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**Title of the Protocol**

**Reopening Schools Safely and Educating Youth (ROSSEY) Research Study Protocol**


| **Investigator List** | |
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| **Principal PI:**<br>Linda K. Ko, PhD<br>Department of Health Systems and Population Health<br>University of Washington (UW)<br>Hans Rosling Center for Population Health 3980<br>15th AVE NE, UW Mailbox 351621<br>Seattle, WA 98195<br>Phone: 206-685-4978<br>lindako@uw.edu | **Co-Investigator:**<br>Allison Cole, MD, MS<br>UW Medicine/Family Medicine<br>University of Washington<br>Phone: 206-685-9879<br>Acole2@uw.edu |
| **Site PI/Co-Investigator:**<br>Parth Shah, Pharm D, PhD<br>Division of Public Health Sciences<br>Fred Hutchinson Cancer Research Center<br>1100 Fairview AVE, N<br>M3-B232<br>Seattle, WA 98109<br>pshah@fredhutch.org | **Co-Investigator/Biostatistician:**<br>Chuan Zhou, PhD<br>Seattle Children's Hospital/ Department of Health Systems and Population Health<br>1920 Terry Ave, Building Cure, #04-228M/S<br>CURE-4, PO Box 5371<br>Seattle, WA 98145<br>Phone: 206-854-128<br>Chuan.zhou@seattlechidlrens.org |
| **Co-Investigator:**<br>Michelle M. Garrison, PhD<br>College of Health and Human Services<br>Purdue University<br>Matthews 229<br>812 W. State Street<br>West Lafayette, IN 47907<br>mmgarris@purdue.edu | **Co-Investigator:**<br>Magaly Ramirez, PhD<br>Department of Health Systems and Population Health<br>University of Washington (UW)<br>Hans Rosling Center for Population Health 3980<br>15th AVE NE, UW Mailbox 351621<br>Seattle, WA 98195<br>maggiera@uw.edu |
| **Co-Investigator:**<br>Paul Drain, MD, MPH<br>Department of Global Health<br>Hans Rosling Center for Population Health 3980<br>15th AVE NE, UW Mailbox 351620<br>Seattle, WA 98195<br>Phone: 206-520-3820<br>pkdrain@uw.edu | |



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**Role of funders:** The funders had a role in the design of this study.

**Summary**
While public health measures with school closure helped mitigate the spread of COVID-19, Latino children from rural agricultural communities are experiencing learning gaps due to disproportionate access to resources. We would like to understand if risk communication can increase COVID-19 testing uptake in students returning to in-person learning in the Yakima School District (YSD). Early COVID-19 testing may provide a mechanism to identify outbreaks early and stop transmission, as well as provide reassurance to families and to staff about the safety of on-site instruction. Risk communication is a health communication strategy that focuses on providing information of health risks and events to the target audience by creating awareness of individuals' susceptibility to and severity of an illness and events. Our risk communication intervention was guided by the health belief model, self-determination theory, and social cognitive theory to: provide education on the benefits of the COVID-19 testing program; promote self-efficay; facilitate goal setting; and increase readiness to engage on COVID-19 preventive measures, including testing and vaccination.

The study has three aims (see Page 5) and involves a clustered randomized controlled trial (RCT) where K-5 elementary schools will be the unit of randomization. Aim 2 includes a clustered RCT conducted in YSD elementary schools to evaluate the effect of risk communication on COVID-19 testing uptake and school attendance. We will assess primary outcome (i.e., school attendance and COVID-19 testing uptake) on students; parent/guardian will provide informed consent through either an online, paper, or telephone process to enroll in the study. Following consent, parent/guardians of participants will receive instructions on study procedures and complete the enrollment questionnaire either via online through Project REDCap, on paper, or over the telephone with a study staff member. If the students attend a school that is randomized into the intervention group, they will receive the risk communication as three comic books and their parents will receive two videos at regular intervals throughout the study in English and Spanish. The risk communication will highlight benefits of and address barriers to preventative behaviors, SARS-CoV-2 testing, and COVID-19 vaccines. Participants in the comparison group will receive the risk communication comic books and videos at the end of the study as part of the delayed intervention. All participants will receive weekly brief reminders to complete an online Symptom/Exposure check-in in REDCap and encouraged to complete weekly testing at the YSD static testing site. Secondary outcome measures will be assessed for one index child in all families who have children enrolled in the study. Post

All students in the YSD have access to the District's COVID-19 static testing site. Screening and symptomatic testing will be available (but not mandated) to YSD students through the static site.

A partnership with the YSD will give permission to our team to access the school attendance data and SARS-CoV-2 test results on students enrolled in our research study. The agreement will also include access to de-identified SARS-CoV-2 test data from the static site. Access to student COVID-19 testing data will allow our team to examine the effect of risk communication on COVID-19 testing, primary outcomes (i.e., school attendance and COVID-19 testing participation), and secondary outcomes (i.e., physical activity, mental health, and COVID-19 vaccination) in this study.

## I. SPECIFIC AIMS

**Aim 1.** Identify rural Latino community's social, ethical, behavioral needs and resources for students to return to school and maintain onsite learning using qualitative assessments with school stakeholders, parents, and students.

**Aim 2**. Evaluate the effectiveness of risk communication on student attendance and participation in SARS-CoV-2 testing using a cluster RCT with two intervention arms: intervention (SARS-CoV-2 Risk Communication) and comparison (control group) arm. Prior to launching Aim 2, a pilot study will be conducted with one school to understand the implementation steps and workflow.

The pilot study was conducted between April and June 2021. After completion of the pilot study, we revised Aim 2 based on NIH's request.

**Aim 3**. Assess implementation outcomes of risk communication and COVID-19 testing with school stakeholders, parents, and children guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework.

## II. BACKGROUND

The COVID-19 pandemic has magnified the issue of health disparities among vulnerable communities in the US.[1] While the outbreak is better contained now, rural agricultural communities in Washington (WA) State's Yakima Valley had the highest positivity and SARS-CoV-2 associated mortality rates in WA State at the height of the pandemic.[2] According to the 2011 census, the Lower Valley has a population of about 100,000; roughly 65% of them are of Hispanic origin. Most of the Hispanic population in the Valley is Mexican American (95%). Many Latinos are employed in agricultural and food packing industries along with some contracted seasonal workers within and outside of the US who move through distant geographical sites during farming seasons.[3] These communities also experienced poor outcomes to COVID-19 due to high rates of comorbidities, including cancer, diabetes, cardiovascular disease, obesity, and obesity-related diseases.[4] Experiences with social determinants of health (food insecurity, housing insecurity, lack of access to healthcare, and unemployment) and limited community infrastructure and resources have been well documented even before the pandemic and were amplified during the pandemic.[4.5]

The slow release of scientific information due to public health experts' limited knowledge base on SARS-CoV-2, limited access to scientific expertise as academic and research centers are often clustered in urban areas of the state,[6] and politicization of the pandemic fueled misinformation (lack of accurate information) and created a breeding ground for disinformation (false information and conspiracy theories) in these rural communities.[7-8] Preventive measures (such as mask-wearing) were affiliated with political statements, and concerns around the effectiveness of SARS-CoV-2 testing and vaccine hesitancy have spread in tandem with the pandemic.[9-10] To turn the tide, consistent, science-based, accurate risk communication is needed to instill trust and confidence in SARS-CoV-2 testing and decrease vaccine hesitancy in these communities.

