Research 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: Integration of DBT Skills and Parent Training for Parents with a History of Substance Use

Protocol Number: STUDY00000041
NCT#: NCT05287178
Date of Document: 3/22/22

Principal Investigator: Yoel Everett

Faculty Advisor: Maureen Zalewski

A. Introduction and Background

Nearly 60% of adults who receive treatment for substance use disorders (SUDs) are parents (Niccols et al., 2012). Parental substance abuse is a risk factor for poor mental health outcomes in children, and this association is partly explained by more negative and ineffective parenting behaviors (Connors-Burrow et al., 2013, Miller et al., 1999). Families with parents in recovery remain at high risk for these poorer outcomes, as even following treatment for SUD, these parents are vulnerable to relapse. Stress and emotion dysregulation are two important proximal risk factors implicated in relapse (Sinha et al., 2001; Kober, 2014), as SUD-related alterations in stress reactivity and emotion regulation deficits may lead to coping-oriented substance use (Fox et al., 2008). Parenting stress, a conceptually distinct type of stress related to the parenting role, is broadly associated with parent mental health, parenting behavior and child mental health outcomes (Holly et al., 2019). Parenting stress is particularly problematic for parents with a history of substance use, as stress responses triggered by stressful, negative interactions with children can increase craving for substance use which previously provided relief from negative emotions (Rutherford & Mayes, 2019). This is further complicated by the fact that children of parents with a history of substance use may be more likely to have emotional and behavioral difficulties that are associated with increased levels of parenting stress (Bailey et al., 2009; Barrosso et al., 2018).

Parent training interventions, aimed at improving parenting behavior and children's internalizing and externalizing problems, have been shown to reduce parenting stress (Colalillo & Johnston, 2016), and thus could benefit families in which a parent has a history of substance use by simultaneously improving parenting and child behavior while also contributing to relapse prevention (Neger & Prinz, 2015). However, parent training programs are less effective for parents with SUD (Suchman et al., 2004). This is due in part to SUD-related deficits in emotion regulation, which in addition to representing a risk factor for maintenance of SUD, also hinder a parent's ability to consistently set limits (i.e. parent management) or respond effectively when a child is emotional (i.e. parental emotion socialization) (Rutherford et al., 2015). Indeed, there is growing interest in integrated SUD treatments which address both parenting and emotion regulation (Neger & Prinz, 2015).

DBT is an evidence-based intervention which focuses primarily on improving emotion regulation (Lynch et al., 2006) and has been found effective in treating substance abuse in severely emotionally dysregulated clinical populations (Linehan et al., 1999; Dimeff & Linehan, 2008). DBT Skills is a group-based mode of DBT, which is an effective treatment on its own (Linehan et al., 2015). The content and format of DBT Skills lends itself well to integration with parent training, because of the shared behavioral approach and group-based, didactic modality. There is increasing interest in both the fields of DBT and parent training in integrating these two interventions in order to improve parental well-being and children's outcomes (Zalewski et al., 2020).

B. Specific Aims/Study Objectives

In an effort towards significantly reducing the intergenerational transmission of a wide range of mental disorders by intervening on parenting practices and clinically significant emotional dysregulation in parents and their preschool aged children, this proposal is to pilot test an integrated mental health and parenting intervention delivered via telehealth for 12 emotionally dysregulated parents with a history of substance use, in order to complete several foundational steps prior to conducting a larger scale randomized controlled trial. The proposed 20-week group therapy will integrate two evidence-based interventions: 1) Dialectical Behavior Therapy (DBT) Skills - targeting parental emotion dysregulation and substance use, and 2) Parent Training (PT) - targeting parenting behaviors linked to children's mental health. The telehealth format will enhance the scalability of the intervention and reduce many of the common barriers to access that parents face when seeking treatment for themselves or their children. The Specific Aims are to:

1. Determine feasibility, acceptability and implementation . Feasibility of recruitment (number of participants meeting eligibility on the initial online screener and number meeting eligibility following intake), feasibility of measurement tools (time taken to complete online questionnaires, missing data from questionnaires) and feasibility of the intervention (number of sessions attended by parents) will all be assessed to determine overall feasibility of the intervention study. Acceptability will be evaluated using measures of client satisfaction and a qualitative exit interview with each parent post-intervention. Implementation will be assessed by examining the frequency with which clients use DBT and parenting skills and by tracking clients' weekly skills use via a diary card.

2. Evaluate pre -post and weekly changes in measures of parental emotion regulation, parenting **stress, parenting quality and children's mental health**. Across all parents enrolled in DBT+PT, we will evaluate the rate and pattern of change in these interlinked domains which represent risk factors for relapse and further adverse outcomes. We anticipate pre-post changes (2 time points, approximately 20-22 weeks apart) will be comparable to well-established change scores from the clinical trial literature base for DBT Skills and parent training interventions. Additionally, qualitative data from exit interviews with each parent will be analyzed using thematic analyses of responses to evaluate parents' perceptions of changes in their own mental health, their parenting and their children's behavior over the course of the intervention.

Weekly repeated measures (20 time points) will allow us to model the rate and pattern of change from week to week. As the intervention is divided into 4 modules (see Procedures), change patterns will also be examined between modules. Data will be presented descriptively and we expect changes to unfold in a cascading order, with increased use of skills preceding reductions in parent emotion dysregulation, followed by improvements in parenting quality and subsequent improvements in child behavior.

C. Methods, Materials and Analysis

Setting. Clinical intakes, the weekly group DBT Skills+PT intervention sessions, and exit interviews will all be conducted via a HIPAA compliant teleconference platform (i.e. Zoom). The initial online screener, and pre-post and weekly assessments will be conducted via UO Qualtrics questionnaires.

Study design. This study utilizes a mixed methods case study design with continuous assessment of quantitative measures. Figure 1 presents the study phases, along with what participating parents will complete in each phase, and the estimated time needed to complete each phase.

