The Growing Together Study

Promoting healthy mother-child relationships for women in opioid treatment and their infants

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Opioid Task Force
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Growing Together Study: Pragmatic Randomized Clinical Trial

- Principal Investigator, Ruth Paris, PhD; Co-Principal Investigator: Ruth Rose-Jacobs SCD, MS
- Funder: Health Resources & Services Administration (HHS/HRSA R40MC31764; 3 Year Award, 07/2018-06/2022)
- Study Team:
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 - Boston University School of Medicine (BUMED): Ruth Rose-Jacobs, Kelley Saia
 - Institute for Health and Recovery (IHR): Annie Query, Karen Gould
 - Jewish Family and Children's Service (JF&CS): Amy Sommer

Growing Together Study team



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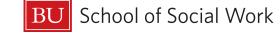
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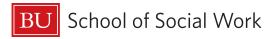
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Growing Together Study: Response to challenges of parenting with OUD/SUD

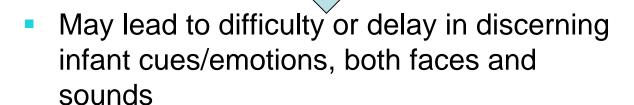
Challenges faced by pregnant and postpartum women with OUD and their infants:

- Opioid misuse during pregnancy is associated with:
 - limited access to prenatal care and OUD treatment (more so for women of color)
 - heightened risk of negative neonatal outcomes (NOWS)
 - long-term risks for problems in child's cognitive and social-emotional development
- Opioid-exposed newborns can be difficult to soothe and parents may experience guilt,
- helplessness, and frustration
- Mothers often have difficulties <u>regulating emotions</u> due to trauma hx, OUD/SUDs and mental health disorders leading to impatient, intrusive, disengaged, and/or challenged parenting
 - children are 3-4 times more likely to suffer <u>maltreatment</u>
- Attachment relationship is essential to infant's development of trust
 - opioid-related disruptions in the brain's dopaminergic system can diminish maternal pleasure and reward usually accompanying parenting; infants begin to miscue caregivers leading to problematic attachment



Neural circuitry disruptions affect caregiving

 Dysregulation in stress and reward neural circuits in substance using mothers (Rutherford & Mayes, 2017)



- Can compromise parental caregiving behavior and infant attachment formation
- Infant may "miscue" a parent who is not picking up on specific signals







Parent and child: "Difficult regulatory partners"

Children exposed in utero may have different abilities to explore, signal distress, experience regulation, or appreciate physical discomfort.

"The substance-exposed mother and child are difficult regulatory partners for each other, as the exposed infant often has an impaired ability to regulate his states ... and needs more parental help. At the same time, the mother usually has a reduced capacity to read the child's signals. This combination easily leads to a viciously negative cycle that culminates in withdrawal from interaction and increased risk for child neglect and abuse." (Pajulo et al., 2006)

Implications for parenting interventions (Suchman, et al., 2006)



Traditional parenting skills training: No clear demonstration of change in parent-child interactions and/or child development; assumes that parents can tolerate the emotional stress of parenting and experience it as rewarding; doesn't address internal mental representations for the parent

Alternative strategies: Relational approaches derived from Infant Mental Health that are attachment-based, emphasize affect and relationship between parent and child as mechanisms to promote child development; help parent invest in their child rather than substances; focus on building reflective functioning (Bosk, Paris, Hanson, Ruisard & Suchman, 2019)

Growing Together Study Design

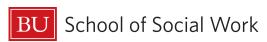
Approximately 12 month, two-armed pragmatic randomized controlled trial for 100 pregnant/parenting women with opioid use disorder (OUD) and their infants

Study arms include:

- BRIGHT- Building Resilience through Intervention: Growing Healthier Together (Treatment): dyadic attachment-based and trauma-informed therapeutic parenting intervention offered in the home
- <u>STAR-Support Teaching and Resilience (Control)</u>: standard of care social service referrals and child development handouts

<u>Primary Aims:</u> Testing BRIGHT to assess its efficacy in improving parent-child relationships and parenting capacities and decreasing child maltreatment

 <u>Secondary aims</u>: Improving maternal mental health and infant social-emotional development, maintenance of OUD treatment and recovery



Boston Medical Center Project RESPECT Clinic: Recruitment Site

- Project RESPECT (Recovery, Empowerment, Social Services, Prenatal care, Education, Community and Treatment), is a high risk obstetrical and addiction recovery medical home at Boston Medical Center and Boston University School of Medicine.
- Project RESPECT provides a unique service of comprehensive obstetric and substance use disorder treatment for pregnant women and their newborns.
- Director: Kelley Saia, MD



