
# A Feasibility Randomised Controlled Trial of a Brief Early Intervention for Adolescent Depression that Targets Emotional Mental Images and Memory Specificity (IMAGINE trial)

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**Author contributions**

VP: Conceptualisation, Methodology, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – Review & Editing, Visualisation, Supervision, Project administration, Funding acquisition. PS: Conceptualisation, Methodology, Writing – Review & Editing, Supervision. ML: Methodology, Writing – Review & Editing. AO: Investigation, Data curation, Writing – Review & Editing. EB: Investigation, Data curation, Writing – Review & Editing. SB: Methodology, Writing – Review & Editing. RMS: Methodology, Writing – Review & Editing. DS: Methodology, Formal analysis, Resources, Writing – Review & Editing. BD: Conceptualisation, Methodology, Writing – Review & Editing. EH: Conceptualisation, resources, Writing – Review & Editing. JL: Conceptualisation, Methodology, Resources, Writing – Review & Editing, Supervision, Project administration.

# A Feasibility Randomised Controlled Trial of a Brief Early Intervention for Adolescent Depression that Targets Emotional Mental Images and Memory Specificity (IMAGINE trial)

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## Abstract

Brief, evidence-based interventions for adolescent depression are urgently required, particularly for school-settings. Cognitive mechanisms research suggests dysfunctional mental imagery and overgeneral memory could be promising targets to improve mood. This feasibility randomised controlled trial with parallel symptomatic groups (n=56) compared a novel imagery-based cognitive behavioural intervention (ICBI) to non-directive supportive therapy (NDST) in school settings. Blind assessments (of clinical symptoms and cognitive mechanisms) took place pre-intervention, post-intervention and follow-up three months later. The trial aimed to evaluate the feasibility and acceptability of the methodology and interventions, and estimate the likely range of effects of the intervention on self-reported depression. The pre-defined criteria for proceeding to a definitive RCT were met: full recruitment occurred within eleven months; retention was 89%; ICBI acceptability was above satisfactory; and no harm was indicated. Intention-to-treat analysis found large effects in favour of ICBI (relative to NDST) at post-intervention in reducing depressive symptoms (d=-1.34, 95% CI [-1.87, -0.80]) and improving memory specificity (d=0.79 [0.35, 1.23]), a key cognitive target. The findings suggest that ICBI may not only improve mood but also strengthen abilities associated with imagining and planning the future, critical skills at this life stage. A fully powered evaluation of ICBI is warranted.

**Trial Registration:** https://www.isrctn.com/; ISRCTN85369879


**Keywords:** Depression; Adolescence; Mental imagery; Imagery rescripting; Autobiographical memory; Memory specificity training

## Introduction

Gold-standard interventions for adolescent depression are difficult to access and expensive, requiring experienced therapists and several months of one-to-one sessions (National Institute for Health and Care Excellence, 2019; Pile, Shammas, & Smith, 2019). When depression begins in adolescence, rather than adulthood, it is associated with more recurrences and an increased risk of chronicity (de Girolamo, Dagani, Purcell, Cocchi, & McGorry, 2012; Richards, 2011). The long-lasting and severe outcomes associated with adolescent depression might be prevented through early intervention (de Girolamo et al., 2012), i.e. targeting symptoms of depression in young people at an early stage of the care pathway. Yet, as many as 75% of young people with depression do not receive an intervention (Pile et al., 2019). Short duration interventions that can be readily and widely deployed are essential to address poor access; schools have been identified as central in efforts to prevent problems deteriorating (Secretary of State for Health and Secretary of State for Education, 2017). Furthermore, evidence-based psychotherapies for youth only show a modest advantage over usual care (Weisz et al., 2013) and a recent large-scale trial indicated that currently recommended intensive psychological interventions (cognitive behavioural therapy and short-term psychoanalytical psychotherapy) are not more effective than a psychosocial intervention (Goodyer et al., 2016). There are two explanations for this finding, both of which we aim to address. The first is that all psychological interventions target common factors, this would mean that intervention development should focus on making interventions briefer and easier to deploy/administer by non-specialists. The second explanation is that that these interventions may not successfully target differential and/or specific mechanisms that lead to depression. Basic science improves our understanding about the underlying cognitive mechanisms that drive and maintain depression (Holmes et al.,

2018). Translating this knowledge into clinical interventions offers promise to reduce depression more effectively (Dunn, Mahen, Wright, & Brown, 2019). Here, we evaluate in a feasibility randomised controlled trial (RCT), a novel and brief early intervention for adolescent depression that targets specific mechanisms.

