

STUDY PROTOCOL

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Study protocol for a hybrid type 2 effectiveness-implementation trial of two interventions for autistic and non-autistic youth in children's mental health settings: one tailored for neurodivergence and one universal

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Abstract

Background Mental health services play a key role in caring for autistic youth given the common and often unmet mental health needs in this population. There is a pressing need to enhance the uptake and use of evidence-based interventions (EBIs) that improve mental health services for autism and optimize outcomes. EBIs targeting transdiagnostic or key factors relevant across autism and mental health conditions exist and have the potential to enhance mental health services for autism. Yet, these interventions have not been widely tested. Similarly, autism EBI training is an implementation strategy with the potential to enhance mental health service quality broadly given specific components and strategies incorporated into the EBI to enhance its impact and fit. This protocol paper describes a multi-site study that examines the clinical and implementation effectiveness of a transdiagnostic EBI developed for autistic children compared to a non-autism transdiagnostic EBI in children's mental health settings (Aim 1), confirms engaged clinical and implementation mechanisms (Aim 2), and examines the generalized and expanded effects of EBI training beyond autism (Aim 3).

Methods This study will employ a hybrid type 2 effectiveness-implementation design to test *Unstuck and On Target*, an executive functioning EBI adapted for mental health services (autism EBI) and *Unified Protocol for Children* (non-autism EBI). Twenty-eight mental health programs will be randomized to an EBI condition and 224 therapists across these programs will be recruited and receive EBI training. Additionally, 224 autistic children and 224 non-autistic children, yoked to participating therapists, will be recruited as EBI recipients. This study will measure clinical (mental health symptom change) and implementation outcomes (EBI fidelity, training engagement, psychotherapy quality, reach) and clinical (executive functioning skills, emotion regulation skills) and implementation (autism self-efficacy and knowledge, perception of fit) mechanisms.

Discussion This study will confirm the effectiveness of a promising executive functioning EBI in mental health settings as well as generate clinical knowledge about the potential of transdiagnostic interventions improve mental

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health outcomes for autistic children. Findings also have immense potential to demonstrate the ability of autism EBIs to enhance mental health services for autistic and non-autistic children more broadly.

Trial registration This study is registered with Clinicaltrials.gov (NCT06651086). Registered on October 18, 2024.

Keywords Children's Mental Health Services, Autism, Transdiagnostic, Effectiveness, Implementation

Contributions to the literature

- Mental health care for autism is hindered by limited availability and uptake of effective interventions designed for community implementation that meet both child clinical needs and therapist training needs related to caring for autism.
- This study will test the clinical and implementation effectiveness of two transdiagnostic interventions, including one specifically designed for autism, to enhance mental health care for autistic and non-autistic children.
- Results from this study are expected to inform effective clinical and implementation methods to enhance mental health services for autistic children and children more broadly.

Background

Need to improve mental health services for autism

Autism is a highly prevalent neurodevelopmental condition, affecting 1 in 31 children [1]. Autistic children experience high rates of co-occurring mental health challenges, most commonly attention-deficit/hyperactivity disorder (ADHD), anxiety, and disruptive disorders that necessitate mental health care [2]. Mental health care spending for autism is large and increases with age [3]. Care disparities and unmet service needs, including mental health needs, are common [4–6]. Community mental health services play a primary role in caring for autistic children, with autistic children comprising as much as 20% of children served in mental health settings [7, 8]. Yet, mental health therapists report frustration serving autistic children and those with poor impulse control, common in autism, due to engagement challenges and limited progress and cite a need for specialized training working with these children [7, 9]. Access to, receipt of, and satisfaction with community services for autism is poor, especially for racial/ethnic minority families, adding to identified service disparities for these children [10–15]. Ensuring that autistic children receive effective, acceptable, evidence-based mental health care is critical. Indeed, a focus on mental health, evidence-based mental health interventions, and community mental health service

capacity for autism is a key priority area for the autistic community [16–18].

Advances and gaps in evidence-based interventions for autism

There have been efforts to develop and test evidence-based interventions (EBIs) that target commonly co-occurring mental health conditions in autism. Yet, several gaps in work to date remain, including: 1) addressing multilevel barriers impeding EBI use (e.g., limited EBI fit with the mental health needs of autistic children, limited fit with therapist training needs related to serving autistic children) [10]; and 2) EBIs designed for community use and tested with the diverse range of children and providers reflective of community mental health services [19–21]. In response to this need, our group engaged in the community-partnered development of a mental health EBI for autism for community implementation (An Individualized Mental Health Intervention for Autism; AIM HI) [22]. Cluster randomized trials support the feasibility and effectiveness of training community therapists with the AIM HI training model, with positive child clinical outcomes [23–25]. Importantly, data, including secondary analyses of AIM HI effectiveness trial data, indicate that child internal processes such as executive functioning (EF) are associated with treatment processes and response and are frequently a target of outpatient and school-based psychotherapeutic services for school-aged autistic children, despite therapists' limited knowledge or experience with specific tools targeting EF [9]. This pointed to the critical need for additional child-directed tools targeting key internal factors such as EF. Responsive to this, our group initiated a systematic line of research that extends and complements our prior work to date (K23MH115100; PI: Dickson) [26] specifically focused on EF, a key mechanism contributing to functional difficulties in autism, in service of further improving mental health services for autistic children.

