MAJOR RESEARCH PROJECT

LITERATURE REVIEW:

Evaluating the effectiveness of emotion regulation interventions in children and adolescents with autism.

EMPIRICAL PAPER:

Evaluating a goal-setting intervention for children and young people with executive dysfunction: a single-case experimental design.

Submitted by Seona Granville, to the University of Exeter

as a thesis for the degree of Doctor of Clinical Psychology, May 2020

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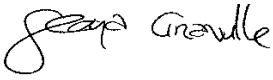
Signature: 

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SCHOOL OF PSYCHOLOGY

DOCTORATE IN CLINICAL PSYCHOLOGY

LITERATURE REVIEW

Evaluating the effectiveness of emotion regulation interventions in children and adolescents with autism

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Abstract

Background: Emotion regulation (ER) impairments are a common feature of autism spectrum disorders (ASD). It is believed that by targeting ER difficulties directly, individuals with ASD might be better able to manage their difficult emotions and consequently improve their quality of life. Emerging research has begun to explore interventions aimed at treating ER difficulties in ASD, however, it remains unclear which approaches are most effective.

Objectives: This review aimed to evaluate the effectiveness of various interventions targeting ER impairments in ASD.

Method: Studies evaluating interventions targeting ER impairments in individuals under 18 years with ASD were included. 772 papers were identified across four databases: Ovid MEDLINE, PsycINFO, Embase, and Global Health. A systematic screening process led to the inclusion of nine papers in the review.

Results: This review found promising evidence to suggest that behavioural and CBT-informed approaches, if appropriately adapted, can be effective at improving ER abilities in children with ASD. One study focused solely on mindfulness techniques with adolescents, demonstrating similarly encouraging findings for its application in ER treatment.

Conclusions: Most studies comprised small sample sizes and thus, all results are interpreted with caution. Preliminary evidence indicates that ER impairments can be treated using a range of CBT, behavioural and mindfulness approaches. Larger randomised control trials are needed to determine confidently the efficacy of such treatments in this population.

Keywords: autism, emotion regulation, children and young people, interventions.

Introduction

Autism spectrum disorders (ASDs) are a range of neurodevelopmental conditions characterised by difficulties with social communication and interaction, inflexible imagination, and restricted and obsessional interests and activities (Weston, Hodgekins, & Langdon, 2016). ASDs are believed to affect approximately one in 59 children worldwide (Baio et al., 2018) and are more prevalent in males than females (Schuck, Flores, & Fung, 2019). The most recent figures from the Centres for Disease Control and Prevention revealed that one in 38 boys and one in 152 girls aged eight years, or a male to female ratio of 4:1, present as autistic (Baio et al., 2018). Furthermore, a prevalence study carried out by Postorino et al. (2015) found that up to 47.6% of children and young people with ASD demonstrate some kind of co-occurring intellectual disability.

Considerable evidence indicates that the majority of individuals with ASD struggle with associated emotional and behavioural problems (e.g., Albaum, Tablon, Roudbarani, & Weiss, 2020; Berkovits, Eisenhower, & Blacher, 2017). Chandler et al. (2016) revealed that high levels of disruptive behaviours are associated with emotional difficulties in children with ASD. Research suggests that such emotional and behavioural problems pose significant challenges to daily functioning (Andy, 2020), often resulting in depression (Mazefsky et al., 2014), anxiety (Mazefsky et al., 2013), and poor social development (Baker, 2008). Indeed, Croen et al. (2015) found that up to 84% of individuals with ASD experience some degree of anxiety, whilst up to 70% experience symptoms of depression. Higher rates of anxiety and low mood have been associated with difficulties such as aggression and self-harm (Folstein, 2012), loneliness (White & Roberson-Nay, 2009), as well as disrupted sleeping patterns (Richdale, Baker, Short, & Gradisar, 2014).

Despite the high prevalence, reasons remain speculative for the causes of these co-morbid symptoms in ASD (Cai, Richdale, Uljarevic, Dissanayake, & Samson, 2018). Emotion regulation difficulties have been found to be a transdiagnostic risk factor for mental health conditions in the general population (Aldao, Gee, De Los Reyes, & Seager, 2016), and emerging research has begun to explore its potential importance as a risk factor in ASD (Weiss, Thomson, & Chan, 2014; White et al., 2014).

Emotion regulation (ER) refers to a complex process in which emotional responses are monitored and modified in a goal-oriented way (Eisenberg & Spinrad, 2004). Mazefsky and White (2014) expanded on this further by proposing that ER is a method of controlling one's emotion before or after a triggering event. ER aims to modify the intensity, duration and types of emotions experienced (Cai et al., 2018), a process that can be either effortful or automatic (Gyurak, Gross, & Erkin, 2011). Gross (2013) describes how ER involves both intrinsic processes (e.g. using strategies such as self-soothing), and extrinsic processes (e.g. being supported by a caregiver).

Chambers, Gullone, and Allen (2009) argue that ER is necessary to maintain an optimal level of arousal, enabling one to progress towards personal goals. ER firstly involves identifying emotions that need regulating, followed by activating strategies to either increase or decrease these emotions (Gross, 2015). Emotion dysregulation occurs when emotions are ineffectively identified and inappropriate strategies are applied in an attempt to regulate, often expressing itself in negative affect or irritability (Cai et al., 2018). ER impairments are believed to be inherent in ASD (Mazefsky & White, 2014), with research highlighting that this population generally has more ER difficulties and is less effective at using ER strategies

compared to neurotypical participants (e.g., Cai et al., 2018). Indeed, typical autistic traits comprise many predisposing factors to developing ER impairments, including poor executive function and self-awareness abilities, and sensory difficulties (Beck, Conner, Breitenfeldt, Northrup, White, & Mazefsky, 2020). Preliminary evidence also highlights the possibility of biological vulnerabilities for impaired ER in ASD (Mazefsky, 2015), including neural reactivity (Pitskel et al., 2014) and atypical heart rate variability (Guy, Souders, Bradstreet, DeLussey, & Herrington, 2014).

People with ASD often rely on patterns of maladaptive ER strategies (Mazefsky, 2015) that can be associated with a wide range of negative outcomes, such as poor prosocial behaviours and peer interactions (Jahromi, Bryce and Swanson, 2013). Bask (2015) defines internalising behaviours as emotional responses that are directed inward (e.g., anxiety or depression), whilst externalising behaviours are typically directed away from the self (e.g., aggression or defiance). It is believed that people with ASD might not only struggle to recognise the emotions of others but also with identifying their own emotions and consequently with matching the nature of those emotions with the appropriate response (Williams & Happé, 2010). When children do not develop adaptive ER, this can sometimes result in emotion dysregulation, or seemingly out-of-proportion reactions typically called “meltdowns” (Baker, 2008), with difficulties expressing or identifying their own mental states (Kuroda et al., 2013). Such experiences can lead to children being less accepted by their peers and might result in missing key learning opportunities in both academic and social environments (Shaffer et al., 2019). This can exacerbate feelings of low mood and anxiety, often resulting in further withdrawal, aggression, or self-harming behaviours that might already be present (Mazefsky, Pelphrey, & Dahl, 2012). Indeed, a large randomised control trial (RCT) found that people with ASD

access psychiatric services significantly more than those without ASD (Croen, Najjar, Ray, Lotspeich, & Bernal, 2006).

Despite the strong evidence indicating the integral role that ER plays in linking one's emotional state and social functioning (Mazefsky et al., 2012), ASD-based research, for the most part, has primarily focused on managing the heightened behavioural difficulties faced by individuals (e.g., Hill et al., 2014). Less attention has been paid to the specific role of ER in this population, and more specifically, how ER impairments should be treated (Reyes, Pickard, &r Reaven, 2019). The most efficacious ER-targeted intervention for individuals with ASD remains ambiguous. The National Institute for Clinical Excellence guidelines (NICE; 2014) recommend that developmentally-adapted psychosocial interventions should be offered for any core feature of ASD, including ER difficulties. Two types of therapeutic approaches are typically applied in interventions targeting ASD symptoms in children and young people: applied behavioural analysis (ABA; e.g., Mohammadzaheri, Koegel, Rezaee, & Rafiee, 2014) or cognitive behavioural therapy (CBT; e.g., Weston, Hodgekins, & Langdon, 2016).

ABA approaches traditionally centre on behavioural and environmental modifications, often with a focus on positive behaviour support plans (Cipani & Schock, 2010). Specific gains from ABA in ASD populations comprise improved productivity and overall quality of life, as well as some reductions in externalising behaviours (Axelrod, McElrath, & Wine, 2012). However, ABA approaches typically fail to address the "emotional" aspects of an ASD presentation (Ross, 2007), and thus, ER impairments are often neglected.

CBT approaches are well-established, evidenced-based treatments, and are believed to be the gold-standard psychosocial treatment for low mood, anxiety and other affective disorders in typically developing children and adults alike (Reaven, Blakeley-Smith, Culhane-Shelburne, & Hepburn, 2012). CBT is grounded in the principle that thoughts, feelings and behaviours all interact, and that dysfunctional thinking and behavioural patterns can be identified and consequently challenged in order to reduce symptomology (Beck, 2011). Although CBT has been shown to be effective with a range of populations across the lifespan (e.g. Evans, 2007), evidence of its effectiveness in treating emotion-related disorders in young people with ASD is still scarce (Vasa et al., 2014). Emerging evidence suggests that, if appropriately adapted, CBT can be effective in reducing mental health difficulties in ASD, as well as improving ER abilities and internalising and externalising behaviours (Albaum et al., 2020). Furthermore, because children with ASD tend to depend on others to regulate their emotions (Nuske et al., 2017) it is argued that involving parents in such interventions is a key component of treatment success (Reyes et al., 2019).

Because a large component of CBT is cognitively based, the intensity of ER impairments in some individuals might overwhelm any attempt to implement newly acquired skills and coping strategies (Shaffer et al., 2019). A small body of research has highlighted that mindfulness approaches can address this challenge (e.g., Conner et al., 2019; Ridderinkhof, de Bruin, Blom, & Bögels, 2018). Mindfulness involves attending to the present moment in a purposeful and non-judgemental way (Herbert & Forman, 2011) and endeavours to cultivate an increased awareness of internal responses, and how these can be managed (Creswell, 2017). However, despite a plethora of research highlighting the vast benefits of mindfulness

approaches on overall well-being (Conner et al., 2019), little attention has been paid to its efficacy in ASD populations.

Research has indicated that ER impairments might function in a transdiagnostic way, being shared across and maintaining multiple emotional disorders (e.g., Chu et al., 2016; Aldao, Nolen-Hoeksema, & Schweizer, 2010). It is argued that ER is a concept that cuts across traditional diagnostic boundaries, representing underlying behavioural and emotional processes in multiple diagnoses, rather than any one specific syndrome (Weiss, 2014). Ehrenreich-May et al. (2017) posit that with appropriate modifications, transdiagnostic CBT might be effective in treating emotional difficulties across a range of neurodevelopmental populations. Transdiagnostic CBT adopts the same underlying principles across conditions, without tailoring the protocol to specific diagnoses (Beck et al., 2020).

Aim of the Systematic Review

Emerging evidence has begun to explore these various interventions in ASD populations; however, it remains unclear as to which methods are most effective at improving ER abilities in children and young people, and to what extent. Reyes et al. (2019) propose that by directly addressing ER difficulties, children and young people with ASD might be better able to manage their emotional experiences and potentially improve their quality of life. Therefore, there is a great need to collate and evaluate the existing literature exploring this area in order to inform future clinical practice.

The aim of this systematic review is to evaluate the effectiveness of different interventions targeting ER impairments in children and young people with ASD.

Method

The systematic review process and report followed the guidelines and checklist of the Preferred Reporting Items for Systematic review and Meta-Analyses Protocols (PRISMA-P) statement (Moher et al., 2015; see Appendix A), as well as the Cochrane Handbook for Systematic Review of Interventions (Higgins & Green, 2011).

Eligibility Criteria

Papers were assessed for review using the population, intervention, comparator, outcome, and study design (PICOS) method of inclusion and exclusion criteria (O'Connor, Green, & Higgins, 2011; see Table 1).

Table 1.

Full inclusion and exclusion criteria using the PICOS approach.

	Inclusion Criteria	Exclusion criteria
Population	Individuals under the age of 18. Must have a diagnosis of an autism spectrum disorder (ASD) (including Asperger's condition).	Populations aged 18 or over, or under 18 with no diagnosis of an ASD.
Intervention	Interventions that at least partly target emotion regulation will be included.	n/a
Comparator	n/a	n/a
Outcomes	Must include a quantitative measure addressing emotion regulation (e.g. the cognitive emotion regulation questionnaire - ERQ), or measures including specific emotion regulation sub-scales (e.g. BRIEF). Both standardised and experimental measures will be included, provided they are all targeting emotion regulation measurement.	Studies that evaluate aspects of cognition affected by ASDs but do not include emotion regulation.
Design	Quantitative designs Randomised controlled trials Experimental designs Single case designs Quasi-experimental designs	Qualitative designs Non-English language Non-peer reviewed Book chapters Theses

Population. Participants comprised children and adolescents with diagnoses of an ASD under the age of 18.

Intervention. Studies were included in the review if they demonstrated an intervention aimed at targeting ER impairments in children and/or young people with ASD, in both clinical and non-clinical settings.

Comparator. The review was not specifically looking at making a comparison between groups; therefore, studies were not limited to include only control group designs.

Outcome. The outcome of interest was the effectiveness of interventions on ER abilities in children and young people with ASD. Studies were included if this was evidenced by the use of a quantitative measure addressing ER or measures including specific ER sub-scales. Non-standardised measures targeting ER that had been purposely designed for a study (e.g. experimental self-report measures) were also considered for review.

Study designs. Only peer-reviewed papers were included, focusing on quantitative designs, including RCTs, single case experimental designs (SCED), experimental studies, and quasi-experimental designs. Mixed-method studies were only considered if the primary focus was on quantitative data.

Information Sources

The following electronic databases were searched on 3rd January 2020: Ovid MEDLINE, PsycINFO, Embase, and Global Health. The references lists of the papers included in the full-text screening were also scanned, to ensure no relevant publications were missed. Because no systematic review had previously been conducted evaluating the efficacy of ER interventions in children and young people with ASD, the database searches were not restricted by date. Due to limited resources, grey literature was not searched.

All identified papers were exported to the reference management software, Mendeley.

Search Strategy

Table 2 illustrates the key search terms entered into the databases. Truncation symbols were used to ensure that all possible variations of key words were targeted.

Table 2.

Key search terms.

	Section 1: Population	Section 2:Intervention	Section 3: Outcomes
Individual Search Terms (in title and abstract fields)	Autis* or ASC or ASD or asperger* or pervasive developmental disorder AND Young people or young person or child* or youth or adolescen* or p?ediatric	Strateg* or treatment or rehabilit* or program* or training or interven* or prevent* or control* or manag* or reduc* or compensat* or remediat*	effortful control or emotion* regulat* or emotion* coping or emotion* dysregulat* or emotion* inhibit* or stress reactiv* or affect* regulat* or self regulat*
Combined Search (in title and abstracts)	Section 1 AND Section 2 AND Section 3		

Selection process. Using the PICOS criteria, studies were initially screened for inclusion using both the “title” and “abstract” fields, to ensure that no key concepts of the research question were missed. The eligibility of each study that met the criteria at this stage was then assessed against the PICOS criteria, through a

full-text screening process. The full-text of one paper (Scarpa & Reyes, 2011), was not freely available and thus access was requested, and granted, from the authors directly via email.

After full-text screening, six of the eligible papers were randomly chosen to be evaluated using the PICOS criteria, by an independent clinical researcher. This process yielded 100% inter-rater reliability.

Data Extraction

The primary researcher extracted all of the data independently. In line with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011), a data extraction database was used throughout the process, to monitor each stage of extraction, ensuring only appropriate data were assessed. Data extracted from each eligible study comprised author details, participant characteristics, recruitment processes, types of intervention, outcome measures used, and main results (see Table 3).

Risk of Bias

Studies that met the inclusion criteria were evaluated according to the Quality Assessment Tool for Quantitative Studies (QATQS; see Appendix B) by the Effective Public Healthcare Practice Project (Thomas, Ciliska, Dobbins, & Micucci, 2004). The QATQS was used as it endeavours to cover evaluation of study design, recruitment, measurement and attrition biases (see Appendix C for scoring criteria).

One study in the review used a SCED approach. As such, the single-case reporting guideline in behavioural interventions (SCRIBE; Tate et al., 2016) statement was deemed more appropriate for assessing quality, and thus, was used to inform discussion of the quality of this study (see Appendix D).

Data Synthesis

A systematic narrative review was conducted to evaluate the effectiveness of the diverse interventions used by each study included in the review.

Results

Search Results

The initial search across the four databases generated 771 results. The removal of duplicates reduced this to 439. A further 416 studies were excluded following the screening of titles and abstracts using the PICOS method, with 23 papers proceeding to full-text screening. An additional paper (Hartmann et al., 2019) was included for full-text review having been identified through scanning reference lists during full-text screening. It is likely that this paper was missed throughout the database searches as it focuses on a “young adult” population, rather than children and adolescents. Therefore, it did not meet the PICOS criteria to proceed to full review and the original search terms did not need to be reviewed. The systematic searches and screening concluded with nine suitable papers for inclusion in the review. See Figure 1 for the full PRISMA-P flow diagram.

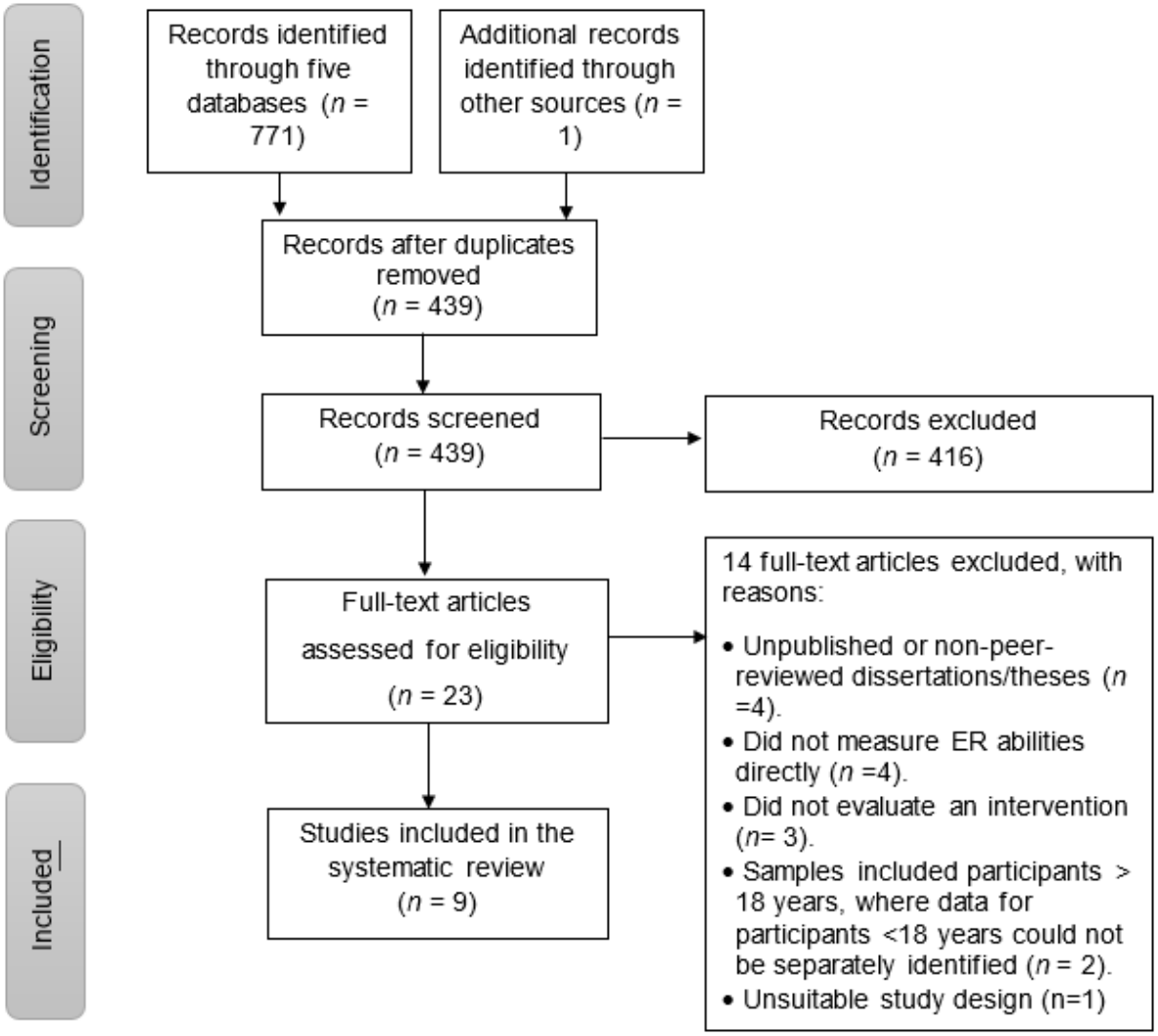

Figure 1. PRISMA-P Flow Diagram.

Excluded Studies

Following the full-text screening process, 10 studies were initially included in the review. However, although one paper (Parent, Birtwell, Lambright, & DuBard, 2016) appeared to meet the PICOS criteria, examination of the methodology during the data extraction phase indicated that it did not meet the basic multiple-baseline SCED criteria of having at least three participants (Tate et al., 2016), and thus, was excluded.

Table 3.

A summary of the studies included in the review, organised by author.