There is evidence that dysfunctional mental imagery (of the past and future) and maladaptive autobiographical memory processes are associated with depression across the age range (Dalgleish & Werner-Seidler, 2014; Holmes, Blackwell, Burnett Heyes, Renner, & Raes, 2016; Hitchcock, Nixon, & Weber, 2014; Pile & Lau, 2018). Adolescence is a key period to target these processes, given that depressive symptoms commonly begin in adolescence, cognitive factors are likely to stabilise during this time and adolescents may harness imagery techniques more readily than verbal approaches (Burnett Heyes, Lau, & Holmes, 2013).

Mental imagery is similar to a weak form of sensory perception and occurs when perceptual information is accessed from memory (Kosslyn, Ganis, & Thompson, 2001; Pearson, Naselaris, Holmes, & Kosslyn, 2015). Being able to imagine clearly is important for a variety of skills, including planning and goal-setting (Pearson et al., 2015). Unhelpful mental imagery, in particular distressing intrusive negative memories and the absence of positive future images, is implicated in depression (Holmes et al., 2016). Intrusive negative images are very common in depression (44-87% prevalence) and associated with severity across the age range (Meiser-Stedman, Dalgleish, Yule, & Smith, 2012; Williams & Moulds, 2007; Williams et al., 2007). Imagery rescripting (IR) for negative intrusive images has been applied to adults with depression with promising results (Brewin et al., 2009; Wheatley et al., 2007) and a meta-analysis indicates good effect sizes of using imagery rescripting across disorders (Morina, Lancee, & Arntz, 2017). In addition, vividness of positive future imagery is inversely associated with depression in youth (Pile & Lau, 2018). Experimental evidence

suggests that the generation of positive images can increase positive affect and reduce negative interpretation bias in adolescents (Burnett Heyes et al., 2017) and studies targeting positive imagery in depressed adults show promise for reducing depressive symptoms (Ekkers et al., 2011; Korrelboom, Maarsingh, & Huijbrechts, 2012; Torkan et al., 2014). Furthermore, a recent study investigated future specificity training (enhanced with mental imagery) in unselected adults (Hallford et al., 2020). The intervention improved ability to mentally simulate specific episodic future thinking, as well as mental imagery and pleasure, relative to a waitlist control.

Autobiographical memory is important for the individual's sense of self and ability to generate images of future events (Williams et al., 1996). Adolescence is a period in which self-concept develops and begins to consolidate (Conway & Pleydell-Pearce, 2000; Kuyken & Dalgleish, 2011) and depression is associated with having reduced self-concept clarity (Chang, 2001). Overgeneral memory (OGM) is a phenomenon where individuals have difficulty retrieving specific autobiographical memories (unique events, occurring at a particular time and place) and instead generate repeated events (categorical memories) or events that last longer than a day (extended memories) (Williams et al., 2007). Increased OGM has been consistently implicated in youth depression, being not only associated with current symptoms but also with the onset, maintenance and relapse of depression (Hitchcock et al., 2014; Warne, Caseras, & Rice, 2020). A recent meta-analysis indicated that, compared to control groups, memory specificity training (MEST, generating specific memories to cue words e.g. happy to increase memory specificity) can improve memory specificity, reduce depressive symptomatology, improve problem-solving abilities and reduce hopelessness (Barry, Sze, & Raes, 2019) however the benefit of MEST was mostly lost at follow-up. One suggestion to enhance MEST is by learning to hold specific memories alongside more general categories and flexibly shift between them (Hitchcock et al., 2018). This has

similarities with therapeutic techniques to generate an individual's values for living (i.e. general categories) and associating specific examples (i.e. memories) with them.

