



Improving emotion regulation ability in autism: The Emotional Awareness and Skills Enhancement (EASE) program

Autism
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DOI: 10.1177/1362361318810709
journals.sagepub.com/home/aut


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Abstract

Emotion regulation impairments are common among individuals with autism spectrum disorder and are believed to often underlie commonly seen problems with aggression, depression, and anxiety. The Emotional Awareness and Skills Enhancement program was developed to reduce emotion regulation impairment and thereby improve behavioral disturbance, via mindfulness. Emotional Awareness and Skills Enhancement consists of a 16-week individual therapy treatment targeting emotion regulation impairments among individuals with autism spectrum disorder. We describe the conceptual framework and development of the program and present data on feasibility and preliminary efficacy from a pilot trial. The Emotional Awareness and Skills Enhancement manual was developed using a participatory action framework, based on emotion regulation research specific to autism spectrum disorder and input from individuals with autism spectrum disorder, therapists, and parents of children with autism spectrum disorder. Emotional Awareness and Skills Enhancement was piloted in a two-site open trial with 20 participants with autism spectrum disorder (12–17 years old, confirmed autism spectrum disorder diagnosis, IQ > 80). Outcome data support program feasibility and acceptability to participants, as well as significant improvement in emotion regulation impairments and related concerns. Findings offer preliminary support for both the feasibility and clinical effectiveness of the Emotional Awareness and Skills Enhancement program.

Keywords

autism spectrum disorder, emotion regulation, irritability, mindfulness, transdiagnostic

Emotion regulation impairments in autism spectrum disorder

Persistence of autism spectrum disorder (ASD) throughout the lifespan, along with better identification approaches, is contributing to a steadily growing population of adolescents and adults with ASD (Seltzer et al., 2004). The successful transition to adulthood is largely dependent on the foundation set in adolescence through the achievement of critical milestones including increased independence, autonomy, and responsibility (Arnett, 2000). Yet, adolescence is also characterized by heightened reactivity to social and emotional stimuli, which appears to increase the risk of psychopathology (Dahl and Gunnar, 2009; Kessler et al., 2005). Unfortunately, research indicates that age-appropriate adaptive skills and independence lag, and co-occurring psychiatric problems often worsen during adolescence and early adulthood for people with ASD (Maddox and White, 2015; Picci and Scherf, 2015; Taylor and Seltzer, 2012).

Problems with effective emotion regulation (ER), defined as the ability to modify one's arousal and emotional state to promote adaptive behavior (Gross and Thompson, 2006), may be at least partly responsible for emergent or worsening psychiatric problems, limited independence, and poor outcomes among adolescents and young adults with ASD. ER impairment may become exacerbated in adolescence due to factors such as heightened social demands and hormonal changes (Mazefsky and White, 2014). ER impairment continues to pose a significant barrier for young adults with ASD and is described by secondary teachers, professors, parents, and individuals

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with ASD themselves as one of the primary challenges to a successful college transition (Elias and White, 2018; White et al., 2016).

Some symptoms intrinsic to ASD are thought to contribute to ER impairment, such as poor perspective taking and problem-solving, lower response inhibition, deficits in recognition of others' emotions, and misreading social cues (Mazefsky and White, 2014). In addition, children with ASD tend to exhibit vague emotional responses and impaired insight (Rieffe et al., 2011), which may interfere with effective ER. Sensory sensitivity may also contribute to ER impairment in ASD, given links between high bodily awareness and internalizing distress in typically developing populations (Rieffe and De Rooij, 2012; Rieffe et al., 2008). Consistent with these theories, previous research has found that higher levels of ER impairment are associated with more severe core ASD symptoms among children with ASD (Samson et al., 2014).

There is a growing body of evidence in support of poor ER in ASD. Children with ASD have higher levels of negative affect in response to frustrating situations (Jahromi et al., 2012). In addition, once upset, they remain upset longer despite soothing efforts (Konstantareas and Stewart, 2006), which is suggestive of a problematic duration of emotion (Gross and Jazaieri, 2014). Among adolescents with ASD, two studies found increased reliance upon traditionally "maladaptive" ER strategies, such as avoidance, denial, rumination, and emotional numbing (Khor et al., 2014; Mazefsky et al., 2014). Furthermore, studies including a wider age range similarly found reliance upon maladaptive ER strategies, and less usage of reappraisal and other strategies traditionally thought to be adaptive (Cai et al., 2018a; Samson et al., 2014, 2015b). Among typically developing individuals, reliance on maladaptive ER strategies has been associated with a range of psychiatric symptoms (Aldao et al., 2010). In accordance with typically developing populations, reliance on strategies generally considered maladaptive has been associated with depression, anxiety, and aggression in ASD (Cai et al., 2018a; Mazefsky et al., 2014; Samson et al., 2015a), as well as many commonly co-occurring diagnoses (Gotham et al., 2015; Hollocks et al., 2016; Saqr et al., 2018). While the distinction between adaptive and maladaptive ER strategies may be overly simplistic, as context is undoubtedly important when considering whether a particular strategy is maladaptive (Aldao and Nolen-Hoeksema, 2012), inflexibility in ER usage is also problematic for individuals with and without ASD (Cai et al., 2018b).

A small number of interventions have recently been designed to address the unmet need for treatment during adolescence and the transition toward adulthood, which is considered a critical developmental period (Bishop-Fitzpatrick et al., 2013; Interagency Autism Coordinating Committee, 2016). At least one such intervention explicitly

targets self-regulation skills to improve readiness for post-secondary education (White et al., 2017). However, this intervention does not have a primary focus on ER impairment; rather, ER has been addressed peripherally, in the service of broader treatment goals. Given the direct impact of ER impairments on social impairment and psychiatric comorbidity, and indirectly on overall functioning and quality of life, ER is an ideal underlying mechanism to target in treatment (Weiss, 2014).

Treating emotion dysregulation in ASD

A growing body of research supports the efficacy of cognitive behavioral therapy (CBT) for co-occurring anxiety in children and adolescents with ASD (Scarpa et al., 2013). However, treatment response has been variable, and preliminary evidence suggests that complex problems (e.g. episodic self-injury) may not be remediated by treatments developed for anxiety (Lickel et al., 2012; White et al., 2013). Moreover, existing treatment protocols are problem-specific (e.g. CBT for anxiety in ASD) and many other common problems such as explosive behavior, irritability, and depression have yet to be sufficiently investigated.

In addition, high-level cognitive regulatory strategies, such as reappraisal (oft targeted in CBT), may be difficult to employ in times of high emotional distress. In such cases, "default" regulatory approaches may overwhelm the ability to engage more adaptive strategies (Aldao et al., 2010). This is especially likely among adolescents, given hormonal and biological changes that influence social-affective engagement and ER in a "bottom up" fashion (Crone and Dahl, 2012). For individuals with ASD, approaches that promote top-down regulatory strategies (e.g. thought restructuring) alone, or those focused on behavioral avoidance of environmental triggers, may be less effective than approaches that develop the client's ability to tolerate distress and be aware of internal states. One potential avenue to develop such skills and improve ER is through mindfulness.