Executive functioning as a key transdiagnostic clinical change mechanism and potent intervention target

EF is a potent mechanism underlying autism and commonly co-occurring mental health conditions [27–30]. EF impairments (e.g., inflexibility, poor goal setting, poor

planning) contribute to negative outcomes in autism [27, 31]. EF impairments increase over the course of development and contribute to increased mental health symptoms and poorer adaptive functioning and life outcomes [29, 32–35], highlighting the deleterious impact on autistic children and their service needs. Our work underscores the impact of EF deficits on mental health services, including its transdiagnostic (or relevant across mental health conditions) impact on the majority of children served in this setting and its role as a barrier to psychotherapy engagement and progress [9]. Fortunately, EF is responsive to treatment, but there is a great need for efforts focused on treatment in accessible settings such as mental health settings [36–38]. Further, a targeted focus on EF has been cited as a disparity reduction strategy to enhance child developmental outcomes given known health disparities (i.e., based on socioeconomic status) reflected in EF development [39–41]. Mental health therapists cite a significant need and motivation for training in EF treatments [9, 42–46]. Together, this underscores the potential of EF as a key target for improving mental health services and outcomes for autism.

However, EF EBIs have not been widely used and tested in such settings, highlighting a critical gap in ongoing efforts to improve community mental health care. To address this gap, we adapted a promising cognitive-behavioral EBI targeting EF (*Unstuck and On Target; Unstuck*) [47] for community mental health services. *Unstuck* was specifically developed for autism and shown effective for autistic children when implemented in school settings. [42, 43] Our formative work indicated the relevance of and need for *Unstuck*, with context-specific adaptations, in mental health settings [48]. Preliminary findings from our feasibility pilot trial support the feasibility, acceptability, and effectiveness of *Unstuck* in mental health settings, highlighting its potential for improving mental health services for autism (Dickson K, Dickson KS, Holt T, Galligan M, Anthony LG, Kenworthy L, et al. Therapist Training and Implementation Outcomes of an Adapted Executive Functioning Intervention for Autism in Children's Mental Health Setting. Under Review;) [49].

Autism EBI training as an implementation strategy

Autism EBIs such as *Unstuck* largely consist of evidence-based practices and strategies (e.g., cognitive behavioral) supplemented with additional considerations and modifications (e.g., incorporation of visuals, child specific interests) to optimize fit and outcomes for autistic children [19]. Data demonstrate enhanced effects of autism EBIs versus standard EBIs for autistic children, supporting the importance of these specialized EBIs for this population

[50]. Yet, these EBIs have the potential to enhance mental health services generally. This is due the explicit inclusion of modifications and strategies to enhance child engagement and effectiveness within autism EBIs that, while recommended for children generally, largely are not routinely or explicitly specified within non-autism EBIs [19, 51]. Also frequently incorporated into autism EBI training models is content and strategies (e.g., autism-specific psychoeducation) aimed to address therapist-level barriers known to impede EBI update and delivery [19]. The potential of autism EBIs to enhance general service quality is supported by prior work indicating that therapists have sustained and expanded their use of autism EBIs, including *Unstuck*, with other populations due to the perceived relevance, fit, and benefit of these EBIs (Dickson K, Dickson KS, Holt T, Galligan M, Anthony LG, Kenworthy L, et al. Therapist Training and Implementation Outcomes of an Adapted Executive Functioning Intervention for Autism in Children's Mental Health Setting. Under Review;) [52–54]. Together, this underscores the potential of autism EBIs, through the considerations and strategies explicitly specified within the EBI and tailored training models, as a key implementation strategy to enhance the effects of EBI training on reach and improved psychotherapy quality for non-autistic children.

Therapist-level implementation change mechanisms to improve EBI fidelity and sustained use

The importance of targeting individual or provider-level factors to optimize effective EBI delivery is well documented [55]. While additional multilevel (e.g., organizational, system) factors are also relevant, therapist-level factors are important targets as proximal, pragmatic, and malleable factors predictive of EBI implementation. Therapist-level factors of perceptions of EBI fit, self-efficacy, and knowledge are theorized as key mechanisms promoting the implementation process and behavior change. These factors are linked to specific practice behaviors and predict EBI adoption and use with fidelity following training [54, 56–61]. Further, recent reviews support self-efficacy, knowledge and perceptions of fit as mechanisms for key implementation outcomes, including EBI fidelity and sustainment [55, 59]. The presence of co-occurring conditions, common in autism, limits EBI fit, adoption, and use among community providers; this points to the potential of promoting EBI fit through a focus on transdiagnostic EBIs that fit the range of co-occurring conditions common in autism as a key implementation target [62, 63]. Therapist self-efficacy and knowledge specific to autism (e.g., knowledge of autism, efficacy working with autistic individuals) are also key mechanisms predictive of autism EBI use, with mental

health therapists reporting limited autism self-efficacy and knowledge and resulting lower intentions to use autism EBIs [64–69]. As such, the current project will explore if the adapted version of *Unstuck*, which includes context-specific adaptations to enhance its fit with mental health service settings and therapist training needs, improves therapist perception of fit and autism self-efficacy and knowledge, in turn leading to enhanced EBI fidelity and use. Figure 1 illustrates our theorized implementation change mechanisms.