Study	Reference	Design/Sample	Intervention	Outcome Measure(s) of Emotion Regulation	Results/Main Findings	QATQS ratings/Evaluation
1.	Beaumont & Sofronoff (2008)	**Design:** Randomised waitlist-control trial. **Sample:** 49 children with Asperger syndrome and their parents. Intervention: *n*=26. (*M* = 9.64, SD= 1.21). Waitlist: *n*=23. (*M*= 9.81, SD= 1.26). IQ level > 85 **Recruitment:** Via an Asperger Syndrome Support Network newsletter and by recommendations of eligible participants made by specialist practitioners in the field. **Setting:** Research clinic in Brisbane, Australia.	"The Junior Detective Training Programme" (JDTP): using CBT principles, it teaches children skills in ER, emotion recognition and social skills. 7 x 2-hour weekly sessions, comprising 1 hour playing a computer game, followed by either small group therapy (child) or training sessions (parent).	**Parent-report:** The ERSSQ-P: designed specifically for this study to measure competency in the ER skills taught in the programme. **Child-report:** 'James and the Maths Test' and 'Dylan is Being Teased' (Atwood, 2004a, 2004b) scenarios were used to assess the children's knowledge of appropriate anxiety and anger management strategies.	**Results:** Mixed-model MANOVA on the 'James' and 'Dylan' measures, revealed a significant main effect between the treatment and control groups on Group, $F(2, 45) = 6.82$, $p < .01$, $\eta^2 = .23$, Time, $F(2, 45) = 11.57$, $p < .001$, $\eta^2 = .34$, and a significant Group x Time interaction, $F(2, 45) = 9.61$, $p < .001$. Significant improvements were found from pre-to-post treatment for the intervention group for the ERSSQ ($p < .001$, $\eta^2 = .57$) compared with the control group. **Main Findings:** Participants in the intervention group were better able to recognise and generate appropriate ER strategies than those in control group. **Conclusions:** The JDTP holds potential for being effective in enhancing ER for children with Asperger syndrome.	**QATQS rating:** Moderate **Strengths:** • Randomisation • Standardised measures. • 6-week and 5-month follow-up data. **Limitations:** • Diagnoses were assessed using parent-report, rather than rigorous screening tools. • Parents were not blind to condition nor to the study's objective – potential bias on EQSSQ data. • No measure of whether such skills were applied in everyday contexts, thus, limiting the conclusions that can be inferred.

2.	Beaumont, Rotolone, & Sofronoff (2015)	**Design** Cohort design **Sample:** 69 children (ages 7-12) with high functioning ASD across 17 schools, were allocated (*not* randomised) to one of two conditions. Condition 1: *n*=35, *M*= 9.82, SD = 1.63. Condition 2: *n*=34, *M*= 9.25, SD =1.48. IQ level > 80. **Recruitment:** School principals were contacted by the researchers via email, and study was advertised at a conference for School Psychologists and Guidance Counsellors. **Setting:** Schools in Brisbane, Australia.	"The Secret Agent Society (SAS) Social Skills Programme": a multicomponent manualised CBT-based treatment. Structured (condition 1) vs unstructured (condition 2). Condition 1: The manualised and structured variant of the full SAS programme was delivered across ten weekly 90-minute group sessions. Facilitators were trained in the programme, which was adapted for use at school only. Condition 2: Teachers administered the programme "as and when they saw fit". No formal training was provided for facilitators in condition 2.	**Parent/teacher report:** ERSSQ-P and ERSSQ-T (Beaumont & Sofronoff, 2008). **Child-report:** 'James and the Maths Test' and 'Dylan is Being Teased' (Atwood, 2004a, 2004b) scenarios.	**Results:** Mixed between-within subjects ANOVAs revealed a significant main effect on the ERSSQ-T, pre- and post-intervention (Wilks' lambda = .70, F (1, 66) = 28.70, $p < .001$, $\eta^2 = .30$). No significant interaction for the intervention type and time on parent-report data, but main effect observed for time (Wilks' lambda = .71, F (1, 63) = 26.16, $p < .001$, $\eta^2 = .29$,) with both groups showing an increase in ER from pre- to post-intervention. Analysis of the child-report measures revealed that participants Condition 1 performed significantly better than those in Condition 2, [F (1, 58) = 8.16, p = .006, η2= .12]. **Main findings:** Both programmes led to ER improvements. Condition 1 (structured) yielded more significant results. Treatment gains generalised to the home setting on all parent-report measures for condition 1 only. **Conclusions:** Provides preliminary support for ER skills training within schools, with treatment gains transferring to home for participants in the structured condition.	**QATQS rating:** Moderate **Strengths:** • Follow-up data to assess for maintained changes. • Standardised measures. • School-based intervention afforded more skills practice and staff support than a community-based programme would have allowed. **Limitations:** • No waitlist-control group. • Lack of randomisation and no blinding to either condition. • For logistical reasons, group configurations (i.e. age, gender, ability level) were determined by the teachers facilitating the group, rather than controlled for by the researcher. • Outcome measures for 22% of the sample were completed by different people at different time-points. • 92.8% of sample was male, limiting generalisability to females.

3.	Conner, White, Beck, Golt, Smith, & Mazefsky, (2019)	**Design** Cohort design **Sample:** 17 adolescents with ASD (age 12-17; *M*= 14.94, SD = 1.54). IQ level > 80 **Recruitment:** Through research registries and via advertisements in the community and mental health providers. **Setting:** Two university-affiliated clinics in the United States of America.	The EASE programme: 16-week individual therapy treatment targeting ER impairments in adolescents with ASD. Parents join the end of each session to practice skills with their child. The programme teaches the use of mindfulness and distress tolerance.	**Parent-report:** The EDI (Mazefsky, et al. 2018) and The RSQ (Connor-Smith et al., 2000). The Involuntary Engagement and the Disengagement subscales were used as these consist of ER strategies that previous research identified as being most pertinent to individuals with ASD. **Child-report:** The child report version RSQ.	**Results:** Effect sizes of parent-report ER measures fell in the medium-to-large ranges (EDI Reactivity, η^2 =0.67; RSQ Involuntary Engagement, η^2 =2.64; RSQ Involuntary Disengagement, η^2 =1.77). All participants displayed meaningful change in score decreases in at least one of the ER measures. **Main findings:** Outcome data support programme feasibility and acceptability, as well as significant improvement in ER impairments and related concerns. Medium to large effects were seen pre/post in reduction of ER impairments as well as associated depression, anxiety, and problem behaviours. **Conclusions:** The EASE programme targets ER impairment in adolescents with ASD. Although the results need to be tentatively considered due to the small sample size, the study shows the potential of mindfulness-based interventions in increasing emotional awareness and decreasing ER impairment.	**QATQS rating:** Moderate **Strengths:** • EASE was developed based on ER research specific to ASD, drawing on feedback from individuals with ASD and their caregivers. • Use of standardised measures. • First study to evaluate a mindfulness-based ER intervention with ASD youths. • Included 3-month follow-up data. **Limitations:** • Small sample size = underpowered. • Lack of randomisation or control group. • Internal validity may have been compromised due to expectancy effects. • Structured programme does not allow for any kind of intellectual disability adjustments. • 88.2% of participants were male - limits generalisability.

4.	Factor et al., (2019)	**Design** Randomised waitlist-control trial. **Sample:** 23 children aged 4-7 with ASD (M = 5.46, SD = 1.01) randomly assigned to intervention (n = 12) or waitlist-control (n = 11), and their parent or guardian. **Recruitment:** Not specified. **Setting:** Research clinic in United States of America.	"STAMP": A CBT programme addressing ER deficits through child skill building and parent training. Children: Nine group treatment sessions on understanding positive and negative emotions, physical and relaxation strategies, identifying positive and negative responses. Parents/caregivers: Nine group sessions included psychoeducation of ER, reviews of homework and discussion child-session material.	**Parent-report:** The ERC (Shields & Cicchetti, 1997). The ERC measures ER and lability/ negativity. **Child-report:** N/A	**Results:** No significant differences in ER observed between treatment and waitlist control groups, t (21) = .55, p = .59. Paired samples t-tests showed significant decreases in lability/negativity on the ERC for the treatment group, with a medium effect size (η^2 = .77). **Main findings:** Overall ER abilities did not significantly change but lability and negativity levels decreased for treatment participants. Parental confidence in their child's ability to manage anxiety and anger in treatment group increased pre- and post-intervention. **Conclusions:** The "STAMP" programme can improve ER skills by improving lability/negative affect in young children with ASD. Reduced lability/negative affect decreased internalising and externalising symptoms. Parents' perceived confidence in their children's ability to manage their behaviour increased.	**QATQS rating:** Weak **Strengths:** • Random assignment. • Use of standardised measures. **Limitations:** • Does not specify how participants were recruited. • Underpowered - small sample size limited scope for more appropriate analyses and larger effect sizes. • Homogeneity of sample (all white, middle class families) limits external validity. • Parent-report and not blind to allocation - possible bias. • No child-report measure. • No follow-up data to determine if results were maintained overtime.

5.	Rispoli, Malcolm, Nathanson, & Mathes (2019)	**Design** A multiple-probe single-case experimental design across participants. **Sample:** Five children with ASD aged 3-6 (*M* = 3.4, SD = 1.53), and their mothers (*M* = 32.4, SD = 5.04). IQ level > 70 **Recruitment:** Participants were recruited from community mental health and therapy clinics in a Midwestern American state. **Setting:** Participants' homes in the United States of America.	"RELACS": a programme grounded in behavioural, social and communication needs of children with ASD. The parent practiced these target skills with the child whilst receiving concurrent feedback from the programme facilitator. Delivered in participants' homes over eight weeks.	**Parent-report:** The TABS measure (Bagnato, Neisworth, Salvia, & Hunt, 1999). **Child-report:** N/A	**Results:** With an absolute value of ≥ 1.96 being considered clinically significant, reliable change calculations revealed that three of the five participants evidenced significantly reduced dysregulation on the mother-reported TABS, at post-intervention, follow-up or both time points (d_{zpost} = .59; $d_{zfo\text{-}up}$ = .14). A medium within-group effect size was observed for the TABS (η^2 = .59). **Main findings:** All mothers reported that RELACS was an appropriate method for learning to support ER skills in their children. **Conclusion:** The study shows promise in improving parent support for children's ER skills as well as children's regulatory capacity.	**SCRIBE rating:** Moderate **Strengths:** • Intervention deemed acceptable and efficacious by participants' mothers. • Standardised measures that were well aligned with the parent and child behaviours targeted in the intervention. **Limitations:** • Did not describe whether randomisation was used. • No child-report measure. • Does not describe blinding. • Individual effect sizes were not reported.

6.	Scarpa & Reyes (2011)	**Design**: Randomised waitlist-control trial. **Sample:** 11 children with ASD aged 5-7 years. (*M* = 5.58, SD = .73) Intervention group: *n*=5, Waitlist-control: *n*=6. IQ > 80 *Baseline group differences:* Control group had significantly fewer ER strategies, and parents reported less confidence in their child's ability to manage difficult emotions, compared with treatment group. **Recruitment:** Advertisements at local hospitals and ASD support groups. **Setting:** Research clinic, United States of America.	Developmentally modified group CBT for young children with ASD, to teach ER strategies for reducing anger and anxiety. Parents participated in group-sessions alongside the children's group where they were taught emotion knowledge and ER skills, and were encouraged to practice ER skills at home with their child.	**Parent-report:** The ERC; (Shields & Cicchetti, 1997). **Child-report:** ER ability was assessed through the child's report of ER strategies that could be used when dealing with anger and anxiety-related emotions presented in vignettes devised for this study (number of different strategies was summed).	**Results:** One-tailed paired t-tests and Wilcoxon-signed rank tests revealed medium effect sizes on the vignettes(η^2 = .65), with children in the treatment group generating more appropriate ER strategies than those in the control. Parent-report indicated that children demonstrated significant reductions in the Negativity/Lability subscale and a trend towards increased scores on the ER subscale after treatment, suggesting lower intensity and better regulation of mood overall. **Main findings:** From pre- to post-intervention, all children had less parent-reported negativity/lability; better parent-reported ER, and shorter outbursts compared to waitlist-control. They also generated more coping strategies in response to vignettes. Parents also reported higher levels of confidence in managing their children's anxiety. **Conclusions:** Supports hypothesis that parents can be taught ER skills and this can in turn improve ER strategies and reduce externalising behaviours.	**QATQS rating:** Weak **Strengths:** • Random assignment to experimental or delayed treatment control group. • Standardised measures. **Limitations:** • Very small homogenous sample size. • Underpowered - small sample size precluded analyses that are more sophisticated. • Effect sizes were not reported for parent-report measures. • Parents were not blind to experimental condition or study objective - potential bias. • Existing group differences at baseline.

7.	Sofronoff, Attwood, Hinton, & Levin, (2007)	**Design** Randomised waitlist-control trial. **Sample:** 45 children with Asperger syndrome. Intervention: *n* = 23, *M* = 10.79, SD = 1.12; Control: *n* =21 *M* = 10.77, SD = .87. Parents of those in the intervention group also took part. **Recruitment:** Recruited via advertisements through media release. **Setting:** University research clinic in Brisbane, Australia.	Children in the intervention participated in six 2-hour weekly group CBT sessions focusing on anger management, using CBT principles. Their parents took part in a parent-group in which they received instruction on the strategies their children were being taught. Parents were then asked to practice these skills and complete homework with their child at home.	**Parent-report:** The ChIA-P (Sofronoff, 2003). **Child-report:** 'Dylan is being Teased' (Attwood, 2004b).	**Results:** Repeated measures ANOVAs revealed significant main effect for group in 'Dylan is being teased', F (1, 43) = 4.87, $p < .05$ and a significant main effect for Time on the ChIA-P, in the intervention group only, F (2, 42) = 9.83, $p < .0001$. Significant difference in number of strategies generated by treatment group between pre-intervention and post-intervention, $p < .0$, maintained at 6-week follow-up, $p < .05$. **Main findings:** Participants demonstrated decreased anger and increased knowledge of ER skills. Parents reported significant decreases in episodes of anger following intervention and a significant increase in their own confidence in managing anger in their child. **Conclusions:** The findings suggest that CBT adapted for ASD can be effective for the management of anger and aggression. Furthermore, it supports suggestion that including parents as part of an intervention programme for this population can yield positive results (e.g. Sofronoff, Attwood, and Hinton, 2005).	**QATQS rating:** Moderate **Strengths:** • Random assignment. • Standardised measures. **Limitations:** • Underpowered - small sample size limited scope for more appropriate analyses. • Did not report effect sizes. • No blinding to condition. • Reliance on parent-report – potential bias.

8.	Thomson, Rioso, & Weiss (2015)	**Design** Cohort Design **Sample:** 13 participants with ASD aged 8–12 years (*M* = 10.4, SD = 1.30), and their parents. IQ level > 80 **Recruitment:** Participants were recruited from the community via postings on local advocacy websites and community organisations, and from clinical referrals. **Setting:** University research clinic in Canada.	A modified version of the Secret Agent Society (SAS; Beaumont & Sofronoff, 2008), a multicomponent manualised CBT-based treatment with a focus on improving ER. Each session progressed from targeting basic emotional awareness, to implementing relaxation strategies and ER tools to cope with difficult emotions such as anger and anxiety. Parents were present in the group to learn about ER skills and to encourage practice at home.	**Parent-report:** The ERC (Shields & Cicchetti 1997) and, The CEM (Zeman, Cassano, Suveg, & Shipman, 2010). **Child-report:** 'James and the Maths Test' and 'Dylan is Being Teased' (Atwood, 2004a, 2004b) scenarios.	**Results:** Two-tailed paired samples t-tests revealed improvements on parent-reported child emotional lability [t (10) = 3.13, *p* = .001]. Results indicated significantly more overall inhibition [t (11) = -2.32, *p* = .04], and less overall dysregulation [t (11) = 2.14, *p* = .061] across three emotions (anger, anxiety, sadness) on the CEM. Children also provided more appropriate ways of coping to the James/Dylan scenarios at post-intervention [t (12) = -2.07, *p* = .06]. **Main findings:** Results demonstrated feasibility of a transdiagnostic CBT intervention for addressing ER in children with ASD. Parent-report of child ER indicated general improvements (e.g. less lability and negativity reported on the ERC and fewer internalising and externalising behaviour symptoms). Children reported an overall decrease in dysregulation and an increase in the number of appropriate helpful ER strategies in response to scenarios. **Conclusions:** Shows promise for a transdiagnostic approach to treating ER.	**QATQS rating:** Moderate **Strengths:** • Standardised measures. **Limitations:** • Underpowered - small sample size limited scope for more appropriate analyses and larger effect sizes. • No control group. • Sample was male only which limits generalisability. • No follow-up data to assess for maintained changes. • Effect sizes were not reported.

9.	Weiss, Thomson, Riosa, Albaum, Chan, Maughan, Tablon, & Black, (2018)	**Design:** Randomised waitlist-control trial **Sample:** 68 children with diagnoses of ASD (*M* = 9.75, SD = 1.27) and 57 parents (*M* = 43.9, SD = 4.16). IQ level > 79 Intervention: *n*= 35 (*M* = 9.63, SD = 1.26) Waitlist-Control*: *n*= 33 (*M* = 9.88, SD = 1.29). *Baseline differences*: Control group demonstrated significant differences to intervention group in externalising symptoms at baseline.	"The Secret Agent Society: Operation Regulation" (SAS: OR; Beaumont, 2013). A manualised 10-session, transdiagnostic CBT intervention, delivered to children with ASD and their caregivers. The programme is aimed at improving ER and mental health difficulties in children. Parents attended a concurrent psychoeducation group.	**Parent-report:** The ERC (Cicchetti & Shields, 1997); and the ERSSQ-P (Beaumont & Sofronoff, 2008). **Child-report.** The CEM (Zeman et al., 2010); 'James and the Maths Test', and 'Dylan is Being Teased' scenarios (Atwood, 2004a, 2004b).	**Results:** No significant results were found on any of the child-reported ER measures. Significant group differences were observed on the parent-report lability/negative affect subscale of the ERC [t (56.38) = -2.16, *p* = .04], effect size (d = .58). The ERSSQ-P also demonstrated significant results, [t (52.80) = 3.20, *p* < .01], with a large effect (d = .79). **Main findings:** Participants in the treatment condition demonstrated significant improvements on parent-report measures of ER (i.e., emotionality, ER abilities with social skills) compared with control participants. **Conclusions:** Supports the idea that CBT for ASD can be adapted to move beyond current anxiety-specific frameworks with a greater focus on underlying mechanisms, targeting multiple emotional problems. Transdiagnostic approaches might assist clinicians in working more broadly and efficiently.	**QATQS rating:** Strong **Strengths:** • Randomisation. • Standardised measures. • Transdiagnostic intervention rather than diagnosis-specific. • Results were maintained at follow-up. **Limitations:** • Parent-report and no blinding to condition – potential bias. • Not representative of typical ASD population (e.g., all participants needed to reach a certain motivation threshold to participate). • Despite randomisation, control group demonstrated higher levels of externalising symptoms as baseline, than intervention group. • 88% of sample was male, limiting generalisability.

	Recruitment: Recruited through local ASD services e-newsletters, website postings and referrals from community healthcare providers. **Setting:** University research clinic in Canada.	

ERSSQ-P= Emotion Regulation and Social Skills Questionnaire parent-report; EQSSQ-T = Emotion Regulation and Social Skills Questionnaire teacher-report; EDI= Emotion Dysregulation Inventory; RSQ= Response to Stress Questionnaire; ERC= Emotion Regulation Checklist; EASE= Emotional Awareness and Skills Enhancement Programme; STAMP= Stress and Anger Management Programme; RELACS = Regulation of Emotional Lability in Autism Spectrum Disorder through Caregiver Supports; TABS= Temperament and Atypical Behavior Scale; ChIA-P= Children's Inventory of Anger; CEM= Children's Emotion Management Scales. Effect sizes: *Small*= 0.2*, Medium*= 0.5, *Large* = 0.8.

Study Characteristics

The characteristics of the nine studies included in the review are described in detail in Table 3. All nine studies evaluated an intervention that at least partly targeted improving ER abilities in children and/or young people with ASD diagnoses.

Design. The included studies were diverse in their methodological approaches, including RCTs (*n* = 5), cohort analytic designs (*n* = 3), and a SCED (*n* = 1).

Sample sizes. The studies comprised 301 participants in total, the majority of whom were male. All sample sizes were relatively small, with the largest samples being 68 and 69 participants (studies 9 and 2, respectively); thus, most did not demonstrate sufficient study power upon which confidently to infer results.

Participants and interventions. All nine studies recruited participants with a diagnosis of ASD. Study 2 comprised only participants with high-functioning ASD (HFASD), whilst studies 1 and 7 only included children with diagnoses of Asperger's syndrome. Participants were recruited from both clinical and non-clinical settings. Three studies (4, 5, 6) focused on young children (*mean age* = 4.81 years) using behavioural and CBT principles, whilst five studies (1, 2, 7, 8, 9) looked at CBT approaches in pre-adolescents (*mean age* = 10.04 years). One study (3) centred on adolescents alone, using a mindfulness approach (*mean age* = 14.94 years).

Outcomes. A variety of measures was used to assess ER, across both child- and parent-report.

The Emotion Regulation Checklist (ERC; Shields & Cicchetti, 1997) was used as a parent-report measure in four studies (4, 6, 8, 9), whilst the Emotion Regulation and Social Skills Questionnaire (ERSSQ; Beaumont & Sofronoff, 2008) was applied

in three studies (1, 2, 9). The teacher-report version of the ERSSQ (Beaumont & Sofronoff, 2008) was also administered in study 2. The Children's Emotion Management Scale (Zeman, Cassano, Suveg, & Shipman, 2010) was administered in two studies (8, 9). The Emotion Dysregulation Inventory (Mazefsky et al., 2018) and the Response to Stress Questionnaire (RSQ; Connor-Smith, Compas, Wadsworth, Thomsen, & Saltzman, 2000) were used as parent-report measures in study 3. The Temperament and Atypical Behaviour Scale (TABS; Bagnato, Neisworth, Salvia, & Hunt, 1999), which is designed to measure self-regulation and dysfunctional emotion in children ages 11–71 months (Rispoli et al., 2019) was applied in study 5. Study 7 used the parent form of the Children's Inventory of Anger (ChIA-P; Sofronoff, 2003). All parent-report outcome measures demonstrated good psychometric properties.