In the last 25 years, psychotherapy has seen an emergence of Mindfulness-Based Interventions (MBI) across diverse populations (Herbert and Forman, 2011). Mindfulness, defined as attending to the present moment purposefully and nonjudgmentally (Kabat-Zinn et al., 1985), is an approach that cultivates increased awareness of internal reactions and an open and accepting attitude through the use of meditative practices and activities (Baer, 2003; Kabat-Zinn et al., 1985). Although there are several candidate mechanisms through which MBI exerts clinical effect, there is a sizable body of research indicating that improved ER and increased awareness are primary target mechanisms in typically developing samples of adults (Gu et al., 2015). Limited emotional insight and

awareness is common in ASD (Griffin et al., 2016). Because awareness of one's emotions is necessary for successful ER, mindfulness may be particularly suited for treatment of ER impairments in ASD. Furthermore, a review paper concluded that mindfulness treatment has been associated with anatomical changes in areas associated with cortical regulation and ER (Hölzel et al., 2011) and functional changes during meditation among typically developing adults following mindfulness intervention (Ives-Deliperi et al., 2011). Sustained (i.e. 4 months post-treatment) effects of mindfulness-based treatment measured via Electroencephalogram (EEG) have also been documented in healthy adults (Davidson et al., 2003).

The term MBI describes a wide range of interventions, including four well-established and standardized mindfulness interventions that vary in their targeted purpose, implementation, and group design, but all remain focused on the core principle of attending to one's life mindfully in the present moment with suspended judgment (Baer, 2003; Chiesa and Malinowski, 2011). These include Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT), which are 8-week interventions that utilize direct experience through mindfulness meditation practice as the primary means to cultivate mindful awareness, and Acceptance and Commitment Therapy (ACT) and Dialectical Behavior Therapy (DBT), which teach attitudes of mindfulness, acceptance, and non-judgment in a psychoeducational and conceptual way. Considering the difficulty that many individuals with ASD have with abstract material (Cooper et al., 2018), MBSR and MBCT may be the most suitable established MBIs to draw from for use with patients with ASD, as they involve learning through direct, applied experiences.

MBSR and MBCT are supported by a large body of scientific evidence and have demonstrated robust effects ameliorating symptoms of depression, anxiety, stress, and quality of life in both nonclinical and clinical populations of depressive disorders, anxiety disorders, chronic pain, cardiovascular disease, and cancer, among children, adolescents, and adults (Baer, 2003; Baer and Krietemeyer, 2006; Gotink et al., 2015). Given the empirical support for the efficacy of MBSR and MBCT, there have been efforts to develop new, or modify existing, MBIs for specific clinical populations (Chiesa et al., 2013; Khoury et al., 2013). These interventions are often similar to MBSR or MBCT but do not follow the standardized curriculum or group format and are tailored to a homogeneous population. These approaches have demonstrated ER-related improvements, including reduced inflexibility and rumination, and strengthening more adaptive approaches such as reappraisal and perspective taking among typically developing adults (Chiesa et al., 2013; Gu et al., 2015).

Despite the benefits in ER, awareness, and mental health symptoms, relatively few researchers have utilized MBIs with people who have ASD. Emerging evidence supports the utility of MBSR and MBCT with adults and

adolescents with ASD (e.g. Cachia et al., 2016; Conner and White, 2018; Spek et al., 2013). Spek and colleagues (2013) conducted a trial utilizing a modified MBCT group treatment for 42 adults with ASD and comorbid depressive and anxiety symptoms, and results indicated decreases in depression and anxiety symptoms and rumination, as well as increases in positive affect. For adolescents with ASD, a specific mindfulness exercise, Mindfulness in the Soles of the Feet, was taught as a strategy for shifting focus to a neutral object during times of distress or aggression (Singh et al., 2011a, 2011b). Singh et al. conducted several small, multiple baseline pilot studies of individual therapy using this approach ($n=3$ each) and found it to be effective in reducing aggression for adolescent males with ASD with varied cognitive abilities.

Current study

While substantial progress has been made regarding the use of CBT to treat anxiety in ASD, there remain gaps in the evidence-based treatment of emotional problems in ASD, particularly for the transition from adolescence to adulthood. Mindfulness has empirical support for the reduction of a range of emotional and psychiatric concerns outside of ASD, and there is a small body of growing research suggesting that MBIs may be beneficial in ASD. While promising, prior research of MBIs in autism has relied primarily on very brief interventions focused on single meditation exercises (Singh et al., 2011a, 2011b) or modified manuals of MBCT (Conner and White, 2018; Spek et al., 2013) that may be beneficial for individuals with ASD but are not optimized to meet the needs of this population. The overall goal of this study was to develop and preliminarily test a new intervention designed to improve ER in verbal adolescents and adults with ASD without intellectual disability that emphasizes the use of mindfulness and distress tolerance, called the Emotion Awareness and Skills Enhancement Program (EASE). While EASE draws on CBT, MBCT, and MBSR, it was developed based on ER research specific to ASD, input from individuals with ASD and their caregivers, and use of an individual therapy modality to allow therapist to meet the diverse needs of the population. The stakeholder-informed process utilized to develop EASE and the resultant primary components of the intervention are described. It was hypothesized that EASE would be feasible and acceptable to participants, and that ER impairment would decline significantly. Reduction in depressive, anxiety, and irritability symptoms was also explored.

Method

Development of the EASE

EASE theoretical model. The EASE program was developed to reduce ER impairment and thereby improve behavioral

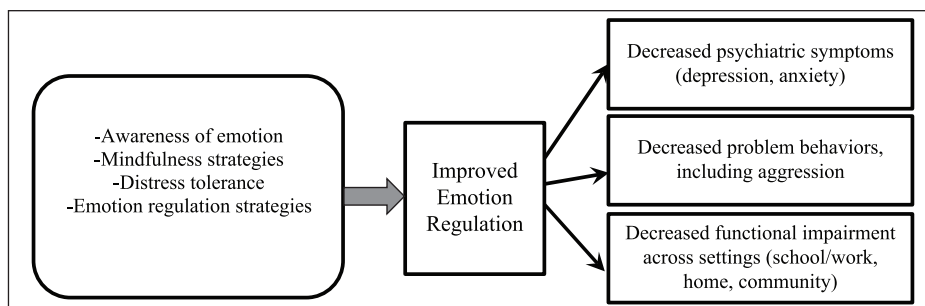


Figure 1. Theoretical model of change.

disturbance, via mindfulness (see Figure 1). Development of EASE was guided by theories on ER in ASD (Mazefsky and White, 2014; Mazefsky et al., 2013; White et al., 2014), research on ER in ASD (Weiss et al., 2017), and evidence-based treatment approaches (Hayes et al., 1999; Kabat-Zinn, 1990; Segal et al., 2002; Semple and Lee, 2007; Stahl and Goldstein, 2010; White, 2008).

