in either an assessment-only control group (SONA 1; completing baseline and 6-week surveys electronically) or an app group (SONA 2; completing the baseline survey in person and the 6-week survey electronically). Individuals participating in the app group had the app downloaded on their phone for them to use over two weeks.

Data Sources/Collection/Analysis:

In *Stage 1 (AIM 1),* participants were asked to provide basic demographic information and fill out surveys online at the baseline session. Their responses were used to create user profiles. These, in turn, were used to generate each user's personalized feedback and text messaging transcripts. Data were also extracted from audio-recorded focus groups to identify needed modifications to the app and to determine what aspects of the app were most well received. Data on usage patterns were also collected via user input through the app.

In *Stage 2 (AIM 2),* baseline surveys were web-based and administered either in person (both mandated groups and voluntary app group) or via the app (control group). The baseline surveys generated personalized feedback that was accessible to both mandated groups and the voluntary app group. Individuals in the face-to-face group provided information about their drinking habits over two weeks via a paper and pencil log. Individuals in the app groups provided information about their drinking habits over two weeks via the app. App usage patterns were also gathered via user input through the app. An app satisfaction survey was administered to the app groups in person via the web after two weeks. Finally, all groups completed 6-week surveys electronically. Data analysis for Stage 2 compared the demographics and drinking related outcomes at baseline between the two groups from Group 1 (pBMI+SP versus in-person) to see if they are homogenous in characteristics of baseline profile. Similarly, we did the same comparison for Group 2 (the SONA 1 group versus the SONA 2 group). Wilcoxon rank sum test[35] was used for continuous variables and Pearson's Chi-squared test[36] was used for categorical variables. Drinking related outcomes including Blood Alcohol Concentration (BAC) levels and seven survey scores (DDQ survey, AUDIT survey, CEA survey, YAACQ survey, PBSS survey, Readiness To Change survey, Importance and Confidence rulers) were tested for differences from baseline to six-weeks within each group. Wilcoxon signed rank test with continuity correction for both continuous and nominal variables and McNemar–Bowker Chi-squared test[37] for categorical variables were used. The change in alcohol use related outcomes from baseline to six-weeks in the two groups were compared using Wilcoxon rank sum test.

Interventions:

pBMI+SP App-based:
    At the baseline session, participants filled out demographic information and surveys. This information was used to create a user profile from which personalized feedback and the text messaging transcript was generated. Research assistants demonstrated the app capabilities to participants after they completed the baseline assessments. The participants were then instructed to use the app over two weeks for at least five minutes a day. The app-based intervention incorporated many features aimed at promoting

motivation to change drinking habits through fun and interactive tools. The app is based on EMI and MI techniques, which have been found to promote motivation to change[38] and help reduce risky drinking in in-person[39] and technology-based settings[18,19,38]. There are eight main components, including *My Coach, Feedback, Strategies, Know Your BAC, Daily Log, Learn More, Games,* and *Where to Go*. *My Coach* sends the app user daily messages of different formats (e.g., myths and facts, inspirational quotes, daily drinking activity) to elicit engagement with the app. The coach tailors the messages based on user characteristics and reported level of motivation to change. *Feedback* contains personalized normative feedback based on user input from the baseline surveys. Feedback is presented in text and graphical form relating information such as drinking patterns and relation to health, risks of drinking, and protective behaviors that can be used to reduce risky drinking behavior. *Strategies* allows app users to select as many or as few protective behavior strategies that will help them to promote healthy drinking behaviors. Examples of strategies include: dropping a glass size, planning ahead drinking occasions, and limiting number of drinks or BAC. *Know Your BAC* contains two sections—one that gives information about how to calculate a BAC and one that provides a BAC calculator, which can help app users approximate their BAC during a specific drinking occasion. *Daily Log* allows users to record their daily alcohol consumption for yesterday or today, and monitor their consumption based on entries over time. *Learn More* contains sections which include facts about alcohol and other topics (e.g., Alcohol and the Law). *Games* incorporates an interactive trivia game to help users learn about alcohol and a game in which participants can indicate which of two listed drinks contains more alcohol (called "Winning Rounds"). *Where to Go* contains information to help users consuming alcohol to travel safely (via taxi or Uber), university resources that are available to app users, and friends' phone numbers. After two weeks, the participants finished using the app and completed a satisfaction survey.