Drastic public health measures along with closures of schools, businesses, public events, and workplaces have slowed the spread of SARS-CoV-2.[11] At the same time, many new societal challenges were introduced as a result of the measures. For children, the lack of in-person opportunities for learning has widened the achievement gap that existed prior to the pandemic among racial and ethnic minority children, who are socioeconomically disadvantaged, and those living in resource-limited communities.[12] The re-opening of educational settings is critical as schools are safe places that meet many needs for families, especially those that are under-resourced. For example, schools are safe places that support the development of a child's social and emotional skills; provide physical, speech, and mental health therapy; fulfil nutritional needs and facilitate opportunities for PA. These basic developmental needs are unmet for families with limited socio-economic resources, challenges with internet connectivity and equipment, lack of family members who are present at home to assist with virtual learning, and inaccessibility of key services such as school food programs, therapy, and after school programs. In addition, reports

of stress and depression have been rising during the COVID-19 pandemic among children, while PA has been significantly reduced.[13] While reinstituting onsite learning in schools is a priority, school administrators note concerns to return to in-person instruction due to the health risks associated with COVID-19.[14]

SARS-CoV-2 testing is a practical tool for instilling confidence in the safe return to school for students, families and staff.[15] Weekly testing of students and staff may provide opportunities to quickly and accurately identify cases early, mitigate transmission in schools, and prevent unnecessary loss of workdays and school days, and school closure.

In addition, implementation of accurate, science-based risk communication, in tandem with testing, can help educate students, staff and parents on testing benefits and safety, address the information gap and quench false information rapidly, and prepare the school community for vaccine readiness. In the current rollout of vaccines for children and adults, and the prevalence of vaccine hesitancy, risk communication may serve an essential function to inform families about the role of testing and vaccines as part of mitigation strategies to allow for safe in-person instruction.

In sum, Latinos living in rural agricultural communities were hit hard during the pandemic, which exacerbated disparities that existed prior to the pandemic. While public health measures with school closure helped mitigate the spread of COVID-19, Latino children from rural agricultural communities are experiencing learning gaps due to disproportionate access to resources. Risk communication may provide a mechanism to identify outbreaks early and stop transmission, as well as provide reassurance to families and to staff about the safety of on-site instruction.

In April 2021, we received funding from the National Institute of Child Health and Human Development as Other Transaction (1OT2HD107544) to test the effectiveness of risk communication for COVID-19 on increasing students' participation in onsite learning using community-based participatory research (CBPR) approach. This project is a collaboration with the community advisory board (CAB) where members are residents from the Lower Yakima Valley.

## III. STUDY DESIGN

This study incorporates three aims that are meant to help students return to school safely by providing free health education to families and their children. Simultaneously, free COVID-19 testing will be offered to families for their children at schools through the Yakima School District and Health Commons' Learn to Return program. We want to understand how to successfully implement health education in schools and learn if health education can increase uptake of COVID-19 mitigation measures, improve children's school attendance, and increase families' physical and mental well-being. Aim 1 involves qualitative interviews and focus groups to assess social, ethical, cultural, and behavioral concerns related to COVID-19 in the community. Interviews will be conducted with school stakeholders (e.g., superintendents, principals, teachers, nutrition service directors) and students from the Lower Yakima Valley area. Focus groups will be conducted in both English and Spanish with parents who have participated in past studies and have agreed to future contact. Transcripts from the semi-structured interviews and focus groups will be uploaded into ATLAS.ti and analyzed separately. Two analysts will use an inductive, constant comparison approach in which concepts will be identified, and themes derived, from the data. We will also create a set of tentative a priori codes based on the interview and the moderator guides. The analysts will follow the inductive coding with deductive coding using the a priori codes to ensure that information from the questions is retained during coding. Using an iterative process, the analysts will meet weekly to refine the codebooks, adding, removing, and revising codes, as

needed, to address inter-rater agreement and to compare new data with existing data. We will build consensus around themes that are identified throughout the coding and analysis process. We will compare the themes arising from the data and determine possible linkages across participants and thematic categories. Aim 2 involves a clustered randomized control trial (RCT) that evaluates the role of risk communication for children attending elementary school in the Yakima School District and their families. Schools will be randomized to receive the intervention (risk communication) or serve as a comparison or control group (continue the current practice). To prepare for this large trial, the study will institute a pilot study conducting weekly SARS-CoV-2 surveillance testing in one school during April to June 2021 to understand the implementation steps and the workflow of working with schools in the Yakima School District. The larger RCT trial will be implemented in 14 Yakima School District elementary schools in the 2021 – 2022 school year. Aim 3 involves conducting focus groups and semi-structured interviews with parents, K-5 students, and school staff to understand the effect of the ROSSEY intervention and Yakima School District COVID-19 mitigation strategies on a variety of school performance and health-related outcomes, using the RE-AIM framework, a widely used framework that explicitly guides research assessment of issues, dimensions, and steps in the design, dissemination, and implementation process of public health programs or interventions that are predictive of successes or failures in achieving broad and equitable population-based impact.

**Aim 1**

All interviews and focus groups will be collected using a HIPAA approved conference line or phone. Semi-structured interviews will be held with 20 school stakeholders. Recruitment of school stakeholder will be conducted using the snowball effect, in which we ask key stakeholders to provide names and phone numbers of other school stakeholders who may be interested in participating in an interview. The guided interview will target schools' readiness to have students return to school and maintain onsite learning; and interventions and implementation strategies that could mitigate those concerns. Four focus groups (2 English, 2 Spanish) will be conducted to examine: concerns for regularly testing children for COVID-19, needs and concerns of children retrurning to school; fears about children contracting COVID-19 and resources needed; and concerns regarding vaccination safety, acceptability, and uptake. Parents who participated in past studies and provided consent for future contact will be mailed a letter and followed up by phone to assess interest and schedule their participation in a focus group. Once parents have agreed to participate in the focus groups, we will elicit parents' interest to enroll their children for the semi-structured interview. We will recruit 20 students. The interviews with students will cover needs and concerns for regularly testing for COVID-19, ability to follow preventive measures at school and the onsite learning protocol, and fears about contracting COVID-19 and ways to mitigate their concerns. All interviews will last 30-45 minutes and will be audio recorded. All focus groups are expected to last 60 to 90 minutes.

**Aim 2**

Prior to randomization, the participant or participants' (for families enrolling more than one child) parent/legal guardian will complete a baseline questionnaire with demographic and COVID-19 mitigation behavior questions after providing informed consent/assent. Randomization will be conducted at the school-level. Participants in the intervention group will receive risk communication materials in the form of: (1) 3 comic books with accompanying read-along videos for children and (2) 2 videos for parents. once a month for three consecutive months. Participants randomized to the comparison group will be provided the same risk communication materials at the end of the school year as a delayed intervention. Parents of participants randomized to the Intervention group will be given two videos focused on COVID-19 topics such as testing and

vaccination throughout the school year. Similarly parents of participants randomized into the comparison group will receive the two videos as a delayed intervention. Throughout the duration of the study, participants will receive weekly brief email or text message reminders to complete an online Weekly Check-in Survey that collects information about COVID-19 symptoms, school absenteeism, and SARS-CoV-2 exposure. Parents of students who report that their child is experiencing COVID-19 symptoms will then be prompted to answer more questions about the illness, and any healthcare that they may have received. At Post Survey 1 and Post Survey 2 assessments, parents will be asked to complete a short online survey to update their demographic information, child's COVID-19 vaccination status, and the child's SARS-CoV-2 mitigation behaviors.

The primary outcomes will be assessed on children and will include school absenteeism and participation in the SARS-CoV-2 testing (data obtained through administrative records). The secondary outcomes will capture physical activity, stress, depressive symptoms and COVID-19 vaccination among both enrolled children (by parent report) and parents or legal guardians of enrolled children. The goal is to conduct secondary outcome assessment surveys with 900 parents: 450 parents of children in the control group and 450 parents of children in the intervention group. The secondary outcome surveys will be completed for one index child per family, if more than one child in a household is enrolled in the study. The index child will be the child with the most recent birthday from time of household enrollment into the study. Parents will be asked to complete surveys about their own and their child's perceived stress, sleep disturbance, and emotional regulation. Parents will be invited to complete secondary outcome survey assessments at the time of enrollment, halfway through the study, and at the end of the study.

