# Can a Chatbot-delivered Alcohol Intervention Engage Users and Enhance Outcomes Over a Smartphone App? Development and Feasibility Testing of a StepAway 'Bot'

**NCT04447794**

**Principal Investigator:**
Patrick Dulin, PhD
University of Alaska Anchorage
3211 Providence Drive
Anchorage, AK 99508

**Sponsor:**
University of Alaska Anchorage
3211 Providence Drive
Anchorage, AK 99508

**Funded by:**

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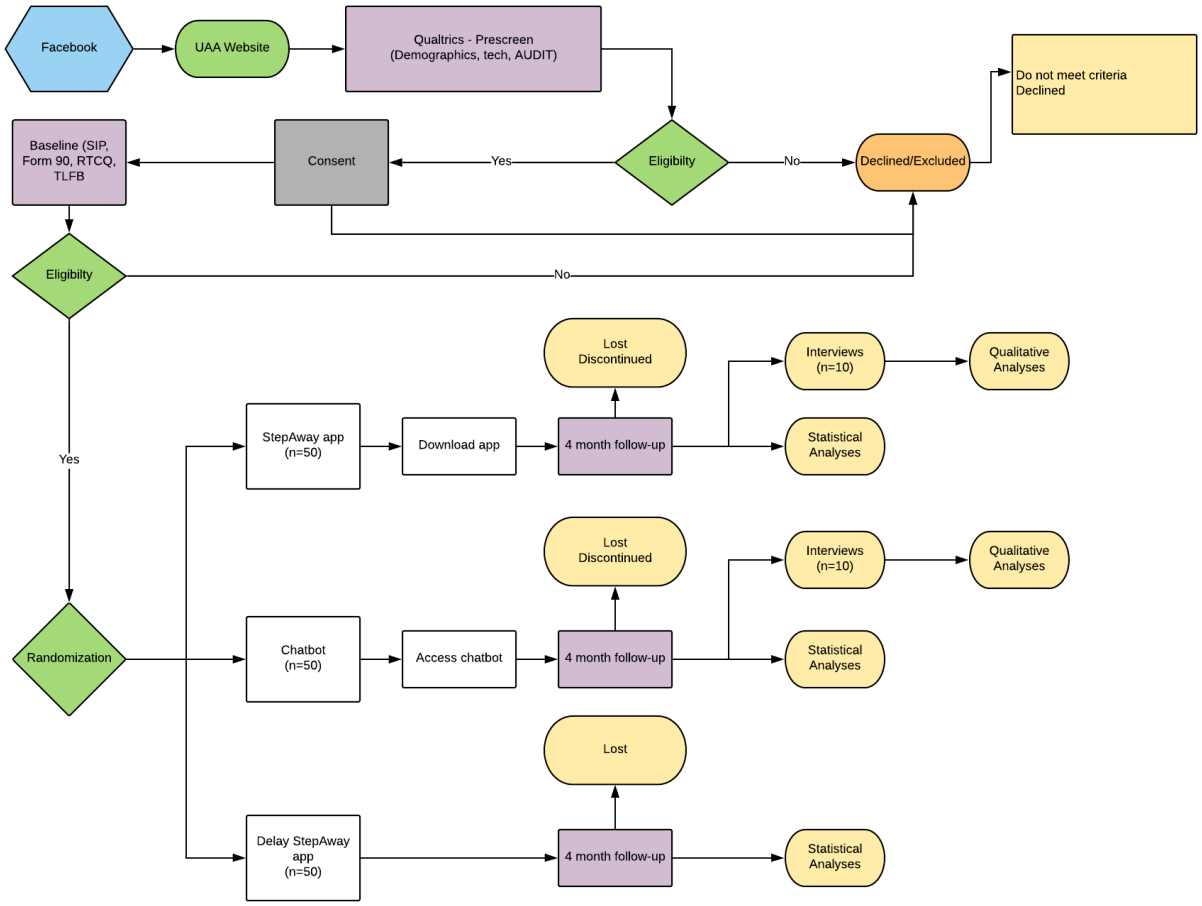
**Statement of Compliance**

The trial will be conducted in accordance with the ICH E6, the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the Terms of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

**Study Summary**

| | |
|---|---|
| Title | Can a Chatbot-delivered Alcohol Intervention Engage Users and Enhance Outcomes Over a Smartphone App? Development and Feasibility Testing of a StepAway 'Bot' |
| Methodology | Randomized controlled trial |
| Study Duration | Estimated duration of the primary protocol (i.e., from completion of baseline to completion of follow-up) is 4 months |
| Study Center | University of Alaska Anchorage |
| Objectives | 1. Develop a chatbot version of Step Away that delivers the interventions through an interactive format, and that proactively introduces the intervention features in a texting-based, narrative framework.<br>2. Conduct a pilot randomized controlled trial with a sample of problem drinkers (N = 150) to identify and compare differences in utilization and alcohol outcome efficacy between the Step Away chatbot, the Step Away app and a wait-list control condition.<br>3. Prepare for a larger RCT, the focus of which will be determined by the results from the pilot study. If one intervention demonstrates a clear superiority, it will be utilized in an RCT comparing it with usual care. If the effect size between groups is small to moderate, a larger RCT will be undertaken comparing the two interventions with a one-year follow up to determine differential effectiveness over time and moderators of effectiveness such as age, gender, alcohol dependence level and goal selection. |
| Number of Subjects | Approximately 150 randomized participants in 3 arms: app, chatbot, and delay (control) |
| Inclusion Criteria | • Are 18 years or older<br>• Have an iPhone or Android phone<br>• Are a U.S. resident<br>• Are not in another form of alcohol treatment<br>• Are actively drinking in the past 3 months<br>• Have English language proficiency<br>• Are not using another mHealth alcohol intervention<br>• Score on the USAUDIT between an 8 to 24 for males under 65<br>• Score on the USAUDIT between a 7 to 24 for females and males over 65 on the USAUDIT |
| Study Product | Step Away app, Step Away chatbot |

