Official Title: The PRO-Parenting Study: Helping Parents Reduce Behavior Problems in Preschool Children with Developmental Delay

Brief Title: Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)

NCT Number: NCT03599648

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Research PlanResearch Plan

IMPORTANT: When completing this outline, please use the **Research Plan Guidance** for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review.

Study Title:Study Title: Testing the Efficacy of Mindfulness-Based Stress Reduction Combined with Behavioral Parent Training in Families with Preschoolers with Developmental Delay (aka the Pro-Parenting Project)

Protocol Number:Protocol Number: 03212018.023

Principal Investigator:Principal Investigator: Laura Lee McIntyre

A. Introduction and Background

Behavior problems are a common and concerning challenge among children with developmental delays (DD). Approximately 50% of children with DD have a comorbid mental disorder or serious behavior problems- a prevalence three times as high as that found in typically developing youths. Behavioral parent training (BPT) is the gold-standard intervention for treating child behavior problems in typically developing children and in children with DD. However, high levels of parental stress are associated with reduced or no response to BPT for children with DD. Consequently, parental stress may attenuate the efficacy of the gold-standard, empirically supported treatment for behavior problems among children with DD. As such, parental stress is a critical point of intervention for improving both parent and child outcomes in families of children with DD. The purpose of this study is to quantify the therapeutic benefit of adding a parent stress-reduction intervention prior to delivering BPT in order to more effectively reduce child behavior problems, and to investigate the mechanisms through which intervention outcomes occur.
This study has significant potential to improve the long-term well-being of children with DD and their families by determining the added benefit of targeting parenting stress and parent management strategies to more effectively reduce behavior problems among children with DD. Findings from this study will improve the scientific understanding of evidence-based interventions for behavior problems among children with DD and the mechanisms underlying therapeutic change.

B. Specific Aims/Study Objectives

Aim 1: Test the efficacy of BPT-M, which adds a parent stress-reduction intervention (MBSR), compared with BPT-E (BPT+ psychoeducational control), for reducing the distal outcome of child behavior problems.

Hypothesis 1: Children of parents who complete the BPT-M intervention will exhibit greater and more sustainable reductions in child behavior problems at posttreatment and at 6- and 12-month follow-up, compared with children whose parents participate in the BPT-E intervention, as evidenced by parent and teacher reports and observational measures of child behavior problems.

Aim 2: Examine if parenting behavior mediates the relation between intervention and child behavior problems.

Hypothesis 2: Changes in parenting behavior, as measured by self-report and observations, will mediate the relation between intervention and the reduction of child behavior problems at post-treatment and at 6- and 12-month follow-up.

Aim 3: Determine if the improvements in parenting behavior are, in turn, mediated by reductions in parenting stress, a proximal target of the BPT-M intervention.

Hypothesis 3: Improvements in parenting behavior will be mediated by a reduction of parenting stress immediately post-treatment and at 6- and 12-month follow up.

C. Methods, Materials and Analysis

Data for this research study will be collected at two sites, the University of Oregon Prevention Science Institute in Portland, OR, and Loma Linda University in Loma Linda, CA. Approximately 1/3 of the sample will be recruited and assessed by the UO site. The UO site will be responsible for all data management and ~~but~~ will ~~not~~ receive ~~any~~ some protected health information (PHI) from the Loma Linda site in order to recruit participants for Cohort 5. For example, names, addresses, birthdays, and medical histories previously collected by Loma Linda research staff when potential participants were added to a waitlist will ~~not~~ be shared with the Oregon site. The data sharing agreement between the two institutions has been modified to allow this sharing of information.

Methods for recruitment, baseline data collection, and parent groups will differ in this study between cohorts 1 and 2 due to the COVID-19 pandemic and the increased physical distancing required to limit spread of the virus. Cohort 1 began with in-person data collection in homes and in-person parent groups. Cohort 1 was in the middle of parent groups when the "stay at home" orders were issued; groups then shifted to a remote/ Zoom format, as did all subsequent data collection. In contrast, all phases of the research project (baseline data collection, parent groups, follow-up data collection) will be conducted remotely for Cohort 2 (and additional cohorts, if any). There is only one exception to this: if/ when it is deemed safe by the University/ State of Oregon for us to meet in person with preschoolers who are not wearing masks, we will conduct the ADOS and Stanford-Binet tests in person (these tests are part of the "lab visit" described below). If current restrictions are not lifted by the end of the study period, we will simply forgo collection of the ADOS and Stanford-Binet.

Because methods for recruitment, baseline data collection, parent groups, and immediate follow-up data collection differed between cohorts, descriptions of these methods are provided separately for each cohort. The methods described for lab visits, teacher data, and 6- and 12-month follow-up data collection apply to both cohorts and are labeled as such.

Data from other cohorts were collected at Loma Linda University using protocols and documents approved by their IRB. Moving forward, the University of Oregon research team has been asked to help the Loma Linda team recruit participants living in California for Cohort 5 and help collect some data components. University of Oregon research team members have been added to the research team included in the protocol at Loma Linda University and will follow the LLU IRB-approved protocols and use the LLU IRB-approved documents when working with participants residing in California. However, University of Oregon team members will continue to use UO IRB-approved protocols and documents when working with participants residing in Oregon. Loma Linda research staff will have no contact with participants living in Oregon nor their identifiable information.

Recruitment and Baseline Data Collection

Cohort 1

Recruitment methods are described below in section D. Interested parents will either contact the PRO-Parenting Project by phone or by completing a form on our project website. If the family indicates interest in participation, trained staff will conduct a phone screen ("Script for initial contact phone screen" and "PRO-Parenting clinical phone screen form"). If the family meets eligibility for the study, an appointment will be scheduled for the initial home assessment ("script for confirmation call to schedule home visit"). Information gathered from the screening calls will be destroyed for families who do not meet eligibility requirements, as well as for those who do meet requirements but choose not to participate. For families who proceed to the study, information gathered from the screening call will be used to assess parenting stress, which is a variable of interest to this study.

As the name implies, the initial home assessment will take place in participants' homes. Prior to the initial home assessment, parents will be mailed a packet of questionnaires ("PP-T1 mailout-PC") that they will complete before the assessors go to the home visit. At the initial assessment, parents will be given a consent form and research staff will review this document with the parent (informed consent process is described below in section E). Parents who do not agree to be videotaped for the study will still be allowed to participate in the study. After completing the consent process, the parent and the child will participate in a 20-minute videotaped play assessment in the home. Parent and child will be given a standardized set of toys and asked to complete 4 tasks: (1) *Unstructured free play task* (parent is instructed to allow the child to choose any activity and play along with the child as they normally would); (2) *Clean-up task* (parent is instructed to give the child a command to clean up); and (3) *Parent teaching task* (parent is instructed to select an activity and to keep the child playing according to the parent's rules); (4) *Child Frustration Task* (child is given a difficult task and asked to complete quickly to earn a prize). We will use established coding systems to evaluate parent and child behavior in these tasks (Simple Affect Code: Jabson &

Dishion, 2004; Relationship Process Code: Jabson & Dishion, 2005; Parent-Child Behavior Observation System: Phaneuf & McIntyre, 2007). After the observation task with the child, parents will meet with an assessor to complete the parent demographic form and the service utilization form (found in "PP-T1_inhome") and the Change Plan Worksheet (see "BPT-E PEI form" and "BPT-M PEI form"; these forms are very similar but one is for participants in the BPT-E condition and one for those in the BPT-M condition). The initial home visit should take 60-90 minutes to complete. After the visit is over and research staff return to the office, staff members will complete the Visit Impressions form (see "Updated VIMP-1.17.2020-pp1vimp").

