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Study: PROACTIVE Parent: PROviding Access To InnoVative & Evidence-Based Intervention

Date: 6/16/21

Statistical Plan

We plan to enroll 14 foster parents with 7 foster parents per condition.

For the primary outcomes: acceptability, usefulness, and feasibility we will conduct descriptive analyses separately for the post-session items and the post-intervention Customer Satisfaction Survey. We will sum relevant items on the post-session questionnaires (administered after each of the 10 sessions) and provide mean ratings for program Acceptability, Usefulness, and Feasibility. We will provide mean ratings for Acceptability, Usefulness, and Feasibility from the Customer Satisfaction Survey. We will also provide descriptive statistics for other aspects of Feasibility as described below.

For the primary Treatment vs. Control group analyses we will examine 2 (Group) x 2 (Time) repeated measures ANOVA, with repeated measures on the second factor (Time). For measures that include subscales we will use K (number of subscales) x 2 repeated measures MANOVA to assess for treatment effect on subscale scores. For the child outcome measures we will use 2 x 2 repeated measures MANOVA with each of the child outcome measures and/or subscale scores in one model, as the child outcomes may share some variance.

For the delayed treatment analyses, we will combine the treatment and the delayed treatment participants to examine a one-way repeated measures ANOVA examining the pre-post scores of each of the groups – essentially using T1 and T2 data for the original treatment group and the T3 and T4 data for the delayed treatment groups. We will use a one-way repeated measures MANOVA for the child outcomes.

Primary Outcomes. Primary Outcomes will be assessed with three types of measures. Post-session measures that assess session content and delivery at the end of each of the 10 sessions, post-intervention in a Customer Satisfaction Survey, and pre- and post-intervention with standardized measures.

Acceptability. Post-session acceptability assesses parent satisfaction with the session, what parents liked about the session, and what they would change about the session. Continuous items will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions. Items on the Customer Satisfaction Survey will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions.

Utility. Post-session utility assesses parent perspectives of the usefulness and relevance of the session. Continuous items will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions. Items on the Customer Satisfaction Survey will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions.

Feasibility. Post-session feasibility assesses parent perspectives of the timing and format of the session. Continuous items will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions. Items on the Customer Satisfaction Survey will be summed and analyzed using descriptive statistics. Qualitative analyses will be used to identify themes in open-ended questions. We will also assess feasibility by using descriptive statistics to assess the extent to which the parent coach was able to adhere

to the session format for each session, the percentage of parents who met eligibility criteria, enrolled in the study, and completed all study-related tasks.

Parent-Patient Activation Measure – Mental Health (P-PAM-MH). We will examine change in parent activation from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Parent activation will be measured using the Parent-Patient Activation Measure- Mental Health. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that parent scores in the treatment group, relative to the control group, will increase from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that parents will demonstrate higher scores on T4 after receiving the delayed intervention.

Family Empowerment Scale (FES). We will examine change in parent empowerment from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Parent empowerment will be measured using the FES. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that parent scores in the treatment group, relative to the control group, will increase from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that parents will demonstrate higher scores on T4 after receiving the delayed intervention.

Secondary Outcomes.

PROMIS Parent Proxy Pediatric Anxiety Short Form 8a (P-P Anxiety). We will examine change in child anxiety symptoms from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Child symptoms will be measured using the PROMIS P-P Anxiety. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that child scores in the treatment group, relative to the control group, will decrease from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that children of parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that these children will demonstrate lower scores on T4 after parents receive the delayed intervention.

PROMIS Parent Proxy Pediatric Depressive Symptoms Short Form 8a (P-P Depression). We will examine change in child depressive symptoms from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Child symptoms will be measured using the PROMIS P-P Depression. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that child scores in the treatment group, relative to the control group, will decrease from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that children of parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention)

will remain the same, but that these children will demonstrate lower scores on T4 after parents receive the delayed intervention.

Pediatric Symptom Checklist-17 (PSC-17). We will examine change in child internalizing, externalizing, and attention symptoms from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Child symptoms will be measured using the PSC-17. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that child scores in the treatment group, relative to the control group, will decrease from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that children of parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that these children will demonstrate lower scores on T4 after parents receive the delayed intervention.

Barriers to Treatment Participation Scale (BTPS). We will examine change in parent perceptions of barriers to treatment participation from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Barriers to treatment will be measured using the BTPS. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that parent scores in the treatment group, relative to the control group, will decrease from baseline to Time 1 (T1) to post-intervention – indicating a reduction in barriers to treatment, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that parents will demonstrate lower scores on T4 after receiving the delayed intervention.

Difficulties in Emotion Regulation Scale (DERS). We will examine change in aspects of parent emotion from baseline (T1) to post-treatment (T2, week 11) in the treatment condition relative to the control condition. Parent emotion regulation will be measured using the DERS. While the study is likely not powered to detect significant differences, our goal is to estimate effect sizes. We predict that total parent scores and subscale scores in the treatment group, relative to the control group, will decrease from baseline to Time 1 (T1) to post-intervention, while scores in the control condition will remain the same from baseline (T1) to T2, week 11. We predict that parents in the delayed treatment group will demonstrate consistent scores on T1, T2 and T3 (re-assessment, prior to delivery of delayed intervention) will remain the same, but that parents will demonstrate lower scores on T4 after receiving the delayed intervention.