BRIGHT History (Building Resilience through Intervention: Growing Healthier Together)

BRIGHT I: Family Residential Treatment programs (SAMHSA; IHR, JF&CS & BUSSW)

BRIGHT II: Outpatient Opioid Treatment Programs (SAMHSA; IHR, JF&CS & BUSSW)

BRIGHT III: Residential, Opioid Treatment Program and Primary Care/Outpatient (SAMHSA; IHR & BUSSW)

Growing Together Study: Pragmatic Randomized Controlled Trial (HRSA; BUSSW & IHR)

<u>People involved with development of BRIGHT since 2009</u> (Norma Finkelstein, Karen Gould, Eda Spielman, Amy Sommer, Beth Marron, Karen Garber, Sue O'Donnell, Brittney Walker, Christine Trendell, Ashley Short Mejia, Ruth Rose-Jacobs, Annie Query, Annie Herriott & research team at BUSSW)



Theoretical foundations of BRIGHT



Infant Mental Health

- Mother-infant attachment
- Focus on reflective functioning (RF)

Trauma and mental health disorders

- Recognition of impact
- PTSD, emotion regulation, affect recognition

Importance of OUD/SUD

- Compromised reward mechanisms in the brain impacting pleasure in parenting
- Relapse as part of recovery

Trauma and SUDs affect the caregiving or attachment system

Comprised of mental representations and parenting behaviors

- Mental representations: What you internalize from your history of being parented
- Lack of positive representations can translate into negative parenting and parent-child interactions (e.g. hostile, harsh, intrusive, disengaged, unattuned)
- Interventions ideally address both levels-representations and interactions-- in order to affect change and promote secure attachment in the child

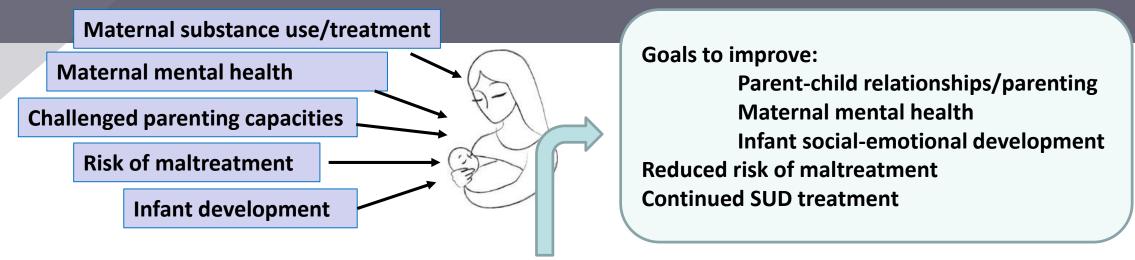


Mentalization-based approaches to build reflective function (RF)

- Parental reflective functioning: the ability to understand behavior of oneself and one's child in terms of underlying feelings, thoughts and intentions
- Mentalization-based approaches promote parental attunement, reflectivity, and responsiveness
- Better parental RF can mediate the negative effects of substance misuse, trauma and mental health challenges on the caregiving relationship



BRIGHT Intervention



BRIGHT INTERVENTION

Promotes developmental play, offers developmental guidance, supports parental protective behavior, translates children's feelings/actions, provides emotional support, encourages emotion regulation and reflective functioning, provides concrete assistance

Growing Together Study Consort Diagram

Enrollment

Assess eligibility: \geq 18 yo. Hx of Opioid Use Disorder and/or Polysubstance Use Disorder, 24-40 weeks pregnancy, English fluent, willing to participate in RCT, capable of giving consent, intending to parent baby, live within 20 miles of Boston

Baseline Enrollment, N=60 & Randomized, N=57

- Assessments
- -Pregnancy Interview

Intervention: Bright, N= 35

Begin BRIGHT Intervention with clinician, study sessions & monthly handouts to 6 months postpartum

Exclusion:

- Not meet inclusion criteria
- Declined
- Other reasons incl gave birth N=3

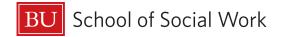
Treatment as usual: STAR, N=22

Monthly handouts from pregnancy to 6 months postpartum

Parent & Child Assessment of both groups when mother is 2,6, & 9 months postpartum

Allocation

Follow-up



Description of pregnant participants at baseline, T0 (N=60)