# 1. Schematic of Study Design



## 2. Key Roles

*Principle Investigator*
Patrick Dulin, PhD
University of Alaska Anchorage
3211 Providence Drive
Anchorage, AK 99508
pldulin@alaska.edu
(907) 786-1653

*Co-Investigator*
Diane King, PhD
University of Alaska Anchorage
3211 Providence Drive
Anchorage, AK 99508
dkking@alaska.edu
(907) 786-1638

*Project Manager*
Alexandra Edwards, MA
University of Alaska Anchorage
3211 Providence Drive
Anchorage, AK 99508
aeedwards@alaska.edu
(907) 786-5465

## 3. Introduction: Background Information and Scientific Rationale

Excessive alcohol use is the leading cause of preventable death in the U.S., responsible for 1 in 10 deaths among adults ages 20-64.[1,2] The National Epidemiological Survey on Alcohol and Related Conditions (NESARC) found that lifetime prevalence for an alcohol use disorder was 30.3% and 12-month prevalence was 8.5%.[3] This survey found that treatment utilization was very low, with only 14.6% of those who have ever had an alcohol use disorder reporting any type of prior treatment.[4] The tremendous gap between those needing and those receiving treatment argue for an urgent need to develop innovative strategies that have the potential to circumvent treatment barriers, particularly in light of the large costs to U.S. society associated with alcohol abuse, which in 2010 exceeded $249 billion,[2] with over 75% of those costs attributed to non-dependent binge drinkers.[5] An underutilized avenue to provide services to individuals who are not able or willing to attend face-to-face treatment is to leverage Americans' high use of smartphones, estimated at 2/3rds of the U.S. population.[6] In prior research funded by the National Institutes of Alcohol Abuse and Alcoholism (NIAAA), we developed a stand-alone, smartphone-based system to deliver empirically-based, ecological momentary alcohol assessment and intervention (EMAI) for individuals with an alcohol use disorder. Short-term results from a 6-week pilot test among individuals with an alcohol use disorder revealed that the system, the Location Based Monitoring and Intervention for Alcohol Use Disorders (LBMI-A), significantly reduced alcohol consumption and was rated by users as being very helpful in changing their drinking.[7] These promising results motivated the creation of a revised version of this intervention approach called Step Away that is currently available for use by individuals

with an iPhone. Step Away represents a substantial step forward in providing needed intervention to individuals through their smartphones but like other health apps, it has limitations related to sustaining user engagement, which is important for successful treatment of alcohol use disorders. This study will develop a new and innovative means of delivering Step Away through an artificially intelligent (A.I.) chatbot and will conduct a pilot test of the comparative effectiveness and user engagement differences between the Step Away app and the Step Away chatbot.

**Known Potential Benefits**

An intervention for alcohol misuse problems, via the Step Away chatbot and the Step Away app will be provided at no charge to participants. The project will contribute information on a new method for delivering and/or enhancing tools for people who are seeking to reduce their alcohol use, especially to those who otherwise are unable or unwilling to seek traditional alcohol misuse treatments. We believe the combined direct therapeutic benefits to participants and the new scientific information to be gained in the proposed study clearly outweigh the risks involved.

**Known Potential Risks**

Potential harms for participants include:

a. Confidentiality: potentially adverse effects if others learn that a participant is participating in an alcohol intervention.
b. Stress: related to completing questionnaires and interviews of a sensitive nature. However, the information obtained will have clinical value in that the participant's treatment and the assessment procedures are similar to those typically used in clinical work.
c. Exacerbation or worsening of alcohol intake or other psychiatric problems during the interventions. This may occur during the study with some participants but is a risk factor for all community treatment programs. All intervention systems will contain immediate access to help (suicide hotline, 911, military or veteran hotline if they indicate they are in the military or are a veteran and the phone number to the SAMHSA treatment helpline if the participant would like to find face-to-face intervention in their geographic area). There is the possibility that one of the apps will experience a crash during the study. Participants will be informed of this possibility upon signup and will be provided with the phone number for Here and Now Systems IT support to report the crash. They will also be given the phone numbers to the SAMHSA treatment helpline, suicide hotline and encouragement to call 911 if they are in an acute emergency and are unable to utilize one of the intervention systems.

The interventions offered in this protocol, although self-administered and delivered via a novel mechanism (smartphones), are consistent in terms of content with interventions for alcohol problems that have research evidence for efficacy (e.g., Relapse Prevention). Further, similar self-administered interventions delivered via smartphone, bibliotherapy and the internet have been shown to be effective in substantially reducing alcohol intake. We have developed procedures to deal with the potential issue of exacerbation associated with participation in this study (see below).

In all studies to date of Step Away (2 with U.S. Veterans and one in New Zealand) and its prototype, the LBMI-A (performed at UAA in 2012), no adverse events have been reported.

## 4. Study Objectives and Purpose

This project will finalize development of the Step Away chatbot, which has been in process for over a year, and create an improved user interface for the Step Away app. We will then conduct a pilot study that compares three conditions, both Step Away interventions (i.e., smartphone app and chatbot) and a wait-list control condition that will receive the app after a 3-month delay. The trial focus will be on determining if the Step Away chatbot has better user engagement with regard to improved utilization of the features, enhanced intervention fidelity and improved alcohol outcomes compared to the Step Away app. Qualitative interviewing of 10 participants in each intervention group will identify perceptions of each intervention's usability and potential barriers to utilization.