EASE embraces a mindfulness approach, teaching participants how to cultivate a present moment and non-judgmental awareness, which can be utilized in times of distress. The mindfulness exercises taught in EASE are similar to the MBSR meditations that anchor in body sensations rather than thoughts and emotions. Similar to MBCT, EASE does incorporate some cognitive behavioral exercises informed by CBT. However, the focus is primarily on emphasizing awareness without judgment. EASE also differs from CBT in the absence of problem-solving as a means to decrease negative emotion. EASE, like MBCT, emphasizes that emotions are natural and unavoidable rather than a symptom of a problem. Thus, the goal of EASE is to learn to remain in control even during the experience of strong negative emotion, rather than avoidance of negative emotions or thoughts.

EASE was designed for adolescents and adults with any manifestation of ER impairment, such as depression, anger/irritability, anxiety, and outbursts, rather than targeting youth with specific co-occurring disorders. It has been argued that ER may be the mechanism underlying a range of psychiatric concerns in ASD (Mazefsky and White, 2014), and a growing body of research supports a strong association between impaired ER and problematic behavior, depression, and anxiety in ASD (Mazefsky, 2015). A transdiagnostic approach to treatment may facilitate effective treatment by addressing multiple behaviors and symptoms simultaneously through engagement of the underlying target process (Barlow et al., 2004). Transdiagnostic treatment models appear to be at least as effective as well-established, disorder-specific treatments in reducing symptomatic impairment (in non-ASD samples) (Norton and Barrera, 2012). The possibility that transdiagnostic approaches may have wider application than disorder-specific treatments suggests that these approaches could promote broader dissemination and adoption (McEvoy et al.,

2009). Furthermore, successful treatment of ER impairments may produce improvement across heterogeneous manifestations of emotion dysregulation in ASD.

EASE development process. The initial EASE manual and supportive materials were developed by three of the co-authors (S.W.W., C.M.C., C.A.M.). It included an integration of some principles and strategies from existing MBI and CBT treatments (see above), as well as newly created material. Recommended adaptations for individuals with ASD in CBT and MBI were also employed (session length, visual schedules and structured sessions, parental involvement, community sessions, online materials to promote generalization, etc.).

Once the initial draft of the EASE manual was developed, a participatory action framework, which is thought to help address the healthcare disparities among individuals with ASD (Nicolaidis et al., 2011), was applied. A range of stakeholders read the manual and provided their input, including adults with ASD, parents of individuals with ASD, and therapists experienced with MBIs, ASD, and manualized intervention trials. The manual was revised to incorporate the stakeholders' feedback, and an initial pilot study across two treatment sites was conducted.

EASE structure and content. An individual therapy approach permits flexibility in the delivery of the treatment and promotes dissemination in clinical settings where groups may not be practical. Furthermore, this format facilitates individualization to accommodate the person's unique needs and circumstances, which may vary in this age range, as well as the individual's particular manifestation of ER impairment. Finally, the individual therapy format and dosage (16 weekly, 45–50 min sessions) are consistent with the parameters of most insurance-approved outpatient therapy.

A Needs Assessment, completed independently by the parent and participant, is used to assess perceptions of the degree of interference of common ER and socialization obstacles. This information guides case conceptualization and aids the therapist in identifying social concerns that may be related to the client's ER impairment. Because so

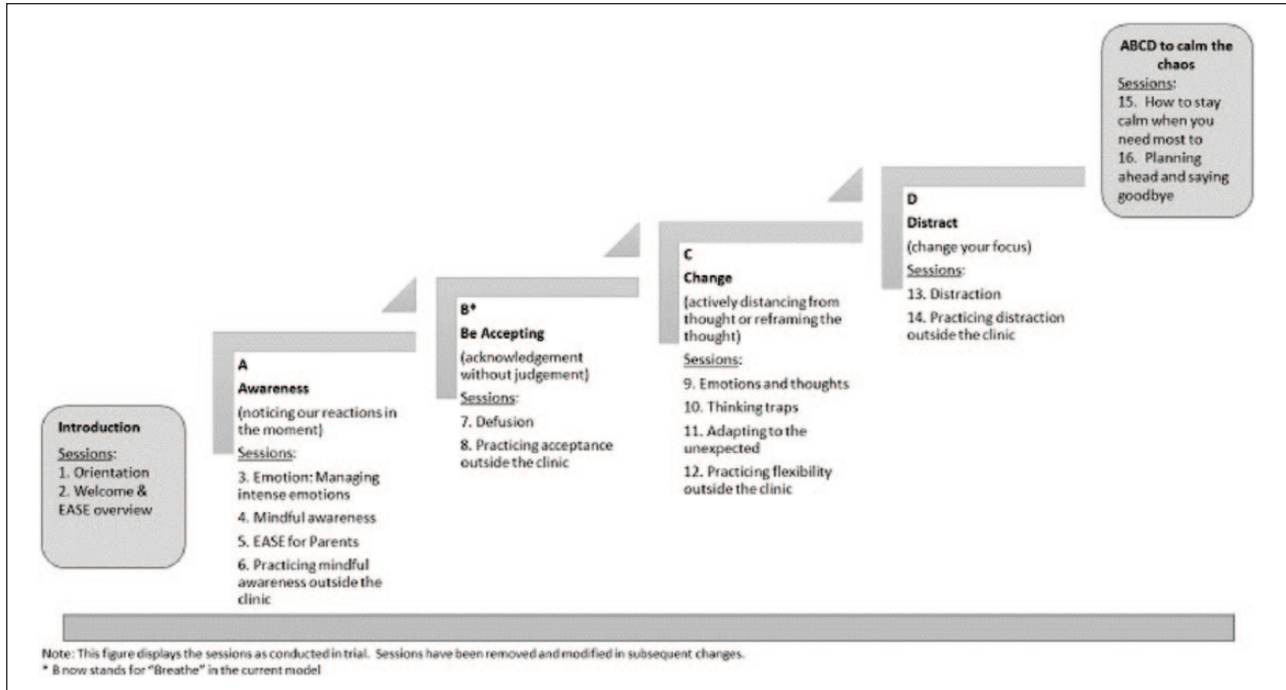


Figure 2. ABCD model and initial EASE session structure.