Current project

The objective of this hybrid type 2 effectiveness-implementation trial is to simultaneously examine the clinical effectiveness and implementation of *Unstuck*, an autism EBI specifically adapted for the children's mental health services context, relative to *Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children (UP-C)*, a non-autism transdiagnostic EBI, in publicly-funded children's mental health services. Both EBIs include evidence-based strategies and prescribed in-session activities targeting child skill building, and similar training models (e.g., didactic introductory workshops supplemented with ongoing consultation). While analogous, each EBI is distinct in its clinical targets, with *Unstuck* targeting EF and *UP-C* targeting distress tolerance and emotional regulation. Only *Unstuck* was specifically developed for autism, with its curriculum and training model supplemented with several evidence-based strategies to optimize its fit with this population. The transdiagnostic focus with

a distinct clinical target and not specifically developed for autism supports the role of *UP-C* as an ideal active comparator, allowing for the isolation and testing of the proposed key mechanisms and outcomes of interest in the current project. Specific aims and corresponding hypotheses are to (see Fig. 1.):

1. Evaluate the effectiveness and implementation of *Unstuck* relative to *UP-C* for autistic children. Hypotheses: a) *Unstuck* (autism EBI) will contribute to greater clinical outcomes of improved mental health symptoms for autistic children compared to *UP-C* (non-autism EBI) given its specific development for autism; b) the autism-specific nature of *Unstuck* (implementation strategy) will lead to more positive therapist implementation outcomes compared to *UP-C* during delivery to autistic children.
2. Evaluate mediators of EBI training effects to confirm engaged change mechanisms of clinical and implementation outcomes. Hypotheses: a) children receiving *Unstuck* will exhibit greater gains in EF skills given its clinical target of EF where as children receiving *UP-C* will exhibit greater gains in emotion regulation skills given its target of emotion regulation; b) EF gains will mediate effects of EBIs on clinical outcomes for autistic children given the role of EF in autism; c) therapists trained in *Unstuck* will report greater improvements in autism self-efficacy and perceptions of fit compared to *UP-C*; d) therapist-reported improvements in autism self-efficacy and perceptions

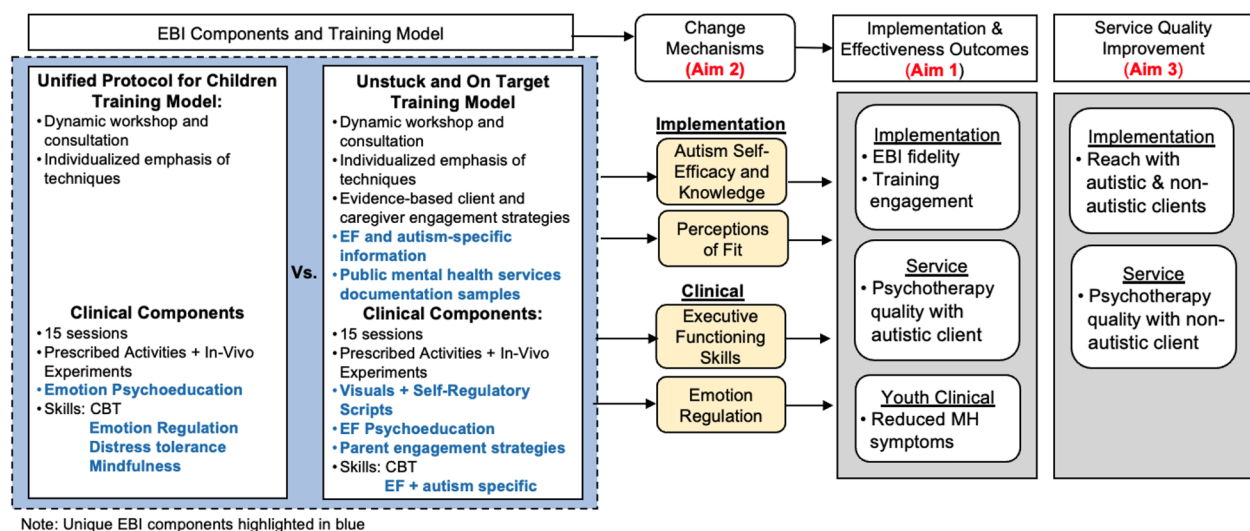


Fig. 1 Evidence-based Intervention Components and Training Model, Theorized Change Mechanisms and Outcomes

of EBI fit will mediate effects of EBI training on implementation outcomes.

3. Explore the generalized effects of EBI training on reach (continued delivery) and improved psychotherapy quality with non-autistic children. Hypotheses: a) Both EBIs, as transdiagnostic interventions, will demonstrate strong reach via generalized use with non-autistic children and lead to improved evidenced-based strategy delivery, including *Unstuck* and *UP-C* specific strategies; b) The specific patterns of reach and improved quality indicators will differ by EBI given the development of each EBI for specific and distinct populations.

Methods

In this multisite hybrid type 2 effectiveness-implementation trial, we will use a cluster randomized design in which random assignment will occur at the mental health program to prevent cross-contamination of intervention content across therapists working within the same program. All study procedures have been approved by ethical review boards at participating institutions as well as participating healthcare programs and overseeing health and human services department, as relevant.