Specific aims:

1. Develop a chatbot version of Step Away that delivers the interventions through an interactive format, and that proactively introduces the intervention features in a texting-based, narrative framework.
2. Conduct a pilot randomized controlled trial with a sample of problem drinkers (N = 150) to identify and compare differences in utilization and alcohol outcome efficacy between the Step Away chatbot, the Step Away app and a wait-list control condition.
3. Prepare for a larger RCT, the focus of which will be determined by the results from the pilot study. If one intervention demonstrates a clear superiority, it will be utilized in an RCT comparing it with usual care. If the effect size between groups is small to moderate, a larger RCT will be undertaken comparing the two interventions with a one-year follow up to determine differential effectiveness over time and moderators of effectiveness such as age, gender, alcohol dependence level and goal selection.

## 5. Study Design

This study will consist of three phases. Phase I will focus on developing the AI chatbot version of Step Away, improving the Step Away app and developing procedures for the pilot study, including evaluating the different program elements using an expert panel. Phase II will entail a feasibility study that will contrast the Step Away chatbot with the Step Away app and an assessment and feedback-only app (the first step of the Step Away app but nothing else) utilizing a randomized, controlled study design. One hundred and fifty participants who are 18 years of age and older who screen positive for unhealthy alcohol use will be recruited throughout the U.S. with Facebook and Google ads. All participants will complete an online, baseline research assessment and a follow-up at 4 months, allowing a minimum of 3 months of intervention use. Three months of intervention use will allow enough time for participants to utilize all aspects of the intervention system (the set-up phase), extended exposure to the daily assessment and weekly feedback functionality and provide a mid-length follow up period. Data from the app and chatbot usage will be continually uploaded to a secure server to determine usage and treatment fidelity information for each intervention. In addition, 10 participants in the chatbot and app conditions will be interviewed based on their degree of engagement with each intervention to obtain their perspectives on each intervention's usefulness and barriers to engagement. (At the 4-month follow-up, all participants will be given the Substance Abuse and Mental Health Services Administration's (SAMHSA) national treatment locator helpline to identify treatment services in their area.) Phase III will focus on quantitative and qualitative data analysis, manuscript development, conference presentations, revisions to StepAway intervention based on findings

from this study, and design of a large-scale follow up trial to test the effectiveness of the improved intervention.

## 6. Participant Enrollment and Withdrawal

### Participant Inclusion Criteria

Participants will be eligible to participate in the study if they:

- Are 18 years or older
- Have an iPhone or Android phone
- Are a U.S. resident
- Are not in another form of alcohol treatment
- Are actively drinking in the past 3 months
- Have English language proficiency
- Are not using another mHealth alcohol intervention
- Score on the USAUDIT between an 8 to 24 for males under 65
- Score on the USAUDIT between a 7 to 24 for females and males over 65 on the USAUDIT
- Electronically sign the consent form

For the interviews, from back-end data capture we will determine high and low users by the amount of time they spend using the app or the chatbot. High utilizers will be selected from amongst those participants in the top third of each intervention's use (based on total frequency and duration of use) and low utilizers will be selected from those in the bottom third for each intervention. Only participants in either the app or the chatbot intervention groups will be randomly selected to be interviewed.

### Participant Exclusion Criteria

Participants will be excluded from participating if they indicate they are:

- more than 30 days abstinent at baseline
- in alcohol or drug abuse treatment currently
- pregnant or nursing
- having a moderate to severe level of alcohol use disorder, defined as having a score of 25 or higher on the USAUDIT
- unwilling or unable to complete follow-up assessment
- not residents of the U.S.
- unable to read or text in English

### Recruitment and Enrollment

Participant recruitment will be conducted through Facebook advertisements. The advertisements will provide a link to the study website which will describe the study and provide a link to the prescreen survey. Facebook analytics will be reviewed weekly by the graduate research assistant and project manager. Analytics will be reviewed on each of the ads for which ads are more successful at recruiting interested participants and the demographics the ads are more successful at recruiting. These analytics will inform how to alter advertisements if the sample being recruited is largely one race or gender. Recruitment will begin in June 2020 and will end when the target sample is reached.

*Prescreen*

A prescreen survey will be hosted through Qualtrics. It will survey for eligibility criteria which includes demographic questions and the US AUDIT screening questionnaire. Participants will be automatically directed to the consent form hosted on Qualtrics if they are eligible. They will automatically be directed to a debriefing screen and resources if they are not eligible. The AUDIT is the most widely used alcohol screening test in the world with more than 25 years of validation studies worldwide. We will use the USAUDIT, a recent adaptation of the original AUDIT that uses U.S. standard drink amounts and NIAAA drink limits. A score of 8 or greater on the USAUDIT suggests that they are at risk of experiencing significant problems from drinking alcohol. This cut point has been found to yield high sensitivity and specificity when compared to a number of criteria for problematic alcohol use (e.g., alcohol dependence); thus, numerous studies have found it to be an accurate screening tool for alcohol problems among numerous groups including women and older adults. In the current study, the standard cut point of 8 for men and 6 for women and men over 65 will be used to establish problem drinking. Participants with high likelihood of alcohol dependence, evidenced by a score of 25 or above will be screened out of the study.

*Target Sample Size*

The target sample size is a minimum of 50 participants per intervention arm (i.e., app group, chatbot group, delay group). This will provide adequate power to detect modest effect sizes, pre to post, in outcomes for pilot purposes. For the interviews, 20 participants (10 from the app group and 10 from the chatbot group) will be randomly selected and asked to participate.