Prior to the baseline assessment, parents will be randomly assigned by the Data Manager to either the behavioral parent training group with a mindfulness component (BPT-M) or an education component (BPT-E) by means of a random numbers table. An approximately equal distribution of families will be assigned to each of the two conditions. Families will be told of their condition assignment at the end of the observation task in the baseline visit.

Cohort 2

Recruitment methods are described below in section D. Interested parents will either contact the PRO-Parenting Project by phone or by completing a form on our project website. If the family indicates interest in participation, trained staff will conduct a phone screen ("Cohort 2 Script for initial contact phone screen" and "Cohort 2 script clinical screen baseline"). If the family meets eligibility for the study, they will be mailed an assessment packet, consent form, and return envelope, and will be scheduled for a series of 3 remote appointments for the purposes of baseline data collection ("Cohort 2 script for confirmation call to schedule remote home visit"). Information gathered from the initial screening calls will be destroyed for families who do not meet eligibility requirements, as well as for those who do meet requirements but choose not to participate. For families who proceed to the study, information gathered from the screening call will be used to assess parenting stress, which is a variable of interest to this study.

Baseline data collection for this study will be collected via a packet of questionnaires mailed to participants' homes ("PP-T1 mailout-PC") and a series of 3 appointments conducted via Zoom. Parents will complete questionnaires prior to the first of the 3 appointments and mail them back to project staff as soon as possible (see "c2 cover letter baseline survey packet" and "Oregon PRO-Parenting study KIT Form"). The first appointment will be between the parent and a research assistant and conducted over Zoom (see "C2 Baseline DEM-Serv Script Zoom#1"). At this appointment, research staff will complete consent procedures (informed consent process is described below in section E), the parent demographic form and the service utilization form (found in "PP-T1_inhome"), and provide preliminary instructions for the family observation tasks that will occur in appointment 2 (see "virtual play task instructions #1 sent with survey"). The research assistant will also trouble-shoot any sort of technology- or materials-related issues at this appointment to make sure that the parent is prepared for the family observation task.

Prior to the second Zoom appointment, parents will receive a box of assessment materials in the mail intended to help facilitate the family observation task (see "c2 cover letter_baseline assessment kit" and "virtual play tasks instructions #2 sent in kit"). This box will include 3 puzzles and a play mat that will be used for the home visit; families may keep these items and add them to their child's toy collection after the visit. The second Zoom appointment will involve a research assistant, the parent, and the target child. The purpose of the second appointment is to record the family observation task, a 20-minute videotaped play assessment between the parent and target child. At the beginning of this appointment research staff will go over the remaining instructions for the family observation task. The parent and child will then be asked to complete 3 tasks (see "C2 baseline play task script protocol"): (1) *Unstructured free play task* (parent is instructed to allow the child to choose any activity and play along with the child as they normally would); (2) *Clean-up task* (parent is instructed to give the child a command to clean up); and (3) *Parent teaching task* (parent is instructed to select an activity and to keep the child playing according to the parent's rules). We will use established coding systems to evaluate parent and child behavior in these tasks (Simple Affect Code: Jabson & Dishion, 2004; Relationship Process Code: Jabson & Dishion, 2005; Parent-Child Behavior Observation System: Phaneuf & McIntyre, 2007).

The third Zoom appointment is a rapport building appointment between the family interventionist and the parent and will be conducted via Zoom. At this appointment, the parent and family interventionist will complete the Change Plan Worksheet (see "BPT-E Change Plan Worksheet PEI baseline" and "BPT-M Change Plan Worksheet PEI baseline"; these forms are very similar but one is for participants in the BPT-E condition and one for those in the BPT-M condition). The family interventionist will also complete a Qualtrics COVID survey as an interview (see "Impact of covid-19 survey for qualtrics") during this appointment to gather additional information about family stressors during this unique historical period. See "c2 PEI BPT-M Protocol script" for script for this

visit for participants assigned to the BPT-M group and “c2 PEI BPT-E protocol script” for participants assigned to the BPT-E group.

Prior to the baseline assessment, parents will be randomly assigned by the Data Manager to either the behavioral parent training group with a mindfulness component (BPT-M) or an education component (BPT-E) by means of a random numbers table. An approximately equal distribution of families will be assigned to each of the two conditions. Families will be told of their condition assignment at the end of the observation task in the baseline visit.

Parent Groups

Cohort 1

For our first cohort, two parent groups were run concurrently and face-to-face at King School in Oregon City, OR (this facility is a former elementary school managed by the Clackamas ESD for HeadStart classes and early childhood special education classes) until the COVID-19 pandemic forced the CESD to close the building on March 12, 2020. Prior to the building closure, childcare was offered during all sessions and provided by staff who worked at the ESD, who had experience working with children with DD, and who were willing to work for our project as a paid second job. After the building closure, the two parent groups for Cohort 1 were run as virtual meetings through the Zoom platform, and no childcare was provided.

Cohort 2

For our second cohort (and any later cohorts), the two parent groups will be run 100% as virtual meetings through the Zoom platform and no childcare will be provided. All materials required for participation in parent groups will be mailed to parents prior to the first session.

Both Cohorts

The BPT-M group and the BPT-E groups will be led by staff with a minimum of a Masters-level education in clinical or counseling psychology or social work. These individuals will be trained and supervised by a doctoral-level licensed psychologist. Parents randomly assigned to the BPT-M group will receive six sessions of Mindfulness-Based Stress Reduction followed by the 10-week BPT intervention described below. The MBSR component of the BPT-M intervention will include six weekly 2-hour group sessions and 30–45 minutes of daily home practice guided by instructional audio CDs and an MBSR parent workbook (see “Baer Mindfulness Home Practice Log” for sample homework for the Mindfulness group). Formal mindfulness exercises aim to increase the capacity for mindfulness (present moment awareness with a compassionate, nonjudgmental stance) and include a body scan, mindful yoga, and sitting meditation. In the sessions, participants practice formal mindfulness exercises and ask questions relating to the practice of mindfulness in everyday life, and the instructor provides didactic instruction on stress physiology and using mindfulness for coping with stress in daily life.

Parents randomly assigned to the BPT-E group will receive six sessions of education about children with developmental delays. The BPT-E group will also consist of 6-weekly 2-hour education sessions where families will gain information regarding their child's development, disability, and associated considerations. Each week has a general topic for discussion. Topics include Preparing for Individualized Education Plan (IEP) meetings, Navigating regional service agencies, communicating with Teachers, Advocacy, Sibling Issues, and Community Resources. At the start of each session, group leaders provide some didactic material on the topic. Parents then break up into pairs for small group discussion (via “breakout rooms” when groups conducted via Zoom) followed by a larger group discussion and questions. Parents in this group will also receive homework each week (see “BPT-E Hand Out Session 2”). Following the 6-week educational intervention, families will receive the same 10-week Behavioral Parent Training intervention described below.