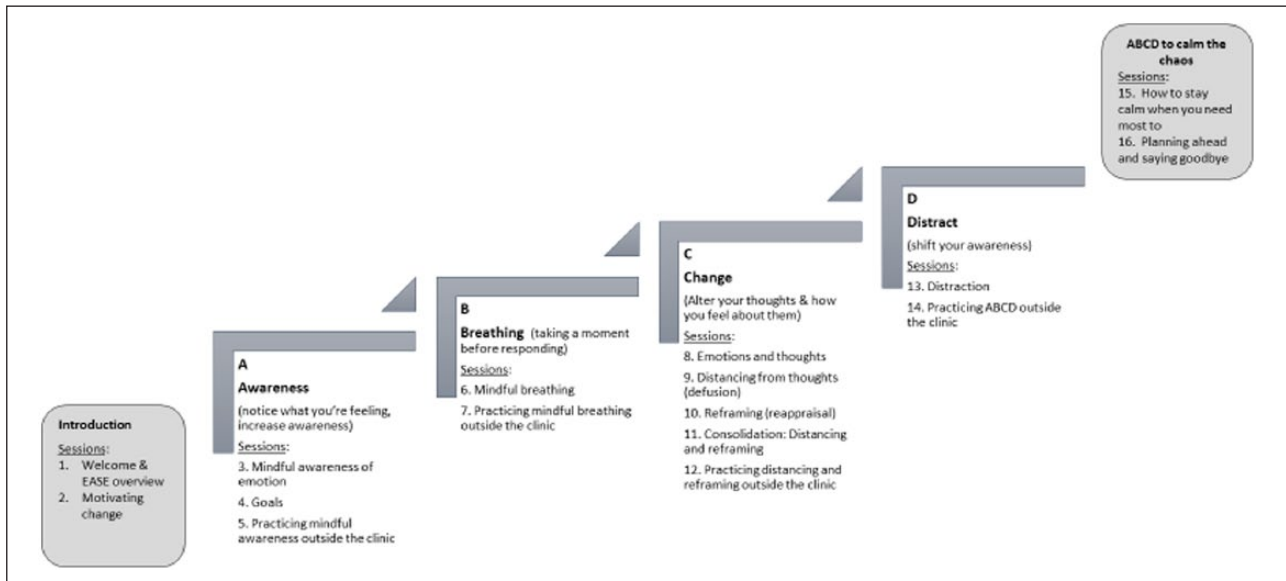


Figure 3. ABCD model and current EASE session structure with modifications incorporated based on open trial feedback.

much of the ER impairment experienced by individuals with ASD is expressed in the context of social interaction, social challenges are embedded into every session. Prior to each session, the therapist identifies a social “challenge” relevant for the client (e.g. being given a directive by parent, interacting with unfamiliar peers) and applies the skill being taught to this challenge.

The 16 sessions are grouped into four sequential modules, which emphasize different ER strategies, termed the “ABCD” model. Each module builds upon each other, including: Awareness (building awareness of emotions and reactions); Be accepting (acknowledge feelings without judgment); Change (do something different); and Distract (focus on something different). Figures 2 and 3

depict the ABCD model as well as the sessions that focus on each area of the model.

Each of the four ABCD modules consists of several individual content sessions and one community session, which serves as the culmination (information consolidation) session for each module. The community sessions often occur outside of the clinic and consist of practicing the ABCD skills in an applied way, in the natural environment. The community sessions are individually tailored to the problematic or triggering social contexts for each client in order to maximize learning and improve generalization. The goal of the community sessions in EASE is not to simply practice ER in social situations, but rather to apply the newly learned ER skills in settings and situations that most closely mimic the specific context where the participant experiences the most dysregulation.

Every session is conducted with the same structure: (1) begin with agenda setting and a mindful check-in, (2) review of prior material and homework completion; (3) teaching and practicing new ER skills or meditations; (4) ending with a mindfulness exercise; and (5) post-session planning and homework. Clients are encouraged to begin leading the mindfulness exercises for the therapist as they progress through EASE to facilitate confidence and independent use of the mindfulness meditation exercises. The majority of the session is completed with the client only but the parent is invited into the session at the end to practice the mindfulness exercise and review post-session homework. However, clients are able to request that their parent does not join the end of the session.

To improve mastery of material, EASE utilizes a multimodal teaching approach, in which individual therapy sessions are augmented by technology-based supports and teaching aids. A proprietary online platform developed for EASE (termed emotion-Coach or “e-Coach”) has session summaries with accompanying audio files of a therapist-led mindfulness meditation exercise. There is also specific information for parents on how to support their child during the program such as guidance on how to reinforce newly learned skills at home and in the community, FAQs about mindfulness, and strategies for handling problems when they arise. Participants and parents are both provided with a username and password to log into the site. Parents are provided with a tablet and seated in a separate private room during each session in order to access e-Coach and maintain an understanding of what topics their child is covering in session.

Pilot study

In accordance with guidelines regarding treatment development, the primary aim of this open trial was to gauge feasibility and acceptability of the new intervention (Leon et al., 2011). Subject enrollment took place across two university-affiliated clinics in the Eastern United States.

One site was a university medical center in an urban setting, and the second site was a university psychology specialty clinic in a rural college town. Both sites obtained approval from their institutional review boards to conduct this study. A two-site investigation, utilizing therapists with differing levels of experience, was conducted to ensure replicability across sites and therapists. Nine therapists, including doctoral-level psychologists or rehabilitation counselors, doctoral students in clinical psychology, and a research clinician with a master’s in education delivered EASE. Diversity in clinician experience level was sought in order to replicate the range seen in community settings. Clinicians completed a treatment fidelity form after each treatment session assessing adherence to session goals and inclusion of social challenges. Supervision was conducted weekly at each site, along with weekly cross-site teleconference supervision with video sharing to ensure implementation consistency.

Pilot participants. Recruitment was conducted via advertisements targeting the local ASD communities and mental health providers, and through utilization of research registries. Participants were not compensated for attending therapy sessions but were reimbursed at each assessment time point for a total of US \$125. Inclusion criteria included (1) ages 12–17, inclusive; (2) a clinical diagnosis of ASD, confirmed by research reliable administration of the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2; Lord et al., 2012); (3) verbal IQ score >80 as measured by the Wechsler Abbreviated Scale of Intelligence, Second Edition (WASI-2; Wechsler, 2011); (4) fluent in English; (5) ER impairment, as defined by at least one area of concern per parent report on the Severe Mood Problems scale (Simonoff et al., 2008), which includes a range of potential manifestations of poor ER (depression, anxiety, labile mood, or rage); (6) parent/guardian available to attend sessions. Exclusion criteria included serious suicidal/homicidal ideation warranting more intensive treatment; past or current diagnosis of a psychotic disorder; and receiving concurrent psychotherapy treatment for emotional issues that overlaps with the current study. The average age of participants was 14.94 (SD=1.54) and the majority were male (15; 88.20%) and White/Caucasian (14; 82.40%) (Table 1).

Procedures. A phone screen was conducted with the participant’s parent to determine initial eligibility, followed by in-person eligibility assessments with the parent and participant. Parents and participants were consented/assented prior to the eligibility appointment. Once eligibility was confirmed, participants and parents completed questionnaires at baseline (prior to beginning treatment), midpoint (following session 8), post-treatment (following session 16), and at 3-month follow-up. Parent and self-report measures were collected using a secure online

Table 1. Demographics.