*Participant Withdrawal or Termination*

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

## 7. Study Procedures and Schedule

This study will consist of three phases. Phase I will focus on developing the AI chatbot version of Step Away and developing procedures for the pilot study, including evaluating the different program elements using an expert panel.

Phase II will entail a feasibility study that will contrast the Step Away chatbot with the Step Away app and a wait-list control condition, utilizing a randomized, controlled study design. A face-to-face control condition will not be utilized in this study as research has indicated that mobile health apps reach a different population of potential users whom we want to recruit for this study. A minimum of one hundred and fifty participants who are 18 years of age and older who screen positive for unhealthy alcohol use will be recruited throughout the U.S. with Facebook advertisements. All participants will complete an online, baseline research assessment and a follow-up at 4 months, allowing a minimum of 3 months of intervention use. Three months of intervention use will allow enough time for participants to utilize all aspects of the intervention system (the set-up phase), extended exposure to the daily assessment and weekly feedback functionality and provide a mid-length follow up period. Data from the app and chatbot usage will be continually uploaded to a secure server to determine usage and treatment fidelity information for each intervention. In addition, 10 participants in the chatbot and app conditions will be interviewed based on their degree of engagement with each intervention to obtain their perspectives on each intervention's usefulness and barriers to engagement. (At the 4-month

follow-up, all participants will be given the Substance Abuse and Mental Health Services Administration's (SAMHSA) national treatment locator helpline to identify treatment services in their area.)

Phase III will focus on quantitative and qualitative data analysis, manuscript development, conference presentations and preparation of a large-scale follow up grant.

All screening, baseline, and follow-up assessments will be performed online through Qualtrics.

*Screening*

All participants will be screened for eligibility. A copy of the screening questionnaire is available in the appendix.

*Baseline*

- The Timeline Followback (TLFB) will be used to gather information on alcohol and drug use. The TLFB will be used to calculate the following drinking variables: average (mean) drinks per week, days abstinent, and heavy drinking days. Heavy drinking days will be defined as days with 4 or more standard drinks for women and 5 or more standard drinks for men.
- Short Inventory of Problems – Revised (SIP-R) will be used to assess the adverse consequences of substance use.
- The treatment history section of the Form 90 will be modified to be administered online at baseline and follow-up, to gather lifetime treatment history, self-help attendance, and treatment use.
- Readiness to Change. We will utilize the Readiness to Change Treatment Version (RCQTV), which RCQTV has been shown to have solid reliability and validity and has been modified for individuals contemplating or engaged in treatment for alcohol problems.

*Follow-Up*

The US AUDIT, TLFB, SIP-R, and Readiness to Change questionnaires will be used for the follow-up assessments. In addition, those in the app and chatbot groups will be asked to complete the System Usability Scale to assess their perceptions of the interventions' usability. The follow-up survey will be sent to participants at 4 months post-enrollment.

*Interviews*

Interviews will be conducted after the completion of the follow-up survey. Interview questionnaires will focus on users' experiences with the app or the chatbot. These interviews will be conducted over the phone.

## 8. Assessment of Safety

Several safety measures will be put in place to ensure the safety, comfort, and confidentiality of all participants. Care will be taken to inform potential participants fully before they consent to participate about all potential risks that may arise from their participation. The two most important aspects of participant protection in the proposed work are assuring the adequacy of informed consent (including full disclosure of all potential risks) and protecting confidentiality. To minimize risk, we will clearly explain all procedures to participants in our informed consent documents and clearly outline safeguards for confidentiality implemented in the study. Further, in order to protect their confidentiality, all participants will be encouraged to set a password to access their smartphone home screen.

Also, a Data Safety Monitoring Board (DSMB) will be convened in Year 1 of the project and will include the following two members with expertise in psychology, behavioral health, and

research ethics. The DSMB will meet twice during each year of the project to review the status of the project.

## 9. Statistical Considerations

All randomized study participants who complete both the baseline and follow-up surveys will be the primary population for the analysis. Three subgroups will be analyzed: the app group, the chatbot group, and the delay group.

*Outcomes, Statistical Methods, and Statistical Analyses*

All outcomes will be presented using descriptive statistics. Binary and categorical variables will be presented using counts and percentages. SPSS 27 will be used for all statistical analyses.

**Research Question 1:** Do participants reduce their alcohol consumption more when using the app or the bot?

**Hypothesis 1:** Participants using either the app or bot will show a significantly greater reduction in alcohol consumption and alcohol related problems than participants in the delay group.

**Method:** Repeated Measures Anova

Baseline and Follow-up data from the Alcohol Use Disorder Identification Test (USAUDIT), Short Inventory of Problems-Revised (SIP-R), Readiness to Change Questionnaire (RTCQ), and Timeline Followback (TLFB) will be compared between app, chatbot, and delay groups. Consumption data used from the TLFB will include drinks per day, percentage of days abstinent, and heavy drinking days. Average drinks per day will be calculated from the reported last 14 days of drinks. Percentage of days abstinent will be calculated as the percentage of days in the recent 14 days that participants reported 0 drinks. Heavy drinking days will be calculated as the number of days in the past 14 days that participants report drinking more than 3 drinks if they are an assigned female at birth or 4 drinks if they are an assigned male at birth. Repeated measures ANOVA will be ran to identify if there is an interaction between time and group. An interaction would indicate a significant difference between app, bot, and delay groups in the difference of their baseline and follow-up drinking data.

**Research Question 2:** Do participants utilize the app and bot differently?

**Hypothesis 2:** Participants in the bot group will utilize the intervention significantly more than the app group due to the intervention's conversational interface.