All participants will then receive the Incredible Years Parent Training-Developmental Disabilities modified intervention. The IYPT-DD intervention is 10 weeks in duration, with each weekly session lasting 2 hours. Each weekly session is structured around videotape vignettes and uses discussion, role-playing, modeling, and feedback techniques to create an effective learning environment for the parenting skills that are taught. Topics include: using developmentally appropriate play to engage children, using praise and rewards to encourage children’s development, and using effective behavior management strategies to reduce challenging behavior. Parents are given weekly homework assignments and have the opportunity to practice their skills both inside and outside of intervention sessions (see “Hand Out BPT Session 1 Play Time”).

All participants, regardless of treatment condition, will complete a brief Subjective Units of Distress Scale (SUDS; see “PP-PDX-tx-SUDS”) at the beginning of each session and a weekly evaluation form at the end of each session (see “PP-PDX-tx-PWE-s1-6” and “PP-PDX-tx-PWE-s7-16”). For Cohort 1, these forms were collected via

Teleform surveys when groups met face-to-face. Once parent groups shifted to a virtual format, these forms were collected via Qualtrics. These forms will continue to be collected via Qualtrics in Cohort 2 and future cohorts. Participants will also complete a survey packet at the end of week 6 (see "PP-PDX-tx-PSI4", "PP-PDX-tx-FFMQ", and "PP-PDX-tx-GROUPQuestionnaire"), and at the end of week 16 during group time (see "PP-PDX-tx-PSI4", "PP-PDX-tx-FFMQ," "PP-PDX-tx-PCBC," "PP-PDX-tx-GROUPQuestionnaire," "PP-PDX-tx-PPSQ-E" and "PP-PDX-tx-PPSQ-M"; note the last two are very similar packets but one is for the BPT-M group and one is for the BPT-E group). During week 16, participants will also complete a brief telehealth satisfaction survey (see "Telehealth questions_final_6.4.2020") via Qualtrics to assess their satisfaction with the parent groups/ interactions with group leaders after the transition to a remote format as a result of the COVID-19 pandemic. This questionnaire was slightly modified for cohort 2 to reflect the fact that this cohort did not transition to a remote format but instead did the entire intervention in a remote format (see "Telehealth questions_c2w2").

In addition, research staff will collect data about parents during each parent group via the Group Attendance and Homework Completion Checklist (see "PP-PDX-tx-ATTN") and Group Leader Ratings of Engagement/ Disruption (see "PP-PDX-tx-GLR-AC").

Throughout the intervention, group leaders will have weekly phone check-ins with parents. During the check-in prior to the week 7 and week 16 groups, group leaders will collect additional data using the Change Plan Worksheet that was completed during the initial home visit (described earlier; see "BPT-E PEI form" and "BPT-M PEI form").

Immediate Follow-up Data Collection

Cohort 1

After the completion of the intervention, parents will be asked to schedule a follow-up (virtual) home assessment. The same set of questionnaires used at the initial home visit will be mailed to the home to be completed prior to the home visit (see "PP-t1-mailout-PC"). Due to the physical distancing required by the COVID-19 pandemic, the post-intervention home visit will be conducted remotely and broken into two appointments: a phone appointment and a virtual home visit. Prior to the phone appointment, parents will receive a box of assessment materials in the mail intended to help facilitate the later virtual home visit. This box will include a cover letter, parent instructions, three puzzles, and a play mat (see "Assessment Kit Cover Letter_6.4.2020" and "Virtual Play Task Instructions-Parents_6.4.2020"). They will then complete a 45-minute phone appointment in which the assessor goes over the previously signed consent form, collects the DEMO and SERV via interview with the primary caregiver, collects a 12-item survey regarding the impact of the COVID-19 pandemic on their family, and then explains the logistics of the virtual home visit to parents using the instructions provided to parents in their box of materials (see "Demo-Serv Interview Protocol_6.19.2020" and "Impact of COVID19 Measure_6.12.2020"; note that the DEMO and SERV were originally part of the in-home packet completed during home visits and can be found in "PP-T1_inhome"). During the virtual home visit, the parent and child will complete 3 of the 4 play tasks completed at baseline: (1) *Unstructured free play task* (parent is instructed to allow the child to choose any activity and play along with the child as they normally would); (2) *Clean-up task* (parent is instructed to give the child a command to clean up); and (3) *Parent teaching task* (parent is instructed to select an activity and to keep the child playing according to the parent's rules). Virtual home visits will be scheduled for 30 minutes, but these play tasks should take a total of 15 minutes to complete (see "Post Treatment Virtual Obs Protocol_6.19.2020").

Cohort 2

After the completion of the intervention, parents will be asked to schedule a follow-up (virtual) home assessment. The same set of questionnaires used at the initial home visit will be mailed to the home to be completed prior to the home visit (see "PP-t1-mailout-PC"). Parents will also receive a link to Qualtrics to complete a brief survey about the impact of the covid-19 pandemic on their family (see "Impact of covid-19 survey for qualtrics"). The post-intervention home visit will be conducted remotely and broken into two Zoom appointments. Prior to the first Zoom appointment, parents will receive a box of assessment materials in the mail intended to help facilitate the later virtual home visit. This box will include a cover letter, parent instructions, three puzzles, and a play mat (see "Cover Letter Assessment Kit_c2w2" and "Virtual Play Task Instructions-c2w2"). They will then complete a 45-minute Zoom appointment in which the assessor goes over the previously signed consent form, collects the DEMO and SERV via interview with the primary caregiver, and then explains the logistics of the virtual home visit to parents using the instructions provided to parents in their box of materials (see "Demo-Serv Interview Protocol_6.19.2020." Note that the DEMO and SERV were originally part of the in-home packet completed during home visits and can be found in "PP-T1_inhome"). During the virtual home visit, the parent and child will complete the 3 play tasks completed at baseline: (1) *Unstructured free play task* (parent is instructed to allow the child to choose any activity and play along with the child as they normally would); (2) *Clean-up task* (parent is instructed to give the child a command to clean up); and (3) *Parent teaching task* (parent is instructed to select an activity and

to keep the child playing according to the parent's rules). Virtual home visits will be scheduled for 30 minutes, but these play tasks should take a total of 15 minutes to complete (see "Play Obs Task Script/ Protocol_c2w2").

6-month and 12-month Follow-up Data Collection

Both Cohorts

Six months and twelve months after the groups have finished, there will also be phone appointments and virtual home visits to collect the 6-month and 12-month follow-up assessments. At these assessments, the parents will again be mailed the same packet of questionnaires used at prior waves of data collection and asked to complete it prior to the virtual home visit. They will again participate in a 45-minute phone or Zoom appointment and a 30-minute virtual home visit in order to complete the 3 play activities. In addition, a link to a Qualtrics survey regarding the impact of the covid-19 pandemic on their family will be sent to parents at the same time as the 6- and 12-month follow-up survey packets *(See "*Impact of covid-19 survey for qualtrics_rev2").

