

# WAYNE STATE UNIVERSITY

## THE MERRILL PALMER SKILLMAN INSTITUTE FOR CHILD & FAMILY DEVELOPMENT

To Whom it May Concern:

Regard: Clinicaltrials.gov documents

Project Title: The Parenting Young Children Check-up: Proof-of-Concept Trial

ID: K01MH110600

Document Date: January 20, 2020

Enclosed are documents to accompany the results of this small proof-of-concept trial. The present investigation is “Phase 2” of the enclosed protocol. Data were collected through Henry Ford Health Systems in the United States between October 22, 2019 and March 4<sup>th</sup>, 2020. Within this investigation 30 parents were screened and 6 participated in the non-randomized trial. Trial participants went through parent of the Parenting Young Children Check-up intervention while waiting at a pediatric visit. Through mixed methods, parents reported on program ease of use, perceived usefulness, and how much they liked the intervention. Moreover, parents reported if going through the first parent of the program led them to want to use the program parent training website (with video-based content aimed at teaching behavioral parenting skills). This was not a hypothesis driven investigation, but rather an exploration of this mode of intervention delivery.

1. Protocol (see phase 2)

**The following documents are enclosed:**

3. Consent to complete screening

4. Consent to participate in

Sincerely,



Kathleen “Lucy” McGoron, Ph.D.  
Assistant Professor of Research  
Merrill Palmer Skillman Institute  
Wayne State University



## **RESEARCH STRATEGY**

### **SIGNIFICANCE**

**Disruptive behavior disorders are a substantial and under-treated public health threat.** Disruptive behavior disorders in young children are highly prevalent, with ODD and ADHD each affecting over 10% of preschool-aged children (Lavigne et al., 2009). Such disorders often persist into adolescence (Thompson et al., 2011), raising the likelihood of negative outcomes such as substance use (Moffitt, Caspi, Dickson, Silva, & Stanton, 1996). Further, as children grow, disruptive behavior problems become more severe and treatment resistant (Ruma, Burke, & Thompson, 1996). A number of parent training (PT) programs have shown clear efficacy in preventing (Dishion et al., 2008) and treating (Eyberg et al., 2001; Reid, Webster-Stratton & Hammond, 2003; Sanders, Markie-Dadds, Tully, & Bor, 2000) disruptive behavior disorders in young children. These programs have common elements, such as teaching strategies to prevent and respond to children's disruptive behavior. Unfortunately, only 3% of young children with emotional or behavioral disorders receive any treatment at all (Lavigne et al., 2009), and rates of receiving evidence-based PT are likely lower. Further, of families who do sign up for PT, 40% never complete a treatment session (Fernandez, Butler, & Eyberg, 2011); of those who complete at least one session, approximately half drop out early (Beveridge et al., 2015). Disruptive behavior disorders in young children are prevalent, consequential, and under-treated. Strategies taught in PT are effective, but are reaching only a minority of parents in need.

**Parents face many barriers in connecting with evidence-based parenting training.** As reviewed by McGoron and Ondersma (2015a), many barriers prevent families from receiving traditional services for children's disruptive behaviors. For example, there is a well-recognized shortage of mental health services for children (Cummings, Wen, & Druss, 2013); waitlists are common (Sherman, Barnum, Buhman-Wiggs, & Nyber, 2009; Werba et al., 2006); and many parents do not know where to find help (Pavulri, Luk, & McGee, 1996). Further, many families faced with significant disruptive behavior do not even recognize there is a problem in need of attention (Girio-Herrera, Owens, & Langberg, 2012; Pavulri et al., 1996). Other parents adopt a "wait and see" approach and defer seeking help (Girio-Herrera et al., 2012). Creative solutions are needed to overcome barriers and to connect parents with PT interventions.

**Technology may be an ideal response.** A technology-based response can (a) be implemented in healthcare settings, thus increasing access and identification of at-risk children; (b) provide motivational content designed to promote use of PT; and (c) provide more tailored online treatment with minimal barriers. The vast majority of children in the U.S. receive regular health care from a doctor's office (Bloom, Jones, & Freeman, 2012), and current guidelines encourage incorporating mental health screening, parenting information, and mental health treatment into pediatric healthcare visits (Hagan, Shaw & Duncan, 2008). Notably, self-administered PT in healthcare settings (i.e., giving parents packets outlining evidence-based parenting skills) shows promise for responding to confirmed disruptive behavior diagnoses as well as elevated levels of disruptive behavior problems in young children (Berkovtis et al., 2010; Lavigne et al., 2008). Technology could greatly enhance this self-administered approach to responding to disruptive behavior problems. Importantly, as access to the Internet becomes ubiquitous—even among low-income populations (Zickuhr & Smith, 2013)—internet-based PT becomes an increasingly viable solution to dissemination-related barriers. Using an NIH-recommended intervention development framework, the ORBIT model (Czajkowski et al., 2015), this project will develop a technology-based parenting system, the "Parenting Young Children Check-Up" (PYCC), which will dramatically increase the reach of PT through motivating use of an evidence-based PT website.

