

NCT04561544

Pilot Test of a Cultural Intervention to Enhance Alaska Native Students' Behavioral Health

7/21/2020



PILOT TEST OF A CULTURAL INTERVENTION TO ENHANCE ALASKA NATIVE STUDENTS' BEHAVIORAL HEALTH
Adult Consent Form

Key information

- We are asking you to participate in a research study. Your participation is voluntary.
- We are studying the impact of a cultural identity program at the University of Alaska Anchorage (UAA). This research will tell us if the program helps you strengthen your cultural identity or not. We also will learn if your identity helps you be well and prevents problems or not.
- If you choose to participate, you will participate in the program for eight weeks in the Fall or Spring semester. You can participate in the program for half of your UNIV 150 or UNIV 190 class. You will also complete four 15 to 20-minute surveys, two in the Fall and two in the Spring. These surveys ask questions about you, your cultural background, your behavioral health and wellbeing, and your substance use. You may choose to grant us access to your academic records, or you can self-report your enrollment and academic performance.
- The risks of being in this study are small. The risks are no greater than those of a regular day in your life. Exploring your cultural identity may make you feel uncomfortable. You may choose not to participate in any part of the program. You may be asked to share things about yourself that you do not want people to know. You may skip any survey question you do not want to answer.
- By participating in the program, we hope you will better understand who you are and who you are becoming, your gifts, and your life paths. This may improve your wellbeing and help you do well at university. There is the possibility that you do not benefit from participating in the study.
- You are not required to participate in this program. You may choose to participate in Native Early Transitions (NET) without participating in this study. If you choose not to participate in this study, you can attend the entire UNIV 150 and UNIV 190 courses instead of going to the program. You can choose to opt out of the study and return to UNIV 150 or UNIV 190 at any time without penalty.

This form can be read to you if you ask.

This form will tell you about a research study you can join. This study is being done by the University of Alaska Anchorage. If you have questions please ask us. Take as much time as you need to decide. If you choose to be in the study, you will need to sign this form.

What is the name of this research study?

The study is called, "Pilot Test of a Cultural Intervention to Enhance Alaska Native Students' Behavioral Health." We call the program "Knowing Who You Are (Becoming): The Alaska Native Cultural Identity Project" or "Identity Project" for short.

Why is this study being done?

We know that cultural identity helps some people. Cultural identity can sometimes help people be well and do well in school. However, we don't know the best way to help people develop their cultural identities. That's why we are doing this study.

What is the goal of the study?

We are studying the impact of a cultural identity program at UAA. This research will tell us if the program helps you strengthen your cultural identity. We also will learn if your cultural identity helps you be well, develop your strengths, and prevent some problems, such as stress, sadness, and substance use.

Why am I being asked to be in the study?

You are being asked to be in this study because you:

- self-identify as Alaska Native,
- are registered as an undergraduate student at UAA,

- are at least 18 years old,
- speak English, and
- agree to complete self-report study measures.

Who is funding this study?

Money for this study is coming from the National Institute of Health.

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

If you decide to be in this study, we will ask you to do several things:

- You will be randomly selected to participate in the program in the Fall 2020 or Spring 2021 semester. You can participate in the program for half of your UNIV 150 or UNIV 190 class.
- You will attend the program on Zoom, a videoconferencing platform, for 2.5 hours each week for 8 weeks instead of going to your usual online UNIV 150 or UNIV 190 class.
- In the program, you will explore your cultural identity and strengths through storytelling from Elders, talking circles, cultural activities, and connecting with other Alaska Native students.
- You will also develop an 'ePortfolio' to record your cultural identity. If you agree, the research team will check your ePortfolio for completion at the end of the study. You are not required to share your ePortfolio. The ePortfolio content will not be judged. You may choose the privacy settings on your ePortfolio (e.g., private, public). Your ePortfolio is yours to keep and share as you see fit.
- To see how our program is working, we will email you a survey to complete four times. The survey has questions about your identity, cultural strengths, wellbeing (including behavioral health issues and substance use) and connectedness.

Will specimens be taken or stored?

No.

How many people will be in the study?

40 to 50 people.

How much of my time will this study take?

Approximately 21 to 30 hours.

- 20 hours in class
- 1 to 1.5 hours completing surveys
- 0 to 8 hours working on your ePortfolio outside of class

How much time will the whole study take?

The whole study is expected to begin in 2020 and end in 2021.

Is there any risk or discomfort from the study?

The risks of being in this study are small. The risks are no greater than those of a regular day in your life. Exploring your cultural identity may make you feel uncomfortable. You may worry about your reputation by sharing personal information. You may choose not to participate in any part of the program. You may be asked to share things about yourself that you do not want people to know. You may skip any survey question you do not want to answer and you may choose not share your ePortfolio if you do not want to. We have resources available if you feel distressed. We have put together a list of services for your use, if needed. You will need to pay for health care services if they cost money. These costs cannot be paid for by the study.

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

Risks of a study to a community are not always known. The people involved in this study have worked closely with a Community Advisory Board to make a plan to lessen the risk of harm to your community. This study asks questions about behavioral health issues, substance use, and cultural background. Put together, this information could stigmatize a community if confidentiality was breached. We are taking safety measures to ensure that no identifying information is shared. This is described in the 'How will you protect my confidentiality?' section. No information about your home village will ever be shared. Also, all presentations or publications must be approved by our Community Advisory Board. This should lessen the risk of harm to your community.

How will I benefit from this study?