Figure 1. Flowchart of study procedures detailing the study phase, the measures completed by participants, and the estimated time required of participants.		
Study Phase	Participant action	Time Estimate
Recruitment	Parents respond to recruitment materials	N/A
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Initial Online Screener	Parent completes: DERS CAGE-AID	 DERS – 5 minutes CAGE-AID – 2 minutes Total: 7 minutes
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Clinical Intake	Parent completes: Demographic questionnaire PHQ-9 PPVT-V (Q-Global) SCID 5 diagnostic interview	 Demographics – 4 minutes PHQ-9 - 3 minutes PPVT-V – 20 minutes SCID 5– 180-300 minutes Total: 207-327 minutes
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Pre-intervention	Parent completes: HAM-A PHQ-9 ADCS (ADAPTED PACS) DERS DBT-WCCL WACB CBCL ERC PSI PSOC PS CCNES	 3 minutes 3 minutes 3 minutes 5 minutes 5 minutes 3 minutes 10 minutes 5 minutes 7 minutes 5 minutes 7 minutes 8 minutes Total: 64 minutes
↓		
Treatment Phase (20 assessment time points) 20-weekly sessions of DBT Skills +PT	Parent completes weekly measures: DERS DBT-WCCL ERC WACB PS CCNES Skill Use Diary Card Parent participates in weekly DBT Skills +PT sessions + individual check ins (10-15 min) when necessary as part of	 5 minutes 5 minutes 5 minutes 3 minutes 7 minutes 8 minutes 5 minutes Total for Weekly Assessment: 38 minutes 2.5 hours/week

	standard clinical case management	Total: 190 minutes/week
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Post-intervention	Parent completes: HAM-A PHQ-9 ADCS (ADAPTED PACS) DERS DBT-WCCL WACB CBCL ERC PSI PSOC PS CCNES CSQ-8 Qualitative exit interview (including SCID 5 diagnostic assessment of current substance use disorder)	 3 minutes 3 minutes 3 minutes 5 minutes 5 minutes 3 minutes 10 minutes 5 minutes 7 minutes 5 minutes 7 minutes 8 minutes 5 minutes 60 minutes Total: 129 minutes

Procedures

Initial Online Screening. Parents responding to our recruitment materials (see section D: Recruitment Methods) will complete an online survey via UO Qualtrics to assess initial eligibility criteria. Parents will be asked to confirm that they are 18+ years of age, that they reside in Oregon, that they have at least partial custody of a preschool aged child (3-6 years old), that neither they nor their child has any known developmental disability, that they are proficient in English, and that they have the internet access needed to participate in an online remote telehealth intervention. We will also provide the scheduled weekly day and time of group therapy sessions so that parents can verify and confirm they will be able to participate. After confirming all of the above, parents will complete a self-report questionnaire evaluating parents' emotion dysregulation and a screener for drug and alcohol problems. To participate in the study, parents must endorse a score of >88 on the Difficulties with Emotion Regulation Scale (DERS) and meet a cutoff of 2 positive answers on an adapted version of the CAGE-AID screener for drug and alcohol problems, which asks about past (past 5 years) but not current (not in the past 12 months) substance use. Parents who pass the initial online screening will be asked to provide their contact details so that a project coordinator can schedule a clinical intake with them. Parents who do not pass the initial online screening will be thanked for participating and informed that they do not match the eligibility requirements. See Appendix E. Online Screening Script.

Clinical intake. Parents who meet screening criteria will be contacted and invited for the remotely conducted clinical intake (see Appendix F. Intake Scheduling Script). During intake scheduling, the project coordinator will ask for participating parents' permission to be contacted via email, text and phone. The clinical intake will be conducted via a HIPAA compliant teleconference platform (Zoom), and a Zoom link will be emailed to the parent, using an encrypted email service (Hushmail). The purpose of the clinical intake is to: 1) formally determine eligibility and 2) characterize current parental mental health diagnoses. A trained intake clinician will consent parents to the intake process and ask

them to provide consent for the remainder of the study components (for details see section E. Informed Consent Process and Appendix A. Informed Consent Form).

Following this, parents will complete a demographic questionnaire, the Peabody Picture Vocabulary Test-V (PPVT-V Q-Global), the Patient Health Questionnaire for Depression (9-items; PHQ-9), and the Structured Clinical Interview for DSM-5 (SCID 5). Parents will be ineligible to participate if they meet for the exclusionary criteria detailed in section D. Research Population & Recruitment Methods: Participants.

Pre-intervention Assessment. Parents who meet criteria for the study following the clinical intake will be asked to complete a broad battery of questionnaires (see Fig 1. Study Phase: *"Pre*-intervention*"*) to assess parent mental health symptoms, parenting stress, parenting quality and child mental health symptoms. The questionnaires will be completed online via UO Qualtrics and parents will receive an encrypted email (i.e. Hushmail) from the project coordinator with the UO Qualtrics link.

DBT Skills +PT intervention. The study plans to recruit three groups of approximately 4-5 parents/group. Parents will be recruited twice throughout the course of the year to facilitate running up to three groups (see section D. Research Population & Recruitment Methods for more details). Once a group of parents has been recruited, participants will take part in 20 weekly DBT Skills +PT intervention sessions. The group sessions are conducted remotely over a HIPAA compliant version of Zoom and groups are led by Yoel Everett (PI) and three other doctoral level student co-leaders who are supervised by Dr. Candice Mottweiler, a licensed clinical psychologist who is trained in both DBT and parent training. Dr. Christina Gamache Martin (Co-I) and Dr. Maureen Zalewski (Faculty Advisor) may also be consulted and provide supervision, when needed.

Prior to the start of the first session, co-leaders will conduct 1 hour individual orientation sessions over Zoom with each participating parent, in order to orient them to the intervention, review intervention related portions of the consent form, and provide participating parents with an opportunity to ask questions in private if they wish.

Before each weekly session, parents will receive an encrypted email from the project coordinator asking them to complete the 5 measures listed in Fig. 1: Study Phase: *"*Treatment Phase*",* via a set of online UO Qualtrics questionnaires.

