
Study Protocol and Statistical Analysis Plan

Official Title:

**An Evaluation of an Integrated Approach to Prevention and Early Intervention
in the Elementary School Years**

ClinicalTrials.gov ID: NCT03132805

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Note: There were no amendments for changes in the trial design submitted or approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board after the initial release of the ClinicalTrials.Gov protocol on 04/04/2017.

Study Description

Rationale:

There is considerable evidence from long-term longitudinal studies that aggressive/disruptive behavior as early as entrance into elementary school predicts later antisocial behavior, violence, substance abuse and low educational and occupational attainment^{10,11,12,13,14}. In response to that evidence, our Advanced Center for Intervention and Services Research (ACISR), the Johns Hopkins Prevention Intervention Research Center (JHU PIRC), has carried out a series of large scale randomized trials of promising school-based **universal** preventive interventions targeting aggressive/disruptive behavior in elementary school. Each trial has built on the findings of the previous trial in accord with the prevention research cycle as elaborated in the Institute of Medicine Report on *Reducing Risks for Mental Disorders*¹⁵. Although we have found beneficial proximal and distal intervention effects^{10,12,16}, our results point to the need for integrating our universal interventions with evidence-based indicated and early treatment interventions to reduce the number of non-responders and to increase the magnitude of intervention effects. We briefly elaborate below the history of our trials and the findings that formed the basis for this trial.

The 1st Generation JHU PIRC Field Trial. Our 1st generation trial involved the evaluation of two, first grade, universal, preventive interventions in collaboration with the Baltimore City Public Schools (BCPSS). Our use of the term “universal preventive intervention” reflects the fact that we intervened with an entire population of first grade school children¹⁵. This 1st generation trial was fielded in 19 Baltimore City schools with two consecutive cohorts of first graders in the 1985-86 and 1986-87 school years. Two theory-based preventive interventions were evaluated, which were exclusively based in the classroom and did not directly involve families. One intervention, the Good Behavior Game¹⁷ (GBG), was aimed at aggressive/disruptive and off-task behavior, whereas the other intervention, Mastery Learning^{18,19} (ML), targeted poor school achievement.

The results of this 1st generation JHU PIRC field trial yielded evidence that the proximal targets of aggressive/disruptive behavior and poor achievement were malleable^{20,21}, and that change in the proximal targets was associated with change in the distal outcomes in middle school²² and in early adulthood^{10,11,12}. In terms of the immediate impacts, the GBG resulted in significant—albeit modest—reductions relative to controls in aggressive/disruptive and off task behavior based on independent observations²¹ by the end of first grade, whereas Mastery Learning resulted in significant but modest improvement in standardized reading achievement²⁰. Dolan et al.²⁰ also reported significant beneficial impact of the GBG in terms of teacher ratings and peer nominations of aggressive/disruptive behavior in 1st grade. The GBG appeared to have its greatest proximal impact among boys manifesting mild to moderate elevations in aggressive/disruptive behavior at pre-test in the fall of first grade²⁰. With respect to longer term impact, Kellam and colleagues reported significant and beneficial impact of the GBG on antisocial behavior, violent crime, substance abuse/dependence, and high-risk sexual behavior at ages 19-20^{10,11,12}. Consistent with the variation seen in the immediate impact of the GBG in Dolan et al.²⁰, the greatest effects were found for males with mild to moderate elevations in pre-test levels of aggressive/disruptive behavior in 1st grade.

The 2nd Generation JHU PIRC Field Trial. Although promising, we were not satisfied with the magnitude of the effects of the 1st generation interventions on students' behavior and learning. Subsequently, we fielded our 2nd generation of JHU PIRC preventive interventions⁹. We first created an intervention condition wherein we combined the GBG with an academic intervention. The decision to combine the GBG with an academic intervention reflected the fact that in our 1st generation field trial the GBG had modest proximal impact on achievement, whereas Mastery Learning had an impact on early achievement, but had only a modest to moderate crossover, or indirect, effect on aggressive/disruptive behavior. Each intervention thus appeared to be specific to its own proximal target. Consequently, if we were to reduce early aggressive/disruptive behavior and improve academic achievement, both academic achievement and aggressive/disruptive and off-task behavior needed to be targeted in a single intervention condition.

