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Mothering from the Inside Out: Results of a community-based randomized efficacy trial testing a mentalization-based parenting intervention for mothers with addictions

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Abstract

Mothering from the Inside Out (MIO) is a mentalization-based parenting intervention developed to address challenges common among mothers experiencing substance use disorders (SUDs) and previously deemed effective when delivered by research clinicians. This randomized clinical trial was designed to test the efficacy of MIO when delivered by community-based addiction counselors in Connecticut, USA. Ninety-four mothers [M(SD)age= 31.01(4.01) years; 75.53% White] caring for a child 11-60 months of age were randomly assigned to participate in 12 sessions of either MIO or psychoeducation. Caregiving, psychiatric, and substance use outcomes were assessed repeatedly from baseline through 12-week follow-up. Mothers who participated in MIO showed decreased certainty about their child's mental states, and decreased depression; their children demonstrated increased clarity of cues. Participation in MIO was not associated with the same degree of improvement that was observed in prior trials where MIO was delivered by research clinicians. However, when delivered by community-based clinicians, MIO may be protective against a deterioration in caregiving over time often seen in mothers with addictions. The drop in efficacy of MIO in this trial raises questions about intervention-intervenor fit. Research should examine factors influencing MIO effectiveness to close the science-to-service gap common in the dissemination of empirically validated interventions.

Keywords

maternal addiction; reflective functioning; mentalization; community-based efficacy; evidence-based treatment

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Mothers with substance use disorders (SUDs) describe strong motivation to facilitate positive growth and development in their children (Van Scoyoc et al., 2017). Caregiving capacities vary widely among this group, though mothers with SUDs may show poorer emotional availability, caregiving sensitivity, and responsiveness to their children's signals, as well as a tendency to vacillate between being intrusive and withdrawn when interacting with their children (Burns et al., 1997; Goldman Fraser et al., 2010; Haabrekke et al., 2015; Hans et al., 1999). Although addiction among mothers has increased (Greenfield et al., 2010; SAMHSA, 2021), traditional models of addiction treatment do not typically address parenting challenges. This is troublesome given that sensitive caregiving is a key predictor of child outcome, even more than prenatal exposure to substances (Lowe et al., 2017). Unfortunately, many evidence-based parenting programs that have been tested with parents with SUDs have generally not shown improvement in parenting behaviors, the parent-child relationship, or parents' substance use outcomes (Bosk et al., 2019; Milligan et al., 2020; Suchman et al., 2006). Neuroscience research suggests that the efficacy of parenting interventions may be limited for mothers with SUDs because addiction may negatively impact how the maternal brain perceives, attends to, and interprets caregivingrelated stimuli, such as infant facial expressions and cries (Kim et al., 2017; Landi et al., 2011; Lowell et al., 2020; Rutherford et al., 2021; Rutherford et al., 2020). Such findings suggest that the caregiving challenges experienced by mothers with SUDs may be reflective of a dysregulation in mothers' stress and reward neural circuitry (Rutherford et al., 2013; Rutherford et al., 2011). Thus, rather than simply *teaching* caregiving skills, parenting interventions for mothers with SUDs may be more successful if they seek to enhance the emotional quality of the parent-child relationship which may potentially increase the reward of caregiving (Peacock-Chambers et al., 2022; Suchman et al., 2006).

Mothering from the Inside Out: Treatment Model

Mothering from the Inside Out (MIO) was developed specifically for mothers with addictions with these findings in mind. MIO is a 12-week, manualized, individual parenting psychotherapy designed to foster a mother's capacity to *mentalize* in her relationship with her child. Fonagy and Target (1997) defined mentalizing as our capacity to understand ourselves and others in terms of intentional mental states such as emotions, desires, wishes, goals and attitudes. MIO specifically targets the specific mentalizing domain of *parental* reflective functioning (PRF). Slade (2005) defined PRF as the more specific ability for parents to meaningfully and accurately recognize and make sense of their own and their child's behavior in terms of underlying mental states. Based upon the broad outline of reflective parenting approaches put forth by Slade (2007) and standing on the shoulders of other evidence-based reflective parenting programs (e.g., Minding the Baby; Slade et al., 2020; Slade et al., 2005) MIO was originally developed to explicitly support the unique parenting needs of mothers in treatment for substance use disorders. MIO supports the enhancement of PRF during times of arousal and dysregulation through the process of engaging in explicit reflection about one's own and others' mental states (Bateman & Fonagy, 2012). By learning to make sense of her own emotional distress during difficult parenting situations, the mother can then regulate her own emotions and attend to her child's

emotional needs. Ideally, when mothers are better able to mentalize for themselves and their children, the mother-child relationship should grow increasingly adaptive.

MIO is offered in conjunction with standard addiction treatment. Mothers meet with a clinician who helps the mother recognize and manage emotions elicited during stressful parenting situations, as well as understand and tolerate her child's emotional response in these moments. Both the mother's and the child's emotional states are considered in detail since the mother's ability to attend to the child depends on her capacity to manage her own emotions. Because a young child's budding autonomy often elicits emotional distress in mothers with addictions (Suchman et al., 2006), MIO targets mothers caring for toddlers and preschoolers. Attachment-based developmental guidance is also provided to help the mother make realistic assessments of her child's abilities and emotional needs.

Previous MIO Trials

Two previous trials have demonstrated MIO's efficacy for improving mother-child outcomes in the context of addiction (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017). To test this, mothers in SUD treatment were assigned to participate in either MIO or an active psychoeducational comparison intervention (PE). In these initial trials, both interventions were delivered under conditions of high internal validity by the treatment developer and research clinicians with backgrounds in infant mental health, parental reflective functioning, attachment, and psychodynamic psychotherapy. In these trials, when compared to mothers who participated in PE, mothers who participated in MIO showed higher levels of self-focused PRF at posttreatment and 6week follow-up in a randomized pilot study, and significantly higher mean PRF at 12-week follow-up in the second trial.

Mothers who participated in MIO also demonstrated greater caregiving sensitivity and growth fostering behavior, as well as more timely responses to their children during dyadic interactions at the end of treatment and 6-week follow-up in the pilot study, and at 1-year follow-up in the second trial. Children of mothers who participated in MIO demonstrated significantly improved clarity of cues and responsiveness to their mothers at the end of treatment and follow-up in the pilot study, and improved engagement and reciprocity with their mothers at the end of treatment and follow-up in the second trial. In the second trial, attachment security was also assessed, and although there was no main effect, moderation analyses showed that mothers with more severe clinical profiles who received MIO showed improvement in PRF which was associated with improvement in child attachment security; this was not the case for mothers in the low-severity group (Suchman et al., 2017). In addition to these dyadic outcomes, these two prior trials also demonstrated that, compared to participation in PE, participation in MIO was associated with decreases in depression and psychiatric distress at posttreatment (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011), as well as a decrease in proportion of heroin relapses during follow-up (Suchman et al., 2017).

Studies of the mechanisms of change underlying MIO (Suchman et al., 2018; Suchman et al., 2012) have demonstrated that clinician adherence to MIO (i.e., use of specific

techniques for fostering mothers' PRF) predicted improvements in mothers' PRF, which uniquely predicted improvements in downstream caregiving sensitivity. Although PRF was not directly predictive of child attachment security, maternal caregiving sensitivity was, suggesting that improvements in mothers' PRF as a result of participating in MIO may have had indirect impacts on child attachment security via improvements in mothers' actual caregiving behavior. Overall, outcomes from the previous two trials suggest that participation in MIO may elicit a cascade of improvements beginning with changes at the representational or mental level, leading to changes at the behavioral level, which seem to influence enhancements at the relational level.

Next steps in implementation

Given prior research demonstrating MIO's promise as an approach for improving the trajectory of mothers and children impacted by addiction when delivered by research clinicians in a research setting, the next step in the systematic development of this psychotherapy was to conduct a *community-based efficacy trial* in order to avoid the well-documented science-to-service gap where there is a precipitous drop in efficacy when interventions are brought from the research setting into 'real-world' settings (Onken et al., 2014; Weisz et al., 2014). In other words, rather than moving directly from a tightly controlled efficacy trial (i.e., research clinicians delivering interventions in the research setting) to an effectiveness trial (i.e., community-based clinicians delivering interventions in community-based settings), Onken et al. (2014) suggests first moving to a community-based efficacy trial where community-based clinicians deliver interventions in controlled research settings. Doing so allows for the evaluation of whether treatment outcomes and mechanisms of change hold in a more pragmatic trial with high internal validity before pursuing a large-scale effectiveness trial. As a first step in this process and to ensure that MIO was implementable with fidelity when administered by community-based clinicians, we trained addiction counselors at a local substance use treatment agency to deliver either MIO or PE. Analyses showed that these addiction counselors achieved adequate clinical reflective skills and delivered their assigned interventions with fidelity following training and supervision (Suchman et al., 2020). In light of these findings, the next step became determining whether MIO remains efficacious when delivered by these community-based clinicians.

The Current Study

Here we report findings from a Stage III randomized community-based efficacy trial where 22 addiction counselors delivered their assigned treatments (MIO or PE) to 94 mothers enrolled in substance use treatment while caring for a child 11–60 months of age. The primary goal of this trial was to replicate the clinical outcomes seen in the first and second trials, with MIO or PE delivered by trained addiction counselors (Suchman et al., 2020). Consistent with prior findings (Suchman et al., 2018; Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2012; Suchman et al., 2017), we hypothesized that, when compared to mothers who participated in PE, mothers who participated in MIO would demonstrate greater improvement in (a) PRF, (b) caregiving sensitivity, (c) quality of mother-child interaction, and (d) child attachment security from pre-treatment through 12-week follow-up. Further, given our prior findings and in light of other work suggesting

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the transdiagnostic utility of mentalization-based treatment at improving overall psychiatric distress (Burke et al., 2020; DeTore et al., 2022), we hypothesized that, when compared with mothers who participated in PE, mothers who participated in MIO would demonstrate greater decreases in (a) psychiatric distress and (b) substance use from pre-treatment through 12-week follow-up.