The DBT Skills +PT group intervention is a novel integration of three evidence-based treatments (i.e. DBT Skills, Parent Management Training (PMT), and Emotion Coaching (EC)). Each DBT Skills +PT session will last up to 2.5 hours. The structure of each session typically includes a brief mindfulness practice, homework review to discuss use of skills previously learned, a 10-15 minute break, didactics to learn a new set of DBT and PT skills, and assignment of homework. The DBT Skills portion of each session follows the DBT Skills Training Manual Second Edition (Linehan, 2015a) and DBT Skills Training Handouts and Worksheets Second Edition (Linehan, 2015b). The DBT Skills portions cover the four modules of traditional DBT Skills, which each focus on specific goals related to emotion regulation:

1) Mindfulness Skills help clients increase control over their attention and notice present emotions and thoughts. These skills are taught for 2 weeks at the start of the other three modules.
2) Emotion Regulation Skills teach skills to understand and label emotions, decrease the frequency of unwanted emotion, and decrease emotional vulnerability.
3) Distress Tolerance Skills teach clients how to deal with the most intense emotions in which they have urges to self-destruct. One set of distress tolerance skills is specifically focused on managing difficulties with addiction.
4) Interpersonal Effectiveness Skills help clients apply ER skills within interpersonal contexts, which are often highly emotionally evocative for individuals with elevated emotion dysregulation.

Parent training portions (both PMT and EC components) follow the Parenting Hyperactive Preschoolers Clinician Guide (Harvey, Herbert & Stowe, 2015) which was selected because it is an evidence-based parent training program that integrates PMT and EC (Herbert et al., 2013). Parent management training (PMT) portions of the intervention cover: how to use praise effectively, how to

increase positive interactions and use parental attention to reward positive behavior, how to set up a reward system, how to use effective commands, how to use consequences to discourage negative behavior, and how to teach children problem solving. Emotion coaching (EC) portions of the intervention cover: psychoeducation on children's emotional development, how to teach children to identify and label emotions, how to validate children's emotions, handling children's negative emotions, fostering children's positive emotions and how parents can model emotion regulation and expression to their children.

Post-intervention Assessment. Following the 20-week intervention, parents will be asked to complete the set of measures listed in Fig. 1: Study Phase: *"Post-intervention"* via online Qualtrics questionnaires. In addition, they will participate in an exit interview (approximately 1 hour), conducted over Zoom by a trained staff member who was not one of the DBT Skills +PT co-leaders. During the exit interview,
parents will be assessed for any current (since the clinical intake) substance use disorder using the SCID 5. Additionally, parents will be asked to share their thoughts and experiences from participating in the DBT Skills +PT group intervention.

Materials. All measures are well-validated, and have been used with clinical samples, in samples with racial and ethnic diversity, and in intervention studies which demonstrate change. Figure 1 provides a summary of the data collection schedule and measures, which are briefly outlined below in the order in which they appear in Figure 1. This broad battery of assessments is necessary to achieve the study aims, which include evaluating changes in three related domains (parent symptoms, parenting behaviors, and child symptoms), and comparing these changes to the clinical trial literature bases for DBT, PMT and EC (which have often utilized different measures to assess treatment-induced changes). All self and parent-report measures are included in this submission (see Appendices H-T).

A. The Difficulties with Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) is a 36-item self-report measure used to assess adult emotion dysregulation. Items are rated on a scale of 1 to 5, with higher scores indicating higher levels of dysregulation. The measure is comprised of six subscales: lack of emotional awareness, lack of emotional clarity, limited emotion regulation strategies, difficulties with impulse control, difficulties engaging in goal-directed behavior, and nonacceptance of emotional responses.
B. CAGE-Adapted to Include Drugs (CAGE-AID; Brown & Rounds, 1995) is a 4-item screener for alcohol and drug use. Items are scored 0 for "no" and 1 for "yes" responses. Higher scores are an indication of greater alcohol and drug problems. A total score of 2 or greater is considered clinically significant. The original measure focuses on lifetime use. For the purposes of this study, participants will be asked to answer for the time period in the past 5 years, but not in the past year.
C. Demographic questionnaire. Standard questions for assessing parent age, child age, parent gender, child gender, parent marital/relationship status, educational background, sexual orientation, number of people in household, number of children, race, ethnicity, socioeconomic status, and religious affiliation.
D. The Patient Health Questionnaire - depression module (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item self-report questionnaire in which participants rate how often depressive symptoms have bothered them in the past 2 weeks on a scale of 0 (Not at all) to 3 (Nearly every day). Scores are summed for a total score ranging from 0 to 27 with higher scores indicating higher levels of depressed mood.
E. The Peabody Picture Vocabulary Test (PPVT-V Q-Global; Dunn & Dunn, 2007) form A is a forced-choice format test of receptive vocabulary that provides an estimate of verbal cognitive ability of English-speaking adults and children. Participants are shown a page containing four drawings (in color) laid out in a 2-by-2 grid. Participants are then asked to point to the picture that corresponds to a word said by the experimenter. The task consists of 228 numbered items which are grouped into 19 sets of 12 items each and items increase in difficulty across the task. Items are administered

until the participant commits 8 or more errors in a given set. Standardized scores on this measure range from 20-160. The Q-Global administration is a web-based version to administer the test.

F. Structured Clinical Interview for DSM-5 (SCID-5; First, Spitzer, Gibbon & Williams, 2015). The SCID-5 will be used as the diagnostic measure during the intake to assess parents' potential mental health disorders, including substance use disorders. Substance use disorder modules will assess for current (past 12 months) and past (past 5 years) of the following DSM 5 defined disorders: alcohol, cannabis, hallucinogenic, inhalant, opioid, sedative/hypnotic/anxiolytic, and stimulant.

G. The Hamilton Anxiety Scale (HAM-A; Hamilton, 1969) is a 14-item self-report measure that assesses physical symptoms of anxiety. Subjects rate the severity of symptoms ranging from 0 (Not present) to 4 (Very Severe). Scores are summed for a total score ranging from 0 to 56, with higher scores indicating higher levels of anxiety.

H. The Aggregated Drug Craving Scale (ADCS; Costello et al., 2020) is an adaptation of the Penn Alcohol Craving Scale (PACS; Flannery et al., 1999) aimed at measuring a broad range of substance craving. The measure includes five items that assesses intensity, frequency, and duration of craving along with ability to resist substance use if it was available, and it asks responders to give an average craving rating for the past week. The response ranges from 0 to 6 for each item and higher scores indicate greater cravings.

I. The DBT Ways of Coping Checklist (DBT-WCCL; Neacsiu et al., 2010) is a 38-item self-report questionnaire which measures the frequency of DBT Skills use.