**Figure 1.** Timetable of overall study procedures

| | **Enrollment** | **Weekly** | **Study Post Survey 1 & Post Survey 2** | **Once a month after enrollment closed** | **Final Aim 2 data collection** |
|---|---|---|---|---|---|
| Electronic, Phone or Paper Consent/Assent | X | | | | |
| Electronic, Phone or Paper Enrollment Questionnaire | X | | | | |
| Weekly Check-In Survey | | X | | | |
| Update survey collecting changes in COVID-19 vaccination status and mitigation behaviors such as masking | | | X | | X |
| Secondary outcomes (physical activity, perceived stress, COVID-related stress, and depressive symptomatology for parents | X | | X | | X |
| Intervention Group: Risk communication comic books/videos (n=3) | | | | X | |

| | | | | | |
|---|---|---|---|---|---|
| distributed to children at school and parent videos (n=2) distributed by link in email | | | | | |
| Control Group: receives risk communication at the end of the school year (delayed intervention) | | | | | X |

**Aim 3**

**Assess implementation outcomes of the COVID-19 risk communication intervention and school-based mitigations strategies with parents, children, and school staff/administrators**. We will contact parents and students who participated in the COVID-19 risk communication intervention and conduct focus groups (parents) and semi-structure interviews (students) to assess the RE-AIM outcomes of the intervention and study procedures: reach, effectiveness adoption, implementation, and maintenance. Similarly informed by RE-AIM, we will conduct semi-structured interviews with school staff and administrators to assess outcomes associated with the implementation of the schools' or school district's COVID-19 mitigation strategies.

To assess RE-AIM outcomes for the ROSSEY COVID-19 risk communication intervention, we will conduct 4 focus groups with parents/guardians of students (*n*=32-40) who attend participating schools that received intervention components. Two of the focus groups will be conducted in English and the other two will be conducted in Spanish. We will conduct semi-structured interviews with K-5 students (*n*=20) who attend participating schools that received intervention components. Additionally, we will conduct semi-structured interviews with school staff and administrators (*n*=21) who work at participating schools that were randomized to receive intervention components. Focus groups and interviews will be conducted in Summer 2023 (approximately June – August) after the end of the 2022-2022 school year. Focus groups and interviews will be audio recorded and will last approximately 1 hr each. Audio recordings will be professionally transcribed by GMR Transcription and returned to the study team for qualitative analyses.

<u>Representation of women, children, and minorities</u>

All groups are eligible to participate in this study regardless of sex/gender and race/ethnicity.

<u>Co-enrollment guidelines</u>

There are no restrictions on co-enrollment for participants who participated in Aim 1 and Aim 2 who wish to participate in Aim 3 study activities.

<u>Sample size considerations and sampling strategy</u>

*Parents***.** Parents whose children are K-5 students at schools that were randomized to the ROSSEY communication intervention will be contacted by the research team to participate in focus groups. When consenting to participate in the ROSSEY study, parents indicated if they would be willing to be contacted for future studies. Using purposive sampling, the research team will contact parents who have indicated interest in being future study participants. Parents will be stratified by their index child they were reporting on for outcomes assessment in Aim 2. The research team will then select participants in order to get parents whose index children represent all grade levels.

*K-5 students.* Once parents have been identified and consented into the study, the research team will ask for the parent's permission to contact their child who was the index child for this study. The research team will then contact children whose parents gave permission. Children who are interested will provide assent to the research team. Similarly, to the parents, children will be purposively sampled in order to get good representation across all grade levels.

*School staff and administrators.* The research team will work with Jessica Post, YSD Chief Strategy Officer, to identify recruitment of school staff and administrators into Aim 3 study activities. We will aim to recruit one (1) superintendent who oversaw the school district's implementation of COVID-19 mitigation strategies, seven (7) principals who worked at the schools that were randomized to the ROSSEY intervention, six (6) teachers who work at schools randomized to the ROSSEY intervention, and six (6) school nurses. We will also plan to interview Jessica Post, as she helped oversee the implementation and management of the COVID-19 mitigation strategies at the schools.

*Sample size consideration.* Typically for qualitative analysis, thematic saturation is achieved with as few as 10 participants. As such, our proposed sample size between 8 to 10 focus group participants per focus group and approximately 20 participants for the student and school staff interviews should be sufficient to get complete feedback on the ROSSEY study and COVID-19 mitigation strategies implemented at schools.

Final contact
All participants will exit Aim 3 study activities after completing their informed consent/assent and either the focus group (parents) or semi-structured interviews (students, school staff) and completing demographic surveys (if not already completed).

Participant retention
Enrolled participants (i.e., provided informed consent/assent) who wish to participate in focus groups or 1:1 semi-structured interview will be contacted (email, phone call) using contact information obtained at enrollment to schedule activities. A participant will be considered lost to follow up (LTFU) after 5 attempts have been made to contact them on 5 separate occasions without successfully scheduling them into a focus group or semi-structured interview.

Participant withdrawal
Participants may voluntarily withdraw from the study for any reason at any time. The PI and research team may also withdraw participants from the study to protect their safety.

## IV. STUDY POPULATION

We will collaborate with the Yakima School District to recruit Kindergarten through 5th grade elementary students and their parent or guardian(s) into the research study. We will recruit elementary students into the study regardless of their participation in SARS-CoV-2 testing provided by the Yakima School District. This will allow us to evaluate the effect of the risk communication strategies on uptake of SARS-CoV-2 testing and other mitigation measures.

### Sample Size

We plan to enroll at least 900 elementary students from 14 schools in the the Yakima School District during the 2022-2023 school year into the research study. This will give us at least 80% power to detect a difference of at least 4 hours per week of in-person school attendance between the intervention and control arms.

### Enrollment Criteria for Aim 1.

Key Stakeholder interviewers: Interviews will be conducted with individuals directly associated with school districts in the Lower Yakima Valley, including administrators, teachers, and staff. ROSSEY Community Advisory Board (CAB) members will provide names of potential candidates.

Focus Groups: Focus group members must be parents of students who participated in the Together We STRIDE study. Past study participants who provided consent for future contact will be sent a letter of interest to participate in a focus group regarding COVID-19 and schools. Community Health Workers (CHWs) will send letters in random batches to mitigate number of outreach calls to make at one time. CHWs will call participants up to one week after initial letter to confirm enrollment.

Child Interviews: Child interviews will be conducted with students who participate in the Together We STRIDE study. Only the parents participating in the focus groups (see above) can provide permission for their children to be intereviewed for the present study.

### Enrollment Criteria for Aim 2

Eligibility criteria for participation in the RCT include:

- Has a child who attends elementary school in the Yakima School District for at least 2 days/week.
- Must be comfortable speaking and reading English or Spanish.
- Must be able to provide informed consent and legal guardian assent either virtually, on the telephone, or in-person.
- Must have a permanent mailing address available for study staff to mail necessary materials OR a working email address.

### Enrollment Criteria for Aim 3

*Parent Recruitment & screening:* Parents who have consented to be in the study at Aim 2 and completed baseline surveys will be invited to participate in the study. These parents will have an index child who attended K-5 schools that were randomized to receive the ROSSEY intervention. There are approximately 290 parents in our database who meet these inclusion criteria. The research team will work with CCHP staff to contact parents, solicit their interest, answer questions, and consent them into the study. CCHP staff will then coordinate scheduling four (4) focus group discussions; two of them will be in English and the other two will be in Spanish.

Enrollment: Interested parents will participate by completing one focus group.

*Student Recruitment & screening:* Parents who have participated in Aim 3 focus groups will be asked by research staff whether their children can be contacted to participate in semi-structured interviews. Parents who give their permission will be identified and a list generated for contacting students. Research staff will contact students via phone or in-person. and provide study information and answer questions. Expectations for participating in the study will be shared with potential participants

*School staff and administrators Recruitment & screening:* Research staff will work with YSD contact to identify school staff and administrators appropriate for participating in Aim 3 1:1 semi-structured interview. We will aim to recruit one (1) superintendent who oversaw the school district's implementation of COVID-19 mitigation strategies, seven (7) principals who worked at the schools that were randomized to the ROSSEY intervention, six (6) teachers who work at schools randomized to the ROSSEY intervention, and six (6) school nurses. We will also plan to interview Jessica Post, as she helped oversee the implementation and management of the COVID-19 mitigation strategies at the schools.

Enrollment: Interested school staff and administrators will participate by completing a 1:1 semi-structured interview and complete a one-time online demographic survey delivered through REDCap or by paper.