Method

Research Design

This Stage III randomized clinical trial was conducted in collaboration with a private, nonprofit, community-based substance use treatment center. All data collection procedures and treatment sessions took place from January 2015 to December 2019 in four of this center's outpatient clinics located throughout a small northeastern U.S. city where many clients experience poverty, community violence, and limited affordable housing. Interested mothers who were eligible to participate in the research study were randomized to engage in 12 sessions of a parenting intervention. An urn randomization procedure (Wei & Lachin, 1988) was used to balance the treatment groups on key variables related to the clinical outcomes.

Research assessments were obtained by research staff, and treatment was provided by addiction counselors. Suchman et al. (2020) described the recruitment, randomization, training, and initial assessment of the addiction counselors who provided the parenting interventions. Treatment fidelity was measured via an abbreviated version of the Revised MIO/PE Adherence Rating Scale (Suchman et al., 2016) used in the first two clinical trials. The primary clinical outcome was PRF. Secondary outcomes included quality of mother-child interaction and child attachment security, as well as maternal psychiatric distress and risk for substance use. All research procedures were approved by a Human Investigation Committee at Yale University. Procedures were also approved by the private, nonprofit agency that operated the clinical programs, and a Certificate of Confidentiality was secured from the U.S. Department of Health and Human Services to protect sensitive, identifiable information from disclosure without participant permission.

Sample

Mothers were eligible to participate in the study if they were (a) enrolled in outpatient substance use treatment in one of four identified clinics, (b) English-speaking, and (c) caring for at least one child 11–60 months of age at time of enrollment. If mothers had more than one child in their care within this age range, they were asked to choose the child they wanted to focus on while participating in the study. Exclusion criteria included (a) mothers requiring inpatient hospitalization or detoxification, (b) mothers with severe mental health problems (i.e., active psychosis, suicidality), (c) mothers with significant cognitive impairment, and (d) target children with significant developmental delay or severe illness. Sample size estimation completed before the study began suggested that a target sample of 100 mothers would provide adequate power to detect medium to large (d > .40) treatment effects in linear growth models with expectation of moderate correlation of dependent measures and some missing data across at least three time points.

Mothers—Ninety-seven mothers caring for a child 11–60 months of age consented to participate. Of these mothers, 94 completed an initial evaluation and were randomized to one of the two parenting interventions (53 MIO, 41 PE). On average, mothers were approximately 31 years old (SD = 4.01), had completed approximately 13 years of education (SD = 1.88), and were caring for an average of 2 (SD = 1.04) children under 16 years of age. Mothers described themselves as White/European American (75.53%), Black/African American (8.51%), Hispanic/Latina (8.51%), Asian American (1.06%), and other or mixed race-ethnicity (6.38%). Mothers were generally of average intelligence and unemployed. Most reported early initiation of substance use, and most reported primary use of opioids, and enrollment in medication-assisted treatment for opioid use disorder. See Table 1 for demographic information by treatment group.

Children—Target children were approximately 30 months old (SD = 14.27). Girls (50%) and boys (50%) were equally represented. Almost all (97.87%) target children were living with their mother. Most children had been exposed prenatally to cigarettes, about half were exposed to other substances, and about one quarter had been exposed prenatally to illicit opioids. Developmentally, most target children fell within the average range on measures of cognitive functioning, receptive communication, and expressive communication.

Mothers reported that the fathers of their target children were on average approximately 34 years old (SD = 6.19), and about half were living in the home with the mother and the target child. Most fathers were involved in the care of the child, and most were reported to have their own histories of substance use. Approximately a third of the families were involved with child protective services. See Table 2 for complete demographic characteristics of both fathers and target children by treatment group.

Research Procedures

Recruitment Phase—Mothers were recruited via referrals from addiction counselors, research assistant presence in the clinics, brief presentations at group meetings, flyers posted in the clinics, and word-of-mouth. Interested mothers were screened for eligibility by research assistants in person or by telephone. Those eligible met individually with a research assistant to complete informed consent procedures for themselves and a target child. On a few occasions, if mothers were caring for their children but did not have guardianship, the child's legal guardian provided consent for the child to participate.

Baseline Phase—Following informed consent, participants completed four weekly 1 to 2-hour baseline assessment visits. See Table 3 for a summary of these assessments. After the initial baseline visit, mothers were randomized to either MIO or PE and assigned to an addiction counselor who had been trained in the assigned intervention.

Treatment Phase—Throughout the intervention period, mothers met weekly for twelve 1-hour individual treatment sessions with their assigned MIO or PE counselor. At these visits, mothers also completed brief questionnaires designed to track recent substance use. Every four weeks, mothers completed two brief psychiatric symptom questionnaires. Table 3 outlines the schedule of these repeated assessments. As in prior trials, additional supports

were available to all mothers during their involvement in the study (e.g., childcare during visits, referrals to support for basic needs). While delivering MIO or PE in the study, addiction counselors participated in weekly group supervision to promote adherence to their respective treatment approach.

Mothering from the Inside Out.: As noted above, MIO is a brief individual psychotherapy based on the mentalizing approach to clinical intervention and parenting support (Allen et al., 2008; Slade, 2007). The primary goal of MIO is to promote the capacity for PRF in mothers with SUDs by focusing on their ability to reflect about cognitive and emotional reactions to (a) situational stress, (b) self as a parent, (c) a target child, and (d) self in a parenting relationship with a target child. Across sessions, the counselor works to maintain a mentalizing stance toward the mother and the target child by conveying that parenting situations, particularly stressful ones, are best understood by making sense of the thoughts, emotions, and intentions underlying behavior. Unlike psychoeducational parenting interventions which focus on imparting knowledge, the focus of MIO is on building the mother's psychological resources (i.e., PRF) so that she can achieve greater emotional balance, greater sensitivity to psychological states in herself and her child, ultimately resulting in improved mother-child dyadic adjustment. A full description of the approach can be found in published summaries (Lowell et al., 2021; Suchman et al., 2013) and treatment guidelines (Suchman & DeCoste, 2018).

Parent Education .: Parent Education (PE) is based on a psychoeducational approach to intervention that blends supportive counseling and education. PE was developed and manualized as an active, behaviorally based comparison condition designed to (a) resemble parent education programs commonly available in the community for mothers in addiction treatment, (b) control for intervention dose, alliance, and expectations for help with parenting stressors, and (c) minimize overlap with MIO. Like other psychoeducational approaches to parenting intervention, PE seeks to increase positive parenting behaviors by (a) reducing contextual stresses on parenting, (b) increasing emotional and instrumental support for parents, (c) increasing knowledge of normative child development, and (d) providing information about positive parenting practices. Counselors help the mother identify parenting issues of concern to her, provide emotional support for parenting, and engage her in an educational process guided by parenting pamphlets on topics of the mother's choosing. Pamphlets were designed to offer age-appropriate developmental guidance and behavioral strategies for managing typical parenting challenges with toddlers (e.g., tantrums, bedtime, mealtime, co-parenting), as well as topics of importance for parents in substance use treatment (e.g., self-care, child safety). All pamphlets were written at a 4th grade reading level. A full description of the approach can be found in the treatment manual prepared by this research group (Dalton et al., 2015).

Posttreatment Phase—At the conclusion of the intervention period, mothers participated in two posttreatment assessment visits during which they repeated the interview and self-report measures of PRF, and self-report measures of psychiatric symptoms and substance use. Mothers and target children also repeated assessments of dyadic adjustment and child attachment security. Tables 3 lists assessments completed during this phase.

Follow-up Phase—During the 12-week follow-up period, mothers participated in biweekly visits to complete self-report measures of psychiatric symptoms, substance use, and additional services received in the community. At the end of the follow-up period, measures of PRF, psychiatric symptoms and substance use, dyadic interactional quality, and child attachment security were repeated. See Table 3 for assessments completed during this phase. Upon completion of the entire study, mothers and their children participated in a graduation ceremony with the research staff where they received a personalized certificate of completion and small gifts to acknowledge their progress.

Retention and Compensation—The research environment was designed to maximize the comfort of mother-child dyads and reduce barriers for attendance. Participants received telephone reminders, text messages, and outreach letters as needed, as well as bus passes and developmentally-informed childcare during visits. Mothers received monetary compensation ranging from \$15 to \$50 per research visit, with the payment schedule structured to optimize long-term engagement (e.g., higher payments near end of participation, periodic bonuses for assessments completed as scheduled). Children received a toy for each completed assessment.

Constructs and Measures

Clinical History—A 90-minute, structured intake interview was used to collect demographic information and clinical history. Mothers provided information regarding their psychosocial history including their early childhood development, family history, substance use and psychiatric history, and trauma history. Mothers also provided information concerning their legal, employment, and medical history, as well as the target child's perinatal history including prenatal substance exposure.

Screening Measures

<u>Maternal Intelligence.</u>: The *Kaufman Brief Intelligence Test* (KBIT; Kaufman & Kaufman, 1990), a standardized cognitive screening measure, was used to characterize the sample and ensure mothers met inclusion criteria. The KBIT requires approximately 30 minutes to administer and has good reliability and concurrence with other commonly used measures of cognitive functioning (Bain & Jaspers, 2010; Miller, 1995; Young, 1995)

Child Development.: Two brief assessments were used to screen target children for potential developmental delays. Children's cognitive and language development was assessed using the *Bayley Scales of Infant and Toddler Development Screening Test-3rd Edition* (Bayley, 2006) for toddlers 11–36 months of age, and the *Early Screening Profile* (ESP; Harrison et al., 1990) for preschoolers 36–60 months of age. Research assistants (trained and supervised by a developmental specialist) administered these screening measures during the baseline period, and appropriate referrals for child-centered services were provided for children identified as developmentally at-risk.