In addition to combining the GBG with an academic intervention in our 2nd generation intervention trials, we also developed and fielded a universal, family-school partnership (FSP) intervention to contrast with the combination of the GBG and an academic intervention. Like the combination of the GBG with an academic intervention, the proximal targets of the FSP intervention were poor achievement and aggressive/disruptive and off-task behavior. The FSP intervention included a series of 9 workshops led by teachers and school mental health professionals, respectively, over the school year that focused on improving parent child

behavior management practices and support for their child's academic performance. The decision to add a family-based component was consistent with existing theory and the considerable empirical evidence of the important influences that families exert on their children's academic success^{23,24} and social development²⁵, along with the benefits of strong parent-teacher partnerships and parent involvement²⁶ on children's behavior and achievement.

The design of the 2nd generation JHU PIRC trial featured 3 first grade classrooms within each of 9 Baltimore City elementary schools. The three 1st grade classrooms in each of the nine elementary schools were randomly assigned to one of the two intervention conditions or to a control condition. In addition, children within each of the schools were randomly assigned to classrooms. We found significant proximal (elementary school)^{9,16}, intermediate (middle school)^{3,16}, and longer term (high school/early adulthood) intervention impacts on aggressive-disruptive behavior/conduct problems¹⁶ and academic outcomes^{3,9,27}. Both Jalongo et al.³ and Petras et al.¹⁶ provided evidence suggesting that the intermediate³ and longer term¹⁶ intervention impact on aggressive/disruptive behavior/conduct problems was in part a function of the proximal impact of the interventions on aggressive-disruptive behavior in early elementary school and on the parent-child relationship in terms of lower levels of parent rejection in late childhood/early adolescence³.

To summarize, both the immediate⁹ and longer-term results of the 2nd generation JHU PIRC trial^{16,27} supported our hypothesis that the combination of the GBG with an academic intervention would yield greater impact in terms of effect size on academic achievement than that seen in the 1st generation trials, wherein the GBG and Mastery Learning were examined separately²⁰. However, we did not see greater impact on aggressive-disruptive behavior as a result of our combining the GBG with an academic intervention. The family-school partnership did yield significant immediate benefits in terms of aggressive/disruptive behavior and academic achievement, but the breadth of the effects and their size were smaller than for the combination of the GBG and the academic intervention^{3,9}.

The 3rd Generation JHU PIRC Field Trial: The Combination of the GBG & PATHS. Given the combination of the GBG with an academic intervention did not yield greater improvement in aggressive/disruptive behavior than that seen in the 1st generation trial of the GBG alone, a seemingly logical next step would have been to combine the GBG + academic intervention condition with the FSP intervention, given the latter did have an impact on aggressive/disruptive behavior—albeit modest. But the costs and logistics involved in mounting a universal family-school partnership intervention proved daunting.

Consequently, we submitted a successful grant application to the Institute of Education Sciences (IES) in 2007, wherein we proposed to combine the GBG with a second and complimentary, evidenced-based, universal preventive intervention: PATHS. There are a number of reasons why we expected additive, if not synergistic effects, as a result of combining the two interventions. First, the efficacy of PATHS in terms of reducing aggressive/disruptive behavior and increasing prosocial behavior, social competence, inhibitory control and verbal fluency in the elementary school years had been demonstrated in a series of randomized controlled studies (CPPRG)^{28,29,30,31}. Second, PATHS seeks to accomplish reductions in aggressive/disruptive behavior via teacher led instruction aimed at facilitating emotion regulation, self-control, social problem-solving, and conflict resolution skills^{32,33}, whereas the GBG is based on social learning principles and provides teachers with an efficient means of managing student aggressive/disruptive and off-task behavior via reinforcement of the inhibition of these behaviors within a game-like context. The GBG, by increasing attention to task and reducing disruptive behavior in the classroom, may facilitate the acquisition of the emotion regulation, self-control, social problem-solving, and conflict resolution skills taught in PATHS. Third, the social learning based GBG may increase the likelihood that students' newly acquired skills would be appropriately prompted and reinforced by teachers. Consequently, the PATHS skills would be better learned and more frequently employed. Fourth, the increased teacher and child success, as a result of combining PATHS and the GBG, should minimize teacher and child discouragement and subsequent failure to participate or comply fully with the intervention regimens.