BMI In-Person:

Procedures included the delivery of BMI following intervention protocols. The initial session was delivered face-to-face for BMI participants. Interventionists oriented students to the program, built rapport, encouraged commitment, and assessed drinking history and behavior (consumption, consequences, beliefs, and readiness to change). Students completed questionnaires to assess their alcohol use and its negative consequences. Interventionists explained the BAC card that contained BAC levels by sex, weight, and number of standard drinks. BAC levels are color coded based on physical effects and severity. Students were given an alcohol self-monitoring tracking card to return at the two-week visit and a manual to review at home. The manual contained information related to alcohol, including definition of a standard drink, comparison of alcoholic beverages and their alcohol content, physiological effects on the body, myths, BAC, biphasic curve, expectancies, tolerance, high-risk situations for overdrinking, risk reduction techniques, safe drinking guidelines, and assertiveness and drink refusal skills.

Measures:

Stage 1 (AIM 1):
1.   **Readiness Ruler**[40] to assess an individual's readiness to change their drinking behaviors. The Ruler has a scale from 1 = *not important at all* to 10 = *extremely important*. Responses to the Readiness Ruler were used to provide individualized text messages aimed at helping individuals understand their drinking patterns.

2. **Daily Drinking Questionnaire**[41] to measure drinking patterns, including quantity and frequency of use, and daily peak drinking events over a typical week and averaged over the past month.

3. **Usefulness, Satisfaction, and Ease of use survey** (USE)[42] to assess the effectiveness of the app. It is a 26-item questionnaire measured on a 7-point Likert scale, where 1 = *strongly disagree* and 7 = *strongly agree*. Usability is measured in three dimensions: Usefulness (4 items), Satisfaction (7 items), and Ease of Use (15 items). Sample questions include, "I am satisfied with it," "It is useful," and "I learned to use it quickly."

4. **Satisfaction Survey** (developed by the research team) to assess participants' response to pBMI+SP. It is a 22-item measure which includes questions to elicit participants' opinions of pBMI+SP's features. Sample questions include, "Which pBMI+SP feature(s) did you like best and why? Which pBMI+SP feature(s) did you like least and why? On average, how much time did you spend on pBMI+SP each day?"

Stage 2 (AIM 2):
The following seven measures were administered at baseline and 6-weeks to determine changes in alcohol use and consequences among participants. Measure eight was used to determine app users' satisfaction with the pBMI+SP intervention.

1. **Daily Drinking Questionnaire** (DDQ)[43] to measure the frequency and quantity of alcohol consumed each day of a typical week and a peak drinking episode over the past month. We used the DDQ to calculate typical and peak BAC. Typical BAC is defined as the average of the BAC level over a typical week in the past month, and peak BAC as the peak BAC level based on alcohol usage in the past month. Typical BAC and peak BAC were calculated by the following formula: BAC = (A × 5.14) / (W × r) - .015 × H, where: A = total alcohol consumed, in ounces (oz.); W = body weight, in pounds (lbs.); r = the alcohol distribution ratio, 0.73 for men, and 0.66 for women; and H = time passed since drinking, in hours. The Daily Drinking Questionnaire (DDQ) measures the typical alcohol usage over a typical week in the past month and also the peak alcohol usage in the past month.

2. **Alcohol Use Disorders Identification Test (**AUDIT)[40] to identify alcohol misuse. This measure has been validated among college students and is calculated as a sum of items with possible values ranging from 0 = *Never* to 4 = *Daily or Almost Daily*. A score of 0 to 7 indicates low risk, a score of 8 to 15 indicates risky or hazardous drinking behavior, a score of 16 to 19 indicates likely alcohol dependence, and a score of 20 or higher indicates the highest risk in drinking. For example, participants were asked, "how often do you have a drink containing alcohol?" or "how often do you have six or more standard drinks on one occasion?" The higher the frequency, the higher the score is.

3. **Brief Comprehensive Effects of Alcohol (CEA) Survey**[45] to determine participants' expectancies of alcohol's influence on specific effects, and whether these influences are good or bad. The 15-item measure assesses positive (e.g., "I would be courageous") and negative (e.g., "I would take risks") effects with a 4-point scale (1 = *Disagree* to 4 = *Agree*) and valuations of these expectancies using a 5-point scale (1 = *Bad* to 5 = *Good*).