### **INNOVATION**

The PYCC will include two elements: 1) an initial check-up (level 1; delivered in healthcare settings) designed to increase identification of potentially problematic levels of disruptive behavior and an interactive **brief motivational intervention (<20 minutes)**, with subsequent tailored email and text messages; and 2) an associated PT website that teaches specific parenting skills. Email and text messages will guide parents through the website.

Several key, innovative features will be incorporated into the PYCC to help it to overcome barriers limiting other PT approaches, including:

- 1. A proactive approach.** Traditional PT models wait for parents to seek help from professionals before services are delivered. The PYCC proactively identifies at-risk families using universal screening in a healthcare setting, and subsequently uses motivational techniques to facilitate use of the online tool.

2. **Tailored Internet-based PT.** Available online programs progress through preset modules (e.g., Sanders et al., 2012; Sourander et al., 2016) rather than responding to parent input. The PYCC will capitalize on computerized program capabilities and tailor the progression of content based on parent input.
3. **Lifelike, synchronous interactivity with empathic reflections.** The literature on human-computer interactions indicates that people interact with computers as if they are humans, especially when the computer has lifelike characteristics (Nass & Moon, 2000). Additionally, people respond positively to computer programs that express positive regard and empathy (Bickmore, Caruso, Clough-Gorr, & Heeren, 2005). Both levels of the PYCC will have a positive, empathic animated narrator that does the “talking” through the program in order to engage parents and facilitate learning.

## APPROACH

### Preliminary data

**Is there a need for non-traditional PT?** An examination by the PI of PT in a statewide rollout (see Candidate’s Background) showed that nearly 60% of families receiving PCIT dropped out early (Beveridge et al., 2015). Notably, this investigation only considered **treatment seeking** parents; attrition among non-treatment seekers would likely be higher. Recently, the PI and her mentor found that the majority (70%) of parents who rated their young children in the “at risk” range for behavioral health problems had not sought help and did not think it necessary. Relying on parent help-seeking leads to under-identification.

**Do parents support a technology-based approach in health care?** The PI’s data, collected from a group of 50 diverse and low-income parents at Detroit childcare centers, suggests that many parents are already using technology to get information about children’s challenging behavior and parenting, and are open to expanding the ways in which they do so. Of the parents surveyed, 100% reported access to the Internet, 74% said they use the Internet to get information about parenting and/or child behavior, and 20% regularly use the Internet to get information about parenting and/or child behavior (McGoron & Ondersma, 2015b). Further, parents reported high levels of openness to using tablets at healthcare visits to do behavioral screening (78% agreed) and to receive information about parenting (84% agreed; McGoron & Ondersma, 2015b).

**Do health care physicians support a technology-based approach?** The PI and her primary mentor have also examined physicians’ reported need for, and openness to, a technology-based approach to promoting behavioral health for young children (see McGoron & Ondersma, 2015b). Sixty pediatricians were recruited at Children’s Hospital of Michigan (CHM) and completed brief surveys. Over 70% agreed they would like patients to complete pre-visit behavioral health screening on tablets. Nearly 90% reported openness to parents getting information about parenting and child behavior on tablets in the waiting room; and over 90% agreed they were open to recommending a parenting website.

### Theoretical models

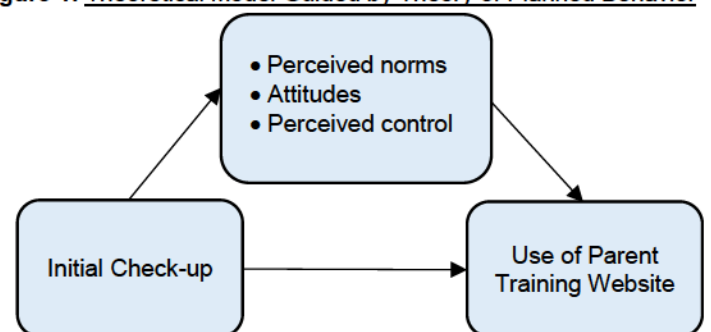
Two theoretical models will guide intervention development and evaluation. First, the technology acceptance model (TAM; Davis, 1989) suggests use of new technology is highest when users perceive it as easy to use (i.e., requiring low effort) and useful (i.e., use will positively impact the users’ performance). Design of the system will center on creating a system that is perceived as easy to use and useful. Second, the Theory of Planned Behavior

(TPB; Ajzen, 1991) suggests that key beliefs, including attitudes, subjective norms, and perceived control, motivate behavior through their effect on change intentions. As depicted in Figure 1, mechanisms linking completion of the initial check-up (level 1) with use of the PT website (level 2) may be consistent with the TPB. That is, the initial check-up (level 1) will motivate use of the PT website (level 2) by altering parents’ attitudes towards children’s behavior, perceptions of child behavior norms, and perceived control over child behavior.