J. The Weekly Assessment of Child Behavior (WACB, Forte et al., 2012) is a brief 9-item parent-report measure in which parents rate (on a Likert scale of 1-7) how often their child engages in positive behaviors on a weekly basis. The measure is based on the positive opposites of behaviors measured by the Eyberg Child Behavior Inventory (ECBI) and yields two scales: Intensity and Need-to-Change. The measure has demonstrated strong convergent validity with other established measures of child behavior problems.

K. The Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000) is a 99-item parent-report ratings scale for children's problem behaviors which provide subscales for both internalizing (e.g. anxious, sad) and externalizing (e.g. hyperactive, aggressive) behaviors. Higher scores indicate greater problem behaviors and symptoms of psychopathology.

L. The Emotion Regulation Checklist (ERC; Shields & Cicchetti, 1997) is a 24-item parent-report measure in which parents rate (on a Likert scale of 1-4) how characteristic of their child are statements which focus on mood lability, lack of flexibility, dysregulated negative emotion, empathy, emotional self-awareness and positive response to others. The measure produces two subscales (lability/negativity and emotion regulation) and a composite of the two.

M. The Parenting Stress Index Short-Form (PSI-4 SF; Abidin, 1995) is a 36-item parent report measure of parental stress (rated on a five point Likert scale), and includes three subscales: Parental Distress, Parent–Child Dysfunctional Interaction, and Difficult Child. Normative scores have been established and raw scores are converted to T-scores and percentiles for interpretation.

N. The Parenting Sense of Competence Scale (PSOC; Johnston & Mash, 1989) is a 17-item measure of parental self-efficacy (rated on a six-point Likert scale). There are two subscales: satisfaction with parenting and self-efficacy in the parenting role. Lower scores indicate less parental self-efficacy.

O. The Parenting Scale (PS; Arnold et al., 1993) is a 30-item self-report questionnaire, in which parents are asked to describe (on a Likert scale of 1-7) how they respond to a variety of child misbehaviors. It yields three subscales: laxness, over-reactivity and hostile parenting.

P. The Coping with Children's Negative Emotions Scale (CCNES; Fabes, Eisenberg & Bernzweig, 1990) assesses parental self-report of emotion socialization practices. Parents are presented with 12 vignettes describing scenarios in which their children exhibit distress. Parents rate (on a Likert scale of 1-7) the likelihood they would engage in 6 potential parental responses to these situations, with each corresponding to 6 subscales: distress reactions, punitive reactions, minimization, expressive encouragement, emotion-focused reactions and problem-focused reactions. The first three can then be summed into an Invalidating/Unsupportive composite and the latter three can be summed into a Validating/Supportive composite.

Q. Skill Use Diary Card. A diary card developed for this study will be used to assess parents' weekly use of specific DBT and parenting skills, both as a study measure of treatment dosage and for treatment purposes. Parents are asked to circle days of the week in which they used each skill. Additionally, they are asked if DBT Skills were used in a parenting or a non-parenting context. Diary cards also include an additional question that assesses for suicidal thoughts over the past week.

R. The Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982) will be used to assess acceptability of the intervention. It is a brief 8-item self-report measure in which clients are asked to rate (on a Likert scale of 1-4) their satisfaction with the intervention.

S. Qualitative Exit Interview. A semi-structured exit interview will be used to evaluate parents' satisfaction with the intervention, challenges they experienced completing the intervention, their use of DBT/Parent training skills, and suggestions they have for improving the intervention delivery. Interviews will be video recorded so that representative quotes and themes can be identified.

Analyses

We will conduct multiple analyses to evaluate how, when, why, and to what extent the DBT Skills +PT intervention was effective in changing parents' mental health and/or parents' parenting quality and/or children's mental health and behavior. All data will be de-identified and all findings from our analyses will be reported anonymously.

Aim 1. Determine feasibility, acceptability and implementation. Three types of feasibility will be examined. Feasibility of recruitment will be assessed by examining the number of participants meeting eligibility on the initial online screener and the number of participants meeting eligibility following the clinical intake. Feasibility of measurement tools will be assessed by calculating the average time taken by participants to complete the online Qualtrics questionnaires, and the average percentage of missing data from the online questionnaires. Feasibility of the intervention will be evaluated by calculating the average number of sessions attended by parents.

Acceptability will be examined by averaging the total scores obtained from the Client Satisfaction Questionnaire (CSQ-8). In addition, using qualitative thematic analyses, we will report on data collected during the exit interview, identifying overall themes about the intervention that emerge from parents' comments.

We will examine implementation by calculating the average daily number of DBT and parenting skills parents report using each week on their diary card (averaged across parents) and comparing these to skill use reported in other published research (ex. 7-8 DBT skills per week; Gamache Martin et al., 2017). We will primarily report data for Aim 1 at an aggregated group level. We may also include de-identified information at the individual level in the form of quotes from parents' exit interviews.

Aim 2. Evaluate pre-post and weekly changes. We will examine pre-post changes for the primary outcomes of DBT Skill use (DBT-WCCL), parental emotion dysregulation (DERS), parenting stress (PSI) and parenting quality (PS, CCNES). Pre-post change scores will also be calculated for the secondary outcomes of child internalizing and externalizing behaviors (CBCL), child emotion regulation (ERC), parent mental health symptoms (HAM-A, PHQ-9, ADCS). Pre-post change scores will be compared to the clinical trial literature base for DBT and parent training interventions which often use the same measures and for which expected change scores are established. Additionally, based on post-intervention reports during the SCID 5 diagnostic interview, the percentage of parents reporting sustained recovery (vs relapse) from substance use disorder will be calculated and reported.

We will examine change across time based on data available in the weekly assessment measures of parents' DBT and parenting skill use (DBT-WCCL, Skill Use Diary Card), parents' emotion dysregulation (DERS), parenting quality (PS), and children's symptoms and behaviors (ERC and WACB). Consistent with common practice in case study designs (Kazdin, 2003; Kazdin, 2019; Rizvi & Nock, 2008), we will primarily use visual inspection (i.e. evaluating graphical displays of participants' weekly scores) to examine the data collected during Weeks 1-20 of the DBT Skills +PT intervention. We will use the same procedures to examine changes in data collected at the four time points representing the start of each DBT module. We will inspect several aspects of these data, such as

changes in the trajectories of each measure, to determine the direction and extent of change in the measured symptoms and behaviors from week to week, and the timing of when those changes occurred. We will also characterize the order in which changes unfold over time (e.g. increased DBT skill use precedes improvement in parent emotion regulation, which precedes improvements in parenting quality measures, which precedes improvements in child behavior measures).These visual inspection analyses will be conducted at both the individual level and at an aggregated group level.