4. **Young Adult Alcohol Consequence Questionnaire** (YAACQ)[46], a 48-question screen, to assess past month alcohol consequences. This measure has demonstrated high internal consistency (alpha = .89) for evaluating changes in alcohol consequences[47]. Response options are rated dichotomously (yes/no) to indicate whether that consequence has been experienced in the past month. Each item is scored as either 0 = *No* or 1 = *Yes*. As the scoring is dichotomous, the total score will reflect the

total number of consequences that the individual has experienced in that time frame. Additionally, the frequency of experienced consequences in the past month is also determined (0 = *1-2 times*, 1 = *3-4 times*, 2 = *5-9 times*, 3 = *10 or more times*)[48].

5.   **Protective Behaviors Strategies Scale (PBSS)**[49] to determine how frequently the participants used specific strategies while drinking. The participants were asked the degree to which they would engage in the 15 strategies when using alcohol, such as using a designated driver or avoiding drinking games. Each strategy is scored based on the frequency *Never* = 0 to *Always* = 5.

6.   **Readiness to Change Questionnaire (RCQ)** to determine which stage of change participants were in. It is a 12-item questionnaire that assigned individuals to the Precontemplation (i.e., not considering making any changes), Contemplation (i.e., thinking about changes and may have started a few), or Action (i.e., already actively making changes) stage. Participants were assigned to the stage with the highest score for that category.

7.   **Importance and Confidence Rulers**[50] to assess participants' willingness and readiness to change. Participants determined the importance of changing on a scale from 1 = *not at all important* to 10 = *very important*, and their confidence that they could have made the change on a scale from 1 = *not at all confident* to 10 = *very confident*.

8.   **Satisfaction Survey** (developed by the research team) to determine participants' opinions about pBMI+SP. This measure was administered to participants using the app after they had used the app for two weeks. It is a 22-item measure which includes sample questions such as, "Which pBMI+SP feature(s) did you like best and why? Which pBMI+SP feature(s) did you like least and why? On average, how much time did you spend on pBMI+SP each day?"

All surveys had high Cronbach's alpha values which illustrates high internal consistency. Cronbach's alpha values for the AUDIT survey (10 items), CEA survey (15 items), YAACQ survey (48 items) and PBSS survey (15 items) were all above 0.8, and that of the Action sub-survey (4 items) in RCQ survey (12 items) was 0.86. Therefore, we can say the set of items are closely related as a group. It demonstrates a high scale reliability of these surveys.

Limitations:

Stage 1 (AIM 1):
While in the development stage of the app, we experienced limitations which could influence the results. These included a small sample size that was drawn from a specific public university in the southeastern United States. In addition, since only 7 out of 10 participants completed the USE questionnaire could potentially limit generalizability, and bias the usability of the app. Despite these limitations, the participants were willing to inform research on pBMI+SP, a mobile-based intervention designed to reduce hazardous drinking.

Stage 2 (AIM 2):
Limitations included a sample size that was drawn from a specific public university in the southeastern United States, which could limit generalizability and self-selection in the voluntary sample and possible bias in this group. The voluntary groups (Sona 1 & 2) participants were from a convenient sample. Also, the study measures were self-reported, so the researchers depended on the participants to be truthful in reporting their levels of alcohol consumption.
Future investigations may expand the longitudinal design during a Phase II full-scale randomized trial.

4. **RESULTS** (Principle Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principle Findings:

