A pilot trial comparing Attachment and Biobehavioral Catch-up (ABC) to ABC plus Depression support (ABC+D)

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ABC/ABC+D STUDY PROTOCOL

Overview

Depression is a prevalent and impairing mental health problem among women with young children. Empirical data indicate that mothers of young children experienced elevated rates of depression during the pandemic (Cameron et al., 2020), and ongoing societal unrest in the past several years likely contribute to ongoing psychological distress among caregivers. The negative influence of maternal depression on child development is well-established; exposure has been linked to a range of negative outcomes, including difficulties in social competence (Wall-Wieler et al., 2020), poorer cognitive development (Liu et al., 2020), and internalizing behavior problems (Roubinov et al., 2022). Moreover, the association may be bidirectional, with elevated levels of children's behavior problems associated with subsequent increases in maternal depression (Roubinov et al., 2022, 2023). To address the intertwined associations between maternal and child mental health problems, treatment strategies must be integrated. Yet, most extant programs are narrowly siloed to intervene on maternal depression ***or*** child behavior.

Depression in adults in treatable and cognitive behavioral therapy (CBT) is particularly effective (Cuijpers et al., 2013). However, CBT-based interventions are not sufficient to improve parenting problems that often co-occur with maternal depression (Forman et al., 2007) and they do not consistently improve children's behavior problems (Galbally et al., 2017). Similarly, parenting interventions are effective for improving children's behavior problems, but they do not robustly reduce parental depression (Maliken et al., 2013). To address this gap in the literature, the current study is conducting a pilot effectiveness trial that compares a parenting-only intervention (Attachment and Biobehavioral Catch-up; ABC) to an integrated parenting-maternal depression intervention (Attachment and Biobehavioral Catch-up plus Depression; ABC+D).

The Attachment and Biobehavioral Catch-Up (ABC) intervention uniquely focuses on enhancing child and parent-child behavioral regulatory capacities in high-risk early family environments by improving parenting and the parent-child relationship. It has been shown to improve depression-related parenting deficiencies that are associated with children's internalizing symptoms, including parental sensitivity, support, attachment quality, and neurobiological emotion processing. Parents in the intervention have also reported a reduction in children's negative affect and behavior problems. We are examining the effectiveness of ABC versus ABC+D (i.e., ABC supplemented with cognitive behavioral therapy for depression) for lowering maternal depression and child behavior problems.

Sources of Materials

Data for the current study will be collected by maternal self-report and proxy-report on standardized and validated questionnaires. All questionnaire data will only be collected after parent consent is obtained and will be used for research purposes only. Pre- and post-intervention assessments of parent and child psychological health will be collected using written questionnaires. No identifying information will be linked to any materials or data collected from study participants.

Study Design

This is a two-arm parallel group design. Participants will be randomized to ABC or ABC+D.

Study Population

This study will include 40 mothers and their 20 biological offspring between the ages of 2 and 4 years old. Inclusion criteria include: maternal age 18 or older, child age 2 to 4 years old, subclinical or higher maternal depressive symptoms (defined as a score of 5 or higher on the PHQ-9), subclinical or higher child behavior problems (defined as a score of 3 or higher on at least one domain of the Impairment Rating Scale), and English- or Spanish-speaking. Exclusion criteria include acute risk for suicidality (current suicidal ideation or reported suicide attempt in the previous 6 months).

Recruitment

Participants will be recruited from primary care clinics at Benioff Children's Hospital Oakland (BCHO), regular referrals made to Early Intervention Services at BCHO, community organizations serving families with young children, and online sources, including parenting listservs, Facebook groups, other internet-based forums, and information on our study website.

Study Procedures

Eligibility screening: Women will complete an online screening to determine eligibility. Women will be eligible if they report: 1. Heightened depressive symptoms (a score of 5 or higher on the PHQ-9) and 2. Heightened symptoms of children's behavior problems (a score of 3 or higher on at least one domain of the Impairment Rating Scale). Additional eligibility requirements for women include biological mother age 18 or older, English- or Spanish-speaking and no self-reported active suicidality as indicated by report of current suicidal ideation or a recent suicide attempt in the previous 6 months. Other eligibility criteria for children include age 2 to 4 years old. Those who are ineligible will be provided with a list of community resources.

Orientation: Eligible participants will complete an orientation appointment by phone to learn more about the study, decide if they would like to participate, and if so, set up an appointment for the pre-intervention assessment.

Pre-intervention assessment: Informed consent will be obtained electronically prior to the beginning of the pre-intervention assessment. Mothers will complete structured questionnaires that assess the following: maternal mood and stress, child physical, socioemotional, and behavioral health, mother and child history of adversity exposure, and other aspects of the family environment.