The novel intervention developed here (based on Holmes, Hales, Young, & Di Simplicio, 2019) combines techniques of imagery rescripting/generation and memory specificity training to target: (1) images of stressful negative events; (2) images of positive future events and (3) memory specificity. The intervention is brief (4 sessions), manualised and clearly structured which will facilitate future scalability through delivery by practitioners without extensive training. The methodology also incorporated technology to provide multiple measures of evaluating treatment outcomes and to deliver homework tasks. Delivering homework tasks via a mobile app could potentially enhance efficacy (without adding to face-to-face therapist time) and generalise intervention techniques outside of therapy.

Development of the experimental intervention has followed recommendations for the phase-based development of novel interventions (Campbell et al., 2000; Craig et al., 2008, 2013). An initial case series (Pile et al., 2020) with young people with depression demonstrated promising pre to post intervention effects in reducing depression (d = -1.32, 95% CI [-2.41, -0.22]; 67% showed reliable improvement) and improving memory specificity (d = -1.80, 95% CI [0.62, 2.98]; 67% showed reliable improvement) and allowed refinement of the intervention and methodology. As the case series demonstrated preliminary proof of concept (Pile et al., 2020), the next step is to compare the intervention to an active intervention that controls for non-specific therapist factors (such as empathy and active listening). Here, the control intervention is a NICE recommended intervention for adolescent depression: non-directive supportive therapy (NDST; National Institute of Clinical Excellence, 2015).

The primary objective of the IMAGINE (Integrating Memories and Generating Images of New Experiences) trial was to evaluate the feasibility, acceptability, and safety of the trial methodology and interventions in order to establish whether to proceed to a definitive RCT (using a set of continuation rules on recruitment, retention, acceptability and safety). The secondary objective was to provide a controlled estimate of the between group effect on both clinical and cognitive outcomes (at post intervention and at follow-up) in order to assess whether the intervention demonstrates clinical promise and prepare for a fully powered RCT (Campbell et al., 2000; Craig et al., 2008, 2013). The third objective was to explore the feasibility and acceptability of incorporating technology into assessment and in delivering some of the intervention.

# Methods

## Trial design

This study consisted of a feasibility randomised controlled trial with parallel groups, conducted across multiple schools in the United Kingdom (UK), with an embedded process evaluation [reported elsewhere (Pile, Schlepper, Lau, & Leamy, under review.)]. The trial compared a novel intervention (imagery-based cognitive behavioural intervention, ICBI) to the control intervention (non-directive supportive therapy, NDST). A CONSORT diagram of study participation is presented in **Figure 1.**

The methods are based on the IMAGINE trial protocol (version 1; 1st April 2017), approved by the trial steering committee. The trial was prospectively registered on ISCTRN registry (https://www.isrctn.com/; ISRCTN85369879) and the trial protocol was published before recruitment was completed (Pile et al., 2018). The protocol paper provides additional information about the trial methodology and interventions. There were no changes to the methodology or trial outcomes after trial commencement.

**Continuation rules**

The criteria for proceeding to a future definitive trial were prespecified (Pile et al., 2018). They are: (Rule 1) recruitment was achievable within a reasonable amount of time (two years for full recruitment); (Rule 2) retention rates for the trial were at least 80% at post-intervention and 70% at three-months; (Rule 3) average acceptability of the ICBI intervention was rated as satisfactory or above; and (Rule 4) there was no harm associated with the trial. Any serious adverse events, serious adverse reactions or suspected unexpected serious adverse reactions that arose were carefully evaluated by the trial steering committee to determine whether these were related to the intervention/trial and would preclude proceeding to a definitive trial.

In terms of the intervention showing clinical promise, the primary clinical outcome was between-group differences in changes in symptoms of depression at T2 (from T1). We did not specify a minimum clinically important difference (MCID) to proceed to a definitive trial *a priori*. However, the literature suggest an appropriate cut off for a standardised mean difference of 0.24 in treating major depression (Cuijpers, Turner, Koole, Van Dijke, & Smit, 2014) and others recommend between 0.3 and 0.5 for self-reported continuous outcomes (Bell, Whitehead, & Julious, 2018; Norman, Sloan, & Wyrwich, 2004). The between group effect size on depressive symptoms (controlling for baseline depression score) is also compared to effect sizes from RCTs evaluating similar interventions.