**Method:** Independent sample t-test

Utilization data will be collected from participants who use either the app or the chatbot. Three variables will be collected to measure utilization: total visits, duration of use, and total active days used. Total visits will be measured by the number of times a participant interacts with a feature of the app or the bot. Duration of use will be calculated as the amount of time in between a participants most recent visit to the app or bot and their date of installing the app or bot. Active days used will be calculated by the number of days a participant interacted with the app or bot. Utilization will be calculated for both app and bot users. Independent sample t-tests will be conducted between the means of each variable to determine if there were significant differences between app and bot users.

**Research Question 3:** Does utilization of the app or bot influence drinking outcomes?

**Hypothesis 3:** Utilization of the app or bot will mediate drinking outcomes, in that the higher the utilization of the intervention, the greater reduction of drinking the participant will have between baseline and follow-up

**Method:** Mediation analysis

Utilization data and TLFB data will be used in this analysis. A mediation analysis will be conducted with group as the independent variable, change in drinking as the dependent variable, and utilization as the mediator. Significant effects of usage on change in drinking will determine if utilization predicts change in drinking for either group. A significant indirect effect will determine if utilization mediates the relationship between group and outcome.

## 10. Ethics/Protection of Human Subjects

### Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

### Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

### Informed Consent Process

*Consent and Other Informational Documents Provided to Participants*

Copies of the consent documents, emails, and other outreach to participants are provided in the Appendix.

*Consent Procedures and Documentation*

A brief overview will tell participants who is conducting the research study, and that it involves trying out a program to address unhealthy alcohol use that involves a program delivered over their smartphone. They will be told that if they want to join the study they will be placed in one of three groups, and that all groups will be of no cost to them and that all programs will also ask them to do activities on their phone to help them manage their drinking. Also, they will be told that no matter which group they are in, they will be asked to complete electronic surveys two times during the study and will possibly be asked to participate in a short interview at the end of the study. They will also be informed that Dr. Dulin has a financial interest in the company, Here and Now Systems, LLC that owns the Step Away intervention and that results may inform future versions as commercial products. They will be informed that Dr. Dulin will not be involved in data management and analysis within this study and that those procedures will be performed by the UAA Center for Behavioral Health Research and Services (CBHRS) under the supervision of Dr. Diane King. They would then be asked to click ‘yes” if they are interested and would like to be screened to see if the study is right for them. If they assent to be screened,

they will be first told that all information they provide will be kept private, and that they can exit at any time. They will then electronically be asked all screening questions and an eligibility determination with be made and communicated to them. Those who are ineligible or who decide not to participate will be offered referrals to other substance abuse treatment services in the community.

Eligible and interested participants will then undergo an electronic informed consent (eIC) process, following guidance for Institutional Review Boards, Investigators, and Sponsors, described in a 2016 Procedural co-authored by the US Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), Center for Drug Evaluation and Research, and other federal agencies (www.fda.gov/downloads/drugs/guidances/ucm436811.pdf).

The eIC will contain all elements of a paper informed consent, will be written at an 8th grade or below reading level, and will include questions to gauge the participants understanding of the project purpose, risks, key study elements, and their right to withdraw without penalty, at any time throughout the study. Incorrect answers to questions related to the eIC elements will highlight areas where participants may need further explanation and will prompt a call from study staff to answer questions. Participants can also request a call to discuss the content of the consent prior to electronically signing. It should be noted that OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted (in this case, Alaska). Dr. Dulin will discuss all plans for using eIC with UAA's IRB before finalizing the eIC development, to assure it complies with institutional, state and federal regulations.

After completion of informed consent, participants will complete baseline assessments via the website. Following baseline assessment completion, participants will be randomly assigned to either chatbot or app versions of StepAway, or a waitlist to app, using a blinded, computer-generated random assignment code. This process will be repeated until at least 50 eligible participants are enrolled in each study arm.

In addition to the eIC that each enrolled participant completes at the outset of the study, each participant who agrees to participate in an interview will be provided with additional consent specific to the interview. As these will be done over the phone with participants who live across the United States, verbal consent will be requested and documented.

*Participant and Data Confidentiality*

Breach of confidentiality is a major source of potential risk and consequently, of utmost importance to us in all our research work. The confidential nature of all participant data to be collected will be emphasized to all members of the research team through staff training and written policies and procedures. Our research group has stringent confidentiality guidelines that must be followed by all staff members; staff members sign agreements that indicate that violation of confidentiality is cause for dismissal. Our facilities comply with all guidelines for the protection of data. Audio recordings will be uploaded to secure files and then deleted from all recording devices. Recordings will be labeled with the Participant ID number and the date of the interview; no identifying data will be included in the interview recording or associated transcription. Only project staff will have access to each recording and the resulting interview transcript.

A federal Certificate of Confidentiality is automatically granted to all research/studies receiving NIH funding as per grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm.

*Data Handling and Record Keeping*

Data will be collected digitally via app utilization data, participant completed electronic surveys (N=191), and through telephone interviews that will be audio recorded (N=10). If they agree to participate, each participant will have their interview audio-recorded and transcribed.

No data are stored on any individual PCs; all data reside exclusively on the secure server or removable media (as USB drives) that is secured in fire-resistant locked file cabinets, inside secure offices. Paper data and USB drives (i.e., all removable media for a PC) are secured in locked file cabinets in secure offices. Access to these file cabinets is limited to core project staff.