Maternal Reflective Functioning

Parent Development Interview.: The *Parent Development Interview* (PDI; Slade et al., 2003), the most widely used instrument for measuring parental mentalization, is a semi-

structured interview designed to elicit a parent's verbal narrative about commonly occurring, emotionally-challenging aspects of parenting infants/toddlers (e.g., times when child might have felt rejected or when parent might have felt angry). As in the previous trial, a 14-item version of the PDI was used in this study with consultation from the principal author of the measure. This brief version was used to minimize assessment burden while also allowing for inclusion of positive emotion items (e.g., Describe a time in the last week when you and your child were really 'clicking') given that in our experience, mothers with SUDs sometimes have difficulty mentalizing about positive experiences. For each item, additional probes were included to encourage the mother to consider her own and her child's experience during these interactions and ways their mental states might have affected their behavior.

PDI interviews were recorded and transcribed verbatim; mothers' responses were coded by reliable coders blind to treatment condition and time of the assessment. Each response was rated on an 11-point scale where a score of 1 indicates complete failure to recognize mental states (events described solely in terms of behavior); a score of 3 indicates limited capacity to acknowledge mental states without any understanding of how mental states function; a score of 5 indicates the presence of a rudimentary capacity for PRF indicating a basic understanding of how mental states work to influence behavior; and scores above 5 indicate increasingly elaborate and sophisticated understanding of how mental states function to influence behavior. A small, randomly selected sample of interviews were used to document the interrater reliability of the PDI coders. In this study, the mean of all responses was calculated, as were the levels of self-focused and child-focused RF (for a discussion, see Suchman, DeCoste, Leigh, et al., 2010). The PDI score of greatest interest was the mean of all 14 items. The coefficient alpha in this sample for this score was .81.

Parental Reflective Functioning Questionnaire.: The Parental Reflective Functioning Questionnaire (PRFQ; Luyten et al., 2017) is an 18-item, self-report instrument that measures three components of parental mentalization: (a) Interest and Curiosity surrounding their child's mental states (e.g., "I like to think about the reasons behind the way my child behaves and feels"), (b) Certainty in the recognition of their child's mental states (e.g., "I always know why my child acts the way he or she does"), and (c) Prementalizing or difficulty in considering the child's mental states (e.g., "My child sometimes gets sick to keep me from doing what I want to do"). Parents indicate their degree of agreement with each statement on a Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). Optimal mentalization is indicated by higher scores on the Interest and Curiosity subscale, moderate scores on the Certainty subscale, and lower scores on the Prementalizing subscale. The PRFQ has good internal consistency, and the subscales are not, or only modestly, related to demographic characteristics. These subscales also do not correlate meaningfully with measures of PRF derived from the PDI in samples of mothers with addictions (Carlone et al., 2022) but are related to attachment, emotional availability, and parenting stress in theoretically consistent ways (Luyten et al., 2017). In this sample the coefficients alpha were .69 for the Prementalization subscale, .47 for the Interest and Curiosity subscale, and .70 for the Certainty subscale.

Mother-Child Dyadic Adjustment

Curiosity Box Paradigm/Coding Interactive Behavior: *The Curiosity Box Paradigm* (CBP; Mayes et al., 1993) was used to assess the quality of mother-child interactions in the context of unstructured setting. The CBP consisted of two sequential 5-minute episodes during which the child and mother were presented with a set of 12 small clear plastic drawers containing novel toys. The first episode included typical toys; in contrast, the second episode included unfamiliar toys meant to cause mild distress in the child (e.g., fake insect, realistic rubber snake). All episodes were audio and video recorded, and the second episodes were coded by an expert coder blind to treatment condition and timepoint using the *Coding Interactive Behavior* system (CIB; Feldman, 1998). The CIB system uses a 5-point Likert scale for rating the quality of interactive behaviors exhibited by the parent, child, and dyad. The presence of specific behaviors is coded from 1 (less prevalent) to 5 (more prevalent), and items are averaged to created subscales representing different dimensions of parent-child interaction. Coefficient alpha for the nine subscales involving two to eleven items ranged from .90 for the 11-item Maternal Sensitivity scale to .45 for the 3-item Child Compliance scale.

Nursing Child Assessment Satellite Training .: The Teaching Scale of the Nursing Child Assessment Satellite Training (NCAST; Barnard & Eyres, 1979) was used to further assess mother-child dyadic adjustment. The NCAST Teaching Scale asks mothers to teach their child a new, age-appropriate skill (e.g., stringing beads, drawing shapes, etc.) selected from the NCAST manual. The assessments, lasting 5 minutes each, were audio and video recorded, and coded by reliable coders based on the interactive behavior displayed within the dyad rather than the child's performance or learning of the skill. Items reflecting different dimensions of parent-child interaction are coded as being present (1) or absent (0), and items are summed to create subscales and totals reflecting different dimensions of parent and child behavior. Specifically, maternal behavior is coded based on (a) sensitivity to the child's cues (11 items, Cronbach's $\alpha = .56$), (b) response to the child's distress (11 items, Cronbach's $\alpha = .72$), social-emotional growth fostering (11 items, Cronbach's $\alpha = .37$), and (d) cognitive growth fostering (17 items, Cronbach's $\alpha = .49$). A total caregiver score representing the sum of the four caregiver subscale scores can also be calculated (50 items, Cronbach's $\alpha = .75$). Each subscale contains a subset of items that can be coded present or absent based on the contingency of the mother's response to the child (i.e., whether the mother's response to the child occurs within 5 seconds of the child's cue; 20 items, Cronbach's $\alpha = .66$). Children's behavior is coded based on (a) clarity of cues (10 items, Cronbach $\alpha = .28$), and responsiveness to caregiver (13 items, Cronbach $\alpha = .54$). A total child score can be calculated as the sum of the two child subscales (23 items, Cronbach's $\alpha = .64$). Within the response to caregiver subscale, 12 items can be coded based on the contingency of the child's response to the mother (i.e., whether the child's response occurs within 5 seconds of the mother's cue).

Child Attachment Security—The *Strange Situation Procedure* (SSP; Ainsworth et al., 1978) was used to document potential changes in child attachment classification. The SSP is designed to elicit child attachment behavior through a series of separations from, and reunions with, the caregiver. Valid and reliable coding systems are available for the SSP

when used with children 12–54 months of age, although there is no single method for coding attachment classification that covers the full age range of target children included in this study. Consistent with previous studies of attachment-based parenting interventions (Hoffman et al., 2006; Solomon & George, 2008; Suchman et al., 2017; Toth et al., 2006) we used the Ainsworth SSP protocol and coding system (8 episodes, 3 with a stranger) for children younger than 24 months, and the MacArthur Preschool Separation-Reunion Procedure and coding system (5 episodes, with no stranger; Cassidy et al., 1992) for children 24–54 months of age. These approaches both include separation and reunion sequences, though they differ in the quantity and length of these sequences, and whether or not a stranger is present. Both approaches allow researchers to classify child attachment into one of three global categories: secure, insecure, and disorganized.

Although our assessments of attachment were at least 3 months apart from one another and practice effects are only likely to occur when the SSP is repeated over very brief intervals (i.e., 2–4 weeks; Solomon & George, 2008), we further minimized practice effects by (a) conducting the SSP in a new setting with a new stranger unfamiliar to the child and mother at each time point and (b) providing novel toys to the child and mother. The SSP was audio and video recorded and then coded by a single reliable rater trained to code attachment status using both SSP procedures. To examine group differences in child attachment security as a function of mothers' participation in either MIO or PE, we collapsed the two age groups and created a binary outcome where a score of 1 represented secure attachment and a score of 0 represented insecure or disorganized attachment.

Maternal Psychiatric Distress

Beck Depression Inventory (Second Edition).: Maternal depression was assessed using the *Beck Depression Inventory-Second Edition* (BDI-II; Beck et al., 1996). The BDI-II is a widely used self-report questionnaire consisting of 21 questions rated on a 4-point Likert scale where higher scores are associated with more severe depression. The BDI-II has well-documented good internal consistency and construct validity (Beck et al., 1996). In this sample, the coefficient alpha for the scale was .91. Scores range from 0 to 63. Scores below 19 reflected the presence of minimal or mild depression, whereas scores ranging from 20 to 63 were reflected moderate or severe depression. The total score represented level of depressive symptoms. A dichotomous marker coded 1 (moderate to severe) versus 0 (minimal or mild) was also created using normative data and guidelines provided by Beck et al. (1996) to represent the presence/absence of clinically significant depression.

Brief Symptom Inventory.: The breadth and severity of mothers' psychiatric distress was assessed via the *Brief Symptom Inventory* (BSI; Derogatis, 1993), a widely-used standardized self-report questionnaire consisting of 53 items rated on a 5-point Likert scale ranging from 0 (*not at all*) to 4 (*extremely*), with higher total scores reflecting greater levels of distress over the previous 2 weeks. The BSI yields a Global Severity Index (GSI), which is the mean of all 53 items and reflects the breadth and severity of psychiatric symptomatology. For this study, the GSI was used as a second marker of psychiatric distress. Again, a dichotomous marker coded 1 (yes) versus 0 (no) to represent the presence of

clinically significant distress was created using normative data and guidelines provided by (Derogatis, 1993). For this sample, the coefficient alpha for the full scale was .97.

Maternal Substance Use—Mothers' substance use was monitored weekly during treatment and biweekly during follow-up using a 12-item, self-report questionnaire consisting of Likert-type questions assessing craving for substances and frequency of substance use since their last visit to the program. After preliminary analysis of the pattern of substance use within the full sample, it was summarized as any use of opioids, any use of cocaine, and any use of alcohol/other illicit substances per week. Use of alcohol and other illicit substances was summarized in a single measure because use of alcohol, benzodiazepines, amphetamines, hallucinogens, and other illicit substances was most limited.

Data Analysis

Because the variables of interest involved a mix of continuous, count, dichotomous, and multinomial variables, generalized linear modeling techniques (Dahmen & Ziegler, 2004; Hoffmann, 2016) were used to analyze the data generated by this randomized clinical trial. When the statistical analysis involved a single measurement of the dependent variable, guidelines similar to those outlined by Hoffmann (2016) were followed. When the dependent measure had been collected repeatedly from the same participant over time, guidelines outlined by Dahmen and Ziegler (2004) concerning the use of generalized estimating equations (GEE), the technical extension of the general linear model to research designs requiring the statistical analysis of correlated measures, were followed.