	M (SD) n = 17		
Age	14.94 (1.54)		
Gender	15 male (88.20%)		
Race	14 White (82.4%), 2 Asian (11.8%), 1 Black (5.90%)		
FSIQ	98.47 (11.71); range 82–115		
CGI-S	4.53—Moderately to markedly ill (0.62)		
CGI-I	2.25—Much improved (0.58)		
	Pre-	Mid-	Post-
EDI Reactivity Theta	0.41 (0.85)	−0.15 (0.47)	−0.20 (0.64)
RSQ Involuntary Engagement-Parent	49.29 (6.13)	40.50 (7.87)	36.35 (7.04)
RSQ Involuntary Engagement-Child	41.81 (10.55)	41.31 (20.30)	42.00 (11.29)
RSQ Involuntary Disengagement-Parent	34.53 (4.65)	29.63 (5.23)	26.24 (5.12)
RSQ Involuntary Disengagement-Child	29.00 (6.76)	30.31 (7.61)	30.18 (8.11)
ABC-I	14.06 (7.71)	10.69 (5.73)	7.94 (7.35)
PROMIS Depression-Parent	24.00 (8.52)	18.50 (6.82)	13.82 (7.27)
PROMIS Depression-Child	27.47 (14.46)	27.60 (17.41)	22.29 (12.40)
PROMIS Anxiety-Parent	18.44 (9.70)	13.69 (7.79)	12.06 (9.30)
PROMIS Anxiety-Child	23.69 (15.98)	23.44 (16.20)	23.00 (15.37)

SD: standard deviation; FSIQ: Full Scale IQ; CGI-S: Clinical Global Impression – Severity; CGI-I: Clinical Global Impression – Improvement; EDI: Emotion Dysregulation Inventory; RSQ: Response to Stress Questionnaire, Social Stress Version; ABC-I: Aberrant Behavior Checklist-Irritability; PROMIS: Patient-Reported Outcomes Measurement Information Systems.

data collection website. The demographic questionnaire, completed at eligibility, included information about parent occupation, past and current treatment history of the child, and the child's current medication use. An independent rater completed the Clinical Global Impression – Improvement (CGI-I) scale (Guy, 1976) following review of questionnaires and clinical interview at pre- and post-treatment.

Pilot measures

Aberrant Behavior Checklist-Irritability subscale. Parents completed the Aberrant Behavior Checklist-Irritability (ABC-I) subscale, which measures tantrums, aggression, and self-injury, as a measure of overall problem behaviors at all study assessment points (Aman et al., 1985). The ABC-I has been utilized in ASD treatment and medication studies (Aman, 2012). Reliability of the ABC-I in this sample was acceptable ($\alpha = 0.85$).

Clinical Global Impression scale. The Clinical Global Impression scale (CGI) was completed by an independent rater, uninvolved in delivery of EASE, at baseline and post-treatment. Raters were not blind to participation in EASE treatment as all participants received the treatment (Guy, 1976). Based on all available information (questionnaires and phone screen) as well as behavioral observations and clinical interview, the CGI-Severity was completed at baseline and the CGI-I was completed at post-treatment. Both scales are rated on a 7-point scales: the CGI-Severity ranges from “among the most extremely ill” (7) to “not ill” (1), and the CGI-I ranges from “very much worse” (7) to

“very much improved” (1). In most clinical trials, scores of 1 (very much improved) and 2 (much improved) are considered treatment-responders (Guy, 1976). The CGI-I scale was designed to measure overall symptomatic change as compared to baseline. The CGI-I has been used in many studies over the past three decades, including clinical trials of treatments for ASD (e.g. McCracken et al., 2002). The CGI rater was trained to reliability, using a set of training vignettes with “gold standard” scores established.

Emotion Dysregulation Inventory. The Emotion Dysregulation Inventory (EDI) was developed to assess ER impairment in ASD following guidelines by National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information Systems (PROMIS) initiative, and its final items were based on factor analyses and item response theory (IRT) analyses using data from 1755 youth with ASD (Mazefsky et al., 2018a, 2018b). The EDI includes two scales: *Reactivity*, which captures intense, rapidly escalating, sustained, and poorly regulated negative emotional reactions, and *Dysphoria* scale, characterized by minimal positive affect and motivation, and the presence of nervousness and sadness. Prior research has demonstrated test-retest reliability in a treatment stable sample of 901 youth with ASD (mean difference of 0.05, and effect size of -0.06 for paired t-tests) (Mazefsky et al., 2018b). An independent rater interviewed the participant at pre- and post-treatment with the full EDI to inform the CGI-I. In addition, parent-reported EDI was collected at each assessment point. Parent EDI Reactivity Theta Scores, which have a mean of 0 and SD of 1 and provide superior dis-

criminative ability to raw scores (Hamleton, 1991), were used in analyses. The EDI was found to have good reliability in this sample ($\alpha=0.94$).

PROMIS Anxiety and Depression Scales. The pediatric PROMIS anxiety (13 items) and depression (13 items) scales were developed via the National Institute of Health initiative as brief change-sensitive outcome measures (Irwin et al., 2010). Data from 1529 participants, recruited from public schools, outpatient clinics, and hospital clinics, were used for a confirmatory factor analysis that confirmed the scales' unidimensional structures and eliminated several items, followed by IRT to select the final items (Irwin et al., 2010). Both self- and parent-report forms of the PROMIS anxiety and depression scales were administered in this study at each assessment time point. Both versions of the Anxiety scale (parent $\alpha=0.91$; child $\alpha=0.96$) and Depression scale (parent $\alpha=0.85$; child $\alpha=0.93$) demonstrated high reliability in our sample.

Response to Stress Questionnaire, Social Stress Version. The Response to Stress Questionnaire, Social Stress Version (RSQ) is a 57-item self- and parent-report questionnaire of adaptive and maladaptive ER strategies, collected at each assessment point during this study (Connor-Smith et al., 2000). The RSQ asks the respondent to identify social stressors that they have experienced and then rate the questions related to these specific stressors, thereby making it more concrete and relevant to the lives of individuals with ASD. The RSQ has been shown to be valid and reliable in ASD samples (Khor et al., 2014; Mazefsky et al., 2014). For the purposes of our analyses, the Involuntary Engagement subscale (consisting of questions relating to rumination, intrusive thoughts, and loss of control of physiological and emotional expression) and Involuntary Disengagement subscale (in which emotional numbness and being unable to think or act is measured) were used, as these subscales consist of ER strategies that individuals with ASD tend to over-rely upon based on prior studies (Khor et al., 2014; Mazefsky et al., 2014). Parent-report RSQ reliabilities were as follows: Involuntary Engagement $\alpha=0.82$; Involuntary Disengagement $\alpha=0.55$, while self-report RSQ Involuntary Engagement was an α of 0.92 and Involuntary Disengagement α of 0.82.