**Participants**

Eligibility criteria

Inclusion criteria were: aged 16 to 18; being able to provide informed consent; being willing and able to engage in psychological therapy and complete assessments; and scoring above cut-off for depression (score of 20) on the Mood and Feelings questionnaire (Angold et al., 1995). A narrow age range was chosen for two reasons: (1) to reduce heterogeneity within

the groups, for example to reduce the influence of individual differences in maturational and experiential factors; (2) because it would have been challenging to create a detailed manualised intervention that was able to competently cover a broad age range, both in terms of language and cognitive demands of the intervention. Exclusion criteria were: diagnosis of intellectual disability or significant head injury, neurological disorder or epilepsy; unable to fluently communicate in spoken English; unable to give informed consent; factors contra-indicating imagery rescripting (verbally assessed with the participant at first interview, e.g. high levels of current risk); currently receiving another psychological intervention (including school counselling); experiencing distressing psychotic symptoms or depressed in the postnatal period (participants with comorbid physical illness or non-psychotic disorders, such as anxiety, were not excluded).

Sample size

A power calculation to determine a sample size was not appropriate as the purpose of the trial was not to establish efficacy. The target recruitment for this feasibility trial was N=56 (28 in each arm) as this was projected to provide sufficient numbers to estimate likely efficacy and acceptability for informing the methodology of a later trial. This was determined with reference to existing studies in the field (e.g. MEST RCT in adults; Hitchcock et al., 2018) and to be consistent with good practice recommendations for such trials, which recommend sample sizes of between 24 and 50 (Julious, 2005; Lancaster, Dodd, & Williamson, 2004; Sim & Lewis, 2012). The sample size of 50 was inflated to allow for drop-out following randomisation, which was estimated to be 10% based on previous trials in this population (Goodyer et al., 2016). Recruitment took place between April 2017 and February 2018, with the last follow-up data collected in June 2018. The trial ended when the target sample size was reached.

**Procedure, randomisation and blinding**

Secondary schools and sixth form colleges were approached, and pupils aged 16-18 invited to complete screening. Assessments were completed at pre-intervention (T1, prior to randomisation), post-intervention (T2) and at the three-month follow-up (T3). T1 was completed two weeks after screening and only participants scoring above cut-off at both assessments were invited to participate. T1 included a clinical interview to assess risk and to check inclusion/exclusion criteria. Following T1, eligible participants were randomised to one of the interventions. Both arms received an active intervention that aimed to improve mood and self-esteem. The interventions were designed to be completed within a school term so that sessions could be completed weekly without disruption by the school holidays.

Participants were randomised by the Kings Clinical Trials Unit (KCTU) in a 1:1 ratio using block randomisation via a web-based system. The sample was stratified by school. Randomly varying block sizes were employed to reduce the predictability of the sequence and ensure allocation concealment. The control intervention was a recommended Tier 2 intervention, which helps to address potential ethical issues related to randomisation. The randomisation system was accessed by the chief investigator (VP) via the web interface in the time period between T1 and the first intervention session.

The T2/T3 assessors were blind to treatment allocation but a full double-blind design was not possible due to the nature of the intervention under investigation (the trial therapist was aware of which intervention group participants were allocated to). As both experimental and control interventions were credible therapeutic interventions, this should reduce any potential bias associated with expectations of the benefits of the intervention. The two interventions were referred to as intervention 1 and intervention 2, and both described as 'programmes aiming to improve low mood and self-esteem' in all participant and staff literature to promote equal intervention credibility between the conditions. That is, participants were not informed as to what the 'new' intervention was, in order to avoid

potential imbalances in expectancy. All reasonable attempts were also made to keep school staff blind as to which condition participants were randomised to in order to reduce any potential differences between the groups. There were no known incidents of unblinding either for the assessors or the school staff.

VP was primarily responsible for gathering the data and conducting both therapeutic interventions. Assessments were completed by appropriately trained individuals, independent from the clinical team (e.g. research assistants). For clinical data collection, risk of assessor bias was also reduced by choosing self-report measures that are less susceptible to bias and by using multiple measures.

