CBT for Youth with Autism and Emotional/Behavioral Needs in Community Care Settings (CYAN): Trial Protocol

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Funding/Support: This research is supported by a grant from the Department of Defense Army Medical Research and Development Command (Award Number W81XWH-21-1-0334).

Introduction:

Clinically significant emotional dysregulation is common and impairing in school-aged youth with autism spectrum disorder (ASD) (e.g., Mazefsky et al., 2018; Samson et al., 2014). Emotion regulation problems place youth with ASD at increased risk for the development of emotional and behavioral disorders; for example, about 50% of all youth with ASD develop an anxiety disorder (e.g., Kirsch et al., 2020). Emotional dysregulation as manifest in symptoms of anxiety and irritability is linked with indices of increased functional impairments in youth with ASD such as greater social disengagement, involvement in bullying (as victim and as perpetrator), family conflict, and academic performance difficulties (e.g., Goldsmith & Kelley, 2018; Jahromi et al., 2013; Storch et al., 2012). Thus, a characteristic feature of ASD is difficulty with emotion regulation (Mazefsky et al., 2018).

Emotional dysregulation is a common reason families seek mental health services for youth with ASD. Handling emotional dysregulation was cited as a reason for service needs by 77% of parents of youth with ASD in a recent survey (Hodgetts et al., 2015) and rated as parents' first or second highest treatment priority for school-aged children with ASD (Brookman-Frazee et al., 2012a; Kuravackel et al., 2014). Psychotherapy (defined as a client working with a trained clinician to understand and change feelings and behaviors and gain coping skills, generally in a one-on-one format in an outpatient setting; Wampold & Imel, 2015) is among the most frequently utilized mental health services by youth with ASD; for example, in a large-scale study of 28,009 youth with ASD, 46.5% of parents reported at least one psychotherapy visit in the past year (Stuart et al., 2017). In the 2011 Survey of Pathways to Diagnosis and Services of a nationally representative sample of 1,420 youth with ASD, parents reported that between 23% and 43% of the youth with ASD were currently receiving psychotherapy (Zablotsky et al., 2015). Thus, a substantial number of school-aged youth with ASD seek psychotherapy to address problems with emotion regulation.

Improving the quality of care for school-aged youth with ASD presenting to psychotherapy with emotional dysregulation in community mental health centers (CMHCs) is a public health

priority. Efficacious evidence-based treatments that address core ASD symptoms and emotional dysregulation are well developed (e.g., Wood et al., 2009a,b, 2015a, 2020). However, the quality of care (defined as the use of evidence-based treatments and improvements in clinical outcomes) in CMHCs where many school-aged youths with ASD receive psychotherapy is variable and typically not evidence-based (Christon et al., 2015; Pickard et al., 2018). Furthermore, few clinicians employed in CMHCs are aware of, or have access to, efficacious evidence-based treatments that target emotion regulation in school-aged youth with ASD, which contributes to the use of "off-label" medical and behavioral psychotherapies in CMHCs (Pickard et al., 2018). To remedy this problem, evidence-based treatments for school-aged youth with ASD and emotional regulation problems need to be implemented in outpatient CMHCs to evaluate effectiveness in real-world, everyday practice and to thereby take a necessary though not sufficient step towards improving the quality of care for you with ASD in CMHCs. The proposed project is intended to be an initial step towards addressing this need.

Cognitive-behavioral therapy (CBT) has established efficacy for addressing core ASD symptoms and emotional dysregulation in school-aged youth (6-14 years old) with ASD (Weston et al., 2016), but virtually no attention has been paid to evaluating the effectiveness of CBT in the settings where youth with ASD typically receive services: community and government facilities such as clinics and medical centers (Wood et al., 2015b). Instead, research has primarily been conducted in university-based research settings with strict eligibility criteria (i.e., efficacy studies). To date, these studies have established that CBT is efficacious for youth with ASD and can be delivered in a time-limited outpatient basis in contrast to in-home services (cf. discrete trial training; Wood et al., 2020). However, few youths with ASD will benefit from this research until the effectiveness of CBT programs for ASD is established in CMHCs (i.e., CBT programs demonstrate significant improvements in clinical outcomes relative to usual clinical care). And recent mental health effectiveness research in other populations (e.g., children with depression) has clearly demonstrated that some treatments become less potent when moved from the university setting to CMHCs (e.g., Sandler et al., 2019; Weisz et al., 2013), underscoring the need to utilize methods to support the successful implementation of CBT programs demonstrated to be effective in CMHCs (McLeod et al., 2018; Wood et al., 2015b).

The primary objective of this project is to determine if CBT is effective relative to the usual clinical services provided to youth with ASD in the settings where they are most likely to receive mental health services – for example, federal government-funded medical centers serving families of members of the US Armed Forces (e.g., Naval Medical Centers serving Navy Exceptional Family Members such as youth with ASD with a parent in the Navy) or free/low-fee CMHCs supported by state government funding (e.g., state Regional Centers). The secondary objective is to investigate implementation factors (i.e., treatment integrity, feasibility, acceptability) that may affect the effectiveness of CBT delivered in CMHCs. We will evaluate the effectiveness of a CBT program for youth with ASD and emotion dysregulation that has

demonstrated efficacy in research settings (Storch et al., 2013, 2015; Wood et al., 2009a,b, 2015a, 2020), with training and implementation supports provided to CMHC clinicians in a format that is cost-efficient and feasible for future implementation: through a combination of consultation from a CBT expert via internet-based video conferencing as well as access to online resources (e.g., video demonstrations of CBT and corresponding written materials) that support treatment integrity across clinicians while reducing consultation and training costs. We propose an effectiveness-implementation hybrid design (i.e., Type I design; Curran et al., 2012) that will experimentally test the effectiveness of CBT and investigate implementation factors that might influence CBT effectiveness in CMHCs. We expect to enroll 100 youth with ASD who are referred for free or low-fee once-weekly therapy by their physician or case coordinator at a Naval Medical Center or state Regional Center, with a treatment emphasis on emotional dysregulation (e.g., anxiety, irritability) and interrelated autism symptom domains such as social initiation and responsiveness, and interfering repetitive behaviors.

Background and Significance:

Phenomenology and Course of Emotional Dysregulation in Youth with ASD. Youth with ASD often experience problems with emotion regulation. Descriptive research illustrates the numerous ways in which emotion dysregulation can manifest for youth with ASD (Mazefsky et al., 2018; Samson et al., 2014). Models of emotion regulation posit that mental processes can be used—involuntarily or volitionally—to diminish, negate, increase, or transform emotional signals that arise in response to specific situations or perceptions (e.g., Gross, 2015). For example, walking into a dark room may trigger an appraisal of potential threat and a corresponding fearful emotional state that motivates fight/flight behaviors, but this feeling may be regulated by mental processes such as reappraisal (thinking of the situation in a way inconsistent with the initial appraisal and corresponding emotion) or suppression (inhibiting the behavioral manifestations of the feeling; e.g., Megias-Robles et al., 2019). Skillful emotion regulation varies as a trait among youth and is strongly linked with less externalizing and internalizing symptomatology in school-aged youth (e.g., Aldao et al., 2016; Compas et al., 2017). In youth with ASD, common manifestations of poor emotion regulation include: (a) anxiety (e.g., a youth who fails to read aloud to her class out of fear of mistakes and humiliation, but experiences panic when compelled to do so), (b) excessive frustration (e.g., a youth who feels frustrated when producing imperfect work, who continuously writes, erases, and rewrites sentences that are appraised as insufficiently neat or descriptive), (c) sensory sensitivities (e.g., a youth who is distressed by the level of noise in a room and spontaneously shouts out for other to be quiet or runs out of the room), (d) sad and dysphoric mood (e.g., a youth who easily feels unappreciated, unworthy, or unhappy when faced with daily frustrations such as not being chosen first or receiving a mediocre test score), (e) irritability (e.g., a youth who becomes easily angry, defensive, or aggressive over minor provocations), or (f) impulsive goal seeking (e.g., a youth who is driven to engage in fun activities and in so doing ignores rules or others' rights) (e.g., Cai et al., 2018; Conner et al.,

2020; Ozsivadjian et al., 2012; Pouw et al., 2013). These difficulties in emotion regulation in youth with ASD are directly related to challenges with functional outcomes such as peer relationships and academic success (e.g., Goldsmith & Kelley, 2018; Jahromi et al., 2013; Storch et al., 2012).

Emotion dysregulation is strongly linked with morbidity in children, adolescents, and adults with ASD. Adaptive functioning in the domains of communication, socialization, daily living skills, and academic performance has been found to be severely compromised in the context of ASD throughout life, even for those with typical-range intellectual ability. For example, youth with ASD (even with IQ > 70) tend to score around the 1st to 4th percentile for their age and gender (i.e., 2 standard deviations or more below the 50th percentile on adaptive behavior scales), a trend that tends to worsen over the course of childhood (Pathak et al., 2017). As another example, in a study of 21-year olds with ASD who had IQ > 70, self-care skills were, on average, 7 to 16 years behind chronological age norms (Bal et al., 2015). In young adulthood, even those with typical range intellectual functioning often exhibit severe adaptive challenges such as non daytime activities and high levels of reliance on support for employment and housing (e.g., Howlin & Moss, 2012; Tillmann et al., 2019). A significant contributing factor to this high morbidity in ASD, even in the context of typical range intellect and verbal ability, is concurrent emotion dysregulation (e.g., Chiang & Gau, 2016), as manifested in anxiety, irritability, and impulsivity, with correlations between indices of dysregulation and a composite adaptive functioning index ranging from .46 to .56 (Kraper et al., 2017).