### Proposed intervention

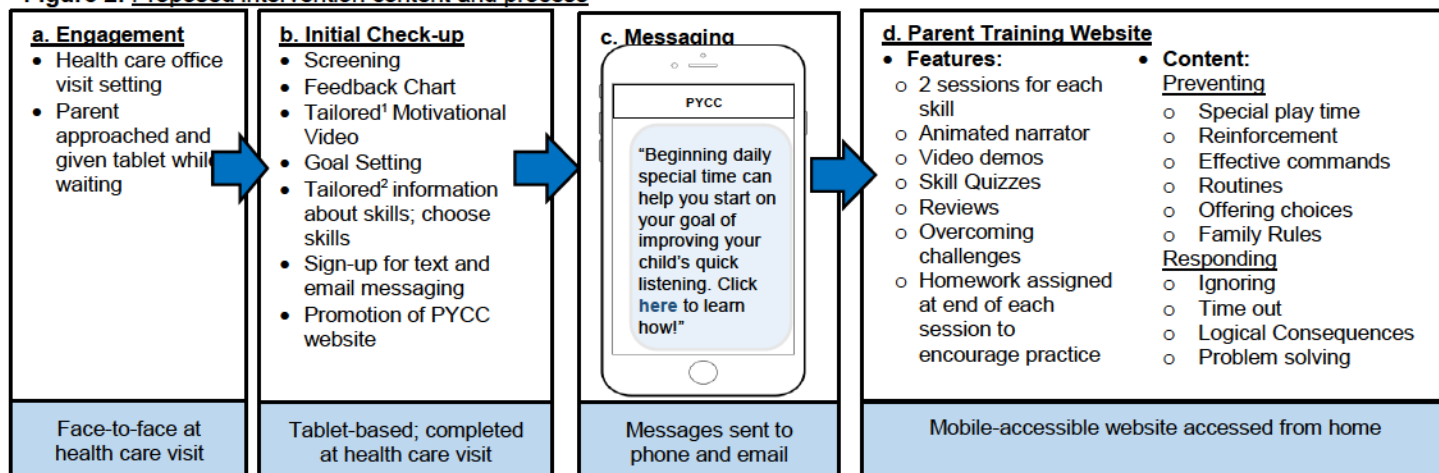
Although page limits prohibit an exhaustive description of the intervention, Figure 2 provides an overview of key proposed PYCC processes and content. As previously mentioned, there will be two main parts to the intervention: An initial check-up completed on a tablet at a healthcare visit (level 1), and a PT website that aims to teach specific skills that are common elements of behavioral PT programs (level 2; reviewed interventions

Figure 1: Theoretical Model Guided by Theory of Planned Behavior



include Parent-Child Interaction Therapy [Zisser & Eyberg, 2010], The Incredible Years [Webster-Stratton et al., 2013], Brief Behavioral Intervention [Axelrad, Butler, Dempsey, & Chapman, 2013], Parent Management Training [Patterson, Reid, & Dishion, 1992], and Triple P [Sanders, Bor, & Morawska, 2007]). Both levels will incorporate an animated narrator and high quality, professionally made videos featuring professional actors (further information below). While parents will be encouraged to access all content on the PT website, parents will have input regarding how they move through the content and, ultimately, what content they use (creating a tailored intervention); this is similar to the tailoring done in the evidence-based Family Check-up (Gill, Hyde, Shaw, Dishion, & Wilson, 2008) as families choose the number and focus of intervention sessions. This choice will be made by parents as part of the initial check-up (see Figure 2b). The two intervention levels will be connected through text and email messaging (see Figure 2c for an example), which will prompt parents to complete sessions. Importantly, intervention creation will be highly influenced by all aspects of the training plan—allowing the candidate to transform gained knowledge into hands-on experiences creating a motivational mHealth intervention (training goal 1), carrying out qualitative data collection (training goal 2), and incorporating the PYCC into the work flow of a health care visit (training goal 3). Further, following the ORBIT framework, specific content will be influenced by data collected during the “Define & Refine” stage (see Figure 3, Step 2). Input from parents and professionals will guide specific decisions about presentation of materials, frequency of contact (e.g., frequency of messages), and presentation of content, in order to maximize technology acceptance.

**Figure 2: Proposed intervention content and process**



<sup>1</sup>tailored based on screening results (e.g., severity of DBP; current motivation to change); <sup>2</sup>tailored based on goals

**Technical aspects of program creation.** The initial check-up will be programmed using the Computerized Intervention Authoring System (CIAS), a web-based authoring tool that allows the creation of highly interactive brief interventions without the need for programming. Consistent with the Elaboration Likelihood Model (Petty & Cacioppo, 1986), which posits that tailoring health content to the individual increases perceived relevance, system logic within CIAS enables branching and tailoring. That is, content is presented in a customized manner, dependent on prior responses. Interventions created through CIAS have been successfully used by parents in multiple previous randomized trials, and these parents have given high ratings for ease of use (e.g., Ondersma et al., 2014). The most recent version of CIAS deploys as a cross-platform compatible mobile web app, making it accessible on any mobile device, and is also able to send tailored emails and text messages.

