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Brief Title:

Testing the Impact of the Parenting Young Children Check-up

Official Title:

Randomized Clinical Trial of the Parenting Young Children Check-up in Pediatric Primary Care

Protocol ID:

IRB-25-07-7947

Project Proposal

Purpose of project. The project aims to conduct a small randomized clinical trial (RCT) on the Parenting Young Children Check-up (PYCC), a technology-based program for parents of young children with behavioral health challenges. While there are multiple evidence-based programs that promote young children's behavioral health by teaching parenting skills, access to these programs is limited, particularly for families facing economic adversity. Barriers, such as lack of transportation and childcare, prevent parents from attending programs, which are generally in person and require a multiweek commitment. The PYCC was designed to overcome health disparities in access to behavioral parenting information. Initial program evaluation demonstrated that parents report reduced child behavioral health challenges. The proposed project aims to further evaluate the PYCC through a small randomized clinical trial in pediatrics in Detroit.

This investigation is designed to build on the initial evidence base of the PYCC. Evaluating the intervention through a RCT within pediatric care is critically important. Furthermore, recruiting from a site that predominately serves families receiving Medicaid will allow for further understanding of whether the program meets the needs of families facing economic adversity. The results of this investigation, depending on the findings, could lead to multiple subsequent investigations. Specifically, the aim of this small RCT is to establish the evidence based of the PYCC such that funding for a larger RCT can be secured from the National Institute of Mental Health. Ultimately, this project is a crucial step toward understanding the impact of this unique and innovative approach to teaching parents evidence-based parenting practices to promote young children's behavioral health.

Description of the need. While all young children have challenging behavior, such as being defiant or aggressive, sometimes, a subset of young children have behavioral health challenges that are more frequent and intense. These challenging behaviors are a substantial source of stress for parents and these parents are in need of support and guidance on how they can promote their child's best behavior and wellbeing. Early delivery of behavioral health intervention is important as serious behavior problems can emerge as early as age two (Shaw et al., 2000). These newly challenging behaviors can negatively impact the parent-child relationship (Chang & Shaw, 2016; Shaw et al., 2000). Additionally, early childhood behavioral health challenges can persist into adolescence and adulthood and increase the likelihood of negative outcomes such as school dropout, substance use, and criminality (Moffitt et al., 1996; Shaw & Taraban, 2017; Trentacosta et al., 2013).

Multiple existing programs promote young children's behavioral health by teaching parents behavioral parenting skills. These efficacious treatment approaches promote young children's behavioral health (e.g., Eyberg et al., 2008; Webster-Stratton et al., 2013). While there are multiple evidence-based behavioral parenting programs, many of these programs have overlapping content and share the broad goal of building a strong, positive parent-child relationship. Key content in behavioral parenting programs includes showing parents how to reinforce children's positive behavior (e.g., using praise), teaching ways to promote child compliance to parents' requests (e.g., using effective commands), encouraging parents to ignore minor misbehavior, and teaching parents a time-out procedure (Kaminski et al. 2008; Sanders, 2023). While there is ample evidence that parenting programs promote children's behavioral health, there is also a clear need for programs that expand the reach of parenting programs as only 3% of young children in need of behavioral health treatment receive it (Lavigne et al., 2009). Given high rates of internet access, technology-based solutions may be an ideal way to expand the reach of behavioral health care for young children.

How this work addresses the need. The Parenting Young Children Check-up (PYCC) is a technology-based solution designed to overcome barriers to accessing behavioral parenting programs and was designed with underserved populations in mind. The PYCC has three components: 1) the initial check-up, 2) text messages, and 3) the parenting program website. Parents who report child behavioral health challenges on a screener then complete the initial check-up, a brief, online program (can be done on a Smartphone or tablet), while waiting at a pediatric visit. The initial check-up introduces parents to the PYCC and provides information about parenting children who are “strong willed” (a term preferred by study participants in early program development; McGoron et al., 2023a). The program offers parents feedback about their child’s behavioral health and motivational content that encourages parenting changes. The program encourages parents to talk to their child’s doctor about their child’s behavioral health and use the PYCC online modules. At the end of the brief program, parents enter their phone number and then begin receiving text messages that contain links to the PYCC program website to connect parents to behavioral parenting content. The website teaches parenting skills through interactive modules with video-based content derived from common elements in evidence-based behavioral parenting programs that are organized into two categories: preventing and responding to children’s challenging behavior.

