

Date: 12/06/2023

National Clinical Trials #: NCT05360888

Study Title: Comparative Effectiveness of Two Culturally-Centered Suicide Interventions
for Alaska Native Youth

INTERVIEWER INSTRUCTIONS SCREEN

Please read the consent form verbatim to the youth or youth's parent/legal guardian. After reading the consent form, ask if there are any questions before moving on to the next section.

CONSENT TEXT SCREEN

BeWeL: Because We Love You Consent/Assent Form

We are asking about 370 youth ages 14-24 across two Tribal health regions of Alaska to be in our project. If you take part, you could earn up to \$340! After we look at this information, we will ask if you want to be in project.

I. WHAT IS THIS ABOUT?

Alaska Native organizations in your community are taking part in a research project with University of Alaska Fairbanks and RAND, a non-profit, nonpartisan research organization. The project is funded by the Patient-Centered Outcomes Research Institute (PCORI). This project is focused on testing some new programs about building social/cultural connections and reducing suicide risk for Alaska Native youth. We want to see how youth like the Tools for Life and the Social Network discussions and whether being a part of those discussions helps them make healthy choices.

II. WHAT WILL WE ASK YOU TO DO?

You will be asked to:

1. **Complete four surveys:** Surveys will take about 30-40 minutes to complete. Questions will ask about your age, gender, Alaska Native heritage, cultural activities, your family and your social network. We will also ask you to tell us your opinions about and experiences with different things including alcohol and other substances, your most recent visit to the hospital or clinic, and mental and physical health. You will complete one survey now, one in 3 months, one in 6 months and one in 12 months. You will be paid \$50 for the 1st survey, \$60 for the survey in 3 months, \$80 for the survey in 6 months and \$100 for the survey in 12 months.
2. **Complete a contact form** where you will provide us with basic contact information like your phone number, address and email address so we can contact you about project activities and surveys, or any future projects you may be interested in.

You will be randomly assigned (like a coin toss) to one of two groups. You will be asked to either:

1. **Take part in an individual Tools for Life Discussion Only.** Youth selected for this will be asked to meet with a wellness team member three times. Each meeting will have some discussion on community and cultural strengths, suicide risk, alcohol use and making healthy choices. Or,
2. **Take part in an individual Tools for Life and Social Network Discussion.** Youth selected for this will be asked to meet with a wellness team member three times in a two-month period. Each meeting will have some discussion on community and cultural strengths, suicide risk and alcohol use and making healthy choices. Youth will also discuss their social networks and see a picture of them.

You *could* be asked to:

- 1. Take part in a conversation with an interviewer after the survey:** About 40 youth will be selected randomly (like a coin toss) to talk individually to an interviewer around 3 months after the first survey. They will be asked to talk about their opinions and experiences with the discussion sessions. We will record these conversations so they can be typed out for us to read, which will help us understand all the topics from the interviews. All recordings will be securely stored and information from the recordings will be presented as a group, and we will not use any identifying information for any quotations. All recordings will be destroyed at the end of the study. Youth who have these conversations will be paid \$50.

III. COSTS

There is no charge for being in the project.

IV. BENEFITS

We hope the project will help us learn more about what Alaska Native youth think about suicide risk and alcohol use, how social/cultural connections may help people, and how having these discussions may help people make healthy choices. You will have the chance to learn new skills and understand more about yourself as an Alaska Native person. These skills may help you and might make you feel better about yourself.

V. RISKS

These discussions will focus on your strengths. However, some survey questions and discussions might bring out bad feelings. If you have bad feelings at any time with the survey or discussions, you can take a break or quit and it will be okay. If you are still having bad feelings after the survey or discussions, we will help you find services. There is also the risk that someone could find out your answers on the survey; however, we have several ways that we will keep your answers safe. We also do not know how well the discussions will work to build social/cultural connections and help decrease suicide risk. This project will help us understand that.

VI. CONFIDENTIALITY

We want you to answer the survey and interview questions honestly, thus, the research team will keep your answers completely private. The research team will also keep what is said at the Tools For Life and Social Network discussions confidential. The only times we may need to share what you say in a discussion is:

- 1) If we need to protect you or others from harm. An example of this is if you say you want to hurt yourself or others. In that case, we will give information about you to others that is needed to protect you or others from harm.
- 2) If you tell us about the abuse of a child (including yourself if you're under 18) or of an elderly person. In that case, we must report it to a supervisor, who may report it to others to protect you from harm.

VII. BEING PART OF THE PROJECT

You do not have to be a part of the BeWeL project if you do not want to and you can stop being in the project at any time. Your choice about being in this project will not change any care that you get in your community.

VIII. WHO IS LEADING THE PROJECT?

Dr. Stacy Rasmus at University of Alaska, Fairbanks and Dr. Elizabeth D'Amico at RAND in Santa Monica are leading the project. If you have any questions or concerns about the project, please call Dr. Rasmus at (907) 328-8919.

IX. IF YOU HAVE QUESTIONS ABOUT YOUR RIGHTS AS A PARTICIPANT

If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Project #2022-N0080. You can also contact Dr. Joseph Klejka from the Yukon Kuskokwim Health Corporation at 907-543-6024 or 6028 or email him at joe_klejka@ykhc.org with questions about your rights as a research participant.