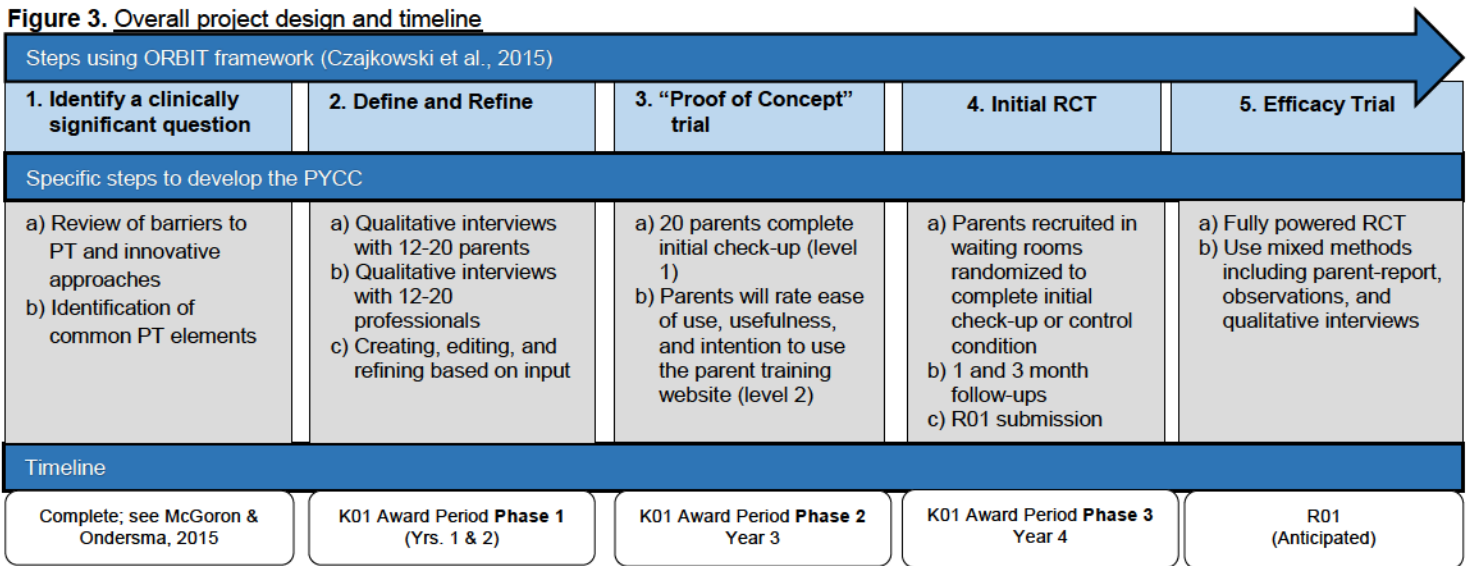
The level 2 PT website will be created using Wix.com. Wix is a user-friendly platform allowing individuals without programming experience to create sophisticated HTML5 websites that use responsive web design, making them compatible with mobile devices of all types and sizes. The website will be created by the PI and project RA. Given how important ease of use is, a Wix programming consultant will be hired in year 1 in order to generate suggestions for improvements. The website will be username protected. Wix websites are highly flexible and scalable, and also allow for implementation of custom coding if necessary.

## Research Design

**Introduction and overview.** As seen in Figure 3, the research project—and complimentary training activities—will follow the steps outlined in the NIH ORBIT framework (Czajkowski et al., 2015). In step 1 (complete), the PI and her primary mentor identified the limited reach of traditional PT programs and proposed an approach to expand the reaching using technology (see McGoron & Ondersma, 2015a). The proposed K

award period will focus on the early stages of intervention development and evaluation. The culmination of the project will be preparation of an NIMH R01 application to conduct a fully powered RCT.

**Figure 3. Overall project design and timeline**



For each phase, parent-participants will be parents of young children (ages 2-5; an age when parents are central change agents for children’s behavior) who report elevated child disruptive behavior problems. Parents will complete the The Eyberg Child Behavior Inventory (ECBI; Eyberg & Pincus, 1999); a widely used measure in PT research (e.g., see Reyno & McGrath, 2006). Those with a t-score at/above 55 (“at risk” range and above; capturing clinical and sub-clinical levels) will be invited to participate further. We anticipate 20% of screened children will be eligible. All screened parents will receive a \$5 gift card.

**Phase 1: Define and Refine (Yrs. 1 & 2)**

**Overview.** The first two years of the K01 award period will focus on creating an mHealth intervention that aligns with parent and professional input. Specifically, consistent with the ORBIT model, we will finalize the process and content for both intervention levels, using **qualitative input** from parents and professionals.