Participants

The combined sample across two sites (San Diego, Denver, and surrounding areas) includes 28 mental health programs, 224 therapists (average of 8 per program) and 224 autistic (1 per therapist) and 224 non-autistic children (1 per therapist). Our sample size was informed by the number of participants necessary to be sufficiently powered to evaluate our proposed aims. Programs are eligible if they provide publicly funded outpatient or school-based psychotherapy services to children and employ at least 8 therapists. Therapist eligibility includes: a) being employed as a staff or trainee at an enrolled program; b) anticipating providing services at their agency for the next 9 months; b) and having eligible client(s) on their caseload. Two types of child participants will be included per therapist: an autistic child and non-autistic child. Inclusion of both child participant types allow for confirmation of EBI effectiveness and mechanisms for autistic children (Aims 1 and 2) as well as evaluate generalized effects of EBI training for non-autistic children via therapist-report and observational ratings of EBI delivery and psychotherapy quality (Aim 3). Inclusion of non-autistic children also permits validation of the effectiveness of both EBIs with non-autistic children. Child eligibility includes: a) between the ages of 7–12; b) have a documented or suspected diagnosis of autism (for autistic child only and confirmed by the research team) or

no history of documented or suspected diagnosis (non-autistic child only); and c) receive services from a participating therapist.

Procedures

Recruitment, enrollment, and randomization procedures

Participants will be recruited in three waves, one per year. Program recruitment consists of informational meetings with program and agency leaders to share study information and participation requirements. Upon agreeing to participate in the study, programs will be randomly assigned to receive *Unstuck* or *UP-C* training. An independent statistician will randomize all programs, with equal assignment probability to each group. Therapist and child participants will be assigned to condition based on their program's condition. Following program randomization, we will recruit therapists from engaged programs, with program leaders facilitating research team appearances at staff meetings and distribution of recruitment emails. Enrolled therapists will identify potentially eligible child participants from their caseload and will obtain permission for research team to contact caregiver to recruit for participation. If a family agrees to be contacted, the research team will contact the family to complete an initial telephone screening and conduct the eligibility assessment to confirm eligibility criteria. If eligible, child clients will be enrolled, yoked to participating therapists. We will recruit and enroll an additional non-autistic child client per enrolled therapist, using the same procedures, following EBI training.

Unstuck and UP-C interventions and training procedures

Adapted Unstuck and on Target intervention *Unstuck* [47] is a cognitive-behaviorally based treatment developed for autism that addresses EF deficits, including flexibility, goal-setting, and planning. It was developed by integrating neurocognitive (e.g., flexibility, planning) and cognitive-behavioral therapy (e.g. emotion identification, coping strategies) targets with pedagogical techniques (e.g., self-regulatory scripts, Socratic questioning). *Unstuck* is effective in facilitating EF skills, namely flexibility, organization, and problem solving, and related behaviors in autistic children and those with ADHD [42, 43, 70]. Intervention content was generated, tested, and refined using an intensive, collaborative, and community-partnered process including autistic individuals and their parents, to maximize fit, acceptability and utility. *Unstuck* includes prescribed activities, in-vivo experiments, and home-extension components to promote generalization. Visuals and self-regulatory scripts known to support learning and facilitate cognitive skills such as EF are also

integrated into the curriculum. As mentioned, we systematically adapted *Unstuck* within the context of a community-academic partnership to ensure feasibility and fit within children's mental health services. Consistent with EBI scale-out recommendations [71], adaptations retained key or core intervention components to ensure impact generalization, but modified these components and added complementary components to enhance alignment to the mental health services context. The adapted version of *Unstuck* for mental health clinics includes 15 sessions corresponding with seven broader modules targeting key EF skills. Consistent with prior *Unstuck* trials in public schools [70, 72], our feasibility pilot trial indicated that *Unstuck* was effective in improving EF and mental health symptoms among autistic children [49]. *Unstuck* also demonstrated strong implementation outcomes, including strong therapist fidelity, acceptability, appropriateness, and feasibility (Dickson K, Dickson KS, Holt T, Galligan M, Anthony LG, Kenworthy L, et al. Therapist Training and Implementation Outcomes of an Adapted Executive Functioning Intervention for Autism in Children's Mental Health Setting. Under Review;). We observed significant increase in autism- and EF-specific knowledge and confidence among therapists trained in *Unstuck*, supporting this as a key implementation mechanism (Dickson K, Dickson KS, Holt T, Galligan M, Anthony LG, Kenworthy L, et al. Therapist Training and Implementation Outcomes of an Adapted Executive Functioning Intervention for Autism in Children's Mental Health Setting. Under Review;).

Unified Protocol for Children intervention *UP-C* [73] is a transdiagnostic, cognitive-behaviorally based treatment targeting shared core dysfunctions underlying emotional disorders in children. Specifically, *UP-C* aims to reduce symptoms of emotional concerns in children (e.g., anxiety, depression) by improving children's ability to tolerate distress and reducing use of avoidant strategies to regulate emotions. Core components of *UP-C* address distress tolerance and emotion regulation by: 1) promoting awareness of emotional experiences; 2) increasing mindful, non-judgmental awareness; 3) linking thoughts to emotions and promoting cognitive flexibility; 4) promoting awareness and tolerance of physical sensations; and 5) promoting engagement in alternative behaviors to emotional avoidance. *UP-C* delivers these core components in a semi-modular, 15-session intervention package through heavy emphasis on prescribed activities, in-vivo experiments, and home learning activities to promote generalization. It includes both a fully developed child and caregiver curriculum, the latter of which may be flexibly incorporated into sessions to help caregivers to support child practice of skills outside of session and to address less helpful caregiver responses to child

emotions (e.g., inconsistency, overprotection and accommodation). An open trial and three subsequent randomized controlled trials have supported the efficacy and effectiveness of *UP-C* in addressing emotional disorder symptoms and improving emotion regulation when compared to active control conditions [74–77]. In addition to its effectiveness for children with emotional disorders, recent work supports its efficacy for children with additional non-emotional disorders (e.g., externalizing challenges, irritability) in both outpatient and higher-intensity treatment settings) [78, 79].