Stage 1 (AIM 1): All 10 participants had consumed alcohol an average of 9.60 times (*SD* = 7.97) in the past 30 days, a value at the 95th percentile of the drinking frequency of the university students. On average, the typical BAC of all participants was 0.061 (*SD* = 0.042), with a range of 0.016 to 0.128. Six of the ten participants reported that the pBMI+SP app had a positive effect on their drinking less. One of the ten participants reported that the pBMI+SP did not have a positive effect and three were undecided. Results from the USE[41] (*n* = 7) indicate good usability of pBMI+SP. The average overall usability score was 5.97 out of 7 (*SD* = 1.20, α = .92). The three sub-scales and their average scores were, usefulness (*M* = 5.68, *SD* = 1.06, α = .78), ease of use (*M* = 6.03, *SD* = 1.24, α = .95), and satisfaction (*M* = 6.02, *SD* = 1.20, α = .65). The Satisfaction survey (*N* = 10) revealed that among the eight features (Games, Know Your BAC, Daily Log, My Coach, Strategies, Feedback, Where to Go, and Learn More), Games was the most frequently selected best feature (chosen by 8 of the 10 participants), with Know Your BAC selected second. Participants reported that Know Your BAC and My Strategies were most useful in monitoring alcohol intake, creating behavioral change plans, and reminding them of their goals. Participants also said that Daily Log, Coach, and Personalized Feedback to be the most useful. Half of the participants reported that Where to Go was the least useful feature of the app. Both focus groups responded favorably to pBMI+SP. Most of the participants (90%) felt that it was not a burden to report drinking and to keep a daily log. The Coach feature connected well with participants. Half of the participants enjoyed interactions with the Coach but also reported that they sometimes ignored information from the Coach. Half of the participants agreed/strongly agreed that they drank less while using pBMI+SP and six agreed that pBMI+SP had a positive effect on reducing their drinking. Participants also reported that it was fun to interact with pBMI+SP, to receive different types of messages, to track drinking with a personalized drinking profile, and to play the competitive Trivia Game, which enhanced their learning. Seven major themes were identified; pBMI+SP was described as very informative, user-friendly, and easy to navigate. Participants also suggested many additional features to add to pBMI+SP's daily log, settings, games, and login.

Stage 2 (AIM 2)

Mandated (Group 1): Group 1 enrolled 141 students (men: women=84:57) who completed the baseline survey. Of the total number, 70 participants were randomized to the standard BMI in-person group and 71 participants were randomized to the app-based pBMI+SP group. There was no significant gender difference between the two groups (p-value=0.7001), men: women is 42:28 and 42:29 respectively. The mean age of participants in the BMI in-person group was 18.94 (SD=0.80), and the mean age of participants (42 men and 29 women) in the app-based pBMI+SP group, was 19.13 (SD=2.55), no significant difference between the two groups. Participants in the BMI in-person group has a slightly higher first drinking age (16.68, SD=1.50) than participants in the app-based (pBMI+SP) group (16.08, SD=1.95), p-value is 0.0354 (Table 1). No significant difference in race, typical BAC and peak BAC at baseline between the two groups was observed. Of note, mean first drinking age of both groups were below the legal drinking age (21); and the average peak BACs in both groups, 0.094 and 0.135, were well above the .08 limit for operation of a motor vehicle by any driver.

Comparison between baseline and six-week follow-up drinking outcomes by group: The AUDIT scores at both time points (baseline, 6 weeks) for the BMI in-person and app based groups (pBMI+SP) were in the risky or hazardous drinking range. At baseline, both groups had experienced similar expectancies of alcohol-related consequences in the past month (CEA 1.22, 1.27 respectively). It is also important to note that the in-person BMI group had fewer alcohol-related consequences (YACCQ, 5.56) at baseline than the app-based pBMI+SP group (7.28). Between baseline and 6 weeks there was no significant change in both groups AUDIT, CEA, and YACCQ scores. The average typical BAC for the in-person BMI group increased at significant level (p-value=0.0114) at six-week while there was no difference in the peak BAC for this group. The app-based BMI+SP group also had a significant increase in the average typical BAC level (p-value=0.0076). While, average peak BAC dropped from 0.131 to 0.079 (p-value=0.0024) in the same group. Peak BAC of participants in the in-person BMI group is increasing slightly from 0.083 at baseline to 0.084 at six-week while it is decreasing from 0.131 at baseline to 0.079 at six-week in app-based p BMI+ SP group, however the difference between two groups was not statistically significant (p-value=0.1863).