**Input from physicians:** We look to develop a process of delivering the initial check-up (level 1) in healthcare settings in a way that minimizes burden to professionals. As such, a central part of developing and refining the system is seeking feedback from physicians (consistent with the ORBIT model; see Czajkowski et al., 2015). We will seek qualitative data from physicians examining behavioral health care, and openness to the proposed PYCC system. Data collection will continue until saturation is reached (anticipating 12-20 participants). To accommodate the schedule of physicians, these will be conducted as one-on-one interviews. A detailed qualitative agenda will be prepared through collaboration with the qualitative mentor and consultant. Participating professionals will receive a \$30 gift card.

**Input from healthcare professionals:** A necessary component of the success of the PYCC is that it fits in with office flow at busy pediatric practices. To ensure this, we will have a focus group with 5-10 pediatric office staff (i.e., medical assistants, receptionists). The focus group will be no more than 40 minutes in length and will take place during a regularly scheduled lunch meeting. Lunch will be provided for staff that participate. A qualitative agenda will guide the focus group; staff will learn about the PYCC and give feedback and suggestions. Participants will receive a \$30 gift card.

**Input from parent-participants.** It is critically important that the PYCC is engaging and perceived as useful to parents. A convenience sample of parents of children ages 2-5 will be recruited through email and face-to-face solicitation at drop-off and pick-up times at the centers. Just as with all parent participants, the ECBI will determine eligibility. Parents will complete one-on-one qualitative interviews. The PI will create a qualitative agenda to guide the interviews and will personally conduct half of the interviews.

**Initial content development and presentation.** Phase 1 participants will learn about planned intervention process and content—seeing examples of questions, text/email messages, and example videos. In terms of videos, video content will initially be made in GoAnimate (www.goanimate.com) in order to make cost-effective examples of content. Following parent input, high quality videos will be produced through a partnership with Wayne State’s University Television, which consists of a team of video production professionals who will

partner with the PI and mentorship teams members on video conceptualization, pre-production, and editing. The goal will be to have a full beta version of the intervention, including high quality videos, that was developed with extensive input from professionals and parent by the end of the second year.

**Feedback data extraction.** All qualitative interviews and focus groups will be audio recorded and transcribed. As part of the training in qualitative research (Training Objective 2), the PI will learn two types of qualitative. In order to meaningfully examine professional and parent qualitative data, framework matrix analysis will be used for this project to extract, summarize, and analyze interview data (thematic analysis will also be complete with collected data as a training experience). In this efficient qualitative data analysis approach, summaries are assigned thematic categories derived a priori rather than de novo based upon the interview agenda. This process will yield specific, recurring information about participant feedback. Results will be discussed with mentors and will inform changes.

## **Phase 2: Proof of concept testing (Yr. 3)**

**Overview.** “Proof of Concept” testing, as outlined by the ORBIT model (Czajkowski et al., 2015), will be completed using a non-randomized design. This phase will allow us to determine acceptance and impact of the PYCC initial check-up on intention to use PT website. It will also allow us to get further input from parents before the RCT data collection year; time will allow for final modifications to the program content (e.g., videos) and process if needed. Finally, participants will be recruited from the same locations as will be used for the RCT, allowing for refining of data collection procedures prior to the RCT.

**Participants and Procedures.** Parents will be recruited from the Henry Ford Health Systems Pediatric clinic at New Center One in Detroit, Michigan. Recruitment approach will follow procedures used in multiple NIH-funded investigations (PI: Ondersma). This recruit approach does create downtime for the RA, but it is necessary in order to be in line with HIPAA regulations and incorporate data collection into health care office flow. The RA will be able to make use of down time by working to manage deidentified data (among other tasks). The project RA will work with office staff to know what times potential participants will be seen. The study will be introduced to parents by front office staff, Medical Assistants, or physicians for well-child visits for children 2-5. If the parent expresses interest in participating, the project research assistant will meet with him/her (either before or after the visit, depending on time) and provide further detail about participation. All parents of children ages 2-5 that agree to participate ( $n = 75$ ) will complete the brief screener (i.e., the ECBI; Eyberg & Pincus, 1999) to determine further eligibility. If eligible, the parent will use a study tablet to answer questions, go through phase 1 of the PYCC, and provide brief feedback. Parents will also receive a list of URLs to access parenting videos and (if they choose) can view the videos and provide feedback (this element is not required for participation). We intent for participation to take <20 minutes; research staff will be mindful not to disruptive office flow. Participants will be compensated with a \$25 gift card for their time.

**Measures and Procedures.** Parents will do the full initial check-up (level 1) at the health care visit, then complete a brief questionnaire intended to evaluate perceptions of 1) ease of use, 2) usefulness of the information (in line with the Technology Acceptance Model; Davis, 1989), and 3) intentions to use the PT website (level 2). Items will be rated on a 1 (strongly disagree) to 5 (strongly agree) scale. Parents will also answer some brief, open-ended questions in order to tap into perceptions of the system and any barriers to using the PT website (level 2). After 5 parents participate, ratings will be examined. Literature on technology development suggests 5 users is generally sufficient for early testing (Turner, Lewis, & Nielsen, 2006). We seek to obtain quantitative ratings exceeding 4 on a 1-5 scale, and positive qualitative feedback. If this goal is not reached, we will recruit an additional 5 parents, in blocks, as needed (we anticipate needing 5-15 parents).