**Monitoring and ethical considerations**

A trial steering committee (TSC) was formed and provided oversight of the trial progress and conduct. Two service user consultants provided consultation throughout the trial and were part of the TSC. Ethical approval was obtained from the Psychiatry, Nursing and Midwifery Research Ethics Committee at Kings College London (ref: HR-16/17-3548). All participants provided their written and informed consent. Whilst parental consent was not sought, since all participants were over age 16, we did follow each school's individual recommendations for contacting parents and discussing participation.

**Interventions**

Both interventions comprised four face-to-face, individual sessions lasting up to ninety minutes. The sessions took place in a small quiet room within each school. Successful completion of the intervention is defined as completing three out of four sessions. Both interventions follow a written treatment manual (available from the corresponding author). All sessions were delivered by the first author (Clinical Psychologist with experience of working with adolescents with depression) with the second author providing clinical

supervision (Consultant Clinical Psychologist). No modifications to the intervention were made. Guidelines for reporting interventions have been followed (TIDieR; Hoffmann, Glasziou, Barbour, & Macdonald, 2014).

Experimental intervention: Imagery-based cognitive behavioural intervention (ICBI).

The intervention combines (A) imagery rescripting to reduce the distress associated with certain negative images and enhance positive future images with their associated positive affect (adapted from Holmes et al., 2019) and (B) memory specificity training to increase specificity and access to memories (adapted from Raes, Williams, & Hermans, 2009). The manualised intervention uses cognitive behavioural procedures (e.g. an agenda and homework) and is accompanied by a workbook.

Session one provides a rationale for 'training memories' and using mental imagery, including concepts such as: memories competing with one another for retrieval (Brewin, 2006); the encapsulated meaning of memories; and the relationship between memories, mood and behaviour. This includes practice for making memories more specific and setting up the homework tasks that are delivered using daily prompts (e.g. participants are asked to generate a memory to a cue word). Session two focusses on imagery rescripting for a negative past image that is associated with school (e.g. a bullying experience in school). The procedure follows three steps, recalling the image in a different way in each step; it was adapted for adolescents based on previous adult literature (Frets, Kevenaar, & Van Der Heiden, 2014; Holmes et al., 2019; Wild & Clark, 2011; Wild, Hackmann, & Clark, 2008). The aim of session three is to script a positive future imagery (e.g. graduating from university). The procedure was developed based on experimental literature (Werner-Seidler & Moulds, 2012), literature on positive image generation (Blackwell et al., 2015; Blackwell & Holmes, 2017; Holmes et al., 2019) and the imagery rescripting principles used in session two. The fourth session provides a review of the intervention and highlights links between specific memories

and more general value-based categories. Throughout the imagery exercises, participants are asked to generate as much detail as possible (including sensory information) as well as thoughts, feelings and the meaning of the images to them. In summary, the exercises aim to both target problematic emotional mental imagery and concurrently increase specificity of these memories, a skill also key to the target of boosting positive future imagery. Homework tasks are delivered via a mobile phone application, Metricwire, which the participants download onto their phones and prompts them to complete the task at 6pm each evening

Control intervention: 'non-directive supportive therapy' (NDST)

NDST involves the planned delivery of individual sessions with an empathic professional for monitoring (e.g. depressive symptoms), emotional support and discussion of participant-initiated options for addressing problems. It is a NICE recommended treatment for depression (National Institute of Clinical Excellence, 2015) and has been used as a control intervention in similar trials (e.g. Birmaher et al., 2000; for meta-analysis in adults see Cuijpers et al., 2012). It includes non-specific aspects of therapy (e.g. speaking to an empathic therapist) that could contribute to symptom reduction and so was an appropriate control condition to assess whether the active components of experimental intervention were leading to change.

**Outcome measures**

Feasibility and acceptability (Objective 1).

Recruitment and retention rates were recorded throughout, including number of schools approached and agreeing to take part; number of young people eligible to complete and then completing the screening questionnaire; number of eligible (and ineligible) participants following screening and T1; number consenting to take part and number randomised; number of participants successfully completing intervention and reasons for non-completion/dropout; numbers retained at each time point (T1, T2 and T3) with reasons

for drop-out. Data completeness was also summarised for each time point. The range and average number of sessions completed (including number of sessions attended as a proportion of those offered) as well as total contact time were measured to provide an indication of therapy compliance for each intervention.