Research relating to research shall be retained for less than three years after the completion of research. Once hardcopy data are scheduled for destruction, UAA staff will either shred the data using their on-site large shredder or prepare data for shredding by a third-party. Third-party shredding is accomplished without compromising the confidentiality of respondents. Specifically, the way third-party shredding works is that data are bundled and secured in such a way that no identifiers are visible. The bundles are then inserted into a large truck-mounted shredder owned by a professional shredding company that is licensed, bonded, and insured. Electronic data destruction is guaranteed through the use of specially-designed software that wipes hard drives and makes data irrecoverable (rather than just deleting files, which can be recovered). Transcriptions are kept for no more than three years before the files are destroyed. Again, no identifying data will be included in either the audio recording or the resulting

Data collected through this study may be used for future research. This information is communicated via the consent form. Participants have an option to agree to be contacted about future research related to this project during the consent process. Participants who do not opt-in during the consent process will not be contacted.

All research data are received and maintained in strict compliance with the University of Alaska Anchorage Institutional Review Board Federal Laws and Regulations (42 CFR, Part 2). We are fully aware of and compliant with HIPAA regulations and have drafted HIPAA agreements with service agencies that provide research and evaluation data. We have developed extensive policies and procedures for the storing of confidential data.

Core project staff access electronic data via UAA secured server. No hard copy data will be collected. Electronically signed informed consent forms will be stored on a UAA secure server. Records relating to research shall be retained for no less than three years after the completion of research. Electronic data destruction is guaranteed through the use of specially-designed software that wipes hard drives and makes data irrecoverable (rather than just deleting files, which can be recovered).

In addition, in accordance with 45 CFR 46.116 (h), a copy of the IRB-approved consent form will be posted on ClinicalTrails.gov when the study is registered. The registration requirements listed on ClinicalTrials.gov will be followed, which notes that the PI (Patrick Dulin) or the sponsor (UAA) will upload the required study registration form (prsinfo.clinicaltrials.gov/Interventional_Study_Protocol_Registration_Template_Jan_2018.pdf), which includes study protocols. This will take place after the study is closed to recruitment, which will occur when each study arm has 50 participants enrolled.

*Conflict of Interest Policy*

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed

and managed. The following statement will be included in all consent information as well as the informational study website (www.uaa.alaska.edu/research/institute-social-economic-research/stepawaystudy/).

> *The Principal Investigator, Dr. Patrick Dulin, has a financial interest in Here and Now Systems, LLC, which owns the Step Away intervention system that participants will engage with as part of this study. Dr. Dulin will not participate in the data collection or data analysis pertaining to drinking outcomes and will not profit from the use of either the app or the chatbot in this study. It is important to note that he has a conflict of interest management plan in place with the University of Alaska Anchorage. Results from this study may inform future versions of Step Away to be sold as a commercial product.*
>
> *Due to this conflict of interest, another researcher at the University of Alaska Anchorage, Dr. Diane King, will oversee data collection, management, and analysis.*

**References**

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## Appendices

**Baseline Consent Form**

# University of Alaska Anchorage
# Consent to Participate in Research

## DESCRIPTION

You are being invited to participate in a study to see how a smartphone program, called Step Away, can be used to help people who want to change the amount of alcohol they drink. Those who participate in the study will receive either a mobile app or an interactive chat program (a "chatbot") to use on their smartphone. The study will enroll 150 adults nationally, who will participate virtually for 3 months. You will not need to travel or meet in person with anyone to participate in this study.

There are three parts to this study:

**Completing surveys**

You will be asked to complete survey questions online through Qualtrics at the beginning and end of the study. The survey will take about 60 minutes or less to complete and will ask you about how much alcohol you drink, how interested you are in drinking less, if drinking alcohol has caused any problems for you in the past, and if you have ever participated in treatment for alcohol use. The survey includes a mix of multiple choice and fill-in-the blank questions.

**Using the StepAway app or chat program (the "chatbot")**

You will be assigned by chance to receive either a mobile phone app (the StepAway app) or interactive chat version of the StepAway program (the "chatbot"). Your assigned program will be available to use either immediately after completing the first survey questions, or in 3 months, after you complete the second set of survey questions. Whether you can access the program immediately or in 3 months, all participants will get to use one of the two versions of the program.

**Interviews**

At the end of the study you may also be invited to participate in a short interview so that we can learn what participants liked or disliked about either program and get suggestions for making it more useful in the future.

## TIME INVOLVEMENT

This research study is expected to take approximately 4 months. The surveys will take about 60 minutes to complete each time. The mobile phone app or chatbot will be available to you 24 hours a day, 7 days a week for 3 months. During that time, you can use it as much or as little as you wish. If you are selected to participate in an interview, you will be conducted by phone and will take approximately 1 hour.

## PARTICIPANT RIGHTS

Being a part of this study is voluntary. In other words, whether you choose to be in this study or not is completely up to you. When completing the surveys or interviews, you are free to skip any questions you choose. If you choose to not answer any questions you will not lose any benefits or receive any penalties. You may also choose to leave the study at any time and you will not lose any benefits for receive any penalties.

## CONFIDENTIALITY

Your study data will be handled as confidentially as possible. Study staff will protect your personal information closely so no one will be able to connect your responses and any other information that identifies you. Directly identifying information (e.g. names, addresses) will be safeguarded and maintained under controlled conditions. You will not be identified in any publication from this study.

To help us protect your privacy we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below. The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.
A description of this study will be available on www.ClinicalTrials.gov as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.
We will keep any information you provide us completely confidential but we do not have control over information that will be on your smartphone. We encourage you to have a password or code enabled on your phone to keep the information you enter private.