The child-report version of the RSQ (Connor-Smith et al., 2000) was used in study 3, which has good validity and reliability in ASD populations (e.g., Mazefsky et al., 2014). Child-report ER outcome measures comprised the 'James and the maths test' and 'Dylan is being teased' (Atwood, 2004a, 2004b) scenarios, which were both administered in four of the nine studies (1, 2, 8, 9). 'Dylan is being teased' was also applied in study 7. These scenarios have shown good inter-rater reliability in ASD samples (e.g., Sofronoff et al., 2007). Vignettes of a similar nature were purposely designed to assess children's ER abilities in study 6.

Quality Appraisal

The QATQS assessment tool (Thomas et al., 2004) revealed a range of bias across the studies, with only one study demonstrating a 'strong' rating (9). Six studies received an overall "moderate" rating (1, 2, 3, 5, 7, 8), whilst two received

"weak" ratings (4, 6). A second-rater validated this process by assessing the quality of three studies, at random, using the QATQS. Inter-rater reliability was calculated, yielding good agreement between both reviewers at 88.6%. Discrepancies were subsequently resolved through discussion.

Synthesis of Results

CBT-based interventions. Seven of the nine reviewed papers evaluated interventions grounded in CBT principles, aimed at improving ER abilities in ASD populations. Six of the studies comprised children aged 7-12, whilst one (6) focused on children aged 4-7. All participants had a minimum IQ of borderline-low average, and each intervention was adjusted for ASD (i.e., shorter sessions, highly structured, appropriate language, and use of reward systems, if necessary).

Four studies (1, 2, 8, 9) addressed ER using adaptations of the "Junior Detective Training Programme" (JDTP; Beaumont & Sofronoff, 2008), or as it later became known as, "the Secret Agent Society" programme (SAS; Beaumont, Rotolone, & Sofronoff, 2015). The JDTP facilitated social skills learning, including appropriate anxiety- and anger-management strategies, via a computer game, small group sessions, parent-training groups, and teacher handouts (Tan, Mazzucchelli, & Beaumont, 2015). The SAS programme differs slightly to the JDTP by placing a greater emphasis on developing ER skills (e.g., subjective units of distress scaling, mindfulness and acceptance activities, planned exposure; Beaumont, 2013).

Beaumont and Sofronoff's RCT (study 1; 2008) found that participants who underwent the JDTP demonstrated significant improvements in generating appropriate ER strategies. Although effect sizes remained small for the child-report measures, a large effect size was seen on the ERSSQ-P, indicating that the skills

taught in the JDTP were effective at improving ER abilities in children, as observed by parents. Study 2 (Beaumont et al., 2015), evaluated a “structured” versus “unstructured” version of the SAS. Whilst both groups showed increases in ER abilities from pre- to post-intervention, a large effect size was found on child-generated ER strategies for those in the structured group compared to the small effect size seen in the unstructured group. The structured group was in line with the JDTP study (Beaumont & Sofronoff, 2008), supporting the argument for a manualised approach when using this programme. Both studies comprised only Asperger’s (1) or HFASD (2) diagnoses with all participants demonstrating a minimum low-average IQ. Both studies had sufficient samples sizes, receiving ‘moderate’ ratings on the QAQTS.

Thomson et al. (study 8; 2015) explored the feasibility of expanding upon the SAS programme further, renamed as “SAS-Operation Regulation” (SAS-OR), which focused solely on ER abilities. The format adopted a more individualised approach than the original SAS, with each session comprising just the child, parent and one therapist. A greater focus was placed on psychoeducation in CBT and relaxation techniques. Although the primary aim was to determine the feasibility of this ER intervention, results showed that as well as demonstrating feasibility, parents reported significant improvements in their children’s ER abilities, including reductions in externalising behaviours, with child-report measures indicating reductions in dysregulation. That said, as there were only 13 participants, the power of the study remains low and thus, results need to be cautiously interpreted.

Study 9 (Weiss et al., 2018) evaluated SAS-OR using a bigger sample (*n* = 68) as part of an RCT, with the view of providing a more transdiagnostic approach to ASD treatment. In line with Beaumont and Sofronoff (2008), large effect sizes were

seen on both parent-report measures, indicating significant improvements in ER abilities in treatment participants compared with those in the control group. Results were maintained at 10-week follow-up. This is the only study to receive a “strong” QAQTS rating, and given the large sample size and effect sizes, the results are most encouraging.

The “Stress and Anger Management Programme” (STAMP; study 4), adopted a similar approach to that of the SAS programme, in that it comprised CBT-focused group sessions for children, with complementary skill-training groups for parents. Although no significant differences were observed between the treatment and control groups, a medium effect size was seen in reductions in the lability/negativity subscale on the ERC, with fewer reported externalising behaviours in treatment participants. However, this study received a “weak” QATQS rating, raising questions around recruitment, the homogeneity of the sample, and whether or not blinding was applied.

Sofronoff, Attwood, Hinton, and Levin’s RCT (study 7; 2007) found that CBT adapted for ASD, alongside parent skills training groups, was effective in helping children to develop their knowledge of ER strategies. Participants generated more ER strategies in response to scenarios, with parents reporting significant decreases in anger/aggressive episodes amongst those in the treatment group, compared with the control. This study comprised only participants with Asperger’s conditions and average IQs. Scarpa and Reyes (2011; study 6) expanded upon Sofronoff and colleagues’ (2007) CBT programme by adapting it to better suit younger children with ASD (ages 5-7 years), with a focus on skill-building via affective education, stress management, and understanding expressions of emotion. This study yielded similar results to those of Sofronoff et al. (2007), with medium effect sizes seen in the

intervention group where participants demonstrated improved ER strategies in response to vignettes. Significant reductions in the negativity/lability subscale indicated lower intensity and better regulation of mood overall. However, given its 'weak' QATQS rating resulting from its small sample size (*n* = 11), initial group differences, and lack of blinding to the study's objective, significant results are tentative.

Mindfulness-based interventions. Although the CBT interventions comprised some mindfulness techniques, study 3 was the only reviewed paper to explore a direct mindfulness approach in targeting ER impairments in adolescents. The Emotional Awareness and Skills Enhancement (EASE) programme was developed by Conner et al. (2019) to improve ER abilities in verbal adolescents with ASD. The EASE programme is grounded in a combination of CBT, mindfulness-based cognitive therapy and mindfulness-based stress reduction principles, with a focus on promoting mindfulness practice to achieve a non-judgmental awareness that can be applied in times of distress. Results showed that the 16-week mindfulness-based programme generated significant improvements in ER impairments, including reductions in internalising symptoms such as depression and anxiety. Medium-to-large effect sizes were observed across all outcome measures.

Behavioural Interventions. Study 5 was the sole study to employ a SCED approach. The Regulation of Emotional Lability in Autism Spectrum Disorder through Caregiver Supports (RELACS) was developed and trialled by Rispoli et al. (2019) to promote ER skills in preschool-age children with ASD. The intervention is grounded in behavioural principles and, given the young ages of participants, it is parent-mediated through direct instruction and skills training from the facilitator. Results found that of the five participants who took part, three demonstrated significantly

reduced levels of dysregulation on the TABS measure (Bagnato et al., 1999). Although individual effect sizes were not reported, a medium effect size was found for the overall group on the ER measure, indicating that the RELACS intervention shows promise in improving children's regulatory capacity.

Overall findings. Given the small sample sizes and weak-moderate QATQS ratings of most of the included studies, all results are interpreted with caution. The review found encouraging evidence to suggest that CBT-informed approaches, if appropriately adapted, can be effective at improving ER abilities in children with ASD. Only one study focused solely on mindfulness techniques with adolescents, however, it similarly demonstrated promising findings for its application in ER treatment. The eight studies with young children/pre-adolescents all comprised a degree of parent involvement. Given the children's ages and diagnoses, it is likely that intensive parental-support is required in their everyday lives, potentially enabling further skills-practice outside of the treatment sessions. This indicates that parental participation is likely to be a key component in delivering effective ER treatments in ASD populations.

Discussion

A child's ability to regulate emotions is directly associated with positive peer relationships and flexibility within a range of important daily activities, and therefore, treating any kind of dysregulation is imperative to overall well-being (Reyes et al., 2019). Despite the high prevalence of ER impairments in ASD, however, attention has only recently turned to treating ER difficulties in this population. The aim of this systematic review was therefore to evaluate interventions used to address ER difficulties in children and young people with ASD. To the researcher's knowledge,

this is the first review of its kind. Nine studies were included in the review, with all reporting on the efficacy of various interventions targeting ER in ASD.

Large RCTs, which are considered the gold standard of research designs (Barton, 2019), are typically lacking in ASD treatment. Indeed, only one reviewed-RCT received a 'strong' QATAS rating due to having a sufficient sample size. However, the results of the current review lend some support to the utility of specific psychological interventions when treating ER impairments, namely, CBT and mindfulness approaches. Despite its common application in other areas of ASD treatment (e.g., Axelrod et al., 2012), no study adopted a purely ABA approach. Rispoli and colleagues' (2019) SCED, however, utilised similar behavioural principles, which generated encouraging preliminary findings.

Taken together, the findings from the CBT-based interventions are promising, particularly as the results were largely consistent in the same direction; however, given the small sample sizes, they must be viewed as preliminary. Feasibility and acceptability were achieved for each new intervention reviewed, providing some efficacy data on ER-focused CBT interventions for children and young people with ASD. Furthermore, results across the studies indicate that improving ER abilities through such interventions has the potential to enable individuals to cope better with negative events (Mazefsky, 2015). Most interventions comprised a parent component, either in the shape of a complementary group to the child's treatment (studies 1, 4, 6, 7, 9), or as part of the treatment group itself (studies 3, 5, 8). Given the level of parental involvement in children's lives, the review indicates that such interventions help to promote the generalisability of ER skills at home, as well as instilling confidence in parents around managing their child's emotional difficulties. For logistical purposes, study 2 (Beaumont et al., 2015) adapted its programme to

include direct teacher contact, rather than parent contact; however, results remained generalisable to the home. Such findings not only indicate that ER skill building can be incorporated into schooling, but also that such adult-support need not be limited to parents.

Conner et al. (2019) highlighted that despite the well-evidenced benefits of mindfulness-based interventions on ER and on a range of mental health difficulties in the general population, relatively few studies have explored mindfulness approaches with people who have ASD. However, each of the CBT-based interventions incorporated some mindfulness techniques and given its efficacy in study 3 (Conner et al., 2019), it is possible that mindfulness skills will have contributed to some of the positive outcomes across the interventions.

Weiss (2014) described a growing enthusiasm about the potential that transdiagnostic treatments might hold in generating greater applicability to the varied manifestations of ER in ASD. Whilst ASD treatment protocols have traditionally adopted a disorder-focused approach (e.g., CBT for anxiety in ASD), this review highlighted that research is beginning to take a more transdiagnostic approach to treatment (e.g., Thomson et al., 2015; Weiss et al., 2018). These studies demonstrated promising results in suggesting that an ER-focused intervention has the potential of improving outcomes regardless of specific diagnoses.

The findings of this systematic review should be considered in light of its limitations, relating both to the quality of the reviewed studies and the review methodology itself. Firstly, four of the studies did not utilise any kind of active control group in their study designs, making it difficult to infer confidently whether any significant findings are a direct consequence of an intervention or other extraneous

variables, including maturation effects. Further to this, some doubt can be cast on the generalisability of these findings.

For example, participants in every study were required to have a certain level of language ability in order to receive any of the interventions. Additionally, although adaptations were made for ASD, the presence of any kind of intellectual disability (ID) was deemed an exclusion criterion in several studies (e.g., Thomson et al., 2015; Weiss et al., 2018). Studies where one's level of intelligence was not listed as an inclusion criterion still only comprised participants with a minimum of low-average IQ levels. Furthermore, some studies limited their criteria to include only those with diagnoses of HFASD (e.g., Beaumont et al., 2015). Given that Postorino et al. (2015) found the rate of ID amongst individuals with ASD to be as high as 47.6%, the findings of the current review are not representative of an ASD population. Similarly, the combined sample of all studies was overwhelmingly male. Whilst this can reflect the higher incidence of ASD amongst males compared with females, such findings therefore cannot be generalised to females with ASD. A conceptual limitation that extends beyond the scope of the review but is nevertheless important, is that evidence suggests that females with ASD are more prone to "camouflaging" their symptoms (Lai et al., 2017) and thus, are less likely to be diagnosed than males (Hull, Petrides, & Mandy, 2020). This makes it more challenging to identify appropriate treatment approaches for this population.

Despite applying a systematic framework when conducting this review, logistical factors prevented the recommended use of a second-rater during the searching and data extraction phases in order to increase reliability (Higgins & Green, 2011). Thus, there remains a risk of subjective bias in the data reported. Furthermore, given the inherent risk of bias in published papers towards reporting

only significant findings (Barton, 2019); it might have been of value to also explore some of the grey literature in this area.

Implications

The review supports the theoretical concept (e.g., Albaum et al., 2020) that ER-targeted approaches could in turn improve overall functioning, including both internalising (e.g., anxiety) and externalising behaviours (e.g., aggression) in individuals with ASD. In line with Nuske et al. (2017), it highlights the importance of parental involvement in ER skill building, supporting the idea that children with ASD tend to depend on others to regulate their emotions.

Findings from this review can be used to provide clinicians with preliminary data regarding the efficacy of various interventions in treating ER. Given the range of negative outcomes associated with ER impairments, ER assessment might be a beneficial component of any psychosocial intervention in ASD populations, and consequently inform any adaptations to treatment. In line with NICE (2014) guidelines, appropriate ASD adjustments should be implemented to all interventions being delivered, and where possible, treatment plans should endeavour to include some level of parent participation. Furthermore, Beaumont and colleagues' (2015) study provides encouraging support for the incorporation of ER skills training into the education system.

Given the encouraging findings in transdiagnostic approaches, ER skills training could serve as the foundation of positive mental health outcomes more broadly in ASD (Reyes et al., 2019). Screening to identify ER difficulties would enable more targeted prevention and treatment efforts, with Beck et al. (2020) arguing that if treatment were to focus on core ER impairments rather than a

problem-specific approach, a broader and more sustained clinical impact might be achieved. This could in turn reduce the impact of the utilisation and cost of health care in ASD populations (Croen et al., 2006).

It is important to be reminded that this area of research has only become a topic of increasing interest in recent years (Shaffer et al., 2019). Indeed, four of the nine papers reviewed were published in the last two years, highlighting an emerging interest in this area. Therefore, all findings are still in their preliminary stages, with scope for future improvements. However, there is promising evidence to suggest that ER can improve with treatment.

Future Research

Continued research is needed to ascertain appropriate ER treatment approaches in ASD. Given that each study included in the review was based in either North America or Australia, similar research needs to be carried out in the United Kingdom, and elsewhere. Larger samples should be explored in order to increase study power and validity, as well as conducting further longitudinal research to gain a better understanding of the trajectory of ER treatment and maintenance. It would also be imperative to expand upon the current evidence base by evaluating similar interventions with individuals within this population who were not represented in this review, e.g., those who are non-verbal or those who demonstrate a significant ID.

Despite the high prevalence of ER impairments in ASD, emotional functioning is rarely assessed in ASD research. Yet this might affect results due to variability in behaviour, cognition, social processing, and overall brain functioning (Mazefsky, 2015). Therefore, a strong argument can be made that ER abilities should be

assessed in all ASD research studies, including ABA approaches, even if ER is not the central research focus. Further exploration of the impact of specific components of each intervention, including cognitive, behavioural and mindfulness techniques, would ascertain which aspects of the intervention are most effective at improving ER abilities. This would help inform a more rigorous, integrative approach.

Finally, in line with Mazefsky (2015), continued research in exploring what the underlying processes are between ER difficulties and overall mental health, and how these difficulties should be treated, will support the need for policies and services that promote improved quality of life in individuals with ASD.

Conclusion

This is the first systematic literature review to evaluate the efficacy of interventions aimed at improving ER impairments in children and young people with ASD. The review indicated that, despite still being in its infancy, research in the field is gathering momentum with evidence suggesting that ER impairments respond to treatment. If appropriately adjusted, behavioural, CBT and mindfulness approaches, with a parent-participation component, hold potential in improving ER abilities. Further research evaluating interventions appropriate for individuals who are non-verbal or who have an ID is needed, as well as RCTs that are more sophisticated, in order to decipher which treatment approaches are most effective at improving ER in children and young people with ASD.

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Appendices

Appendix A: PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)

	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Appendix B

Quality Assessment Tool for Quantitative Studies (QATQS)

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG
2 MODERATE
3 WEAK

Appendix C

Quality Assessment Tool Scoring Instructions

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or b**linding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix D

The Single-Case Reporting guideline In BEhavioural interventions (SCRIBE) Checklist

Item number	Topic	Item description	Notes
TITLE and ABSTRACT			
1	Title	Identify the research as a single-case experimental design in the title	
2	Abstract	Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions	
INTRODUCTION			
3	Scientific background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base	
4	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses	
METHODS			
	DESIGN		
5	Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined *a priori* or data-driven) and, if applicable, criteria for phase change	
6	Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study	
7	Replication	Describe any planned replication	
8	Randomisation	State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized	
9	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked	
	PARTICIPANT/S or UNIT/S		
10	Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment	
11	Participant characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured	
	CONTEXT		
12	Setting	Describe characteristics of the setting and location where the study was conducted	
	APPROVALS		
13	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained	
	MEASURES and MATERIALS		
14	Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured	
15	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions	
	INTERVENTIONS		
16	Intervention	Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication	
17	Procedural fidelity	Describe how procedural fidelity was evaluated in each phase	
	ANALYSIS		
18	Analyses	Describe and justify all methods used to analyse data	
RESULTS			
19	Sequence completed	For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons	
20	Outcomes and estimation	For each participant, report results, including raw data, for each target behaviour and other outcome/s	
21	Adverse events	State whether or not any adverse events occurred for any participant and the phase in which they occurred	
DISCUSSION			
22	Interpretation	Summarise findings and interpret the results in the context of current evidence	
23	Limitations	Discuss limitations, addressing sources of potential bias and imprecision	
24	Applicability	Discuss applicability and implications of the study findings	
DOCUMENTATION			
25	Protocol	If available, state where a study protocol can be accessed	
26	Funding	Identify source/s of funding and other support; describe the role of funders	

**Scoring: 0-8= Weak; 9-17= Moderate; 18-26= Strong.*

Appendix E

Statement of dissemination and Instructions for Authors

Statement of dissemination

The aim is for this systematic literature review to be disseminated via publication in the Journal of Autism and Developmental Disorders (JAAD). See below for instructions for authors, retrieved from the JAAD website.

Instructions for Authors

Manuscript Submission

Submission of a manuscript implies that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink “Submit online” on the right and upload all of your manuscript files following the instructions given on the screen.

Please ensure you provide all relevant editable source files. Failing to submit these source files might cause unnecessary delays in the review and production process.

Title page

The title page should include:

- The name(s) of the author(s)
- A concise and informative title
- The affiliation(s) and address(es) of the author(s)
- The e-mail address, telephone and fax numbers of the corresponding author

Abstract

Please provide an abstract of 150 words or less. The abstract should not contain any undefined abbreviations or unspecified references.

Text

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.

- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

Body

- The body of the manuscript should begin on a separate page. The manuscript page header (if used) and page number should appear in the upper right corner. Type the title of the paper cantered at the top of the page, add a hard return, and then begin the text using the format noted above. The body should contain:
- Introduction (The introduction has no label.)
- Methods (Centre the heading. Use un-cantered subheadings such as: Participants, Materials, Procedure.)
- Results (Centre the heading.)
- Discussion (Centre the heading.)

Headings

Please use no more than three levels of displayed headings.

Level 1: Centred

Level 2: Centred Italicized

Level 3: Flush left, Italicized

Footnotes

Centre the label “Footnotes” at the top of a separate page. Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they

should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes. Type all content footnotes and copyright permission footnotes together, double-spaced, and numbered consecutively in the order they appear in the article. Indent the first line of each footnote 5-7 spaces. The number of the footnote should correspond to the number in the text. Superscript Arabic numerals are used to indicate the text material being footnoted.

Author Note

The first paragraph contains a separate phrase for each author's name and the affiliations of the authors at the time of the study (include region and country).

The second paragraph identifies any changes in the author affiliation subsequent to the time of the study and includes region and country (wording: "authors name is now at affiliation".)

The third paragraph is Acknowledgments. It identifies grants or other financial support and the source, if appropriate. It is also the place to acknowledge colleagues who assisted in the study and to mention any special circumstances such as the presentation of a version of the paper at a meeting, or its preparation from a doctoral dissertation, or the fact that it is based on an earlier study.

The fourth paragraph states, “Correspondence concerning this article should be addressed to…” and includes the full address, telephone number and email address of the corresponding author.

Terminology

- Please always use internationally accepted signs and symbols for units (SI units).

Scientific style

- Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.
- Please use the standard mathematical notation for formulae, symbols etc.:Italic for single letters that denote mathematical constants, variables, and unknown quantities Roman/upright for numerals, operators, and punctuation, and commonly defined functions or abbreviations, e.g., cos, det, e or exp, lim, log, max, min, sin, tan, d (for derivative) Bold for vectors, tensors, and matrices.

References

Citation

Cite references in the text by name and year in parentheses. Some examples:

- Negotiation research spans many disciplines (Thompson 1990).
- This result was later contradicted by Becker and Seligman (1996).

- This effect has been widely studied (Abbott 1991; Barakat et al. 1995; Kelso and Smith 1998; Medvec et al. 1999).

Ideally, the names of six authors should be given before et al. (assuming there are six or more), but names will not be deleted if more than six have been provided.

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

Reference list entries should be alphabetized by the last names of the first author of each work.

Journal names and book titles should be *italicized*.

Journal article Harris, M., Karper, E., Stacks, G., Hoffman, D., DeNiro, R., Cruz, P., et al. (2001). Writing labs and the Hollywood connection. *Journal of Film Writing*, 44(3), 213–245.