"Lab Assessment"

There will be a "lab assessment" for the developmental evaluation of the child; this lab visit was originally intended to occur face-to-face at either the PSI lab in Portland, OR, located at the University of Oregon-Portland campus or in an empty classroom at the King School in Oregon City, OR, but was modified due to the physical distancing restrictions of the COVID-19 pandemic. This "lab assessment" can be scheduled to take place at any point during the study, but is intended to occur close in time to the pre-intervention assessment. The original plan for the lab visit was for the child to complete the Autism Diagnostic Observation Schedule-2 (ADOS-2; Lord et al., 2012) and the Stanford-Binet Intelligence Scales (SB%; Roid, 2003) with a trained master's level (or above) research assistant. The ADOS-2 is a semi-structured assessment that facilitates observation and recording of child behaviors related to language, social communication and interaction, play, and repetitive behaviors and restricted interests. The results would be used to examine the contribution of autism spectrum disorder symptomology to intervention outcomes. The Stanford-Binet Intelligence Scales, Fifth Edition (SB5; Roid, 2003) would be administered to estimate children's general cognitive functioning. Dr. McIntyre would oversee training and supervision of the ADOS-2 and Stanford-Binet administration, scoring, and interpretation for this project.. In addition, the Vineland Adaptive Behavior Scales-III (VABS-III; Sparrow, Cicchetti, & Saulnie, 2016) would be used to characterize children's level of independence in the everyday environment. Scores on the VABS-III would be used to assess the presence of comorbid intellectual disability. During the child's lab assessment, the participating parent would complete the Social Communication Questionnaire, Lifetime Version (SCQ; Rutter, Bailey, & Lord, 2003) to inform diagnostic confirmation. Overall, the lab assessment would take about an hour to complete (forms for these three assessments can be found in "PP-T1_inhome"). However, because of the physical distancing required by COVID-19, we chose to break these "lab visits" into two visits: (1) a phone appointment with the parent, and (2) a face-to-face assessment with the child, assuming it is eventually safe to do face-to-face visits without masks in the future. For the phone appointment, we will collect the VABS-III via telephone interview with the parent. The SCQ will be added to the mail-home baseline assessment packet and completed by the parent as part of the questionnaire packet. The face-to-face assessment with the child will be put on hold until the IRB determines that it is again safe to do face-to-face data collection without masks. At that time, the ADOS-2 and SB5 will be completed with each child. If current physical distancing and masking restrictions are not lifted by the end of the study period, we will simply forgo collection of the ADOS and Stanford-Binet.

Teacher Data

At the time of the baseline assessment, parents will consent to allowing the research team to contact teachers to request information about their child. Each school year parents will be asked to provide research staff with the name, email address, and mailing address of their child's teacher. We will then email an introduction letter and a copy of the teacher consent form to the teacher (see "PP Teacher Email_6.23.2020FINAL" and "PROParenting_teacher consent_11.12.19"). Once the teacher returns their electronically-signed consent form via email, they will receive a second email with a link to a Qualtrics questionnaire about the child's behavior (see "PRO P Teacher Survey Link Email 6.23.20," "PRO-parenting teacher demo," and "PP-t1_teacher"). A copy of the parent's consent form will be emailed to the teacher upon request. Teacher contact information will be collected from the parent at four time points: before the intervention, at the end of the intervention, and at 6 months and 12 months after the intervention is completed. The Qualtrics teacher survey should take no longer than 20 minutes to complete. The duration of teacher participation in the project will depend upon how long the target child is in a given teacher's class. We will be collecting information from teachers up to 18 months from baseline, but this will most likely involve two or more teachers as children tend to transition to new classrooms/ teachers each school year.

COVID-19 Interview

In order to make sure that our intervention remains relevant to families during the COVID-19 pandemic, we will be collecting additional information regarding families' experiences with COVID-19, social distancing, additional stressors they are experiencing, and the impact of possible reductions in services they were previously receiving.

For Cohort 1, these data were initially collected via a phone interview lasting approximately 1 hour (see COVID-19 interview questions for PROParenting families_FINAL" and "COVID-19 survey questions for PROParenting families_4.14.20_Final") as a separate data collection activity in Spring 2020. Longitudinal data will be collected from this cohort via Qualtrics survey in Fall 2020 and at the time of 6-month and 12-month follow-up data collection as described above (see "impact of covid-19 survey for Qualtrics"). The Covid-19 survey collected at the 12-month follow-up will be slightly modified from the one given at earlier time points to have tighter time frames on questions (see "impact of Covid-19 survey for Qualtrics_rev2").

For Cohort 2, these data will be collected via Qualtrics survey at baseline and immediate follow-up data collection, as described above. At baseline, the completion of this Qualtrics survey will be facilitated by the family interventionist in an interview-format during the rapport building appointment; participants will complete it on their own at the time of immediate follow-up (see "impact of covid-19 survey for Qualtrics_rev2").

Data Analysis

Analyses will be conducted using standard normal theory regression and structural equation modeling (SEM) techniques, with a particular focus on latent growth modeling (LGM; Muthén & Curran, 1997). To isolate the added value of the MBSR component of the BPT-M intervention, primary intent-to-treat (ITT) efficacy hypotheses comparing the BPT-M with BPTE will be specified within a set of sequential mediation analyses (DeGarmo, Patterson, & Forgatch, 2004). We will use CACE modeling (Jo, 2002; Little & Yau, 1998) for analyzing and adjusting effect sizes on the basis of participant compliance and dosage in both groups. CACE mixture models allow unbiased estimates of intervention contrasts by modeling unknown compliance status as missing data using the known compliance in the intervention of focus, thereby matching latent characteristics to the two group conditions. We will intentionally assess and control for potential confounding variables that pose a possible threat to the internal validity of the study, namely, child diagnosis (e.g., ASD), child IQ/intellectual disability status, child gender, concurrent child services, and demographic variables (e.g., ethnicity, family language, family structure, SES).

For the primary main effects efficacy evaluation, BPT-M versus BPT-E, we will specify LGMs. For our primary intervention efficacy hypotheses, child outcomes are considered distal because they are not the primary active agent of intervention. Any BPT intervention effects on children are hypothesized to operate through, and be transmitted through, more-proximal mechanisms of reduced parenting stress, and in turn, improved parenting (Forehand, Lafko, Parent, & Burt, 2014). For growth outcomes, a sequential set of models tests the latent variances and model fit comparing a random intercept only versus linear growth or quadratic growth models to determine the optimal pattern of change (Duncan, Duncan, & Stryker, 2006). For example, we will test the hypothesis that the BPT-M will show greater 1-year reductions in child behavior problems relative to the BPT-E condition. This effect is hypothesized to be mediated first by improvements in effective parenting behaviors. Intervention impact on growth in positive parenting skills, in turn, is hypothesized to be mediated by reductions in parenting stress, the target of the E-BPT intervention.

For tests of mediation, we will use approaches outlined for SEM and LGM (Cheong, MacKinnon, & Khoo, 2001; Judd, Kenny, & McClelland, 2001; Kraemer, Wilson, Fairburn, & Agras, 2002; MacKinnon & Luecken, 2008), including tests of indirect effects following recommendations using bootstrapped standard errors for the asymptotically distributed multiplicative indirect terms and estimated bias-corrected confidence intervals (MacKinnon, Fairchild, & Fritz, 2007; Preacher & Hayes, 2008).

