

Study Protocol with Informed Consent Form

Title: R01ES029165, Prevention of Paralytic Shellfish Poisoning in Subsistence Shellfish Harvest Communities of Southeast Alaska

NCT Number: NCT05247229

Document data: September 25, 2023

2. DATA AND METHODS

2.1 Research Team and Reflexivity

This study was a partnership between researchers, educators, and environmental protection staff at the University of Alabama at Birmingham (UAB), the University of California, San Francisco (UCSF), and the Sitka Tribe of Alaska (STA). The community-academic partnership was initiated in 2016 when academic partners were invited to support the efforts of a Tribe-school district partnership in Sitka and a tribally led environmental monitoring program. The partnership involves shellfish toxin testing and modeling and K-12 educational programming to promote cultural, environmental, and health literacy and increase awareness of shellfish poisoning risk reduction strategies and STA risk reduction resources. The intervention evaluated in this study is a new education program for middle school students. This work is community co-led and participatory (Key et al., 2019), reflects reflexive research ethics principles (Cordner et al., 2016), and follows best practices for co-created community engagement in oceans and human health research (Carson et al., 2022). Community-based participatory research offers a model for fostering trust, reciprocity, and long-term collaboration with Indigenous communities (Manson et al., 2004). The research instruments used in this study were developed collaboratively by members of the author team with academic and STA affiliations. Surveys were conducted by coauthors implementing the education program in Sitka, Hoonah, and Juneau and respectively affiliated with STA, the Hoonah Indian Association, and the Central Council of the Tlingit and Haida Indian Tribes of Alaska. Interviews, across communities, were conducted by coauthors with STA and UAB affiliations. This research received human subjects research approval from the University of Alabama at Birmingham Institutional Review Board (IRB protocol number 300006786). In reporting, we draw on three guidelines, including criteria specific to health research with Indigenous Peoples (Hurria et al., 2019), environmental education

research (Smith-Sebasto, 2000), and group-based behavior-change interventions (Borek et al., 2015). We present consolidated criteria for strengthening reporting of health research involving Indigenous Peoples in appendix 1 (Hurria et al., 2019) and relevant items from the other two guidelines in this methods section.

2.2 Middle School Education Program

The middle school education program that this study evaluates teaches participants about traditional knowledge and shellfish harvesting practices in Southeast Alaska, risks posed by shellfish toxins, and risk reduction strategies. The program was designed by STA, run by education and environmental coordinators working for STA, the Hoonah Indian Association, and the Central Council of the Tlingit and Haida Indian Tribes of Alaska, and featured guest speakers, such as staff scientists responsible for shellfish toxin testing and tribal members with expertise in local knowledge and traditional knowledge (Roland, Kohlhoff, Lanphier, Yazzie, et al., 2024). The program was initially implemented only in a middle school in Sitka and was expanded to schools in Hoonah and Juneau in response to Tribes' interest. The semester-long, one hour program took place weekly, either as an after-school program or during school hours as a non-graded elective, depending on the structure most feasible for schools. Lessons offered participants hands-on learning such as experience with laboratory techniques, microscopy, plankton tows, and shellfish harvesting. The program was divided into two units: the first focused on harmful algal blooms and paralytic shellfish poisoning and the second focused on intertidal zones and shellfish harvesting. Research activities included pre- and post-program interviews and surveys and a follow-up survey one year after participation. Pre- and post-program surveys were the primary outcome measure of the clinical trial, and pre- and post-program interviews and the one year post-program survey were secondary measures.

The program was designed with the TPB in mind and especially targeted control beliefs. The program aimed to influence behavioral beliefs by educating students about shellfish harvesting through hands-on, place-based learning; normative beliefs by emphasizing that harvesting with parents or guardians is customary; control beliefs by highlighting exposure risk reduction strategies and tribal paralytic shellfish poisoning prevention resources; and, ultimately, behavioral intentions through shifting behavioral, normative, and control beliefs.