Aim 3 Inclusion and Exclusion Criteria

| | **Aim 3** |
|---|---|
| **Group** | Parents of K-5 students who attend a participating school that received the intervention components.<br><br>K-5 students who attend a participating school that received the intervention components.<br><br>School staff and administrators who work at a participating school that received the intervention components or are a part of the school district leadership |
| **Sample size target** | Parents: *n*=32-40<br><br>K-5 students: *n*=20<br><br>School staff and administrators : *n*=21 (Superintendent [1], Chief Strategy Officer [1], principals [7], nursing staff [6], teachers [6]) |
| **Age restriction** | ≥5 years old for students<br>≥18 years old for parents and school staff |
| **Inclusion** | **Parents**<br>▪ Parents/guardians must have index child enrolled in an intervention school and received the risk communication intervention.<br>▪ Must have completed baseline data collection.<br>▪ Attempt to recruit parents whose index children are enrolled in all grade levels involved in the intervention<br>▪ Only 1 parent per household enrolled in the intervention arm can be included in the sample<br>▪ Proficient in either English or Spanish |

| | |
|---|---|
| | **K-5 students**<br>▪ Student must be enrolled in an intervention school and received the risk communication intervention<br>▪ Attempt to recruit students who are enrolled in all grade levels involved in the intervention<br>▪ Proficient in English.<br><br>**School staff and administrators**<br>▪ School staff working at schools randomized to intervention<br>▪ Staff must have been involved in some way with the schools' COVID-19 prevention and mitigation efforts<br>▪ Proficient in English |
| **Exclusion** | **Parents**<br>▪ Parents whose index child is enrolled in a control school<br>▪ Incarcerated, and any conditions that may preclude or limit the participant's ability to comply with study procedures, according to the investigators<br>▪ Parents who do not complete baseline survey data collection<br><br>**K-5 students**<br>▪ Student who is enrolled in a control school<br>▪ Wards of the state<br>▪ Who have clinically-diagnosed dementia, terminal (<5 years) illness, major psychiatric illness, severe hearing impairment, and inability to move<br><br>**School staff and administrators**<br>▪ Staff working at schools randomized to control<br>▪ Incarcerated, and any conditions that may preclude or limit the participant's ability to comply with study procedures, according to the investigators<br>▪ Staff not involved in some way with the schools' COVID-19 prevention and mitigation effort |

## V. STUDY PROCEDURES

**Recruitment, Screening, and Consent for Aim 1:**

**Key stakeholders**

We will use purposive sampling to select 30 participants from the Lower Yakima Valley. The sampling comes from previous community advisory board members, who are directly associated with school districts, teachers, and staff who participated in the Together We STRIDE Study. In addition, the ROSSEY Study community Investigators will nominate school employees contacts.

A ROSSEY staff member will send two email messages (see Attachment A) roughly two weeks apart to the selected potential participants with an invitation to participate in school stakeholder interviews. When a potential participant responds to the email, they will state whether they prefer the consent and survey to be completed over the phone or through a secure survey link through

email. The Fred Hutch staff member will also confirm a date and time for the in-depth semi-structured interview.

For stakeholders that prefer the online consent and survey, the project manager (at Fred Hutch) will send the stakeholder a personal REDcap survey link to the consent and survey. Prior to the scheduled interview, the Fred Hutch staff member needs to confirm with the project manager that the stakeholder completed the REDcap survey. If the REDcap survey was not complete, the staff member will complete the consent and survey over the phone prior or Zoom (preference of stakeholder) prior to implementing the interview.

For stakeholders who do not respond to the email messages, the staff member will contact the stakeholder via phone to gauge their interest in participating in the interview.

eConsent – Participant Online Survey

Stakeholders who complete the survey online will complete the eConsent process (Attachment B) through RedCap. Collaborative Data Services has experience constructing eConsent surveys. The eConsent must be signed by the participant and a copy of the consent validated/approved prior to moving forward with the survey. REDCap automatically sends a copy of the signed consent to the participant through email. REDCap stores pdf copies of each eConsent in a secure file repository enabling real time access to eConsent files on-demand. For participants who choose to have the survey administered over the phone, the exact consent text will be used as a verbal consent.

Verbal Consent

The staff member will obtain verbal consent from participants (see Attachment B). The staff member will read the consent form to the potential participant verbatim to ensure comprehension and answer any questions that they may have before they consent to participate. If the potential participant refuses participation, the staff member will thank them for their time and end the call session. Once verbal consent is obtained, the staff member will conduct the short survey prior to the semi-structured interview.

Data Collection

The purpose of the survey is to understand more about the community members who are providing critical information to the study. The survey items include questions about demographics characteristics (i.e., ethnicity, race, sex, education, insurance status, age, employment status, title, length of employment, and if workplace is not a school – what is their affiliation with schools).

**Parent Focus Groups**

We will contact parents who participated in a past study (Together We STRIDE) and have agreed to be contacted for future studies. Eligibility will include having a child who is currently in grades K–8 in one of the four school districts in the study.

Recruitment

We will first send an invitation letter explaining the study. CHWs will contact the potential participants by calling the phone number on file from a previous study. A parent can also respond directly the Center for Community Health Promtion (CCHP) office. The CHW will follow the focus group recruitment call script (see attachment D) when contacting the participant.

When 10 parents have been enrolled, the CHW will find a day/time to schedule a focus groups (in English or in Spanish). We will continue this process until four focus groups have been

scheduled (n=30 parents). We aim have at minimum 6 participants in a focus group, although 10 is ideal.

Verbal Consent
As outlined in the recruitment script, the CHW will obtain the verbal consent from the participants (see Attachment E). The CHW will read the consent form to the stakeholder verbatim to ensure comprehension and answer any questions that they may have before they consent to participate. If the potential participant refuses participation, the staff member will thank them for their time and end the call session. The CHW will mark on the participant contact log if verbal consent was agreed or if the potential participant refused.

Once verbal consent is obtained, the CHW will conduct a short demographic survey (see attachment F). The consent and survey will be conducted over the phone prior to the scheduled date/time of the focus group.

**Student Interviews**
Once parents have agreed to participate in the focus groups, CHWs will elicit the parents' interest to enroll their child to participate in a semi-structured interview.

Recruitment:
Study staff will contact parents by phone to see if the student is interested in participating in the semi-structured interview. If interested, the study staff member will schedule a date/time for the interview, obtain parental consent and child assent, and conduct a short demographic survey. The goal is to recruit 20 students for the interview.

Verbal Consent & Demographic Survey
The parent consent and child assent are both housed in REDcap. If it is determined that the child is interested in participating in the interview, the staff member read the consent and assent verbatim from the REDCap screen. If the parent agrees to the consent and participation the staff member checks the appropriate box in REDCap to move to the child assent document. The staff member reads the child assent verbatim from REDCap and asks the child if the agree to participate. Participation is also noted on the contact log. The staff member then conducts the demographic survey with the child. Once consent and the survey are complete, the staff member schedules the parent/child for an interview date/time.

**Recruitment, Screening, and Consent for Aim 2:**
The Community Advisory Board (CAB) will provide guidance and assist in identifying the schools that will participate.

First, we will coordinate with the schools to hold virtual informational meetings with the school principals, teachers and school staff. Teachers/classrooms that show interest in promoting the research study and assisting by providing materials to students, will be enrolled.

We will establish a memorandum of understanding (MOU) with the Yakima School District. The MOU will describe the purpose of the study, benefits to the school district, a description of student eligibility criteria, what schools are asked to do, risk and benefits, who to contact for study related questions, confidentiality, and a statement that explains what the school district is being asked to do. Participating elementary schools in the Yakima School District will be offered a $10,000 honorarium to subsidize the cost of implementing the study in the school.

The Yakima School District and its elementary schools will agree to participate in the following activities:

1. Provide permission to send recruitment consent packets to the families of students
2. Allow study staff members to act as liaisons between the school, Fred Hutch, and UW for purpose of distributing and picking up study materials and to guide students
4. Share information and data on student absenteeism
5. Agree to Data Sharing and provide access to the research team for COVID-19 testing data of all students enrolled in the research study.