**BENEFITS**
You will have no-cost access to technology-based help with reducing or stopping drinking. This approach has been shown to be helpful to people in prior studies. You may learn more about yourself and your habits through participating in this study. You may also learn helpful tips and tools that can help you to cut down or stop drinking alcohol. The information you provide by being a part of this study will also help us to help others who have an interest in reducing their how much alcohol they drink.

**PAYMENTS**
To thank you for your participation, you will receive an Amazon gift e-card worth $25.00 within one week of answering the first set of survey questions. You will receive an additional $25.00 Amazon e-gift card after completing the second set of survey questions. These gift e-cards will be emailed to you at the email address you provide. If your email or other contact information changes during the study, please notify thestepawaystudy@gmail.com.

**RISKS**
The questions may be stressful to answer. You may experience troubling feelings during the study such as guilt or sadness. There will be phone numbers and resources provided for you during the study if these feelings become overwhelming.

If you are given the chatbot to use, you will be entering information about your drinking through a social media platform, Facebook Messenger. Facebook indicates that they only monitor messenger-based data for offensive content but we cannot be sure of exactly how your data may be used by them.
We will contact you at one week and four weeks into the study to check if you have any concerns or technological difficulties.

**CONFLICT OF INTEREST DISCLOSURE**
The Principal Investigator, Dr. Patrick Dulin, has a financial interest in Here and Now Systems, LLC, which owns the Step Away intervention system that participants will engage with as part of this study. Dr. Dulin will not participate in the data collection or data analysis pertaining to drinking outcomes and will not profit from the use of either the app or the chatbot in this study. It is important to note that he has a conflict of interest management plan in place with the University of Alaska Anchorage. Results from this study may inform future versions of Step Away to be sold as a commercial product.

Due to this conflict of interest, another researcher at the University of Alaska Anchorage, Dr. Diane King, will oversee data collection, management, and analysis.

**FUTURE DATA USE**
We will keep your research data to use for future similar or related research. We may share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

**FUTURE STUDY PARTICIATION**
If you agree, we may contact you in the future to participate in a similar or related research study.
[checkbox] Please check this box if you allow us to contact you in the future for research studies similar to this one. You may withdraw your consent to be contacted at any time.

**CONTACT PEOPLE**
If you have any questions about this project or your participation in it, please contact:
Project Manager: Alexandra Edwards at 907.786.5465
Co-Investigator: Dr. Diane King at 907.786.1638
If you need technical assistance, please email thestepawaystudy@gmail.com or call Graduate Research Assistant Robyn Mertz at 907.786.2880.
If you have any questions or concerns about your rights as a research participant, please contact the UAA Office of Research Integrity and Compliance at 907.786.1099 or uaa_oric@alaska.edu.
We recommend you print a copy of this page to keep for future reference. We will also email you a copy at your request.
If you agree to take part in the research study, please confirm that you fully understand the above study, what is being asked of you in this study, and that you are voluntarily consenting to participate by clicking on the “Accept” button below.

**Two-Week Follow-up Call**

A 2-week check-in call will be given to all participants in the app and bot intervention group to assist with technology difficulties and to ensure the intervention is not causing harm to the participant. The GRA will enter the date of completed baseline surveys. When baseline survey data is entered into the spreadsheet, the spreadsheet will calculate the check-in call date (2 weeks after survey completion)

1. On the check in call date, graduate research assistant (GRA) will call the participant on the number provided in the spreadsheet
2. If the participant answers, GRA will read the check-in call script.
    a. If there are questions GRA is unable to answer, they will contact the project manager and email or call the participant back with the answer.
    b. GRA will enter the date into the spreadsheet of when the check in call was completed
    c. GRA will take notes during the check in call and save the notes to the tracking spreadsheet
3. If the participant does not answer, GRA will leave a voicemail from the voicemail script and enter into the spreadsheet the date and time of the missed call.
    a. The second attempt call date will be 2 days after the first failed attempt
    b. On the second attempt date, GRA will call the participant again at a different time of day
        i. If they answer, GRA will read the check in call script and record the date of the completed call in the spreadsheet
        ii. If they do not answer, GRA will leave the voicemail and record the date and time of the missed call
        iii. Third attempt will be email to set up a time to return call

The following script will be the check in call questions read to the participants.

> Hi, my name is _____, and I am a researcher on the Step Away project. I'm calling to ask a few questions about how your experience participating in the Step Away study has been going. Do you have a few minutes?
>
> Great. Thanks for taking the time to answer a few questions.
>
> *If they have downloaded:*
>
> Glad to see you have had the chance to download the app! How has the program been working for you?
>
> Have you encountered any glitches?
>
> Probe: Was there a time when you used the app and it didn't work the way you expected?
>
> What happened?
>
> *Provide tech assistance here if necessary.*
>
> *If they haven't downloaded:*
>
> It looks like we emailed you instructions for downloading the app on [date] but does not look like you have downloaded it yet.

Did you receive the instructions?

If no: Sorry to hear that. I'll resend the instructions right now. Please check your spam as well in case it sent there.

Have you had any challenges setting up the app?

*Assist with any challenges over the phone if possible and help them download the app.*

*If not possible over this call*: I will have someone contact you at this number shortly to help walk you through how to fix this glitch.

If you encounter any future glitches please contact us at uaa.stepawaystudy@alaska.edu.

Now I'm going to ask a few questions about your alcohol use over the past two weeks (so keep that timeframe in mind).

In the past two weeks, how often have you had a drink containing alcohol?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) 2-3 times a week
(5) 4-6 times a week
(6) Daily

How many drinks containing alcohol do you have on a typical day when you are drinking?

