ReOpening Schools Safely and Educating Youth (ROSSEY Study) – Early Learning Ancillary Study

Clinical Trials.gov : NCT05965323

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STATISTICAL ANALYSIS PLAN

1. Introduction to the SAP

This statistical analysis plan (SAP) describes the plans for statistical analyses that will address the study's protocol objectives.

2. Study Schema and objectives

Purpose:	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.
Design:	A single-arm pre/post-study
Central Hypotheses:	Our central hypotheses are that students and parents who view the risk communications will be more likely to have increased COVID-19 testing and vaccine uptake.
Primary Objectives:	• To determine if implementing three COVID-19 education comic books for children and two COVID-19 education videos for parents will increase COVID-19 testing and vaccine uptake in children.
Secondary Objectives:	• To determine if implementing three COVID-19 education comics books for children and two COVID-19 education videos for parents will increase physical activity, improve sleep, increase emotional regulation in children. • To determine if implementing three COVID-19 education comics books for children and two COVID-19 education videos for parents will increase physical activity, improve sleep, decrease depression and anxiety in parents
Population:	Children ages 3-5 enrolled in the Early Learning program in Yakima School District
Study Size:	Early Learning is an ancillary study with no defined sample size. We will enroll and recruit participants for a total of eight weeks
Primary Outcome Measurements:	A. COVID-19 testing data available through self-reported survey B. COVID-19 vaccine data available through self-reported survey
Study Duration:	11 months – September 2022- August 2023

3. Study Design

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)

4. Sample size and power

Early Learning is an ancillary study of 50 participants. We will enroll and recruit participants for a total of eight weeks.

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.

5. Population and Data Source

Participants enrolled in the ROSSEY Study: 50 children and parents from the Yakima School District. Any participants subsequently found to be ineligible will be removed. The data sources for the primary analyses are COVID testing results received from the school administration and the survey data as entered in REDCap. The COVID vaccination status data is obtained through the parent and child surveys, completed in REDCap.

6. Presentation of analyses

For each of the continuous outcomes (including the primary outcome), the mean and standard deviation will be presented pre/post intervention and p value. For binary outcomes, the percentage and frequency of children in the outcome category of interest (e.g., percentage vaccinated) will be presented pre/post and p value.

7. Outcome Definitions

a. Primary Outcomes

The two co-primary outcomes of the trial are COVID-19 testing and COVID-19 vaccine uptake. COVID-19 data are captured through school testing and self-reported survey, and COVID-19 vaccine uptake data are captured through self-reported survey. All children and parent data will be included in the intention-to-treat analysis.

COVID-19 testing: Health reports from the school are provided for the 2022-2023 school year that list positive covid test results of study participants with the date of testing and the school of attendance. Positive test results for COVID will be a binary, yes/no variable.

COVID-19 vaccine uptake: Parents are asked at enrollment to report their vaccination status and their child's vaccination status. At post survey, the parent is asked to report if they or their child have received any COVID-19 vaccine or booster since enrollment. Vaccination status will be a binary, yes/no variable.

b. Secondary Outcomes

Secondary outcomes for the trial include the following outcomes from the PROMIS – Pediatric and Parent Proxy Instruments. The PROMIS instruments used are Children's physical activity (PA), sleep, stress, depression, and anxiety. Parents' PA, sleep, stress, depression and anxiety. The final score is represented by the T-score, a standardized score with a mean of 50 and a standard deviation (SD) of 10.

The outcome measures will be collected at pre-and post-assessment.

8. Primary exposure definition

Receiving the educational materials: three comic books and two graphic motion videos.

9. Interim analysis plan

For this study, there was no interim analysis.

10. Multiple testing

We will adjust for multiple testing by controlling FDR.

11. Missing Data

We will inspect missing data mechanisms and the amount of missing data. We will conduct an additional sensitivity analysis with multiple imputations using multivariate imputation with chained equations (MICE) approach. We will report the amount of missing data and apply appropriate methods to account for the missing data.

12. Planned Statistical Analyses

a. Baseline Demographics

The baseline characteristics of enrolled participants will be summarized in a table.

b. Efficacy Analyses Overview

Pre/post-survey outcome analyses will be conducted after all participants have been contacted and the survey is closed with missing responses marked as loss to follow-up.

1) Descriptive Analyses: Positive COVID test results will be summarized by counts. Vaccine status and COVID testing results will be presented as counts and percentages. Continuous variables will be summarized by mean, standard deviation (SD), and median (IQR). Secondary outcomes will be compared using Chi-squared tests.
2) Primary Objectives: The primary analysis of vaccine uptake and COVID testing will be conducted using a chi-squared test using $\alpha = 0.05$ and report pre/post changes over time.
3) Secondary outcomes: The secondary outcomes for the trial include measures from the PROMIS – Pediatric and Parent Proxy Instruments. The PROMIS instruments used are children's PA, sleep, stress, depression, and anxiety and parents' PA, sleep, stress, depression, and anxiety.