Treatment Satisfaction Scale. Teens completed a 10-item treatment satisfaction scale developed for the current study to obtain their impressions of the overall impact of the interventions. The first six items were rated on a 5-point scale (1=not helpful/no benefit, 5=very helpful/very beneficial) and included such items as "looking back at the program as a whole, please rate how helpful you thought the program was" and "how likely are you to recommend this program to another teenager like you?" Remaining items consisted of open-ended questions

asking participants to describe what participants found most useful, what aspects of the program were not useful, and any suggestions participants had for improving the program. Reliability for this sample was $\alpha=0.80$.

Treatment Fidelity Scale. After each session, the clinician delivering treatment completed a form developed for the current study that assessed client homework completion (options were "not applicable," "no," "partial completion/practice," and "yes"), session rapport (range 1–4 where 1="very poor" and 4="good"), client involvement (range 1–4 where 1="uninvolved" and 4="actively involved"), and adherence to the manual (percentage of objectives completed).

Analyses. Feasibility of implementation was assessed through sample ascertainment and retention, and acceptability through the treatment satisfaction scale. Overall treatment response was defined as "very much improved" or "much improved" (rating of 1 or 2, respectively) on the CGI-I. Preliminary efficacy was examined through paired sample *t*-tests of ER, depression, anxiety, and problem behavior measures to examine symptom level change from pre- to post-treatment. Given the small sample size, however, Cohen's *d* was also utilized to gauge effect size. Beyond statistical significance and effect size, it is also important to consider the clinical significance of change from pre- to post-treatment (Kraemer et al., 2003). Meaningful change scores were examined, defined as changes of >0.5 and >1 pre-test SD.

Results

Feasibility and acceptability

Feasibility was demonstrated through the ease of recruitment (20 eligible participants enrolled within less than 6 months across the two sites). Of these 20 participants, attrition levels were low; 17 (85%) completed the program, while 3 participants discontinued for a variety of reasons unrelated to dissatisfaction with the program (hospitalization, long commute to sessions (>1 h), unable to uphold time commitment). Furthermore, attrition was similar to prior research on adolescents with ASD (e.g. White et al., 2013). Clinician ratings on the treatment fidelity scale indicated high ratings of client involvement ($M=3.55$, $SD=0.65$) and therapeutic relationship ($M=3.55$, $SD=0.65$). The majority of participants at least partially completed homework assignments (session averages: partial completion=50.2%, completed=19.9%, not completed=20.8%, none assigned=9.1%). In most sessions, all objectives were accomplished ($M=86.36\%$; $SD=18.53$). Out of a 1 (e.g. "not helpful") to 5 (e.g. "very helpful") scale, helpfulness of the program ($M=4.29$, $SD=0.85$), impact of the treatment in their lives ($M=4.18$;

Table 2. Preliminary effect size estimates from pre- to post-EASE.

Construct	Measure	<i>n</i>	Mean difference (SD)	<i>d</i> (95% CI)	<i>t</i>	<i>p</i>
Parent report						
Impaired ER	EDI Reactivity Theta Scores	17	-0.71 (0.72)	0.67 (0.02 to 1.36)	3.03	0.008
Maladaptive ER strategies	RSQ Involuntary Engagement	17	-12.94 (5.36)	2.64 (1.72 to 3.56)	9.96	<0.000
	RSQ Involuntary Disengagement	17	-8.29 (4.97)	1.77 (0.97 to 2.56)	6.88	<0.000
Problem Behavior	ABC Irritability	16	-8.13(6.14)	0.76 (0.05 to 1.48)	4.32	0.001
	Depression	PROMIS Depression	16	-11.25 (6.93)	0.96 (0.23 to 1.69)	4.19
Anxiety	PROMIS Anxiety	16	-10.50 (5.63)	0.59 (-0.12 to 1.30)	2.22	0.043
Child report						
Maladaptive ER strategies	RSQ Involuntary Engagement	16	6.69 (5.72)	0.07 (-7.95 to 8.09)	-0.03	0.978
	RSQ Involuntary Disengagement	16	8.29 (4.97)	0.94 (-4.53 to 6.41)	-0.81	0.432
Depression	PROMIS Depression	16	-8.47 (6.65)	0.52 (-0.17 to 1.20)	2.23	0.041
Anxiety	PROMIS Anxiety	16	-6.06 (5.65)	0.08 (-0.61 to 0.76)	0.267	0.793

Cohen's *d* 0.2=small, 0.5=medium, 0.8=large.

SD: standard deviation; CI: confidence interval; ER: emotion regulation; EDI: Emotion Dysregulation Inventory; RSQ: Response to Stress Questionnaire, Social Stress Version; ABC: Aberrant Behavior Checklist; PROMIS: Patient-Reported Outcomes Measurement Information Systems

SD=0.88), and relevance of the content ($M=4.41$, $SD=0.87$) were all rated highly by participants. Homework completion averages were significantly correlated with parental depression ratings from pre- to post-treatment change scores ($r=0.53$, $p=0.035$) and also positively correlated with EDI Reactivity change scores ($r=0.19$, $p=0.46$) and parental anxiety change scores ($r=0.43$, $p=0.09$), but not with irritability change scores or self-report scores (all $r < 0.33$).

Efficacy

Twelve of the 17 participants (71% of sample) were treatment-responders on the CGI-I. The effect size of parent-report ER measures fell in the medium-to-large range, per parent report (EDI Reactivity $d=0.67$; RSQ Involuntary Engagement $d=2.64$; RSQ Involuntary Disengagement $d=1.77$; see Table 2 and Figure 4), with no changes noted by RSQ self-report (RSQ Involuntary Engagement $d=0.07$; RSQ Involuntary Disengagement $d=0.94$). Parents also reported a medium decrease in irritability/aggression ($d=0.76$) as measured by the ABC-I. While parents reported a large decrease in symptoms of depression, self-reported change scores indicated a medium effect ($d=0.52$). Similarly, parents reported a medium effect decrease in anxiety symptoms ($d=0.59$), although participant self-report change in anxiety was not statistically significant ($d=0.08$).

Eight (47.09%) participants had at least 0.5 SD or greater decrease in ER impairment as measured by the EDI Reactivity Score, while 17 (100%) saw reductions on parent-report RSQ Involuntary Engagement and 15 (88.24%) on RSQ Involuntary Disengagement. Beyond ER, 11 (68.75%) saw at least 0.5 SD or greater reduction in PROMIS Depression parental report, 9 (56.25%) on PROMIS Anxiety parental report, and 11 (73.33%) on

ABC Irritability subscale. All participants displayed meaningful change score decreases in at least one of the ER measures, and 15 (93.75%; one parent did not complete) had such reductions in either parental report of depression, anxiety, or problem behaviors (see Figure 5).

Discussion

ER impairments are common and interfering for individuals with ASD, there are few psychosocial treatments targeting these difficulties among adolescents and adults with ASD, and none do so directly. The EASE program was designed to remediate ER impairments through mindfulness awareness instruction. Initial findings support feasibility of implementation and acceptability of EASE to consumers. Moreover, medium to large effects were seen in reduction of ER impairments as well as associated depression, anxiety, and problem behaviors. These promising findings support the further development and large-scale evaluation of EASE, especially among adolescents and emerging adults, for whom impairment in ER is a barrier to successful transition to optimal adult outcomes.