2.3 Sample and Consent

Study participants were recruited from all middle school students (grades 6-8) in Blatchley Middle School in Sitka, Hoonah City School in Hoonah, and Dzantik'i Heeni Middle School in Juneau. The program enrolled 11 participants in Sitka, 20 in Hoonah, and 19 in Juneau for a total of 50 participants across communities. Research participation was not required to participate in the education program, and students opted into the survey and interview research components through a tiered informed consent process. Written consent was obtained from parents after information on research activities was shared, and verbal consent was obtained from participants before data collection activities. Of the 50 study participants, all consented to participate in the surveys and all but one consented to participate in the interviews. Participants in either or both research components were offered a \$10 cash card incentive for each lesson attended, with a total possible incentive of \$100 for attending all ten lessons. Incentives were used to encourage program participation and regular attendance.

2.4 Survey Design

A five-point (1-5) Likert scale survey was administered to participants at the beginning and end of the program, as well as one year after program completion. The instrument used in

these three instances of data collection included 16 questions relevant to the three types of TPB beliefs—behavioral beliefs (attitudes toward the behavior), normative beliefs (perceived attitudes of peers and respected figures toward the behavior), and control beliefs (perceived ability to perform the behavior)—and was divided into two sections. In the first section, on shellfish harvesting, questions asked about participants' perceptions of and experience with shellfish harvesting, perceptions of peers' views about shellfish harvesting, and sense of agency and behavioral intentions related to engaging in shellfish harvesting. For example, related to normative beliefs: "Most of the people who are important to me would approve of me participating in subsistence clam harvesting" (disagree – agree Likert scale). In the second section, on checking toxin levels using the SEATOR website, questions asked about participants' perceptions of this risk reduction behavior, perceptions of peers' views about checking toxin levels, and sense of agency and behavioral intentions related to checking toxin levels. For example, related to control beliefs: "I am confident that I can check the SEATOR website before clam harvesting" (disagree – agree Likert scale). In both sections, the last question asked about behavioral changes related to program learning and thus was relevant in only the post-program survey. Full survey response data is presented in appendix 2.

2.5 Survey Data Analysis

2.5.1. Accounting for Missing Data

Missing data at the person-visit level were imputed for age (n missing = 6) and each of the questions (n missing = 9-20, depending on question), treating each person-visit as a separate observation. The predictor variables in the imputed model included all question responses and all regression model predictors: age, gender identity, Alaska Native identity, and site. We used listwise deletion, excluding cases from analysis if data was missing, for gender (n missing = 10), Alaska Native identity (n missing = 6), and pre-post-program differences (n missing = 9-15, depending on question). No site data was missing. We generated 80 imputed

datasets via multiple imputation by chained equations (Azur et al., 2011). Across our models, the largest average relative increase in variance (RVI) due to nonresponse was 0.44 and the largest fraction of missing information (FMI) was 0.55, suggesting that our analysis based on 80 imputed datasets was reasonable. Statistical analyses were conducted using STATA 18.0 M/P (StataCorp, 2023).

2.5.2. Pre-Post-Program Changes in Theory of Planned Behavior Beliefs and Behavioral Intentions

To evaluate pre-post-program changes in beliefs and behavioral intentions related to shellfish harvesting, consumption, and risk reduction, we tested the association between pre- and post-program responses (i.e., the intervention effect). We included covariates for site (Sitka, Hoonah, and Juneau), age, Alaska Native identity (Alaska Native, non-Native), and gender identity (girls, boys, and nonbinary). To consider within person pre-post-program changes in TPB Beliefs and behavioral intentions, we used generalized estimating equation linear regression (GEE) to cluster pre-post measures (Liang & Zeger, 1986). We also evaluated differences in pre-post-program changes in TPB beliefs and behavioral intentions among the three participating communities and Alaska Native and gender identities using interacted models. Results of interacted models are presented in appendix 3.

We present individual participants' responses to the one year post-program survey as the number of participants in this follow-up survey was small. When we closed the study on July 31, 2024, only 7 participants had completed the program at least one year prior and were available for one year post-program recontact, having completed the program in either fall 2022 or spring 2023 semesters. These participants were all from Sitka. Of these 7 participants, 4 completed the follow-up survey. One year post-program survey responses are presented in appendix 4.