CONSENT/ASSENT ACKNOWLEDGEMENT SCREEN

[PROGRAMMER: All fields are required in Consent/Assent Acknowledgement section except for: "I agree to allow the project team to contact me to about future research projects conducted by our team" check boxes under 18Consent1, AdultConsent1, Assent1. Also, if minor is not present do not force Assent1]

Youth First Name _____ [C_FNAME]
Youth Last Name _____ [C_LNAME]

Date of Birth: MM/DD/YYYY [DOB_M; DOB_D; DOB_Y]
[IF 15 TO 17 YEARS OLD SKIP TO AdultRelation, IF UNDER 15 YEARS OR OVER 24 YEARS OLD SKIP TO Ineligible Info, ELSE CONTINUE]

18Consent1

I understand the above information.

I agree to take part in this project.

I agree to allow the project team to contact me to about future research projects conducted by our team.

[IF R REFUSES TO CHECK BOTH 'I understand the above information' and 'I agree to take part in this project' BOXES SKIP TO Ineligible Info, ELSE SKIP TO Tracking and Locating Intro]

AdultRelation

My relationship to [FILL C_FNAME] is...

1. Parent/Legal Guardian
2. OCS (Office of Children's Services) approved representative

First Name _____ [AdultFNAME]
Last Name _____ [AdultLNAME]

AdultConsent1

I understand the above information.

I agree to let my teen take part in this project.

I agree to allow the project team to contact me to about future research projects conducted by our team.

[IF ADULT REFUSES TO CHECK BOTH 'I understand the above information' and 'I agree to let my teen take part in this project' BOXES SKIP TO Ineligible Info, ELSE CONTINUE]

MinorCheck

Is [FILL C_FNAME] present now?

- 0. No
- 1. Yes

[IF 0, SKIP TO Tracking and Locating Intro, ELSE CONTINUE]

Assent1

I understand the above information.

I agree to take part in this project.

I agree to allow the project team to contact me to about future research projects conducted by our team.

[IF R REFUSES TO CHECK BOTH 'I understand the above information' and 'I agree to take part in this project' BOXES SKIP TO Ineligible Info, ELSE CONTINUE]

TRACKING AND LOCATING SCREEN**Tracking and Locating Intro**

We would like to collect some information that will help us contact you in the future about things like project events and follow-up surveys. This information, like your responses to all questions in the interview, is completely confidential.

C_CPNUM

Cell Phone: (XXX) XXX-XXXX

OKT

Ok to text? Yes or No _____

C_Addy

Street Address _____

C_City

City _____

C_Zip

Zip code _____

C_Email

Email address: _____

[PROGRAMMER: Required Field. If R OR ADULT REFUSES C_Email SKIP TO Ineligible Info. IF ADULT DOES NOT KNOW C_Email AND MinorCheck=0, ALLOW TO CONTINUE]

FamIntro

In case we have difficulty getting in touch with you in the future for project events and follow-up surveys, please give us the name, address, and phone number of a close family member who is over 18 (e.g. parent, sibling, spouse). We would only contact this person if we are unable to get hold of you.

First Name _____ [FamFNAME]

Last Name _____ [FamLNAME]

Relationship to you: _____ [RELTOR]

FamCell

Cell number: (XXX) XXX-XXXX

FamHome

Home number: (XXX) XXX-XXXX

SameAddy

Same address as mine? Yes or No. [If yes, autofill address.]

FamAddy

Street Address _____

FamCity

City _____

FamZip

Zip code _____

FamEmail

Email address: _____

OTHINFO

How about a close friend or another family member? Please give us info on 1 more person who might be able to help us contact you in the future.

First Name _____ [OTHFNAME]

Last Name _____ [OTHLNAME]

Relationship to you: _____ [OTHRELTOR]

OTHCell

Cell number: (XXX) XXX-XXXX

OTHHome

Home number: (XXX) XXX-XXXX

OTHEmail

Email address: _____

[PROGRAMMER: IF MinorCheck=0, SHOW INTERVIEWER INSTRUCTIONS SCREEN, THEN CONSENT TEXT SCREEN, THEN Assent1, ELSE END SURVEY

INTERVIEWER INSTRUCTIONS SCREEN

[Copy/Paste Instruction Text from above]

CONSENT TEXT SCREEN

[Copy/Paste Consent Text from above]

[PROGRAMMER: Only "I agree to allow the project team to contact me to about future research projects conducted by our team" check box is not required]

Assent1

I understand the above information.

I agree to take part in this project.

I agree to allow the project team to contact me to about future research projects conducted by our team.

[IF R REFUSES TO CHECK BOTH 'I understand the above information' and 'I agree to take part in this project' BOXES SKIP TO Ineligible Info, ELSE CONTINUE]

[Programmer: FILL ALL FIELDS FROM Tracking and Locating form above. ALLOW R TO CORRECT ANY INFO]

TL Check

I would like to confirm I have your correct info...

C_CPNUM

Cell Phone: (XXX) XXX-XXXX

OKT

Ok to text? Yes or No _____

C_Addy

Street Address _____

C_City

City _____

C_Zip

Zip code _____

C_Email

Email address: _____

[Programmer: Required field. If R REFUSES C_Email SKIP TO Ineligible Info, ELSE END SURVEY.

END SURVEY

INELIGIBLE SCREEN

Ineligible Info

It looks like at this time you are not eligible to participate in this project. Here are some resources that may be of interest to you.

<https://randus.sharepoint.com/sites/srg/BeWeL/Shared Documents/Programming/www.ykhc.org>

<https://randus.sharepoint.com/sites/srg/BeWeL/Shared Documents/Programming/www.tananachiefs.org>