Emotion dysregulation is linked with higher autism symptom severity and is hypothesized to reciprocally exacerbate some of the underlying core aspects of ASD. For example, the low social motivation that typifies many children with ASD can lead to situational social withdrawal due to a lack of initiative in approaching others; this social withdrawal can be exacerbated by feelings of social anxiety and shyness that promote active avoidance and engender dysphoria in the presence of perceived social threats (Spain et al., 2018; Wood & Gadow, 2010). Heightened social withdrawal then leads to isolation in the peer group and a lack of peer conversation and friendship, amplifying or worsening these core ASD symptoms (cf. Dawson, 2008). Similarly, the dysregulated anger and frustration that often typify externalizing psychopathology can exacerbate ASD-related difficulties in social interactions and relationships (Shea et al., 2018). The development of both emotion regulation skills and social skills in an integrated treatment therefore has the potential to promote reciprocal progress in each domain as well as overall adaptive functioning. Complementarily, the rigid behaviors that typify aspects of the RRB domain (e.g., insistence on performing actions or engaging in routines one particular way) are likely driven by poorly regulated affect such as frustration and anxiety (rigid reactions to the possibility that deviations from expectations may either prevent reward/satisfaction, or increase the unknown and, thus, risk of punishment; Istvan et al., 2020; Samson et al., 2014). The phenotypic and psychometric resemblance of the RRBs with other manifestations of emotion

dysregulation suggest that at least some aspects of the RRB constellation are products of poor emotion regulation and may be partially addressed in treatments targeting regulation in ASD (Istvan et al., 2020).

Poor emotion regulation is a risk factor for youth with ASD that can lead to more impaired adaptive functioning and morbidity throughout childhood, adolescence, and adulthood. Poor emotion regulation increases the likelihood of developing emotional and behavioral disorders in the longer term, which is a significant risk factor for compromised functional and educational outcomes in individuals with ASD in adolescence and beyond. Improved emotion regulation is a critical target of treatment for many youths with ASD with likely implications for mental health outcomes as well as the core symptoms of ASD.

Efficacious Treatments for Emotion Dysregulation in Youth with ASD. Cognitive behavioral therapy (CBT) has been found to be efficacious for emotional disorders and autism symptoms in youth with ASD in studies conducted in research settings (see Weston et al., 2016). A CBT program developed in our laboratory, Behavioral Interventions for Anxiety in Children with Autism (BIACA), has been evaluated and found efficacious for clinical anxiety and core ASD symptoms across research settings (i.e., university-based clinics) in 6 to 14 year-olds with ASD. Wood et al. (2009a,b) examined the efficacy of BIACA relative to a waitlist control (N = 40, ages 7-11). Youth randomized to BIACA had primary outcomes comparable to those found in CBT for typically developing anxious youth, with BIACA demonstrating superiority to waitlist in response rate (76.5% vs. 8.7%), clinical severity (d = 2.5), and Social Responsiveness Scale scores (d = .75; Wood et al., 2009a,b). We extended and replicated these findings in a study of BIACA that included observational ratings of peer interactions during recess (Fujii et al., 2013; Wood et al., 2014), and two studies of early adolescents with ASD (Ehrenreich-May et al., 2014; Wood et al., 2015). Storch et al. (2013; 2015) independently replicated our findings in two separate randomized controlled trials (RCTs). BIACA is the only CBT program for ASD that meets criteria as “efficacious” based on American Psychological Association Division 53 Criteria (Southam-Gerow & Prinstein, 2014), based on its multiple successful replications by independent research groups and use of fully randomized designs at the youth level. BIACA is also unique in that it includes components to assist with social cognition and adaptive functioning (Drahota et al., 2011). Given that CBT has been efficacious in treating the anxiety of typically developing preschoolers (e.g. Hirshfeld-Becker et al., 2010), and that youth with ASD and intellectual disability have benefitted from gradual exposure to fearful stimuli (Koegel et al., 2004; Luiselli, 1978; Luscre et al., 1996), another strength of BIACA is that Danial and Wood (under review) have successfully adapted this therapy for those with moderate levels of intellectual disability (IQ > 50). Other CBT programs for youth with ASD have yielded similar promising results, although these RCTs have tended to be small (e.g., DeRosier et al.,2011; Reaven et al., 2012). In short, in research settings, CBT has been established as an efficacious

non-pharmacological treatment for emotion dysregulation and core autism symptoms in verbal youth with ASD (see meta-analysis conducted byWeston et al., 2016).

In our NICHD-funded multi-site study recently published in JAMA Psychiatry (Wood et al., 2020), impacts of BIACA were seen for emotion regulation and autism severity outcomes in comparison with a standard-of-practice CBT program. We recently completed a three-site RCT conducted at UCLA (PI: Wood), Baylor University (PI: Eric Storch), and Temple University (PI: Philip Kendall; R01-HD080098) in which 167 youth with ASD aged 7-13 years old were randomly assigned to BIACA, Coping Cat (a nonadapted CBT program for youth anxiety), or usual clinical care (Wood et al., 2020). The primary outcome measure was the Pediatric Anxiety Rating Scale, which is rated by an independent evaluator unaware of the child's condition. Additionally, general measures of emotion regulation (the Child Behavior Checklist; CBCL) and core autism symptoms (the Social Responsiveness Scale-2; SRS) were administered to parents. BIACA outperformed Coping Cat and usual care on each measure. This study is noteworthy as it is the first major test of BIACA in comparison with another established, manualized evidence-based CBT program. BIACA outperformed this treatment across each site, illustrating the specificity of its effects and the importance of designing CBT programs specifically for youth with ASD instead of relying on treatments developed exclusively with typically developing youth.

Several features distinguish BIACA from non-ASD-specific treatments. The BIACA manual has been developed and revised over the course of years beginning with pilot work (e.g., Sze & Wood, 2007, 2008), clinician feedback, and ongoing experience implementing BIACA with youth with ASD. Drawing from standard CBT practices, cognitive restructuring(challenging irrational thoughts), perspective taking, exposure therapy (facing fears), antecedent management, self-management, modeling, and role-play are core strategies of BIACA. BIACA also includes design features that make the program accessible to youth with ASD. Youth motivation is emphasized using pivotal response features of youth choice and shared control, embedding special interests into treatment, and setting motivating conditions for engagement (e.g., operant procedures). The BIACA program incorporates parent and teacher consultation. BIACA is attuned to the social environment in which emotion dysregulation arises for many youth with ASD by providing compensatory social engagement skills that promote success when confronting emotionally provocative social situations (Wood et al., 2009a,b; Wood et al., 2011). BIACA is informed by evidence-based treatments well-established for youth with ASD (NAC, 2015; NPDC, 2017) and has high treatment satisfaction among consumers (Wood et al., 2020). Although several other CBT programs have been developed for youth with ASD that have a narrower scope (e.g., focusing on anxiety), these are designed for group therapy(e.g., DeRosier et al., 2011; Kilburn et al., 2020) and none addresses the broad range of emotion regulation needs targeted in BIACA.

Although CBT programs have demonstrated efficacy for emotional dysregulation and core autism symptoms in youth with ASD, research has yet to establish the effectiveness of CBT in CMHCs. At present, the quality of care (defined as the use of evidence-based treatments and improvements in clinical outcomes) for youth with ASD in CMHCs where many youths with ASD receive services is variable and typically not evidence-based (Christon et al., 2015; Pickard et al., 2018). As a first step in remedying this problem, the effectiveness of CBT for youth with ASD needs to be evaluated in CMHCs.

Can CBT for Youth with ASD Be Effective in CMHCs? To date, work on therapy for youth with ASD has consisted of RCTs conducted under tightly controlled research conditions with limited attention to how, where (i.e., which settings), and by whom efficacious treatments are implemented. For example, the CBT studies conducted by Wood and others described above were all conducted in university settings. While this type of research (efficacy research) is an important step in determining the promise of a treatment, it does not necessarily foreshadow how successful the program might be in CMHCs (e.g., Kamio et al., 2015; Sandler et al., 2019). For example, CBT for anxiety in typically developing youth has found to be no more effective than usual care (Barrington et al., 2005; Southam-Gerow et al., 2010; Wergeland et al., 2014), and poor implementation of CBT by CMHCs clinicians may have accounted for these findings (McLeod et al., 2019; Smith et al., 2017). Also, a meta-analysis concluded that, although evidence-based treatments tend to outperform usual clinical care, the average effect was small (d = .29; Weisz et al., 2013), suggesting that a number of factors may undermine the effectiveness of evidence-based treatments for youth emotional and behavioral disorders in CMHCs. Given these gaps, research testing the effectiveness of promising treatments targeting emotion regulation for youth with ASD seeking treatment in CMHCs is an important first step towards improving the quality of care for youth with ASD in CMHCs.