PYCC development and evaluation is guided by the ORBIT model, an intervention development approach (Czajkowski et al., 2015). The ORBIT model specifies two early intervention development phases, which have already been completed for the PYCC, that should be completed before moving on to a randomized clinical trial to establish intervention efficacy. In fulfilling these early intervention steps, we first gathered qualitative and quantitative data from 17 Detroit parents, all of whom had a young child with behavioral health challenges, and 17 Detroit area pediatricians and family medicine doctors who see children. Early versions of PYCC intervention materials were refined and modified based on input and suggestions from parents and physicians. Next, at a Detroit pediatric clinic, which predominately serves families receiving Medicaid, we conducted a proof-of-concept trial to assess parents’ response to engaging in the PYCC as part of a pediatric visit and to ensure that the initial check-up prompted parents’ interest in using the PYCC website (McGoron et al., 2023b). This phase also allowed us to collect additional feedback and suggestions about the PYCC. Parents ($n = 30$) completed a screener; 9 parents reported elevated DBPs, and 6 completed the proof-of-concept trial. After going through the initial check-up, all parents reported interest in using the PYCC website and rated the PYCC program elements highly. Feedback from parents was incorporated into the PYCC. After incorporating these changes into the PYCC, two pilot investigations were completed to initially examine the impact of the PYCC. These investigations serve as preliminary data for the proposed investigation. In these early investigations, which did not randomize the participants to intervention or control conditions (i.e., results regarding the impact of the program were using a pre-post design), we found that there was a statistically significant reduction in child behavior problems from baseline to follow up in two small samples of parents (38 parenting in investigation 1; 68 in investigation 2). These early investigations suggest there is potential for the PYCC to have a meaningful impact on children’s behavioral health and support moving onto randomized clinical trial, which is the goal of the proposed project. In the proposed project, 50 parents of young children, recruited at Wayne Pediatrics, will be randomized to intervention (i.e., going through the PYCC initial check-up, receiving text messages, and having full access to parenting program modules on the PYCC website) or a waitlist control (assessment only at baseline; access to the program after the final assessment). We will conduct follow-up assessments to examine the impact of the program.

How this work addresses health equity and social determinants of health. Children from minoritized groups and those from families experiencing economic adversity face disparities in accessing behavioral health care (Hoffmann et al., 2022). Cobb (2023) highlights these points: children's behavioral health needs are increasing, parents are vital agents of change in promoting their child's behavioral health, disparities exist for minoritized and low-income parents in access to behavioral health, and technology-based programs delivered to parents have the potential to reduce these disparities. Given that access to the internet is becoming ubiquitous, technology-based programs, such as the PYCC, are a logical approach to disrupting existing disparities. In our investigation of 160 predominantly low-income and Black/African American mothers of toddlers and preschoolers in Detroit, Michigan (McGoron et al., 2018), we found high levels of access, openness and comfort with the Internet; these outcomes were not impacted by participants' reported race or income.

Programs that are accessible by Smartphone, which the PYCC is, are particularly important to promote health equity. With 15% of people being Smartphone-dependent, Smartphones are their only way of accessing the internet (Perrin, 2021). A relatively high portion of people living in communities facing economic adversity are Smartphone-dependent compared to people living in higher-income communities—thus, Smartphones are an important gateway to resources on the internet, including internet-based parenting programs, such as the PYCC. Cobb (2023) also points out that there needs to be a stronger evidence base for technology-based parenting-focused interventions to promote youth behavioral health and that programs have not yet been developed to meet the needs of diverse populations. The PYCC was created specifically to promote health equity for underserved families. Before creating the full PYCC program, extensive time was spent reviewing the literature and surveying parents facing economic adversity to understand if a technology-based program would meet their needs.

