Study Protocol and Statistical Analysis Plan

Study Title: SKIPping with PAX: An Integrated Gross Motor and Social-Emotional Skill Intervention

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SPECIFIC AIMS

The specific aims for the study include:

Aim 1: Evaluate the preliminary impact of the integrated intervention on social-emotional, behavioral, and gross motor outcomes at post-intervention (9 months after baseline).
H1: Children in the intervention condition will show significant improvements for the social-emotional, behavioral, and gross motor variables in comparison with children in the "usual classroom" control condition.
Aim 2: Evaluate the sustained impact of the integrated intervention on social-emotional, behavioral, and gross motor outcomes at three-month follow-up.
H2: Compared with the control group, the intervention group will show greater positive impact at three-month follow-up for social-emotional, behavioral, and gross motor outcomes, controlling for baseline levels.
Aim 3 (Exploratory): Explore whether baseline cognitive skills moderate intervention effects on post- and follow-up assessment of social-emotional, behavioral, and gross motor outcomes**.**

BACKGROUND AND SIGNIFICANCE

Early childhood is an especially critical time for intervention to prevent modifiable risk factors such as social-emotional, behavioral, gross motor, and related difficulties from contributing to the development of more serious problems over the lifespan. Important targets include social-emotional-behavioral adjustment (e.g., interactions with others, seeking out teacher assistance, management of emotions, staying on task, behaving well in class and on the playground) and gross motor development (e.g., running, catching, jumping, and throwing), which collectively contribute to reduced risk for adverse behavioral-health, physical health, and life outcomes in adolescence and beyond. Developmental difficulties in the social-emotional, behavioral, and gross motor domains occur in all communities but can be exacerbated for children residing in predominately low-SES communities. The need for early preventive interventions to foster healthy development is amplified in calls for research to address gaps about how to effectively intervene with children experiencing lower-SES conditions and disproportionately facing health challenges. The proposed project will help to address this gap by testing whether an integrated health intervention is effective in improving social-emotional, behavioral, and gross motor outcomes for children in early childhood.

RESEARCH DESIGN, METHODS AND DATA ANALYSIS

A total of 20 preschool classrooms were randomly assigned to either the integrated intervention condition (n=10) or the control condition (n=10). Measurement took place at the level of individual children and occurred at baseline, at the end of the intervention period (i.e., 9 months after baseline), and at three-month follow-up (i.e., 12 months after baseline).

Study Population and Recruitment. The study took place in a semi-rural community in South Carolina that is in relative proximity to a metropolitan area. South Carolina provides public preschool support for Title 1 schools through the Child Development Education Program in districts across the state—of which the Early Childhood Center is a prime example. Children attending these preschool classes are four years old at time of entry, from families with an annual income of no greater than 185% of the federal poverty level. Consequently, the study sample included preschoolers residing in low socio-economic households, with 70% of the

children qualify for free or reduced lunch. For data collection, all children in the 20 preschool classrooms were eligible for inclusion in the research sample. Parental consent was obtained to permit the child assessments.

Intervention. The intervention summarized below consisted of two components, a classroom program called PAX Good Behavior Game (PAX GBG) and a gross motor skills program called Successful Kinesthetic Instruction for Preschoolers (SKIP).

PAX GBG. Teachers first implement the GBG for a 10-minute period three days per week and then gradually increase the frequency to three 10-minute periods per day five days a week throughout the school year. Best practices for the PAX GBG indicated that while there is individual variation, teachers on average played the GBG 152 times over the school year (averaging 1488 minutes/year), with more positive outcomes in classrooms where the game is played more often.

PAX-GBG teachers participated in an orientation meeting to get an overview of the program and materials. Then, they completed a one-day online training regimen followed by two 90-minute follow-up meetings with project staff before classes began. After the program started, project staff met individually with each teacher for a brief (15 minute) check-in 3-4 times per month to support implementation and troubleshoot issues. Teachers received continuing education credit (CEUs) for their time and effort in training and mastering the PAX GBG.

SKIP. This gross motor skills training intervention is delivered on the playground by project staff to all children in the intervention classrooms. SKIP adopts an approach that teaches gross motor skills in a manner which promotes health-enhancing bouts of physical activity while fostering motivation related to social-emotional development. Children received SKIP two times per week, for 30 minutes per session, throughout the school year.

Intervention Integrity. Research staff periodically observed intervention classrooms to document implementation fidelity for the PAX GBG. SKIP intervention sessions on the playground were digitally recorded to permit observational coding of lesson plan fidelity from the videos. Data from PAX GBG and SKIP fidelity checks were used early and throughout the intervention period to take corrective action when there were indications of slippage in intervention integrity (e.g., additional support, prompts/reminders, follow-up checks). In addition to the fidelity checks, classes of children in both the intervention and control conditions were observed periodically on the playground by research team staff. The purpose of playground/recess observation was two-fold: (1) to make sure children in the intervention condition were not receiving extra training in gross motor skills during recess periods when SKIP was not being conducted, and (2) to verify that children in the control condition were not receiving gross motor skills training that mimics SKIP.

Outcomes. The outcome measures and putative moderator measures are summarized below.

Outcome Measures. The outcome measures were collected at the three assessment time points: baseline, post-intervention period, and follow-up. The outcome measures for this study focused on gross motor skills and social-emotional skills—all considered primary outcomes. At each time point, teachers completed the Social Skills Improvement System—Rating Scales (SSIS-RS). Gross motor skills were assessed using a staff-administered Test of Gross Motor

Development-3 (TGMD-3). The testing tasks were digitally recorded and then scored by trained coders who were blinded to condition and time point. The secondary outcomes were physical activity behaviors as assessed by GT3X+ accelerometers. If possible, accelerometry data were to be captured during the school day, with logs kept to denote on and off times, and all data were to be uploaded into ActiLife Software. However, because this study was a pilot RCT rather than a fully implemented RCT, there was a distinct possibility that it would not be feasible to collect the accelerometry data.

Putative Moderators. Three putative moderators were measured at baseline using executive-function cognitive-skills tasks from the NIH Toolbox. Attention and inhibitory control were assessed with the Flanker Task, cognitive flexibility with the Dimensional Change Card Sort Task, and working memory with the List Sorting Working Memory Task.

Demographic Data. Child's date of birth, gender, and ethnicity were acquired through school records.

Analytic Method for Aims 1 and 2. The preliminary step in the analytic plan was to examine the range and frequency distributions for all outcome variables, to transform variables, when necessary, to examine the zero-order correlations among baseline variables, and to confirm baseline equivalence for intervention and control groups. The analytic multi-level model used three-level hierarchical linear modeling (HLM), which involves time points (level 1: baseline, post, follow-up) nested within children (level 2) who are nested within classroom (level 3), to test intervention effects on each of the three outcome variables (social-emotional skills, problem behavior, and gross motor skills). Intervention condition was represented as a dummy variable (1 = intervention, 0 = control. Additional supplemental analyses were conducted for each of the outcome variables to explore whether intervention effects vary as a function of child sex.

Analytic Method for Aim 3 (exploratory). Aim 3 explored whether baseline executive-function cognitive skills moderate intervention effects on post- and follow-up assessment of social-emotional, behavioral, and gross motor outcomes**.** Exploratory moderator analysis was conducted by adding the putative moderators and their interactions with intervention condition and time to the overall analytic model. A separate model was estimated for each of the three putative cognitive-skills moderators.