Little effectiveness research using stringent methodology has been conducted in the ASD field, and the small number of extant trials - none done on psychotherapy -offer a cautionary tale. Several effectiveness studies of early intervention programs for ASD based on applied behavior analysis (i.e., not psychotherapy) have produced positive gains for youth with ASD akin to those found in efficacy studies, but these studies tend to lack the methodological rigor of efficacy trials (i.e., no independently evaluated outcome measures, random assignment, and experimental control) so it is difficult to be confident in the findings (e.g., Cohen et al., 2006; Eldevik et al., 2011). Most effectiveness trials of early intervention programs for ASD that have adhered to rigorous methodological standards have yielded outcomes that fall short of those obtained in research settings (see meta-analysis by Nahmias et al., 2019). To date, no known effectiveness trials of psychotherapy - one of the most common types of treatment used by school-aged youth with ASD (Stuart et al., 2017; Zablotsky et al., 2015) - have been undertaken. Taken together, these factors make it difficult to draw conclusions about the effectiveness of psychotherapy for youth with ASD being served in CMHCs. Moreover, the mixed results from the intensive early

intervention studies suggest that there are likely barriers to implementing even treatments with promising efficacy data for ASD in community settings(Mandell et al., 2013; Nahmias et al., 2019), which is consistent with findings from the broader youth mental health field (Weisz et al., 2013). Based on these findings, there have been calls for alternative approaches to evaluating the effectiveness of evidence-based treatments for ASD that directly address potential implementation barriers (Kasari & Smith,2013; Wood et al., 2015).

The high cost of treatment and the high clinical needs experienced by youth with ASD necessitate an empirically-informed special education, and related supports can exceed $50,000 for youth with ASD (see review by Rogge & Janssen, 2019). Despite the cost entailed, the services provided to youth with ASD in CMHCs are often not evidence-based and outcomes for many youth are not optimal (e.g., Christon et al., 2015; Pickard et al., 2018). Relatively few mental health clinicians are trained to use evidence-based treatments such as CBT for ASD (Aiello et al., 2017; Combes et al., 2016; Sansosti & Sansosti, 2013). In a pilot study we conducted on clinicians' use of evidence-based treatments for mental health challenges in youth with ASD (N = 52 clinicians), our interview and self-report data suggest that few clinicians have access to the training and consultation required to learn how to implement evidence-based treatments designed to address emotion regulation for school-aged youth with ASD, and that many practices used are not tied to the evidence base (Klebanoff & Wood, 2018). To remedy this problem, two steps are needed:

1. First, we need to determine if evidence-based treatments that promote emotion regulation in youth with ASD are effective in CMHCs. CBT programs such as BIACA clearly have promise, demonstrated in multiple efficacy studies, to provide structure in the treatment for youth with ASD to significantly improve clinical care.

2. Second, in conducting effectiveness research in this area, robust and field-tested clinician training and consultation procedures that can address barriers to implementation are needed. Inadequate clinician expertise and availability is a barrier to offering psychotherapy to those with psychiatric need (e.g., Fairburn & Patel, 2014). Research suggests that evidence-based treatments require sustained clinician training and consultation procedures for successful implementation in CMHCs (Schoenwald, 2012). However, if clinician training and consultation procedures are too costly, this could effectively exclude many community mental health settings and thus limit efforts to improve the quality of care for youth with ASD (Brookman-Frazee et al., 2012b; Wood et al., 2015b). Thus, efforts to evaluate the effectiveness of evidence-based treatments require effective clinician training and consultation procedures that support clinician mastery and expertise and are also cost-effective and scalable (e.g., McLeod et al., 2018; Schoenwald, 2012).

Using A Distance Consultation Model to Address a Common Implementation Barrier. Efficient training and consultation methods are needed to ensure treatment models for ASD are acceptable and feasible for mental health clinicians in CMHCs (cf. Wood et al., 2015b). Contemporary training and consultation procedures can produce meaningful changes in clinicians' delivery of evidence-based treatments in research settings (Herschell et al., 2010), including evidence-based treatments for youth with ASD (Stahmer et al., 2016). However, financial, geographic, and structural barriers make it difficult for clinicians treating youth with ASD to access the training and consultation opportunities needed for high quality implementation of evidence-based treatments (Brookman-Frazee et al., 2019; Maddox et al., 2020). Most training and consultation models rely on face-to-face contact, which limits the accessibility of evidence-based treatments in CMHCs. Thus, there is an emerging consensus that the internet represents a feasible and scalable platform for training clinicians and paraprofessionals (Fairburn et al., 2014; Neely et al., 2018). We therefore will utilize an efficacious distance training and consultation model to support the implementation of BIACA in CMHCs, drawing from the successful Practice Based Coaching model used in previous BIACA trials.

Practice-based coaching is an efficacious consultation method used in BIACA. The successful implementation of evidence-based treatments in CMHCs requires clinician training and consultation strategies that support treatment integrity (Hogue et al., 2013; McLeod et al., 2018). Defined as the quantity (i.e., treatment adherence, extent to which prescribed strategies of an evidence-based treatment are delivered) and quality (i.e., clinician competence, how well each prescribed strategy is delivered) of treatment delivery, achieving treatment integrity is key to implementation success (Proctor et al., 2011; Sutherland et al., 2018). Since research suggests that professional development in the form of one-time training does not result in proficient delivery of evidence-based treatments in CMHCs (Bearman et al., 2017; Becker & Domitrovich, 2011; Sholomskas et al., 2005), BIACA uses a manualized Practice Based Coaching consultation model where a trained consultant meets weekly with a clinician to provide support in treatment delivery via practice-based feedback. This model is supported by a large literature that suggests that consultation strategies such as collaborative decision making, modeling, performance feedback, and opportunities to problem solve enhance and sustain clinicians' delivery of treatment components (e.g.,McLeod et al., 2018; Reyes et al., 2012). Research suggests that practice-based coaching models result in increased adherence and competence of delivery beyond training alone, highlighting the importance of this approach for both increasing and maintaining treatment integrity (Sutherland et al., 2013, 2014). Moreover, integrity data from our BIACA studies suggest that our practice-based consultation model results in high integrity (Wood et al., 2009a, 2015a, 2020). Thus, the training and consultation model that is used in BIACA will address a common implementation barrier that can undermine the effectiveness of evidence-based treatments in CMHCs.

In summary, CBT is well-suited to address poor emotion regulation among youth with ASD, yet barriers exist to implementing CBT for youth with ASD in CMHCs. The Practice Based Coaching model used in BIACA addresses one significant barrier–the need for effective training and consultation methods to ensure high quality care. Implementing this model via video conferencing in the present study will transform the Practice Based BIACA training and consultation model into an affordable and scalable method that could be utilized in future dissemination efforts should the proposed effectiveness study yield promising results. However, other potential implementation barriers may influence the effectiveness of CBT for youth with ASD in CMHCs, so we will employ an effectiveness-implementation Hybrid I design (see Curran et al., 2012) that will allow us to collect data on clinician- and client-level factors that influence BIACA's effectiveness.

Identifying Youth- and Clinician-Level Factors that Predict Treatment Response in CMHCs. To maximize the effectiveness of CBT for youth with ASD in CMHCs, more information about client and clinician factors that influence CBT outcomes in community settings is needed. To facilitate the transition of evidence-based treatments from effectiveness testing (does it work in community settings) to implementation research (what strategies are required to integrate a treatment into a community setting), researchers have proposed an innovative effectiveness-implementation hybrid design (Curran et al., 2012), which allows for testing a treatment's effectiveness while simultaneously collecting information on factors that influence effectiveness and its potential for implementation in CMHCs. The sole focus on clinical outcomes in effectiveness studies limits understanding of the factors that might influence implementation, for example, ensuring that a treatment is correctly deployed. A key feature of this study is the examination of how clinician-level (e.g., treatment integrity, acceptability, feasibility) and client-level (e.g., verbal ability) factors influence the effectiveness of BIACA and may influence its potential for implementation and sustainment in CMHCs.

Clinician-levels factors, such as mastery of core CBT strategies, are possible predictors of CBT effectiveness that represent key indicators to the uptake and sustainment of CBT. As noted above, for example, poor treatment integrity of CBT by CMHCs clinicians may have accounted for the underperformance of CBT versus usual clinical care in an effectiveness trial for youth anxiety in typically developing youth (McLeod et al., 2019; Smith et al., 2017). Poor treatment integrity indicates that the training and consultation procedures are not leading to mastery of core CBT strategies, which is important for positive youth outcomes (Hogue et al., 2008; Sutherland et al., 2018). Along with treatment integrity, other key indicators of CBT uptake and sustainment are important to assess during effectiveness evaluation (Proctor et al., 2011). Specifically, when initially introduced into a new setting, clinicians may react to a new program such as CBT either with resistance or with positive perceptions, so it is important to assess acceptability (i.e., perception that the treatment is agreeable, feasible, or satisfactory) and feasibility (i.e., extent to which a treatment can be successfully carried out in a particular setting). Information gathered

about clinician-level factors that predict CBT effectiveness are important to identify so that specific strategies can be developed to support future adoption, effective delivery, and sustainment of CBT for youth ASD in CMHCs.