## **Phase 3: Pilot RCT (Yr. 4)**

**Overview.** Forty parents of young children will be randomized to intervention (i.e., initial check-up [level 1]) or control conditions (i.e., assessment only), with follow-up assessments at 1-month and 3-months.

**Participants and Procedures.** Parent recruitment methods will be identical to those described in Phase 2. A second assistant (i.e., a research technician) will be hired at the beginning of this year in order to make recruitment feasible. Participating parents will be compensated \$25 for baseline participation, \$25 for completing the 1-month follow-up, and \$50 for completing the one-month follow-up.

**Randomization.** Randomization will be automatically generated by CIAS. Parents randomized to the control condition will only complete the evaluation measures (see Table 1) and select goals. Parents randomized to the intervention condition will complete the full initial check-up (Level 1; see Figure 3b). All parents (both

control and intervention) will be given a brochure to access the PT website by the research assistant; including unique login number that will allow us to examine if completing the full initial check-up impacts website use.

**Follow-up.** We will follow up with participants in both conditions by sending links to online surveys at one month and three months after baseline (these questionnaires will be done through Qualtrics; see [www.qualtrics.com](http://www.qualtrics.com)). Parents will complete all evaluation measures (Table 1) at each time point. We will communicate by phone and by regular email with participants who do not complete the survey in an attempt to prompt participation or establish that the participant is choosing to stop their participation.

**Measures.** Table 1 outlines measures used for evaluation, the construct each measure taps into, and assessment points for each measure. The primary outcome of interest—use of the PT website—will be measured via rates of visiting the website for each assigned user ID (gathered via using Google Analytics). The secondary outcome of focus, items consistent with the TPB, will be measured with items made specifically for this project; rated on a 5-point scale with 3 items tapping into each domain. Internal consistency will be examined for the measure as a whole and item domains. As mentioned previously, the ECBI will be used to screen children for disruptive behavior problems. The ECBI taps into parents' perceptions of child disruptive behavior through 36-items in which caregivers rate the frequency of specific challenging child

**Table 1:** Evaluation Measures

Construct	Measure name (author)	Assessment Point		
		BL	1-month	3-month
Disruptive behavior problems	Eyberg Child Behavior Inventory (ECBI; Eyberg & Pincus, 1999; Intensity and Problem scales)	X	X	X
Parenting practices	Alabama Parenting Questionnaire—Preschool Revision (Clerkin, Marks, Policaro, & Halperin, 2007)	X	X	X
Parents' Theory of Planned Behavior (TPB)	Items made specifically for this project with three items tapping into each domain of TPB	X	X	X
Use of Parenting Training Website	Tracking of username logins through Google analytics tool		X	X
Technology Acceptance Questionnaire (intervention group)	Items made for this project tapping into ease of use, usefulness, and overall satisfaction	X	X	X

behavior (e.g., “does not obey”) on a 7-point Likert scale (ranging from 1 = Never to 7 = Always) and also if the behavior is perceived as a problem for the parent (rated as “yes” or “no”). The ECBI will be re-administered at follow-up. The Alabama Parenting Questionnaire—Preschool Revision (Clerkin, Marks, Policaro, & Halperin, 2007) will be incorporated in the initial check-up, and will be re-assessed at each follow-up. The APQ-PR stems from the widely used Alabama Parenting Questionnaire (Frick, Christian, & Wooton, 1999) and has parents rate how typical specific parenting behaviors occur (e.g., “You let your child know when he/she is doing a good job with something”) on a 5-point scale (ranging from 1=Never to 5=Always). For the intervention group, intervention acceptance will be measured through a brief questionnaire made for this project. All measures are purposefully brief and the number limited to increase feasibility.

**Data Analyses.** Data analyses will use an intent-to-treat approach using multiple imputation for participants lost to follow-up. Primary Hypothesis: The intervention group (i.e. those randomized to complete the full initial check-up [level 1]; n = 20) will visit the PT website more often than the control group (i.e., assessment only; n = 20). Secondary Hypothesis (a): Participants assigned to the intervention group, as compared to those in the control group, will have higher scores for all domains consistent with the TPB at follow-up. For both primary and secondary (a) hypotheses, we will examine descriptive analyses and conduct ANCOVA, t-test analyses, and effect size calculation (Cohen's d) to determine group differences. Low power may inhibit finding statistically significant results. Secondary Hypothesis (b): Participants in the intervention group will report high levels of satisfaction (>=4 on a 5-point scale); examined through descriptive statistics. Exploratory analyses: We will also explore if randomization to the intervention group and actual use of the PT website leads to fewer disruptive behaviors and improved parenting practices at follow-up. ANCOVAS, t-tests, and effect size (Cohen's d) calculation will be used for these exploratory analyses.

