Study Protocol and Statistical Plan

Project Title: The Healthy Child Development Program Study

NCT04622969

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Study Protocol

Scientific Background

Children's behavioral and emotional problems, on the one hand, and childhood obesogenic lifestyle related behaviors on the other, each heighten risk for adverse health outcomes such as depression, substance use disorders, and obesity in adolescence, and suicidality and diabetes in adulthood. Prevention in both child domains is warranted. At school entry, many children encounter difficulties because of social, emotional, and behavioral (SEB) problems, which can co-occur with, and be complicated by, unhealthy lifestyles such as low physical activity, excessive screen time, and inadequate sleep. Even though both domains are critical to child development, most of the research on preventive interventions with young children has focused on either one domain or the other, but seldom both.

There is a clear need for family-based interventions that integrate the two domains because parents exert major influence on both SEB functioning and healthy lifestyle. With preschool age children, addressing parenting and family environment represents one of the stronger modes of intervention. Preschoolers spend a lot of time at home. Their early behaviors can set lifelong patterns of social interaction, cooperative and self-regulated behavior, physical activity, and sedentary and screen time habits.

Drawing on referrals of high-risk families from multiple community organizations, this study seeks to address both SEB and health domains through a family-based intervention. Young children living in economically disadvantaged circumstances experience elevated risk for SEB problems and obesogenic behaviors. The dual focus is on family-based intervention to improve young children's SEB adjustment and to promote healthy lifestyle behaviors (i.e., physical activity, reduced screen time, and adequate sleep). The integration of the two target domains in the intervention is viable because both are impacted through parenting, strengthening of the parent-child relationship, and home routines. In addition, preschoolers' physical activity, screen time, and sleep patterns can directly impact their SEB adjustment. For example, hyperactivity and inattention (i.e., two behavioral concerns common in young children) can be exacerbated by insufficient sleep and excessive screen time. Addressing these multiple concerns in young children has the potential to launch positive trajectories and reduce the likelihood of long-term adverse behavioral and health outcomes.

The research project focuses on intervention with high-risk families and preschoolers. The high-risk population selected for the project consists of economically disadvantaged families who are experiencing parenting challenges due to child behavior concerns, with referrals by agency or organization staff reflecting that the child and family need preventive services. The home-delivered prevention intervention being tested includes content on strengthening positive behaviors in children, managing misbehavior, and addressing healthy lifestyle choices. Families participating in the intervention will be engaged in practical skill building (e.g., behavioral teaching; planned activities training) and will have the opportunity to practice these skills and receive feedback.

Objectives

The study was designed to collect data ultimately to inform decisions about the design of a future well-powered R01-magnitude prevention clinical trial, pursuing these objectives:

Objective 1: Examine preliminary impact of the intervention on primary outcomes for child behavior problems and child physical activity, compared with the control condition.

Objective 2: Examine preliminary impact of the intervention on primary outcomes for child screen time and child sleep duration, compared with the control condition.

Objective 3: Examine preliminary impact of the intervention on secondary outcomes for parenting difficulties, parental stress, and parental confidence, compared with the control condition.

Design

The project involves preliminary evaluation of a family-based intervention that seeks to improve preschool children's SEB adjustment as well as promote healthy lifestyle behaviors (i.e., physical activity, reduced screen time, adequate sleep, and positive eating habits). The sample consists of high-risk families referred for prevention-based family services (i.e., differential response services) or receiving health services from a low-income-focused community healthcare center. Parents will receive in-home parenting education and coaching from intervention staff on how to use positive parenting strategies to strengthen child behavior, reduce screen time, increase moderate and vigorous physical activity, improve sleep duration, and promote healthy eating habits. The design involves randomization of families in equal proportion to either intervention or wait-list control conditions. The goal is to recruit at least 60 famlies for the study. Assessment of outcome measures were set to be conducted at baseline and six months after baseline (i.e., pre, post). Randomization was set to occur after completion of the consent process and baseline assessment.

Methods

Recruitment of prospective participants focuses on referrals from numerous community organizations and agencies serving families and young children.

The implementation plan is for the intervention to be delivered by trained staff and conducted in the homes of the participating families. The intervention takes 15 weekly sessions to cover the content.

For the measurement plan, assessments for all outcome measures take place at baseline and then six months after baseline.

Statistical Plan

For each of the outcome variables, the intervention and control groups will be compared on post-intervention outcome adjusting for baseline (preintervention) as a covariate. All outcome analyses will adopt an intent-to-treat approach. The analytic method will be ANCOVA, with estimation of the model based on bootstrapped standard errors to address any potential non-linearity in the outcome variable. The study is meant to conduct a preliminary examination of the potential impact of the family-based intervention on both the primary and secondary outcomes. As needed where appropriate, linear mixed-models analysis will be conducted in place of ANCOVA.