Youth factors such as age and communication skills may also be linked with CBT effectiveness. Little is known about the potential similarities and differences in the youth with ASD who were treated in the efficacy trials and those who seek mental health services in CMHCs. Existing CBT programs have been designed for the youth with ASD seen in efficacy trials may thus not be an optimal fit for the youth in CMHCs. To ensure that CBT is a good fit for the clinical needs of youth with ASDseen in CMHCS we will evaluate whether a series of youth characteristics predict CBT effectiveness. Our selection of predictor variables is based on empirical precedent, theory, and logic. A number of RCTs for pediatric anxiety have found that older youth age predicts better treatment outcomes (see Skriner et al. 2019). Puleo and Kendall (2011) found that ASD symptom severity in typically developing youth predicted treatment response in standard CBT versus family-based CBT. A similar relationship is expected in the proposed trial. For example, greater ASD-related communication impairments may be a hindrance to optimal response to CBT due to impacts on comprehension and, hence, motivation. Although BIACA uses ASD-specific adaptations and collateral support to overcome communication challenges, it is possible that further modification may need to be made in order to optimize fit with youth with ASD in CMHCs.

In summary, to help maximize the effectiveness of CBT for youth with ASD in CMHCs, it is critical to assess how client- and clinician-level factors influence implementation outcomes (Lewis & Simons, 2011; Palinkas et al., 2008)–do some clients benefit more from CBT than others? Do clinicians find the CBT program feasible, acceptable, and usable? What clinician factors most strongly predict youth outcomes (e.g., training engagement, CBT knowledge, integrity)? This information could help us develop implementation strategies that support the implementation of the BIACA program in CMHCs.

Specific Aims

The specific aims of this study are:

1. Aim 1. To compare the effectiveness of CBT and usual clinical care for addressing emotion dysregulation (e.g., irritability, anxiety) and core autism symptoms in youth with ASD who are referred for mental health treatment by their providers in Naval Medical Centers, state-funded Regional Centers, or California public schools.

2. Aim 2. To characterize the mental health clinicians' (e.g., psychologists') level of engagement in online training and consultation, knowledge of CBT, perceptions of feasibility and acceptability, and treatment integrity.

3. Aim 3. To examine how clinician-level factors (i.e., treatment integrity, feasibility, acceptability) and youth-level factors (e.g., age, communication ability) influence youth outcomes in the context of CBT delivered in community mental health centers in which training and consultation is provided via video conferencing.

Research Plan:

Overview. The proposed investigation is a randomized, controlled trial comparing CBT to usual clinical care for youth (aged 6-14 years) with ASD and emotional dysregulation (e.g., irritability, anxiety). We will randomly assign practitioners (at least 50) who address mental health needs in children with autism (e.g., therapists, counselors, speech/language pathologists, occupational therapists, psychologists, and behavior analysts), each treating up to 4 youth (N = 100 youth total), to (a) Consultation-Based Training on BIACA (referred to as "BIACA" below, for brevity) or (b) Usual Care Augmented by Self-Instruction Resources for CBT for Autism (referred to as "Usual Care/Self-Instruction" below), in a 1:1 allocation. The BIACA manual is well-supported in our efficacy research, has been replicated in other centers (Storch et al., 2013, 2015), is free/open-access (meya.ucla.edu), and has user-friendly digital and traditional print materials for mental health clinicians (e.g., psychologists, counselors) to use in preparing for and conducting therapy sessions. The primary outcome measure will be assessed weekly. Additional assessments will occur at Screening, Mid-treatment, Post-treatment and 3-month Follow-up.

Participant Enrollment. Participants will include 50 to 80 practitioners whose practice includes some clients with autism and emotional/behavioral needs whose clinical services (e.g., therapy, counseling) are paid for by the US military Tricare Health Program or the California public schools, or who are clients of the California Regional Centers; and 1 to 4 youth with ASD (ages 6-14 years) and their parents per practitioner (for a total of 100 child and parent dyads). Practitioners will be encouraged to recruit 2 of the families they work with to participate with them, however, to accommodate varying capacity to recruit client families on the part of individual practitioners, a range of 1 to 4 client families per participating clinician will be permitted.

Inclusion/Exclusion Criteria

<u>Clinician Inclusion Criteria:</u>

(1) All practitioner participants will regularly treat at least some youth with ASD within a recognized field of practice (e.g., clinical psychology, counseling, marital and family

therapy, social work) and will serve youth with ASD referred by the Regional Centers, Tricare/NMCSD, or the California public schools.

(2) Practitioners will agree to invite one or more potentially eligible families of youth with ASD so that at least 2 (and no more than 4) of the new families referred to them participate in the study (i.e., each clinician will aim to have a cluster of two families randomized to the same condition with them; however, the two referrals can be non-parallel and clinicians will not be required to enroll a second client to remain in the study, since there is no way for them to guarantee future enrollment from client families. As needed, additional clinicians can be enrolled in the study to reach the target of 100 youth.).

Youth Inclusion Criteria:

(1) Youth participants will be boys or girls between 6 and 14 years of age with a documented clinical diagnosis of ASD and will be newly referred for outpatient services with a participating clinician.
(2) Youth will have a pre-existing clinical diagnosis of ASD made by an appropriate licensed professional (e.g., clinical psychologist, developmental pediatrician) which will be documented in a report or medical note provided by the family or confirmed telephonically by the diagnosing professional.
(3) The parent-reported Social Responsive Scale-2 (SRS-2; Constantino & Gruber, 2012) Total T-Score will be > 60 (cut-score maximizing ROC curve parameters for screening for ASD; area under the curve = 98.8%; Schanding et al., 2011).
(4) Youth will meet criteria for clinically significant emotion dysregulation symptoms as defined by a minimum T-score of 60 on the Externalizing or Internalizing subscales of the parent-reported Brief Problem Monitor (BPM) and at least 15 T-score points over 50 between these two BPM subscales (e.g., Internalizing = 60 + Externalizing = 55).
(5) The youth has a Vineland Adaptive Behavior Scales-3 Communication Composite Standard Score > 60 and Expressive Communication subscale v-score > 8 (in both cases > 1st percentile).

Exclusion criteria. For youth participants presenting with severe comorbid symptomatology (e.g., psychotic symptoms), the comorbid conditions cannot be sufficiently severe to warrant immediate treatment or require ongoing medication titration. Current clinically significant suicidality at screening or youth who have engaged in suicidal behaviors within 6 months will be excluded and referred for appropriate clinical treatment.

Screening Procedures

Clinician Phone Screening: Potentially eligible direct providers (i.e., practitioner participants as described above) will respond to the introductory letter, flyer, email, web contact message, or

phone call by contacting the project director at UCLA using the phone number provided in the letter. The clinician will be provided with information about the study, have questions answered, and, if interested in possibly participating, will be asked several screening questions and sent or emailed an IRB-approved clinician consent form in the mail (with a stamped, pre-addressed return envelope addressed to the project director. The clinician's consent form thoroughly describes the procedures to be followed in the study, the type of assessments involved, and the data that will be recorded (i.e., treatment sessions, consultation sessions, and Google Analytic data from the website). It will be emphasized that a decision to participate or not in the study will have no bearing on the clinician's status with UCLA, NMCSD or Tricare, the Regional Centers, the California public schools or CAPTAIN. Mental health clinicians who continue to be interested in the study will have a second phone call with the project director to review the consent form and have any additional questions answered. During this phone call the research team will provide a full description of procedures to be followed and the type of assessments involved. Participants will also be informed at this point that all information they provide will be kept confidential to the fullest extent allowable by law. No information gathered as part of this research will be shared with agency directors or supervisors. Those who consent in writing to participate will be considered probably eligible for randomization when a family referred to them consents to participate, pending submission of their baseline measures.

Youth Participant Screening Procedure: Participating mental health clinicians will be given a study recruitment flyer to share with potentially eligible parents of youth with ASD and emotion/behavioral target problems referred through the Tricare (US armed forces) health program or through the Regional Centers or via the California public schools. To avoid coercion of families, clinicians will be reminded not to use study enrollment as a condition for providing treatment, and to emphasize that not participating will not affect the family's access to care or relationship with the relevant institutions. The study flyer has contact information for the research team, enabling the family to contact the team directly should they wish to learn more about the study. Families will be reassured via written materials that choosing not to participate in the study will in no way affect their access to clinical care or relationship with their clinician, UCLA, Tricare, NMCSD, the Regional Centers, or the California public schools. All written study materials (e.g., flyers, consents, questionnaires) for families are available in both English and Spanish.

Potentially interested families of youth with ASD will contact our project director. The project director will provide information about the study, provide a full description of procedures to be followed and the type of assessments involved, answer questions, conduct a brief screening and email or mail an IRB-approved written consent and assent forms for the parents and youth with a stamped, pre-addressed return envelope addressed to the project director if the family remains interested. The consent (parents) and assent (youth) forms thoroughly describe the procedures to be followed in the study, the type of assessments involved, and the data that will be recorded

(i.e., treatment sessions). Families will be reassured by the project director that choosing not to participate in the study will in no way affect their access to clinical care or relationship with UCLA, Tricare, NMCSD, the Regional Centers, or the California public schools. Families who continue to be interested in the study will have a phone call with the project director to review the consent form (with the parent) and child assent form or teen assent form (with the child/teen and the parent) and have any additional questions answered. There will be no consequences for individuals who indicate interest and then do not enroll in the study. All participants will be free to withdraw their participation at any time of their choosing. Those who consent (parents) and assent (youth) in writing to participate will be considered potentially eligible for the study and proceed to Screening measures.