To measure acceptability, participants completed a questionnaire. Three rating scale questions asked about: overall satisfaction, how much the intervention had helped them and whether they would recommend it. Participants were asked to respond using a five-point Likert scale, from one being a negative response (e.g. 'very dissatisfied') to five being a positive response (e.g. 'very satisfied'), and three being a neutral response (e.g. 'neither satisfied or dissatisfied'). A final question asked about the number of sessions, with a rating of three being "I was happy with the number of sessions'; one and two indicated preferring fewer sessions (1 being '2+ less' and 2 being '1-2 less') and 4 and 5 preferring more sessions (4 being '1-2 more' and 5 being '2+ more'). In addition, a purposive sample of twelve participants from the ICBI group were invited to complete semi-structured interviews following a topic guide. The main purpose of these interviews was to understand the active ingredients and valued outcomes of the intervention for participants and is reported elsewhere. Please see **supplementary material A** for the methods and analysis of these interviews that related to feasibility and acceptability of the intervention and for a summary of the written responses on the feedback questionnaire (**supplementary material B**).

Therapist adherence

To measure therapist adherence to each intervention, a random sample of 20% of the therapy sessions (40 sessions) were rated by an independent rater (clinical psychologist with experience of working with young people with depression) using a modified version of the cognitive therapy scale (Vallis, Shaw, & Dobson, 1986). There were 3 sub-scales to the adherence and competency scale: Scale A consisted of non-specific therapy factors (present

in both interventions); Scale B was on ICBI-specific components and Scale C on NDST-specific components. The competency rating ranges from zero (poor) to six (excellent) with a score of three being satisfactory. This evaluation also indicated whether there had been contamination between the conditions from the therapist having knowledge of both interventions.

Safety (Objective 1)

All adverse events were recorded and are reported here. Please see **supplementary material C** (or Pile et al., 2018) for a full explanation of the definition of adverse events.

Symptom measures (Objective 2)

The *Mood and Feelings Questionnaire* (MFQ; Angold et al., 1995) was used to measure depression. The long version of the MFQ (33-items rated on a 3-point Likert scale from zero to two) was used at each of the assessment time points and is the primary clinical outcome measure for this trial. A clinical cut-off score of 20 on the MFQ was used as the inclusion criteria, this is considered to be an efficient cut-off to identify mood disorders (Daviss et al., 2006) and is consistent with similar studies (Smith et al., 2015; Wright et al., 2014). For the screening stage, the four risk items were removed from the MFQ due to ethical considerations in mass testing conditions and so the cut-off score was correspondingly reduced at screen. The *Short MFQ* (12 items) was administered at the beginning of each intervention session alongside a risk item to monitor any change in risk. The *Screen for Child Anxiety Related Disorders* (Birmaher et al., 1997) *(SCARED)* is a 41-item scale used to measure anxiety. The 13-item *Child Revised Impact of Event Scale* (Perrin, Meiser-Stedman, & Smith, 2005) *(RIES-C)* measured post-traumatic stress symptoms (PTSS) in reference to a negative event. The *Rosenberg Self Esteem Scale* (Rosenberg, 1965) *(RSES)* is a ten-item measure of self-worth.

Measures of cognitive targets (Objective 2)

The *Autobiographical Memory Task* (Williams & Broadbent, 1986) (AMT) was administered to measure memory specificity to ten cue words (five positive; five negative), following Williams & Broadbent (1986) procedure and coding scheme. Participants were given 60 seconds to respond to each cue word. The AMT was audio-recorded and the responses co-rated. Responses were coded as specific, general categoric, general extended, semantic association or omission. In the current study, inter-rater consistency (across all categories) was excellent (93% agreement at T1; 92 % at T2; 96% at T3). The adult version of the *Prospective Imagery Task* (Holmes, Lang, Moulds, & Steele, 2008; Stober, 2000) (PIT) was adapted for use in young people (Pile & Lau, 2018) to measure vividness of positive and negative future images. In addition to the adult version, participants were asked to specify how often they have had this image before on a five-point scale. The *Self-Concept Clarity scale* (Campbell et al., 1996; SCCS) is a twelve-item self-report measure of a participant's confidence in being able to define themselves clearly. This was included as memory specificity (and depression) is linked to having a clear sense of self. The *Children's Response Style Questionnaire* (Abela, Vanderbilt, & Rochon, 2004) (C-RSQ) measured cognitive responses to low mood, using twenty-five items across three subscales: ruminative responses; distracting responses; and problem-solving responses. As response styles were not directly targeted in the intervention, this was included to assess whether changes in cognitive targets were unique to those targeted.