Training procedures In addition to the similar nature and structure, *Unstuck* and *UP-C* training models include analogous and unique components, including a corresponding implementation model developed as part of the systematic adaptation of *Unstuck*. Together, this further enables our isolation and testing of key mechanisms and outcomes, particularly those related to the autism and context-specific nature of *Unstuck*.

Common training components Consistent with other cognitive-behavioral models, both EBI training models include systematic, direct, explicit instructional methods (e.g., step-wise training of general principles then specific strategies; interactive practice with feedback; ongoing training) associated with improved provider competence and patient outcomes [80, 81]. Training includes a one-day, introductory multi-modal didactic workshop providing an overview of curriculum, targets, and activities and ongoing consultation during implementation to promote treatment delivery and fidelity. To ensure analogous training processes across EBIs and fit to the mental health services context, we are conducting ongoing consultation session for approximately six months during implementation with participating autistic child clients. EBI trainers and coaches across interventions will participate in analogous training processes, with both including ongoing fidelity monitoring for trainers by the PI and/or intervention developers. We will employ separate EBI trainers and coaches for each intervention condition and will ensure that trainers and coaches have met standards for certification in each intervention.

***Unstuck* training and implementation model components** The *Unstuck* training model was informed by the original, effective school-based training [42, 43] as well as additional therapist training models shown effective in training therapists in evidence-based mental health strategies, particularly for autism (e.g., AIM HI) [22, 82]. Training specifically incorporates strategic education aimed at promoting autism and EF knowledge and evidence-based caregiver and child engagement strategies shown effective in enhancing in-session engagement in children's mental health and autism services [83]. Ongoing consultation

includes case- and performance-based feedback based on review of recorded sessions of delivery. Informed by a formative needs assessment, the corresponding implementation model includes discrete implementation strategies identified as key in supporting the adoption of a new EBI, particularly an autism EBI. Strategies include: a) EF and autism-specific educational information to address knowledge and confidence; b) supports enhancing the adaptability of *Unstuck* for individualized child or therapist needs; c) development of *Unstuck*-specific clinic documentation materials; and d) provision of multimodal (e.g., paper-based, electronic) and multilingual (e.g., English, Spanish) intervention materials.

UP-C training and implementation model components The *UP-C* training model for this trial was developed to be consistent with models used in prior *UP-C* and *Unified Protocol for Adolescents* [74, 84] trials but adapted to fit the mental health services context and to achieve consistency across the two interventions (e.g., monthly rather than weekly consultation sessions). Training begins with a full-day workshop that provides a brief overview of the history and rationale for transdiagnostic interventions for emotional disorders such as the *UP-C* and briefly

summarizes the intervention's research base. Most of the workshop focuses on clinical application of both child-directed and caregiver-directed intervention components using multimodal strategies, including didactic education, live skill demonstration, video illustrations, and paired or small-group role-plays. The workshop also includes an overview of exposure therapy and applied practice with conducting exposures with children to a variety of emotional targets. Therapists then participate in ongoing, small-group consultation, which typically includes case-based feedback, skills review and demonstration, and role-play practice if time permits. Competency is monitored during consultation, and additional 1:1, targeted feedback and support may be provided if a therapist is not meeting competency standards.

EBI implementation and data collection procedures (see Table 1)

Following enrollment of autistic child participants, enrolled therapists will participate in EBI training (as described above) and implementation with yoked child client; monthly EBI consultation meetings will occur during the 6-month implementation period with the autistic child.

Table 1 SPIRIT Flow Diagram

Activity	Study Period			
	PRE	MID	POST	F/UP
Enrollment				
Therapist	X			
Informed Consent	X			
Autistic Child				
Eligibility Screen	X			
Informed Consent/Assent	X			
Non-Autistic Child				
Eligibility Screen			X	
Informed Consent/Assent			X	
EBI				
<i>Unstuck and On Target</i>				
<i>Unified Protocol for Children</i>				
Measures				
Demographics	X*		X [^]	
Sample Characterization	X		X [^]	
Mental Health Symptoms	X*		X* [^]	X* [^]
Executive Functioning	X*		X* [^]	X* [^]
Emotion Regulation	X*		X* [^]	X* [^]
EBI Fidelity via session recordings	X	X	X	X
EBI Training Engagement	X	X	X	
EBI Reach			X	X
Psychotherapy Quality			X	X
Self-Efficacy and Knowledge	X		X	
Perceptions of EBI Fit	X		X	

*Refers to measures collected with participating autistic youth at this timepoint, [^]Refers to measures collected with non-autistic youth at this timepoint