Screening Measures: Families who provide written consent and assent for study participation will receive Screening assessment materials (Brief Problem Monitor, Social Responsiveness Scale-2) either electronically via REDCap or in paper format; the Vineland Adaptive Behavior Scales-3 Communication Scales interview will be administered over the phone.

Baseline measures: Eligible families, mental health clinicians, and teachers will complete the Baseline measures (see Assessment and Measures below) prior to randomization.

Treatment Conditions

Randomization. A cluster-randomized design will be implemented (clients nested within mental health clinicians); thus, the unit of randomization will be at the clinician level. Eligible mental health clinicians will be randomized to the BIACA arm or the Usual Care/Self-Instruction arm in a 1:1 ratio. Randomization will be computer-generated at VCU using the stratification and randomization procedure developed at UCLA and will stratify on (a) site and (b) mental health clinicians' years of experience treating youth with ASD (< 2 years or > 2 years). The stratification plan will allow for enrollment across the three sites to accrue on a first-come-first-serve basis in order to ensure that the sample is broadly representative of each site (as opposed to arbitrarily turning potential participants away at a site because their "quota" for the year has been met). It is unclear what ratio of more experienced to less experienced clinicians are practicing at these sites. Therefore, stratification efforts will aim to maintain the same ratio of practitioners from the three sites in the two arms (BIACA and Usual Care/Self-Instruction; i.e., a 1:1 ratio at each site) and to maintain the same ratio of more experienced and less experienced practitioners in the two arms at each site. Randomization status will not be revealed to independent evaluators (IEs) or the statistician. Advanced graduate trainees who have been approved by the IRB to work on the study and trained to research reliability to administer the study assessments will serve as IEs.

Consultation-Based Training on BIACA. In the BIACA program (Wood et al., 2009b), clinicians work with families for 16 weekly sessions, each lasting up to 60 minutes (30 minutes with the youth and 30 minutes with the family/parents). The BIACA approach has expanded traditional anxiety-focused CBT and irritability-focused parent-training models to include the ASD-related clinical characteristics (e.g., social withdrawal, inflexibility) that are closely related to anxiety and irritability and often are the initial referral focus in ASD. Youth with ASD and significant emotional dysregulation are doubly impacted: they have core social deficits related to ASD (e.g., impaired conversation initiation and maintenance) as well as debilitating emotional reactivity/dysregulation that is associated with further social maladjustment in ASD. The BIACA manual includes 4 emotion coping skills training modules. Anxiety, rigidity and inflexible routines, and stimuli that trigger frustration and irritability are all addressed using in vivo exposure therapy strategies (in some cases with response prevention; i.e., the client planning to suppress a strong emotional reaction) during sessions. Friendship skills, social entry skills (e.g., joining games at school), and reciprocal conversation skills are addressed with modeling, self-management, and parent- (or teacher-) implemented social coaching in daily settings. Therapeutic concepts are taught to youth using modeling, guided discussion,drawing/cartooning, writing (e.g., “thought bubbles"), role playing, and Socratic questioning. In-session reward and youth-choice principles are used to enhance the alliance and motivation to participate in therapy procedures. Behavioral parent training elements are emphasized in most sessions to help motivate youth towards treatment goals at home and in the community and to reduce unintended reinforcement of target symptoms (key parent-mediated evidence-based strategies include contingency management, extinction, antecedent management and “special play time”, and participation in home-based exposure and response prevention practice). The CBT program is flexible and employs a partially modular format guided by a treatment algorithm designed to emphasize clinical components addressing each youth¿s most pressing/severe emotional dysregulation and ASD symptoms. For youth with Vineland-3 Communication Standard Scores >60 and <70,therapy is adapted through the use of toy and play-based representations of challenging situations for the coping skills training phase, simplified mantras for cognitive restructuring, and more action-oriented rehearsal and exposure work instead of verbally mediated preparation for exposure (Danial & Wood, under review).

Clinician training and consultation: All mental health clinician training and consultation will be conducted remotely online. Online training materials (e.g., demonstration videos of CBT sessions; corresponding written session materials) have been developed in the context of a NIMH R34 grant awarded to Drs. Wood and McLeod (available on meya.ucla.edu; 1R34MH110591).

In addition to ongoing access to these online training and clinical resources for BIACA, mental health clinicians will be provided with weekly 30-minute video-conference-based consultation

sessions with an expert in BIACA (Dr. Sze-Wood) to provide a professional but cost-effective means of developing expertise in BIACA. These consultation sessions are manual-driven and utilize a Practice-Based Coaching format, in which a trained consultant (in this case, Dr. Sze-Wood) meets weekly with clinicians to provide practice-based feedback (cf. McLeod et al., 2018). The core premise of Practice-Based Coaching is that in order to promote long-term learning, consultation must help clinicians further develop procedural knowledge along with the metacognitive skills required to apply that knowledge and skills to novel situations (Bennett-Levy, 2006; Falender &Shafranske, 2014). In our BIACA Practice Based Coaching model, consultation meetings include agenda setting, case material review, planning for the next treatment session, and a meeting summary. Within this structure, two core active strategies are embedded (McLeod et al., 2018; Rakovshik et al., 2016; Sholomaskas et al., 2005): (a) behavioral rehearsal of the core therapeutic strategies found in BIACA and (b) cognitive rehearsal in which the case formulation for a client is discussed and applied to the particular circumstances of the client. Across BIACA consultation meetings, the delivery of these active strategies is guided by three principles from adult learning theory (Rakovshik & McManus, 2010; Soderstrom & Bjork, 2015): (a) Variability and distribution of practice¿this principle involves having clinicians engage in the skill- and cognitive-based tasks across different conditions (e.g., asking a clinician to formulate a case conceptualization based on a child with ASD, with or without conduct problems), over time (i.e., rehearsal of specific skills is spread over weeks), and with multiple clients (Jackson et al., 2017). The BIACA consultation manual focuses on a single set of therapeutic strategies each week related to the content of the BIACA manual to be delivered next; however, massed practice (i.e., intense practice of the same skill in a single meeting) does not promote long-term learning (Soderstrom & Bjork, 2015). To optimize long-term learning, cognitive and behavioral rehearsals related to varying BIACA strategies (e.g., exposure, reward, self-management) are spread across multiple consultation sessions. (b) Retrieval practice: this principle involves asking clinicians to demonstrate core cognitive- and skill-based tasks in different conditions to help promote long-term learning. Research indicates that prompting trainee knowledge retrieval over time helps to solidify learning gains and promote long-term learning(Soderstrom & Bjork, 2015). (c) Difficult cognitive- and skill-based practice: this principle involves posing “what if” questions regarding complex clinical situations in cognitive rehearsals and engaging clinicians in challenging behavioral rehearsals (e.g., by varying the level of difficulty of the client) to help with skill acquisition and the development of active encoding processes (McLeod et al., 2018). Treatment integrity data from our BIACA studies suggest that our practice-based consultation model results in high clinician fidelity (Wood et al., 2009a, 2015a, 2020).

Although clinicians in this treatment arm will be encouraged to apply CBT/BIACA techniques where appropriate, ultimately decisions on what therapy topics and practices are used throughout treatment are their own, and there will be no pressure or consequences of any sort for clinicians who choose to utilize therapeutic strategies that differ from those discussed in the consultation

meetings. Rather, the consultation meetings will continue on as per schedule, with the clinician and consultant discussing therapeutic options in a collegial way throughout the study.

Usual Care Augmented by Self-Instruction Resources for CBT for Autism. Youth in this arm will receive any therapy, counseling, and/or behavioral treatment that is normally provided by their mental health clinician. However, this arm will also be congruent with DoD guidance (FY20-ARP-GAI-1.pdf) stating, "Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements." Because of this requirement, therapists randomized to the Usual Care/Self-Instruction arm with at least one client participating will be informed that they have immediate access to CBT-for-autism self-instruction materials that are already freely available to any clinician at meya.ucla.edu, to supplement their usual clinical care, if they so choose, until they complete their Usual Care/Self-Instruction participation and are offered direct training and weekly consultation in BIACA. While self-instruction in any psychotherapy approach often has only modest effects on the practices of many clinicians, making clinicians aware of a training resource they already had free access to (but may have been unaware of) offers an authentic means for therapists to improve upon the standard of care while still maintaining the critical element of a usual care condition, which is the therapist's autonomy in selecting any treatment approach they view as most suitable. The BIACA observational measurement tools (see below) will be used to characterize the overlap and differences between UsualCare/Self-Instruction and BIACA. Mental health clinicians randomized to Usual Care/Self-Instruction will be offered training and consultation on BIACA specific to the youth enrolled in the study (if they are still in treatment) after the follow-up measures have been collected. Families will be free to accept or decline ongoing treatment from the mental health clinician, or to begin any other clinical service they wish, throughout the Usual Care/Self-Instruction arm. To document the overall set of clinical services sought during the study by each family throughout the acute phase, the Services Assessment for Children and Adolescents will be administered to parents by the IE at Pre- and Post-Treatment (see Assessment Measures, below).

Assessments and Measures

Assessment measures were selected to address the critical need to avoid participant burnout in effectiveness research. First,we took the approach of beginning with identification of primary outcomes variables, measures needed to assess eligibility, and only then considering the most salient secondary outcome variables or possible predictors. Second, we focused on convenience. If two measures had an equally good psychometric rationale for use in the study but there was greater convenience and efficiency for the participant in one of the measures (e.g., shorter to complete, easier to understand, superior accessibility via electronic entry options), then the more convenient and efficient measure was chosen.