This study represents, to our knowledge, the first evaluation of a MBI developed for adolescents with ASD to target ER impairment. Despite tremendous interest in MBI for a range of mental health concerns (Baer, 2003; Baer and Krietemeyer, 2006; Gotink et al., 2015), application with clients who have ASD is quite recent. In addition to EASE's acceptability to the clients, feasibility of implementation, and homework completion rates similar to traditional CBT in this population (White et al., 2013), preliminary data suggest that it may be clinically efficacious with adolescents at a medium effect size, comparable to CBT for ASD (Weston et al., 2016) and social skills interventions (Gates et al., 2017). This preliminary indication of efficacy is consistent with prior interventions with

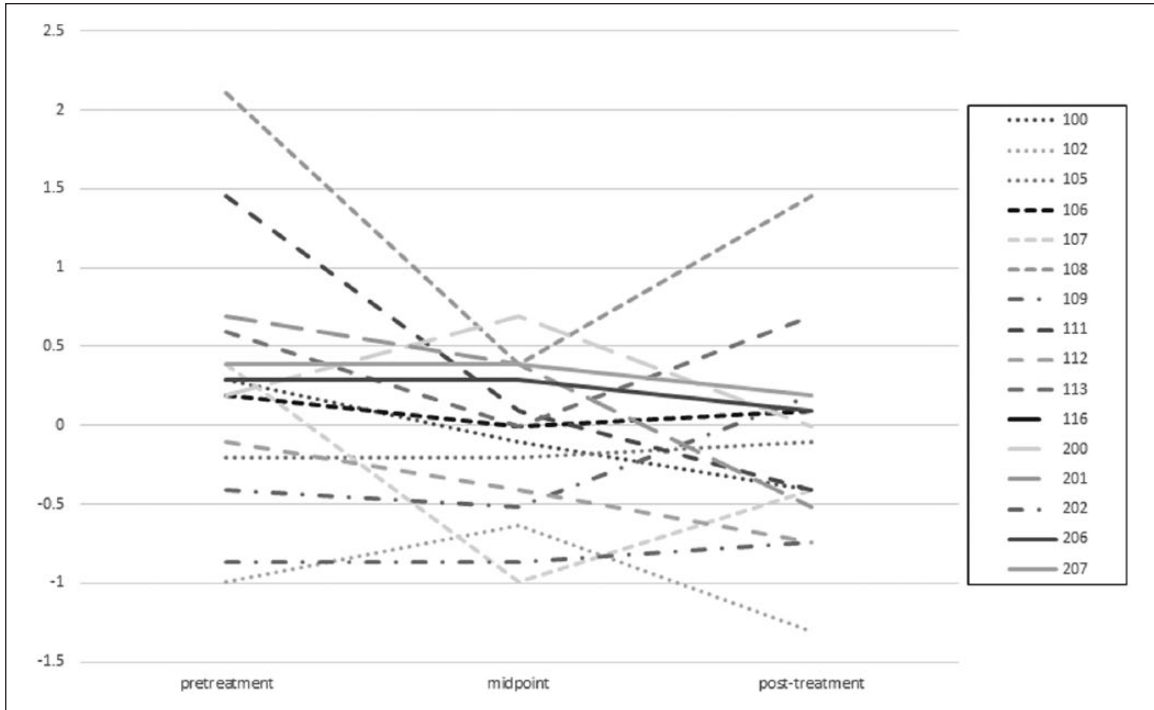


Figure 4. EDI Reactivity Theta Scores.

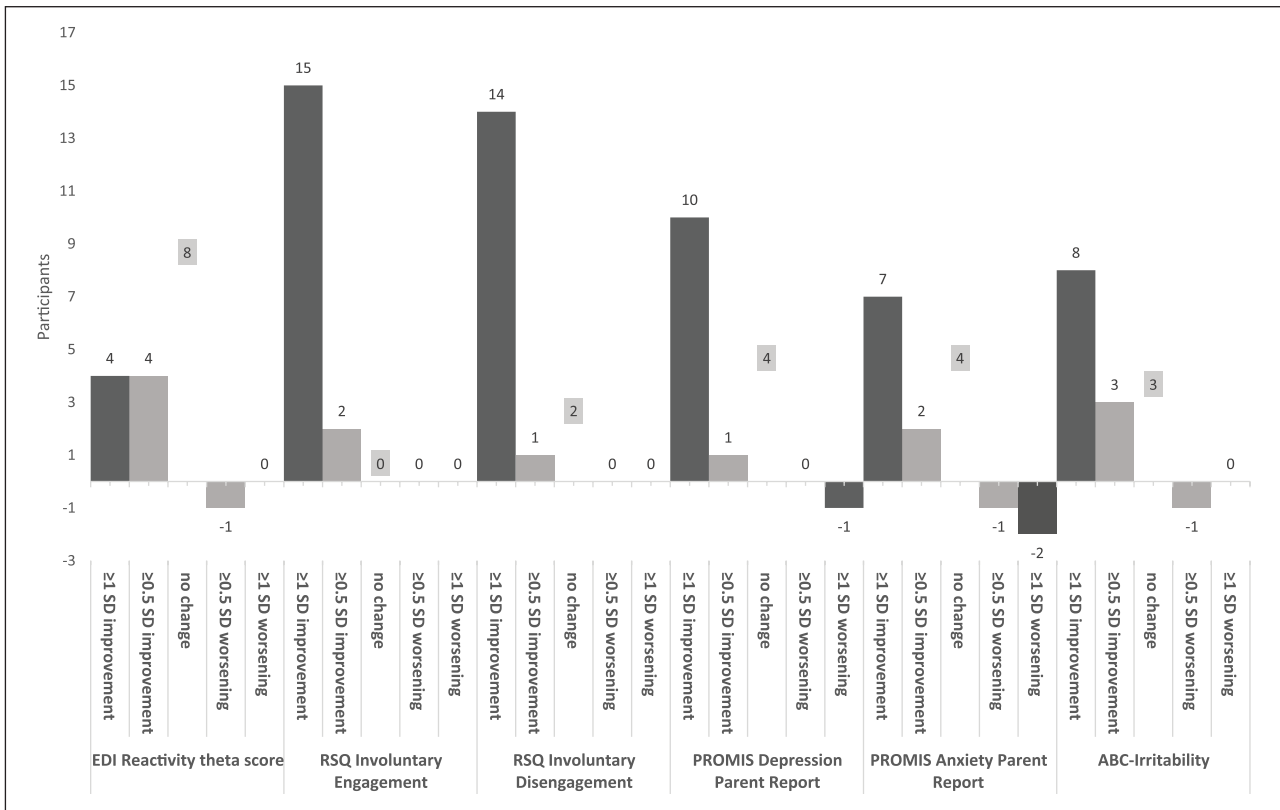


Figure 5. Participant change from pre-test to post-test compared to group pre-test SD.

individuals with ASD focused on a single mindfulness exercise (Singh et al., 2011a, 2011b) as well as open trials of MBIs for adults with ASD (Conner and White, 2018; Spek et al., 2013), suggesting that MBI is beneficial for individuals with ASD.