D. Research Population & Recruitment Methods

1. Participant Population:

Between the Oregon and California sites, we anticipate screening 300 families to recruit 230 children with DD and their families (n=150 in CA; n=80 in OR). This would result in roughly 115 participants in each of the treatment conditions, which will provide adequate statistical power to minimally detect modest to medium effects in our primary analyses. These effect sizes are conservative based on past research.

Participation will be limited to parents of children ages 3 to 5 who are English-speaking. The rationale for the age restriction is that parents of children often exhibit heightened stress during the preschool years, while simultaneously experiencing a reduction in services because Early Intervention services in Oregon terminate when the child is 3 years of age. All parents must speak and understand English because the clinicians who will be delivering the intervention are all English speaking.

Inclusion Criteria:

- Having a child ages 3 to 5 years with an agency-identified DD in one or more functional areas who is receiving early intervention or early childhood/ preschool special education through an individualized family service plan (IFSP) or individualized education plan (IEP);
- Elevated parent-reported child behavior problems, as indicated by a T-score of 60 or above on the Total Problems scale of the child Behavior checklist;
- Elevated parenting stress, as indexed by a total score above the recommended cutoff at the 85th percentile on the Parenting Stress Index-4.
- Access to internet/ Zoom to complete online intervention and assessments during the study period.

Exclusion Criteria:

- Parents will be excluded if they screen positive for active psychosis, substance abuse, or suicidality through endorsement of screening questions for associated modules of the Structured Clinical Interview for DSM Disorders (SCID)-Research Version Non-Patient Edition;
- They are currently receiving any form of psychological or behavioral treatment at the time of referral (e.g., counseling, parent training, parent support group);
- The parent or child does not speak or understand English; or
- The child has sensory impairments (e.g., deafness, blindness,) or nonambulatory conditions that would necessitate the need for significant modifications to the lab and home visit protocols

Please note that lack of access to the internet/ Zoom is not an exclusionary criterion for this study. The PRO-Parenting Study is inviting every family who is interested to reach out to them. Our family interventionists will work with families to connect with community resources and existing supports to access the internet or acquire needed technology.

The child is only involved in the assessment aspects of the study pre-intervention, post-intervention, and at follow-up. During these assessments the child is instructed to play on the floor with the parent for 20 minutes. This task requires the child to understand the researcher's directions, sit up on his or her own, explore different toys in the room, and interact with the parent. Therefore, if the child has a physical disability or sensory impairment that prevents him or her from participating in the play task, the family will be excluded from the study.

The sample will also include the teachers of each of the target children. "Teacher" will be defined as any professional that works directly with the child who would be able to report on behavior. If a child is not in school, this person may be a behavioral therapist or other service provider who works with the child. Babysitters who regularly care for the child and are able to accurately report on the child's behavior would also be allowed if there are no other options. A teacher will be identified at baseline, at the end of the intervention, and at 6 and 12 months post-treatment. These assessment points will span a total of 18 months, and children are likely to transition between teachers/ classrooms during this time frame. Thus, it is likely that different teachers will report on a given child's behavior across the span of the study. We anticipate that the final sample may include up to 500 teachers (150 in OR).

2. Recruitment Methods:

In order to reduce the burden on ESD staff during the COVID-19 pandemic, we altered our recruitment methods between Cohort 1 and Cohort 2. The two methods are described below and organized according to Cohort.

Cohort 1

Families at the Oregon site will be recruited through the Clackamas ESD. Families who meet the study criteria will be identified from this agency's computerized databases, and screened by agency staff. In order to protect

confidentiality, letters and brochures about the project will be sent to prospective families by the staff of the Clackamas ESD, informing parents about our project ("Recruitment letter_11.12.2019"; "Oregon Copy of PRO-Parenting Brochure_11.12.2019"). Interested parents will either contact the PRO-Parenting Project by phone or by completing a form on our project website: www.oregonproparenting.org . If the family indicates interest in participation, research staff will conduct a phone screen ("Script for initial contact phone screen" and "PRO-Parenting clinical phone screen form"). If the family meets eligibility for the study, an appointment will be scheduled for the initial home assessment. Informed consent will be sought by research staff at the intake interview. In addition, consent will be sought to conduct the home-based videotaped caregiver-child interactions and to conduct lab assessments of child functioning.

To recruit teachers for the study, parents will be asked on their consent form to provide the name and contact information of a teacher or other professional who works directly with the child and would be able to report on the child's behavior. The research team will then email consent forms and send electronic links to assessment materials (see details above in "method, materials, and analysis" section).The cover letter included with the consent form will contain contact information for project staff who can answer any questions about the study.

Cohort 2

Families at the Oregon site will be recruited through the Clackamas ESD and by flyers to be used with other agencies and community programs that serve this population (see "PRO-Parenting Flyer Final Draft"). The Clackamas ESD regularly sends out an email newsletter, and they have agreed to include a blurb about our study and a link to our website in several of these newsletters so that interested families can reach out to learn more (see "recruitment blurb_cohort 2"). Interested parents will either contact the PRO-Parenting Project by phone or by completing a form on our project website: www.oregonproparenting.org . The website includes a similar level of information as the flyer, but also includes a FAQ section and a short "welcome" video intended to give potential participants a better sense of what parent groups would be like (see "Intro Script for PRO-P_final"). If the family indicates interest in participation, research staff will conduct a phone screen ("Cohort 2 Script for initial contact phone screen" and "Cohort 2 script clinical screen baseline"). If the family meets eligibility for the study, a series of 3 appointments will be scheduled to complete the baseline assessment ("cohort 2 script for confirmation call to schedule remote home visit"). Verbal informed consent will be sought by research staff at the first of these 3 appointments and a paper consent form will be included in the assessment packet mailed to the family's home. In addition, consent will be sought to conduct the lab assessment of child functioning.

To recruit teachers for the study, parents will be asked at their first phone appointment to provide the name and contact information of a teacher or other professional who works directly with the child and would be able to report on the child's behavior. The research team will then email consent forms and send electronic links to assessment materials (see details above in "method, materials, and analysis" section).The cover letter included with the consent form will contain contact information for project staff who can answer any questions about the study.

3**. Compensation/ Reimbursement:**

Because the assessment strategy changed between the beginning of cohort 1 and cohort 2, the compensation structure was also altered between the 2 cohorts. The two methods are described below and organized according to cohort. Payment was increased for cohort 1 because of the addition of 4 waves of covid-related data collection and the unanticipated need to split the "lab visit" into 2 visits because of our inability to see children face-to-face during the pandemic.

Parents in cohort 2 are aware at the time of initial consent that the lab visit will be split into 2 visits, and thus we don't feel the need to pay them double for this data collection. Covid-related data collection will only occur 2x for this cohort (compared to 4x for cohort 1), and thus their total payment is lower.