We will employ a number of standard methods of statistical analysis of single-case experimental design (SCED) data to further examine, quantify and corroborate results of visual inspection. Consistent with previous SCED studies, we will calculate Tau-U effect sizes (Parker et al., 2011; Vannest & Ninci, 2015; Brossart et al., 2018), linear regressions (Ramaiya et al., 2018) and perform hierarchical linear modeling which can be used to aggregate single-case results (Van den Noortgate & Onghena, 2007; Ugille et al., 2012). These analyses will provide preliminary information on the rate and order of change for the different targeted symptoms and behaviors, and enable us to report on the degree to which DBT Skills +PT changed parent-reported symptoms and behaviors at the level of individual parents as well as at the group level, aggregating data across all participating parents.

D. Research Population & Recruitment Methods

Participants. We intend to recruit and conduct intakes with approximately 18 parents, enroll up to 15 eligible parents in DBT+PT, so as to reach our target of 12 parents who complete at least 4 sessions. This attrition rate is based on our lab's prior experience providing DBT Skills to a parent population. Participating parents will be split into three DBT Skills +PT groups that are run at different times over the course of the year. Recruitment efforts will take place twice over the course of the year to facilitate this.

To participate, parents must be 18+ years of age and reside in Oregon, have at least partial custody of a 3-6 year old child, neither parent nor child may have any known developmental disability, and the parent must be proficient in English, as our laboratory is unable to conduct the clinical intake, assessments, and DBT Skills +PT intervention with non-English speaking participants. Parents must also have internet access to facilitate participating in the remote telehealth DBT Skills +PT intervention. Additionally, eligible parents must endorse elevated emotion dysregulation (a score of >88 on the DERS, equivalent to +.5 SD above a normative score; Ritschel, Tone, Schoemann, & Lim, 2015) and endorse 2 or more items on the CAGE-AID screener for past (past 5 years), but not current (not in the past 12 months), substance use.

Only one eligible parent can participate in the study. In the case of two parents who wish to participate and both meet inclusion criteria, the family will decide which parent is most likely to complete all assessments and intervention sessions and that parent will be the research participant. If a participating parent has more than one preschool aged child (age 3-6), we will ask parents to decide which child is the target child for whom they will report during assessments. Parents will be excluded if they have a current (past 12 months) substance use disorder, if they do not have a past (past 5 years) substance use disorder, if they or their child have a known developmental disability or if during the clinical intake parents are determined to have a low IQ score (IQ<70) on the PPVT-IV, are psychotic as determined by the SCID 5, actively manic or psychotic as determined by clinical observation, are actively suicidal with an active plan as determined by the SCID 5 and/or PHQ-9, or are determined by clinical judgement to be at high risk of violence towards others. Additionally, if clinical judgement suggests a parent requires a higher level or different form of care, we may exclude them from participating or request that they secure an individual therapy provider in order to participate in the study.

Recruitment. Participants will be recruited through a number of recruitment strategies:

1. Team Duckling (https://teamduckling.uoregon.edu/) developmental database, which is maintained by the UO Psychology Department. Parents of children aged 3-6 will be initially contacted through email using a standard email script (see Appendix B. Recruitment Email).

2. Craigslist postings to recruit participants (see Appendix C. Craigslist Posting).

3. Social media posts. We may use social media posts/advertisements targeting parents within the state of Oregon (including but not limited to Facebook; for an example, see (Appendix D. Facebook Posting).

4. Contacting parents who have participated in previous studies within Dr. Zalewski's START Lab or other research labs, and who have indicated they are interested in being contacted to participate in future studies (see Appendix B. Recruitment Email).

5. Referrals from various mental health clinics (including, but not limited to the University of Oregon Psychology Clinic, HEDCO Clinic (College of Education), and the University of Oregon Counseling Center (University of Oregon Health Services), the Child and Family Center (Prevention Science Institute at UO), Portland DBT Insitute, Willamette Family, Serenity Lane, Parenting Now, Vista Counseling, Strong Integrated Behavioral Health. We will provide such clinics with an online virtual flyer with information about the study and a link to our online Qualtrics screener, which they can then provide to clients (see Appendix EE. DBT+PT Recruitment Flier).

6. Direct mailings. With the assistance of local agencies (i.e. Department of Human Services, Head Start of Lane County) through which our lab has recruited for previous studies, we will directly mail letters describing our study to the agencies mailing list of families that have children ages 3-6. A recruitment letter (see Appendix FF. Mailing Recruitment) will be provided to the agencies who have agreed to mail the letters on our behalf as to maintain privacy of their clientele. This is a template of what will be stated in the letter. It will be modified slightly (ex. specify agency name) to fit with the population the agency serves.

All recruitment materials will briefly discuss the details of the study and invite parents to complete an initial online screening survey to see if they are eligible to participate.

Parents who pass the initial online screening (see Appendix E. Online Screening Script) will be contacted by a trained research staff member to schedule the diagnostic clinical intake. Parents who do not pass the initial online screening will be thanked for participating and informed that they do not match the eligibility requirements. All parents who complete the online screening will be provided with a list of community mental health resources (see Appendix BB. Community Resources).

Compensation/Reimbursement. Participating families who are eligible for the full study can be compensated up to $360 for their participation in the study. Payments will be made after participants complete each phase of the study and are broken down as follows: $60 after the intake, $30 after the pre-intervention assessment, $10 after each weekly measure they complete during the 20 weeks of treatment, $30 after the post-intervention assessment, and $40 after the exit interview. Compensation will be provided via check payments which will be mailed to participants or via reloadable debit cards that will be provided to them. Potential costs to the participants include childcare expenses during the clinical intake, the assessments, intervention sessions and the qualitative exit interview.

Attrition. Efforts to minimize attrition include provision of incentives (which calculated across time spent on assessments are estimated to be in excess of $20/hour for those participating in the full study). Furthermore, the case study design, which does not necessitate inferential statistical analyses, ensures that our research aims can still be accomplished despite participant attrition.