The data were analyzed in four steps. First, general linear modeling was used to test for between-group (MIO versus PE) differences in the demographic, clinical, and family characteristics of mothers assigned to each parenting intervention. Second, general linear models and GEE were used to test for between-group (MIO versus PE) differences in intervention and research process measures. Finally, GEE was used to test for (a) between-group differences in the baseline measures of treatment outcomes, (b) within-group change over time, and (c) between-group differences in change over time. Because preliminary analysis indicated the pattern of missing data was best characterized as intermittent rather than monotone, an unweighted GEE was computed using the GEE procedure available in SAS/STAT 9.4 (SAS Institute, 2021).

Across statistical analyses, dummy coding was used to represent treatment assignment (MIO versus PE); and descriptive statistics, graphical representation, and goodness of fit statistics were used to determine the most appropriate response distribution and link function for use in the final analysis of each dependent variable. Across the cluster of repeated-measures analyses, time was coded as a continuous variable representing weeks since the baseline measurement of each outcome, and the repeated measures were consistently modeled with specification of an autoregressive covariance structure. Years of maternal education and age of the child were entered as demographic covariates.

Consistent with the CONSORT recommendations (Moher et al., 2012; Schulz et al., 2010), primary and secondary outcomes were analyzed for the intention-to-treat (N= 94) and

then the per-protocol (n = 60) samples. Specifically, per guidelines elaborated upon by Moher et al. (2012), our intention-to-treat sample consisted of "all participants according to their original group assignment, regardless of what subsequently occurred" in order to "avoid bias associated with non-random loss of participants" (p. 44). However, given that "non-compliance with assigned therapy may mean that the intention-to-treat analysis underestimates the potential benefit of the treatment," we also included a per-protocol analysis (Moher et al., 2012, p. 44). The per-protocol sample included all mothers who participated in an adequate dose of their assigned intervention, defined as six or more treatment sessions. Given the limited sample size and the potential costs of a Type II error in a randomized clinical study with relatively small intention-to-treat and per-protocol samples, statistics with p values less than .10 were considered statistically significant. As in previous evaluations of these interventions (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017), there was interest in documenting the presence of theoretically consistent findings across variables and across the intention-to-treat versus per-protocol samples.

Results

Preliminary Analyses

Demographic, clinical, and family status of the mothers assigned to the two treatment groups are summarized in Tables 1 and 2. As noted, there were no significant between-group differences in demographic characteristics, patterns of substance use, or characteristics of the target child. Mothers in the PE group were more likely than mothers in the MIO group to have a biological father who used substances, and they were more likely to be living with the father of the target child.

Process measures reflecting participation in the study by treatment group are summarized in Table 4. Of mothers assigned to participate in MIO, 70% attended one or more treatment sessions following randomization; of mothers assigned to participate in PE, 86% attended one or more treatment sessions following randomization. There was, however, no significant difference in number of treatment sessions attended by treatment group. Mothers participating in MIO attended 57.25% of intervention visits and 59.20% of research visits. Mothers participating in PE attended 67.25% of intervention visits and 67.53% of research visits. As expected, MIO counselors used MIO techniques more frequently than PE counselors. PE counselors also used PE techniques more frequently than MIO counselors. There was no difference in the frequency of generic relationship-building techniques used.

As noted in Tables 5 and 6, mothers in the intention-to-treat and per-protocol samples demonstrated generally low mean, self-focused, and child-focused PRF on the PDI at baseline after controlling for years of maternal education and age of the child. Mothers also began with high interest and curiosity, moderate certainty about mental states, and low prementalizing scores on the PRFQ. In terms of dyadic adjustment, mothers demonstrated relatively frequent positive parenting behavior and relatively infrequent negative parenting behavior on the CIB and the NCAST Teaching Scale. In terms of children's contribution to dyadic adjustment, they proved relatively responsive to their mothers on both the CIB and the NCAST Teaching Scale. Fifty-nine percent of the children demonstrated secure

attachment at baseline. The correlation between years of maternal education and most parenting behaviors was low to moderate (.05 < |r| > .30) at baseline. Correlation with age of the child and the clinical variables of interest was minimal (|r| > .20).

As indicated in Tables 7 and 8, psychiatric distress was, on average, clinically significant for both the intention-to-treat and per-protocol samples at baseline after controlling for maternal education and the age of the child with 45% of the mother reporting at least mild depression on the BDI and 29% reporting clinically significant psychiatric distress on the BSI. There was very little report (< 1%) of opioid use during the week before enrollment, limited report (3%) of cocaine use, and some report (21%) of other substance use, including the use of alcohol.

As also noted in Tables 5 through 8, there were, with few exceptions, no significant between-group differences at baseline in PRF, most dimensions of mother-child dyadic adjustment, child attachment security, psychiatric distress, or substance use within either the intention-to-treat or per-protocol sample. In the intention-to-treat and per-protocol samples, mothers assigned to MIO demonstrated significantly more cognitive growth fostering behavior during the NCAST compared to mothers assigned to PE, and children of mothers assigned to MIO demonstrated significantly less timely responses compared to children of mothers assigned to PE. In the per-protocol sample, mothers assigned to MIO demonstrated more adaptive overall caregiving behavior on the NCAST.

Primary Outcomes

Intention-to-treat sample.—Mothers who participated in MIO demonstrated a significant decrease in one dimension of PRF (certainty about their children's mental states on the PRFQ). Compared to mothers in the PE group, there was a significant difference in the pattern of change. In contrast, there were no significant findings involving mothers' prementalizing, or interest and curiosity on the PRFQ. There were also no significant within-group change and no significant between-group differences in the rate of change for any of the dimensions of maternal PRF as measured by the PDI. See Table 5 for more detail.

Per-protocol sample.—A similar pattern involving change in PRF emerged in the perprotocol sample for mothers' certainty about their children's mental states on the PRFQ, but the within and between-group differences did not prove statistically significant. There were also no significant within-group change or between-group differences in the rate of change for any of the other dimensions of PRF as measured by the PRFQ and the PDI. See Table 6 for more detail.

Secondary Parenting Outcomes

Dyadic Adjustment

Intention-to-treat sample.: Results concerning change in dyadic adjustment are summarized in Table 5. As noted, there were several significant within-group changes and between-group differences in the rate of change across the two measures of dyadic adjustment. On the CIB, there was a decline in maternal sensitivity within both groups that proved significant for the MIO group and not the PE group, but the difference in the rate

of change did not prove significant. Contrary to this, there were no significant changes in maternal sensitivity within either group on the NCAST. On the CIB, there were significant declines in limit setting within both groups, and no significant differences in the rate of change. On the CIB, there was an increase in maternal behavior promoting cognitive growth within both groups that proved significant for the PE group and not the MIO group, but the difference in the rate of change did not prove significant. There were no other significant findings involving maternal behavior on either the CIB or the NCAST.

As noted in Table 5, there were more significant and more consistent changes in the behavior of the children during the two dyadic assessments. On the CIB, children in the PE group demonstrated a significant decline in compliance that was not evident in the MIO group, and the difference in the rate of change proved significant. There were no significant changes in children's involvement with their mothers or their withdrawal from their mothers on the CIB. However, when compared to children of mothers who participated in PE, children of mothers who participated in MIO demonstrated a significant increase in clarity of cues, and the difference in the rate of change proved significant. Similarly, children of mothers who participated in PE demonstrated a significant decrease in their responsiveness to their mothers that was not evident in the MIO group, but the difference in the rate of change did not prove significant. Children of mothers who participated in PE also demonstrated a significant decrease in the timeliness of their response to their mothers that was not evident in the rate of change did prove significant. Finally, there were no significant findings on the CIB for dyadic reciprocity or negative dyadic states.

Per-protocol sample.: An identical pattern of results concerning dyadic adjustment emerged in the per-protocol sample where there were again significant findings involving maternal sensitivity and limit setting on the CIB and maternal behavior fostering cognitive growth on the NCAST. There was an increase in maternal intrusiveness within both groups that only proved significant within the MIO group. Likewise, there were again consistent findings involving the children's general behavior involving compliance, clarity of cues, responsiveness, and timeliness of responsiveness. Table 6 outlines these findings in more detail.

Child Attachment Security

Intention-to-treat sample.: There were no significant findings involving within-group change or between-group differences in rate of change for children's attachment security as assessed by the SSP. Children of mothers who participated in MIO versus PE did not differ in the probability of change to a secure attachment classification. See Table 5 for more detail.

<u>Per-protocol sample.</u> There were also no significant findings for attachment security in the per-protocol sample. Children whose mothers participated in at least six sessions of MIO versus PE did not differ in the probability of change to a secure attachment classification. See Table 6.

Secondary Maternal Outcomes

Psychiatric Distress

Intention-to-treat sample.: Within the intention-to-treat sample, mothers in the MIO group, but not the PE group, demonstrated a significant decrease in their depressive symptoms on the BDI-II, though the rate of change did not differ significantly between the two groups. No significant within-group changes nor between-group differences in the rate of change were noted for mothers' clinically significant depressive symptoms on the BDI-II or psychiatric distress on the BSI. See Table 7.

Per-protocol sample.: For mothers who participated in six or more treatment sessions, the significant decline in depressive symptoms was again evident, and the rate of change differed significantly from that for the PE group. There was also a significant decline in psychiatric distress within the MIO group that was not evident in the PE group, but the rate of change did not differ significantly between the two groups. A lower rate of clinically significant distress over time in the MIO group also differed significantly from the higher rate over time evident in the PE group. See Table 8.

Substance Use

Intention-to-treat sample.: Compared to mothers who participated in MIO, mothers who participated in PE demonstrated a significant increase in self-report of opioid use over time, and the rate of change for the two groups differed significantly. Similarly, there was a significant increase in self-report of other substance use that was not evident in the MIO group, but the rate of change for the two groups did not differ significantly. There were no significant findings for change in maternal cocaine use. See Table 7.