Incorporating technology (Objective 3)

The feasibility and acceptability of two tasks using technology was assessed. The tasks were included at T1 and T2 (but not at T3 to limit burden on participants). The *Memory Recall Task* measured participants' emotional response to a positive autobiographical

memory pre-intervention and a matched memory post-intervention (adapted from Gadeikis, Bos, Schweizer, Murphy, & Dunn, 2017). Emotional response was measured using subjective ratings of mood before and after recall, where participants were asked to rate four subscales for positive affect (happy, joyful, excited, energetic) and four for negative affect (sad, angry, nervous, and upset) on a Likert scale from 1 (not at all) to 9 (extremely). Heart rate variability (HRV, recorded with Polar RCS800CX) was also recorded during this task. This was administered using the software package, PsychoPy. Participants were asked to complete *daily ratings of mood and social connectedness* for one week before and after the intervention. They were asked to rate positive and negative affect (using same scales as above) and to specify who they were with (family, friends, on my own, other: please specify) each day at 6pm using a mobile phone app. Participants were asked to install an app on their phone and prompted to complete the questions once per day (with a reminder) for seven days pre-intervention and seven days post-intervention. If the app did not work for certain participants' phones, then alternative methods were used that best suited the participant (for example, text messages or providing them with a phone). In addition, homework tasks for the ICBI intervention were delivered via mobile phones. Feasibility and acceptability were assessed by the number of participants consenting to complete the assessment and intervention tasks and data completeness.

**Data analysis**

Feasibility data is presented descriptively and flow through the trial is presented in a standard CONSORT diagram. Descriptive statistics are reported for all other relevant outcomes at each time-point by trial arm. These statistics are presented for the two follow-up time points, using the intention-to-treat population (all participants randomised regardless of adherence to treatment). Last observation carried forward was used for missing follow up data. If any of the self-report measures had missing items, scales were pro-rated for an

individual if 20% or fewer items are missing. For all scales at all time-points, no participants missed more than one item (for further details please see data completeness section). To assess data entry quality, the data was checked using range checks and a small proportion of the entered data (10%) was compared to the raw data by a member of the team blind to participant allocation. All statistical analysis was performed in IBM SPSS Statistics, version 24 (Arbuckle, 2016). Formal statistical testing was not conducted as recent guidance identifies that it is not appropriate as this is a feasibility trial and not powered for testing hypotheses about effectiveness (Eldridge et al., 2016). Data for this study are available in Mendeley Data [dataset](Pile, 2020).

Additionally, for the clinical and mechanistic outcomes, we estimated between-group mean differences using ANCOVA with 95% confidence intervals (CI). The dependent variable in each case was score at T2 or T3, with 2 independent variables: treatment condition (ICBI vs. NDST) as a fixed factor and score at T1 (baseline score) as a co-variate. Between group effect sizes were estimated using Cohen's d. This was calculated by dividing the mean difference at T2 or T3 (from the relevant ANCOVA model) by the pooled standard deviation at T1 (baseline), where pooled standard deviation = $SQRT[((n_1-1)SD_1^2+(n_2-1)SD_2^2)/(n_1+n_2-2)]$. Similarly, 95% confidence intervals for d were calculated by dividing the unstandardized 95% CIs by the pooled baseline SD. Suggested interpretation for Cohen's d is small = 0.20; medium =0.50 and; large = 0.80 (Cohen, 1988). Effects are commented upon if d>0.2. All results presented use the intention-to-treat population, results were similar when analyses were repeated using the per protocol population (only participants adhering to treatment which is defined as completing at least three sessions, $n$ = 50; see **supplementary material D**).

