Attachment and Biobehavioral Catch-up for Depression
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ABC STUDY PROTOCOL

Overview

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. The current study will test the preliminary effects of ABC on pre-to-post intervention changes in maternal depressive symptoms and children's internalizing symptoms in a small sample specifically recruited on the basis of heightened symptoms in these two areas.

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 single-arm, open trial of ABC. All dyads participating in the present study will receive ABC.

Study Population

This study will include a minimum of 20 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 ≥16 on the Center for Epidemiologic Studies Depression Scale (CES-D), subclinical or higher child internalizing symptoms (defined as a raw score of 14 or higher on the internalizing subscale of the Child Behavior Checklist (CBCL), and English-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 online sources, including parenting listservs, Facebook groups, other internet-based forums, and information on our study website. We will also work with colleagues in UCSF clinics that see women and children to receive referrals. Colleagues will be provided with study flyers and brochures and will also be directed to ask potential participants if they can be contacted by a member of the ABC study team to receive more information about the study. The study team will only reach out to potential subjects after such individuals have agreed to be contacted.

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 16 or higher on the Center for Epidemiologic Depression Scale (CES-D), a cut-off that suggests at least subclinical depressive symptoms; Radloff, 1977) and 2. Heightened symptoms of internalizing within their child (a raw score of 14 or higher on the Child Behavior Checklist, a cut-off that suggests at least subclinical depression/anxiety symptoms; Achenbach & Rescorla, 2002). Other eligibility criteria for mothers include: English-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, marital relationship quality, and parent-child relationship quality.

10-week intervention: Attachment and Biobehavioral Catch-up (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.

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 (Service Agreement and HIPAA Business Associate forms signed by the University of Delaware are in place). During weekly meetings with individuals at the University of Delaware, the ABC 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.

Following the onset of the COVID-19 pandemic, study procedures were adapted such that telehealth-only ABC sessions were conducted (no in-person contact). All intervention sessions will be conducted by HIPAA-compliant Zoom. All other aspects of the study remain the same.

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:

- Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977) plus one additional item to assess suicidality
- Internalizing subscale of the Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000)
- Self-reported status as biological mother of target child
- Maternal age
- Child age

Pre-intervention assessment:

- Demographic data to characterize the sample (e.g., race, ethnicity, highest level of education attained, income, marital status)
- Self/proxy-reported history of maternal or child treatment for mental health problems, including inpatient hospitalizations, residential treatment, outpatient therapy, or medication
- Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977)
- Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000)
- PROMIS Adult Anxiety Scale (Ader, 2007)
- Perceived Stress Scale (PSS; Cohen & Williamson, 1998)
- Parenting Stress Index-Short Form (PSI-SF; Abidin, 1990)

- Adverse Childhood Events Questionnaire (ACE-10; Felitti et al., 1998)
- Traumatic Life Events Questionnaire (Kubany et al., 2000)
- Trauma Exposure Symptom Inventory-Parent Report Revised (TESI-PRR; Ghosh et al., 2002); maternal report of children's exposure to trauma with mandated reporting items removed
- Parental Efficacy Scale of the Parent Locus of Control Scale (Campis, Lyman, & Prentice Dunn, 1986)
- Couples Satisfaction Index (Funk & Rogge, 2007)
- PROMIS Emotional Support Scale (Ader, 2007)
- Global Physical Health Scale from the Health and Behavior Questionnaire (HBQ; Essex et al., 2002)

Post-intervention assessment:

- Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977)
- Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000)
- PROMIS Adult Anxiety Scale (Ader, 2007)
- Perceived Stress Scale (PSS; Cohen & Williamson, 1998)
- Parenting Stress Index-Short Form (PSI-SF; Abidin, 1990)
- Parental Efficacy Scale of the Parent Locus of Control Scale (Campis, Lyman, & PrenticeDunn, 1986)
- Couples Satisfaction Index (Funk & Rogge, 2007)

Compensation

Payments to mothers will be given in retail gift cards. The pre-intervention assessment will be compensated $75 and the post-intervention assessment will be compensated $50.

Data Collection

Data will be collected from participants using the Qualtrics and Redcap survey systems. The Qualtrics system allows participants to read questions on the screen (or have questions read to them) and press the response buttons to answer. Qualtrics maintains data behind a firewall. all data is accessed only by the owner of the survey who must provide a unique combination of a username and password. All pieces of data are keyed to that identification profile and cannot be accessed by anyone else. REDcap also 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) carries minimal risk for emotional discomfort or stress. Previous randomized controlled trials of the intervention 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 or affiliated clinics.

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 nature of the ABC intervention and aims of this study are such that recruitment and assessment procedures may identify high-risk families, as defined by subclinical or higher child internalizing 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 PI Dr. Roubinov, a California-licensed clinical psychologist (license #28292), 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 intervention 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 (individuals who developed the intervention and directed previous trials) 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, questionnaires, and biological specimens. 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 has been primarily designed and tested among mother-child dyads. Future research will consider expanding the intervention to fathers and other caregiver types. There are no exclusions based on race or ethnicity. Participants will be recruited from the San Francisco 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 small, proof-of-concept examination of ABC on maternal and child mental health in a sample of mothers and their offspring. Although the small sample size and absence of randomization precludes more complex analyses, descriptive approaches will be used to evaluate changes child and parent mental health symptoms from pre-intervention to post-intervention.

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.