E. Informed Consent Process

A single informed consent form (see Appendix A. Informed Consent Form) will cover all phases of the study (clinical intake, pre-intervention assessment, intervention, and post-intervention assessment). Prior to the clinical intake, a copy of the Informed Consent Form will be emailed to participants. At the start of the clinical intake, a trained research staff member will give each parent an overview of the study in its entirety and review confidentiality practices, potential risks, and any benefits. Participants will also be informed that as this is an intervention development project, the intervention group co-leaders are involved in the research and will have access to assessment data. Limits to confidentiality will be covered (as in the case of abuse of vulnerable populations, harm to self or others), as will the steps that will be taken if this information is revealed. Because the clinical intake and the assessments will specifically ask about suicidality, parents will be told in detail what procedures will occur if they are judged to be a risk to themselves or others (see Appendix X. Critical Risk Protocol). Parents will be invited to ask questions and will then provide consent via electronic signature on the Informed Consent Form and email it back to the staff member conducting the clinical intake.

At the start of the post-intervention qualitative interview, the trained research staff member conducting the interview will briefly cover the purpose of the exit interview and review the relevant portion of the consent form with the parent. Parents will be asked to verbally reaffirm their consent to participate. We will clearly track that the parent's consent to participate in the study was collected at the clinical intake and at the post-intervention exit interview (see Appendix Z. Documentation of Informed Consent).

A copy of the informed consent form will be posted on a Federal website (e.g. clinicaltrials.gov) after the study is closed to recruitment and no later than 60 days after the last study visit by any subject.

Research roles for consent procedures. All research staff members involved in collecting informed consent will be highly trained. Specifically, through the first two years of a clinical graduate student's studies, they take courses on assessment procedures, psychopathology and development, and begin working as individual and group therapists in the local psychology clinic under a licensed psychologist's supervision. This training includes exposure to a clinical population directly, and specialized training in assessing risk.

F. Provisions for Participant Privacy and Data Confidentiality

Methods of data collection from participating parents will occur through UO Qualtrics and a HIPAA compliant version of Zoom. Zoom will be used for clinical intakes, the intervention sessions and the final exit interview. OneDrive will be the primary cloud storage method for identifiable or highly sensitive data. OneDrive includes security controls and encryption of data that satisfy the requirements of the HIPAA Security Rule (https://www.hipaajournal.com/onedrive-hipaa-compliant/).

Upon entering the study, the parent will be assigned a unique, random ID number, which will be used to label each parent's data throughout the study phases (i.e. intake, pre-intervention assessment, intervention, post-intervention assessment). Participants will be explicitly directed not to provide any identifying information, including their name or their child's name when completing Qualtrics questionnaires, and instead will be directed to provide only their unique ID number. A master list linking the ID number to identifiable information (i.e. parent and child's real names, contact information) will be stored separately from all other data, on a password-protected server, only to be accessed by key study personnel.

Questionnaire data will be collected via the Qualtrics system and will be accessible on the Qualtrics website. Qualtrics assigns a random code to each participant. Once the data are downloaded, the Qualtrics codes will be replaced with the family's unique ID number. Data will be downloaded

temporarily and moved to be stored on OneDrive, accessible only by the research team. Copies of the data will be immediately deleted from local computers after being added to OneDrive.

Video recordings from the clinical intake, intervention sessions and final exit interview will initially be stored on secure servers of the University of Oregon and later transferred to secure, online cloud storage (OneDrive) with extra security features to encrypt and protect the data. All video recordings will be accessible only by the research team. Video recordings will be labeled with a random code number and not participant's names or other identifying information. Video recordings will be stored on OneDrive for 3 years after publication of the data, at which time they will be destroyed. Video recordings of the clinical intake and intervention sessions may be used for the purpose of internal review when consultation about a diagnosis or treatment is needed, to enhance therapist skill, further refine the development of the intervention, and train other future therapists. Research assistants will be trained to qualitatively code the exit interviews. All research assistants will complete human subjects training and will therefore be bound to confidentiality rules.

Clinical records which are a standard part of maintaining a client file such as session notes, emergency contacts, and release of information forms (see Appendix Y. Release of Information Authorization Form) are not considered study data and will also be stored on OneDrive, but kept separate from study data. No person who is not part of the research team will have access to this identifiable data.

Emails to enrolled participants (e.g. Zoom links, Qualtrics questionnaire links) will be sent via an encrypted email service (Hushmail). Phone communication with the research team may be conducted using Google Voice. Text messages sent to participants will not include identifying participant information unless first volunteered by the individual (e.g. a first name). Participant names will not be saved in a contact list connected to the Google Voice account. Their unique phone number will be used to search for the message thread. All messages will be permanently deleted from the device upon fulfillment of the intended purpose.

Sharing data. This research study is part of a larger set of related studies being conducted by the Center on Parenting and Opioids (CPO), a National Center co-located at UO's Prevention Science Institute (PSI), UO's Center for Translational Neuroscience (CTN) and Oregon Health and Sciences University (OHSU). The research at CPO is funded by an award from the National Institute on Drug Abuse (NIDA). De-identified data collected as part of the current study will be shared to the CPO Data Repository (CPO-DR). This repository stores data from many CPO-affiliated studies and is maintained by CPO staff. This expectation for data sharing is in accordance with guidelines from national funding agencies (e.g., see NIH Data Sharing Policy here: http://grants.nih.gov/grants/policy/data_sharing/index.htm).

We will not share any personally identifiable information about the participants in our study to the CPO-DR. We will securely transfer data as in accordance with CPO policies and procedures. The CPO-DR is designed to store encrypted, password-protected data behind firewalls. Data in the CPO-DR will be preserved indefinitely. Because we will not share identified data to the CPO-DR, data from participants in our study cannot be directly linked to data collected by other CPO research. In other words, no CPO researchers will be able to know if someone who participated in our study also participated in another CPO-affiliated study. Instead, data from our study may be combined with data from other CPO studies. Many of the studies that are part of the CPO have agreed to administer the same set of questionnaires, so that we can combine the responses across multiple studies. Increasing the sample size in this manner will make us more licensed to generalize the findings. Other researchers outside of the research team and the CPO research teams can request access to the data in CPO-DR. Only researchers who have agreed to protect the confidentiality of participants and the privacy of the data will be authorized to access the CPO-DR. CPO staff will be responsible for determining which researchers have access to the data.