Attachment and Biobehavioral Catch-up (ABC): ABC was developed by Dr. Mary Dozier at the University of Delaware. It is an extensively researched, empirically-supported intervention that is delivered by "parent coaches" in one hour, once per week sessions in the home or virtually. It has been nationally and internationally disseminated at other academic settings and community mental health organizations in 17 states and 7 countries. It has also been endorsed by the U.S. Department of Health and Human Services Home-Visiting Coalition, The California Evidence-Based Clearing House California House for Child Welfare, and the National Registry of Evidence-based Programs and Practices of the Substance Abuse and Mental Health Services Administration. The intervention includes three main targets: Improving mothers' sensitive and nurturing behavior, improving mothers' ability to detect and respond to their child's cues, and reducing the use of any intrusive or negative parenting behaviors. Each of the 10 intervention sessions includes manual-guided discussion of the intervention content, review of between-session assignments that were given to parents, play-based activities that allow parents to practice each of the three aforementioned targeted behaviors with their child, and video feedback (parents will view clips of their own behavior from prior sessions, as well as standardized video examples (developed and provided by the ABC program) of target parenting behaviors). Throughout each of the sessions, parents coaches use "In the Moment" comments to provide feedback to parents regarding their behaviors that relate to the targets of the intervention. These comments bring parents' attention to opportunities to provide nurturing behavior, respond to their child's cues, etc. These comments are positive and supportive in nature, assisting parents in improving their interactions with their child. These comments are interspersed throughout the manualized content. The intervention is only provided by parent coaches who have been trained by ABC staff at the University of Delaware and who receive ongoing clinical supervision until they demonstrate certification criteria.

ABC+D: ABC+D includes the same 10-session *ABC* home visiting program described above, and additionally includes supplementary CBT for depression content (i.e., *+D*). The primary means of delivering the *+D* content are short video modules that mothers view during and in-between *ABC* home visiting sessions with the parent coach. Development of the *+D* content is heavily guided by *Mothers and Babies/Mamás y Bebés*, an intervention for maternal perinatal depression that has an extensive history of RCTs and empirical support. *ABC+D* content will span 12 videos, with 1-2 video viewed weekly before, during, and/or after each of the 10 ABC home visits and available for repeated viewings between visits. The *+D* content naturally extends and supplements the parenting-focused *ABC* material to address maternal depression and mood regulation. For example, *ABC* sessions that focus on responding to a child's emotional needs with sensitivity have an analogous *+D* session to help mothers identify and respond to their own needs. Each *ABC+D* session teaches the interrelated nature of CBT for maternal depression and parenting skills training for children's behavior problems (see Table 2 for a summary of *ABC* and *ABC+D* intervention modules). More specifically, Sessions 1 and 2 of *ABC+D* will introduce cognitive behavioral therapy (CBT) and the relations among mood, thoughts and behavior. The concept and practice of behavioral activation will be reviewed in Sessions 3 and 4. In Sessions 5 and 6, social support and healthy interpersonal relationships are introduced as therapeutic targets

and in Sessions 7 and 8, strategies to identify and challenge negative thoughts are taught. Sessions 9 and 10 will be spent reviewing core CBT concepts and their relation to parenting, celebrating improvements, and planning for the future.

All sessions will be recorded with audiovisual equipment for supervision purposes. Recorded sessions will also be uploaded via a secure server for supervision and fidelity review by researchers at the University of Delaware and Palo Alto University. During weekly meetings with ABC intervention supervisors, the parent coaches will discuss intervention progress and review randomly selected 5-minute clips from one of the intervention sessions to ensure that In the Moment commenting is being provided accurately and at the ideal frequency. During monthly supervision with +D supervisors, the parent coaches will discuss intervention progress and review progress toward fidelity and adherence benchmarks.

Post-intervention assessment: The post-intervention assessment administers a subset of same structured questionnaires as the pre-intervention assessment. All questionnaires are completed online

Study Measures

Eligibility screening:

- Patient Health Questionnaire (PHQ-9)
- Interaction Rating Scale (IRS)
- Self-reported status at biological mother of target child
- Maternal age
- Child age

Pre-intervention assessment:

- Patient Health Questionnaire (PHQ-9)
- Early Childhood Screening Assessment (ECSA)
- General Anxiety Disorder (GAD-7)
- Perceived Stress Scale (PSS-4)
- Behavioral Activation for Depression Scale – Short Form (BADS-SF)
- Pleasant Events Schedule
- Automatic Thoughts Questionnaire (ATQ)

Post-intervention assessment:

- Patient Health Questionnaire (PHQ-9)
- Interaction Rating Scale (IRS)
- Early Childhood Screening Assessment (ECSA)
- General Anxiety Disorder (GAD-7)
- Perceived Stress Scale (PSS-4)
- Behavioral Activation for Depression Scale – Short Form (BADS-SF)
- Pleasant Events Schedule
- Automatic Thoughts Questionnaire (ATQ)
- Video Questions

Compensation

Payments to mothers will be given in retail gift cards. The pre- and post-intervention assessment will be compensated $50 each.