Therapist-autistic child dyads will submit monthly video recordings of sessions to be used to assess EBI fidelity and for performance-based feedback. As mentioned, non-autistic child clients will be enrolled after EBI training to assess for continued EBI delivery. During this time, data collection aims to capture therapist service delivery with their non-autistic child client, including continued EBI delivery beyond the EBI training phase. Therapist-non-autistic child dyads will also submit three video recordings to be used to assess for continued EBI delivery and fidelity. Data will be collected at the following timeframes: Pre Training (*PRE* – following enrollment and prior to EBI Training); During Implementation (*MID* – ongoing during EBI delivery); Post Implementation (*POST* – following 6 months of EBI implementation); and Follow Up (*F/UP*- 12 and 18 [for providers only] months post *PRE*). Importantly, we will use analogous data collection (e.g., baseline, 6-month, 12-month) timeframe and measures with autistic and non-autistic child participants, with

non-autistic child data collection aligning with the *POST* and *F/UP* timepoints for their yoked, enrolled therapist. All participants receive compensation for completion of data-collection activities at each timepoint. Data include quantitative surveys, observational and standardized assessments, and qualitative interviews. Observational and assessment data will be collected by research team members masked to the study condition. Qualitative interviews will be conducted at *POST* (for autistic youth) and *F/UP* (for caregivers and therapists) using a secure, HIPAA-complaint videoconferencing software. Mixed-methods data collection will consist of sequential *QUAN*→*QUAL* approach, with qualitative used to expand on and provide depth and breadth to previously collected quantitative data [85].

Measures (see Table 2)

Consistent with a hybrid type 2 trial, primary outcomes include child (mental health symptoms) and

Table 2 Study Measures

Construct	Measure	Data Source	Timing
Demographics			
Therapist Demographics	Age, gender, race/ethnicity, education level, years of experience, EBI and autism experience	T	PRE
Child and Family Demographics	Age, gender, race/ethnicity, clinical characteristics, inventory of received mental health services	C	PRE
Sample Characterization			
Cognitive Functioning	Wechsler Abbreviated Scale of Intelligence-2 nd Edition (WASI-II) [86]	A	PRE
Autism Classification	Social Responsiveness Scale-2 nd Edition [87]; Autism Diagnostic Observation Schedule- 2 nd Edition [88]	C, A	PRE
Clinical Outcomes			
Mental Health Symptoms (Aim 1 & 2)	Child Behavior Checklist (CBCL) [89]; Eyberg Child Behavior Inventory (ECBI) [90]	C	PRE, POST, F/UP
Clinical Mechanism			
Executive Functioning (Aim 2)	Brief Rating Inventory of Executive Function-2 nd Edition [91]; EF Challenge Task [92]; NIH toolbox Dimensional Change Card Sort and Flanker tests [93]; WASI-II Block Design	C, A	PRE, POST, F/UP
Emotion Regulation (Aim 2)	Emotion Dysregulation Inventory [94]	C	PRE, POST
Implementation Outcomes			
EBI Fidelity (Aim 1 & 3)	A trained observer masked to EBI condition and time will assess EBI delivery during recorded sessions of participating therapist-client dyads. Unique fidelity forms with items corresponding to associated EBI will be used.	O	PRE, MID, POST, F/UP
EBI Training Engagement (Aim 1)	Therapist EBI training engagement will be operationalized as adherence to training requirements, including participation in training/consultation.	O	PRE, MID, POST
EBI Reach (Aim 3)	Therapists will report on EBI reach as operationalized by the number and types of clients (e.g., presenting problem, diagnostic profile) of clients treated with EBI	T	POST, F/UP
Psychotherapy Quality (Aim 3)	Evidence-Based Practice Concordant Care Assessment-Therapist Report [95]	T	POST
Autism and Executive Functioning Self-Efficacy and Knowledge (Aim 2)	Therapist Confidence Scale for Autism Spectrum Disorder [96]; Therapist Knowledge for Autistic Clients [97]	T	PRE, POST
Perceptions of EBI Fit (Aim 2)	Perceived Characteristics of Intervention Scale [98]; Intervention Appropriateness Measure [99]	T	PRE, POST

T=Therapist survey; C=Caregiver survey; O=observation; A=Assessment. Timing: PRE (pre EBI Training); MID=During EBI Implementation; POST=6mos Post EBI training; F/UP = 12mos & 18mos (Provider Only) after EBI training

implementation (EBI fidelity, training engagement, psychotherapy quality, reach) outcomes. We will also collect data regarding proposed clinical mechanisms (EF skills, emotion regulation) and implementation mechanisms (autism self-efficacy and knowledge, perceptions of fit). Measure selection criteria included best practice measures for each construct and those utilized in prior similar community trials and/or shown sensitive to change [23, 42, 43]. To the extent feasible, multi-modal, multi-informant, and objective measures will be used to assess outcomes and mediators.

Therapist EBI fidelity

Session recordings with therapist-autistic child participants collected monthly for six months during EBI delivery will be used for EBI fidelity coding (see Table 2). We will also collect three session recordings of therapist-non-autistic child participants bimonthly, coded for EBI fidelity, to capture therapist continued use of EBI strategies with non-autistic child clients. All session recordings will be observationally coded for both *Unstuck* and *UP-C* strategy use using established fidelity coding procedures. Fidelity will capture use of core EBI strategies included within the *Unstuck* and *UP-C* interventions, including both dosage and quality of therapist strategy delivery to the participating child. EBI coders will be trained to code EBI fidelity and will be blind to treatment group and time frame. They will be trained to 80% reliability on both dosage and quality compared to EBI developers and study investigators before beginning independent fidelity coding. Twenty percent of all video samples will be coded by a second person for the purpose of monitoring coding reliability.