### Summary and Future Directions

This project will follow the ORBIT framework (Czajkowski et al., 2015) for the initial design, refinement and evaluation of a novel and innovative technology-based system to respond to disruptive behavior in young children. Based on results, particularly data on the use and impact of the PYCC, an R01 application will be submitted to NIMH during year 4. If awarded, the R01 will allow for evaluation of the PYCC in a fully powered RCT.

**Do you have a little time today while you wait?**

**Are you a parent?**

**APPROVED**

**Is your child 2, 3, 4, or 5 years old?**

Jan. 16, 2020

**If you answered YES...**

INSTITUTIONAL REVIEW BOARD

Please consider being in a brief project.

Participate while you wait!

You will receive \$10 for about 10 minutes of your time. Our staff can help keep your child entertained. You may also be eligible to further participate.




Participation includes answering questions on a tablet for about 10 minutes. If you complete the survey, you will receive **\$10 on a debit-like card.**

If you are eligible and choose to further participate, you will go through a short program on a tablet and give your feedback. You will receive **\$15 on a debit-like card.**

**Please meet with the project assistant immediately if you are interested in participating today!**



	<b>CONSENT TO PARTICIPATE IN A RESEARCH STUDY</b> <small>(HFH IRB form rev: 12/7/2018)</small>	DATE: MRN: NAME:
<b>APPROVAL PERIOD</b>  Jan. 16, 2020 – Aug. 20, 2020  INSTITUTIONAL REVIEW BOARD	<b>PROJECT TITLE:</b>  <b>Pediatric Motivational mHealth Parent Training for Child Disruptive Behaviors: Proof-of-Concept Trial</b>	


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**Lucy (Kathleen) McGoron, PhD**  
**71 E. Ferry St, Detroit MI, 48202**

**1. INTRODUCTION**

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
<p><b>Voluntary Consent.</b> You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.</p>
<p><b>Purpose.</b> The purpose of this research is for parents to learn about the Parenting Young Children Check-up, an internet based program for children’s disruptive behavior, and provide feedback on it.</p>
<p><b>Duration.</b> It is expected that your participation will last 15 minutes.</p>
<p><b>Procedures and Activities.</b> You will be asked to go through a brief program on a tablet, answer some questions, and provide feedback.</p>
<p><b>Risks.</b> Some of the foreseeable risks or discomforts of your participation may include feeling uncomfortable answering some of the questions.</p>

	<b>CONSENT TO PARTICIPATE IN A RESEARCH STUDY</b>	DATE:
	(HFH IRB form rev: 12/7/2018)	MRN:
		NAME:
<b>APPROVAL PERIOD</b>	<b>PROJECT TITLE:</b>	
Jan. 16, 2020 – Aug. 20, 2020	<b>Pediatric Motivational mHealth Parent Training for Child Disruptive Behaviors: Proof-of-Concept Trial</b>	
INSTITUTIONAL REVIEW BOARD		

**Benefits.** You may not directly benefit from this research. However, the information learned from your participation may help others in future.

**Alternatives.** Participation is voluntary and the only alternative is to not take part in this research study.

**2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST**

The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. HFHS receives funding from National Institute of Mental Health to help cover administrative costs such as record keeping, mail and telephone expenses. However, investigators do not receive salary or other financial support from the study sponsors in exchange for conducting this study.

**3. WHY IS THIS RESEARCH BEING DONE?**

You have been asked to take part in a research study because you are a parent with a child ages 2-5 and you are eligible based on a survey you just completed. This study is being conducted at Henry Ford Health Systems and Wayne State University.


There will be approximately 15 people in this research study at Henry Ford Health System (HFHS).

This study is sponsored by National Institute of Mental Health. This means that the sponsor is compensating HFHS for the costs of carrying out this research.

The purpose of this study is for parents to learn about the Parenting Young Children Check-up and provide feedback.

**4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?**

If you take part in the study, you will go through a brief program on a tablet, answer some questions, and provide feedback. The process should take about 15 minutes.

	<b>CONSENT TO PARTICIPATE IN A RESEARCH STUDY</b>	DATE:
	(HFH IRB form rev: 12/7/2018)	MRN:
		NAME:
<b>APPROVAL PERIOD</b>	<b>PROJECT TITLE:</b>	
Jan. 16, 2020 – Aug. 20, 2020	<b>Pediatric Motivational mHealth Parent Training for Child Disruptive Behaviors: Proof-of-Concept Trial</b>	
INSTITUTIONAL REVIEW BOARD		

**5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?**

The researchers believe there are no reasonably foreseeable risks associated with this research study. There may be additional risks or discomforts that are not known at this time.