Data Collection

Data will be collected from participants using the Redcap survey system. REDcap allows participants to read questions on the screen (or have questions read to them) and press the response buttons to answer. REDcap is hosted at the UCSF Minnesota Street data center, which is locked and guarded 24 hours per day/7 days per week. Entrance to the data center is only allowed by key cards that first unlock the data center and then unlock the security cage that protects the servers. The security of the data center is further protected by an Operations desk that is staffed 24 hours per day/7 days per week and by an advanced security camera

system. REDcap servers are guarded by multiple firewall and intrusion detection systems. All electronic connections to the REDcap environment are encrypted. The REDcap production system is comprised of a web server front-end and a MySQL database server on the back-end. The web server resides in a demilitarized zone to ensure that survey participants are able to access REDcap surveys from any device connected to the internet. The back-end MySQL server resides in the protected ISU subject that kept secure by firewalls maintained by UCSF. The data stored in the REDcap MySQL database server can be accessed by REDcap end users by logging into https://REDcap.ucsf.edu and opening the REDcap projects that they have been granted to by owners of the projects. Only ITS and ISU administrations have authorization to access the back-end database server directly (by logging into the virtual private network in which the database user resides (from https://myresearch.ucsf.edu/REDcap-faqs). All research staff will be trained in data collection and management procedures.

Potential Risks

Psychological and socioemotional questionnaires: Responding to the questions on these measures carries minimal risk for emotional discomfort or stress. Efforts will be made to place families at ease during questionnaire completion and procedures will be stopped upon request from parents.

Although it is not anticipated that this study will cause significant psychological distress, it is likely that recruitment and assessment procedures will identify parents and children with distress. Protection procedures are outlined below in the event that significant distress is encountered during the study.

Participation in the intervention: Engagement in the Attachment and Biobehavioral Catch-up (ABC) intervention activities (e.g., facilitator-directed parent-child interactions, review of videotapes of adaptive parent-child relationships) and ABC+D intervention activities (watching brief videos) carries minimal risk for emotional discomfort or stress. Previous randomized controlled trials of ABC and Mothers and Babies (the intervention from which the +D content is derived) have demonstrated its efficacy and safety with no adverse events reported. The intervention only by providers who have been trained by the intervention developer and associated staff at the University of Delaware. Additionally, all individuals who deliver the intervention will receive supervision and consultation throughout implementation of the intervention. Parents and children will be advised of their right to withdraw from the intervention at any time without consequence on their receipt of future healthcare services at UCSF Benioff Children's Hospital or affiliated clinics.

Confidentiality: Participation in research may involve a loss of privacy, however information will be handled with the upmost confidentiality. Consent forms and documentation of visits for intervention participation may be included in medical records. Thus, other UCSF healthcare staff may become aware of an individual's study participation, however hospital regulations require that all healthcare providers treat medical records information confidentially.

Inconvenience: There may be some burden associated with completing the questionnaires and attending the in-person visits to engage in the intervention sessions. However, families will be provided with compensation for travel and parking.

Protection Against Risk

Mothers and children will be told that their participation is voluntary and they can choose to withdraw from the study at any time without further obligation. Assurance will be given that their decision to participate, decline, or withdraw will not affect their current or future healthcare at UCSF Benioff Children's Hospital, affiliated clinics, or community resources.

Discomfort associated with questionnaires: In the case of discomfort that arises from completing questionnaires, parents will be told that they do not have to answer any questions they do not want to answer and can stop at any time.

Identification of parents and/or children with heightened distress: The aims of this study are such that recruitment and assessment procedures may identify high-risk families, as defined by subclinical or higher child behavior problems and parent depressive symptoms. Some of these families may be experiencing particularly significant distress requiring additional clinical services beyond that which is provided by the

intervention. These determinations will be made by MPIs Dr. Roubinov and Dr. Pfiffner, California-licensed clinical psychologists, through specific statements, interactions, situations, and endorsed survey items that signify risk of suicidality or high levels of distress. All study staff will be trained to probe for suicidal thoughts, intent, and psychotic behavior and will contact Dr. Roubinov so that appropriate steps can be taken to ensure the safety of the participants. It may also be the case that families present with significant distress in the absence of psychosis or suicidal intent, but may still benefit from more intensive clinical services, a list of supportive resources at UCSF and in the greater San Francisco Bay Area will be provided to all participants at the first intervention session regardless of their current expressions of distress.