Measures will be administered at Screening/Baseline, Mid-treatment (session 8), Post-treatment (session 16), and/or 3-month Follow-up (3-months after Post-treatment), except for the primary outcome measure (Brief Problem Monitor) and secondary outcome measure (Youth Top Problems) which will be administered at Screening/Baseline, weekly throughout therapy, and at 3-month Follow-up. To minimize avoidable error variance, the parent respondent will be the same across timepoints (i.e., families will not switch from a mother to a father reporting on outcome measures from one assessment to the next). Families who drop out of treatment before session 16 will be offered the opportunity to continue with study assessments on the same timeline as if they had remained in treatment through session 16.

In terms of measure administration, paper-and-pencil measures, such as the Brief Problem Monitor (BPM; below), will be offered to participants either by mail (with a self-stamped and self-addressed envelope for return to UCLA) or by online administration using a proprietary secure, HIPAA-compliant internet-based questionnaire data capture tool developed for this study at UCLA by Computing Technologies Research Laboratory (CTRL) at the UCLA Semel Institute and REDCap. REDCap is a secure web application for building and managing online surveys and databases. REDCap can be used to collect virtually any type of data in any environment (including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR), and it is specifically geared to support online and offline data capture for research studies. All measures, like the BPM, will also be offered to participants in Spanish (if preferred) either by mail (with a self-stamped and self-addressed envelope for return to UCLA) or by online administration using a proprietary secure, HIPAA-compliant internet-based questionnaire data capture tool.

Interview measures (e.g., YTP, SACA, and Vineland-3, below) will be administered over the phone.

Primary Outcome Measure

Brief Problem Monitor (BPM). The BPM (Achenbach et al., 2011), an abbreviated version of the widely used Child Behavior Checklist for Ages 6-18 (CBCL/6-18) will be used as an entry criterion for this study, with pretreatment T-scores of = 60 on the Externalizing or Internalizing subscale and at least 15 T-score points over 50 between these two subscales (e.g., Internalizing = 60 + Externalizing = 55) being required for study eligibility. The sum of the parent-report BPM Internalizing and Externalizing subscales will also be utilized as the primary outcome measure in this study to index treatment-related improvement in symptoms of emotion dysregulation that cut across multiple mental health disorders (i.e., anxiety, irritability, depressed mood, anger, defiance).

Imperative to effectiveness research, the BPM was selected for both psychometric properties and efficiency. Completed in 1 to 2 minutes, the BPM reduces the parent form of the 113-item CBCL

to 19-items for rating internalizing, externalizing, and attention problems central to evaluations of symptoms of emotional dysregulation. Each item is rated 0 = not true, 1 = somewhat true, or 2 = very true. Psychometric research shows strong support for the BPM, with high correlations between the CBCL and BPM identified for the total score (r = 0.95) as well as the Internalizing (0.86), Externalizing (0.93), and Attention (0.97) scales (Piper et al., 2014). BPM subscale scores were also higher for children with psychiatric diagnosis (e.g., autism, depression, anxiety, attention-deficit hyperactivity disorder) when compared to a sample that had not been diagnosed with these disorders. The BPM can be administered remotely via the internet (we have a written agreement with the test publisher). The BPM will be administered at baseline, weekly during the 16 weeks of acute treatment, and again at the 3 month follow up.

Secondary Outcome Measures

Youth Top Problems (YTP) Rating Scale. The YTP approach is a valid and reliable personalized assessment method that is sensitive to psychotherapy treatment response in children that allows clinicians and researchers to identify problems of the children or adolescents that are especially important from the perspective of a caregiver (Weisz et al., 2011, 2012). The YTP caregiver interview (YTP) will be administered after the Vineland and SACA at screening.

This interview allows caregivers to state in their own words what current symptoms/problems experienced by their child are the most concerning to them. The specific problems are transcribed in the parents' own words. Interviewers then obtain Initial YTP Symptom Severity Ratings for each symptom/problem on a scale ranging from 0 (not at all) to 10 (very, very much). Up to 12 top symptoms/problems will then be rated weekly throughout the child's therapy by the caregiver.

The YTP will be administered at baseline, weekly during the 16 weeks of acute treatment, and again at the 3 month follow up.

Satisfaction with services (SWS). Caregiver satisfaction with treatment will be assessed at Mid- and Post-treatment with a short caregiver-report measure used in Hawley and Weisz (2005).

Additional Screening/Baseline Measures

Service Assessment for Children and Adolescents (SACA). The SACA (Horwitz et al., 2001) is a psychometrically sound parent interview about the broad use of mental health services. It will be administered over the phone by an Independent Evaluator at Baseline and Posttreatment. If the youth is taking medication during the study period, the portion of the SACA focused on medication type and dosage will be administered to the parent or the treating physician, depending on parental awareness of prescription and dose.

Vineland Adaptive Behavior Scales-3 (Vineland 3). The Vineland 3 (Sparrow et al., 2016) will be administered in its parent-report format to assess youth communication skills for study eligibility screening (e.g., communication skills). The Vineland-3 has established psychometric properties in ASD samples and its Communication Domain score is strongly associated with IQ scores in individuals with ASD (e.g., Kanne et al., 2011). It will be administered over the phone at baseline.

Therapy Procedures Checklist (TPC). The TPC (Weersing et al., 2002) is a 62-item self-report measure used to assess practitioners' use of treatment techniques that correspond to cognitive, behavioral, psychodynamic, or family orientations. Techniques in each orientation are summed to create total scores, with high scores reflecting extensive use of techniques consistent with that orientation. The TPC has excellent internal consistency and test-retest reliability (Baumann et al., 2006; Weersing et al., 2002). The TPC also collects information on educational and training background (e.g., years of clinical experience). It will be administered at post-treatment.

Background Information Questionnaires. This form collects basic demographic data about the family or clinician. It will be administered at baseline. There is a version for families, and a version for clinicians.

Implementation Measures

Google Analytics. CBT clinicians' level of engagement in online training and consultation will be evaluated. In the BIACA arm, clinicians' time spent in video-chat based weekly consultation, the initial video-based training, and the use of the online BIACA therapy support materials (e.g., reviewing video models of therapy strategies on the meya.ucla.edu website) will be measured weekly during the acute phase of treatment. Google Analytics will be used to record the amount of time that mental health clinicians are watching the training video and using the support materials.

The BIACA Therapist Quiz. Clinicians' knowledge of CBT will be assessed with the BIACA Therapist Quiz consisting of 4 items per module (24 items total) that assess clinicians' knowledge of BIACA concepts and clinical scenarios. This measure will be administered to clinicians at posttreatment to assess development of CBT knowledge through the process of training and consultation BIACA versus Usual Care/Self-Instruction. The score on the BIACA Therapist Quiz ranges from 0 to 24. It will be administered at baseline and post-treatment.

BIACA Fidelity Scales. An important aspect of our previous BIACA work has been the development of the *BIACA Fidelity Scales* (McLeod & Wood, 2018; Wood et al., 2009a) to evaluate treatment integrity. These scales measure both the adherence and competence of

clinician delivery of key components of BIACA. Adherence refers to the extent to which the clinician delivers the treatment as designed, while competence refers to the level of skill and responsiveness demonstrated by the clinician when delivering the strategies. Each component captures a unique aspect of treatment integrity (Sutherland et al., 2013). Beginning in session 1, and then every 4 sessions thereafter, clinicians in both treatment arms will record their treatment session with the child and family. These recordings will be rated by trained IEs using the BIACA Fidelity Scales. The scoring strategy for the Adherence scale is based upon past treatment integrity research designed to yield quantitative data that are non-subjective and are specific with regard to how clinicians deliver cognitive-behavioral strategies (e.g., Carroll et al., 2000; Hogue et al., 1996; McLeod et al., 2015; Southam-Gerow et al., 2016).

Coders are asked to estimate the extent to which clinicians engage in each strategy during a session using a 7-point Likert-type scale with the following anchors: 1 = not at all, 3 = somewhat, 5 = considerably, 7 = extensively. The Competence scoring strategy is also based upon exemplar coding systems (e.g., Hogueet al., 2008; McLeod et al., 2018). Coders rate items on a 7-point Likert-type scale. For each item, coders rate whether a clinician demonstrated: (a) Expertise, commitment, motivation; (b) Clarity of language; (c) Appropriate timing (skillfulness); and (d) Ability to read and respond to where a child appears to be (responsiveness). The BIACA Fidelity Scales will be used not only to assess treatment integrity in the BIACA arm, but also to help differentiate and partially characterize the strategies used in the Usual Care/Self-Instruction arm.

BIACA Consultation Fidelity scale. Evaluation of consultant's integrity to the Practice-Based Coaching model. All weekly BIACA consultation meetings will be recorded. Consultation integrity will be assessed using the BIACA Consultation Fidelity scale. The BIACA expert consultant will self-report on this form following each consultation session, and 20% of the consultant sessions will be independently observed by a trained RA using the form's 3-point Likert-type scale (Not at all, Somewhat, Extensively) to assess the adherence to the components of the consultation model.