Qualitative interviews

We will conduct qualitative interviews with a subset of therapist, child, and caregiver participants to identify factors unaccounted for by our theorized mechanisms of change (Fig. 1). For example, interviews will probe for explanations of instances when therapists demonstrate strong EBI fidelity or training engagement but poor autism self-efficacy or when children demonstrate improved symptoms but limited changes in EF. Therapist interviews will also include a focus on assessing how EBI training has benefited therapist's service provision, specific components or elements utilized and benefits for children on their caseloads. We will also probe for perceptions regarding the specific EBI features (e.g., components, specified activities or materials, structure) contributing to generalized use. Interview participants will be purposely sampled, focused on those include those whose scores are >1 standard deviation from their predicted behaviors.

Interviews will be continuously conducted until we reach thematic saturation regarding this topic.

Data analysis

General analytic plan aims 1–3

Quantitative analyses Our analytic strategies follow the Brown et al. and Prevention Science and Methodology Group for randomized field trials recommendations [100]. Preliminary data screening and cleaning will require examination of the data distributions for normality and missing data patterns at both the univariate and multivariate level. A statistical test of baseline group differences will determine if random assignment ensured comparability across *Unstuck* and *UP-C* conditions. Covariates may be included in the models to adjust for nonequivalence at baseline and to minimize bias if random assignment is not observed. Multilevel (mixed-effects) modeling (MLM) [101, 102] will be used as the primary statistical model for all Aims due to the nested structure of the data: (a) repeated measures (time) [level-1] nested within (b) provider/child dyads [level-2] nested within (c) programs [level-3]. Intraclass correlation coefficients will be examined to identify the magnitude of the dependency at both the provider/child dyad and program levels. Subsequent predictive models will use time as a level-1 predictor variable and intervention group (*Unstuck* vs. *UP-C*) as a level-3 predictor variable. Of primary interest in analyses is the Time (level-1) X Intervention Group (level-3) cross-level interaction effect. Statistically significant interaction terms will employ the simple slope follow-up analyses [103]. All multilevel regression analyses will use AR(1) to model a first-order autoregressive correlation structure for the repeated-measures data and include variables associated with missing data as auxiliary variables [104]. Statistical evaluation of all intervention effects will follow the intent-to-treat principle.

The primary analyses assessing impact on clinical and implementation outcomes will be tested using individual MLM. Aim 1 outcomes include child clinical outcomes (i.e., mental health symptoms) and therapist outcomes (i.e., EBI fidelity with autistic child client, therapist EBI training engagement). Importantly, while Aim 1 analyses of clinical outcomes will primarily focus on autistic child clients, we will also conduct secondary analyses to test the clinical effectiveness of *Unstuck* and *UP-C* with non-autistic child clients. Aim 3 analyses include implementation outcomes (i.e., EBI reach, psychotherapy quality via the ECCA, EBI fidelity with non-autistic child), with analyses conducted with data collected from non-autistic child clients. Analyses will consider differences

in number of measurements taken (i.e., clinical outcomes at PRE, POST, F/UP; service quality via ECCA administered weekly at POST). Child demographics variables will be assessed as potential moderators of effects, with significant moderators included as needed. Finally, multilevel path analysis with formal tests for mediation will be used to examine clinical (i.e., EF, emotion regulation) and implementation (i.e., autism self-efficacy, perceptions of fit) mechanisms, with the 3-level nested data structure (Aim 2). Given the longitudinal nature of the data, these models will be able to test both lagged (mediator preceding outcome in time) and simultaneous (mediator and outcome assessed concurrently) mediated effects. The biased-corrected bootstrap test of mediation will be used to formally test for the different mediated effects examined [105, 106]. All mediation models will also account for all autoregressive effects. The target mediation paths will be embedded in the MLM framework outlined earlier.

Qualitative and mixed-method analyses For qualitative data of semi-structured interviews, we will use a rapid qualitative assessment to identify broadly emerging themes [107] regarding explanations for factors unaccounted for by our theory of change (Aim 2) and gain perspectives on how EBI training has impacted therapists' psychotherapy service provision (Aim 3). Subsequently, we will use an in-depth qualitative analysis for a subset of qualitative interviews via an iterative thematic coding process; we will develop and apply a preliminary codebook informed by our rapid assessment to a text sample. We will then revise the codebook to ensure all relevant themes are captured and applied to all transcripts [108]. Coders will be trained via didactics, group practice, and discussion and will reread the codebook weekly and attend investigator-led booster maintenance sessions. We will use a consensus process in which all coders independently code all the transcripts, then meet to compare their coding through open dialogue [109, 110] and arrive at consensus judgments. This approach is designed to capture data complexity, avoid errors, reduce groupthink, and circumvent some biases. For mixed-method analyses, we will merge data types (i.e., qualitative and quantitative) via triangulation and combined analyses for complementarity and qualitative data expanding on quantitative data [85].