Our IES funded trial of the GBG+PATHS--or as we refer to it from hereon as PATHS to PAX--featured a group-randomized design, wherein 27-schools (grades K-5) were assigned to one or 3 conditions: 1) Comparison/Control; 2) GBG Alone; or 3) PATHS to PAX (GBG+PATHS). Approximately, 300 teachers and 5,000+ students participated in the trial and provided data, which included classroom observations and teacher ratings of student behavior at pre- and post-test over a 1-year period. The evidence from this group randomized trial, which was completed in 2012, suggested that PATHS to PAX resulted only in modest improvement over the GBG Alone in terms of aggressive/disruptive behavior and teacher outcomes (e.g., perceived behavior management self-efficacy)³⁴.

The Need for Research on the Combination of Evidence-based Universal, Indicated and Treatment Interventions. The relatively modest improvements found for PATHS to PAX (GBG+PATHS) over the GBG Alone served in part as the impetus for our testing the nesting of indicated and treatment interventions within our universal intervention: PATHS to PAX. Also moving us to evaluate such an integration was that despite evidence of long-term benefits of the GBG in terms of the reduction of antisocial behavior and drug use^{10,12} in our 1st and 2nd generation JHU PIRC trials, closer analyses of these data suggest that about half of those children in the highest trajectory of aggressive/disruptive behavior from grades 1-7 demonstrated no GBG impact in the short or long term¹¹. In addition, based on individual interview, focus group, and questionnaire data from our PATHS to PAX trial, the primary reason teachers gave for not implementing PATHS to PAX was because it did not prove helpful with their most aggressive/disruptive students. This was consistent with Han & Weiss' model³⁵ of the factors influencing teacher implementation of evidence-based interventions in school settings. More specifically, Han & Weiss³⁵ argue that teacher perception of the effectiveness of an intervention is a central factor in their level of its implementation. Relatedly, data from our PATHS to PAX trial suggested that the greater the number of highly aggressive/disruptive children in a PATHS to PAX classroom at baseline, the lower the level of teacher implementation of the GBG and PATHS.

Our rationale for expecting an added benefit from the combination of PATHS to PAX with an indicated and treatment intervention was that the latter interventions were more likely to be effective with the non-responders to PATHS to PAX. These non-responders typically represent the most aggressive/disruptive students in the classroom. We also hypothesized that the improvement in the behavior of the non-responders via the indicated or treatment intervention would increase teacher perception of the effectiveness of PATHS to PAX, which would lead to increased PATHS to PAX implementation. This increased implementation should then result in improved student outcomes overall, not just for the non-responders.

Our choice for an indicated and treatment intervention was the Incredible Years^{36,37,38,39,40}. The Incredible Years (IY) has been evaluated in multiple randomized controlled trials as a preventive⁴¹ and treatment^{37,38,39,42,43} intervention. IY has been found to be efficacious in reducing aggressive/disruptive behavior in the home and school over the short^{37,38,39,41,42,43} and long term^{38,44,45}. In addition, Webster-Stratton and colleagues report effects for the IY child component alone^{37,42,46}—the importance of which is highlighted by the relatively modest to moderate parent participation rates often found among urban and economically distressed populations⁹.

We also believed that there was a strong conceptual rationale for combining these three interventions. First, all three interventions share a common focus on facilitating the development of the child's capacity to self-regulate. Second, all 3 attempt to achieve that goal through the use of social cognitive learning theory principles to varying degrees. Third, the content of small group Dina and PATHS emanates from a common theory of socioemotional development^{6,7}.