Per-protocol sample.: The same pattern of results for opioid use emerged in the perprotocol sample. Compared to mothers who participated in MIO, mothers who participated in PE demonstrated a significant increase in self-report of opioid use over time, and the rate of change for the two groups differed significantly. Within the per-protocol sample, there were no significant findings for change in maternal cocaine use or other substance use. See Table 8.

Discussion

MIO, a brief individual mentalization-based parenting intervention for mothers in recovery from an SUD, has demonstrated efficacy at improving parenting and decreasing psychiatric distress and substance use in two prior randomized clinical trials (Suchman et al., 2008; Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017). In an effort to scale the delivery of MIO, increase its reach to mothers who may benefit, and avoid the science-to-service gap in which evidence-based interventions lose efficacy when translated directly to the community setting, we began by training addiction counselors to deliver MIO or PE with fidelity (see Suchman et al., 2020 for a description of these training outcomes). Here, we reported the results from the randomized community-based efficacy trial aimed at examining the efficacy of MIO vs. PE when delivered by these addiction counselors.

The primary goal was to test MIO under conditions of high internal validity where addiction counselors were provided with the training and supervision necessary to deliver MIO or PE with sustained fidelity. Given our previous findings that the addiction counselors who participated in this study could be trained to deliver treatment with fidelity (Suchman et al., 2020), we expected similar results seen in the two prior trials. Specifically, we anticipated that when compared to mothers who participated in PE with an addiction counselor, mothers who participated in MIO with an addiction counselor would demonstrate greater improvements in PRF, greater improvements in dyadic adjustment, and more frequent improvements in child attachment security. We also expected that they would demonstrate greater decreases in psychiatric distress and risk for relapse to substance use.

Our hypotheses were partially supported. As would be expected, the pattern of findings for the intention-to-treat sample versus the per-protocol sample (where there was exposure to at least six sessions of MIO) were similar but more robust in the per-protocol sample. This absence of large differences between the intention-to-treat and per-protocol samples is consistent with the most recent MIO trial (Suchman et al., 2017). However, given that findings across both the intention-to-treat and per-protocol samples were generally consistent, our discussion focuses on the results in general rather than dissecting any minor differences between the two groups. Overall, we found that mothers who participated in MIO demonstrated a significant decrease in certainty about their child's mental states, as well as a significant decrease in depression and psychiatric distress. Further, children whose mothers participated in MIO, but not children whose mothers participated in PE, demonstrated significant increases in the clarity of their cues when interacting with their mothers. In contrast, mothers who participated in PE demonstrated a significant increase in the use of opioids and other substances; their children also demonstrated a significant decline in responsiveness to their mothers, compliance with maternal requests, contingency of responses, and overall dyadic adjustment that was not evident in the MIO group. Mothers in both groups demonstrated a decline in limit setting behavior. Mothers in the PE group demonstrated an increase in behavior designed to promote cognitive growth, and mothers in the MIO group demonstrated an unexpected, inconsistent decline in maternal sensitivity on one observational measure but not the other. These findings and their implications are discussed in greater detail below.

Representational, Behavioral, and Relational Outcomes

Theoretical work underpinning the development of MIO highlights the importance of maternal behavioral change occurring as a result of change at the representational or mental level. That is, change should occur *from the inside out*, with improvements in the mother's PRF (representational level) cascading to improvements in caregiving behavior by the mother (behavioral level) followed by improved dyadic outcomes (relational level). Our prior work supports these proposed mechanisms (Suchman et al., 2018; Suchman et al., 2012); however, the current study yielded a somewhat different, unexpected pattern, with changes appearing at the relational level despite an absence of observed improvements in the mother at the representational or behavioral level.

One potential reason for this is that, except for the PDI, the mothers and children in our sample were faring relatively well at baseline. Prior to any treatment, mothers in both the MIO and PE groups showed generally high levels of interest and curiosity and frequent positive parenting behavior, representing potential ceiling effects, paired with low levels of pre-mentalizing and relatively infrequent negative parenting, resulting in potential floor effects. We did, however, observe a decrease in certainty about mental states on the PRFQ exhibited by mothers who participated in MIO, which may potentially reflect increased flexibility and openness in thinking about their children's mental states, a desired outcome of MIO. However, this finding alone, in conjunction with lack of improvement on the PDI, is not enough to assert that mothers became more reflective as a result of participation in MIO delivered by an addiction counselor. The discrepancies between mothers' PRF scores on the PRFQ and PDI may also reflect social desirability effects on self-report measures (PRFQ) that interview measures (PDI) are more immune to. The question of changes in one measure of PRF versus the other is also complicated by recent work demonstrating minimal correlation between the PDI and PRFQ in several samples of mothers, including samples of mothers in substance use treatment (Carlone et al., 2022). Overall, however, our present findings raise important questions about why MIO showed diminished efficacy at improving mothers' PRF when it was delivered by community-based providers.

Given the lack of broad change in mothers' PRF beyond a decrease in certainty about mental states, we were not surprised by the lack of improvement in mothers' caregiving behavior following MIO. The decline in maternal sensitivity in our sample was contrary to our expectations and is worth exploring. It may be possible that the increase in intrusiveness shown by mothers who participated in MIO reflects an increased yet ineffective effort to be more engaged during dyadic interactions, or perhaps an unconscious performative attempt to display to the observer a close bond with her child. The decrease in limit-setting observed in both the MIO group and the PE group and the decrease in sensitivity observed in the MIO group is disappointing and raises important implementation questions as to why sensitivity would decrease in response to MIO when it was delivered by community-based clinicians, but increase in response to MIO delivered by research clinicians. Lastly, given that PE was psychoeducational in nature, it is no surprise that mothers in this group demonstrated an increase in cognitive growth fostering behavior whereas mothers in the MIO group did not show increases in this area.

Notably, however, we replicated previous findings that participation in MIO was associated with positive downstream outcomes for children. Specifically, children of mothers who participated in MIO demonstrated a significant increase in their clarity of cues during dyadic interactions and maintained their overall level of dyadic adjustment over time, whereas children of mothers in the PE group demonstrated worsened dyadic adjustment over time. Specifically, participation in PE was associated with decreased child compliance, clarity of cues, responsiveness to their mothers, and overall adjustment within the mother-child relationship. These results mirror the ways in which behaviorally-based psychoeducational approaches have not typically supported parent-child relational outcomes (Suchman et al., 2006). This deterioration in children's behavior may not necessarily indicate that psychoeducational parenting interventions are harmful; rather, the longitudinal design of the study may be highlighting risk for the early development of externalizing behavior

frequently evident in preschool children exposed to parental addiction (Edwards et al., 2006; Eiden et al., 2014; Jaekel et al., 2021) that some researchers believe represents temperamental differences aggravated by early exposure to family adversity (Tarter et al., 1999). The lack of behavioral deterioration in children whose mothers participated in MIO suggests that MIO may be protective of the parent-child relationship, but when delivered by addiction counselors in community-based settings, MIO may not be powerful enough to broadly improve PRF, caregiving behavior, and children's attachment security.

Other Maternal Outcomes

Previous trials of MIO suggested that participation in mentalization-based parenting support was associated with decreased substance use and decreased depression (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017). The current trial replicated some of these results, with MIO mothers, particularly mothers who participated in 6 or more sessions, demonstrating significantly reduced depressive symptoms, less psychiatric distress, and less frequent use of opioids. These results are important in light of our findings that children of mothers who participated in MIO demonstrated increases in their clarity of cues during dyadic interactions. Whereas we previously thought that this improvement in child behavior may have resulted from an improvement in mothers' PRF and caregiving sensitivity, our current findings may suggest that children's behavior may be impacted by decreases in their mothers depression and substance use, corroborating previous research (Cuijpers et al., 2015; Weissman et al., 2006; Weissman et al., 2015) with potential links to a reduction in parenting stress (Rutherford & Mayes, 2019).

Implications

The results of this community-based efficacy trial have important implications when it comes to determining the next steps for the implementation and dissemination of MIO. Given two prior trials showing that MIO was effective at improving mothers' PRF and caregiving behavior when it was delivered by research clinicians (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017), the current findings raise the question of why MIO was less efficacious at improving these same outcomes when it was delivered by community-based clinicians. Despite prior work showing that addiction counselors could be trained to deliver MIO with fidelity (Suchman et al., 2020), there may still be an issue of *intervention-intervenor fit*. For example, although there is significant variability across the United States with regard to training requirements for licensure and certification as an addiction counselor, training programs and community-based training sites are often grounded in the Minnesota model (i.e., 12-steps) or emphasize cognitivebehavioral and solution-focused approaches (Olmstead et al., 2012; Whittinghill, 2006). The theoretical foundations underlying these approaches that emphasize problem-solving and curriculum are in stark contrast to those of mentalization-based approaches grounded in attachment and psychodynamic theories that emphasize relationships and process. Further, the daily activities of addiction counselors typically center around case management, problem solving, assessment, treatment planning, relapse prevention, and harm reduction (Whittinghill, 2006). These activities are in contrast to the work of mentalizing which emphasizes slowing down and thinking collaboratively with a client to make sense of

behavior in terms of underlying mental states and becoming more attuned to one's own and others' emotional needs.