Power analyses

Power analyses for each Aim were conducted primarily using the Power Analysis and Sample Size (PASS) [111] software given a 3-level nested data structure with randomization at the program level (level-3). The PASS program implements the longitudinal and clustered-data approach and formulas of Ahn and colleagues for MLM

[112]. For the analysis presented here, a nested data structure of 28 programs (level-3) with an average of 8 therapist/dyads (level-2), and 3 time-points (level-1) were specified. Based on previous research [23, 113], ICCs at the therapist/dyad and program level were set to 0.40 and 0.06, respectively. Finally, a 20% attrition rate was accounted for at the therapist/dyad level. Using a significance level of 0.05, 82% power is achieved to detect an Intervention Status X Time interaction with a Cohen's d value = 0.40; we used a Cohen's d value = 0.40 given data from prior trials of *Unstuck* indicating a medium to large effect size on a similar primary outcome of mental health symptoms. Lastly, a series of power analyses were conducted to explore effect size estimates for the mediation relationships specified in Aim 2. Using the assumptions/estimates outlined previously, the Monte Carlo approach outlined by Schoemann and colleagues was used [114]. Within the context of each analysis, 1000 replications with 20,000 Monte Carlo draws per replication was implemented. Power was calculated using a variety of effect sizes to reflect the magnitude of antecedent to mediator path (path a) and the mediator to outcome path (path b). Given the specifications above, 80% will be achieved for mediation model that accounts for approximately 2% of the variance in a target mediator and outcome.

Discussion

There is strong and compelling evidence that autistic children are at high risk for problematic outcomes and an urgent need to enhance community services, particularly mental health services, for this population. The current study will simultaneously examine the impact of *Unstuck and On Target* (an autism EBI) and *UP-C* (a non-autism EBI) and participating in autism EBI training on clinical and implementation outcomes in children's mental health settings. Generating evidence for the clinical and implementation effectiveness of *Unstuck* fills a significant gap in feasible interventions that address the significant mental health service needs of autistic children. Specifically, transdiagnostic interventions such as *Unstuck* or *UP-C* hold immense potential for children's mental health services given the focus on addressing child clinical and therapist training needs related to transdiagnostic factors such as EF and their specific design for community implementation. Study findings will also provide key insights into effective therapist training models, responsive to prioritization of and calls for methods and strategies to strengthen mental health workforce capacity to effectively serve autistic individuals [10]. This includes how autism EBI training can serve as a key implementation strategy to enhance the impact of EBI training on outcomes through the explicit inclusion of intervention and training model components within these EBIs that

enhance effectiveness. If successful, this project has the potential to demonstrate the clinical and implementation value of transdiagnostic tools to improve mental health services for autism, and for children more broadly.

The current study offers several points of innovation. First, the current project leverages and expands on several prior, systematic lines of research aiming to develop, adapt, and test pragmatic interventions and tools in community settings (Dickson K, Dickson KS, Holt T, Galligan M, Anthony LG, Kenworthy L, et al. Therapist Training and Implementation Outcomes of an Adapted Executive Functioning Intervention for Autism in Children's Mental Health Setting. Under Review;) [23, 42, 43, 49, 115], thereby maximizing the potential for success and impact of the current project. Second, the inclusion of *UP-C* as an active contact control condition enables simultaneous testing and verification of clinical and implementation outcomes and mechanisms of change. Few implementation trials have tested clinical EBIs and implementation strategies with well-matched active contact control conditions and even fewer have rigorously tested change mechanisms linked to outcomes [116]. Such tests are vital to isolate the effects and mechanisms and increase confidence in results. Additionally, testing the clinical and implementation effectiveness of *Unstuck* and *UP-C* with both autistic and non-autistic children offers substantial efficiency and generalizability over testing *Unstuck* alone or focusing on autistic children alone.

Lastly, the current study is one of the first to directly examine the impact of EBI training, particularly autism EBI training, on improving psychotherapy quality and generalized use of EBIs in community settings. Given the transdiagnostic targets, both EBIs have high potential for enhancing psychotherapy quality via sustained use. Further, data indicate the expanded, generalized use and benefits of autism EBI training beyond autism, highlighting its potential to improve mental health services for children. Yet, few studies to date have directly tested this. Our study will examine the reach of EBI training via its use with autistic and non-autistic children and the extent to which it improves psychotherapy quality, including how the salient EBI features and provider-level mechanisms contribute to these key outcomes.

Abbreviations

AIM HI	An Individualized Mental Health Intervention for Autism
EBI	Evidence-based intervention
EF	Executive Functioning
UP-C	Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children or Unified Protocol for Children
WASH-II	Wechsler Abbreviated Scale of Intelligence-2nd Edition

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Note about language used

We use identity-first language in our research when referring to autistic children. This decision was based on our collaboration with the autistic community and current research in the field [117, 118].

Authors' contributions

KD is the principal investigator of this study, generated the idea and designed the study. SK, LA, and LBF are site principal investigators. SK, LA, LBF, and JS supported the conceptualization of this paper. SR is the statistician for the project and contributed to the design of the study. All authors were involved in developing, editing, reviewing, and providing feedback for this manuscript and have given approval of the final version to be published.

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Data availability

Data will be made available upon request to the corresponding author.

Declarations

Ethics approval and consent to participate

Ethical approval for was approved by the Institutional Review Board (IRB) at participating institutions and partnered community mental health programs, with the primary IRB overseen by San Diego State University (HS-2024-0105-SMT). All participants consented to participate in the current project.

Consent for publication

Participants completed a written disclosure form and were provided a copy for their records.

Competing interests

Laura Anthony is an author of and receives royalties for the sale of the of the *Unstuck and On Target*. Sarah Kennedy is an author of and receives royalties for the sale of *Applications of the Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children*. Dr. Kennedy also receives payment for providing consultation and implementation support in this intervention.

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