Voluntary (Group 2): Group 2 also includes two groups, called sona1 and sona2. Sona1 for assessment solely as a control group enrolled 157 students (men: women=42:115). Of the total group, 157 finished the baseline survey and 101 (64.3%) participants completed the six-week survey. The Sona1 group was composed of 42 men and 115 women, 39% freshman and 10 students had previous alcohol or drug sanctions. Sona 2 the app-based group had 81 participants (men: women=32:49) enrolled. All participants have finished the baseline survey and 69 (85.2%) of them completed the six-week survey. The average age of participants in the Sona1 group was 19.87 (SD=2.84), and 19.84 (SD=3.10) for participants in Sona2. While, for those in the Sona2 group, the mean age was 19.84 (SD=3.10). There were 32 men and 49 women, 44% freshman, and 7 students had previous alcohol or drug sanctions. There was no statistically significant difference of the demographic information between two groups Sona1 and Sona2 in study 2 at 5% significance level, except first drinking age (p-value<0.0001), gender (p-value=0.0440), and typical BAC level at baseline (p-value<0.0001). There is no statistically significant difference of the demographic information between two groups Sona1 and Sona2 in study 2 at 5% significance level, except first drinking age (p-value<0.0001), gender (p-value=0.0440), and typical BAC level at baseline (p-value<0.0001)

Comparison between baseline and six-week follow-up drinking outcomes by groups: For Sona 1 and 2, we can see that there are similarities between the groups at baseline with mean AUDIT scores in the risky or hazardous drinking range (13.31 Sona1 and 13.77 Sona2 respectively). Both groups employ similar number of strategies when they are drinking (2.88 Sona 1 and 2.66 Sona 2). However, for the Sona 1 control group there were no statistically significant difference between baseline and six-week survey results. For Sona 2 group there is a significant reduction in the AUDIT score (p-value=0.0100), and YAACQ score (p-value=0.0066). For this group all of the baseline scores were higher than those of six week score in AUDIT, and YAACQ while the typical BAC is lower in baseline than in six week for Sona2 group. The AUDIT, CEA and YACCQ score decreased in Sona 2 app-based group significantly (p-value=0.010, 0.030 and 0.007, respectively).

Outcomes:

Stage 1:
We developed the pBMI+SP application designed to reduce risky alcohol use. After development, we conducted iterative theater testing, field testing, and focus groups to evaluate the acceptability of the app with college students. Results indicate good usability of pBMI+SP.

and satisfaction. Seven major themes were identified; pBMI+SP was described as very informative, user-friendly, and easy to navigate. Participants also suggested many additional features to add to pBMI+SP's daily log, settings, games, and login. **Stage 1** also identified salient issues that might arise from use and to create an intervention pairing mHealth technologies with MI and EMI theoretical constructs. During the iterative testing, we identified and updated pBMI+SP to address the resolutions to enhance the app usability and functionality. We developed pBMI+SP with a suite of features to enable effective communication and interactions with college students to address high-risk drinking. pBMI+SP has a wide variety of purposes, including data collection, intervention, behavior tracking, incentive offers, and education. Using variable methods (e.g., quantitative surveys, qualitative focus groups), we found that the majority of participants (90%) agreed that pBMI+SP was easy to use, and the information provided was useful and had a positive effect on decreasing their drinking. Using variable methods (e.g., quantitative surveys, qualitative focus groups), we found that the majority of participants (90%) agreed that to pBMI+SP's was easy to use, and the information provided was useful and had a positive effect on decreasing their drinking. The major themes that emerged endorsed to pBMI+SP's ability to motivate, encourage, and support reflection on drinking behaviors. Features included a choice of personal strategies to reduce drinking, self-monitoring on alcohol intake, and choice of coach. Participants' suggestions were used to modify the app. The major themes that emerged endorsed pBMI+SP.ability to motivate, encourage, and support reflection on drinking behaviors. Features included a choice of personal strategies to reduce drinking, self-monitoring on alcohol intake, and choice of coach. Participants' suggestions were used to modify the app.

mHealth Technology and Features

The app is composed of both a mobile and a server component, both components complement each other and provide different features. The app provided several features to provide information and motivational interviewing concepts to the participant.