You may feel uncomfortable answering some of the questions. The researchers believe there are no other reasonably foreseeable risks associated with this research study. There may be additional risks or discomforts that are not known at this time.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

**6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?**


You may not directly benefit from this research; however, we hope that others are helped in the future by what is learned.

**7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?**

Participation is voluntary. You do not have to participate in this study.

**8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research information will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password

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protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers.

Your identifiable private information or identifiable biospecimen, even if stripped of identifiers, will not be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

**9. WHAT IF I GET SICK OR I AM INJURED?**

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.


**10. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?**

Dr. Tisa Johnson-Hooper, MD, Dr. Lucy McGoron, PHD, or her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Dr. McGoron at (313) 664-2553 or by email at [lucy.k.mcgoron@wayne.edu](mailto:lucy.k.mcgoron@wayne.edu). Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone

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at (313) 874-4464 or by email at [research\\_admin@hfhs.org](mailto:research_admin@hfhs.org). The IRB is a group of people who review the research to protect your rights.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### 11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

### 12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

### 13. WILL IT COST ANYTHING TO PARTICIPATE?


We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

### 14. WILL I BE PAID TO PARTICIPATE?

For taking part in this research study, you will be paid for your time and inconvenience. You will be paid \$15. You will be paid following participating today. If you complete the study, you will be paid a total of \$15. If you do not finish the study, you will be paid for the part that you did complete.


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You will receive payment via a ClinCard, which is a specially designed debit card for clinical research that works like a bank debit card. Each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. The debit card system is administered by an outside company. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. In order to receive payment, we will need to collect some information about you, including your name, address, date of birth, medical record number, social security number, and your patient study ID code. All information is stored in a secure fashion and will be deleted from our records once the study has been completed and the funds on your ClinCard have been exhausted.

You may use this card at any store that accepts credit cards. You may also withdraw cash. Please be aware that there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and any fees that may apply.

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**DOCUMENTATION OF CONSENT**

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason and without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Witness to Signature

\_\_\_\_\_  
Date


\_\_\_\_\_  
Time

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

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**Tisa Johnson-Hooper, MD**  
**3031 W Grand Blvd Suite 800, Detroit, MI 48202**


**Lucy (Kathleen) McGoron, PhD**  
**71 E. Ferry St, Detroit MI, 48202**

### 1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
<p><b>Voluntary Consent.</b> You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.</p>
<p><b>Purpose.</b> The purpose of this research is to see if you are eligible to be part of a second project, which focuses on a resource for parents called The Parenting Young Children Check-up.</p>
<p><b>Duration.</b> It is expected that your participation will last 30 minutes.</p>
<p><b>Procedures and Activities.</b> You will be asked to answer a survey on a tablet. The survey will take 10-15 minutes and will ask questions about you and your child. Most of the questions focus on your child's behavior.</p>
<p><b>Risks.</b> Some of the foreseeable risks or discomforts of your participation include feeling uncomfortable answering some of the questions, but you can choose not to answer these</p>



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questions. More detailed information can be found in the “*What Are The Risks, Discomforts, And Inconveniences Of The Study?*” section in the Consent Form.

**Benefits.** You may not directly benefit from this research. However, the information learned from your participation may help others in future.

**Alternatives.** Participation is voluntary and the only alternative is to not take part in this research study.

## 2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. HFHS receives funding from National Institute of Mental Health to help cover administrative costs such as record keeping, mail and telephone expenses. However, investigators do not receive salary or other financial support from the study sponsors in exchange for conducting this study.

## 3. WHY IS THIS RESEARCH BEING DONE?


You have been asked to take part in a research study because you are a parent with a child ages 2-5. This study is being conducted at Henry Ford Health Systems and Wayne State University.

A total of approximately 75 people will be enrolled at Henry Ford Health System (HFHS).

There will be approximately 75 people in this research study at Henry Ford Health System (HFHS).

This study is sponsored by National Institute of Mental Health. This means that the sponsor is compensating HFHS for the costs of carrying out this research.

The purpose of this study is to see if you are eligible to be a second project, which focuses on a resource for parents called The Parenting Young Children Check-up.

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**4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?**

If you agree to take part in this study, you will answer a survey on a tablet. The survey will take 10-15 minutes and will ask questions about you and your child. Most of the questions focus on your child's behavior.

**5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?**

You may feel uncomfortable answering some of the questions. The researchers believe there are no other reasonably foreseeable risks associated with this research study. There may be additional risks or discomforts that are not known at this time.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

**6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?**


You may not directly benefit from this research; however, we hope that others are helped in the future by what is learned.

**7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?**

Participation is voluntary. You do not have to participate in this study.

**8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any

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codes) in a locked, secure location. Your research information will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers.

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**14. WILL I BE PAID TO PARTICIPATE?**

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You may use this card at any store that accepts credit cards. You may also withdraw cash. Please be aware that there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and any fees that may apply.

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**DOCUMENTATION OF CONSENT**

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason and without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Witness to Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

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Time

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