Additionally, although weekly reflective supervision may have facilitated counselors' fidelity to MIO in our study, the substance use treatment system in the United States often presents barriers to mentalization and reflective practice including large caseloads in combination with high acuity patients and high productivity demands. MIO's efficacy in this study may thus have been impacted by burnout experienced by community-based substance use counselors, which recent research indicates is negatively associated with constructs akin to mentalizing (i.e., emotional intelligence; Gutierrez et al., 2019). There is also evidence that individuals who enter the helping professions very often have experienced childhood trauma of their own (Black et al., 1993; Esaki & Larkin, 2013; Howard et al., 2015), and individuals who enter the substance use treatment field in particular are frequently in recovery from addiction themselves (Curtis & Eby, 2010; Knudsen et al., 2006; McNulty et al., 2007). Scholars have suggested that these lived experiences have the potential to elicit countertransference reactions, influence providers' reflective capacity and clinical decision making, and predispose counselors to vicarious trauma and compassion fatigue (Bosk et al., 2020; Esaki & Larkin, 2013; Howard et al., 2017; Novotna et al., 2013). Similar to previous qualitative work investigating the adaptation and implementation of MIO into home visiting settings, an overarching paradigm shift toward a relational framework may be necessary in the substance use treatment system as well in order to support the effective implementation of this intervention (Peacock-Chambers et al., 2022). Of course, this initial shift will likely require significant training and support at multiple levels, and the sustainment of such changes will likely require time, funding, staffing, and flexibility (Lowell et al., 2022).

Given that we did not see the robust improvements in PRF and caregiving behavior that was seen in prior trials, more information is needed from hybrid implementationeffectiveness studies about what addiction counselors and addiction programs need in order to deliver efficacious parenting interventions. Our findings confirm prior work suggesting that psychoeducational parenting interventions do not have a robust effect on dyadic outcomes (Milligan et al., 2020; Niccols et al., 2012; Suchman et al., 2004; Suchman et al., 2006). However, because MIO prevented deterioration in children, was not associated with increases in substance use, and was associated with improvements in depression, we suggest that there is promise in these principles and future work should seek to identify ways to maximize their fit within the addiction treatment context. This may be most effective in the context of a systemic change toward more family-oriented intervention within the addiction treatment system that minimizes the harm parental addiction has on parents and their children, something that researchers have been advocating for over many years (McMahon & Luthar, 1998).

Limitations

Although the results of the study support the continued development of MIO, there are some limitations associated with the research design that should be acknowledged. First, the sample was relatively small, particularly the per-protocol sample. Consequently, the sample may not have been adequate to detect small, but potentially meaningful, within and between-

group differences in the clinical outcomes because of limited statistical power, particularly for the per-protocol analysis. Second, despite substantial effort to engage mothers by both the addiction counselors and the research assistants, participation in treatment was rather limited, particularly in the MIO group where 30% of the mothers did not attend any intervention sessions following randomization. By design, MIO was also delivered by addiction counselors with adequate training and supervision. Although 12 weeks of exposure to MIO proved adequate when delivered by expert clinicians in previous trials, exposure to the treatments may not have been consistent or persistent enough to produce substantial change in the targeted outcomes when delivered by addiction counselors who, by virtue of their professional background, had limited experience delivering child and family interventions.

There are also unresolved questions about how to best measure PRF, parenting behavior, and the quality of parent-child relationships. Although the measures chosen for use in this study have been used in similar research, including previous comparisons of these parenting interventions (Suchman, DeCoste, Castiglioni, et al., 2010; Suchman et al., 2011; Suchman et al., 2017), there is not agreement about the best methods for measuring parenting constructs, and there was some inconsistency in the pattern of results across measures of PRF and dyadic adjustment within mothers that participated in MIO. Further, given that child attachment is a deep structural quality that may be resistant to change unless the external circumstances in a family's life change dramatically, our repeated measurement of attachment over relatively short time periods may have been insufficient at capturing other clinically meaningful changes in the emotional quality of the parent-child relationship. Overall, it is possible that other approaches to measurement of key constructs may have produced different results.

Future Directions

In future research it will be imperative to examine factors underlying the diminished efficacy of MIO when delivered by community-based clinicians. This raises the question of intervention-intervenor fit and how we may identify clinicians and settings best suited to deliver MIO so its efficacy is maintained. Future research is needed to clarify how to effectively integrate parenting interventions that have proven efficacious in research settings into community-based programs. Specifically, future studies should be designed to clarify how (a) characteristics of the client, (b) characteristics of the counselor, (c) characteristics of the clinical setting, (d) treatment dose/intensity, (e) quality of training and supervision, (f) counselor fidelity to the treatment model, and (g) measurement issues may be affecting the impact of MIO on parent and child outcomes. Our findings also highlight the need for an implementation science approach to examine barriers and facilitators to the delivery of MIO by addiction counselors. Qualitative work should specifically seek to understand the experiences of addiction counselors who deliver MIO, including whether MIO fit with their goals and values, whether they think MIO should be used as compared to other approaches used within their treatment settings, and whether they feel their own trauma or addiction histories may have influenced their delivery of MIO or their family-based work more broadly.

Clarification of mediators and moderators of clinical outcomes will also undoubtedly inform the design of implementation-effectiveness research done with larger samples (Curran et al., 2012). Given research being done on different approaches to the measurement of key constructs in parenting research (Carlone et al., 2022), additional work might also explore the utility of more economical, ecologically valid assessments of PRF, parenting behavior, and quality of the parent-child relationship (e.g., parental embodied mentalizing, mind-mindedness; Shai & Meins, 2018) rather than more expensive, time-consuming measures that may not capture these phenomena occurring in more naturalistic settings.

Conclusions

MIO is a mentalization-based parenting intervention designed specifically for mothers in treatment for addictions, aimed at improving the quality of mother-child relationships during early childhood by increasing mothers' capacity for PRF. Two previous trials documented a theoretically consistent pattern of efficacy and mechanisms of influence when MIO was delivered by research clinicians in a research setting. When MIO was delivered by community-based clinicians, the pattern of efficacy differed, raising questions about influences in a science-to-service gap and intervention-intervenor fit. Future research should identify influences on implementation and effectiveness to inform the dissemination of MIO as an adjunct to treatment-as-usual for mothers experiencing addiction and other threats to sensitive caregiving.

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Research data are not available to be shared.

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Key Findings

- When compared to mothers who participated in a psychoeducational parenting intervention, mothers who participated in Mothering from the Inside Out (MIO), a mentalization-based parenting intervention, demonstrated some improvement in reflective functioning and psychiatric symptoms. Their children also demonstrated some improvement in behavior during mother-child interactions.
- When compared to children of mothers who participated in MIO, children
 of mothers who participated in a psychoeducational parenting intervention
 demonstrated some deterioration in behavior during mother-child interactions
 and an increase in the use of opioids and other substances. Participation in
 MIO was not consistently associated with a similar deterioration, though the
 improvement in the quality of mother-child interaction and substance use
 were limited.
- When compared with the results of previous research using research clinicians, the positive changes associated with exposure to either parenting intervention when delivered by addiction counselors in a community-based setting were less robust. Further research is thus needed to clarify how to effectively integrate parenting interventions that have proven efficacious in research settings into community-based programs.

Table 1

Demographic and Clinical Characteristics of Mothers by Treatment Group: Intention-to-Treat Sample

Construct			
Characteristic	MIO	PE	X ² between
Demographic			
Age in years	31.36 (4.00)	30.56 (4.03)	0.94
Years of education	13.13 (1.77)	12.95 (2.04)	0.21
Employed	16 (30.19%)	10 (24.39%)	0.39
Racial-ethnic heritage			0.25
European American/White	39 (73.59%)	32 (78.04%)	
African American/Black	6 (11.32%)	2 (4.88%)	
Hispanic/Latina	5 (9.43%)	3 (7.32%)	
Asian American	0 (0.00%)	1 (2.44%)	
Other/multiple	3 (5.66%)	3 (7.32%)	
Marital status			0.45
Never married	20 (37.74%)	11 (26.83%)	
Married/cohabitating	28 (52.83%)	28 (68.29%)	
Separated/divorced	5 (9.43%)	2 (4.88%)	
Living independently ^a	35 (66.04%)	26 (63.41%)	
Number of biological children	1.94 (1.03%)	1.95 (1.07%)	0.00
Substance use			
Primary use of opioids	49 (92.45%)	38 (92.68%)	0.00
Withdrawal symptoms d	10.68 (2.73)	10.63 (2.94)	0.01
Dependence symptoms ^e	7.17 (1.22)	7.29 (1.23)	0.24
Medication-assisted treatment	48 (90.57%)	36 (87.80%)	0.18
Early initiation of substance use			
Alcohol ^b	21 (39.62%)	15 (36.59%)	0.09
Cannabis ^b	19 (36.54%)	14 (35.00%)	0.02
Opioids ^C	23 (46.94%)	22 (56.41%)	0.78
Cocaine ^c	30 (61.22%)	21 (56.76%)	0.17
Child welfare involvement	16 (30.19%)	13 (31.71%)	0.02
Maternal intelligence			
Standardized verbal score f	92.24 (11.01)	90.83 (10.73)	0.26
Standardized non-verbal score f	100.31 (15.63)	97.73 (13.53)	0.48

Note. N = 94 for the intention-to-treat sample; n = 53 for the MIO group; and n = 41 for the PE group. Values for each group (MIO versus PE) represent the mean (standard deviation) for continuous variables and the count (percent) for the categorical variables. $X^2_{between}$ represents the X^2 statistic associated with a test for significant between-group differences in a generalized linear analysis done with specification of the appropriate distribution and link function for the dependent variable.

^aLiving independently in the community with the target child either as a single parent or with a spouse or domestic partner

b 13 years of age

^c 18 years of age

^dCount of 15 symptoms

^eCount of 8 symptom

 ${}^{f}_{M}$ = 100 (SD = 15) for the standard scores in the general population

$$p^{**} < .05.$$

p < .01.