It is possible that data in the CPO-DR could be accidentally shared with an unauthorized person who may attempt to learn participants' identities. We will not share any personally identifiable information from our study to the CPO-DR. So, the risk is small of someone learning the identity of any of our study's participants by accessing CPO-DR data.

We will ask participants to consent to sharing their de-identified data to the CPO-DR in the Informed Consent Form (see Appendix A. Informed Consent Form). Participants who prefer not to share their de-identified data to the CPO-DR may opt not to participate in the study.

Certificate of Confidentiality. To help us protect the privacy of participants, a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) was automatically issued as part of the CPO's NIDA P50 grant. This CoC will cover the current research. The research team can use the CoC to legally refuse to disclose information that may identify participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (e.g., if there is a court subpoena). The researchers would use the Certificate to resist any demands for information that would identify participants. The Certificate of Confidentiality would not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others. It will also not be used to prevent an audit by the UO IRB or federal funders.

G. Potential Research Risks or Discomforts to Participants

Clinical intake risks. While the clinical intake will invite parents to share potentially painful life events, the intake will be similar to what would be experienced in any clinical or psychological treatment setting. There could be a risk in that parents may meet criteria for mental disorders, which could be upsetting to them. Additionally, if the parent is actively suicidal, the intake clinician will conduct a suicide risk assessment using the Linehan Risk Assessment and Management Protocol (See Appendix W. LRAMP). Following the diagnostic interview, the intake clinician will inform parents about any diagnoses made and will provide referrals upon request. If the parent IQ scores are lower than 70 on the PPVT-IV (i.e. the parent is ineligible), the intake clinician will provide the parent with the results and the intake will be ended prior to completion of the SCID-5 (see Appendix AA. Clinical Intake Debriefing Script). Intake clinicians are well-trained and supervised (by Dr. Mottweiler) research staff members with experience in assessment and provision of clinical feedback to individuals from clinical populations. Intake clinicians will also provide referrals if needed and participants will be provided the PI's contact information should they have additional questions about their experience during intake. Parents will be informed of the risk of experiencing upsetting emotions during the informed consent process.

Assessment risks. Answering questionnaires about their mental health, their child's behavior and their own parenting may bring up negative emotions, but the level of distress expected is minimal. Parents will be informed of these risks during the informed consent process and reminded that their participation is voluntary.

DBT Skills +PT intervention risks. Parents in the DBT Skills +PT group will potentially encounter risks by virtue of being in a weekly intervention. By applying DBT and parenting skills in their everyday lives, and by being asked to share about these experiences, parents may experience painful emotions. However, it is our estimation that the negative emotions experienced would be similar to parents engaging in other forms of psychological treatments and in fact, is likely to be very beneficial. Risks of psychotherapy are explicitly discussed in the informed consent form.

Telehealth-related risks. There are some specific risks associated with telehealth services. First, although it is HIPAA compliant, it is not possible to completely guarantee the security of the Zoom software. As with any technology, there is a chance of a security breach that would affect participants' privacy of personal and/or medical information. Second, as parents will be completing sessions in their own home, it is not possible to guarantee the same level of privacy as in a clinic. Third, it is possible

that parents' confidentiality may be breached if other members of the therapy group are not in a confidential setting. Fourth, it is more difficult for therapists to respond immediately to an emergency situation, should that occur during a session.

We will mitigate these risks by providing instruction to group members on how best to create a private and secure space for themselves and other group members (e.g. use of a secure internet connection, use of headphones during session, conducting sessions in a private room, instructing participants not to record or photograph sessions). To mitigate the risks of emergency situations, participants will be asked to provide their location at the start of each session and therapists will maintain emergency contacts for each group member. Based on best practices for assessing and treating suicidal individuals via telehealth, Appendix X. Critical Risk Protocol includes guidelines for such cases which will inform our procedures. All telehealth related risks will be covered in the consent form (see Appendix A. Informed Consent Form).

Unimproved or worsening of symptoms. Continued or worsening of symptoms is always a risk, even for those engaged in treatment. While these risks are not specific to the proposed study intervention, it is important for the study team and parents to be aware of the potential adverse events associated with emotion dysregulation and mental disorders.

Confidentiality. The potential for breach of confidentiality exists with the clinical intake, assessment, and DBT +PT intervention digital files and for clinical records. Furthermore, as will be reviewed for all parents at the intake, confidentiality may be broken if child abuse or neglect, or intention to harm self or other is disclosed by the parent. As the intervention will involve parents sharing and discussing different parenting situations, it is possible participants may disclose information regarding child abuse or domestic violence. In such cases, the co-leaders will follow-up with parents to clarify the risk and current safety of their children and determine whether mandated reporting is warranted. The PI and clinical supervisor will report this information to child protection services, a primary health care provider, or emergency services, depending on the specifics of the disclosure. Procedures for responding to such critical incidents are detailed in Appendix X. Critical Risk Protocol.

Data Safety Monitoring Plan. The funding agency required a Data Safety Monitoring Plan for this research (see Appendix CC. Data Safety Monitoring Plan). There was no funder requirement for an established Data and Safety Monitoring Board/Committee (DSMB/C) as noted in the DSMP.

H. Potential Benefits of the Research

Parents who participate in the DBT +PT intervention will receive an evidence-based treatment that has been found effective in treating substance abuse in emotionally dysregulated populations, and which is scarcely available (or not adherently provided) in Eugene (i.e. DBT Skills), as well as evidence-based parent training for children's emotional and behavior problems. They may experience improvements in their mental health and parenting skills, however there may be no direct benefit of participating in the intervention.

Beyond that, participation in this research will contribute to scientific understanding of the effectiveness and feasibility of integrating these treatments. Our study will facilitate future research and the development of new clinical interventions that will ultimately benefit other parents and families.