For recruitment of students, an information sheet with the study activities will be distributed via teachers to students in grades K-5 at participating schools. The information sheet will include information on an upcoming virtual Q&A session for families to attend; one Q&A session will be organized at each school and a separate Q&A sheet (with the study call number) will also be included in the packet for families who cannot attend the information session. Families (parent/legal guardian) interested in enrolling into the study will have the options to consent online, on paper, or over the telephone.

We will coordinate with schools to send automated emails introducing the study, reminding the participants to attend the Q&A session, or to call CCHP if they need assistance accessing the website or if they have questions. The local CCHP office is staffed with four bilingual/bicultural (English and Spanish) employees from the community). Additionally, parents of eligible students will be able to refer their children into the study by contacting study team members or by enrolling into the study online.

Parents can will be screened for eligibility via a standardized screening questionnaire on: REDCap web-based portal, telephone, or the paper packet. If enrollment assistance is needed, participants may be screened over the telephone with a study team member.

Informed consent or assent will be obtained from all individuals. Parents/legal guardians aged 18 years and older will read and e-sign their own consent form through a web-based portal. They will also have the option to provide consent on paper or over the telephone. The online consent portal will encourage parents/legal guardians to contact research staff by phone or email to review the risks and benefits of study participation, or to review the study procedures outlined in the consent form. There will be two separate assent forms for children: one for the 7-12 year age group and one for children in the 13-17 year age group. Both forms will have simplified language that explains the study's purpose and study procedures. Children will read and sign the assent form that corresponds to their age group, along with a parent or legal guardians signature on the consent form. Children below the age of 7 will have a parent or legal guardian sign the consent form, and the child will provide verbal assent if able. Electronic copies of the e-signed consent and assent documents will be automatically emailed to participants. For those who enroll on paper or over the telephone, copies of the consent and assent documents will be sent to the participants either via e-mail, through the mail, or in-person. Parental permission will also be obtained to allow us to access test data and school attendance data of children enrolled in the study.

**Recruitment, Screening, and Consent for Aim 3:**

*Parent recruitment and consent into the study*

1. Research team, in conjunction with CCHP, will provide study information to parents who completed baseline surveys and gave permission to be contact about future study activities. The study information materials will contain pertinent study information and instructions for parents can contact study staff (e.g., study email and phone number) if they wish to participate in a focus group. Research team members will contact parent who have provided

their contact information by email or phone and provide additional information about the study and answer questions. Expectations for participating in the study will be shared with potential participants.
2. If parents express interest, research team members will consent parents into the study, either through an online consent form or verbally depending on parents' preference. Consenting may happen at time of first contact or at a later date depending on the parent's availability to go through the consent process.
3. After consent has been given, research team will schedule parent to one of four focus groups depending on parents' preference for time and focus group language. For the 4 focus groups, a minimum of 32 parents but up to 40 will be recruited and participate.
4. Focus groups will be conducted in-person at a YSD facility, at a participating school, or other community space to improve convenience for parents to attend.
5. Trained research staff will moderate a 60-minute focus group that will be audio recorded. A second research team member will be in the room to help assist and take additional notes.
    a. If parent participants had not provided their informed consent already, research staff will consent parents before beginning the focus group.

*K-5 student recruitment and consent into the study*

1. Parents who participated in Aim 3 focus groups will give permission and consent for their index child (i.e., the child they reported outcomes on during Aim 2 who is a K-5 student at a participating school in the study). Research staff will contact students using provide contact information from the parents either over the phone or in person. Research team members will contact parent who have provided their contact information by email or phone and provide additional information about the study and answer questions. Expectations for participating in the study will be shared with potential student participants.
2. If the child is interested, research team members will assent the student into the study, either in-person or verbally over the phone depending on the student's preference. Assenting may happen at time of first contact or at a later date depending on the student's availability to go through the assent process.
3. After assent has been given, the research team will schedule the child for a 1:1 semi-structure interview.
4. Student interviews will take place in-person at a YSD facility, the student's school, or other location depending on the student's and their parent's preference.
5. Trained research staff will conduct a 60-minute interview that will be audio recorded. If needed, a second research team member will be present to assist.
    a. If student had not provided assent before the interview, research staff will assent the student before beginning the focus group

S*chool staff participant recruitment and consent into the study*

1. Research staff will work with YSD contact to distribute study information (emailed, paper flyers distributed on campus) to school staff and administrators.
2. Interested school staff participants will contact the research team by phone or email to participate and ask any questions.
3. Research staff will send consent and demographic survey link through REDCap link and schedule a 1:1 interview. Once participant completes consent, a copy of the consent will be emailed to the participant.
    a. Attempts will be made to recruit a superintendent, principals at each school, school nurses, and teachers at each school. YSD primary contact will also be invited to participate in an interview.
4. Interviews will take place online through HIPAA-compliant video conferencing software (e.g., Zoom, MS Teams). If participant prefers in-person interview, interviews will be schedule at

CCHP office, the participant's school or at a preferred location near the participant's residence.

**Aim 1 Study Procedures:**

School Stakeholder Interviews

Interviews will be held with 25–30 school stakeholders (e.g., superintendents, principals, teachers, nutrition service directors). The interview will assess 1) social, ethical, cultural, and behavioral concerns related to COVID-19 in the community; 2) schools' readiness to have students return to school and maintain onsite learning; and 3) interventions and implementation strategies that could mitigate those concerns. We will use purposive sampling to select 30 participants. Interviews will last 45–60 minutes and will be audio recorded. Dr. Ko will develop the interview guide with input from the Community Investigators and the CAB. The CHWs will conduct the interviews.

Parent focus groups

We will contact parents who have participated in past studies and have agreed to be contacted for future studies. Eligibility will include having a child who is currently in grades K–8 in one of the four school districts in the study. We will first send an invitation letter explaining the study. When a parent responds to the letter and contacts the research team, the CHW will follow-up with phone calls. When 10 parents have been enrolled, the CHW will find a day/time to schedule a focus groups (in English or in Spanish). We will continue this process until six focus groups have been scheduled (n=60 parents). Each focus group will be moderated by a trained bilingual (English and Spanish) focus group moderator. Dr. Ko will develop the moderator guide with the community partners' input. The guide will examine 1) concerns for regularly testing children; 2) needs and concerns of children returning to school and preventive measures implemented in schools, and ways to mitigate those concerns; 3) fears about children contracting COVID-19 and resources needed to quarantine; and 4) concerns regarding vaccine safety, acceptability, and uptake. All study materials will be translated from English to Spanish using forward and back translation. Translation quality will be assessed by Dr. Ko (an Asian Latina) and a native Spanish speaker with skills in translating study materials from English to Spanish and vice versa. For the Spanish focus groups, the audio recordings will be first transcribed in Spanish and then translated in English.

Student Interviews

Once parents have agreed to participate in the focus groups, we will elicit parents' interest to enroll their children for the semi-structured interview. We will recruit 25–30 students. The interviews with students will cover 1) needs and concerns for regularly testing for COVID-19; 2) ability to follow preventive measures at school and the onsite learning protocol; and 3) fears about contracting COVID-19 and ways to mitigate the concerns. Interviews will last 25–30 minutes and will be audio recorded.

**Analysis of Quallitative Data**

Transcripts from the semi-structured interviews and focus groups will be uploaded into ATLAS.ti and analyzed separately. Two analysts will use an inductive, constant comparison approach in which concepts will be identified, and themes derived, from the data. We will also create a set of tentative a priori codes based on the interview and the moderator guides. The analysts will follow the inductive coding with deductive coding using the a priori codes to ensure that information from the questions is retained during coding. Using an iterative process, the analysts will meet weekly to refine the codebooks, adding, removing, and revising codes, as needed, to address inter-rater agreement and to compare new data with existing data. We will build consensus around themes that are identified throughout the coding and analysis process.

