

Cover Sheet

Full Title: Cultural Innovations for Recovery in Community-Based Learning Environments (CIRCLE) Phase 3: Testing an Online Learning Community Application

Brief Title: mHealth App for Changing Alcohol Use in ANAI People (CIRCLE)

NCT ID: [not yet assigned] Unique Protocol ID: 2021-12-056

Document Type: Informed consent form

Document IRB Approval Date: January 18, 2022

Document Tribal Approval Date: March 15, 2022

**Cultural Innovations for Recovery in Community-Based Learning Environments
(CIRCLE) Phase 3: Testing an Online Learning Community Application**

Adult Consent Form

Principal Investigator: Ann Collier, Ph.D.

Southcentral Foundation Research Department, 4085 Tudor Centre Drive, Anchorage, Alaska 99508

Phone: (907) 729.8623

Email: acollier@scf.cc

Principal Investigator: Susan B. Trinidad, MA

Research Scientist, Department of Bioethics and Humanities, University of Washington, 1959 NE Pacific St., Box 357120, Seattle, WA 98195-7120

Phone: (206) 543.2508

Email: sbtrini@uw.edu

Key Information

You are invited to join a research study about alcohol recovery. This form will tell you about the project so you can decide if you want to join. This study is being done by Southcentral Foundation (SCF) and the University of Washington (UW). Money for this study comes from the National Institutes of Health. If you have questions at any time, please ask us.

- a) Being a part of this research is entirely voluntary.
- b) The goal is to better understand whether a smartphone application (app) can help Alaska Native and American Indian (AN/AI) people better manage their use of alcohol.
- c) We anticipate minimal risks to taking part in this study.
- d) You will not directly benefit from this study. We do hope this study will improve services in the future for AN/AI people who want to change the way they use alcohol.
- e) You can stop your participation at any time. If you are uncomfortable, let the research staff know. We can provide alternative resources.

Why is this study being done?

Many people choose to manage their alcohol use on their own and some do not need treatment. Others do not want treatment, and some have trouble getting into treatment. For many people who have trouble with alcohol, peer support – being able to talk with other people about their challenges – can be helpful. It can also be helpful to learn skills to manage sobriety. The goal of this study is to better understand whether an app can help with alcohol self-management and peer support. We have developed an app based on previous feedback from customer-owners and providers. This app can be used on smartphones or tablets. This learning community will be for AN/AI people who are seeking support for their alcohol use. We will recruit up to 125 people in this study. Eligible participants must be: 1) AN/AI, 21 years or older, have a self-reported history of alcohol misuse or alcohol use disorder, receive services at SCF, have access to a smartphone or tablet, and feel comfortable using a smartphone.

If I agree to be in this study, what will I be asked to do?

We will ask you to:

1. Complete a short survey on information about you. This will include your age, gender, employment, and other basic information about you possibly including history of alcohol use.
2. Agree to read the SCF Virtual Learning Circle Agreement (a copy will be provided to you).
3. For up to 6 months, use the app we have developed. Activities could include answering survey questions, reviewing messages, listening to, or reading about app topics, and trying out app features.
4. Give feedback (on surveys) about what you like and don't like about the app.
5. If you choose, you may provide information to be contacted about results or for future participation. This is optional.
6. If you choose, you may invite friends, family, or others to learn more about the study. This is optional, and you can still participate in this study if you choose not to share study contact information with others.

Voluntary nature of participation:

It is up to you whether to take part in this study. Study participation is completely voluntary. If you chose not to participate, you will not lose SCF or Alaska Native Medical Center services. You do not have to answer any questions that you don't want to. You may stop at any time, for any reason, without penalty.

Is there any risk or discomfort from the study?

Some people may feel uncomfortable or upset discussing alcohol misuse. You may feel that answering personal questions is an invasion of privacy. There is a risk that someone other than the researchers could find out that you were in a study about alcohol misuse. There is a small risk someone outside the study could get access to what you share. If you participate in the messaging or group chat features of the app, there is a chance that other users could identify you or share your information with others outside of the app. Although the researchers will do their best to protect your confidentiality and will ask other participants not to share anything they learn about or hear from others through their use of the app, we cannot guarantee that none of your personal information will be shared outside the study.

How will you protect my confidentiality?

All information will be kept confidential unless required by law. We will assign each participant a study ID (e.g., Customer-owner #1). This will be used on all study data. Your name and other identifying information will be kept separate from study data. We will need to keep some basic identifying information on your app profile, but you will be able to use a username of your choice when you use the app. Only select study staff will have access to your information. Information collected on paper will be stored in locked cabinets on the medical campus. Electronic information will be kept on password-protected computers in secure network folders. These are only accessible to study staff. Data will be completely destroyed when no longer needed for the study. We will ask that all app users read our SCF Virtual Learning Circle

Agreement, which goes over the importance of confidentiality, keeping user information private, and not sharing other participants' stories or experiences. Investigators will not ask about alcohol problems in public settings. Finally, the study team will avoid using your app username on our forms and instead use your study ID.

Alternatives to the App

You can stop using the app at any time. If you feel uncomfortable at any time while you use the app, please let a researcher know. We can help connect you to other Behavioral Services Division resources at SCF and provide you with a list of different commercial stress or mood management apps.

What are the possible risks of this study to my community?

Risks of a study to a community are not always known. We do not anticipate that this study poses risk of harm to your community. The researchers on this study have worked closely with SCF to lessen the risk of potential harm. All presentations or write ups from this study will be reviewed by SCF leadership before they are shared outside SCF. No information about this study will be made public without SCF approval.

How will I benefit from this study?

There will be no direct benefits to you. We do hope the study will help us learn how to improve resources for AN/AI people who have trouble with alcohol.

Will I be paid to be in the study?

Yes. To thank you for your time, you will receive a \$20 gift card at your first (baseline) study visit, \$25 at your second study visit 3 months later, and \$30 at your third study visit 3 months after that. If you are eligible and participate in a 6-month follow-up interview, at the time of the third study visit, you will receive an additional \$40 gift card. Lastly, based on your participation in the app, your name may be added to raffles for additional \$50 gift cards. Participants may win one \$50 gift card through the raffles.

What happens to the findings from the study?

Your name will not appear in any report or papers from this study. All results that are made public will be summary results. These results will not report anything that would identify a person. Findings will be shared with participants upon request after the findings have been approved by Tribal leadership. Papers will be written for publication in scientific journals. These papers will be reviewed and approved by SCF before being published. If you would like to know the findings from this study, you may choose to share your contact information at the end.

Who has reviewed and approved this study?

This study has been approved by the Alaska Area Institutional Review Board (AAIRB). The AAIRB reviews studies to make sure they follow federal regulations for the protection of research participants. This study has also been approved by SCF and the Alaska Native Tribal Health Consortium. SCF reviews studies to make sure they are respectful of AN/AI people and align with the SCF mission.

Questions:

If you have any questions about the study, you may contact one of the Principal Investigator(s).
Ann Collier, SCF, (907)-729-8623 or acollier@scf.cc, or
Susan Trinidad, University of Washington, (206)-543-2508 or sbtrini@uw.edu.

If you have questions about *your rights as a study participant*, you may call the AAIRB.
Yvonne R. Tanape, AAIRB Administrator, (907) 729-3924 or
Shanda Lohse, MD, the chair of the AAIRB, at akaalaskaarealRB@anthc.org.

Verbal Agreement:

Your verbal agreement means that you have read this document or have had it read to you and that you agree to participate. If you have questions, please ask them now or at any time. A copy of this consent form is yours to keep.