Table 2

Family Characteristics of Mothers by Treatment Group: Intention-to-Treat Sample

Construct			
Characteristic	MIO	PE	X^2 between
Target child			
Age in months	31.17 (12.79)	29.73 (16.11)	0.23
Female gender	28 (52.83%)	19 (46.34%)	0.39
Prenatal exposure to substances			
Cigarettes	35 (67.31%)	30 (75.00%)	0.64
Opioids	12 (22.64%)	9 (21.95%)	0.01
Cannabis	8 (15.09%)	9 (22.50%)	0.83
Cocaine	6 (11.32%)	6 (14.63%)	0.23
Sedatives	7 (13.21%)	5 (12.20%)	0.02
Alcohol	5 (9.43%)	1 (2.44%)	1.89
Hallucinogens	3 (5.66%)	1 (2.44%)	0.59
Other drugs of abuse	1 (1.89%)	1 (2.44%)	0.03
Infant birth weight in pounds	6.86 (1.38)	6.83 (1.25)	0.02
Infant opioid detoxification	18 (33.96%)	20 (48.78%)	2.09
Days hospitalized at birth	6.38 (6.17)	8.26 (10.11)	1.66
Developmental status			
Bayley Scales ^a			
Cognition	21 (75.00%)	20 (68.97%)	0.26
Receptive communication	19 (67.86%)	19 (51.72%)	1.52
Expressive Communication	20 (71.43%)	22 (75.86%)	0.14
Early Screening Profiles b			
Cognition/language	16 (100%)	9 (90%)	0.00
Father of target child			
Age	33.67 (5.81)	34.88 (6.65)	0.94
Living with mother and child	24 (45.28%)	26 (63.41%)	3.01*
Involved care of the child	46 (86.79%)	33 (80.49%)	0.68
Family history of substance use			
Biological mother	32 (61.54%)	22 (56.41%)	0.24
Biological father	33 (63.46%)	30 (81.08%)	3.15*

Note. N = 94 for the intention-to-treat sample; n = 53 for the MIO group; and n = 41 for the PE group. Values for each group (MIO versus PE) represent the mean (standard deviation) for continuous variables and the count (percent) for the categorical variables. $X^2_{between}$ represents the X^2 statistic associated with a test for significant between-group differences in a generalized linear analysis done with specification of the appropriate distribution and link function for the dependent variable.

^{*a*}The Bayley Scales Bayley Scales of Infant and Toddler Development Screening Test (3rd Edition) (Bayley, 2006) were administered to children 11to 36 months of age. n = 28 for the MIO group; n = 29 for the PE group. Values for each group (MIO versus PE) indicate the count (percent) of children demonstrating competence in each domain of cognitive and language development.

bThe Early Screening Profiles (Harrison et al., 1990) were administered to children 37 to 60 months of age. n = 16 for the MIO group, n = 10 for the PE group. Values for each group (MIO versus PE) indicate the count (percent) of children demonstrating competence in cognitive and language development.

* p<.10. ** p<.05. *** p<.01.

Table 3

Assessment Schedule

Assessment	Baseline	Weekly	Monthly	Posttreatment	Follow-up
Clinical history	Х				
Parent Development Interview (PDI)	Х			Х	Х
Parental Reflective Functioning Questionnaire (PRFQ)	Х			Х	Х
Kaufman Brief Intelligence Test (KBIT)	Х				
Developmental assessment	Х				
NCAST Teaching Scale	Х			Х	Х
Curiosity Box Paradigm (CBP)	Х			Х	Х
Strange Situation Paradigm (SSP)	Х			Х	Х
Beck Depression Inventory (BDI)	Х		Х	Х	Х
Brief Symptom Inventory (BSI)	Х		Х	Х	Х
Self-report of substance use	Х	x ^a		Х	Х

Note. An X indicates the assessment was completed at the corresponding point in the research process.

 a During the follow-up period, the self-report measure of substance use was collected biweekly.

Table 4

Process Measures: Intention-to-Treat Sample

Component of the study			
Process outcome	ΜΙΟ	PE	X ² between
Treatment component			
Any treatment sessions	38 (70.37)	36 (85.71)	3.03*
Treatment sessions	6.87 (5.58)	8.07 (4.90)	0.52
Weeks in treatment component	9.72 (9.12)	11.83 (8.80)	1.33
Research component			
Research assessments	56.83 (39.24)	64.83 (34.06)	1.12
Parenting assessments	9.54 (5.87)	10.48 (5.14)	0.69
Weeks in the study	25.44 (18.57)	29.00 (16.91)	0.96
Treatment fidelity			
MIO elements	2.56 (0.50)	1.19 (0.32)	49.26***
PE elements	1.92 (0.60)	2.39 (0.43)	23.02 ***
Generic elements	2.73 (0.33)	2.72 (0.30)	0.03

Note. N = 94 for the intention-to-treat sample; n = 53 for the MIO group; and n = 41 for the PE group. Values for each group (MIO versus PE) represent the mean (standard deviation) for continuous variables and the count (percent) for the categorical variables. N = 334 treatment sessions for the measures of treatment fidelity; n = 214 for the MIO group; and n = 120 for the PE group. $X^2_{between}$ represents the X^2 statistic associated with a test for significant between-group differences in a generalized linear analysis done with specification of the appropriate distribution and link function for the dependent variable. The statistical analysis of treatment fidelity allowed for the clustering of treatment sessions within participants.

p < .10.

*

** p<.05.

*** p<.01.

Caregiving and Child Variables: Baseline and Pattern of Change from Baseline for Intention-to-Treat Sample

Construct								
Measure	Base	line (Intercept	0	Pa	ttern of cha	inge from baseline	(Slope)	
Dimension	OIM	PE	Z between	OIM	Z within	PE	Z within	Z between
Parental Reflective Functioning								
Parent Development Interview								
Mean RF	2.75 (0.46)	2.61 (0.44)	1.16	-0.002 (0.002)	-0.98	0.002 (0.003)	0.77	-1.19
Child RF	2.86 (0.51)	2.69 (0.50)	1.26	-0.002 (0.002)	-1.04	0.002 (0.002)	0.64	-1.14
Self RF	2.81 (0.58)	2.70 (0.58)	0.74	-0.001 (0.003)	-0.47	0.005 (0.004)	1.17	-1.22
Parental Reflective Functioning Questionnaire								
Prementalizing	2.15 (0.61)	2.18 (0.62)	-0.18	0.0006 (0.003)	0.176	-0.0005 (0.004)	-0.11	0.19
Certainty	2.92 (0.78)	2.88 (0.79)	0.17	-0.008 (0.004)	-1.73 *	0.004 (0.005)	0.73	-1.65 *
Interest and curiosity	6.08 (0.45)	6.12 (0.46)	-0.30	0.001 (0.002)	0.61	-0.003 (0.004)	-0.59	0.81
Mother-Child Dyadic Adjustment								
Coding Interactive Behavior								
Mother								
Sensitivity	1.64 (0.51)	1.64 (0.48)	-0.00	-0.007 (0.003)	-2.11	-0.005 (0.005)	-1.09	-0.23
Intrusiveness	2.82 (0.35)	2.84 (0.35)	-0.14	0.004 (0.003)	1.53	0.004 (0.003)	1.19	0.10
Limit Setting	1.49 (0.65)	1.61 (0.63)	-0.65	-0.008 (0.004)	-1.86^{*}	-0.01 (0.007)	-1.69^{*}	0.46
Negative Emotionality	1.84 (0.23)	1.86 (0.22)	-0.22	0.001 (0.002)	0.61	0.003 (0.003)	0.94	-0.33
Child								
Involvement	2.29 (0.28)	2.18 (0.28)	1.16	-0.0006 (0.002)	-0.26	-0.002 (0.003)	-0.81	0.49
Withdrawal	1.76 (0.27)	1.72 (0.26)	0.39	0.0002 (0.003)	0.06	0.004 (0.003)	1.46	-1.09
Compliance	1.89 (0.39)	1.93 (0.38)	-0.25	-0.001 (0.003)	-0.47	-0.01 (0.004)	-2.86 ***	2.05
Dyadic								
Reciprocity	0.90 (0.68)	0.94 (0.66)	-0.19	-0.005(0.01)	-1.04	-0.009 (0.007)	-1.35	0.44
Negative States	3.27 (0.48)	3.32 (0.46)	-0.35	0.004 (0.004)	0.94	0.005 (0.005)	1.04	-0.22
NCAST Teaching Scale								
Mother								
Sensitivity	7.06 (0.79)	6.59 (0.76)	1.47	0.002 (0.008)	0.23	0.01 (0.01)	1.21	-0.83

Measure	Base	line (Intercept	_	Ра	uttern of ch	ange from baseline	(Slope)	
Dimension	OIM	PE	Z between	MIO	Z within	PE	Z within	Z between
Response to distress	5.53 (1.36)	5.86 (1.34)	-0.72	-0.002 (0.01)	-0.16	-0.007 (0.01)	-0.53	0.30
Social-emotional growth fostering	6.37 (0.94)	5.85 (0.92)	1.49	-0.01 (0.007)	-1.56	-0.003(0.01)	-0.25	-0.61
Cognitive growth fostering	7.96 (1.08)	6.96 (1.07)	2.32 **	0.003 (0.01)	0.20	0.02 (0.01)	1.85^{*}	-1.11
Contingency	11.26 (1.79)	10.50 (1.84)	1.23	-0.01(0.01)	-1.00	0.0003 (0.02)	-0.02	-0.64
Total maternal behavior	27.16 (2.88)	25.47 (3.04)	1.62	-0.008 (0.02)	-0.35	0.02 (0.03)	0.92	-0.93
Child								
Clarity of cues	9.57 (0.56)	9.61 (0.54)	-0.21	0.007 (0.004)	1.73 *	-0.007 (0.005)	-1.25	2.03 ***
Responsiveness	10.40 (1.12)	10.87 (1.04)	-1.34	-0.003 (0.007)	-0.38	-0.02 (0.01)	-2.21	1.60
Contingency	9.79 (0.96)	10.33 (0.90)	-1.66^{*}	0.001 (0.007)	-0.11	-0.02 (0.01)	-2.31	1.83
Total child behavior	20.00 (1.56)	20.51 (1.46)	-1.07	0.004~(0.01)	0.38	-0.03(0.01)	-2.18^{**}	1.96^{**}
nild attachment								
Strange Situation Paradigm								
Secure attachment	1.11 (1.45)	0.65 (1.47)	1.07	0.006 (0.01)	0.43	0.02 (0.02)	1.01	-0.57

Note. N = 94 for the intention-to-treat sample; n = 53 for the MIO group; and n = 41 for the PE group. Values for each group (MIO versus PE) represent the parameter estimates (standard errors) from a GEE analysis done with specification of the appropriate distribution and link function for the dependent variable and an autoregressive covariance matrix. Years of maternal education and age of the child were entered as covariates. The values for 2between represent between-group tests for significant differences in the intercept and slope. The values for zwithin represent within-group tests for a slope significantly different from 0.