Cohort 1

To compensate families for their participation and to keep attrition to a minimum, we will offer subject payment to families. Families will be reimbursed, via check, following the completion of the initial home visit ($50), baseline lab assessment ($50 for the phone interview with parents; $50 for the portion conducted face-to-face with children), post-intervention ($75), 6-month follow-up ($100), and 12-month follow-up

($125). The amount increases as the study progresses, reflecting the increased value of longitudinal participation over time. In addition, participants will be offered bus passes or parking vouchers to alleviate transportation costs and facilitate their completion of the lab assessment or attendance at group sessions when groups meet face-to-face. Families will also be offered free childcare or a childcare stipend in order to facilitate their attendance at group sessions when groups meet face-to-face. This childcare will be provided by staff who work at the ESD, who have experience working with children with DD, and who are willing to work for our project as a paid second job. If the family withdraws from the study before completion, they will not receive the remaining payments. In the event that a visit needs to be rescheduled, the family will be compensated upon completion of the rescheduled visit.

Families will also be paid $25 via check for completion of the COVID-19 related data collection at each of 4 time points (Spring 2020, Fall 2020, 6-month follow-up, and 12-month follow-up).

In total, families in cohort 1 can earn up to $550 for participation across their time in the study.

Teachers will receive a $25 check for completion of each of the four teacher assessments (pre-intervention, post-intervention, 6-month follow-up, and 12-month follow-up).

Cohort 2

To compensate families for their participation and to keep attrition to a minimum, we will offer subject payment to families. Families will be reimbursed, via check, following the completion of the baseline home visit ($50), baseline lab assessment ($25 for the phone interview with parents; $25 for the portion conducted face-to-face with children), post-intervention immediate follow-up ($75), 6-month follow-up ($100), and 12-month follow-up ($125). The amount increases as the study progresses, reflecting the increased value of longitudinal participation over time. If the family withdraws from the study before completion, they will not receive the remaining payments. In the event that a visit needs to be rescheduled, the family will be compensated upon completion of the rescheduled visit.

Families will also be paid $25 via check for completion of COVID-19 related data collection at each of 2 time points (baseline data collection and post-intervention immediate follow-up).

In total, families in cohort 2 can earn up to $450 for participation across their time in the study.

Teachers will receive a $25 check for completion of each of the four teacher assessments (pre-intervention, post-intervention, 6-month follow-up, and 12-month follow-up).

E. Informed Consent Process

We will be using information obtained during the phone screening and prior to obtaining parental consent for the study. Thus, we request an alteration of informed consent. This alteration does not involve more than minimal risk to the participants, and will not adversely affect the rights and welfare of the participants. The research could not be practicably carried out without the alteration. Participants will be provided with additional pertinent information at the time of informed consent, and will be provided with a method to indicate their consent to their screening information being used in the study (i.e., a separate line to initial to indicate use of these data).

Cohort 1

Informed consent will be obtained at the first home visit (pre-intervention assessment) by the research staff. Parents will be given the informed consent form ("Informed consent_PRO-Parenting_11.12.19") and asked to read the form. If the parent prefers, research staff will read the form to the parent. Research staff will also provide a summary of the study (e.g., timeline for intervention, expectations with regard to pre, post, and follow-up assessments, compensation, components of assessment, and potential risks of study). Parents will be informed that group assignment is random and that they may be assigned to the Behavioral Parent Training-Mindfulness (BPT-M) group or the Behavioral Parent Training-Education (BPT-E) group. Research

staff will be available to answer any and all questions the parent(s) has and to address any concerns. Parents will be reminded that their consent is voluntary, that they can withdraw from the study at any point, and that they do not have to answer any question or participate in any task that they do not want to. Given the young age of the children in the study (ages 3 to 5), parents will consent for their children's participation. Again, children will only be involved in one laboratory and four home assessments (at pre-intervention, post-intervention, and follow-ups) to measure intervention outcomes, but will not be involved in the proposed intervention. The participant will be given 30 minutes to consider study participation.

The research study that was described in the consent document signed by participants in cohort 1 was modified in response to the covid-19 pandemic. Thus, the study that participants agreed to participate in is not exactly the same study they found themselves in after March 2020. All participants were called by a family interventionist in mid-March to notify them that the parent groups would be moving to a virtual format in response to the covid-19 pandemic, effective immediately. All participants provided verbal consent to move forward in the virtual format. Consent and date of consent were recorded in an internal tracking spreadsheet. The family interventionists called families again a few weeks later to tell them about the Covid-19 interview, how the "lab" visit would be altered, and the payment for each. Again, all parents provided verbal consent to these changes in protocol, and consent and date of consent were recorded in an internal tracking spreadsheet. At the time of the post-treatment follow-up, a blank copy of the baseline consent form was sent through the mail along with follow-up surveys and a box of assessment materials for the virtual home visit. Research staff went over the consent form at the time of the virtual home visit, and provided a summary of the study (e.g., confidentiality, compensation, components of assessment, and potential risks of study), highlighting changes that had been made due to physical distancing. To indicate their on-going consent, participants signed the copy of the consent form included with their survey and mailed it back to the research office.

In fall 2020 participants in cohort 1 will be contacted by phone and read a script that explains changes in study procedures to ensure on-going consent (see "cohort 1 changes to consent script-verbal consent"). Verbal consent will be obtained at that time and recorded via Qualtrics form. This script will be shared again at the 6- and 12-month follow-up assessments to ensure on-going consent.

Cohort 2

Informed consent will be obtained at the first Zoom appointment (baseline assessment appointment 1) by the research staff. Parents will be mailed a copy of the consent form ("Informed consent_PRO-Parenting_10.7.20") with their packet of questionnaires. At baseline assessment appointment 1, the research assistant will present the consent video, which goes over each element of the consent form (see "Consent Script PP_final" and "informed consent slides_final"). Parents will be informed that group assignment is random and that they may be assigned to the Behavioral Parent Training-Mindfulness (BPT-M) group or the Behavioral Parent Training-Education (BPT-E) group. After the video, the research assistant will offer to answer any and all questions the parent(s) has and to address any concerns. Parents will be reminded that their consent is voluntary, that they can withdraw from the study at any point, and that they do not have to answer any question or participate in any task that they do not want to. Given the young age of the children in the study (ages 3 to 5), parents will consent for their children's participation. Again, children will only be involved in observation tasks at four virtual home assessments (at pre-intervention, post-intervention, 6-month, and 12-month follow-ups) to measure intervention outcomes, but will not be involved in the proposed intervention. Children will also be involved in the "lab visit" to complete the Stanford-Binet and ADOS-2 testing, but only if physical distancing and face covering restrictions are lifted during the study period. If restrictions are not lifted, we will forgo this piece of data collection.

Parents will be asked to sign their consent form if they have not already done so, and to provide verbal consent to participation in order to continue with the appointment. Research staff will have a copy of the consent form available to them via qualtrics. They will check a box to indicate that they have received verbal consent before proceeding with the rest of the appointment.

Both Cohorts

The PI for this project has had extensive training in conducting research with similar families and has a history of federally-funded randomized controlled prevention and early intervention trials. Staff working on the project will complete training with the PhD-level project coordinator on providing informed consent and administering the standardized protocol.