Article by DOI Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. *Journal of Molecular Medicine*, https://doi.org/10.1007/s001090000086

Book Calfee, R. C., & Valencia, R. R. (1991). *APA guide to preparing manuscripts for journal publication.* Washington, DC: American Psychological Association.
Book chapter O’Neil, J. M., & Egan, J. (1992). Men’s and women’s gender

role journeys: Metaphor for healing, transition, and transformation. In B. R. Wainrib (Ed.), *Gender issues across the life cycle* (pp. 107–123). New York: Springer.

Online document Abou-Allaban, Y., Dell, M. L., Greenberg, W., Lomax, J., Peteet, J., Torres, M., & Cowell, V. (2006). Religious/spiritual commitments and psychiatric practice. Resource document. American Psychiatric Association.

SCHOOL OF PSYCHOLOGY

DOCTORATE IN CLINICAL PSYCHOLOGY

EMPIRICAL PAPER

Evaluating a goal-setting intervention for children and young people with executive dysfunction: a single-case experimental design.

Trainee Name:	**Seona Granville**
Primary Research Supervisors:	**Dr Jenny Limond** Consultant Clinical Neuropsychologist and Senior Lecturer, School of Psychology, University of Exeter.
	Dr Nick Moberly Senior Lecturer, School of Psychology, University of Exeter.

Target Journal:	Journal of Autism and Developmental Disorders
Word Count:	7,998 words (excluding abstract, table of contents, list of figures, references, footnotes, appendices)

Submitted in partial fulfilment of requirements for the Doctorate Degree in Clinical Psychology, University of Exeter

Abstract

Objective: Research shows that structured goal-setting enables goal progress and engenders well-being; however, it is not clear the extent to which this is true in executive dysfunction (EDF) populations. This study aimed to determine the effectiveness of a goal-setting intervention, supported by the Brain in Hand (BiH) app, on goal progress and well-being in individuals under 18 years with EDF.

Methods: Using a multiple-baseline single-case experimental design, six participants (*mean age* = 14.8 years; *SD* = 1.94; male: female 2:1) underwent structured goal-setting sessions, during which goals were identified and broken down into achievable steps. Potential challenges to reaching these goals, along with suggested solutions were also considered. This information was uploaded to participants' personalised BiH accounts on their smartphones, with scheduled prompts/reminders to encourage progress. Repeated measurements of "happiness" and goal satisfaction ratings were taken each weekday over a period of seven weeks. Outcome measures were administered pre- and post-intervention to determine if there were reliable changes in overall functioning and well-being.

Results: Statistically significant improvements were found for goal progress, at a group level. No statistically significant changes were observed in participants' "happiness" ratings. Two participants demonstrated reliable improvements in everyday functioning, with one showing reductions in negative affect.

Conclusion: The findings suggest that structured goal-setting supported by the BiH app has the potential to aid young people with EDF progress towards their goals. Future recommendations are made, including extending the data collection period and investigating gender differences. Clinical implications are also described.

Introduction

Background

Executive Function (EF) is an umbrella term describing a collection of interrelated cognitive processes that enable activities such as goal-directed behaviours, and regulatory and control mechanisms (Rapport, Eckrich, Calub, & Friedman, 2020). Diamond (2013) describes three core EFs comprising inhibition, cognitive flexibility and working memory, from which higher-order EFs are built, such as reasoning, problem solving and organising goal-directed behaviour (Lezak, Howieson, Bigler, & Tranel, 2012). EF abilities develop throughout childhood and adolescence (Anderson & Reidy, 2012), and are central to almost every aspect of our daily functioning, enabling the organisation of behaviour in an intentional manner whilst simultaneously monitoring performance and responding flexibly to surrounding experiences (Mullin, Perks, Haraden, Snyder, & Hankin, 2020). EFs are particularly relevant when people are faced with unexpected situations that require new patterns of action (Heyl & Hintermair, 2015).

Executive dysfunction (EDF) represents deficits in one or more elements of EF and is a prominent feature in many paediatric clinical populations (Zelazo, 2020), including autism (ASD; e.g., Demetriou et al., 2018), attention deficit hyperactivity disorder (ADHD; e.g., Petrovic & Castellanos, 2016), and other neurodevelopmental conditions such as dyslexia, dyspraxia and dyscalculia (Rubinsten & Henik, 2009). Cognitive deficits associated with EDF include planning and organisational problems, poor goal-directed behaviour, emotion regulation impairments, poor impulse control, poor reasoning ability, difficulties generating and/or implementing strategies, perseveration, mental inflexibility, and reduced working memory (Anderson, 2002).

EDF is strongly associated with a child's development, learning, behaviour, and overall well-being (Sanz et al., 2017).

Mood and affect are often disrupted in individuals experiencing EDF (e.g., Nelson et al., 2018; Alfstad et al., 2016), with some presenting as apathetic, unmotivated and unresponsive, and others being impulsive and argumentative (Anderson, 2002). Goal-setting and planning impairments are prevalent amongst individuals with EDF (e.g., Sibley et al., 2019). Furthermore, there is strong empirical evidence indicating a causal link between the act of setting and planning for personal goals, and well-being (MacLeod, Coates, & Heatherton, 2008). Therefore, the focus of the present study is on the goal-setting, planning components of EF, and well-being.

A goal is "the object or aim of an action that an individual is trying to accomplish" (Carr, Moore, & Anderson, 2014, p. 225,). 'Approach' goals involve movement towards a desired outcome, whilst 'avoidance' goals involve movement away from an undesired outcome (Carver & Scheier, 1998). Both types of goals can generate both positive affect (PA) and negative affect (NA; Carver & Scheier, 2012). Goals provide structure and meaning to a person's life, with Wrosch and Scheier (2020) arguing that goal attainment contributes to patterns of successful development by enabling subjective well-being. Indeed, MacLeod (2012) found that individuals who have a goal-based orientation and a tendency towards planning, report a higher sense of well-being. Eudemonic aspects of well-being that are likely to be related to goal progress comprise the facilitation of personal growth, connections with others, and subjective well-being. Subjective well-being, usually defined as a combination of high PA, low NA, and life satisfaction, can be

systematically measured and thus, is regularly explored in the goals literature (e.g., MacLeod et al., 2008).

Carver and Scheier (1990; 2012) proposed the “model of behavioural self-regulation”, which posits that goal-directed behaviour reflects a hierarchical set of feedback loops. These loops monitor discrepancies between one’s current state and one’s valued reference point, leading to ruminative thoughts and behaviours that can minimise such discrepancies (Thürmer, Scheier, & Carver, 2019). Embedded within this cognitively-based model is believed to be an emotion-driven loop that creates or reduces affect (Baumeister, Schmeichel, & Vohs, 2007). Carver & Scheier (2012) suggest that a felt sense of satisfactory progress towards approach goals results in increased PA (e.g., joy, pride) and progress towards avoidance goals leads to decreased NA (e.g., anxiety). Conversely, stress is experienced when people believe that progress towards a goal will not be made, causing high levels of rumination or worry (Carver & Scheier, (1998). They further argue that confidence, motivation, and doubt influence whether or not an individual continues to struggle against adversity.

In this model, goals are conceptualised as hierarchical (Carver & Scheier, 2012). Although abstract goals can be useful in setting general directions for behaviour and principles of action, goals that are too vague are characteristically difficult to progress towards, as the concrete actions to fulfil them are often unclear, causing passivity (Coote and MacLeod, 2012). Goal-setting theories posit that structured goal-planning helps make goals more concrete and more attainable, whilst simultaneously allowing for the creation of more abstract sub-goals (Locke & Latham, 2002). Such structure could be of value in enabling young people with poor EF abilities to function more effectively, by providing them with a scaffold for their targets.

Planning and organisational skills develop rapidly between 7 and 10 years of age in healthy individuals and gradually thereafter into adolescence (Krikorian & Bartok, 1998), when strategic behaviour and reasoning abilities become more organised and efficient (Anderson & Reidy, 2012). However, such skills can be significantly delayed and/or impaired in individuals with EDF (Sibley et al., 2019). Nonetheless, several reviews highlight that EF abilities can be taught (e.g., Kenworthy et al., 2014), and that goal-setting and goal progress are important components of self-determination for school-aged individuals with various neurodevelopmental disorders (e.g., Fowler, Konrad, Walker, Test, & Wood, 2007). Carr et al. (2014) suggest that the ability to independently set and progress towards attainable and appropriate goals is an important skill for such young people to develop and might contribute to improved awareness, task performance, fulfilment and independent functioning. Goal-setting and planning are cognitively-based processes that can be targeted by interventions (e.g., Coote & MacLeod, 2012); however, it is unclear to what extent this is true for children, and indeed, for EDF populations. Assistive technology (AT) is one platform through which such an intervention can be supported and its efficacy explored.

AT is an umbrella term used to describe assistive, adaptive and rehabilitative devices designed for people with disabilities (Kettlewell, Phillips, & Radford, 2018). Technology has had a significant impact on the way people organise their lives and interact with others (Godine & Barnett, 2013), notably through smartphone or tablet applications (apps; Krageloh et al., 2018). AT strives to compensate for loss of function and promote greater independence by enabling individuals to feel supported in leading more fulfilling lives (Kettlewell et al., 2018). Meta-analyses indicate benefits of smartphone apps in delivering treatments for conditions such as

depression (Firth et al., 2017a) and anxiety (Firth et al., 2017b). Technology has also long played an important role in interventions for individuals with neurodevelopmental conditions (Grynszpan, Weiss, Perez-Diaz, & Gal, 2014).

'Brain in Hand' (BiH) is an app designed for people who struggle to cope with change, have difficulties remembering things and experience anxiety (Kettlewell et al., 2018). BiH was originally designed for adults with ASD; however, it has also been shown to assist individuals with brain injuries (Kettlewell, 2020) and as such, might hold potential for being effective for individuals demonstrating EDF traits in other conditions. Although it does not provide a clinical service, BiH supports EF abilities by helping users to create structured diaries with identified challenges and proposed solutions, attach reminders, and record task completion on their personalised accounts (Kettlewell et al., 2018).

When an individual feels overwhelmed, EFs in everyday life can weaken, often resulting in the individual panicking, making poor decisions and responding impulsively (Reising, 2013). As a result, previously rehearsed strategies and solutions are frequently forgotten. BiH endeavours to address this by providing its users with access to immediate "solutions" to potential difficulties. The pre-planned coping strategies for managing possible challenges, as well as the reminders are intended to help individuals progress towards their goals by completing everyday tasks and responding effectively to problems encountered (see Figure 1).

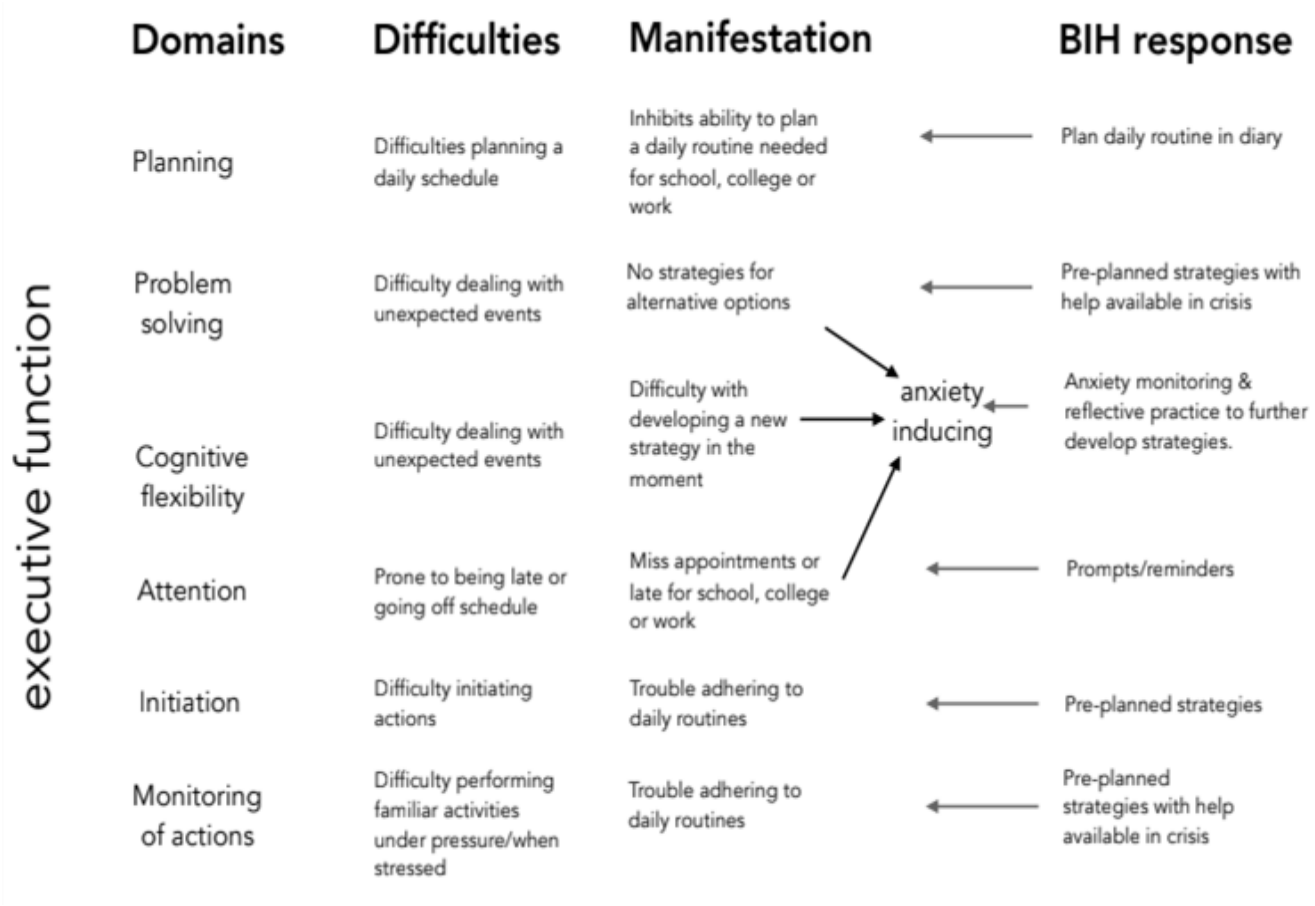


Figure 1. An overview of the functions of Brain in Hand (retrieved from L. Morpeth, personal communication, July 5th 2018)

There is minimal robust research evaluating the effectiveness of this relatively new BiH app. User-feedback indicates it can be effective in helping individuals with ASD to socialise, communicate, organise daily life, and increase independence (Brain in Hand, 2019). Kettlewell (2020) examined the use of BiH using a single-case experimental design (SCED) with participants with brain injuries and found a significant increase in goal attainment over a six-month period. A National Autistic Society review (2015) found that 53% of university students with ASD rated BiH as being extremely positive in helping them to implement strategies and feel more confident, with over 30% reporting substantial decreases in distress levels. This trial was industry-conducted research, however, with the possibility of reporting bias.

There is therefore a need for a more robust evaluation of BiH, and to date, no data exist on the impact of BiH on improving functioning and well-being in school-age individuals with EDF traits. The present study aims to address this knowledge gap by exploring whether BiH can be incorporated into a goal-setting and coaching intervention with this population.

Present study

The present study set out to evaluate the effectiveness of a goal-setting and coaching intervention in adolescents with EF impairments. In line with Carver and Scheier's (1990; 2012) model of behavioural self-regulation, it endeavoured to determine whether goal-setting and coaching sessions supported by BiH i) improve goal progress, and ii) enhance well-being. Because the effects of a novel and individualised intervention were under examination with a limited pool of participants over an extended period, a SCED approach was applied, as recommended by Southall and Gast (2011).

Research questions.

1. Can a goal-setting intervention supported by the BiH app improve goal progress in adolescents with EDF traits?
2. Can a goal-setting intervention supported by the BiH app improve affective well-being in adolescents with EDF traits?

Hypotheses.

1. The goal-setting sessions supported by the BiH app will improve participants' satisfaction with daily goal progress.

2. The goal-setting sessions supported by the BiH app will improve participants' affective 'happiness' ratings.
3. Participants will demonstrate statistically reliable and clinically meaningful improvements in everyday life functioning, as measured by the BRIEF scale (Gioia Isquith, Guy, & Kenworthy, 2000).
4. Participants will demonstrate statistically reliable improvements in overall well-being, as measured by the PANAS-C scale (Laurent et al., 1999).

Method

Design

A multiple-baseline SCED was employed to determine whether there was a causal relationship between the goal-setting intervention (independent variable) and the target behaviours, daily goal satisfaction and "happiness" ratings (dependent variables). SCEDs allow for in-depth evaluations of the effects of an intervention on individual participants (Barlow & Nock, 2009), with the aim of better understanding their behaviours or functional states (Barnett et al., 2012). Reliable change of EF and overall well-being was also explored.

Repeated measurements of "happiness" ratings and goal satisfaction with respect to pre-specified overarching goals were taken five days a week over a period of seven weeks (35 data collection days), from baseline (phase A) through to intervention (phase B). Participants served as their own control, with each completing both phases of the study. The introduction of the goal-planning intervention on a randomly staggered basis increased internal validity and allowed causal inferences to be made (Rhoda, Murray, Andridge, Pennell, & Hade, 2011).

Any improvements in goal satisfaction and ‘happiness’ levels observed during the intervention phase could thus be validly attributed to the intervention itself, rather than to extraneous variables such as individual differences or maturation effects of statistical regression (Kinugasa, Kerin, & Hooper, 2004).

The study required participants to complete the daily measures via their smartphone or tablet device each weekday across both phases. The minimum number of baseline days was 10 whilst the minimum number of intervention days was 15. This allowed 11 possible moments of phase change for random assignment of each participant. The large number of possible phase changes increased the likelihood that any change observed in goal satisfaction and/or happiness ratings was due to the intervention. Random assignment was determined using Excel (see Table 1 and Appendix A).

Table 1

Sequence of phase A (baseline) and phase B (intervention) for individual participants.

Participant	Sequence
1	AAAAAAAAAAAAAAAAA*BBBBBBBBBBBBBBBBB*
2	AAAAAAAAAAA*BBBBBBBBBBBBBBBBBBBBB*
3	AAAAAAAAAAAAA*BBBBBBBBBBBBBBBBBBB*
4	AAAAAAAAAA AAAAA*BBBBBBBBBBBBBBBBBB*
5	AAAAAAAAAAAA*BBBBBBBBBBBBBBBBBBBB*
6	AAAAAAAAAAAAAAAAAA*BBBBBBBBBBBBBB*

For pragmatic reasons it was not possible for all participants to begin the baseline phase on the same day. However, the final participant began their baseline

phase before the first participant had completed their intervention phase. This allowed for simultaneous design analysis, thus, increasing external validity (Onghena & Edgington, 2005).

Ethics

The study was approved by the University of Exeter Psychology Department Research Ethics committee (see Appendix B).

Sample

Recruitment. The study endeavoured to recruit six to eight participants between the ages of 12 and 18, who demonstrated traits of EDF, including but not limited to, conditions such as ASDs (e.g., Demetriou et al., 2018) and ADHD (e.g., Petrovic & Castellanos, 2016). Purposive sampling was therefore applied, and to maximise the number of potentially eligible participants, professional contacts were established with:

1. Special educational needs and disabilities coordinators (SENDCos) working in mainstream schools.
2. Educational psychologists working with a large range of schools across the county.
3. Support groups for families of young people with ADHD.
4. Support groups for adolescents with diagnoses of ASD.

Four students and parents, identified by a SENDCo at a mainstream school, were sent information sheets (see Appendices C & D) and asked to return signed consent and assent forms (see Appendices E & F), if they were interested in participating. One parent expressed interest, allowing screening to take place by

telephone using the parent-report version of the Behavior Rating Inventory of Executive Function (BRIEF-PR; Gioia et al., 2000).

The researcher also attended local support groups for young people with ASD and their parents. This facilitated informal discussions about what the study entailed. Those who were interested were then provided with information sheets and consent forms and were asked to email the researcher if they were happy to take part. As above, screening for these participants took place by telephone in order to reduce burden on the parents. Five participants were recruited via these support groups.

Inclusion and exclusion criteria. Inclusion criteria comprised being aged between 12 years and 18 years 11 months and having access to and the ability to use a smartphone or tablet device. A demonstrated level of motivation to work towards goals was also deemed necessary, gauged through interview with both the participant and their parent. Participants were excluded from the study if they were already active users of the BiH app. For logistical purposes, participants living over a two-hour drive from the university were not included in the study.

If these criteria were met, the BRIEF-PR measure was administered and participants were included in the study if they received a T-score of 60 or more on any of the subscales. Previous diagnoses of EF impairments, neurodevelopmental conditions or mood disorders served neither as an inclusion nor as an exclusion criterion.

Participants. Twelve parents contacted the researcher expressing interest in their child partaking in the study. Six participants were excluded: two for being outside the eligible age range, one for geographical reasons, two because of inability to handle a mobile device in the opinion of a parent, and one due to insufficient motivation of the young person, made apparent in discussion with the researcher.

All six remaining participants met the threshold for inclusion on the BRIEF-PR (see Table 2). Individual characteristics of each of the six study participants are displayed in Table 3. The male: female ratio was 2:1. At the time of recruitment, ages ranged from 12 years 7 months to 18 years 2 months (M = 14.8; SD = 1.94).

Table 2

T-scores for each participant using BRIEF-PR screening measure (T-score > 60 across any subscale required for eligibility).