Although it has been argued that it may be fruitful to target ER in transdiagnostic psychosocial interventions for youth with ASD (Weiss, 2014), prior treatment development research in ASD has primarily focused on the treatment of specific comorbid disorders (e.g. Lickel et al., 2012; White et al., 2013). Results of this open trial indicated that the majority of participants responded to a mindfulness-based ER intervention with marked improvement across domains, despite highly variable pre-treatment presentations. A methodological hurdle of transdiagnostic treatment research is identification of primary outcome measures that are sensitive to change for participants with heterogeneous clinical presentation. In our sample, we saw tremendous pre-treatment variability across ER impairment as well as symptom domains (e.g. baseline standard deviations for all measures were considerable). As such, it was not expected that participants would experience a reduction in every psychiatric symptom domain (e.g. they may not have had problems in each domain at baseline). Therefore, it was particularly encouraging that medium to large effect sizes were observed across a range of manifestations of impaired ER, including reliance on maladaptive ER strategies, irritability/problem behavior, depression, and anxiety. Furthermore, all youth demonstrated clinically meaningful improvement in ER and improved in at least one psychiatric symptom domain. The observed benefits across different psychiatric symptoms is pertinent given that few youth with ASD present with a single co-occurring condition (e.g. Simonoff et al., 2008). As such, development of evidence-based transdiagnostic interventions for ASD that target an underlying shared process (such as ER) may serve to improve the efficiency of clinical care. Other open trials have similarly shown promising preliminary efficacy of emotion-focused transdiagnostic interventions for younger children with ASD (Scarpa et al., 2012; Sofronoff et al., 2007). The EASE results are the first, to our knowledge, to demonstrate the potential of an ER-focused transdiagnostic treatment for adolescents.

When interpreting these promising findings, it is important to keep in mind that although self-reported treatment satisfaction was high and self-report measures were indicative of positive change, the observed effects were stronger when evaluated based on parental report. A meta-analysis of reporter concordance among children and adolescents in the general population found low-to-medium correspondence (De los Reyes et al., 2015). Similarly, differences in parent- and self-report have also been observed in psychopathology and social skills in ASD (Blakeley-Smith et al., 2012; Lerner et al., 2012; Mazefsky et al., 2011). While questions remain regarding the use of self-report

measures of co-occurring psychopathology among children and adolescents with ASD given difficulties in emotional insight and theory of mind (Blakeley-Smith et al., 2012; Lerner et al., 2012; Mazefsky et al., 2011), the lower symptom ratings in self-report compared to parent-report of ER, depression, and anxiety symptoms in the present study have been noted in several other studies (Lerner et al., 2012; Mazefsky et al., 2011). Future research in ASD should address the potential sources of reporter discrepancies, including factors affecting the validity of self-report as well as explanations proffered in the typically developing literature, such as the effects of context, differing reporter perspectives and biases, and other factors in providing incremental validity when such reporter discrepancies are observed (De los Reyes et al., 2015).

Future directions

Consistent with a stepwise and additive approach to treatment development (Smith et al., 2007), upon completion of this open trial, all qualitative feedback from participants and their families, as well as EASE therapists, was integrated to inform refinement of the EASE curriculum. The breadth of mindfulness practices was reduced to afford more time to practice a fewer number of strategies (a “depth over breadth” approach). Given some client and therapist reactions to a focus on “acceptance,” we removed this aspect, replacing it with a focus on breathing to build awareness, in support of EASE’s emphasis on awareness as the foundation for improved ER (see Figure 3). Therapists noted that several participants struggled with the abstract nature of acceptance, including interpreting it as requiring them to “accept” all emotionally difficult situations that could be modifiable. Furthermore, removing acceptance provided more time for more in-depth and repeated coverage of the remaining concepts in the subsequent version of the manual. Although homework completion rates were commensurate with other studies, the positive association between homework completion and post-treatment change suggests that additional efforts to support homework compliance, such as the use of positive reinforcement, may be useful.

The current pilot study has several limitations that should be considered when interpreting the findings and addressed in future research. The primary limitation is the small sample and lack of randomization or a control condition. The lack of a comparison group may have diminished internal validity, as treatment expectancy effects may have influenced reporters. Furthermore, it is unknown whether EASE is comparable or an improvement upon other existing therapies. As such, we are now evaluating the refined EASE protocol in a two-site randomized controlled trial (RCT) to formally test efficacy. Although designed to also be appropriate for adults, we began with a more homogeneous sample of adolescents for the initial evaluation of

EASE in the open trial. In the ongoing RCT, both adolescents and young adults with ASD are being included. The open trial participants were primarily White/Caucasian and thus generalization of results to other racial and ethnic groups is limited. Other limitations include a lack of biological measures of ER, recruiting only from verbal individuals, and individuals on the autism spectrum without intellectual disability. Nonetheless, this work represents the first step in treatment development including writing a structured manual, demonstration of feasibility and acceptability, and preliminary assessment of efficacy.

Future research, beyond the refinement of EASE and demonstration of efficacy through the RCT, should focus on the mechanisms of action that underlie these changes in ER impairment that occur as a result of EASE. In addition, future studies can target implementation and dissemination, as well as evaluate moderators of treatment response. Finally, it would be informative to employ other methods of ER measurement, such as ecological momentary assessment, psychophysiological measures (e.g. heart rate), and neurological measures (e.g. functional magnetic resonance imaging (fMRI), EEG).

Conclusion

EASE targets ER impairment among adolescents and young adults with ASD, an underserved and growing population. Theoretically, ER impairment is believed to contribute to the poor outcomes documented among adults with ASD and contribute to high rates of psychiatric comorbidity. EASE's innovation as a treatment stems from its transdiagnostic focus on ER (Mazefsky et al., 2014; Samson et al., 2012; Weiss et al., 2014), via heightened mindful awareness, which has growing support among individuals with ASD (Cachia et al., 2016; Conner and White, 2018; Singh et al., 2011a; Singh et al., 2011b; Spek et al., 2013; Thomson et al., 2015). Future research will determine EASE's effectiveness via an RCT (currently underway). The potential of MBIs for increasing emotional awareness and decreasing ER impairment is considerable, as the field seeks to improve outcomes and quality of life for individuals with ASD.

Acknowledgments

The authors would like to acknowledge Dr. Nancy Minshew and Dr. Shaun Eack for their support and guidance in the design, conduct, and funding procurement for this study.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article:

Support was provided by the Pennsylvania Department of Health, R01HD079512 (PI: Mazefsky), and the Edith L. Trees Charitable Trust.

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