- Age: M=31.3 yrs (sd=4.6)
- **Gestational age, recruitment** M=31.9 (sd=4.5)
- Race/ethnicity: (not mutually exclusive) 83% White; 15% Black; 1.7% American Indian; 15% Latinx; 1.7% Asian; 8.3% other
- Housing: Housed=87%; Where: Shelter= 13%; Home/apt = 40%; Family/friend=21%; Residential treatment=35%
- Marital status: married=8%; divorced=18%; never married=73%
- Other children: 78%
- Prior DCF (Child Welfare) involvement: 68%

- Education: Less than HS: 23%; Completed HS: 40%; Greater than HS: 37%
- **Employment**: Unemployed= 70%; part-time=20%; full-time =8%; other= 2%
- Income: under \$10K=50%; \$10K-19K= 10%; \$20-29K=12%; \$30-39=8%; over \$40K=16%; refused=6%
- Food insecurity: sometimes/often= 53%
- Housing instability: 78%
- **WIC**: 43%
- SNAP: 75% (food stamps)

Select measures from pregnancy (T0) and early parenting (T1)

- Trauma
- Average trauma hx: M=16.23 types of events (with SD=5.11)
- PTSD (using the PCL-5)
 53% flagged at risk with having 30+score
- Current DV (HITS)- 5% positive screen
- Mental Health
- Brief Symptom Inventory (GSI total): M=1.13
 - Community non-clinical sample: M=.30
- CD RISC (Resilience): M=26.9
 - Community non-clinical sample: M=32.1
- Adult Attachment Scale (AAS)
- <u>Secure</u>=33%; <u>Preocc</u>=10%; <u>Dismiss</u>=15%;

Lifetime Substance Use

- Marijuana: 82%; Alcohol to intox: 48%; Cocaine/crack: 87%; Heroin: 82%; Other opioids: 83%
- Methamphetamines: 37%
- Ever used <u>Medication Assisted Treatment</u>
 Buprenorphine/Suboxone: 80%; Methadone: 71%;
 Naltrexone/Vivitrol: 22%; Subutex: 16%
 - Ever overdose: 42%
- Parental reflective functioning during pregnancy (PI): M=3.16 (SD=1.26; -1-7)
- Parenting stress: M=76; 57% at-risk, 14% high stress
- Parenting confidence: 30% low confidence

Core Concepts in Project BRIGHT: Principles of Child-Parent Psychotherapy and best Infant Mental Health practices for parents with SUDs

- 1. Facilitating shared experiences of pleasure and connection
- 2. Exploration of relationships
- 3. Linking past and present
- 4. Containing/regulating strong affect
- 5. **Building parental reflective function**

Validation of feelings and recovery support

- Work in conjunction with SUD treatment
- Anticipate cravings and plan for baby's care

Encouraging problem solving

Any issue relevant for mother and baby

Mother and baby/young child

- Supporting positive attachment patterns
- Holding the baby in mind using verbal and nonverbal cues
- Wondering/speaking for the baby
- Encouraging self-regulation strategies to support co-regulation within dyad
- Fostering play and connection



Encouraging containment for emotion regulation

- Responding to intense affect in a crisis
- Reflecting on strong feelings about self, adult relationships, parenting experiences

Bearing witness to processes and experiences

- Challenges with child welfare (including meetings with child welfare workers and custody hearings)
- Experiences in SUD treatment programs





Supporting reflective functioning through questions, conversation, and exploration about issues important to the mother

 Being "curious" about mothers experiences with and feelings about partner, parents, child, providers, etc.

- Flexible intervention
- Demonstrating availability
- Providing concrete assistance
- Meeting client "where they are at"





Overall reflection and recognition of strengths and growth

 Reviewing mother and child's accomplishments over the course of treatment

Reflective supervision

- Clinical work is highly evocative and potentially triggering for clinicians
- Families are challenging to engage and make even experienced clinicians doubt their skills
- Essential to have "good enough" reflective supervision to process treatment experiences

Overview of study progress and next steps



60 women enrolled in the study

Recruitment ended 3/2021; completing data collection

Adapted BRIGHT intervention to prenatal clinic, home environment and now remote

Demonstrated feasibility and acceptability of the intervention for mothers with OUD/SUD

Listed as *Emerging Practice* with Association for Maternal Child Health Programs

Impact of COVID 19: Challenges/successes with recruitment, data collection, BRIGHT intervention

Data analysis: Near complete data set; preparing to analyze data by group

Numerous presentations: 2021 World Association for Infant Mental Health Congress; grand rounds at University of Maryland and Boston Medical Center, University of Maine and University of Wisconsin SSW, and more

Continue development of manuscripts, research proposals, replication of the intervention, presentations/trainings and collaborations