Participant (parent-report)	Inhibit	Shift	Emotional Control	Behavioural Regulation	Initiate	Working Memory	Plan/ Organise	Org. of Materials	Monitor	Meta-cognition	General Executive Composite
1	87	85	82	90	77	92	84	65	81	88	90
2	103	94	75	94	89	82	75	69	79	82	90
3	76	95	85	90	76	73	70	57	69	72	81
4	71	85	75	80	73	80	79	69	66	78	81
5	81	87	65	80	86	93	81	72	82	86	88
6	52	79	75	72	71	74	80	71	71	79	77

Table 3

Characteristics of participants

Participant Number	Gender	Age	Diagnosis
1	Female	15 years 2 months	Attention Deficit Hyperactivity Disorder
2	Male	14 years 5 months	Autism Spectrum Disorder
3	Male	12 years 7 months	Autism Spectrum Disorder
4	Male	13 years 4 months	Autism Spectrum Disorder
5	Male	15 years 1 month	Autism Spectrum Disorder
6	Female	18 years 2 months	Autism Spectrum Disorder

Power

Ferron and Sentovich (2002) found that 11 phase changes and as few as four participants and 20 measurement points is sufficient to detect an effect size of $d \geq 1.0$ with adequate power (> 0.8). Given that the present study also comprised 11 phase changes, with six participants and 35 daily measurements, this indicated that there would be sufficient power to detect statistically significant change across the phases.

Measures and materials

Brain in hand app. Brain in Hand (BiH) is a cloud-based app available from Brain in Hand Ltd. It allows users to add personalised details to a diary function (including prompts/reminders), as well as specific coping strategies for managing potential challenges they might encounter.

Participants used the BiH app throughout each phase of the study, however, during the baseline phase, the app served *only* as a medium on which goals were

displayed and the outcome measures were accessed. For study purposes, the researcher served as a BiH administrator in order to monitor participant usage.

Prior to data-collection, the researcher attended a two-day specialist-training programme to become qualified in delivering BiH to users.

Daily measures. Participants completed two separate daily measures, accessed via a hyperlink through the BiH app. The measures comprised two rating scales devised by the researcher using Qualtrics Software, an online secure survey software platform, hosted at the University of Exeter (Qualtrics, 2019). The first measure asked participants to rate their daily levels of 'happiness' using a seven-point Likert scale: 'I have felt happy today'; *strongly disagree, disagree, slightly disagree, neutral, slightly agree, agree, and strongly agree.* The second measure asked participants to rate their overall goal progress satisfaction using a seven-point Likert scale: *extremely dissatisfied, moderately dissatisfied, slightly dissatisfied, neutral, slightly satisfied, moderately satisfied, and extremely satisfied*. Scores were measured on a scale of 1-7, with higher numbers indicating greater agreement or satisfaction. Participants were prompted by the app to complete these measures at their own pre-specified time at the end of each weekday.

Pre- and post-interventions measures.

Measure of executive function. The BRIEF-PR (Gioia et al., 2000) was used to screen participants for EF difficulties and was re-administered post-intervention. The BRIEF-PR is a widely-used measure in both clinical and research settings for children with a range of developmental and acquired neurological conditions, demonstrating reliability (r = .81), validity and clinical utility as an ecologically valid assessment of EF (Gioia et al., 2000). The 86-item scale comprises eight non-

overlapping clinical scales measuring different aspects of EF including the following indices and subscales: Behaviour Regulation Index comprising inhibit, emotional control shift (with behavioural shift and cognitive shift subscales) and the Metacognition Index comprising monitor, working memory, plan/organise, organisation of materials and initiation subscales. With a T-score of 60 for eligibility, normative data suggests that this represents the top 15-20% of the general population distribution for EDF.

The self-report version of the BRIEF (BRIEF-SR; Guy, Isquith, & Gioia, 2004) was used as a pre-baseline and post-intervention measure to monitor any change in EF abilities of each participant across the study. As with the BRIEF-PR, the self-report scale demonstrates good validity and reliability (r = .89), and comprises 80-items across the same eight scales of executive functioning.

Measure of well-being. The Positive and Negative Affect Schedule for Children (PANAS-C; Laurent et al., 1999) was administered as a baseline measure for affective well-being (See Appendix G). The PANAS-C is a 10-item self-report measure comprising two mood scales measuring PA (five items; e.g., ‘happy’, ‘proud’) and NA (five items; e.g., ‘sad’, ‘scared’) and has evidenced favourable psychometric properties (r = .89) across various clinical and research samples (e.g., Chorpita & Daleiden, 2002; Hughes & Kendall, 2009). It is scored on a five-point Likert scale: *Very slightly or not at all, a little, moderately, quite a bit, and extremely.* Higher scores on the PA items and lower scores on the NA items indicate a greater sense of overall well-being. The PANAS-C was re-administered at the end of baseline and post-intervention to ascertain any changes in affective well-being levels.

Intervention

The goal-setting sessions at the beginning and end of baseline, paired with weekly ‘coaching’ phone calls made up the intervention. This phase of the study was supported by the prompt, challenge and solution functions of the BiH app, which were activated during phase B only. These goal-setting sessions with the researcher were grounded in cognitive behavioural therapy goal-elicitation techniques, including Socratic questioning; a method of guided discovery using carefully sequenced questions to help define goals (Beck & Dozois, 2011). This helped each participant to elicit potentially valuable day-to-day goals towards which they were not already progressing (Cooper & Law, 2018). The “SMART” goal technique, i.e. specific, measurable, achievable, realistic and time-limited (Doran, 1981), was applied. These goals should not be such that could have been easily attained during the data collection period (e.g., “I want to go swimming next Thursday”), nor should they have been too abstract (e.g., “I want to be happy”). Rather, participants were asked to identify goals to which they could work progressively over a number of weeks (e.g., “I want to learn coping skills for when I feel anxious”). As phones might not always be permitted during school hours, participants were encouraged to think of goals that were not solely classroom-based. These goals were then added as reminders onto each of their personalised BiH accounts (see Appendix H for examples of suggested goals).

At the end of baseline, these pre-determined ‘overarching’ goals remained the same. However, with the help of the researcher and using the guidance of the BiH workbook (see Appendix I), participants were asked to break each goal into smaller, more achievable steps, or ‘sub-goals’. The researcher also encouraged them to think about any possible barriers or challenges they might encounter in progressing towards

their goals and helped them to identify possible strategies to overcome them. For instance, potential challenges that participants volunteered included “I am too anxious to do anything” and, “I do not know what I am supposed to pack”. Suggested solutions therefore included having access to a range of coping skills (e.g., breathing techniques, or ‘go outside’) and having lists of pre-specified items to be packed daily. Each participant agreed how and when they wanted to be prompted by BiH with the availability of these different strategies for consideration. All of these suggested challenges, solutions and prompts were inputted onto each participant’s BiH app by the researcher, allowing the intervention phase to commence.

Each Sunday throughout the intervention phase, a telephone ‘coaching’ session between the researcher and participant took place, to reflect on each participants’ weekly progress, address any difficulties encountered, and provide motivation for the coming week.

Pilot of intervention. A pilot study was conducted with two adolescents who met the eligibility criteria for the study. This consisted of a two-hour session centred on goal elicitation, consideration of problems and solutions, inputting said information onto personalised BiH accounts, and navigating the app. Feedback was gathered regarding the goal elicitation techniques, exploring the app and the feasibility of accessing and completing the daily measures. Amendments were then made to the intervention based on feedback received, e.g., the Socratic questioning technique was introduced after the pilot study participants reported difficulties in goal formulation. The pilot participants were granted the same ethical considerations as the participants in the main study.

Procedure

The procedure for the study comprised the measures and approaches outlined above. Figure 2 sets out the process and sequence adopted under the following headings: screening, pre-baseline, baseline, end-of-baseline/pre-intervention, intervention and end-of-intervention,

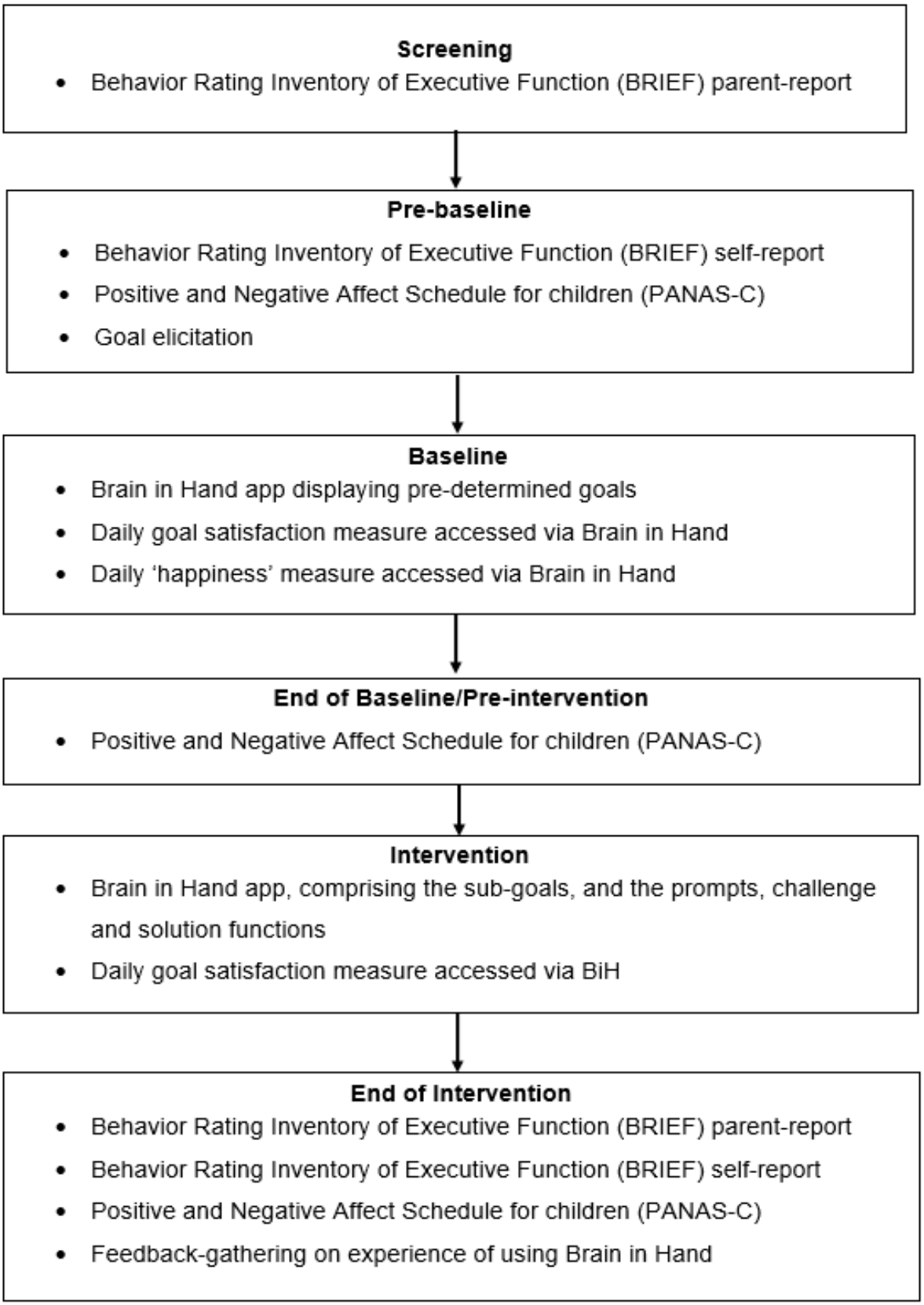


Figure 2. Sequence of measures.

Data Analysis Plan

Hypotheses one and two. Visual analyses (VA) were completed to explore whether the intervention improved daily goal satisfaction ratings (hypothesis one) and/or daily 'happiness' ratings (hypothesis two). All VA graphs, comprising central tendency (median), trend and overlap of variability, were completed using Microsoft Excel.

Although VA remains the most prevalent technique used in examining SCED data (Bulté & Onghena, 2008), there is an increased risk of type 1 errors associated with its use. Randomisation tests (RTs) were therefore also applied to mitigate this risk (Heyvaert & Onghena, 2014). RTs evaluate the statistical significance of SCEDs and are particularly useful when VA conclusions are debatable (Bulté & Onghena, 2013). They comprise randomising participants to moments of change *a priori* (Marascuilo & Busk, 1988) and ask the probability of a particular set of observations occurring, taking into account all of the possible randomisations (Morley, 2018). Using the R-software package (Bulté & Onghena, 2008), the test statistic is calculated to determine where it falls within the distribution of all possible test statistics (Heyvaert et al., 2017).

More data points yield greater statistical power (Morley, 2018). The present study comprised 11 possible moments of phase change (k) to the power of N (six participants), which generated 88,578 potential randomisation points. Given this large number, the Monte-Carlo simulation needed to be applied (Bulté & Onghena, 2013). The smallest possible p-value for individuals was calculated using the inverse of the number of randomisation phase changes (i.e. 1/11), which was determined as being $p = .09$.

Effect sizes were calculated using the Non-Overlap of all Pairs analyses to determine the effectiveness of the intervention for each participant (NAP; Parker & Vannest, 2009). Taking the desired direction of the intervention into account, the NAP method compares each data point in baseline to every point in intervention, with the score representing the proportion of all possible pair comparisons where the intervention scores differ from the baseline scores (Morley, 2018). A NAP calculator was used to generate this, which was accessed at http://www.singlecaseresearch.org/calculators/nap.

Hypotheses three and four. Hypotheses three and four were explored using the reliable change index (RCI; Jacobson & Truax, 1991), to determine whether or not there were any statistically reliable changes in BRIEF scores (hypothesis three) and PANAS-C scores (hypothesis four), from baseline through to end of intervention. RCI ascertains whether any observed change is greater than the expected measurement error, with the standardised error of the difference providing an estimate of error in measurement of change (Elliott, 2002). An RCI calculator was used to compute the RCI scores in the present study, accessed at https://www.psyctc.org/stats/rcsc1.htm.

Both the parent- and self-report versions of the BRIEF were administered at two time-points (pre-baseline and end of intervention) and were compared accordingly. The PANAS-C scores were analysed comparing pre-baseline and end-of-intervention scores; however, pre-baseline and end-of-baseline scores were also inspected.

Informal feedback. Informal feedback was gathered from participants and their parents at the end of the study, exploring their experiences of the goal-setting

sessions and their use of the app. This information was examined using a narrative synthesis.

Results

Six participants completed the seven-week data collection period, comprising baseline and interventions phases. Compliance was variable across participants, with all but one presenting with missing data points across one or both phases of the study (see Table 4). Reasons provided for missing data were that participants did not have access to their smartphone, had been feeling unwell, or had been experiencing external life stressors (e.g., family member hospitalised, school exams). Each participant met the minimum of 50% of total data needed to conduct VA (De, Michiels, Tanious, &Onghena, 2020). Therefore, in order to ensure a robust estimate of central tendency and in turn, be able to complete the further recommended VAs, missing data points were imputed using the broadened median (Morley, 2018). RTs were calculated using participants' raw data without the imputed broadened medians.

Table 4.

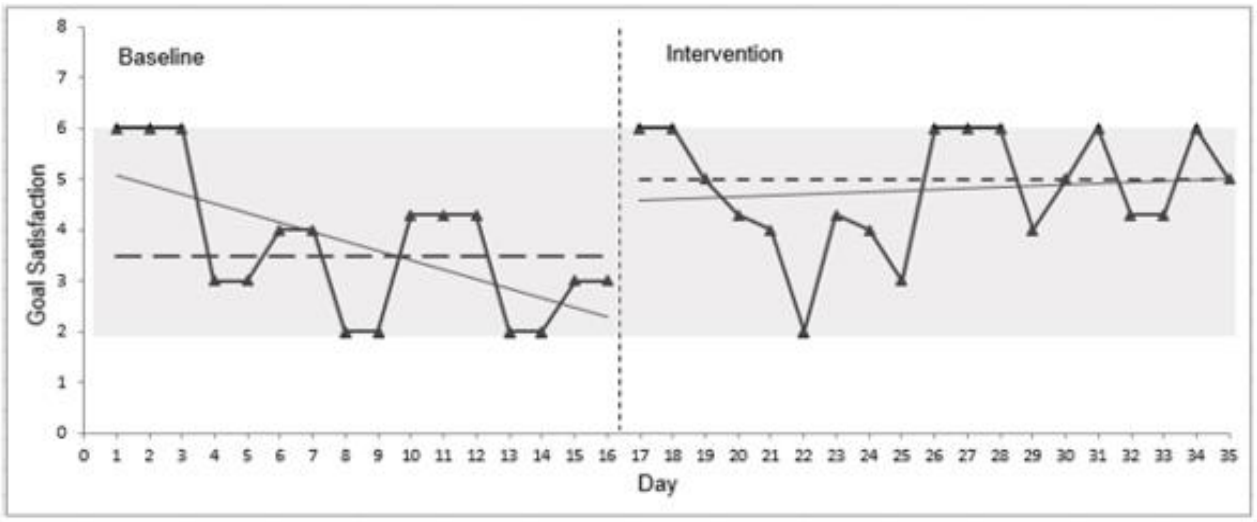
Number of missing data points across phases

Participant	Number of missing data points in baseline phase	Number of missing data points in intervention phase
1	2/15	4/20
2	0/10	0/25
3	3/12	5/23
4	0/14	7/21
5	0/11	6/24
6	0/18	4/17

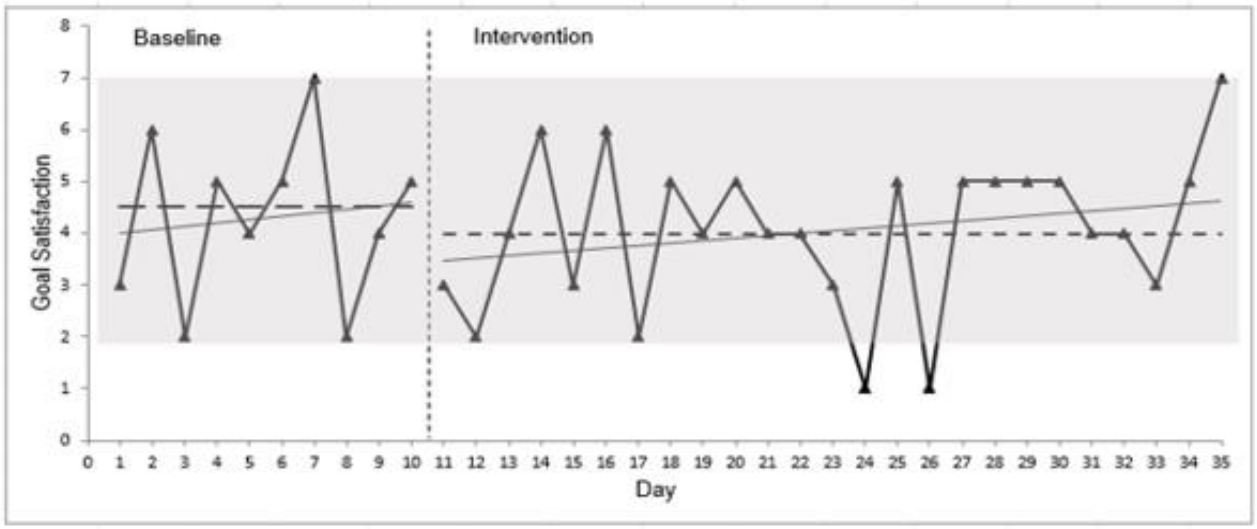
The presented graphs in Figures 3 and 4 depict the median as the line of central tendency, as well as the overlap of variability and trend line, for each participant's goal satisfaction and 'happiness' ratings, respectively. Descriptive statistics per phase and effect sizes for both ratings across baseline and intervention phases are presented in Tables 5 and 6. RTs are also described.

Hypothesis 1

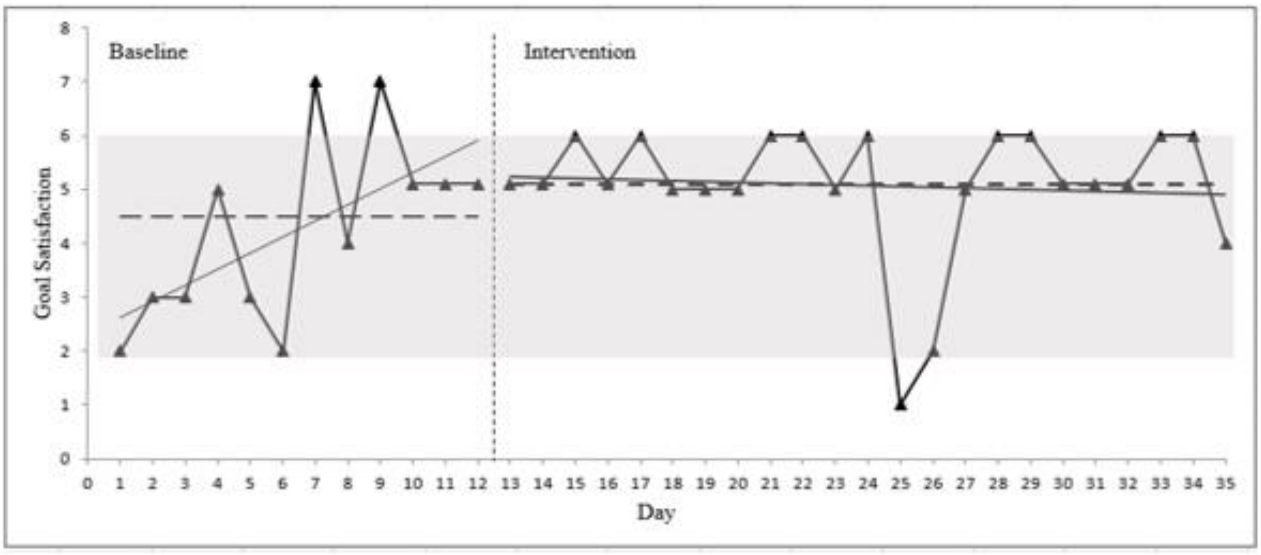
Hypothesis 1 stated that the goal-setting sessions supported by the BiH app would improve participants' satisfaction with daily goal progress, compared with that of the baseline period.