Description of program activities. The PYCC, which has 3 parts, was designed for parents to begin engaging in when bringing their child in for a pediatric primary care appointment. The program begins with the brief "initial check-up," which can be completed on any internet-enabled device, including tablets and Smartphones. The initial check-up takes about 10 minutes and aims to build motivation to make parenting changes and introduce the PYCC. Second, parents receive text messages to connect them with program content. Text messages contain hyperlinks to access program content. Third, a program website provides parents with interactive modules containing video-based content on evidence-based parenting skills. These skills are organized around preventing challenging child behavior (e.g., using labeled praise) and responding to challenging child behavior (e.g., using a time out procedure). We will recruit 50 parents who report evaluated child behavioral health challenges. Parents will be randomized to an intervention group (25 parents) or the control group (25 parents). Both groups will answer questionnaires at the time of recruitment. Then parents in the intervention group will go through the PYCC initial check-up, begin receiving PYCC text messages, and have full access to the PYCC website. Finally, both groups of parents will complete follow-up questionnaires 1 and 3 months after they are recruited.

Description of potential problems or obstacles in project and plan to overcome them. The primary anticipated obstacle we could face is lagging recruitment—that is, we may not recruit parents at the anticipated pace. To overcome this potential challenge, we will closely track recruitment rates within the context of the number of how many patients in the age range are seen/rates of no shows for appointments, which will allow for a quick response to lagging numbers. Importantly, a research team member will attend all clinical staff team meetings and clinical staff huddles at the clinic to ensure they are integrated into the office flow—this will be important if recruitment numbers are low as we will work closely with the clinic team to make changes to recruit more parents. If needed, we will also make

changes to the project such as changing recruitment approach or making changes such as increasing participation incentives. Ultimately, forming a close relationship with pediatric staff will be important for working together to overcome possible barriers.

Expected impact or outcomes; include measurable outcomes and what impacts and outcomes you expect the target population to experience as a result of the project. Based on the findings in our initial study of the PYCC, with a pre-post design, we anticipate that for the intervention group, but not the control group, there will be reductions in child behavioral health challenges, reductions in parenting stress, and gains in positive parenting practices from baseline assessment to follow up assessments. These three outcomes will be measured with parent self-report questionnaires at baseline, 1-month follow-up, and 3-month follow-up. Specifically, we will use the Preschool Pediatric Symptoms Checklist, the Alabama Parenting Questionnaire, and several questions designed for this investigation about parenting stress. While we will not be able to measure the long-term impact of the PYCC on these outcomes in the proposed project, this one-year project will lay the groundwork for further projects to measure if the impact of the PYCC is maintained over time. Additionally, we will also measure how much parents use the modules on the PYCC website and have parents report their satisfaction with the program, including offering open-ended feedback about the program.

Evaluation and methodology. This project will use a randomized clinical trial design with 50 parents of young children (ages 2-5 years old) with behavioral health challenges reported on a screener. Recruitment by project research assistants will take place at Wayne Pediatrics, a primary care pediatric clinic located on Mack Avenue in Detroit. This clinic predominately serves families receiving Medicaid and Dr. McGoron has a history of successful project completion at Wayne Pediatrics in collaboration with their lead physician, Dr. Christopher Youngman (see enclosed letter of support). The proposed project would also leverage a strong partnership with the social work team at Wayne Pediatrics in order to recruit a sample of parents of young children with behavioral health challenges. Research team members will meet with parents who are interested in participating—participation will take no more than 20 minutes (including time for the consent form) and will include answering questionnaires and randomization to the intervention ($n = 25$) or control condition ($n = 25$). The project team will have read-only access to the office Electronic medical Records (i.e., the practice uses Epic) to know what times potential participants will be seen. Follow-up assessments will take place by phone and online questionnaires 1 month and 3 months after baseline.