2.5.3. Relationships Between Changes in Theory of Planned Behavior Beliefs and Changes in Behavioral Intentions

To characterize TPB constructs most influential in shifting planned behaviors, we again used GEE to test the association between pre-post-program changes in TPB beliefs and pre-post-program changes in harvesting and exposure risk reduction behavioral intentions. Similar to the models we used to assess pre-post-program changes, we adjusted for site, age, Alaska Native identity, and gender identity. We also adjusted for changes in other TPB beliefs related to either shellfish harvesting or exposure risk reduction, depending on the behavioral intention outcome.

2.6 Interview Structure

Together with the surveys, pre- and post-program structured interviews followed a convergent parallel study design, with interviews contextualizing the beliefs and behavioral intentions measured in surveys. For example, interview questions related to normative beliefs asked: “How do the people in your life (friends, family, etc.) feel about subsistence clam harvesting? What do you think of their feelings towards subsistence clam harvesting? Have these individuals’ feelings about subsistence clam harvesting influenced how you feel about harvesting? If so, how?” Like the survey, interviews were organized by TPB constructs. The 10 question interview script is included as appendix 5.

2.7 Interview Data Analysis

Interview audio recordings were transcribed using Otter.ai transcription software. Coauthors who conducted interviews reviewed these initial transcripts for quality control, listening to each recording and editing transcripts for accuracy. A codebook was generated

using both inductive and deductive approaches. First, codes were identified based on major themes in the interview protocol and relevant to the TPB. Next, all transcripts were reviewed to identify further themes not captured in deductively developed codes. This grounded theory approach was important to identify new themes raised by participants. The inductive coding process was open and collaborative, with members of the research team involved in the process meeting frequently during coding scheme generation and coding. Each interview was coded by a minimum of two research team members. To support high intercoder reliability, team members checked intercoder agreement and collaboratively reviewed coding results throughout the coding process, identifying differently coded excerpts and reaching consensus on correct coding. Data was coded and analyzed using Dedoose software (Dedoose Version 9.2.12, 2021).

Consent to be a Research Participant

Title: Safe Shellfish in Southeast Survey (part of a research project titled “Prevention of Paralytic Shellfish Poisoning in Subsistence Harvest Communities of Southeast Alaska”)

Principal Investigator: Matthew O’Madigan Gribble

Funding Source: National Institute of Environmental Health Sciences

Introduction

The Sitka Tribe of Alaska and the University of Alabama at Birmingham are conducting a research study that your child could participate in, with your permission. This packet provides information you would need to know before deciding whether to involve your child in the study. Your child’s participation is entirely your choice.

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can keep a copy of this consent form. You are not giving up any legal rights by signing this form.

Purpose of the Research Study

Consuming shellfish can sometimes present a health risk due to Paralytic Shellfish Poisoning (PSP). PSP can lead to serious health risks, and even death. This study is being done to determine what children know about harvesting shellfish safely in Southeast Alaska, what they believe about harvesting shellfish safely, and if education results in changes in their knowledge, beliefs, or behaviors related to shellfish safety. We respect that eating shellfish is an important part of culture in Southeast Alaska and do not want to discourage it. Instead, our education efforts are intended to reduce the risk of children contracting PSP through the consumption of shellfish.

The Sitka Tribe of Alaska and the University of Alabama at Birmingham have developed education units centered around the harvest and consumption of shellfish in Southeast Alaska. The units consist of in-class lessons, field trips, and guest speakers from local experts. The program is intended to help middle school students feel like they have some control over their ability to prevent PSP toxin exposure by raising awareness of resources for PSP prevention, such as the Southeast Alaska Tribal Ocean Research (SEATOR) toxin monitoring program. The units will be offered as an elective class (optional) and students taking the class will be able to opt into the research study. These lessons and related optional research activities will be facilitated by Sitka Tribe of Alaska, Hoonah Indian Association, and Hoonah School District staff. Whether or not students opt into the research will have no effect on their ability to participate in the class or on their class grades.