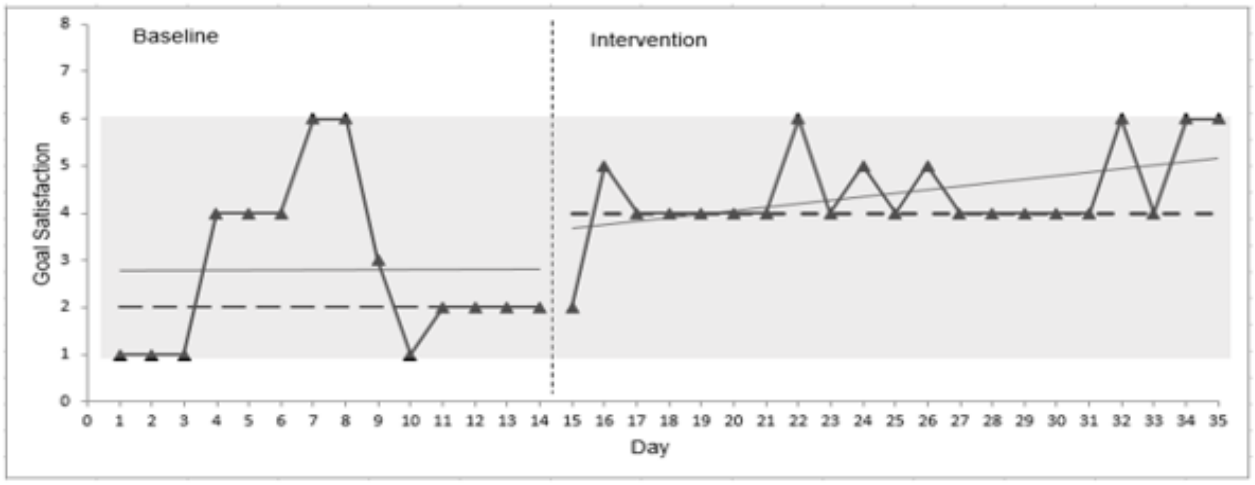
Participant 1: Median, trend line and overlap of variability between phases



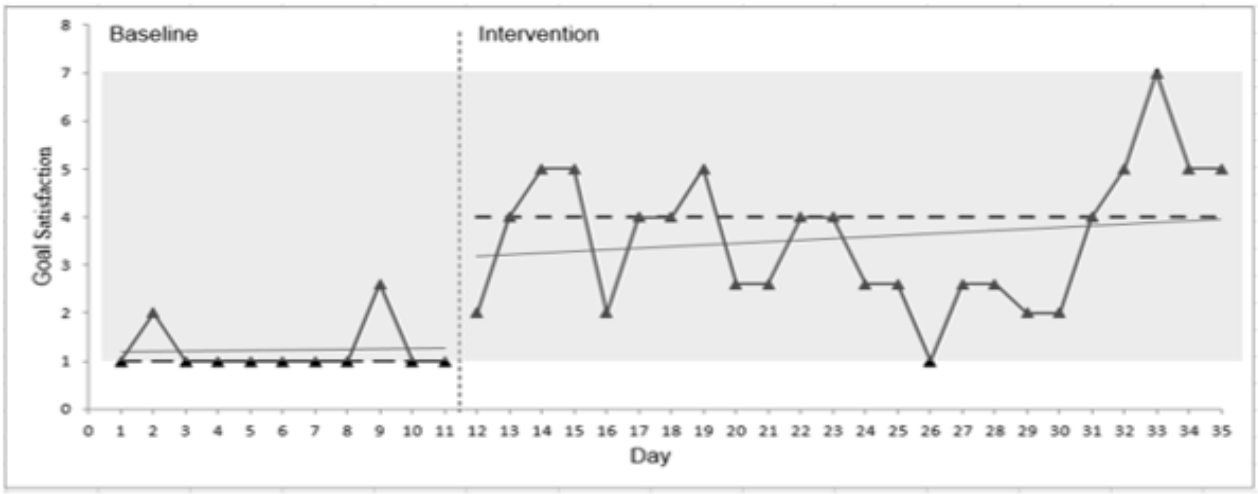
Participant 2: Median, trend line and overlap of variability between phases



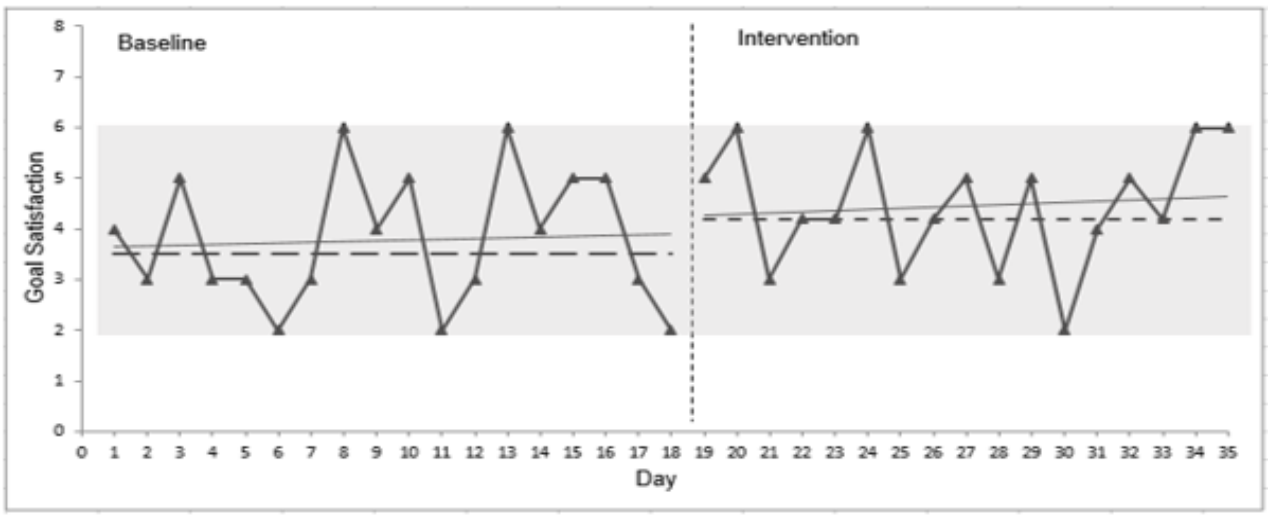
Participant 3: Median, trend line and overlap of variability between phases



Participant 4: Median, trend line and overlap of variability between phases



Participant 5: Median, trend line and overlap of variability between phases



Participant 6: Median, trend line and overlap of variability between phases

Figure 3. The measures of central tendency, trend lines and overlap of variability of goal progress satisfaction for each participant.

Table 5

Goal progress satisfaction ratings: Descriptive statistics and effect sizes.

Participant	Phase A length (data points)	Phase B length (data points)	Phase A Median *(Interquartile-Range)*	Phase B Median *(Interquartile-Range)*	NAP*	NAP *p*-value
1	16	19	3.5 *(1.55)*	5 *(1.85)*	0.73	.02
2	10	25	4.5 *(1.75)*	4 *(2)*	0.46	.70
3	12	23	4.3 *(2.1)*	5.1 *(1)*	0.65	.16
4	14	21	2 *(2.75)*	4 *(1)*	0.78	.01
5	11	24	1 *(0)*	4 *(2.4)*	0.94	.00
6	18	17	3.5 *(2)*	4.2 *(1)*	0.66	0.11

**NAP = Non-overlap of All Pairs effect size measure. Scores < .50 represent an effect in the unwanted direction. Tentative NAP ranges are as follows: 0.50-0.65 for weak effect; 0.66-0.92 for medium effect; 0.93-1.00 for large effect (Parker & Vannest, 2009)*

Visual analyses and effect sizes. Given that the data in the baseline phase for each participant were highly variable, a stable level of the dependent variable was not established. This makes it difficult to ascertain whether any change in the intervention phase was attributed to the change in condition, and thus, results need to be interpreted with caution.

Tentative visual inspection of the measure of central tendency (median; Figure 3) revealed that five of the six participants demonstrated an increase in goal progress satisfaction during the intervention, with only participant 2 showing a marginal reduction in satisfaction levels. Further statistical analyses using non-overlap of all pairs (NAP) calculations revealed a large effect size for participant 5,

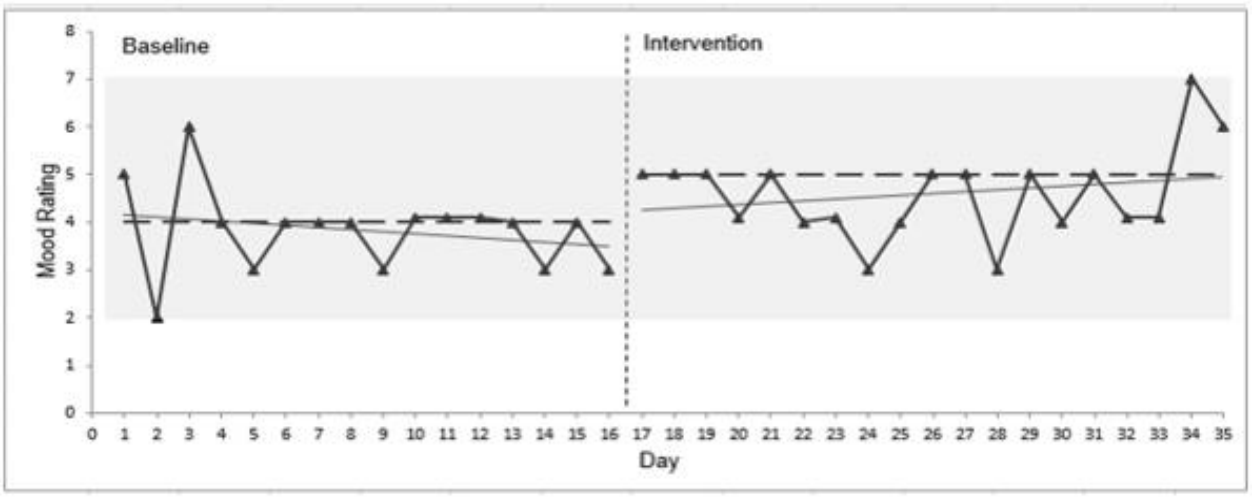
and medium effect sizes for participants 1, 4, and 6 (see Table 5). NAP calculations revealed weak effect sizes for participants 2 and 3.

Examination of the trend lines showed upwards trends in goal satisfaction ratings for participants 1, 4, 5, and 6 during the intervention phase (see Figure 3). Participant 3 demonstrated a downward trend data in the intervention phase, which corroborates the associated weak NAP value. Although participant 2 presented with an extremely fluctuating profile, VA revealed that overall, he demonstrated an upward trend throughout the intervention, concluding the study on the highest possible point. Despite this, however, medians calculated indicated lower average levels during the intervention compared to baseline, counter to the study hypothesis. This is corroborated by his NAP value demonstrating an effect in the unwanted direction.

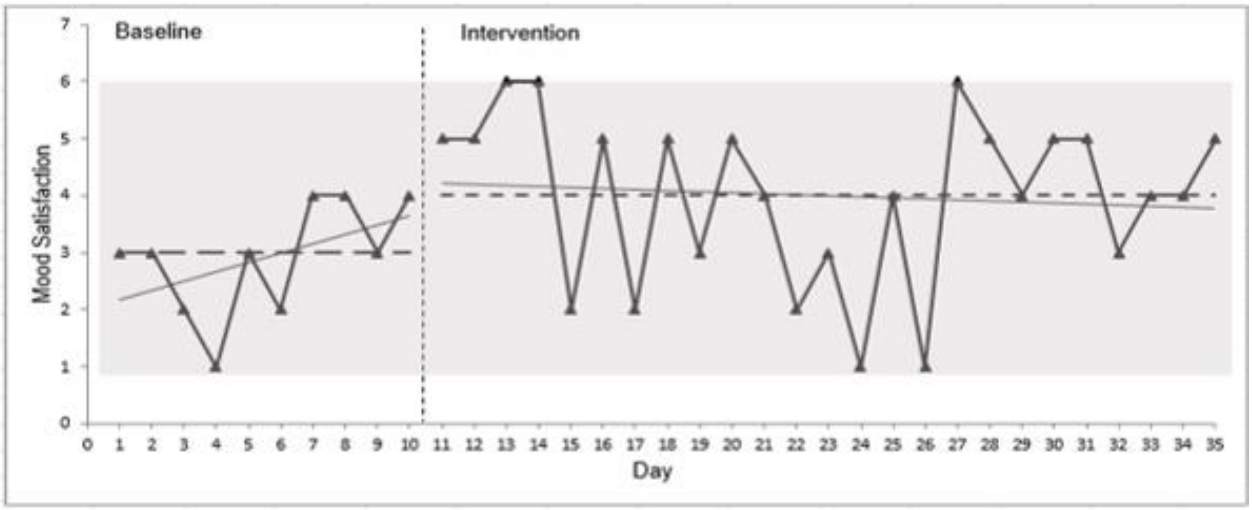
Randomisation tests (RTS). As described, given that there were 11 moments of phase change, the smallest p-value for an individual participant was p = .09. Therefore, RTs for each participant were not completed, as they would not show statistically significant changes for goal satisfaction between the baseline and intervention phases. RTs were carried out on the overall group data, however, revealing a significant difference between baseline and intervention phases (p = .03).

Hypothesis 2

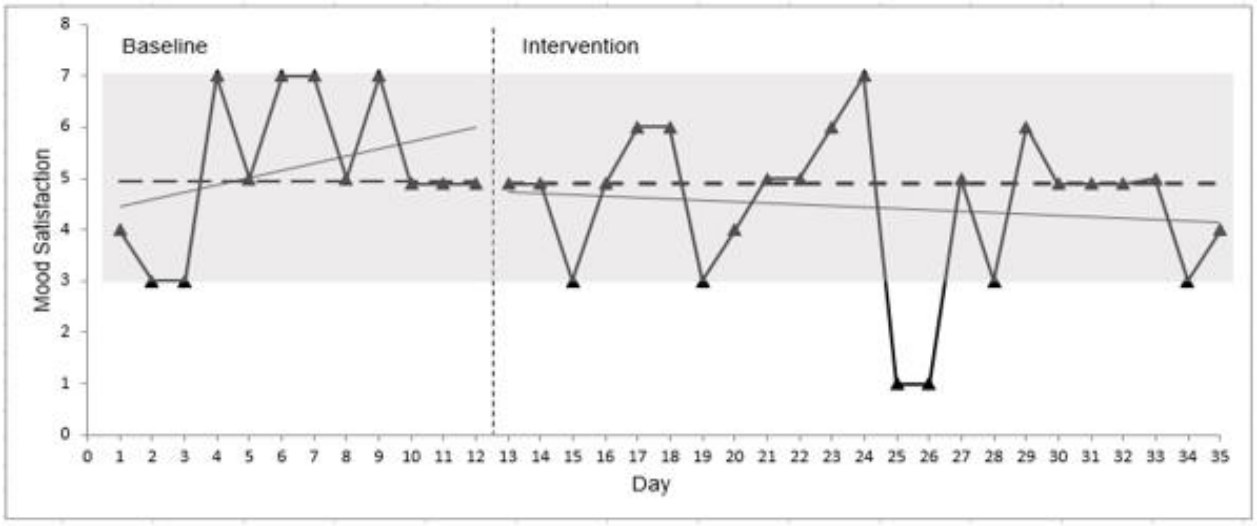
Hypothesis 2 stated that the goal-setting sessions supported by the BiH app would improve participants' affective "happiness" ratings, compared with the baseline period.



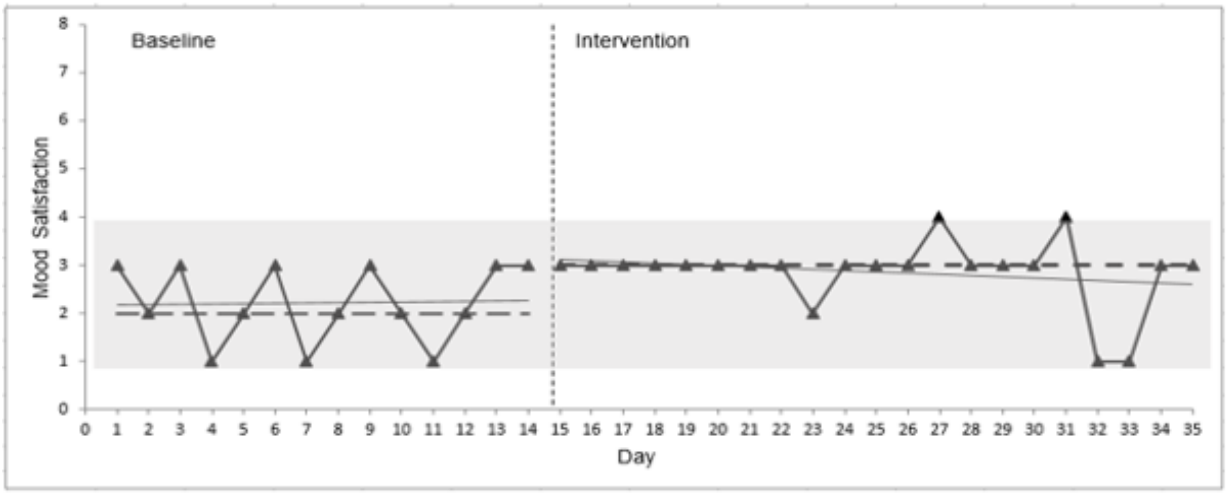
Participant 1: Median, trend line and overlap of variability between phases



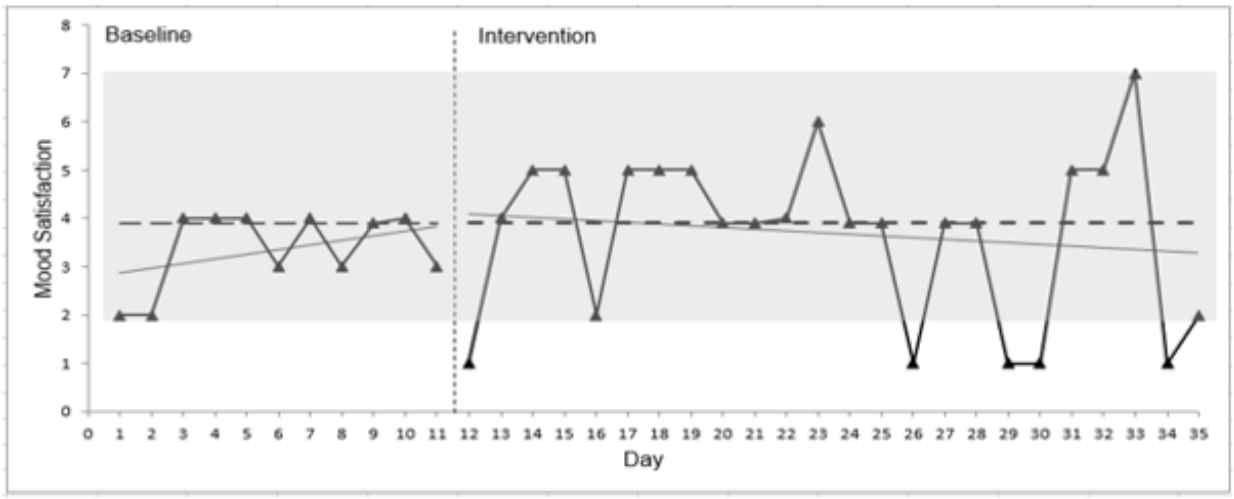
Participant 2: Median, trend line and overlap of variability between phases



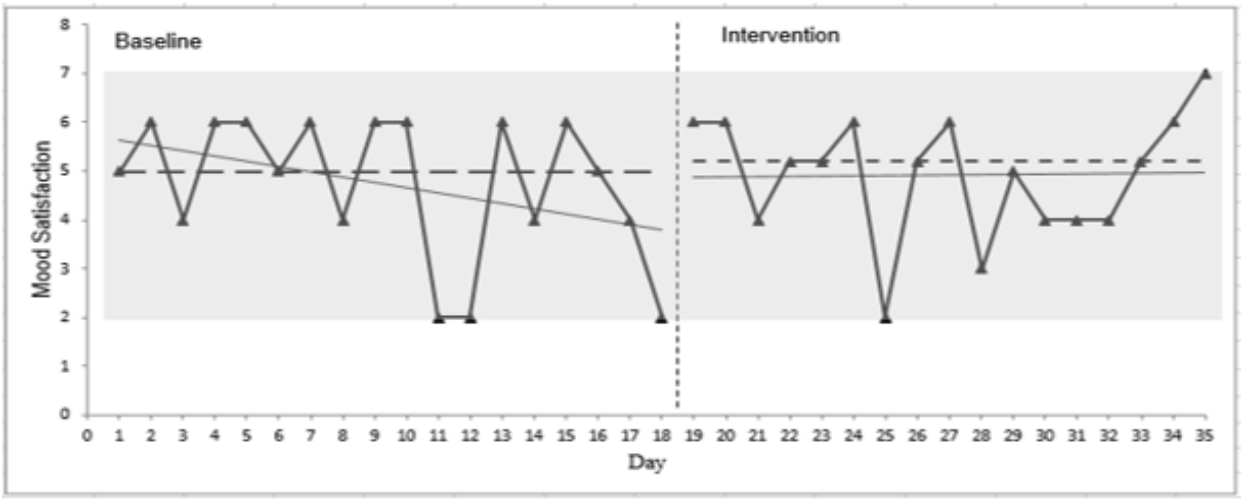
Participant 3: Median, trend line and overlap of variability between phases



Participant 4: Median, trend line and overlap of variability between phases



Participant 5: Median, trend line and overlap of variability between phases



Participant 6: Median, trend line and overlap of variability between phases

Figure 4. The measures of central tendency, trend lines and overlap of variability of ’happiness’ levels for each participant.

Table 6

"Happiness" daily ratings: Descriptive statistics and effect sizes.

