

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

NCT04447794

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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:

1. **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.

2. **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.

3. **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.