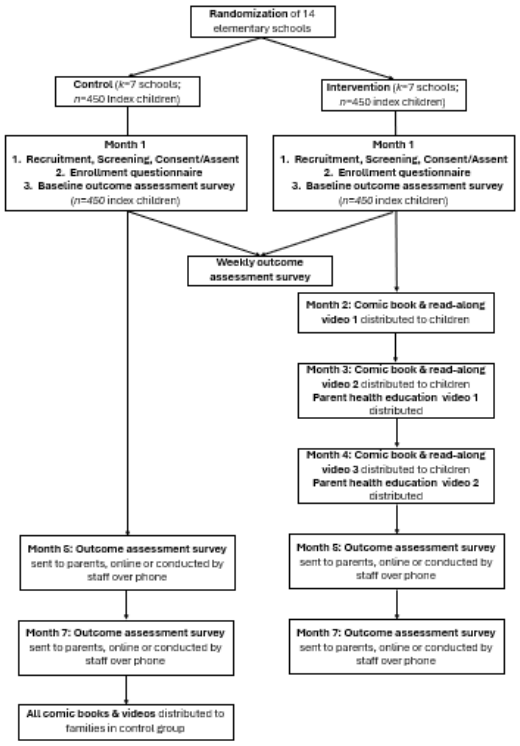
We will compare the themes arising from the data and determine possible linkages across participants and thematic categories.

**Aim 2 Study Procedures:**

Families will have three options to enroll children in the study: online through a website portal (Project REDCap), through a paper enrollment packet that will be distributed by our staff to students at school, or with assistance from study staff over the phone.

- Parents/guardians who choose to enroll children in the study online will provide informed consent by reading and e-signing consent and assent forms through a web-based REDCap portal, and then the participant's parent/legal guardian will complete a baseline enrollment questionnaire.
- The paper enrollment packet will include a flyer advertising the study, a guide for filling out the packets, consent and assent forms, and the enrollment questionnaire. Parents who prefer to enroll their child with the paper enrollment packets will fill out the enrollment packet and their child will return the completed packet to a secure lock box available at school. Study staff will pick up the consent enrollment packets from the lock box and enter the participant's information into REDCap. If there is information missing or issues with the paperwork, a staff member will call or email the parent of the participant to collect any missing information from their paper packet.
- Parents/guardians who choose to enroll with staff assistance over the phone will be verbally guided through the REDCap consent/assent forms and enrollment questionnaire.

**Figure 2. Outline of Study Procedures**




Upon enrollment, randomization will occur per plan below:

**RCT Randomization Plan:** The randomization plan was developed by the study biostatistician. The schools will be matched in pairs with the primary match guided by the population of English Language Learners in the elementary schools and the secondary match on the size of the schools. The proportion of English Language Learners is highly correlated with low income and migrant status so will serve as a surrogate for all three characteristics. Size is moderately correlated to the proportion of English Language Learners. Once the study launches, each school within a pairing will be randomly assigned to either the Control or Intervention group.

**After enrollment is complete, parents/guardians of study participants will take part in the following study procedures:**

**Weekly Check-in Survey**: Parents of enrolled students will be asked to complete an online weekly 5-minute survey throughout the duration of the study that asks if their child is experiencing symptoms consistent with COVID-19 and has sought health care, if they have been absent from school in the past week, or if they have been exposed to someone with suspected COVID-19. Parents will also be asked if their child has been tested for SARS-CoV-2 at the Yakima School district static test site.

**Secondary Outcome Assessments:** Participants will be asked to participate in secondary outcome assessment surveys for the index child in each family collected either online, on paper, or by phone, based on their preferences. The index child will be selected based on the child with the most recent birthday from the time of enrollment if there is more than one child enrolled in a family. The goal is to conduct 900 secondary outcome assessments: 450 parents of children in the intervention group and 450 parents of children in the control group. Study surveys are available in both English and Spanish, as chosen by the participating parent or guardian.

Parents will be asked to complete surveys on topics such as their own and their child's perceived stress, sleep disturbance, physical activity, and emotional regulation (including both depressive and anxiety symptoms). Secondary outcome survey assessments will be offered to participants to be completed at the time of enrollment, halfway through the study (month 4), and at the end of the study (month 6). In order to better understand potential moderators and mediators of intervention effects, these surveys will also assess health literacy (at enrollment only), positive and negative outcomes expectations around testing and vaccines, and self-efficacy around testing, mask use, discussing COVID-19 with a healthcare provider and risk communication/information relevancy.

**Follow-up (Post 1 and Post 2) Behavior Update Surveys:** At the end of the study, parents will be asked to complete the first post survey either online or by phone. The surveys will ask for updates to their contact and demographic information, child's COVID-19 vaccination status, and child's SARS-CoV-2 mitigation behaviors. For students with missing or phone numbers no longer in service, ROSSEY staff will contact the YSD to 1) determine if the student is still attending YSD 2) find out which school and teacher to send a notice to the parent. Sealed letters, requesting updating contact information, will be sent to the school for the teacher to send home with the student. Students determined to still be enrolled at YSD, and are non-responders to the follow up survey, will receive an at home follow up visit by ROSSEY staff as a final attempt to reach student and parent to complete survey. Follow-up assessment closure will take place one week after completion of home visits.

**Risk Communication:** Risk communication, in the form of printed comic books and accompanying read-along videos for the children (n=3), and videos for the parents (n=2), will be distributed in English and Spanish once a month after enrollment closes to children and their families randomly selected into the intervention group. For children and families in the control group, the same materials will be shared at the end of the study. Comic books will be distributed to the students by mail and parents will be mailed a password protected link to access the online health education videos and comic book read along videos.

The risk communication will highlight benefits and address barriers around preventive behaviors, such as SARS-CoV-2 testing and COVID-19 vaccination. The comic book will follow the main characters (siblings Hector, Mia, and Ava) and their experiences during the COVID-19 pandemic. The comic books will be narrated into videos for children with limited reading abilities and whose parents and/or siblings cannot read the comic books to them (this is what we refer to as "read

along" videos). The messages in the risk communication will be infused with constructs from the Health Belief Model, Social Cognitive Theory, Transtheoretical Model of stages of change and the Self Determination Theory.

We will adapt the messages created by our team for another study to address COVID-19 misinformation, preventive behaviors, and HPV vaccine hesitancy in the risk communication. The CAB will provide input on the messages and the visuals and approve the final version before printing. The English and the Spanish comic books (and read-along videos) ensure that both parents and students can read the communication. Health education videos focused on COVID-19 safety will also be given to the parents of participating students randomized to the intervention arm. Below is a table with examples of how the comic book and video messages will be operationalized.

**Table 2. Examples of Comic Book Messages**

| Constructs | Message objective | Operationalized in the comic book |
|---|---|---|
| Perceived susceptibility | Increase perceived susceptibility | "Most children infected will never know." |
| Perceived severity | Specify consequences of the risk and condition | "COVID-19 can make people sick fast and die." |
| Perceived benefits | Define action to take; clarify the expected positive effects | "The test can help find people that have the virus."<br>"The vaccine will protect me from COVID in the future." |
| Perceived barriers | Identify and reduce barriers through reassurance, incentives, assistance | "The covid-19 vaccine is like a flu shot." |
| Cues to action | Provide how-to information; promote awareness; give reminders | "Wear your mask, wash your hands and maintain social distancing from your peers at school." |
| Self-efficacy | Provide training and guidance in performing action | "I am sure I can ask my parents that I want the shot." |
| Autonomy | Foster autonomy-supportive environment | "Your mask protects me. My mask protects you." |
| Competence | Provide realistic, actionable recommendations | "This advice is easy for me to follow." |
| Relatedness | Foster solidarity in the school community | "My school is my community - we are all in this together" |
| Disinformation | Correct disinformation "drinking bleach kills SARS-CoV-2" | Do not introduce bleach or disinfectant in your body. Bleach and disinfectant should be used carefully to disinfect surfaces only. |
| | Correct disinformation "adding pepper to my soup prevent or cure COVID-19" | Hot pepper in your food, though tasty, cannot prevent or cure COVID-19. Use preventive measures, practice social distancing, wear mask, and wash hands regularly. |

**COVID-19 Testing Information and Procedures**

COVID-19 testing strategies and implementation of testing procedures occur outside of this study's scope, therefore is not determined by the research team. Screening and symptomatic testing is being offered (but not mandated) to Yakima School District students through the Yakima School District static testing site. The possibility for the Yakima School District to implement weekly testing in schools for all students may occur at a later time in the study period. The test currently being utilized is the BD Veritor System for Rapid Detection of SARS-CoV-2. SARS-CoV-2 testing will be offered to students on a weekly basis. The BD Veritor rapid antigen test conducted by the Yakima School District is CLIA approved by the WA DOH.

