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Official Title: Evaluation of Phase I Fathering In Recovery Prototype

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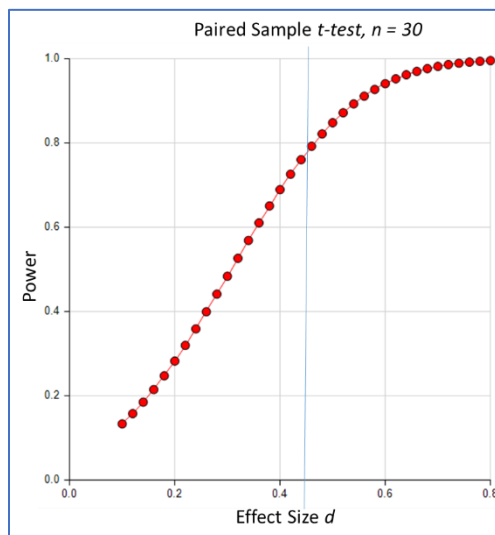
## Study Protocol

Thirty fathers were enrolled in the Fathering In Recovery (FIR) Phase I pilot study. Fathers were recruited through residential and outpatient drug and alcohol treatment centers located across the nation. The majority were recruited from Hazelden drug and alcohol treatment centers (83%) and CODA opioid treatment centers (7%). Drug treatment staff identified individuals who they believed met eligibility criteria and were currently or had recently participated in either residential or outpatient treatment. Those individuals were provided with brief information describing the study and provided with a website address that took them to a Qualtrics screener to assess eligibility. If individuals were eligible, they were asked to provide their contact information so that research staff could follow up to provide additional information regarding the study and a consent document to enroll in the study.

Fathers were invited to complete the 4-session FIR program over 4 weeks. Fathers completed outcome questionnaires approximately 1 week prior to starting the program and approximately 1 week after completing the program. Fathers also evaluated acceptability and usability. Twenty-eight fathers completed post-intervention assessments (93% retention).

## Statistical Analysis Plan

To address promise of efficacy, the primary approach will be standard normal paired sample  $t$ -tests for evaluation of pre-post improvements in the benchmark outcomes. Although this is not a randomized trial and we therefore cannot demonstrate program efficacy, a critical component of the feasibility analysis will be observed pre-post improvements in parenting knowledge, parenting efficacy, parenting skill, and pre-post reductions in substance use. We will test the hypothesis  $H1: \mu_{POST} > \mu_{PRE}$  for knowledge, efficacy, and parenting skill, and  $\mu_{POST} < \mu_{PRE}$  for substance use. The paired  $t$ -test assumes that the paired differences individual  $i$  ( $\mu_{POST} - \mu_{PRE}$ ) are a simple random sample from a population of normally-distributed difference values that all have the same mean and variance. This assumption implies that the data are continuous, and their distribution is symmetric. The paired sample  $t$  is the same formula shown above with the standard deviation given as the paired differences:



$$s = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n - 1}}$$

The primary outcomes, parenting efficacy and parenting skill are measured on a Gaussian normal, the test  $\mu_{POST} > \mu_{PRE}$  is powered .802 to detect a pre-post effect size of .46 standard deviations, a medium effect; likewise, for substance use also on a continuous scale on the PhenX, the test  $\mu_{POST} < \mu_{PRE}$  is powered .80 to detect an effect size of .46. For all discrete outcomes such as the Phenx psychopathology, a sample size of 30 is powered .809 to detect pre-post change of .22 in proportions of the sample above item thresholds. For example, items are measured on a scale of 0 to 4, with 1 “slight” the threshold for suicidality, psychosis, and

substance use, and 2 “mild” the threshold for depression, anxiety, or sleep disorder, etc. For Poisson frequencies of substance use, the study is powered .802 to detect a .58 mean reduction in the pre-post rate of use, and effect size of .46.