Participant	Phase A length (data points)	Phase B length (data points)	Phase A Median *(Interquartile - Range)*	Phase B Median *(Interquartile - Range)*	NAP	NAP *p*-value
1	16	19	4 *(1.1)*	5 *(0.95)*	0.75	.01
2	10	25	4 *(1.5)*	4 *(2)*	0.74	.03
3	12	23	4.95 *(2.325)*	4.9 *(1.5)*	0.55	.56
4	14	21	6 *(1)*	5 *(0)*	0.72	.03
5	11	24	3.9 *(1)*	3.9 *(3)*	0.57	.68
6	18	17	5 *(2)*	5.2 *(1)*	0.53	.79

Visual analyses and effect sizes. As with the goal progress ratings, the baseline ratings of 'happiness' fluctuated considerably, making it difficult to determine a stable level of the dependent variable and consequently infer any change caused by the independent variable.

Tentative visual inspection of the measure of central tendency (median) revealed that participants 1, 2, and 4 demonstrated increases in 'happiness' levels ratings during the intervention. This was corroborated by the NAP calculations that revealed medium effect sizes for said participants. Examination of the central tendency data for the remaining participants (3, 5, & 6) showed no notable changes

in ‘happiness’ ratings across both phases, which was supported by NAP calculations revealing weak effect sizes for said participants.

Trend lines for each participant were variable, with only participant 1 demonstrating a significant steady upward trend in the intervention phase, whilst participant 6 showed a marginal upward trend (see Figure 4). Since each participant had considerable overlap of variability across both the baseline and interventions phases, these results are cautiously considered.

Randomisation tests. Randomisation tests were conducted on the overall group data of ‘happiness ratings’ but did not reveal a significant statistical difference between phases (p = .94).

Reliable Change Index (RCI)

RCI data are displayed in Table 7. For the PANAS-C, absolute values of ≥14.93 (PA) and ≤12.31 (NA) were considered statistically significant (Crook, Beaver & Bell, 1998). See Appendices J and K for the RCI values for individual participants on the BRIEF-PR and BRIEF-SR subscales.

To establish whether the baseline phase prompted any significant change in well-being, RCI was calculated using the PANAS-C pre-baseline and post-baseline scores. No reliable change was found (see Appendix L), allowing the RCI to then be calculated for hypothesis 4. No reliable change was found for any of the participants on the PANAS-C on the PA scale, from pre-baseline to end-of-intervention. However, participant 1 demonstrated significant reductions in NA at the end of the study.

Inspection of the BRIEF-SR results show that participants 1 and 3 demonstrated statistically reliable reductions in scores pre- to post-intervention.

Participants 2 and 5 both showed reliable change in the unexpected direction (i.e. symptoms disimproved) across varying indices (see Table 7). No participant self-reported clinically meaningful changes. Results reveal that parents of two of the six participants (1, 6) reported statistically meaningful improvements in the Behavioural Regulation Index (BRI), Metacognition Index (MCI), and Global Executive Composite (GEC) subscale of the BRIEF-PR measure. Participant 6 is the sole participant who demonstrated clinically meaningful changes on the parent-report measure (i.e., T-scores <65 at end of intervention).

Table 7

T-scores of the BRIEF and raw scores of the PANAS-C, presented with RCI findings.

	Participant 1			Participant 2			Participant 3			Participant 4			Participant 5			Participant 6		
Measure	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?
BRIEF-SR																		
GEC	94	84	***Yes***	67	72	*No*	60	51	***Yes***	62	57	*No*	73	74	*No*	75	82	*Yes**
BRI	97	90	***Yes***	68	83	*Yes**	57	51	*No*	58	55	*No*	65	73	*Yes**	78	79	*No*
MCI	86	73	***Yes***	65	61	*No*	62	51	***Yes***	64	59	*No*	77	75	*No*	70	80	*Yes**
BRIEF-PR																		
GEC	90	75	***Yes***	90	89	*No*	81	79	*No*	81	80	*No*	88	84	*No*	77	60	***Yes***
BRI	90	77	***Yes***	94	92	*No*	90	81	*No*	80	77	*No*	80	80	*No*	72	52	***Yes***
MCI	88	73	***Yes***	82	81	*No*	81	79	*No*	81	80	*No*	88	84	*No*	77	60	***Yes***
PANAS-C																		
Positive Affect	15	18	*No*	8	11	*No*	14	17	*No*	19	17	*No*	13	8	*No*	12	17	*No*
PANAS-C																		
Negative Affect	23	10	***Yes***	20	13	*No*	10	13	*No*	9	7	*No*	16	6	*No*	8	9	*No*

*Change in unexpected direction.

Coaching Calls

Participants were scheduled to receive a weekly “coaching” call throughout their respective intervention phases. Table 8 depicts the number of coaching calls each participant completed. Reasons given for incompletion were illness (participant 3) and unavailability due to the Christmas holiday period (participants 1 & 6).

Table 8

Frequency of coaching calls per participant

Participant	No. of scheduled coaching calls	No. of coaching calls completed
1	3	2
2	5	5
3	4	3
4	4	4
5	4	4
6	3	2

Participants utilised the coaching calls in various ways. Participants 1, 2, 5 and 6 were keen to reflect on their weekly progress and were able to offer insight into how they felt they were progressing. Participant 3 was reluctant to speak on the phone and thus, the conversation took place via his mother. Participant 4 struggled to reflect on his own experience throughout the intervention process and instead the coaching calls served as a motivator for the coming week.

Adherence to Intervention

Because BiH provides a personalised ‘calendar’ for each user, usage of the app varied significantly depending on how frequently or infrequently participants felt they would require scheduled prompts and solutions throughout their respective

weeks. The researcher was able to monitor each participant's daily usage of the app which revealed that some participants were not accessing the app at their pre-scheduled times. This enabled discussion during the coaching calls around each participant's potential enablers and barriers in accessing BiH, and allowed the opportunity to explore motivation, and remind participants of their overall goals. Indeed, all participants reported that they valued the weekly coaching calls as it served as motivation for the coming week.

Participant Feedback

Informal feedback was gathered from participants and parents at the end of the intervention. All participants reported that BiH was easy for them to use and that the prompts provided by the app were sufficient in reminding them of their goals. Participants 1 and 2 expressed some frustration at not being able to access BiH during school hours, which they felt would have been helpful. Participants 1, 2, and 3 reported that the goal-setting sessions, alongside the app had been extremely useful in helping them to feel more confident in progressing towards their goals. Participant 6 noted that the intervention had been particularly helpful in helping her break down her goals into smaller steps but noted that she observed a dip in motivation each evening compared with mornings and afternoons. Participants 4 and 5 both reported that they found the goal-setting sessions helpful but felt the prompts on the app were inconvenient at times, if they were otherwise busy. All participants reported that it was difficult to adhere to BiH and the daily measures when unwell or experiencing external life stressors, such as exams. Parental feedback included a notable increase in their child's autonomy, as well as significant reductions in their anxiety levels. See Appendix M for a full overview of feedback responses.

Discussion

Using a SCED approach, the current study aimed to evaluate the effectiveness of a goal-setting intervention in young people with EDF. The first hypothesis, that the goal-setting sessions supported by the BiH app would improve participants' satisfaction with daily goal progress, was supported at a group level. This is broadly consistent with the literature suggesting that structured goal-setting can enable goal progress (e.g. MacLeod et al., 2008). The second hypothesis, that the goal-setting sessions supported by the BiH app would improve participants' "happiness" ratings, was not supported at a group level, with RTs failing to reach statistical significance. Two of the six participants demonstrated statistically reliable improvements in everyday functioning on the BRIEF-SR, partially supporting hypothesis three. Furthermore, two participants showed statistically reliable improvements on the BRIEF-PR, with one participant also demonstrating clinically meaningful changes. Hypothesis four, which proposed that participants would demonstrate statistically reliable improvements in overall well-being, as measured by the PANAS-C scale, was supported by participant 1, who demonstrated significant reductions in negative affect (NA) ratings.

Data from individual participants were promising with respect to goal progress and general improvements in EF abilities. Inspection of individual goal-progress satisfaction ratings was encouraging across all participants, except participant 2. The coaching calls, paired with clinical judgement, allowed the researcher to ascertain that anxiety stemming from external stressors was affecting his progress. Despite the non-significant findings, however, qualitative feedback was most positive from participant 2 and his mother, who both noted significant increases in his ability to manage his identified daily challenges.

Although the present study did not set out to improve EF directly, RCI calculations on the BRIEF scale indicate that the intervention is likely to have provided a scaffold on which individuals who struggle with EDF could function more effectively. Given the documented evidence of discrepancies between child- and parent-report outcome data (e.g., Patel, Lai, Goldfield, Sananes, & Longmuir, 2017), it is unsurprising that findings varied across the BRIEF-PR and BRIEF-SR, with parents reporting more symptoms of EDF than participants. Furthermore, of those who showed statistically significant improvements, parent-report demonstrated notably greater improvements than self-report. Given that children with EDF often have difficulties with insight, parents are likely to be more aware of impairments and consequently, any subtle improvements in such impairments. Interestingly, the participants who showed statistically reliable change on the BRIEF-PR were the two females of the sample, which raises the question, however tentatively, of possible gender differences in how the intervention was experienced.

Although only one participant demonstrated statistically reliable change on the PANAS-C NA scale, examination of the scaled scores revealed that participants 1, 2, 4 and 5 demonstrated marginal reductions in self-reported NA, post-intervention. Increases in PA were also reported by participants 1, 2, 3 and 6. Similarly, despite the non-significant group data findings in “happiness’ ratings, participants 1, 2, and 4 demonstrated moderate effect sizes between phases, indicating a potential benefit of the intervention on day-to-day affect. However, effect sizes were calculated using the imputed broadened medians to replace the missing data, and thus, must be cautiously inferred.

Participant 3 was the sole participant to demonstrate weak effect sizes in both daily measures across phases. Interestingly, he was the only participant who was

reluctant to engage in the weekly coaching calls, which lends to the possibility of the potential impact the calls held in engendering progress in other participants. It is also worth noting, however, that participant 3 was the youngest to take part at the age of 12, where higher-level EF skills are still in their early stages of development (Zelazo & Muller, 2002). Indeed, qualitative feedback from his mother indicated that the intervention would likely be of greater benefit to him when he is older. This thought was echoed by the parent of participant 4, who was of a similar age.

To the researcher's knowledge, this is the first study exploring a goal-setting intervention supported by assistive technology (AT) in young people with EDF. The multiple-baseline SCED enabled a combination of VAs, randomisation tests and effect size calculations to be completed, providing greater insight into individual differences that would not have been possible had a traditional randomised control trial approach been used. Furthermore, the administration of standardised pre- and post- outcome measures alongside the continual week-daily measures enabled an in-depth understanding of the day-to-day changes experienced by each participant throughout both phases.

A further strength of the study is that it facilitated young people in setting meaningful and personally relevant goals in a structured format, something they might otherwise have struggled with given their EDF. These goals were devised by the participants themselves, with a focus on their values and most pressing concerns, enhancing the ecological validity of the study.

Once set up on the app, all participants reported that BiH was easy to use, requiring minimal support from the researcher and allowing for an extended data collection period. Despite conducting weekly coaching calls with each participant,

however, the high number of missing data points indicates that participants might have benefited from further prompts (e.g. from a parent) to ensure greater adherence to the intervention.

The findings of the present study should be considered in light of its limitations. Firstly, as part of the screening process, participants needed to demonstrate a certain level of motivation to participate. Motivation is often an intrinsic difficulty for people with EDF (Anderson, 2002), and thus, this might limit the generalisability of the findings to wider EDF populations. Similarly, despite endeavouring to recruit participants who showed “traits” of EDF, all participants had clinical diagnoses of either ASD or ADHD, demonstrating significant difficulties across the board. Therefore, it must be acknowledged that some participants were already receiving varying levels of support, which might have contributed to their performance in the study.

Goals were not separately categorised as ‘approach’ or ‘avoidance’, limiting any exploration of the differentiated impact that goal-type might have had on affect. Furthermore, given the significant variability in each participant’s baseline phase, it was not possible to determine a stable level of the dependent variables (i.e. week-daily goal satisfaction and “happiness” ratings). It is plausible that this might be a direct consequence of what and how the researcher chose to continually measure. This particularly applies to the construct of “happiness”, which is highly subjective. Furthermore, neither daily measure controlled for extraneous variables, many of which (e.g., illnesses, exams) were reported by participants as having had a significant impact on their ratings.

Finally, there are some logistical concerns to consider in the study. To allow for simultaneous design analysis and thus, increase external validity (Onghena & Edgington, 2005), the final participant needed to begin their baseline phase before the first participant had completed their intervention phase. Although this was successfully achieved, it meant that the data collection period was not always practical for each young person, with two participants' intervention phases concluding over the Christmas period. This is likely to have compromised the amount of missing data and possibly introduced more noise to the data.

Clinical Implications

The findings can inform interventions aiming to improve EF abilities in adolescents with EDF. In line with Carr et al. (2014), the goal-setting intervention holds potential in improving awareness, task performance, fulfilment and independent functioning in young people with EDF. A high prevalence of mainstream students possess neurodevelopmental condition traits but do not have clinical diagnoses (e.g., Alloway, Elliott, & Holmes, 2010; Baron-Cohen et al., 2009). Therefore, children should be routinely assessed for EDF during therapeutic and/or educational assessments, given that such impairments are likely to affect their need for support around goal progress, as well as their engagement in treatment and/or education. Furthermore, evidence of EDF-prevalence is needed to inform policy change and commissioning in treating EDF. In terms of service delivery, given the suggestion that an interaction might exist between one's age and motivation, clinicians might benefit from greater parent-involvement with younger children. Indeed, goal-setting interventions can sometimes highlight personal difficulties for children, and thus, parent-support would be crucial in helping them make sense of this new awareness.

Participant-feedback reported that the use of AT was helpful in providing a scaffold on which to focus. Training clinicians in the application of AT could potentially see far-reaching benefits for children who might otherwise struggle with traditional therapeutic approaches. Given the cost incurred with technology, where AT is not accessible similar approaches could be incorporated into clinical practice, e.g., eliciting valued goals, providing structured timetables, pre-empting potential challenges and solutions, and having parents/teachers provide prompts. AT research in EDF populations is still in its infancy and further exploration is needed before being confidently able to advise clinicians.

Theoretical Implications

The results partly support Carver and Scheier's (1990; 2012) model of behavioural self-regulation, in that structured goal-setting enabled individuals to progress towards their valued goals. The goal-setting session alongside BiH provided a framework on which the goal hierarchy could be targeted in a structured way. They mirrored the feedback loops described in Carver and Scheier's model with goal-setting sessions enabling young people to identify discrepancies between where they are and where they would like to be, with respect to valued goals. This supported the applicability of these elements of the model in an EDF population with ASD/ADHD diagnoses. The model describes a distinction between the effects both approach and avoidance goal progress can have on well-being. Given that goals were not categorised by type in the present study, the extent to which such effects could be explored was limited.

For the most part, evidence did not find that goal progress engendered well-being in this population.

Future Research

This is the first study to examine a goal-setting intervention supported by AT in this population, therefore, it would be important to replicate such an intervention with other individuals with EDF to increase generalisability. Given parent-feedback regarding age, it might be beneficial to target individuals in their mid-late teens. Greater parental involvement might prove useful in encouraging motivation in participants, as well as enabling greater insight into interactions between personal and environmental factors that might be affecting a young person's performance. In light of the current findings, it would be interesting to explore whether gender differences exist regarding how the intervention is experienced. Drawing on the relevant literature (e.g., Prevatt et al., 2017), a greater focus on building motivation should be embedded into the coaching element of the study. Categorising goals into "approach" versus "avoidance" would also enable more in-depth analyses and further exploration of Carver and Scheier's (1990; 2012) model.

Finally, the data collection period ran into the Christmas holidays, and thus, it is likely that noise was introduced to the data. Future research would benefit from undertaking the study over a longer period where such factors could be accounted for and controlled.

Conclusion

The present study endeavoured to evaluate the effectiveness of a goal-setting intervention supported by BiH, on goal progress and overall well-being in young people with EDF. Using structured goal-setting, participants came up with valued goals towards which to progress. Over a seven-week period, they were required to rate their goal progress satisfaction and "happiness" levels, five days a week.

Results revealed that five of the six participants demonstrated increases in their goal progress satisfaction levels between baseline and intervention phases. No statistically significant changes were observed in participants' "happiness" ratings. There are a number of plausible explanations for the non-significant findings, most pertinently, the inability to control for extraneous variables that are likely to have affected participants' subjective daily "happiness" ratings. Future research might benefit from targeting a marginally older population, as well as taking place over an extended period. Structured goal-setting supported by the BiH app has the potential to aid young people with EDF progress towards their goals.

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Appendices

Appendix A

11 possible moments of phase change for a participant as part of AB multiple baseline SCED.

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Appendix B

Ethics Documentation

Dear Seona Granville,

Application ID:	**eCLESPsy000808 v4.1**
Title:	**Evaluating a goal setting intervention supported by a smartphone app with adolescents with executive dysfunction.**

Your e-Ethics application has been reviewed by the CLES Psychology Ethics Committee.

The outcome of the decision is: **Favourable**

Potential Outcomes

Favourable:	The application has been granted ethical approval by the Committee. The application will be flagged as Closed in the system. To view it again, please select the tick box: View completed
Favourable, with conditions:	The application has been granted ethical approval by the Committee **conditional** on certain conditions being met, as detailed below. Unless stated otherwise, **please resubmit the requested amendments** via the online system before beginning the research.
Provisional:	You have **not** been granted ethical approval. The application needs to be amended in light of the Committee's comments and re-submitted for Ethical review.
Unfavourable:	You have **not** been granted ethical approval. The application has been **rejected** by the Committee. The application needs to be amended in light of the Committee's comments and resubmitted / or you need to complete a new application.

Please view your application here and respond to comments as required. You can download your outcome letter by clicking on the 'PDF' button on your eEthics Dashboard.
If you have any queries please contact the CLES Psychology Ethics Chair:
Nick Moberly n.j.moberly@exeter.ac.uk

Kind regards,
CLES Psychology Ethics

Appendix C

Participant Information Sheet

Participant Information Sheet
Child and Young Person

Evaluating a goal setting intervention supported by a smartphone app with adolescents with traits of executive dysfunction.

Researcher name: Seona Granville, University of Exeter
Research Supervisors: Dr Jenny Limond and Dr Nick Moberly, University of Exeter

We would like to invite you to take part in our research study. It is really important that we give you all of the information you need to know about the study, before you say 'yes' or 'no'. If you like, you can talk about this information with someone else, like your parents or your teacher. You can also ask us for more information at any time. Our email addresses are at the end of this document.

What is the study about?
Some young people experience difficulties such as preparing for the school day or finding homework a bit stressful. The study aims to help young people work towards goals they would like to achieve by helping them to manage such difficulties. The researcher will help young people to break down their goals into small steps and think of ways you can progress towards them. A smartphone app has been developed which may help you to progress towards your goals. The app can be used to help you plan and work towards your goals, whilst keeping track of your progress and mood. At the end of the study, you will be able to see whether or not the goal-setting session and app helped with your progress or improved your overall mood.

Why am I being asked to take part?
We would like you to take part in this study because you are a young person between the ages of 12 and 18. The researcher is interested in evaluating a goal-planning intervention using a smartphone app designed to help young people plan and progress towards their goals.

Do I have to?
No, you do not have to take part if you do not want to. It is up to you and your parents. You can say yes or no.

What will happen in the study if I say yes?

If you say yes, we will send a questionnaire to your parents, which will be used to see if you are eligible for the study. If you are, the researcher will meet with you to show you how to use the app on your own smartphone or tablet. With the researcher's help, you will be asked to come up with a number of goals you would like to work toward. The researcher will then put these goals onto your app so that you can see them whenever you like. Every school day your phone will notify you with a link to rate how satisfied you are with your goal progress. You will also be asked to rate your overall mood.

After a few weeks, the researcher will help you think of small steps that might make it easier to reach your goals. You will also think about problems that might be making your goals harder to reach and together we can think of ways of overcoming these problems. These small steps and solutions will then be added to your app and will be there to remind you of your goals and to help you in reaching them.

The researcher will phone/Skype you for a quick check-in every week, to help keep you motivated and ensure you are finding the study okay. Your parents can join this conversation, if you would like them to. You will continue to rate your goal progress and mood on a daily basis. At the end of the study, you will be able to see if the goal-planning sessions supported by the app helped you to progress towards your goals or if they helped you feel a little more positive.

What is good about taking part?

You would be helping us to understand whether or not the goal-setting sessions and the app are effective in helping young people progress towards their goals. Other benefits of taking part in the study include developing some skills towards setting and progressing towards your goals. You will also be given the choice of continuing to use the app on your own device once the study has ended.

You will also receive a £20 Amazon voucher for taking part. If you choose to leave the study at any stage, you will still receive the Amazon voucher.

What is bad about taking part?

One possible bad thing about taking part is that thinking about some of your difficulties might make you feel upset. The researcher will check-in with you regularly to make sure you are okay and will be able to direct you to services that could support you, if needed. If you want to stop the study at any point, that is no problem at all.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point, without having to give a reason. This will not affect your rights or your time at school in any way. All of your information will remain fully confidential.

If you do wish to remove your data from the study, you can email the researcher at any stage until the end of the study (February 2020); after this time, the electronic

consent forms will be destroyed and so it will not be possible to identify which information is yours.

Risk and Confidentiality

We may have to break confidentiality if you say something that worries us. We will follow risk procedures and might have to tell someone else, such as your parents, what you have said to keep you safe. If we do this, we will talk to you first and provide you with support around getting help. You will be reminded of this when you first meet the researcher.

Will information be kept private?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

The company behind the assistive technology app is committed to protecting and respecting your privacy. Please visit the following website for a comprehensive overview of how your data will be stored: https://braininhand.co.uk/privacy-policy/

Each participant will be allocated an identification number to record their smartphone app data. These data will be stored on a university secure server computer which will be password-protected. Consent forms will be scanned, electronically stored and then shredded. Each form will be assigned the associated identification number in order to allow participants to withdraw throughout the study, if needed; however, all forms will be stored removed from any other identifiable information. Participants will only be identifiable by this number, which will be accessible only by the researcher and relevant members of app team. The electronic consent forms will be destroyed at the end of the study. Any anonymised data can be stored for up to five years before being destroyed.