**Aim 3 Study Procedures:**

We will conduct focus groups and semi-structured interviews with parents, K-5 students, and school staff to understand the effect of the ROSSEY intervention and YSD COVID-19 mitigation strategies on a variety of school performance and health-related outcomes, using the RE-AIM framework, a widely used framework that explicitly guides research assessment of issues, dimensions, and steps in the design, dissemination, and implementation process of public health programs or interventions that are predictive of successes or failures in achieving broad and equitable population-based impact. We provide examples measures in Table 1. The completed focus group and interview guides can be shared upon request. Focus group discussions and semi-structured interviews will be about 60 minutes each.

Aim 3 Endpoints and variables

**Table 1. Example of measures from focus group/interview guides mapped to RE-AIM outcomes**

| Construct | Definition | Example measures |
|---|---|---|
| Reach | The absolute number, proportion, and representativeness of individuals who are willing to participate in each initiative, intervention, or program, and reasons why or why not. | What are some reasons you wanted to participate in the ROSSEY study? |
| Effectiveness | The impact of an intervention on important individual outcomes, including potential negative effects, and broader impact including quality of life and economic outcomes; and variability across subgroups (generalizability or heterogeneity of effects). | How did the comics/videos affect your COVID safety behaviors? |
| Adoption | At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's key functions or components, including consistency of delivery as intended and the time and cost of the intervention. Importantly, it also includes adaptations made to interventions and implementation strategies. | How many times did you read/watch the comics/videos? |
| Implementation | The extent to which: a) behavior is sustained 6 months or more after treatment or intervention; and b) a program or policy becomes institutionalized or part of the routine organizational practices and policies. Includes proportion and representativeness of settings that continue the intervention and reasons for maintenance, discontinuance, or adaptation. | Can you describe your experience participating in this study? |
| Maintenance | The extent to which: a) behavior is sustained 6 months or more after treatment or intervention; and b) a program or policy becomes institutionalized or part of the routine organizational practices and policies. Includes proportion and representativeness of settings that continue the intervention and reasons for maintenance, discontinuance, or adaptation | What kinds of changes would you make to the intervention (videos) so it could work better for your community? |

Enrollment & Demographic Survey Information

Data collection instruments will be developed by the research team. Focus group and interview guides will be developed and collected by study staff. Survey data will be collected electronically

using REDCap or paper forms when needed. Compared to paper data collection, electronic data collection has the potential to be more secure, in that all data will be password protected from the moment of data collection. Data will be uploaded directly to the study's secure server from REDCap. The secure server that warehouses data will be password protected and accessible only to study personnel directly involved in data cleaning and analysis. We will plan to use wireless internet to send digital data. To protect the data, the website to which data will be uploaded will use existing well-known SSL/TLS (Secure Socket Layer/Transport Layer Security), as indicated by "HTTPS" in the URL. SSL/TLS is used by sites such as Google to protect data. All digital data will be sent and received using HTTPS.

Record Storage**:** PI and study team will maintain, and store in a secure manner, complete, accurate, and current study records throughout the study. The investigator will retain all study records for at least seven years after completion of the study. Study records include administrative documentation and regulatory documentation as well as documentation related to each participant screened and enrolled in the study, including informed consent forms, contact information forms and case report forms from all visits during the study.

Data analysis

Aim 3 will collect qualitative data to understand the implementation of the ROSSEY intervention and the COVID-19 mitigation strategies at Yakima School District. The qualitative data will be used to empirically corporate and understand the quantitative data collected in Aim 2 and compare how responses among study participants may have changed from Aim 1 focus groups and interviews.

We will use similar data analysis procedures as used in Aim 1 qualitative analyses. Transcripts from the semi-structured interviews and focus groups will be uploaded into Dedoose and analyzed separately. Two analysts will use an deductive approaches based on RE-AIM framework definitions as well as an inductive, constant comparison approach in which concepts will be identified, and themes derived, from the data that do not fit RE-AIM constructs. We will also create a set of tentative a priori codes based on the interview and the moderator guides. The analysts will follow the inductive coding with deductive coding using the a priori codes to ensure that information from the questions is retained during coding. Using an iterative process, the analysts will meet weekly to refine the codebooks, adding, removing, and revising codes, as needed, to address inter-rater agreement and to compare new data with existing data. We will build consensus around themes that are identified throughout the coding and analysis process. We will compare the themes arising from the data and determine possible linkages across participants and thematic categories.

Training procedures and quality assurance: Study PI will supervise training of study staff and clinic/pharmacy staff in study procedures, including recruitment, enrollment, conduct of the interviews, and maintenance of confidentiality and privacy. Specific expertise in the conduct of qualitative research will be provided by our team’s qualitative expert, who has conducted qualitative research in numerous settings. All staff have been or will be trained in the responsible conduct of human subjects’ research (NIH or CITI courses).

Adherence to protocol: For Aim 3, weekly reporting of enrollment will enable us to monitor if the study is running according to approved protocols. Frequent reporting will also enable us to quickly respond to any problems that may arise during the study.

Data and safety monitoring plan

There will be no independent Data Safety Monitoring Committee utilized to oversee the conduct of this minimal risk study. All members of the research staff and the personnel employed by the community-based organization will be trained in responsible conduct of research, including enrollment of human subjects, by Dr. Ko and the research training offered by the University of Washington and Fred Hutch.

To protect against the risk of loss of confidentiality, only Dr. Linda Ko and designated research team members (i.e., Project Coordinators) will have access to identifiable information or the study database. The study database will be password-protected and housed on a secure server at the UW. Data collected during the semi-structured interviews and focus groups will be transported back to the locked offices at the UW by the Project Coordinator, designated study staff, or PI if conducted in-person. Survey data will be collected via a secure online survey platform or by paper. Paper survey data and consent forms will be kept in a secured cabinet under lock and key in the locked office at the UW. For analysis, identifiable information will be removed from the datasets and participants will be assigned a unique study identifier. Audiotaped data from the semi-structured interviews/focus groups will be transcribed and kept on a password-protected server. The transcripts will identify each participant by unique study identifier.

## VII. RISKS AND BENEFITS

There is minimal risk of breach of confidentiality in this study. This risk is minimal because there are multiple safeguards in place (see VIII. Data Management section) to ensure participant confidentiality is protected.

**Cost of participation**:

There is no cost to subjects for participation in this study.

## VIII. STUDY COMPENSATION

**Aim 1:** Community members that participate in the key stakeholder interviews, child interviews and focus groups will be compensated for their time. Consented key stakeholders who complete the short REDCap survey and complete the semi-structured interview received a $30 compensation for their time. Students who consented and completed the semi-structured interview receive $15 as a thank you for their time and help. Parents who consented and attended the focus group will receive $30 for participating.

**Aim 2:** Participants enrolled in the ROSSEY study will be entered into a drawing to receive a free pizza during each month of the school year for their family as a thank you for their enrollment. In addition, parents will receive a $5 gift card for every weekly check-in survey that they complete for each child enrolled in the study. They will also receive an additional $5 gift card for each child enrolled in the study to encourage parents to travel to the YSD COVID-19 testing each week. In addition, families who participate in the secondary outcome assessments will be provided a $50 gift card for each assessment that they complete.

**Aim 3:**
*Parents*. Will receive $20 (in the form of cash, check, or gift card) for participating.
*Students***.** Will receive $10 (in the form of cash, check, or gift card) for participating.

*School staff and administrators.* Will receive $30 (in the form of cash, check, or gift card) for participating.