App flow:
1. **Participant Survey:** Once the participant is enrolled, a username and password is assigned to the participant. Then the participant is asked to complete a survey that collects demographics, drinking behaviors, perception to change, and behavior metrics from the participant, which is delivered in the form of a comprehensive survey that is delivered through the server app. In addition, the survey asks the participant to provide the time of the day they prefer to receive push notification messages from the study server on the mobile app.
2. **Participant customized personalized feedback:** The survey responses are stored in the server, and are used to generate a participant profile and a personalized feedback.
3. **Mobile app setup:** After completing the survey the participant is asked to install the mobile app on their smartphone. The participant logs into the mobile app using the provided username and password associated with the participant. The participant is provided with a walkthrough the app to demonstrate the different features provided by the app.
4. **Coach Interactions:** The participant is then asked to interact with the coach through the mobile application and answer the coach questions. The coach interacts with the user and points the user to the access their personalized feedback.
5. **Daily Messages:** The participants are sent daily messages motivating them to adopt better behaviors and alternative strategies towards their drinking behavior. In addition, the daily messages ask the participants about their drinking behaviors and motivates them to log their drinks they have consumed so far for a given day. The daily messages also alert the participants to important features provided by the app such as the Learn More feature, Trivia

Games, and the Emergency features. Daily messages are delivered through the app throughout the 2 weeks of the study.

6. **Participant Monitoring and Logging:** The mobile app monitors the participants' usage of the app and generates reports that could be accessed by the study administrators through the administrator portal provided by the server admin portal.

Web and Database Server: The mobile app is complemented by the server app which provides the required storage, messaging and logic to support the mobile app. The server hosted the database used to store the user survey responses, profiles, logs, and app generated data. The server also provided the event and messaging services required to enable push notifications and coach features, for example the server provided schedule events that triggered the sending of push notifications to specific users based on the user provided preferences. The server was also used to provide the participants' onboardking surveys that were used to create the user profiles. The mobile app interacted with the server through web APIs which enabled the secure communication and delivery of content to and from the app. The user behavior was monitored and is stored on the server, which enabled the study administrator to make sure the participants are actively interacting with the app and recording their activity logs. The server was accessed by the study administrators though an admin portal that is protected by a username and password only provided to the study administrators. The admin portal provides data reporting and export features.

Stage 2:
We conducted a randomized controlled trial with mandated participants to compare delivery of pBMI using smartphone (SP) applications (or "app") with in-person BMI. The pBMI+SP group When comparing the change from baseline to six week between BMI in-person group and app-based (pBMI+SP), we can see that Peak BAC of participants in the in-person BMI group is increasing slightly from 0.083 at baseline to 0.084 at six-week while it is decreasing from 0.131 at baseline to 0.079 at six-week in app-based p BMI+ SP group, however the difference between two groups was not statistically significant (p-value=0.1863). For the voluntary groups the AUDIT, CEA and YACCQ score decreased in Sona 2 app-based group significantly (p-value=0.010, 0.030 and 0.007, respectively).

As expected pBMI+SP is more convenient for participants (mandated & voluntary) and the app-based self-monitoring with personalized feedback features to increase compliance with study protocols.

Discussion:

The aim of this project was to design an innovative app intervention to address risky underage drinking by college students and tested its feasibility and acceptability. To accomplish this, we modified the in-person brief motivational interviewing (BMI) intervention for use with mHealth technology as the method of delivery of a new Health IT intervention (pBMI+SP) (**Stage 1**). We adapted the intervention to make it effective with this method of delivery. Once modifications were complete, we examined the feasibility of pBMI+SP use by conducting theater testing and pilot field testing to determine acceptability with the college population. Then we conducted a randomized controlled trial to compare delivery of pBMI using a smartphone (SP) application (or "app") with a BMI delivered in person (**Stage 2**). From Stage 1, we identified salient issues that might arise from pBMI+SP use and created an intervention pairing mHealth technologies with MI and EMI theoretical constructs. During the iterative testing, we identified and updated pBMI+SP to address the resolutions to enhance the app usability and functionality. We developed pBMI+SP with a suite of features to enable effective communication and interactions with college students

to address high-risk drinking. pBMI+SP has a wide variety of purposes, including data collection, intervention, behavior tracking, incentive offers, and education. Using variable methods (e.g., quantitative surveys, qualitative focus groups), we found that the majority of participants (90%) agreed that pBMI+SP was easy to use, and the information provided was useful and had a positive effect on decreasing their drinking. The major themes that emerged endorsed pBMI+SP's ability to motivate, encourage, and support reflection on drinking behaviors. Features included a choice of personal strategies to reduce drinking, self-monitoring on alcohol intake, and choice of coach. Participants' suggestions were used to modify the app.