Because this is a longitudinal study, the research team will have multiple contacts with these families over an 18-month period of time and will be assessing families via virtual home visits at multiple waves. Prior to each wave of data collection, we will send parents a copy of the consent form for them to review. We will begin the first virtual home visit of each wave by going over the consent form and asking parents if they have any questions or concerns. In this way we will ensure ongoing consent.

Informed consent will be obtained from teachers at each of the four time points of assessment. The research team will email a cover letter and an electronic copy of the teacher consent. Teachers will indicate their consent to participate by signing and returning their consent form, and by completing their teacher survey. It is possible that a different teacher will report on a given child at each time point. Thus, each wave of teacher assessment will include teacher consent forms. The cover letter will include the contact information for the Project Coordinator and instructions to contact this person with any questions or concerns about the study. The consent form includes contact information for the Research Compliance office if they wish to speak to someone other than the research team.

This project is registered on clinicaltrials.gov (NCT03599648). A copy of the consent form will be posted there once approved. Results from this research trial will also be reported there once they are available.

F. Provisions for Participant Privacy and Data Confidentiality

1. Privacy

To protect the privacy of participants, the research team will take the following precautions:

- Ask agencies from whom these families are already receiving services to identify potential participants for the research study, to share information about the project with them, and to ask interested parties to contact our research team if they desire more information about the project. In this way, we will not know the identities of all families at the agency who qualify for the study, but only those who reach out to us to indicate interest in participation;
- Assess families in their homes to ensure their privacy, safety, and comfort;
- Once it is safe to do so, conduct lab assessments in our PSI-Portland lab in assessment rooms with doors that close, or at the King School in empty classrooms with doors that close, and with white noise machines located in the hallway to reduce the possibility of those outside the room hearing private conversations;
- Allow families to identify the teacher who will provide data about their child;
- Collect questionnaire data via Teleform survey with participant ID numbers printed on them rather than participant names or other identifying information. Our Teleform surveys will invite participants to "bubble in" their responses to multiple-choice questions rather than respond in ways in which handwriting might easily be identified;
- Collect questionnaire data via Qualtrics survey with a "special word" used to link surveys to child participants rather than participant names or other identifying information. Our Qualtrics surveys will invite participants to select their responses to multiple choice questions rather than respond in ways in which handwriting might easily be identified; and
- Use the HIPAA-compliant version of Zoom, which establishes strict access control rules and strong AES256 encryption to prevent transmission of any PHI (protected health information), for remote home visits and parent groups. Parent intervention groups will be recorded in order for research staff to evaluate group leaders' fidelity to the intervention model. In addition, the "virtual home visits" will be recorded via Zoom so that coding staff may observe and code family interactions. In each of these

cases, meetings will be recorded to the local machine (not the cloud), uploaded to the project file on the PSI secure server, and then deleted from the local machine once the recordings have been safely transferred to the server.

To protect the privacy of participating teachers, the research team will take the following precautions:

- Refuse to share information provided by teachers with the child or his/ her parents;
- Collect questionnaire data via Qualtrics survey with a "special word" used to link surveys to child participants rather than participant names or other identifying information. Our Qualtrics surveys will invite participants to select their responses to multiple choice questions rather than respond in ways in which handwriting might easily be identified.

2. Data Disposition and Confidentiality

Consent documents will be stored in locked cabinets in a locked room within the PSI lab in Portland, which is located on the University of Oregon-Portland campus (a locked building with a security team). After 7 years' time, the consent documents will be disposed of through a recycling service contracted by PSI.

To protect confidentiality, data will be coded by subject number rather than name, and all identifying information will be kept separate from the data. Only the Data Manager, Project Coordinator, and Assessment Coordinator will have access to the key that links names to subject numbers. This key must be retained in order to link participant data over time in this longitudinal study. All hard copies of measures will be kept at PSI-Portland in a locked storage cabinet that is kept in a locked room within a locked research building until it is transferred between sites by project staff in a locked box. PHI will be blacked out before data is transported to Eugene. Once files arrive in Eugene, they will immediately be stored in locked cabinets, in a locked room, in a locked building.

Data collected through Qualtrics is protected by Qualtrics' high-end firewall systems. Their servers are scanned regularly to ensure that any vulnerabilities are quickly found and patched, and complete penetration tests are performed yearly. Their confidential system component design uses multiple checks to certify that packets from one subsystem can only be received by a designated subsystem. Access to systems is severely restricted to specific individuals, whose access is monitored and audited for compliance. Qualtrics uses TLS encryption for all transmitted data, and they protect surveys with passwords and HTTP referrer checking. Qualtrics' services are hosted by trusted data centers that are independently audited using the industry standard SSAE-16 method.

In addition, all hard copy and electronic data will be stored by identification number only. Electronic copies of the data will be stored on University-owned computers and servers with strong passwords for future analyses. Data will be saved in a secure location on the PSI server. If a portable device (e.g. laptop or video camera) is used at any point in the study, the device will be encrypted, data will only be stored on the device temporarily, and the device will be stored in a physically secure location (e.g. locked in laboratory room). Access to the data is restricted to authorized study personnel. Data will be retained in locked files until it is clear that no further analyses will be done.

Parent intervention groups and "virtual home visits" will be conducted via Zoom videoconferencing services. Zoom is accessible to all UO faculty members, staff, and students. For UO Zoom users who handle HIPAA-regulated data, a HIPAA-compliant environment is available that includes Zoom, which establishes strict access control rules and strong AES256 encryption to prevent transmission of any PHI (protected health information). All research staff members who use Zoom for data collection purposes have acquired the HIPAA-compliant version of Zoom. Parent intervention groups will be conducted via Zoom and recorded in order for research staff to evaluate group leaders' fidelity to the intervention model. In addition, the "virtual home visits" will be conducted via Zoom and recorded so that coding staff may observe and code family interactions. In each of these cases, meetings will be recorded to the local machine (not the cloud), uploaded to the project file on the PSI secure server, and then deleted from the local machine once the recordings have been safely transferred to the server.

Copies of questionnaires and video recordings will ultimately be stored in Eugene at the University of Oregon (UO) at the Prevention Science Institute (PSI) for data management and coding. Videotaped recordings obtained from subjects will be uploaded from PSI-Portland to a secure STP from which project staff at the PSI-Eugene can access the information for management and coding. Videos will then immediately be deleted from the video

camera (or local machine, in the case of Zoom recordings). All paper questionnaires will be entered through Teleform scanning at PSI-Eugene.

The Prevention Science Institute (PSI) is isolated from the rest of the University of Oregon network using high end network firewall appliances (WatchGuard Soho 6). The PSI network uses industry-standard IPSec VPN protocol, which uses Triple DES Encryption, one of the strongest encryption types currently in use. All data files are protected by an authentication scheme, providing access to only a small group of trusted users who require access, thus reducing the exposure of sensitive data.

The informed consent form states that information about the family cannot be released to anyone other than the consenting parent unless the parents have granted written permission. The informed consent form states that information about the child can be released only if the investigators learn of physical or sexual abuse of the child or the investigators learn that someone is in imminent danger of harm. There is no plan to release data to any agency. Information provided by one study participant (mother, father, teacher, youth) will not be shared with any other participants. These stringent safeguards are likely to be effective and will remain to fully protect the participants, with very little likelihood of risk.