CBT clinicians' perceptions of feasibility and acceptability. Acceptability (i.e., satisfaction with various elements of BIACA) and Feasibility (i.e., suitability for use; practicability) will be measured using existing measures presented and recorded over video chat at the end of treatment. Acceptability and feasibility will be assessed quantitatively using the (1) Evidence-Based Practice Attitude Scale (Aarons, 2004) and the (2) Usage Rating Profile-Intervention (Chafouleas et al., 2011). We will review answers on the measures and use them (3) to guide an approximately 20-minute semi-structured interviews with the mental health clinician at the end of the acute treatment for clinicians in the BIACA arm. In addition, the following areas will be queried in these interviews: the quality and strengths/weaknesses of the online training and consultation interface (e.g., length and content of training and session materials and video chat

consultations), system efficiency (how much time was put into the weekly session preparation and was this viewed as too much or acceptable), and clinical strategies as applied to their clients. Recorded interview responses will be transcribed.

Rater Training

All symptom-oriented assessments will be conducted by qualified IEs. Primary IE training for symptom measures will be conducted by Dr. Wood during the study startup phase.

Observational coding procedures. For the Implementation measures, Dr. McLeod will train research assistants via video conference over 6 weeks during Year 1 using a 3-step process:

(1) Step 1: Coders will receive didactic instruction, review the scoring manuals, and engage in coding exercises to expand understanding of each item.
(2) Step 2: Coders will independently score sessions from examples pulled from 5 BIACA sessions/consultations/training sections selected to maximize variation across each item - i.e., illustrate high, medium, and low scores.
(3) Step 3: Coders will independently score 5 randomly selected BIACA sessions/consultations and be required to achieve acceptable item-level reliability (ICC > .60) prior to independent coding. These procedures have been used by Dr. McLeod to train coders who have achieved adequate reliability in previous studies (e.g., McLeod et al., 2015; McLeod et al., 2018; Southam-Gerow et al., 2016; Sutherland et al., 2013).

Maintaining IE blind. Clinicians cannot be blinded to treatment assignments. Accordingly, IEs who code the therapy sessions will not attend clinically-oriented meetings and will be trained to avoid any discussion of treatment programs with the research team, clinicians and families. The inclusion of all participants in the follow-up phase of the study will serve to further uphold the blind nature of IEs within the study.

Analytic Design

Data management and analyses will be the primary responsibility of Co-Investigator Dr. Michael Seltzer, a professor of Education at UCLA with an international reputation for expertise in hierarchical linear modeling in applied research, including the analysis of cluster-randomized data. In this proposed study, youth with ASD will be nested within mental health clinicians. Hence, Dr. Seltzer's expertise in cluster-randomized data is essential for appropriate treatment of the data. Under Dr.Seltzer's direction, the graduate student researchers will develop and maintain a computerized database for the quantitative study variables, including a double-entry system, monthly random auditing, and direct review of the database in weekly research meetings.

Definition of Primary Outcome Measure: The sum of the BPM Internalizing and Externalizing subscales is the primary study outcome measure.

Hypotheses and Analytic Plans for Specific Aims 1-3.

Aim 1. To compare the effectiveness of CBT and usual clinical care for addressing emotion dysregulation (e.g., irritability, anxiety) and core autism symptoms in youth with ASD who are referred for mental health treatment by their providers in Naval Medical Centers, state-funded Regional Centers, or California public schools.

Hypotheses for Specific Aim 1. It is hypothesized that the Consultation-Based Training in BIACA condition (referred to as "BIACA") will outperform the Usual Care Augmented by Self-Instruction Resources for CBT for Autism condition (referred to as "Usual Care/Self-Instruction") as evidenced by differing slopes during treatment on the primary and secondary outcome measures, including the sum of the BPM (BPM) Internalizing and Externalizing subscales and YTP scores. Additional outcome measures will include the individual BPM subscales, SRS-2 scores, and Satisfaction with Services scores. For the BPM subscales, it is similarly hypothesized that BIACA will outperform Usual Care/Self-Instruction as evidenced by differing slopes during treatment. For the SRS-2 and Satisfaction with Services, it is hypothesized that similar group differences will be observed at the Mid-Treatment and Post-Treatment assessments. For all measures except Satisfaction with Services, it is hypothesized that similar group differences will be observed at the 3-month Follow-Up assessment.

Analyses for Aim 1. Numerical and graphical descriptive statistics will be used to summarize the data on mental health clinicians and youth, and to assess for the presence of group or site differences in screening, demographic or clinical characteristics. Distributional assumptions will be checked and appropriate statistical methods for the observed distribution will be applied as necessary. Our primary and secondary outcome hypotheses (Aim 1) concern group differences in slope between BIACA and Usual Care/Self-Instruction on BPM scores and YTP scores. To appropriately handle the cluster-randomized design and maximize the efficiency of parameter estimates, we will analyze the outcomes employing linear mixed models (LMMs; Brown & Prescott, 2014) or, if there are violations of normality, generalized linear mixed models (GLMMs), with timepoints nested within youths, and with group (BIACA, Usual Care/Self-Instruction) and time as main effects and a group x time interaction term, with a random intercept. More complex nesting structures will initially be modeled (with youth nested within clinicians, and clinicians nested within sites) and any upper-level effects found to be statistically significant will be retained as an additional level of nesting in the final models (cf. Weisz et al. 2012). Time will be modeled as session number.

The primary and secondary hypotheses will then be evaluated with the group x time interaction term, including estimates of Cohen's d effect sizes, and we will follow up on any significant group x time interaction term with appropriate contrasts. Mixed models automatically handle missing data, probing unbiased parameter estimates via maximum likelihood techniques as long as observations are missing at random (Gibbons et al., 1993; Laird & Ware, 1982). This will allow us to use all available data from all participants in an intent-to-treat (ITT) framework. We are also able to control for potential confounding variables in terms of their impact on group differences. To protect against Type I error, the principal analyses are designed to answer clearly stated major research hypotheses and are based on well-specified dependent variables. All tests will be reported using two-tailed family-wise significance level a=.05, using the Holm-Bonferroni correction (Holm, 1979).

For analyses of the SRS-2 and Satisfaction with Services outcomes, and for all Follow-up analyses, LMMs/GLMMs will be used for each post-baseline time point, with group (BIACA, Usual Care/Self-Instruction) as a main effect, pre-treatment score as a covariate, and a random intercept (the same evaluation and selection of final nesting structures described above will also be used for these analyses).

Sensitivity Analysis. To examine and control for the potential effects of variations in services provided in Usual Care/Self-Instruction, the possible presence of some CBT techniques in Usual Care/Self-Instruction, the quality of CBT provided in both conditions, and the clinician's background experience with CBT, three sensitivity analyses will be undertaken.

(1) First, pre-and post-treatment SACA data will be used to construct variables pertaining to new episodes of school counseling, social skills groups, speech and language therapy, applied behavior analysis, medication dosage increases, and new psychiatric medications during the acute treatment phase. The LMM/GLMM models, above, will be rerun with these service variables as a block of covariates to test whether concurrent services in either treatment condition account for the pattern of findings in the main analyses.
(2) Similarly, to examine the potential impact of the use of some CBT strategies in the Usual Care/Self-Instruction condition (and the quality of the CBT in either condition) on treatment outcomes in the main analyses, the LMM/GLMM models, above, will be rerun with BIACA Fidelity Scales across all rated sessions combined into an average score and included as a covariate.
(3) Finally, to examine the clinician's comfort and prior use of CBT in her/his clinical practice, the LMM/GLMM models, above, will be rerun with clinicians' Therapy Procedures Checklist (TPC) scores for cognitive and behavioral practices serving as covariates. Follow-up exploratory correlational analyses will be conducted within-group should either the SACA service variables, the BIACA Fidelity Scales average score, or the TPC cognitive and behavioral scale scores affect the statistical significance or reduce

the treatment effect size by 25% or more, to identify the source of the covariate's impact on treatment outcome findings.

Aim 2. To characterize the mental health clinicians' (e.g., psychologists') level of engagement in online training and consultation, knowledge of CBT, perceptions of feasibility and acceptability, and treatment integrity.

Hypotheses for Specific Aim 2. It is hypothesized that the BIACA condition will outperform the Usual Care/Self-Instruction condition on clinicians' knowledge of CBT (BIACA Therapist Quiz scores) and treatment integrity scores (BIACA Fidelity Scales), that clinicians will engage in at least 75% of the training (4 hour video), session preparation (30 min. each on the website), and consultation tasks (covering required consultation topics on the BIACA Consultation Integrity scale), on average, and that average feasibility and acceptability scores for the CBT arm will be within the 95% confidence interval (CI) of mean scores published for these measures (utilizing a benchmarking approach; Hogue et al., 2017). For the consultant's fidelity to the Practice-Based Coaching model, we hypothesize that the Consultant will have an average score of at least 75% of the maximum possible score of 28 (i.e., $M = 21$) on the BIACA Consultation Fidelity scale. Although there is no specific empirical basis for the value of 75% serving as the benchmark in these analyses, it represents a balance between complete engagement or fidelity and a realistic "cushion" for unexpected circumstances to occur that periodically disrupt engagement/fidelity. It is also hypothesized that qualitative analyses of clinician interview data will reveal themes characterizing both positive attitudes towards CBT for youth with ASD as well as complications related to the time commitment needed to take on the additional training, consultation, and engagement in the study procedures.