 $^{*}_{P < .10.}$

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p < .05.

p < .01.

Table 6

Caregiving and Child Variables: Baseline and Pattern of Change from Baseline for Per-Protocol Sample

Construct								
Measure	Base	line (Intercept	0	Pat	tern of chai	nge from baseline	(Slope)	
Dimension	OIM	PE	Z between	OIM	Z within	PE	Z within	Z between
Parental Reflective Functioning								
Parent Development Interview								
Mean RF	2.88 (0.49)	2.71 (0.48)	1.41	-0.002 (0.002)	-0.98	0.003 (0.003)	0.99	-1.39
Child RF	3.00 (0.58)	2.90 (0.56)	0.80	-0.001 (0.002)	-0.54	0.002 (0.003)	0.65	-0.85
Self RF	3.12 (0.62)	2.90 (0.64)	1.22	-0.003 (0.003)	-0.83	0.005 (0.004)	1.35	-1.59
Parental Reflective Functioning Questionnaire								
Prementalizing	2.24 (0.67)	2.43 (0.66)	-1.04	0.003 (0.003)	0.85	-0.001 (0.004)	-0.34	0.77
Certainty	2.22 (0.85)	2.24 (0.90)	-0.09	-0.006 (0.004)	-1.42	0.004 (0.005)	0.80	-1.51
Interest and curiosity	6.29 (0.54)	6.30 (0.54)	-0.09	0.002 (0.003)	0.73	-0.002 (0.005)	-0.39	0.70
Mother-Child Dyadic Adjustment								
Coding Interactive Behavior								
Mother								
Sensitivity	1.77 (0.61)	1.84 (0.57)	-0.37	-0.007 (0.003)	-2.06^{**}	-0.006 (0.005)	-1.32	-0.05
Intrusiveness	2.77 (0.36)	2.83 (0.38)	-0.48	0.005 (0.003)	1.89	0.004 (0.003)	1.10	0.35
Limit Setting	1.82 (0.76)	1.94 (0.73)	-0.50	-0.009(0.004)	-1.98	-0.01 (0.007)	-1.80^{*}	0.44
Negative Emotionality	1.91 (0.23)	1.94 (0.23)	-0.32	0.002 (0.003)	0.72	0.003 (0.003)	0.84	-0.18
Child								
Involvement	2.16 (0.33)	2.04 (0.33)	0.93	-0.0009 (0.002)	-0.37	-0.003 (0.003)	-0.82	0.44
Withdrawal	2.00 (0.26)	1.90 (0.26)	0.81	-0.0006(0.003)	-0.20	0.003 (0.002)	1.31	-1.05
Compliance	1.64 (0.45)	1.70 (0.41)	-0.32	-0.002 (0.004)	-0.44	-0.01 (0.004)	-2.47	1.62
Dyadic								
Reciprocity	0.93 (0.79)	1.00 (0.76)	-0.30	$-0.006\ (0.006)$	-1.12	-0.009 (0.006)	-1.44	0.37
Negative States	3.36 (0.56)	3.34 (0.53)	0.07	0.003 (0.005)	0.70	0.004 (0.005)	0.83	-0.21
NCAST Teaching Scale								
Mother								
Sensitivity	7.27 (0.82)	6.70 (0.77)	1.46	0.002 (0.009)	0.27	0.01 (0.01)	1.31	-0.76

Measure	Base	line (Intercept		Pai	ttern of cha	nge from baseline	e (Slope)	
Dimension	OIM	PE	Z between	OIM	Z _{within}	PE	Z within	Z between
Response to distress	4.94 (1.44)	5.62 (1.40)	-0.60	-0.001 (0.01)	-0.09	0.0007 (0.01)	0.06	-0.22
Social-emotional growth fostering	5.62 (1.05)	5.13 (0.99)	1.15	-0.006 (0.008)	-0.69	-0.002 (0.01)	-0.16	-0.23
Cognitive growth fostering	8.40 (1.06)	6.98 (1.00)	2.66 ***	-0.003 (0.01)	-0.23	0.03 (0.01)	2.09 **	-1.45
Contingency	10.58 (1.98)	9.62 (2.00)	1.20	-0.01 (0.02)	-0.67	0.01 (0.02)	0.65	-0.91
Total maternal behavior	26.43 (3.02)	24.19 (3.06)	1.67	-0.007 (0.03)	-0.27	0.04 (0.03)	1.39	-1.16
Child								
Clarity of cues	9.35 (0.62)	9.40 (0.60)	-0.25	0.007 (0.005)	1.49	-0.01 (0.005)	-2.31	2.64 ***
Responsiveness	10.13 (1.20)	10.44 (1.09)	-0.80	-0.003 (0.008)	-0.33	-0.03 (0.01)	-2.41	1.79^{*}
Contingency	9.67 (1.02)	10.02 (0.94)	-0.97	-0.001 (0.008)	-0.14	-0.03 (0.01)	-2.41^{**}	1.88
Total child behavior	19.52 (1.68)	19.89 (1.55)	-0.69	0.004 (0.01)	0.37	-0.04(0.01)	-2.76^{***}	2.34 **
Child attachment								
Strange Situation Paradigm								
Secure attachment	0.40(1.50)	0.02 (1.51)	0.78	0.009 (0.01)	0.62	0.02 (0.02)	1.02	-0.46

GEE analysis done with specification of the appropriate distribution and link function for the dependent variable and an autoregressive covariance matrix. Years of maternal education and age of the child were entered as covariates. The values for Apetween represent between-group tests for significant differences in the intercept and slope. The values for zwithin represent within-group tests for a slope (standard errors) from a significantly different from 0. Not

 $_{p < .10.}^{*}$

Infant Ment Health J. Author manuscript; available in PMC 2024 March 02.

p < .05.

p < .01.

Table 7

Maternal Psychiatric and Substance Use Variables: Baseline and Pattern of Change from Baseline for Intention-to-Treat Sample

Manerina	Bess	line (Intercent	ć	Datt	orn of chanc	a from heeding	(Clone)	
A TRADU	Dag		6	Tan			(adate)	
Dimension	OIM	PE	Z between	OIM	Z_{within}	PE	Z within	Z between
Psychiatric distress								
Beck Depression Inventory								
Severity of depressive symptoms	19.18 (5.46)	16.51 (5.38)	1.32	-0.09 (0.03)	-2.62 ***	0.02 (0.06)	0.36	-1.57
Clinically significant depressive symptoms	-0.12 (1.29)	-0.36 (1.25)	0.55	0.009 (0.008)	-1.06	$0.005\ (0.01)$	0.32	-0.81
Brief Symptom Inventory								
Global Severity Index	0.76 (0.37)	0.72 (0.37)	0.35	-0.002 (0.002)	-0.93	0.001 (0.004)	0.42	-0.78
Clinically significant psychiatric distress	-0.92 (1.40)	-0.91 (1.38)	-0.01	-0.006 (0.01)	-0.52	0.01 (0.01)	1.02	-1.12
Substance use								
Opioids	-3.45 (1.48)	-4.42 (1.56)	1.11	-0.03 (0.02)	-1.25	0.05 (0.02)	2.16 ^{**}	-2.42 **
Cocaine	-6.79 (3.50)	-7.05 (2.89)	0.33	-0.02 (0.02)	-1.06	0.01 (0.03)	0.39	-0.81
Other	-1.78 (1.57)	-2.20 (1.63)	0.89	0.003 (0.008)	0.34	0.02 (0.009)	2.04 **	-1.29

GEE analysis done with specification of the appropriate distribution and link function for the dependent variable and an autoregressive covariance matrix. Years of maternal education and age of the child (standard errors) from a were entered as covariates. The values for Zetween represent between-group tests for significant differences in the intercept and slope. The values for Zwithin represent within-group tests for a slope significantly different from 0.

 $^{*}_{P < .10.}$

Infant Ment Health J. Author manuscript; available in PMC 2024 March 02.

P ^ .10.

p < .05.p < .01.p < .01.

Table 8

Maternal Psychiatric and Substance Use Variables: Baseline and Pattern of Change from Baseline for Per-Protocol Sample

Measure	Base	line (Intercept)	_	Patt	ern of chan	ge from baseline	(Slope)	
Dimension	OIM	PE	Z between	MIO	Z within	PE	Z within	Z between
Psychiatric distress								
Beck Depression Inventory								
Severity of depressive symptoms	20.84 (5.87)	17.68 (5.81)	1.43	-0.09 (0.03)	-2.95 ***	0.04 (0.06)	0.64	-1.81
Clinically significant depressive symptoms	0.04 (1.36)	-0.17 (1.36)	1.13	-0.007 (0.008)	-0.90	0.02 (0.02)	1.01	-1.31
Brief Symptom Inventory								
Global Severity Index	0.92 (0.43)	0.81 (0.43)	0.74	-0.002 (0.001)	-1.67 *	0.003 (0.004)	0.79	-1.30
Clinically significant psychiatric distress	-0.13(1.60)	-0.53 (1.59)	0.73	-0.01 (0.01)	-1.03	0.02 (0.01)	1.59	-1.91
Substance use								
Opioids	-3.97 (1.68)	-4.53 (1.62)	0.58	-0.02 (0.02)	-0.98	0.04 (0.02)	1.82^{*}	-1.98
Cocaine	-7.27 (3.69)	-7.49 (2.92)	0.23	-0.02 (0.02)	-1.23	0.01 (0.03)	0.32	-0.83
Other	-2.08 (1.71)	-2.42 (1.74)	0.65	-0.001(0.01)	-0.13	0.01 (0.01)	1.41	-1.14

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 $_{p < .10.}^{*}$

p < .05.p < .01.p < .01.