A Certificate of Confidentiality will automatically be granted to this project by NIH.

The information gathered in this study will be used for scientific, educational, or instructional purposes and will only be reported in aggregate form without identifying information or individual cases.

G. Potential Research Risks or Discomforts to Participants

Risks for participants are minimal. All procedures for this study have been used widely in previous research, with little to no discomfort or risk to either the parents or the child. Nevertheless, some of the questions in the questionnaires and interviews do seek personal information, and might be considered an invasion of privacy (e.g. questions about the marriage). Some young children may show mild frustration or distress during the home situations involving parents placing demands on their child (e.g. asking them to clean up). Additionally, the child may also face some mild frustration / boredom during the “lab visit” while completing the ADOS due to its length (approximately 40-60 minutes). In the PI’s experience using these tasks in similar studies, the risks or likelihood of discomfort is minimal. In order to minimize risks, participants will have the right to refuse to answer any question or terminate their involvement in the study at any time. In order to minimize demands on the parent and child, the assessments will not be longer than one hour, with the exception of the baseline assessment, which may take longer due to the inclusion of two additional questionnaires. However, parents and children will be able to take breaks as needed.

Other potential risks and discomforts involved in participation include possible violation of confidentiality, possible misunderstanding regarding the use of data, and minimal psychological risk resulting from possible feelings of coercion about consenting to participate in components of the study. To minimize these risks, the research procedure and precautions taken to protect privacy are explained to potential participants both verbally (via video recording and/ or research assistant) and on the consent forms at each phase of the research. All parents/guardians are required to read and sign a detailed consent form before participating in the study. The consent form fully emphasizes the voluntary nature of participation, the participant’s right to withdraw from the study at any time without penalty, and their right to have all data relating to the child or family removed from data analysis. Parents will review these consent forms prior to each follow-up assessment to remind them of these potential risks. All teachers will receive a consent form with their survey. Teachers will indicate their consent by returning completed consent forms and surveys to research staff. Teachers will receive a new copy of the consent form prior to any follow-up assessments in which they participate. Teachers will be assured that the information that they share with investigators will remain confidential and will not be shared with the child or his/ her parents.

Should parents/caregivers, target children, or teachers experience an adverse reaction to the assessments and require medical or psychological assistance, project staff will be prepared to evaluate the situation and, if necessary, make appropriate referrals. Referrals will be made by the PI, who is a licensed psychologist and is prepared to make referrals to community mental health providers.

We have a Data Safety and Monitoring Plan (DSMP) in place for this research project. (Please see “Data Safety and Monitoring Plan.”)

H. Potential Benefits of the Research

All participating caregivers receive intervention to promote positive parenting and reduce child behavior problems. Those randomized to receive the BPT-M will also receive intervention targeting stress reduction. Thus, potential benefits of participating in this research include possible reduction in parental stress, possible improvement in parenting behaviors, and possible decline in children's behavior problems. All participants, regardless of condition (BPT-M or BPT-E), will receive assessments from trained staff and may feel positive benefits associated with participating in a research study. These assessments may also offer participants the opportunity to reflect and gain perspective about their family's needs and priorities. In addition, parents will receive a short summary of their child's current and previous behavioral functioning based on study assessments after completion of the 12-month follow-up visit. This may be especially valuable to families given disparities associated with access to services and resources for underserved, under-represented families of children with ASD. Parents will also have access to research staff with expertise in child development and DD to answer questions about their child's development, need for services, and local resources.

Community practitioners may benefit from this research because they will have opportunities to refer families to participate in this study. Family-based interventions are not available in all communities; thus, practitioners may appreciate the opportunity to refer families to participate. If findings support the efficacy of the BPT-M on child and family outcomes, community practitioners may wish to incorporate aspects of this intervention in their community care.

The scientific community may benefit from the knowledge gained in respect to the efficacy of the BPT-M in families with young children with DD, an area that is virtually unexplored. The risks associated with this study are minimal in comparison with the benefits that family members, community practitioners, and the scientific community may experience. If study findings suggest that the BPT-M has effects on promoting healthier child and family outcomes, relative to a standard behavioral parent training with an education component (BPTE), and can be delivered in a cost-effective manner, this intervention has the potential to make revolutionary contributions to both the practitioner and the scientific communities.

I. Investigator Experience

Dr. Laura Lee McIntyre, PI, is a licensed psychologist and board-certified behavioral analyst with more than 20 years of experience working with children with DD and their families, including a focus on early intervention and prevention of behavior problems. She has experience adapting evidence-based interventions for use with families of children with DD, and she completed and RCT that assessed the efficacy of BPT in a sample of preschool-age children with DD and their families and recently completed a large-scale RCT of this intervention. Dr. McIntyre has a strong record of community partnerships, and she and her team have recruited more than 300 families across these funded projects.

Dr. Cameron Neece, Co-PI (PI of Loma Linda site), is also a licensed psychologist with experience working with diverse community samples of families with young children with DD. During the past 6 years she has conducted a study using waitlist-control design to examine the feasibility and efficacy of MBSR for a diverse sample of parents of preschool children with DD.

Dr. Allison Caruthers, Project Coordinator, is a developmental psychologist with 23 years of data collection experience, including 14 years as a Project Coordinator and Research Associate on various projects at the Prevention Science Institute. In this role she has created research protocols and consent processes, and trained and supervised dozens of research staff to adhere to these protocols.

Nicole Smith, Assessment Coordinator, has 6 years of research experience at PSI, in which she has worked closely with research protocols, consent processes, and data collection procedures.

Roles and Research Duties

The Principal Investigator and Co-PI will be in charge of oversight of all project activities and data analysis, as well as training and supervision of clinical staff.

The Project Coordinator will be in charge of all day-to-day research activities and communications with PI and Co-PI.

The Assessment Coordinator will be in charge of training and supervising research assistants and ensuring high quality data collection.

The Data Manager will be in charge of randomly assigning participants to condition, and cleaning and organizing data to prepare for analysis.

The Recruiters will be in charge of conducting phone screens to determine eligibility to participate in the research study.

Data Collectors will be in charge of conducting home visits, reviewing parent surveys with parents to ensure minimal missing data, and guiding the family (and recording them) in the videotaped play tasks.

Interventionists will be in charge of leading the parent groups and teaching from the Incredible Years curriculum.

Training and Oversight

All research staff who will have contact with participants and/ or data will complete the CITI training course, including the Good Clinical Practice training module, in order to ensure proper understanding of ethics involved in human subjects' research.

Research staff involved in the collection of questionnaires and observational data will be trained by the assessment coordinator to follow the protocol written for this project to ensure uniformity in data collection and handling.

Research staff responsible for coding family observations will be trained by our Coding Lab Supervisor in the appropriate application of our observation coding systems. At least 25% of tapes will be coded by a second observer to ensure adequate inter-observer agreement (80% agreement or better).

Research staff responsible for conducting clinical lab assessments of child development and autism symptoms will have graduate-level training in these assessments and/or advanced trainings from the PI or other trained staff, and will receive ongoing supervision from the PI.

Research staff responsible for running the treatment groups will be trained and supervised by the PI or another doctoral-level, licensed psychologist.