By participating in the program, we hope you will better understand who you are and who you are becoming, your gifts, and your life paths. This may improve your wellbeing and help you do well at university. There is the possibility that you do not benefit from participating in the study.

Will I be paid to be in the study?

You will receive a Samsung Galaxy Tablet to complete your ePortfolio that you may keep after the program ends. We will email you a \$20 Visa gift card for each set of surveys (\$80 total) you complete as a thank you. Visa gift cards can be used at most stores in Anchorage and online. You can also get university credit for participating in this program. Specifically, this program counts for 8 of the weeks you would usually attend UNIV 150 or UNIV 190.

Who will be able to see my medical records?

No one will see your medical records.

Who will be able to see my academic records?

Only Sara Buckingham and the research team will see your academic records. You can choose to self-report your academic information if you do not want the team to see your academic records.

How will you protect my confidentiality?

All information will be kept confidential to the extent that is legally possible. You are responsible for taking the survey in a private location to protect your privacy. Information we collect from you will be stored with your study identification number and not your name or other information that would identify you. Consent forms and any information collected on paper will be stored in locked cabinets and electronic data in password-protected secure computer files. Data will be kept for at least 3 years after the funding period ends. It may be kept longer, but all protections of the data must stay in place. Information collected for this study will be stripped of identifying information and might be used in other research in the future. Data will be completely destroyed when it is no longer needed. Government staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

If you share that you are planning to harm yourself or someone else at any point during the study, the Principal Investigator, Dr. Sara Buckingham, will reach out to you to via phone to develop a safety plan. If Dr. Buckingham is still unable to reach you, she may need to break confidentiality to keep you and others safe. In this case, she will reach out to your emergency contact. The emergency contact form on the last page contains information about when Dr. Buckingham would break confidentiality by contacting your emergency contact and what she would say. Dr. Buckingham may need to also reach out to other people to make sure you and others are safe, but she will always start by attempting to talk with you.

What happens to the findings from the study?

Names will not appear in any report or papers resulting from this study. All results that are made public will be summary results. They will not report anything that would identify a person. Summary results will be shared with participants, our community advisory board, and campus leadership. Papers will be written for publication in scientific literature. These papers will be reviewed and approved by our Community Advisory Board before they will be published.

Can I access my individual results?

You will not have access to your individual results. You may access the summary results of the study. These include what participants thought about the program and the impact of the program on wellbeing. If you share your email and/or phone with us, we will contact you when the results are available. We will send you a written report and invite you to a discussion about the results.

Can I refuse to be in the study?

Yes, taking part in this study is your choice. If you decide to join the study, you can leave it at any time. You may participate in Native Early Transitions (NET) without participating in this study. If you choose not to participate in this study, you can attend the entire UNIV 150 and UNIV 190 courses instead of going to the program. Opting out of the study will not negatively affect your academic standing. If you wish to receive course credit for UNIV 150 or UNIV 190, but do not want to participate in the program anymore, you will be asked to return to the usual course programming.

Can I be removed from the study?

If you are disruptive or disrespectful to group members, an Elder facilitator will speak with you individually. If you continue to cause harm, an Elder facilitator will share concerns with the Principal Investigator, Dr. Sara Buckingham. Dr. Buckingham will schedule a meeting with you to create a plan for you to participate in the program in a way that does not harm others. If you do not follow this plan, you can be removed from the program. If you are removed, you will be asked to return to the regular section of UNIV 150 or UNIV 190. You will still be eligible to complete survey measures.

Who do I call if I have questions later or I decide to leave the study?

If you have any questions or complaints, you may contact the Principal Investigator(s):

Sara Buckingham

sbuckingham@alaska.edu

(907) 786-1767

The clinical trial consent form will be posted at <https://clinicaltrials.gov/>

If you have questions about *your rights as a study participant*, you may call the Alaska Area Institutional Review Board (AAIRB):

Terry Powell, AAIRB Administrator

907-729-3924 (collect calls accepted)

akaalaskaarealRB@anthc.org

Dr. Shanda Lohse, AAIRB Chairperson

akaalaskaarealRB@anthc.org

You may also call the University of Alaska Anchorage Institutional Review Board:

University of Alaska Anchorage Research Compliance Officer

(907) 786-1099

To make sure we understand your wishes, we would like you to initial if you agree to participate in the following procedures:

_____ I consent for my academic records to be reviewed. I understand that if I do not consent to my records being reviewed, I will be asked to self-report this information. I may refuse to report information.

_____ I would like to receive a copy of the study findings and publication(s).

Participant Email: _____

Participant Phone Number: _____

Participant Address: _____

Program materials will be mailed to this address.

Who can we contact if we are worried about you?

Dr. Sara Buckingham will **only** contact this person if the research team **cannot get in contact with you and:**

1. You share that you are planning to harm yourself or someone else;
2. You leave a program session distressed; or
3. You do not attend the program for two sessions in a row.

When she calls your emergency contact, Sara Buckingham will say:

“This is Sara Buckingham from the University of Alaska Anchorage (UAA). [Your name] is enrolled in a project at UAA and we have not been able to get into contact with them. [Your name] listed you as someone to contact if we were worried about them. Have you talked with [your name] recently? Could you ask [your name] to contact us at (907) 786-1767?”

Emergency Contact Name: _____

Emergency Contact Relationship to Participant: _____

Emergency Contact Phone Number: _____

CONSENT:

I have read or been told about this research study and all of my questions have been answered to my satisfaction. I have been offered a copy of this consent. **I agree to be in the study.**

Signature of Participant

Date

Signature of Person Obtaining Consent

Date