Analyses for Aim 2. For clinicians' knowledge of CBT, the LMM/GLMM models for Aim 1 will be refit with BIACA Therapist Quiz scores at post treatment serving as the response variable and corresponding BIACA Therapist Quiz scores at pretreatment serving as the covariate. For treatment integrity scores, BIACA Fidelity Scales across all rated sessions will be combined into an average score and the LMM/GLMM models for Aim 1 will be refit with these composite scores serving as the response variable (there will be no pretreatment covariate in this model). For clinician engagement, each CBT session will be coded for the length of time in minutes that the clinician engaged in session preparation and consultation (Google Analytics is used to monitor clinician use of the meya.ucla.edu website and tabulates when and how long training resources are used by each clinician; the clinical consultant notes how many consultation topics on the BIACA Consultation Integrity Scale were covered in each clinician consultation), and we will also code how many minutes of the BIACA training video was watched (assessed with Google Analytics). For the clinicians randomized to the BIACA arm, the average length of time in which clinicians engaged in preparation/consultation on the meya.ucla.edu website; the length of time viewing the training video; and the average proportion of required consultation topics on

the BIACA Consultation Integrity scale covered in each clinician consultation will be reported in descriptive tables and also compared to the benchmark of 75% of the maximum possible score or amount of time recommended (explained in the previous paragraph). For feasibility and acceptability scores for the BIACA arm, the 95% CI for the published means for the Evidence-Based Practice Attitude Scale (Aarons, 2004) and the Usage Rating Profile - Intervention (Chafouleas et al., 2011) will be derived to serve as the comparison parameter for the means on these two scales.

Qualitative Data Analytic Plan for Aim 2. Each semi-structured clinician interview will be digitally recorded and transcribed. Using a constant-comparative approach to data analysis, interview transcripts will be coded and reviewed to identify emerging patterns and themes related to: (a) feasibility and acceptability of using the CBT strategies with the youth referred to the clinician; (b) feasibility and acceptability of the training and consultation procedures in light of the clinician's other work responsibilities and available time; (c) feasibility and acceptability of the study procedures (e.g., assessments); (d) administrative or practical supports/barriers to implementation of BIACA; (e) any suggestions that the clinician may have pertaining to revisions of the CBT strategies, training and consultation, or research procedures. To enhance rigor, Dr. McLeod will lead efforts to use qualitative analysis to code the transcripts that emerge from these interviews. The initial stage of data analysis (e.g., open coding) will be completed by research assistants with supervision via video conference from Dr. McLeod (DeSantis & Uganrriza, 2000; Hill et al., 1997; Strauss & Corbin, 1998). Codes will be developed, and measures of inter-coder reliability will be calculated and any issues regarding the interpretation and application of codes as well as coding disagreements will be discussed by the research assistants and investigators and decision rules will be determined. Coding will be refined through the process of constant comparison, recoding, and memos. Preliminary findings will be evaluated by all investigators for consistency with the definitions related to the five areas. The findings will be strengthened by the triangulation of data sources (e.g., transcripts, memos, literature review).

Aim 3. To examine how clinician-level factors (i.e., treatment integrity, feasibility, acceptability) and youth-level factors (e.g., age, communication ability) influence youth outcomes in the context of CBT delivered in community mental health centers in which training and consultation is provided via video conferencing.

Hypotheses for Specific Aim 3. It is hypothesized that in the BIACA arm, improvement on the primary, secondary, an additional outcome measures (BPM, YTP, SRS-2, and SWS) over the course of treatment will be predicted by higher treatment integrity scores, feasibility and acceptability scores, clinicians' knowledge of CBT, clinicians' engagement in CBT training, older child age, and higher child communication skills.

Analyses for Aim 3. Analyses for Aim 1 (LMM/GLMM) for the primary, secondary, and additional youth outcome measures (BPM, YTP, SRS-2, and SWS) will be refit, selecting only clinicians randomized to the BIACA arm, and replacing treatment condition in the model with the continuous predictor variables specified in the Analyses for Aim 2, each modeled individually instead of as a block of predictors due to power limitations. The same clinician variables used to model treatment integrity, feasibility and acceptability, clinicians' knowledge of CBT, and clinicians' engagement in CBT training and consultation in Analyses for Aim 2 will be used as predictors in these models. In addition, youth age and youth scores on the Vineland-3 Communication scale will be used as predictors in separate models.

Power Analyses and Sample Size Considerations. We will enroll at least N = 50 mental health clinicians with 1 to 4 youth clients each (minimum N of clients = 100), with a 1:1 allocation to each treatment arm. This sample size was chosen to provide an optimal balance between feasibility of recruitment and maximization of power for the primary and secondary aims outlined above. Assuming an attrition rate of 10% over the acute treatment period and another 10% over the 3-month follow-up, which is realistic based on our prior experience (e.g. Wood et al., 2009a; 2015; 2020), we expect to have approximately 44 clinician (88 youth) participants at the end of acute treatment and 40 (80 youth) at the end of follow-up. All calculations use a 2-sided significance level of a = .05 and assume a moderate correlation of r = .6 between time points within subjects and an ICC = .28 within clinicians, consistent with our previous CBT studies (Wood et al., 2006, 2009a,b, 2014, 2015a, 2020). Under these assumptions, using LMM we have approximately .86 power to detect a two-group (BIACA vs. Usual Care/Self-Instruction) difference of d = .50 (a medium effect size) at Post-treatment for LMM models in Aims 1-2, even with a complete lack of data from 6 mental health clinicians and the youth nested within them (i.e., N = 44).

These power calculations are conservative in that they are based on less favorable assumptions than our actual research experience would predict. For example, we have found a maximum ICC of .20 for clinician effects in our CBT studies (cf. Wood et al., 2006) so this would be a reasonable estimated value; however, the largest clinician effects reported in a large study of NIMH RCT data was approximately ICC = .28 (Kim et al., 2006), hence our decision to use this value instead of .20. Pre- to post-treatment correlations in our measures of emotion dysregulation have averaged r = .71 in our CBT trials for ASD (e.g., Wood et al., 2009a), but we used r = .6 for the power analysis to include the lowest hypothetical value for this correlation. Data from efficacy studies comparing BIACA to waitlist, usual care, and standard-of-practice CBT have consistently yielded effect sizes d > .6 on primary emotion dysregulation outcome measures, and in most cases d > 1.0. Although one might suspect the group differences to narrow in an effectiveness trial, our power should be adequate to detect the treatment effects of primary interest. Further, our power is sufficient to detect group differences at Follow-up, with group differences in the order of d = .5 at the 3-month Follow-up resulting in .82 power at alpha = .05

assuming a clinician N of 40 (again, conservatively assuming the worst-case scenario, a complete lack of data for 10 clinicians and 20 associated youth).

For the predictor analyses in Aim 3, LMMs/GLMMs will be refit with just BIACA arm mental health clinicians, and .90 power will be achieved for a predictor of Post-treatment scores with an effect size of f = .25 (a medium effect). Power calculations for the LMMs were performed in GLIMMPSE multilevel power software, a project funded by the National Institute of Health (Kreidler et al., 2013).

Missing Data and Attrition. Our primary analytic tool is LMM, which provides unbiased parameter estimates when data are missing at random. LMM estimates are based on maximum likelihood techniques and do not require imputation. However, because the intermediate time points for participants who do not complete the full protocol provide information about their trajectory, if warranted by unexpectedly high dropout rates, we will consider imputation and propensity score approaches to project post treatment and follow-up scores or to handle bias problems. Imputation with fully conditional specification using all variables in the primary model as the predictors of post-treatment scores was used as a sensitivity analysis in our recent large RCT of BIACA (Wood et al., 2020), and this, or a similar approach, to imputation can be used in the proposed trial as needed. Every effort will be made to prevent dropouts/missing data, and to complete relevant assessments for youth who drop out.

We understand that participants may voluntarily withdraw for various reasons (e.g., relocation or additional time commitments). Though we have experienced minimal attrition in our previous work (i.e., Wood et al., 2020), we have incorporated design features into the proposed study to minimize attrition. We will collaboratively schedule consultation sessions with clinicians, ensure that meeting length is not excessive, and provide financial incentives for completion of assessments to the clinicians and families in both the BIACA condition and Usual Care/Self-Instruction condition. The same training in the BIACA arm (with associated compensation for treating one youth with BIACA and completing assessments) will be offered to Usual Care/Self-Instruction clinicians once they complete the study protocol in Usual Care/Self-Instruction.

Even if attrition occurs in the middle of the treatment, all available data from all participants will be included in the analyses using an intent to treat framework (Salim et al., 2008). If attrition is above 10%, we will conduct chi-square tests and mean comparisons to determine whether this attrition is related to any demographic or baseline clinical variables, and if so, we will include these variables as covariates.

A recent meta-analysis found that the number of sessions completed in head-to-head comparisons of evidence-based treatments and usual care was greater for evidence-based treatments in 11 studies and the number of sessions was greater in usual care in 8 studies (Weisz

et al., 2013), suggesting premature dropout would not be expected to differentially impact usual care in studies of the sort we have proposed. However, should either condition exhibit a greater rate of dropout in this study, the number of sessions completed will be incorporated in the statistical models assessing treatment effectiveness.