Study Participation and Procedures

At the beginning and end of the units, we will survey students about their beliefs in eating shellfish safely, and about their knowledge on how PSP toxin producing algae live in the environment. Additionally, we will conduct short Zoom or in-person interviews with students at the start and end of the education program. Interviews conducted over Zoom will be recorded via Zoom and interviews conducted in-person will be audio recorded. A year later, we will contact participants to ask if they have harvested shellfish and visited the SEATOR website in the past year.

Shellfish Testing and Consumption

The Southeast Alaska Tribal Ocean Research (SEATOR) network posts results of local shellfish toxin testing to their website, www.seator.org. On the website, an interactive map displays beaches where shellfish exceed the regulatory limit for PSP toxins and are unsafe to eat.

The program will involve the option to consume shellfish following the end of all units. This is done to celebrate Tlingit culture and encourage students to practice safe harvesting practices. The shellfish will be harvested a week before consumption, frozen, and tested for toxins. If toxin levels are high, the shellfish will not be consumed and commercial shellfish will be purchased and used. Students may choose not to eat the shellfish for any reason (vegetarian, shellfish allergy, any reason, which students need not share).

Risks and Discomforts

Most of the risks associated with participation in this research study are low, such as needing to adjust your families' schedule to accommodate the extra education. Other risks include anxiety from learning about PSP. Since this study is occurring in a group setting, other risks include stigmatization and psychological distress. Other potential risks include the loss of privacy or confidentiality if there is a data breach.

Benefits

Participants may benefit from a greater knowledge of shellfish toxins and how to reduce risks of harmful exposures.

Compensation

If opting into participating in research components, your child will receive a cash card as compensation for participation in the two short interviews and surveys (up to \$100). Your child will receive the participation incentive amount related to their attendance regardless of whether they continue in the program.

You will have access to free shellfish safety testing (paid for by the study) and additional education opportunities for your child.

Other Options

There are no negative repercussions if you decide not to have your child participate in this study.

Confidentiality

Certain offices and people, other than the researchers, may look at study records. Study records include your child's name and contact information, the pre and post education surveys your child completes, and interview data. Government agencies and University of Alabama at Birmingham employees overseeing proper study conduct may look at study records. These offices include the Office for Human Research Protections, the National Institute of Environmental Health Sciences, the UAB Institutional Review Board, and the UAB Office of Compliance. UAB University will keep any research records we create private to the extent we are required to do so by law. A study number, rather than the participant's name, will be used on study records wherever possible. Names and other facts that might point to your child will not appear when we present this study or publish results.

Certificate of Confidentiality

This study has a Certificate of Confidentiality from the National Institutes of Health. The Certificate of Confidentiality helps keep others from learning that you participated in this study. UAB will rely on the Certificate of Confidentiality to refuse giving out information that might identify your child; for example, if UAB were to receive a subpoena for study records.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your child's participation in this study. This means you and your family also need to protect your own privacy.

The Certificate does not stop UAB from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly, or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Family Educational Rights and Privacy Act (FERPA) Information

The following people may become aware of your child's participation in the study: other students and parents, teachers at the middle school, and study staff.

Withdrawal from the Study

You have the right to leave the study at any time, without penalty.

The researchers have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest, or if you were to object to any future changes that may be made in the study plan.

Contact Information

Contact Matthew Gribble at 205-934-3928, or email seator@uab.edu:

- If you have any questions about this study or your part in it.
- If you have questions, concerns, or complaints about the research.

You can also contact Jacob Kohlhoff, the Environmental Education Coordinator for the Sitka Tribe of Alaska, at jacob.kohlhoff@sitkatriben-nsn.gov.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Consent and Authorization***TO BE FILLED OUT BY PARTICIPANT ONLY***

Please **print** your child's name and your name below. Then sign **one** of the consent levels below.

Name of Participating Child

Name of Parent or Guardian

Please **sign** and **date** below if you agree to allow your child to be in this educational program as well as **both** research gathering activities (survey and interview). By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Signature of Parent or Guardian (18 or older and able to consent)**Date** **Time**

Please **sign** and **date** below if you agree to be in this educational program as well as **just** the survey. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Signature of Parent or Guardian (18 or older and able to consent)**Date** **Time*****TO BE FILLED OUT BY STUDY TEAM ONLY***

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion**Date** **Time**