Parent participants will be those bringing their child (ages 2-5 years old) to a healthcare visit. Parents will complete a screener for child behavioral health challenges called the Preschool Pediatric Symptoms checklist and those that report elevated behavioral health challenges (i.e., a total score of 9 or more; Sheldrick et al., 2012) will be invited to participate in the PYCC project. Parents in both the control and intervention conditions will be paid \$50 through Tango cards (i.e., an online system that allows participants to pick a specific gift card they would like) for their participation.

Randomization will be automatically generated. Parents randomized to the control condition will complete the evaluation measures but will not engage in the PYCC; at the end of the project period (i.e., after the 3-month follow-up), a research assistant will work with parents who were randomized to the control condition to get them access to the full PYCC if they are interested. Parents randomized to the intervention condition will complete baseline questionnaires, go through the full initial check-up, and then begin receiving PYCC text messages that have embedded links to access the parenting program modules on the PYCC website. These parents can use the PYCC website as much, or as little, as they

choose during the study period. Parents will receive three text messages a week for four weeks to prompt use of the PYCC website. Parents in both the intervention and control group will complete follow-up assessments one and three months after baseline and complete each of the questionnaires.

High study retention will be an important goal of this work. We will take multiple steps to ensure strong retention rates. At baseline, at the pediatric clinic, parents will be given a reminder card with the dates of their 1-month and 3-month follow-up appointments with the research team. Parents will be encouraged to take a picture of this reminder card and put these dates in their Smartphone calendar. A reminder about follow-up calls will also be included in text messages. A postcard reminding parents about the follow-up assessment will also be mailed. On the day of each follow-up assessment, the research assistant will then contact participants in both the intervention and control condition through a phone call, with additional text messages and emails if needed. The research assistant will ask them questions over the phone. Parents will then receive a link to complete additional questionnaires through an online survey. Parents will be paid \$50 for the 1-month follow-up and \$50 for the 3-month follow-up through Tango Cards.

Implications to cost, quality, and/or access to healthcare. The PYCC is a free, online resource that any parent can access (their carrier text message rates and data use, when applicable, would apply, however). The PYCC was created to be highly accessible such that parents can use it in the comfort of their own home, at a time that works well for them. The PYCC was designed overcome barriers that are often experienced in accessing traditional behavioral parenting intervention, which are generally in person, such as transportation, childcare, time commitment, and cost.

Sustainability plan. Identifying practical ways to ensure program sustainability in pediatric primary care is an important goal of this project. While evaluating the program in the RCT, we will also collect data from parents and providers to gain insight into delivering the program in pediatric primary care and suggestions for continuing to offer the program once the current project is complete. These results will be summarized and shared with pediatric staff to generate discussions about approaches to offer the PYCC program. Importantly, the PYCC program is low cost to maintain and can be offered to patients at no cost to them or the pediatric clinic—it is a free online resource. Additionally, results of this project will be used as pilot efficacy data in a grant application to be submitted to the National Institute of Mental Health, which could provide additional funding for program implementation and further evaluation.

Potential for replication. This project will tie directly into a project to replicate findings in a larger scale RCT. Based on findings of this project, we will submit an application to the National Institute of Mental Health for an R01 award. If awarded, this 5-year project would allow for testing replication in a large sample of Detroit parents. Additionally, the PYCC content about parenting strategies is derived from multiple, evidence-based parent training programs, which are generally taught through an in-person format. Numerous studies, across decades show that teaching parents these strategies are impactful. Given the strong evidence-based for teaching these parenting strategies, we believe there is a high chance of finding positive results and further replicating these results in future investigations.