## IX. DATA MANAGEMENT

**Data security and privacy:** All information from the study subjects will be kept confidential. All forms will use a unique participant identification number that is assigned to the participant upon enrollment in the study. All forms will use this unique participant identification number, except for direct communications with the participant which will include their names. Data will be collected electronically in REDCap. REDCap is Title 21 CFR Part 11 compliant, password protected and is an auditable database. The list linking the participant to the ID number will be stored separately from the REDCap database. Access to identifiable information will be limited to the study staff; their grounds for employment regarding this study will be contingent on maintaining the security of study records and any identifiable information. Electronic files will be secured via logon password protection for study accounts. Any datasets that include identifiable information will be stored in a HIPAA-compliant manner via OneDrive for Business at the University of Washington. No identifying information will be included in any data sent to the broader study team or any other data-sharing repositories. All data files transferred for the purpose of this study will be transferred via encrypted software and the original files will be kept on our server.

Identifiers will be kept on all data files until the study is closed out. Primary data collection sources will be kept for at least 5 years following the publication of the primary result from this trial. Once this time elapses and the electronic data files are fully cleaned, any paper forms containing identifiable information will be destroyed.

**Test Information & Results Data Use Agreement:** The study team will create a Data Transfer and Use Agreement (DTUA) in collaboration with the Yakima School District to receive access to enrolled participant's test information and results collected by the Yakima School District. SARS-CoV-2 data will primarily originate from the Yakima School District's static test site. The DTUA will also provide the study team access to identifiable school attendance data for students enrolled in the study. Test data and school attendance data will only be stored and used for students whose parents or legal guardians have given formal consent to participate in the study. Before the research team has access to the identifiable test data and identifiable school attendance data, the Yakima School District will identify an Honest Broker, a person within the school district to clean and remove non-study participant data. The Yakima School District and all ROSSEY study teams with the University of Washington and Fred Hutch will sign and agree to all requirements of the agreement.

The Yakima School District may also provide de-identifiable, grade-level SARS-CoV-2 positive test results from their static testing site. The data and type of data shared is subject to change based on the Yakima School District's capacity and their plans for their school-based weekly testing program. This de-identifiable data may be stored and used for research purposes only, as outlined in the DTUA and will include only study participant data.

**Data quality:** Data will be checked for logic and checked for consistency within individual participants and households by automatic error-checking within REDCap and by study staff in the centralized data capture system. Computerized checks will be conducted weekly to identify missing, inconsistent or out of range data. Any suspect data will be raised as data queries. Examples of suspect data (while not an exhaustive list) will include:

- Invalid or improbable dates of birth
- Dates in the future, dates greater than 100 years in the past

- Invalid or incompatible contact or symptom data

The study coordinator will investigate data queries to provide an explanation and possible resolution of discrepancies on a weekly basis using the data quality module overview on REDCap. The study coordinator will raise queries and share them with the study staff who are involved in the enrollment process or are involved in data collection and management. The study staff will contact participants via their preferred method of communication to clarify instances of suspect data. Following this communication, the data items will be marked as "verified," and an additional review will be conducted by the study coordinator then the query will be closed. When there are no longer any open queries on a survey it can be locked by the study coordinator.

## X. PROTECTION AGAINST RISKS:

This is a multicenter study. All identifying data will be stored at the University of Washington or Fred Hutchinson Cancer Research Center using standard security techniques. Hard copies of data collection materials that have identifiers will be locked in the office of the study PIs or a room with limited access by specific individuals. When possible, redacted (de-identified) versions of the data will be used for coding and data analysis. Personal identifiers will be stored in the database on OneDrive, which is HIPAA-compliant, password protected, and only accessible to specific individuals. Transfer or storage on portable devices (e.g., laptops, flash drives) will be encrypted. The devices on which this information is stored will be accessible only to individuals who need access to the data.

To reduce distress, study participants will be given the opportunity to skip any questions that they are not comfortable answering. Additionally, all participants will be reminded that participating in research is always optional, and they may terminate their participation at any time without consequences. All members of the research team will be required to complete Protecting Human Research Participants training offered before enrollment of participants begins. Only those research team members with login credentials and passwords will be granted access to the centralized data capture system, where data are stored and audited. As previously stated, to mask participant identity, participants will be assigned unique study identifiers (participant ID numbers) at the time of enrollment. Only specific members of the study team will be able to link the participant ID to the participant's name. As all survey data collected will be via parent report only, there are no concerns in this study about the confidentiality of the youth's answers from the parent. Individual subject level data collected from the secondary outcomes surveys will not be shared with the schools in order to protect the privacy of participating youth; school and study level summary reports from the secondary outcome surveys will be shared with participating schools, but in order to protect youth confidentiality, no summary tables will include cell sizes smaller than five.

## XI. STATISTICAL ANALYSES

The primary analysis will be based on the average number of onsite learning hours per week over the study period for each student. The data will be analyzed using a linear mixed effects model with district and randomization arm as fixed effects, and school and classroom within school as random effects. We will first test for any difference between the randomization arms using $\alpha = 0.05$ and report the comparisons between arms.

## XII. ADVERSE EVENT REPORTING

**Serious Adverse Events**: Serious adverse events (SAEs) under Good Clinical Practice (GCP) guidelines include death, a life-threatening reaction to a study procedure, hospitalization, or

significant or persistent disability or impairment. Other events may also be considered a serious adverse event if, based on medical judgement, the event jeopardized the patient to the point of requiring medical or surgical intervention.

**Other Adverse Events**: This will include any untoward medical event that occurs in a participant, any unfavorable sign or symptom disease temporally associated with the study, or any noxious or unintended response to the study procedures. These other adverse events can be anticipated based on what we know about reactions to study procedures, or unanticipated.

Unanticipated adverse events are those that are either unexpected in terms of nature, severity, or frequency, especially if they indicate that there is greater risk of harm than previously recognized.

Participants will be instructed to report any adverse events related to the study procedures to research staff by phone call or email. Emails received by study staff indicating that an adverse event has occurred in a household will be followed up by a phone call to that participant. All adverse events will be reported using an official Adverse Event Report Form to the designated principal investigator (Linda Ko, PhD) or designee for review within 48 hours. The review will determine if there is any indication of the event being related to study procedures. If this review determines the event to be both anticipated and related to the study, it will be logged in the centralized data capture system. If the review determines the event to be unanticipated and related to the study, a report of the event will be submitted to the UW IRB.

## XIII. END OF STUDY

The end of the study is defined as when the last participant has had their last data collected at the end of the study period. Overall, the study is projected to last until June 2023 when the school year ends, and the overall study is projected to end between April to June 2024, if funding allows.

## XIV. DEFINITIONS

**Acute Respiratory Illness (ARI):** We will use the CDC definition of ARI that includes disease that typically involves the airways within the nose and throat and may or may not include fever. ARI is generally defined by the presence of two or more symptoms such as fever, cough, runny nose or nasal congestion, or sore throat. ARI is more sensitive (broader) than influenza-like illness to describe illness consistent with influenza because fever/feverishness is not required.

**Exposure/Close contact:** Per CDC definition[16], a close contact is someone who was less than 6 feet away from infected person (laboratory-confirmed or a clinical diagnosis) for a cumulative total of 15 minutes or more over a 24-hour period (for example, *three individual 5-minute exposures for a total of 15 minutes).*

- **Exception:** In the **K–12 indoor classroom** setting or a structured outdoor setting where mask use can be observed (i.e., holding class outdoors with educator supervision), the close contact definition excludes students who were between 3 to 6 feet of an infected student (laboratory-confirmed or a clinical diagnosis) if both the infected student and the exposed student(s) correctly and consistently wore well-fitting masks the entire time.

**Laboratory Confirmed COVID-19 Infection:** an individual who tests positive for SARS-CoV-2 via an approved rapid antigen or PCR test.

**Absenteeism**: total number of school days missed by each individual student participant, both for the entire year and month-by-month, as captured and shared with us by school district administrative data systems.

**Emotion Regulation**: these can also be referred to as "internalizing symptoms", or as depressive and anxiety symptoms.

## XV. REFERENCES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