Project 5

Asthma disproportionately affects low-income African-American and Hispanic children residing in inner city areas such as the Bronx, New York (NY). Physical activity (PA) is an important component of asthma management in children, as it is associated with decreased severity of symptoms, reduced school absenteeism and improved quality of life. However, urban minority children with asthma face barriers to PA on the personal, family, school, health care system and community levels. Schools can be an ideal setting for optimizing asthma management and promoting PA. Unfortunately, they often do not facilitate appropriate asthma management and related exercise and may even discourage PA. Consequently, *there i*s *a need for comprehensive school-based interventions in collaboration with communities to reduce asthma morbidity and promote PA in* <u>*urban minority children with persistent asthma.*</u>

Several investigators proposed an 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. They conducted 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.

Recruitment of study schools. The characteristics representative of Bronx and other NYC schools included that among the school students, 1) 89%-99% were eligible for free lunch (a marker of poverty); 2) 48%-52% were male; 3) 62%-78% were Hispanics and 20%-38% were African Americans. Among the 104 Bronx elementary schools that expressed their interest in the study participation, <u>4 Bronx elementary schools were recruited into the pilot study</u>.

Study participants. Because the intervention is developmentally appropriate for child age 4-11 years, the pilot 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 (in which participants just follow the routine provided by each school, i.e., the standard of care) (2 schools). The participated children were followed at 6 and 12 months after baseline.

***Goal of the study*.** The investigators had primary interest on 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. The table below listed the name and description of the variables in the file (Proj 5.xlsx) of pilot data prepared for analysis.

For data file: Proj 5.xlsx		
Variable	**Definition**	**Coding**
ID	Participant's ID	
Time	Follow up time	1: Baseline 2: 6-month follow up 3: 12-month follow up
Group	Intervention group indicator	0: Control 1: Intervention
SFD	Symptom free days in the past two weeks prior to each follow up visit	Quantitative
School	School recruited for the study	1: School 1 2: School 2 3: School 3 4: School 4

Examine the data and use appropriate models to answer questions below.

Questions

1) Did the pilot study provide any evidence for effectiveness of the intervention program (i.e. any clues to answer their questions for primary interests)? Describe and comment on the effect sizes. The primary outcome of interest is SFD (symptom free days in the past two weeks prior to each of the *three* time points).

2) The investigators wish to propose a cluster-randomized clinical trial (RCT) in 30 Bronx schools (i.e., the unit of randomization is school, NOT students) to evaluate the effectiveness of their intervention program. The primary hypothesis is that compared to the control group, children in schools randomized to intervention group will experience a greater improvement in the number of SFD (symptom free days in the past two weeks) at any of the 3, 6, 9, and 12 months assessment. In other words, if children in the intervention group perform better than those in the control group at any of those four assessment time points, the intervention is considered as success. 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. As a study statistician, you are asked to use the above information and the result from analyzing the data of the above pilot study to conduct a power analysis for total sample size of children needed to the proposed study. (Hint: Consider intra-class-correlation (ICC) in your design.)

Instruction: Answer the above questions with statistical and descriptive justifications including,

i) Formulation of the hypotheses relevant to specific questions and testing those hypotheses;
ii) Presenting graphical displays and relevant descriptive statistics;
iii) Justification and description of the statistical modelling approach used (i.e. write down the statistical models with interpretation of model parameters);

iv) Summary of the results, with appropriate comments, tables and figures to support your answers.