(0) 1
(1) 2
(2) 3
(3) 4
(4) 5-6
(5) 7-9
(6) 10 or more

How often do you have X or more drinks on one occasion? (5 for men under age 65; 4 for men aged 65 or older and all women)

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) 2-3 times a week
(5) 4-6 times a week
(6) Daily

Do you believe the Step Away app is causing you to drink more than you usually do?

Total AUDIT 1-3:

If 3 points above baseline:

It seems like you may benefit from further treatment. If you would like, I can connect you with some treatment centers in your area.

If yes: Do you have a few more minutes to stay on the line while I call for services in our area with you?

If yes: call 1.800.662.4357 and begin warm handoff (ask them what state they are from)

Hi, my name is ____ and I'm a researcher on a current alcohol study. I have ____ (name of participant) here on the phone line with me and they are interested in finding services in _____ (their state). Can you help connect them?

If no: What email would you like me to send the resources to?

(findtreatment.gov/ or call 1.800.662.4357)

The last few questions are about how you have been feeling over the past two weeks.

1. How often have you been bothered by feeling down, depressed, or hopeless?
   (0) Not at all
   (1) Several days
   (2) More than half the days
   (3) Nearly every day
2. I am going to read some statements to you. Please tell me which statement best describes how you have been feeling over the past two weeks.
   (0) I do not feel sad
   (1) I feel sad
   (2) I am sad all the time and I can't snap out of it
   (3) I am so sad and unhappy that I can't stand it
3. 
   (0) I am not particularly discouraged about the future
   (1) I feel discouraged about the future
   (2) I feel I have nothing to look forward to
   (3) I feel the future is hopeless and that things cannot improve

If 5 or higher:

Have the symptoms I just asked about gotten worse over the past two weeks?

**If yes:** Do you believe the Step Away app is contributing to your increased level of distress?

If yes: It sounds like this study is not a good fit for you. You may delete the app and discontinue using it. [*Continue with resources].*

**All positives:** Based on your answers you may benefit from discussing these issues further. I'm going to send you some phone numbers, where you can either text or call to talk to someone with experience discussing these issues.

Is that OK? (wait for response before moving on)

You may also text "MHA" to 741-741 to speak with a professional via text.

If you are feeling distressed and wish to talk over the phone, you may call the National Suicide Prevention Hotline at 1-800-273-8255. They also have a live online chat at suicidepreventionlifeline.org.

What email would you like me to send these resources to?

Is there anything else you would like to share about your experience in the study so far? Thank you for taking the time to answer these questions. If any issues or glitches occur when using the app, please email us at: uaa.stepawaystudy@alaska.edu. This email is also included in the instructions you received to download the app.

**Interview Consent Form**

**University of Alaska Anchorage**
**Consent to Participate in Research**

## WHAT ARE THE REASONS FOR THIS INTERVIEW?

You are being invited to participate in an interview to help us better understand study participants' experiences using a smartphone program, called Step Away. We will use this information to make improvements to the app/chatbot.

## WHY ARE YOU BEING ASKED TO PARTICIPATE?

As a user of the Step Away app/chatbot, we want to hear more about how you used the app/chatbot, what you think was good or could be made better, and any other thoughts you would like to share that can help us improve the Step Away app/chatbot.

## WHAT DOES THE INTERVIEW INVOLVE?

People who agree to participate will complete a telephone interview lasting about 45 minutes. The questions will ask about your experiences using Step Away smartphone app/chatbot.

With your permission, we will record your interview for transcription and data analyses. No personal information that identifies you will be asked for or kept in the transcriptions.

## WHAT ARE THE POTENTIAL BENEFITS AND RISKS?

There are no expected or significant risks connected with participation in this interview. The only cost is your time. It is possible that you may find some of the questions uncomfortable. You can skip any questions you do not want to answer.

Interview participants will receive a $25 Amazon egift card within three business days of their interview. There are no personal benefits; however, your willingness to share information, knowledge, and experience will help to improve the Step Away app/chatbot.

Participation in this interview is voluntary. You may stop at any time. No negative consequences will happen if you choose not to answer certain questions or if you decide not to participate.

## WHAT ABOUT CONFIDENTIALITY?

Your study data will be handled as confidentially as possible. Study staff will protect your personal information closely so no one will be able to connect your responses and any other information that identifies you. Directly identifying information (e.g. names) will be safeguarded and maintained under controlled conditions. You will not be identified in any publication from this study.

We do not include participant names anywhere on the interview transcripts and we will not share identifying information of individuals who participated. We will report about the interviews only with group summaries and representative opinions without including the identity of anyone to their specific responses.

All materials will be stored in securely locked and confidential file storage at UAA CBHRS offices. Interview recordings will be deleted after being transcribed but transcriptions will be kept indefinitely or until CBHRS disbands.

To help us protect your privacy we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below. The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this study is available on www.ClinicalTrials.gov as required by U.S. law. This website does not and will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT IF YOU HAVE QUESTIONS?
If you have questions about the study, you may contact the study's project manager, Alexandra Edwards at **aeedwards@alaska.edu** or 907.786.5465 or the principal investigator, Patrick Dulin, PhD, at 907.786.1653.

If you have questions or concerns about your rights as a participant in the study, you may contact the UAA Office of Research Integrity and Compliance, 907.786.1099.

| | | |
|---|---|---|
| *The consent form was read to me* | *Yes* | *No* |
| *I agree to be interviewed* | *Yes* | *No* |
| *I agree to have my interview recorded* | *Yes* | *No* |
| *I understand my participation is voluntary* | *Yes* | *No* |
| *My questions have been addressed* | *Yes* | *No* |

Interviewer initials: _____ Interview date: _____