I. Investigator Experience

Investigator Qualification. Yoel Everett, M.A.: Yoel Everett (PI) is a graduate student researcher in the UO START Lab, and is a 4th year student in the clinical psychology doctoral program at the University of Oregon. He received his Bachelor's of Arts in Psychology from Tel Aviv University in 2015, a Master's of Arts from the University of Oregon in 2019 and has been involved in research on emotion and emotion regulation for the past 6 years. He also spent one year working in a parent training program for parents of severely disruptive children, and co-authored the English version of a parent training program manual. He is now in his third year of clinical training at the UO Psychology clinic and

in external practicum sites in Eugene, where he has assessed and treated individuals with a variety of psychological symptoms in both in-person and telehealth settings. He currently leads a DBT+ Parent Training group as part of an IRB-approved case study with 3 parents. He will be responsible for all aspects of the project, including integrating and manualizing DBT and Parent Training materials, development of recruitment materials, conducting clinical intakes, co-leading the DBT +PT intervention, data analysis, and authorship of resultant manuscripts.

Christina Gamache Martin, PhD.: Christina Gamache Martin, Ph.D. (Co-I) is a research associate in the Department of Psychology at the University of Oregon. She is a licensed clinical psychologist in Oregon and is currently a clinical interventionist for Dialectical Behavior Therapy (DBT) on a NIMH funded randomized control trial (PI Dr. Zalewski). She has supervised clinical psychology graduate students in the DBT practicum in the Psychology Department at the University of Oregon. Her program of research centers around the development of psychopathology within the broader context of parental psychopathology and emotional distress, and it seeks to clarify potential clinical challenges encountered when both parents and their children present with psychopathology or other stressors such as trauma, with the ultimate goal of bridging the current gap between developmental and adult psychopathology through basic science research and the development of interventions to better meet the needs of families where both children and parents are at risk.

Candice Mottweiler, PhD.: Candice Mottweiler is a postdoc in the Department of Psychology at the University of Oregon (UO). She received her PhD in Clinical Psychology from the University of Oregon in 2017 following a one-year internship at the University of Kansas School of Medicine. Her clinical specialties include working with children and families, using behavioral and cognitive behavioral techniques; as well as providing dialectal behavioral therapy (DBT) to adults struggling with emotion regulation. Dr. Mottweiler has led DBT groups for parents at the University of Oregon since 2018. She also works as a therapist (since 2017) at Options Counseling and Family Services, providing individual therapy to children, adolescents, and adults as well as leading an adult DBT group. In addition, she has provided clinical supervision for graduate students and interns leading/co-leading DBT groups at UO and Options since 2019. She has worked in varying roles on several research projects since 2006, generally focused on child development and/or parenting. Her responsibilities on this project will include providing direct supervision for DBT group leaders during a scheduled weekly meeting as well as between scheduled meetings to address clinical challenges and/or emergencies as needed.

Maureen Zalewski, PhD.: Dr. Maureen Zalewski (Faculty Advisor) has a doctorate in clinical psychology and is a licensed psychologist in the state of Oregon. She currently trains and supervises clinical doctoral students in the provision of DBT to clients of the UO Psychology clinic. Dr. Zalewski is formally trained in Dialectical Behavior Therapy, a treatment designed for women with Borderline Personality Disorder, by the treatment developer, Dr. Marsha Linehan. She has treated many individuals with BPD and emotion dysregulation and conducted suicide risk assessments. As a researcher, Dr. Zalewski has been involved in intervention development efforts of extending DBT for mothers. Dr. Zalewski has first authored and co-authored publications on parents with BPD and BPD symptoms such as severe emotion dysregulation, and on the effects of parental emotion dysregulation on child development.

Roles and Research Duties. The principal investigator (Everett) and faculty advisor (Zalewski) will be involved in all aspects of this research. The co-Investigator (Martin) will help in the development and refinement of intervention session plans and will be highly involved in preparing resultant manuscripts from this study. The clinical supervisor (Mottweiler) will provide supervision for all intervention co-leaders by reviewing video recordings of sessions and meeting with co-leaders regularly to provide clinical feedback. The project coordinator will be involved in the development of recruitment materials, recruitment efforts, scheduling, data collection, data storage and following of procedures for this protocol. Yoel Everett (PI) will train all research assistants who may be involved in qualitative coding of the exit interviews. In addition, Yoel Everett and the additional co-leaders will be responsible for

conducting clinical intakes and co-leading the DBT+PT intervention. A trained clinical psychology graduate student will be responsible for conducting the exit interviews.

Training and Oversight. Yoel Everett (PI), the other group co-leaders and Dr. Mottweiler, will participate in weekly consultation meetings. These consultation team meetings are designed to assist co-leaders in adhering to the DBT treatment model and the Parent Training manual. All research personnel involved in recruitment, screening, intakes, assessments and the intervention will complete the Collaborative Institutional Training Initiative's (CITI) Protection of Human Research Subjects program for Social-Behavioral-Educational Researchers as well as the Good Clinical Practices training to ensure ethical and professional conduct of the research. Study personnel will complete and have up-to-date CITI training certificates on file with the Project Coordinator. Additionally, each member of the study team will be trained by the PI to follow the approved research protocol.

Appendices submitted with this application

A. Informed Consent Form
B. Recruitment Email
C. Craigslist Posting
D. Facebook Posting
E. Online Screening Script
F. Intake Scheduling Script
G. Difficulties with Emotion Regulation Scale (DERS)
H. CAGE-AID Screener
I. Demographic Questionnaire
J. Patient Health Questionnaire 9 (PHQ-9)
K. Hamilton Anxiety Rating Scale (HAM-A)
L. The Aggregated Drug Craving Scale (ADCS)
M. DBT Ways of Coping Checklist (DBT-WCCL)
N. Weekly Assessment of Child Behavior (WACB)
O. Emotion Regulation Checklist (ERC)
P. Parenting Stress Index (PSI)
Q. Parenting Sense of Competence Scale (PSOC)
R. Parenting Scale (PS)
S. Coping with Children's Negative Emotions Scale (CCNES)
T. DBT/Parenting Skill Use Diary Card
U. Client Satisfaction Questionnaire (CSQ-8) Sample Text
V. Sample Exit Interview Questions
W. Linehan Risk Assessment and Management Protocol (LRAMP)
X. Critical Risk Protocol
Y. Release of Information Authorization Form
Z. Documentation of Informed Consent
AA. Clinical Intake Debriefing Script
BB. Community Resources
CC. Data Safety Monitoring Plan
DD. Child Behavior Checklist (CBCL)
EE. DBT+PT Recruitment Flyer
FF. Mailing Recruitment