All of your data will remain fully confidential. Should you indicate any risk to yourself or to others, the researcher may have a duty of care to breach confidentiality.

Thank you for reading!

Further information and contact details

If you would like further information regarding this study or would like to take part, please contact the researcher or research supervisor on the below details.

Seona Granville, Researcher
Sg601@exeter.ac.uk

Dr Jenny Limond, Project Supervisor
J.Limond@exeter.ac.uk

or

Dr Nick Moberly, Project Supervisor
N.J.Moberly@exeter.ac.uk

If you are not happy with any aspect of the project and wish to complain, you can contact the Researcher's University based tutor, or the University of Exeter's Research Ethics and Governance Manager.

Gail Seymour, Research Ethics and Governance Manager
g.m.seymour@exeter.ac.uk, 01392 726621

Thank you for your interest in this project.

Appendix D

Parent Information Sheet

Parent Information Sheet

Title of Project: Evaluating a goal setting and planning intervention supported by a smartphone app with adolescents with traits of executive dysfunction.

Researcher name: Seona Granville, University of Exeter
Research Supervisors: Dr Jenny Limond and Dr Nick Moberly, University of Exeter

Invitation and brief summary:
Your child is invited to take part in this study because they are a young person between the ages of 12 and 18. The researcher is interested in evaluating a goal planning intervention supported by an assistive technology app designed to help young people plan and progress towards their goals.

Purpose of the research:
Some young people experience difficulties such as difficulties with planning, decision-making, inhibition or problem-solving. If your child is found to have such difficulties, the present study aims to help them work towards goals they would like to achieve by helping them manage such difficulties. The researcher will help your child break down their goals into small achievable steps and help them think of ways they can progress towards them. An 'assistive technology' smartphone app has been developed which may help young people progress towards their goals. The present study will use this app to help your child plan and work towards their goals, whilst monitoring their progress and mood. At the end of the study, they will be able to see whether or not the goal-planning intervention supported by the app helped with their progress or improved their overall mood.

What would taking part involve?
The researcher will meet with your child to train them in using the app on their smartphone or table. This should take no longer than 1-2 hours. With the help of the researcher, your child will be asked to come up with a number of goals they would like to work towards relating to school, for instance preparing their belongings for the day ahead, or completing homework tasks. The researcher will then input these goals onto their app. Each school day they will be asked to rate how satisfied they are with their goal progress and their overall wellbeing. After a few weeks, your child will spend time with the researcher thinking about small achievable steps that might help them in reaching their goals. They will also think about problems that they might encounter and can think of ways of overcoming these problems. These small steps and solutions will then be added to your child's app and will be there to remind them of their goals

and to help them in reaching them. During this stage, the researcher will speak with your child weekly by phone/skype to encourage motivation and ensure they are finding the study okay. As their parent, you are invited to be present for these conversations, if your child wishes. Your child will continue to monitor their goal progress and mood on a daily basis. At the end of the study, they will be able to see if the goal-planning sessions and assistive technology helped them to progress towards their goals or if it improved their overall mood.

What are the possible benefits of taking part?
If you choose for your child to take part, they would be contributing to research around whether or not the app is effective in helping young people progress towards their goals. Other benefits of taking part in the study include developing some skills towards setting and progressing towards their goals. Each participant will also be given the choice of continuing to avail of the assistive technology on their own device once the study has ended, free of charge.

Will my child receive any payment for taking part?
Yes, each participant will receive a £20 Amazon voucher for taking part. If your child chooses to leave the study at any stage, they will still be eligible for the Amazon voucher.

What are the possible disadvantages and risks of taking part?
The researcher does not believe that taking part in the research has any foreseeable risks to participants. Because your child will be thinking about some difficulties they might have in reaching their goals, they might experience some anxiety. The researcher will check-in regularly with your child and respond appropriately, including signposting them to sources of support, if needed. They will be reminded that they are free to withdraw at any stage of the study, should they become dissatisfied with the study for any reason. There are no known risks of the app in terms of any electronic viruses.

Throughout the study, your child will be asked to complete some measures, looking at their mood and executive function abilities (e.g. planning or problem-solving abilities). If these measures show that they are experiencing significant difficulties, the researcher will discuss this with you and might recommend that you speak with your child's GP. With your consent, the researcher can contact their GP outlining the concerns.

We may have to break confidentiality if your child says something that worries us. We will follow some of the risk procedures outlined in the Exeter Mood Disorder Centre risk protocol, and will liaise with you in order to ensure they are safe. If necessary, we will contact the emergency services. If we do this, we will talk to your child first and ensure they feel supported in getting help.

What will happen if my child does not want to carry on with the study?
Your child can withdraw from the study at any point, without having to give a reason. This will not affect their rights or their time at school in any way. All of their data will remain fully confidential.

If your child wishes to withdraw their data throughout the study, this can be arranged by emailing me at any stage until the end of the study (February 2020); after this time, the electronic consent forms will be destroyed and so it will not be possible to identify participants for deletion.

How will my child's information be kept confidential?
The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your child's personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your child's personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

The assistive technology app is committed to protecting and respecting your privacy. Please visit the following website for a comprehensive overview of how your data will be stored. https://braininhand.co.uk/privacy-policy/

Each participant will be allocated an identification number to record their smartphone app data. These data will be stored on a university secure server computer which will be password-protected. Consent forms will be scanned, electronically stored and then shredded. Each form will be assigned the associated identification number in order to allow participants to withdraw throughout the study, if needed; however, all forms will be stored removed from any other identifiable information. Participants will only be identifiable by this number, which will be accessible only by the researcher and relevant members of the app team. The electronic consent forms will be destroyed at the end of the study, whilst the anonymised data can be stored for up to five years before being destroyed.

All of your child's data will remain fully confidential. Should your child indicate any risk to yourself or to others, the researcher may have a duty of care to breach confidentiality.

What will happen to the results of this study?
The results of this study will form part of a report submitted to the University of Exeter as part of the researcher's Doctorate in Clinical Psychology. The results might also be included in an academic article submitted for publication, and to the team behind the assistive technology; however no participant information will be identifiable. If you would like an additional copy of the report or results, please contact the researcher who will be able to provide these after September 2020.

Who has reviewed this study?
This project has been reviewed by the Research Ethics Committee at the University of Exeter (Reference Number eCLESPsy000808 v4.1).

Further information and contact details
If you would like further information regarding this study or would like to take part, please contact the researcher or research supervisor on the below details.

Seona Granville, Researcher
Sg601@exeter.ac.uk

Dr Jenny Limond, Project Supervisor or Dr Nick Moberly, Project Supervisor
J.Limond@exeter.ac.uk N.J.Moberly@exeter.ac.uk

If you are not happy with any aspect of the project and wish to complain, you can contact the Researcher's University based tutor, or the University of Exeter's Research Ethics and Governance Manager. Gail Seymour, Research Ethics and Governance Manager
g.m.seymour@exeter.ac.uk, 01392 726621
Thank you for your interest in this project.

Appendix E

Consent Form

Participant Identification Number:

PARENT CONSENT FORM

Title of Project: **Evaluating a goal setting intervention supported by a smartphone app with adolescents with traits of executive dysfunction.**

Name of Researcher: Seona Granville

Name of Child: _____

1. I confirm that I have read the information sheet dated 05/08/19 (version 3.0) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my child's participation is voluntary and that they are free to withdraw at any time without giving any reason and without their legal rights being affected. ☐
3. I understand that relevant sections of the data collected during the study may be looked at by members of the research team and individuals from the University of Exeter and the team behind the app, where it is relevant to my child's taking part in this research. I give permission for these individuals to have access to my child's relevant records. ☐
4. I understand that my child's taking part involves collecting data via a smartphone app. This data will be identifiable by an identification number, which will be stored separately from any other identifiable information. I understand that all data will remain confidential to be used for the purposes of a report published in an academic publication. ☐
5. I understand that my child's data will be stored securely for a period of up to 5 years. ☐
6. I understand that my signed consent form and my child's signed assent form will be securely stored separately from any other data. ☐
7. I understand that the researcher may wish to contact my child's GP, with my consent. ☐
8. I agree for my child to take part in the above project. ☐

If you are happy for your child to participate, please sign below.

Name of Parent (print)	Date	Signature

Contact number: _____

Child's phone/Skype details (for weekly check-in): _____

Child's GP contact details (optional): _____

Name of **researcher**	Date	Signature

Appendix F

Assent Form

Participant Identification Number:

PARTICIPANT ASSENT FORM

Title of Project: **Evaluating a goal setting intervention supported by a smartphone app with adolescents with traits of executive dysfunction.**

Name of Researcher: Seona Granville

Please circle **yes** or **no** to the following questions:

1. Do you understand what the project is about? **YES / NO**

2. Have you asked all the questions you want to ask? **YES / NO**

3. Have you had your questions answered in a way that you understand? **YES/NO**
4. Do you understand that you can stop taking part at any time, without giving a reason? **YES / NO**
5. Are you happy to take part? **YES / NO**

If *any* answers are 'no' or if you do not want to take part, please do not sign your name.

If you **do** want to take part, please write your name below.

Your name: _____

Date: _____

Name of researcher _____

Date _____

Signature _____

Appendix G

PANAS-C Scale

Feelings and Emotions (PANAS-C)

This scale consists of a number of words that describe different feelings and emotions. Read each item and then ***tick*** the appropriate box next to that word.

Indicate to what extent you have felt this way during the past few weeks.

Feeling or Emotion	**Very slightly or not at all**	**A little**	**Moderately**	**Quite a bit**	**Extremely**
Happy					
Scared					
Sad					
Proud					
Mad					
Lively					
Miserable					
Joyful					
Afraid					
Cheerful					

Appendix H

Examples of participants' goals

- "I want to learn how to manage my anxiety better."
- "I want to be able to attend lessons without feeling overwhelmed."
- "I want to leave the house on time for school every morning."
- "I want to be able to make my own lunch and pack my schoolbag by myself."
- "I want to attempt my homework every night."
- "I want to feel more confident getting the bus by myself."
- "I want to feel less anxious about leaving the house".

Appendix I

Brain in Hand Workbook

Your skills, values and successes

What are some of the things you value most about yourself? These could be skills, personal strengths, or achievements. Take a look at the examples below and see if you can come up with some of your own:

Example: "I am good at listening to other people"

Example: "I really value being a good friend"

Example: "I am reliable: if I say I'm going to do something, then

Example: "I am good at using technology, like mobile phones and a computer"

Strengths and difficulties

Please look at the areas of life below and decide whether it is something you are good at, something you find difficult, or if it is somewhere in between.

Area of life	Rate how you find this activity (please tick)			
	I find this difficult			I am good at this
	1	2	3	4
Travelling on public transport	☐	☐	☐	☐
Making and attending appointments	☐	☐	☐	☐
Daily routines	☐	☐	☐	☐
Self-care	☐	☐	☐	☐
Going shopping	☐	☐	☐	☐
Meeting new people	☐	☐	☐	☐
Going to social events	☐	☐	☐	☐
Relationships	☐	☐	☐	☐
Communicating with others	☐	☐	☐	☐
Managing stress and anxiety	☐	☐	☐	☐
Motivating myself	☐	☐	☐	☐
Managing my workload	☐	☐	☐	☐
Organising myself	☐	☐	☐	☐
Doing well in work or education	☐	☐	☐	☐
Remembering things	☐	☐	☐	☐
Add your own…	☐	☐	☐	☐
Add your own…	☐	☐	☐	☐
Add your own…	☐	☐	☐	☐

Managing difficultsituations

Choose one area of life from the previous page that is important to you but you find difficult. Below you can write about a situation in which you found this area of life difficult:

What have you done to cope with difficult situations like this in the past?	Was this helpful?	
	Yes	No
1.	☐	☐
2.	☐	☐
3.	☐	☐

You can use Brain in Hand to remind yourself of the helpful things to do in difficult situations, and avoid unhelpful things you have done in the past.

Your goals with Brain in Hand

Now that you have some ideas for situations when you might use Brain in Hand, write down some goals you would like Brain in Hand to help you achieve. For example, this might be starting a new activity, growing in confidence, or managing anger or worries.

Goal	How will you know when you have reached that goal?
Example: “I want to feel more confident when travelling”	Example: “I will be travelling to college on the bus on my own”
1.	
2.	
3.	

Planning Diaryevents

Does the difficult situation you listed on page 9 happen at a particular time of the day or the week? If it does, you might want to add it to your Brain in Hand Diary. If it doesn't, you might want to add it to the Unplanned page on page 19.

Here is an example:

Event	Travel to uni
Day & time	Weekdays at 8.30

Activities	Problems	Solutions
Leave the house	What do I need?	Bag, keys, phone, money
Catch the bus	The bus is late	Wait for 10 minutes for the next bus Check the bus timetable: www.bustimetable.co.uk
	Lots of people at the bus stop	Put my headphones in Do my breathing exercises

You can have as many problems or solutions as you like. The same solutions might also be useful for more than one problem.

Worksheet: Diaryevents

Think of your own Diary event and activities, with possible problems and solutions that might help.

Event	
Day & time	

Activities	Problems	Solutions

Finding solutions: Is there a time when you've coped with the problem in the past? What did you do that was different or helpful?

Unplanned events

Unplanned events can be used for problems that might happen unexpectedly, or worries and anxieties that might crop up at any time. For example, this might be crowds, unexpected changes, or forgetting things.

Here are some examples:

Unplanned event	Problems	Solutions
Feeling anxious	Feeling anxious in a crowd	Do my breathing exercises Put headphones in Find somewhere quiet to sit
	Anxious about my workload	Prioritise tasks Take a 5 minute break

Unplanned event	Problems	Solutions
Lost and forgotten things	I've lost my wallet	Don't worry, check my bag Think about where I last had it Check my pockets
	I've lost my keys	Don't worry, check my bag Think about where I last had it Check my pockets Check with my housemates

Unplanned events

You can also use your Unplanned page for events that might happen at any time rather than according to a schedule. For example, this might be free time, going to the shops or being home alone. You might want to break these events down into activities and add problems and solutions to each activity.

Here are some examples:

Unplanned event	Activities	Problems	Solutions
Home alone	Free time	What to do?	Have I done exercise today? Walk the dog Watch an episode of my favourite show

Unplanned event	Activities	Problems	Solutions
Shopping	In the shop	Too much noise	Put headphones in Step outside for 5 minutes Look at my list and get my shopping done quickly
		Anxious about paying	Have my money ready Smile and remember to say “thank you”

Worksheet: Unplanned events

Think about some of the problems that worry you that could happen at any time. Use your answers to the questions on pages 8 and 9 to help you. Use the table below if you would like to add problems to your Unplanned event:

Unplanned event	Problems	Solutions

Use the table below if you would like to add activities (with problems and solutions) to your Unplanned event:

Unplanned event	Activities	Problems	Solutions

Finding solutions: Is there a time when you've coped with the problem in the past? What did you do that was different or helpful?

Appendix J

Reliable Change Index data for each participant on BRIEF parent-report measure

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
BRI* Reliability Coefficient	.94	.94	.94	.94	.94	.94
Standard deviation	9.45	8.92	8.86	8.86	8.92	9.45
Mean	40.32	37.32	40.12	40.12	37.32	40.32
Reliable Change Index	**6.42**	**6.06**	**6.02**	**6.02**	**6.06**	**6.42**
MCI** Reliability Coefficient	.96	.96	.96	.96	.96	.96
Standard deviation	14.77	17.31	18.05	18.05	17.31	14.77
Mean	65.46	68.04	73.02	73.02	68.04	65.46
Reliable Change Index	**8.19**	**9.60**	**10.01**	**10.01**	**9.60**	**8.19**
GEC*** Reliability Coefficient	.97	.97	.97	.97	.97	.97
Standard deviation	23.07	23.79	24.34	24.34	23.79	23.07
Mean	106.56	105.22	113.36	113.36	105.22	106.56
Reliable Change Index	**11.08**	**11.42**	**11.69**	**11.69**	**11.42**	**11.08**

*BRI: Behavioural Regulation Index

**MCI: Meta-Cognition Index

***GEC: General Executive Composite

Appendix K

Reliable Change Index data for each participant on BRIEF self-report measure

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
BRI* Reliability Coefficient	.93	.93	.93	.93	.93	.93
Standard deviation	10.19	9.95	9.95	9.95	9.95	9.95
Mean	49.49	51.67	51.67	51.67	51.67	51.67
Reliable Change Index	**7.47**	**7.30**	**7.30**	**7.30**	**7.30**	**7.30**
MCI** Reliability Coefficient	.95	.95	.95	.95	.95	.95
Standard deviation	11.27	8.89	8.89	8.89	8.89	8.89
Mean	50.09	48.54	48.54	48.54	48.54	48.54
Reliable Change Index	**6.99**	**5.51**	**5.51**	**5.51**	**5.51**	**5.51**
GEC*** Reliability Coefficient	.96	.96	.96	.96	.96	.96
Standard deviation	10.85	9.49	9.49	9.49	9.49	9.49
Mean	49.76	49.89	49.89	49.89	49.89	49.89
Reliable Change Index	**6.01**	**5.26**	**5.26**	**5.26**	**5.26**	**5.26**

*BRI: Behavioural Regulation Index

**MCI: Meta-Cognition Index

***GEC: General Executive Composite

Appendix L

Raw scores and RCI findings of PANAS-C pre-baseline and post baseline

	Participant 1			**Participant 2**			**Participant 3**			**Participant 4**			**Participant 5**			**Participant 6**		
Measure	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?	Pre	Post	Is there reliable change?
PANAS-C Positive Affect (*pre-baseline – post-baseline*)	15	15	*No*	8	9	*No*	15	16	*No*	19	17	*No*	13	6	*No*	12	15	*No*
PANAS-C Negative Affect (*pre-baseline – post-baseline*)	23	11	*No*	20	16	*No*	10	11	*No*	9	9	*No*	16	16	*No*	8	10	*No*

Appendix M

Feedback on using Brain in Hand

1. *Was Brain in Hand easy for you to use?*
    - Yes, very easy.
    - Yes, it helped with things that usually are muddled in my head.
    - Yes, although sometimes my notifications did not work (*phone issue unrelated to app).
    - Yes, very straightforward.
    - Yeah it was really easy.
    - Yes, it was really user-friendly.

2. *Were you able to use it whenever you needed to?*
    - Yes, but some days it was not relevant and other days I needed it lots.
    - I could not use it at school except at break-times.
    - Yes, except if I forgot to bring my phone with me somewhere.
    - Yes, whenever I needed to.
    - Yes.
    - Yes.

3. *Did you require any further prompts to use Brain in Hand? (E.g. from your mum or teacher?)*
    - No, the prompts always showed and stayed on my phone until I opened them.

- At the beginning, I sometimes forgot, but after about a week, it became habit and no one needed to remind me.
- Sometimes if I did not have my phone on loud, Mum would ask if I had checked the app.
- No, the prompts on the app were enough. If I were busy, I would return to them later.
- Only if I did not have my phone on me.
- The app prompts were enough.

4. *Did you find Brain in Hand useful?*
    - Yes, it helped when I was feeling anxious because it reminded me of my distractions.
    - (Participant) *Really* helpful. It helps me feel less anxious. (*Parent response*): He has a lot more autonomy and independence and is significantly less anxious. BiH provided him with a structured framework on which he can focus. Really pleased with the app.
    - Yes, the reminders were helpful and reminded me what I needed to do, when.
    - Yes but I am really busy with exams at the moment so sometimes I didn't have time to use it.
    - It was helpful but I am not sure how it is all that different to other diary apps.

5. Yes but I was better at using it in the mornings because I am always tired in the evening and have no motivation. *If you could change anything about Brain in Hand, what would it be?*
    - It would be helpful to be able to view the full calendar of the month on the app.
    - Nothing.
    - *Mum:* It is very useful for awareness and thinking about how to make things more habitual. The goal-setting sessions were extremely helpful in thinking about difficult things more positively, which helped to encourage him. I can see how helpful it will be as he gets older*. It is good now but I think he still needs my help *(*this was the youngest participant, aged 12).*
    - Being able to set alarms would be good to make the prompts louder.
    - A tick/check box on the notification without always having to open the app would be helpful.
    - It would be good to be able to see your overall calendar on the app rather than just going to each day.

Appendix N

Statement of dissemination and Instructions for Author

Statement of dissemination

The aim is for this empirical paper to be disseminated via publication in the Journal of Autism and Developmental Disorders (JAAD). Participants will also be offered a summary of results. Findings will be shared with the Brain in Hand Ltd. team. See below for instructions for authors, retrieved from the JAAD website.

Instructions for Authors

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Author Note

The first paragraph contains a separate phrase for each author's name and the affiliations of the authors at the time of the study (include region and country).

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presentation of a version of the paper at a meeting, or its preparation from a doctoral dissertation, or the fact that it is based on an earlier study.

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References

Citation

Cite references in the text by name and year in parentheses. Some examples:

- Negotiation research spans many disciplines (Thompson 1990).
- This result was later contradicted by Becker and Seligman (1996).

- This effect has been widely studied (Abbott 1991; Barakat et al. 1995; Kelso and Smith 1998; Medvec et al. 1999).

Ideally, the names of six authors should be given before et al. (assuming there are six or more), but names will not be deleted if more than six have been provided.

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Journal names and book titles should be *italicized*.

Journal article Harris, M., Karper, E., Stacks, G., Hoffman, D., DeNiro, R., Cruz, P., et al. (2001). Writing labs and the Hollywood connection. *Journal of Film Writing*, 44(3), 213–245.

Article by DOI Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. *Journal of Molecular Medicine*, https://doi.org/10.1007/s001090000086

Book Calfee, R. C., & Valencia, R. R. (1991). *APA guide to preparing manuscripts for journal publication.* Washington, DC: American Psychological Association.

Book chapter O'Neil, J. M., & Egan, J. (1992). Men's and women's gender role journeys: Metaphor for healing, transition, and transformation. In B. R. Wainrib (Ed.), *Gender issues across the life cycle* (pp. 107–123). New York: Springer.

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