P9185 - Project 3: Protocol of a Cluster-randomized trial for Asthma-PASS

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Background

- There is a need for comprehensive school-based interventions in collaboration with communities to reduce asthma morbidity and promote PA in urban minority children with persistent asthma.
- Focused intervention – Asthma-PASS: intervention program that includes collaborations with primary care physicians (PCPs) for promoting availability of guideline-based preventive medications and rescue medication at schools, with community health workers (CHW) to deliver education for children, caregivers, and with school personnel to encourage physical activity.

Pilot study

- a pilot cluster-RCT (i.e., the unit of randomization is school, NOT students) of Asthma-PASS in four Bronx elementary schools with 108 asthmatic children in total.
- 4 Bronx elementary schools were recruited into the pilot study.
- Study recruited 108 children aged 4-11 years with physician-diagnosed persistent or uncontrolled asthma attending kindergarten to 5th grades from the 4 Bronx elementary schools
- The four elementary schools were randomly assigned into Asthma-PASS intervention group (2 schools) or AM comparison group (2 schools).
- The participated children were followed at 6 and 12 months after baseline.

Study goal

whether Children in schools receiving Asthma-PASS intervention may experience a greater improvement in the number of SFD at 6 **or** 12 months follow up than the children in the AM comparison group.

Data exploration

- barplot at each time point – verify poisson might be less reasonable
- barplot for 6 v.s. baseline and 12 v.s. baseline – see distribution to verify normal trend – middle high, 2 tail low
  - equal variance plot – see if the control/trt group have roughly equan variance to decide 2 sample t test with equal/unequal var (continous)
- sphagetti plot to disprove the linear trend
- Box/point plot for intra-class correlation visualization, facet by month. (https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Intraclass_Correlation_Coefficient_Cheat_Sheet_March_15_2020.pdf)

Analysis for the pilot study

- Paired proportion test (binomial) / Paired T test (continuous, normal)
- For 6 months v.s. baseline, compair pass v.s. control
- For 12 months v.s. baseline, compair pass v.s. control
- Multiple adjustment
- Describe and comment on the effect sizes.
- Estimate intra class variation

Cluster RCT design

- The investigators wish to propose a **cluster-randomized clinical trial (RCT)** in 30 Bronx schools to evaluate the effectiveness of their intervention program.
- Primary hypothesis: compared to the control group, children in schools randomized to intervention group will experience a greater improvement in the number of SFD at **any of the 3, 6, 9, and 12 months** assessment.
- The investigators would like to have at **80% probability** to declare the trial is successful if the true effect size in **improvement of SFD over time** is **at least 1/3 standard deviation**.

Study design proposal:

3 level structure:[1]

$$y_{ijk} = \beta_0 + \delta_{(3)} X_{ijk} + \mu_i + \mu_{j_i} + e_{ijk}$$

- i for school, j for subjects, k for measures
- $\mu_i \sim N(0, \sigma_3^2)$ random intercept for school
- $\mu_{j_i} \sim N(0, \sigma_2^2)$ random intercept for school random intercept for subject
- randomize on school level, $X_{ijk} = X_i = 0/1$ indicating the control/intervention
- Hypothesis: $H_0 : \delta_{(3)} = 0, H_1 : \delta_{(3)} \neq 0$
  - **Q**: $H_1 : \delta_{(3)} > 0$?
- calculate N based on normal distribution, with multiple adjustment: $\alpha* = \alpha/4 = 0.025/4$ for the 4 comparison;
  - **Q**: Need multiple adjustment or not?
- $\beta = 0.2$