

Protocol version: 1

Date updated: 1/03/24

Reopening Schools Safely and Educating Youth (ROSSEY): Early Learning Ancillary Study

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

Funding: National Institute of Child Health and Human Development

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

I. Study Design

This ancillary study incorporates one primary aim which is 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. We want to learn if health education can increase the uptake of COVID-19 mitigation measures, improve children's school attendance, and increase families' physical and mental well-being using single-arm pre/post-study.

The ancillary study runs parallel with the larger ROSSEY RCT. Recruitment, enrollment, and baseline assessment are expected to last two months (September-November 2022). Enrolled participants will not receive the comic book and parent video series until after completion of the ROSSEY RCT Post 1 follow-up Survey to not bias the data of older siblings participating in the ROSSEY RCT. A follow-up assessment for Early Learning participants is anticipated to take place 10 months after the launch of recruitment (July-August 2023)

II. Aim 1

Evaluate if risk communication health education can increase uptake of COVID-19 mitigation measures, improve children's school attendance, and increase families' physical and mental well-being using a single-arm pre/post study.

III. Study Population

We will collaborate with the Yakima School District to recruit Early Learning students (3, 4 and 5 years old) and their parent or Guardian(s) into the research study. We will recruit Early Learning 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 the uptake of SARS-CoV-2 testing and other mitigation measures.

IV. Sample Size

Early Learning is an ancillary study with no defined sample size. We will enroll and recruit participants for a total of eight weeks.

V. Enrollment Criteria

Parent/Guardian eligibility criteria for participation in the study include:

- Must have a child attending the Early Learning Program in the Yakima School District
- 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.

VI. Study Procedures

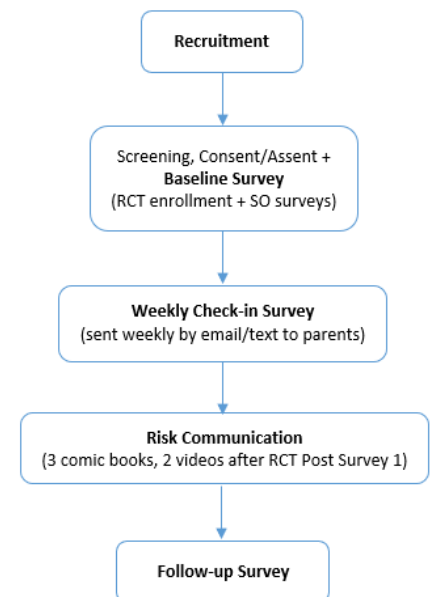
Recruitment, Screening and Consent

Enrollment and recruitment of the Early Learning ancillary study will start the second academic year of the RCT (2022-2023). Study information in the form of a flyer will be sent home with students to parents through school email by the principal and posted on the school Parent Square site in September of 2022. In addition, ROSSEY staff will attend the Early Learning Open House to hand out study information and obtain the phone number or email address of interested parents. ROSSEY staff will follow up with interested parents and provide further information about the study.

Families will have two options to enroll children in the study: online through a website portal (Project REDCap), 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 survey (same enrollment and secondary outcomes survey from the RCT of the main study).
- Parents/guardians who choose to enroll with staff assistance over the phone will be verbally guided through the REDCap consent/assent forms, enrollment questionnaire and secondary outcomes questionnaire.

Outline of Early Learning Study Procedures



Parents who choose online enrollment will be screened for eligibility via the REDCap web-based portal. Parents who choose enrollment with staff assistance will be screened 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. Since all children are under the age of 7, the parent or legal guardian will 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 enrolled by telephone, copies of the consent and assent documents will be sent to the participants either via e-mail, through the mail, or in person.

NEEDS A SECTION ON BASELINE SURVEY.

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

Risk Communication: Risk communication, in the form of comic books with accompanying read-along videos for the children (n=3) and videos for the parents (n=2) will be distributed in English and Spanish to all enrolled students within two weeks of completion of the ROSSEY RCT final assessment (December 2023). Three comic books will be distributed by mail and parents will be sent a password-protected link with the mailed comic to access the parent videos and comic book read-along videos. All intervention materials (i.e., children's comic books and parent videos) will be distributed after the final assessment of the larger ROSSEY RCT study is complete. The delay is to eliminate possible contamination of the RCT by siblings of comparison students who will receive the comic books as part of this ancillary study.

Follow-up Survey: We will contact parents 6 weeks after the risk communication intervention distribution. Parents will be asked to complete the follow-up 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 and the secondary outcome measures.

Following the protocol from the ROSSEY RCT, the post assessment will take place over 6 weeks, allowing two weeks for final contact prior to closure. For EL participants 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 school and teachers name to send a notice through the school to the parent letting them know we are trying to reach them. Students determined to still be enrolled at YSD, and are non-responders to the follow up survey, will receive an at home 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.