Discomfort associated with participation in the intervention: Parents and children will be provided with a thorough description of the ABC and ABC+D interventions prior to initiating treatment. In the case of significant distress during intervention sessions, parents and children will be told that they may stop at any time. Prior to delivering the intervention and throughout the study, Dr. Roubinov will consult with Dr. Mary Dozier and her staff (who developed the ABC intervention and directed previous trials) and Dr. Ricardo Muñoz and his team (who developed the *Mothers and Babies* intervention from which the +D content is derived) to minimize participant distress or address any significant discomfort that arises.

Confidentiality: All data gathered in the present study will be handled with the upmost attention to participants' confidentiality. Subjects will assigned unique, coded, confidential identifiers (code numbers), which will be used to label all data forms, data entries, and questionnaires. The key linking the subjects' identity to their unique coded identifier will be encrypted and stored on secure servers at UCSF, which will only be able to be accessed by the study team.

Inconvenience: All efforts will be made to minimize participant burden. Participants may be inconvenienced by the time spent completing questionnaires and efforts involved in engaging in the ABC intervention. Families' schedules will be accommodated to the extent possible.

Trained study staff will report any adverse events immediately to the PI. They will be dealt with right away, and if necessary, discussed with the team of mentors and consultants. If it is determined that a participant is experiencing high levels of distress or discomfort, any study activity will be stopped. Time will also be set aside during regular research meeting to discuss any small or large adverse event. If participants have any concerns or are experiencing distress, they will be given contact information for the PI.

Inclusion of Women and Minorities
Parents recruited into this pilot study will be limited to mothers, as ABC and the +D content has been primarily designed and Bay Area community and efforts will be made to recruit a sample that reflects the racial and ethnic distribution of the geographic area.

Statistical Analyses
The current study is a randomized controlled trial that examines the two study arms, ABC and ABC+D, at pre-intervention and post-intervention time points. The primary outcomes are change in maternal depressive symptoms (as measured by the PROMIS Depression Measure) and change in child behavior problems (as measured by the Early Childhood Screening Assessment).

- Aim 1 and Aim 3
    - Descriptive data
- Aim 2a and 2b
    - Independent t-test
    - MANCOVA - within-subjects (pre/post) and between-subjects (ABC vs. ABC+D)

Study Risk Assessment
The minimal risks involved in this study may include psychological distress that can arise when individuals answer questions about mental health issues, however the risk is equivalent to what may be expected in standard medical practice or psychotherapeutic practice.

Anticipated Adverse Events

There are risks associated with physiological/psychological assessment and loss of confidentiality. None are expected at a frequency above 5%.

Safety Monitoring
The full study team will monitor participant symptoms. Any concerns that arise will be discussed at weekly meetings with the study team.

Adverse Event Grading
Severe adverse events (AE) are not expected in this study, the full adverse event grading scale will be followed as recommended by the UCSF IRB:

- No AE or within normal limits
- Mild AE, did not require treatment
- Moderate AE, resolved with treatment
- Severe AE, resulted in inability to carry out normal activities and required professional medical attention
- Life threatening or disabling AE
- Fatal AE

Plan for Reporting Adverse Events
Any AE will be immediately reported to the PI (Dr. Roubinov), handled immediately, and if necessary, discussed with the team of mentors. If it is determined that a participant is experiencing a high level of distress or discomfort, the activity will be stopped. Any small or large adverse event will also be discussed during weekly research meetings. Acute, adverse reactions to any procedure will be treated by physicians at UCSF. On-site severe AEs (grades three through five) and unexpected AEs that are related to research and result in a change to risk/benefit and/or require protocol and consent modifications will be reported within 10 working days of PI awareness. All other AEs related to research that are not serious (grades zero through two) and are expected will be reported annually. The only AE not related to research that would be reported within an annual report would be the death of a participant for an unrelated cause. All AE reports will be submitted to IRB.

Safety Reviews
The study team will set aside time during weekly scheduled meetings to review participant safety issues. The meeting agenda will include participant numbers and accrual rates, AEs (if any), determination of whether the AE was due to the study procedures, and determination of whether the AE was expected or unexpected. Based on these determinations, study adjustments will be made as necessary. If there are any AEs or side effects, Dr. Roubinov will request immediate consultation with Drs. Epel and Bush, and any other member of the study team, as needed. The UCSF IRB will be notified of any study changes that are deemed necessary via a modification and updated study consent prior to proceeding with the study.