In **Stage 2**, based on this information and final modifications, we conducted an RCT to determine the efficacy of pBMI+SP on a larger scale. We found that when comparing the change from baseline to six week between BMI in-person group and app-based (pBMI+SP), we can see that there was no statistically significant difference between two groups. The groups are very similar in their drinking levels at the risky or hazardous range (AUDIT). As we hypothesized there was no significant difference in alcohol use and alcohol-related consequences between the mandated groups between baseline and 6 weeks. The app-based voluntary group (Sona2) demonstrated a significant decrease in the drinking, expectancies and consequences between baseline and 6 weeks when compared to the control.

Conclusions:

Widespread implementation of in-person, evidence-based interventions in the substance abuse field has been slow. This is due, in part, to feasibility issues in training staff, providing in-person services, and funding such interventions. Therefore, we created the pBMI+SP app to take advantage of students' smartphones as a platform for delivering a real-time alcohol intervention for college students with high-risk drinking behaviors. As expected there was no significant difference in alcohol use and alcohol-related consequences between the groups. This finding supports that the pBMI+SP and the in-person BMI intervention produced similar results. Testing with the voluntary groups was also promising with the app-based group decreasing drinking, expectancies, and alcohol-related consequences relative to the control group. For all app-based groups, this mHealth mobile approach had greater reach, adoptability, portability and sustainability than current in-person approaches.

Significance:

Our preliminary work and a sizeable literature[10 (51),11(52),12(53)] show that in-person BMI is effective in reducing high risk drinking and its consequences in college students; this project tested the translation to mHealth delivery, reaching more students who need it in a more sustainable and cost-effective manner. We developed and tested the feasibility and beginning efficacy of mHealth delivery of BMI. Since we found similar efficacy between to the in-person BMI intervention and pBMI+SP, we will develop a more definitive study of efficacy, sustainability, and cost-effectiveness of pBMI+SP. pBMI+SP is among the first empirically tested mHealth interventions developed using evidence-based, in-person behavior change techniques. Outcomes could be translated to address other health issues with new health IT interventions (smoking, obesity, etc.).

Implications:

Administration of mHealth interventions to address risky alcohol use in college students is able to reach a larger population and may be more accessible to college students who are avid users of technology. With reduced costs and reduced needs for staff training, time, and space,

mHealth interventions represent a prime delivery method to supplement or replace in-person interventions. pBMI+SP is an evidence-based intervention targeting risky drinking among college students, but this type of mHealth intervention can be modified for use in other health issues, including risky sexual behavior, HIV risk reduction, smoking cessation, and obesity. This project directly addressed the AHRQ program's interest in health IT pilot and feasibility studies to improve the quality, safety, efficiency, and effectiveness of healthcare. We addressed AHRQ's research area by developing the pBMI+SP. As expected, participants receiving pBMI+SP reported greater satisfaction with the intervention than those receiving BMI in-person and this suite of health IT features resulted in better outcomes.

Findings will be used to prepare for a Phase II full-scale randomized clinical trial that will have significant implications for adoption, implementation, and sustainability of health IT applications for alcohol misuse interventions with college students and other at-risk populations. The smartphone app approach also has the potential to be translated to address other important health issues, such as risky sexual behavior, HIV risk reduction, smoking cessation, and obesity.

List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study) with the following format:
https://www.ahrq.gov/research/publications/pubcomguide/pcguide1.html#refs

Kazemi DM, Borsari B, Levine MJ, et al. A systematic review of the mHealth interventions to prevent alcohol and substance abuse. J Health Commun 2017;22:413-432. PMID: 28394729.

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Kazemi DM, Borsari B, Levine MJ, et al. Real-time assessment of participants' responses to a mHealth app designed to reduce drinking. Psychological Services: Clinical Apps and Public Service Settings, in-press.

Publications in Progress.

Kazemi DM, Borsari B, Levine MJ, et al. mHealth brief intervention for hazardous alcohol use among college students: A randomized controlled trial. In progress*.*

Patent: The research team presented the app to the patent review panel at UNC Charlotte, which saw the potential of the app in enhancing the delivery of alcohol education based interventions. The patent committee voted to support the patent application for the app. The team has submitted patent application titled "ALCOHOL AND DRUG INTERVENTION SYSTEM AND METHOD" with number 15/476,023 filed on 03/31/2017.

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