Study Design

Overview of the Research Setting, Design, and Procedures for the Trial. The trial was conducted in the Baltimore City Public Schools (BCPS) which serves a predominantly African American population--84% of which are eligible for free or reduced lunch. We carried out a school-based, group-randomized trial (GRT) to determine whether the PATHS to PAX + Incredible Years arm yielded superior student and teacher outcomes, relative to the PATHS to PAX Alone arm. We also tested whether the PATHS to PAX + Incredible Years and the PATHS to PAX Alone arms both yielded superior student and teacher outcomes relative to the control arm. These comparisons with the control arm were only carried out to insure that in the case of no significant differences between the two active intervention arms the reason was not because both interventions failed to yield superior outcomes relative to the control arm. A GRT was required given randomization occurred at the level of the school. Four consecutive cohorts of 12 elementary schools for a total of 48 schools were randomly assigned to 1 of 3 conditions: 1) Control; 2) GBG+PATHS Alone; or 3) GBG+PATHS+IY. We confined the study to K-2 teachers given evidence from our most recent trial that the GBG is most effective in K-2.

We also recruited approximately ~ 25 K-2 students per school assigned to the GBG+PATHS+IY condition for participation in the ***IY child and parent groups*** across the four cohorts. Students were selected for inclusion in the IY intervention based on teacher completion of a checklist version of the Oppositional Defiant and Conduct Disorder modules of the teacher version of the Computerized-Diagnostic Interview Schedule for Children IV (C-

DISC IV). Those students who were sub-syndromal (falling just below the threshold number of symptoms/behaviors to meet DSM-IV diagnostic criteria for Oppositional Defiant or Conduct Disorder) and those who met diagnostic criteria for one or both of these disorders were recruited for inclusion in the IY groups. Randomization. The 12 schools making up each cohort were rank ordered based on school characteristics obtained from prior year archival records, including % Black, % free or reduced lunch, % males, % disciplinary removals, % receiving special education, number of students, and mean levels of standardized achievement scores. Schools adjacent in rank were grouped into triads, or sets of 3. Schools were then randomized to the 3 conditions from within these matched sets of 3. Timing of the Assessments. Classroom observations of student behavior, peer nominations, and child perceptions of peer acceptance were gathered in the fall (October) and spring (May) of the first year for each cohort, whereas teacher ratings of student behavior were gathered in the fall (October) and spring (May) of the first year for each cohort and at 1-year follow-up in Year 2 for each cohort.

Statistical Analysis Plan

Aims 1 & 2. Outcome Analyses. Trials Aims 1 and 2 were centered on testing whether the PATHS to PAX + Incredible Years arm yielded superior student and teacher outcomes relative to the PATHS to PAX Alone arm. We also tested whether the PATHS to PAX + Incredible Years and the PATHS to PAX Alone arms both yielded superior student and teacher outcomes relative to the control arm. These comparisons with the control arm were only carried out to insure that in the case of no significant differences between the two active intervention arms the reason was not because both interventions failed to yield superior outcomes relative to the control arm. The General Linear Mixed Model was employed given teachers were nested within schools and students nested within teachers and repeated observations nested in both. The General Linear Mixed Model is appropriate when there are multiple sources of random variation and all sources are distributed Gaussian. Murray and colleagues report that even in the case of violations of the Gaussian distribution assumption, the General Linear Mixed Model provides the same Type 1 error protection as the Generalized Linear Mixed Model^{47,48}. Importantly, Aims 1 & 2 outcomes included pre-test-post-test only (e.g., classroom observations, peer nominations, and teacher reported self-efficacy and burn out), pre-test, post-test and 12-month follow-up (e.g., teacher reports of student behavior). General Linear Mixed model analysis of covariance was used in the case of the pre-test-post-test, and pre-test and 1-year follow-up outcomes. In addition to intervention status, the baseline level of the outcome variable was included as a covariate. School was treated as a random effect. Given all the comparisons between conditions were planned and directional, no correction was made for the experiment-wise level of error since such a correction would have only been appropriate in the case of exploratory analyses. Results reported in the Outcome Measures section include the adjusted post-test means and standard errors for the planned comparisons between the 2 intervention arms and between the intervention and control arms.

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