In addition, the within group effect sizes (both for pre to post-intervention and pre-intervention to follow-up) were calculated, using the formula: Cohen's d = ($M_{POST/FU-}$

441 $M_{PRE}$)/$SD_{PRE}$ based on previous literature (Cohen, 1988; Ritter & Stangier, 2016). The 95%
442 confidence intervals for this effect size were calculated using the formula d +/-
443 1.96*SQRT(Var) where variance is $[(n_{1+}\ n_{2/}\ n_{1*}n_2) + (d^2/2(n_1 + n_2\text{-}2)][n_1+n_2/(n_1 + n_2\text{ -}2)]$.
444 (For all within group effect sizes please see **supplementary material E**). This was
445 calculated, first, to compare the change in depression score and memory specificity in the
446 trial with the case series (to check for replication) and, second, to describe whether the
447 control condition reduced symptoms of depression (although interpretation is limited by
448 potential confounding). For depression, we will also summarise individual MFQ scores
449 according to the reliable change index [(Jacobson & Truax, 1991), operationalised using
450 Morley & Dowzer (2014) guidelines] and the percentages of participants whose scores
451 reduced by the suggested clinically meaningful difference (10 points).

452 # Results

453 **Sample characteristics.**

454 Fifty-six participants were randomly assigned to one of the two interventions (ICBI,
455 n= 29; NDST, n=27). Baseline means for participant demographics, primary clinical and
456 cognitive measures are presented in **Table 1 and Table 2**. The majority of participants had
457 not been previously diagnosed with depression. Two had diagnoses of depression and anxiety
458 (n=1 ICBI; n=1 NDST) and two participants had a diagnosis of Autism Spectrum Conditions
459 (n=1 ICBI; n=1 NDST). In addition, seventeen participants had at least one other medical
460 diagnosis including Asthma (n=9); learning difficulties (n=3); Turner syndrome (n=1);
461 Irritable bowel syndrome (n=2); and sickle cell anaemia (n=1). Eleven participants were
462 taking medication, but none were taking medication for mental health difficulties. Thirteen
463 participants had previously visited their GP with concerns about depression (n=6, ICBI; n=7,
464 NDST). Eighteen participants had previously had a psychological intervention (n=12, ICBI;

n=6, NDST), with the majority having received counselling (n=16) with the remainder receiving CBT (n=2).

AT T2 and T3, no participants had received new mental health diagnoses. Following recommendation from the trial therapist, one participant sought help from their GP for sleep difficulties, one participant was referred to CAMHS and one participant began school counselling.

**Feasibility and acceptability**

Feasibility and adherence.

Our main feasibility outcomes are found in the consort diagram (**Figure 1).** Twenty-one schools were contacted and five (24%) agreed to take part in the trial. 1020 young people were potentially eligible to complete the screening questionnaire and 839 (82%) completed it. Fifty-six participants were recruited into the trial over eleven months, therefore meeting continuation rule 1. [In addition, 101 potentially eligible participants were not contacted by the research team as the recruitment target was met (at the screening stage, it was explained to participants that a random sample would be contacted)]. Continuation rule 2 was also met as retention rates for the trial were 89% at T2 and T3. All participants completed all questionnaire measures and the AMT at T1, except two participants who did not complete the RIES-C at baseline (one due to a photocopying error and one because they were unable to identify a negative life event). All participants who completed therapy (n=50, 89%) completed all questionnaire measures and the AMT at T2 and T3.

In terms of therapy compliance, the groups were not dissimilar for the average number of sessions completed, average number of sessions offered by the therapist and total contact time (**see Table 1**; all $p>0.05$).

Acceptability.

Acceptability was measured by the feedback questionnaire **(see Table 3)**. Overall, participants were satisfied with both interventions, felt that the intervention they received had helped them, and would recommend the interventions to a friend. The average acceptability of the ICBI intervention was rated as 4.26 (out of 5) therefore meeting continuation rule 3.

Most participants felt happy with the length of the interventions (this is a score of three on the scale). However, looking at the frequencies of responses in each group, the majority of those in the ICBI group were "happy with the number of sessions" (n=21) with few asking for "1-2 less" (n=3) or "1-2 more" (n=2) and one participant asking for "2+ more". The distribution was different in the NDST group with nine participants being "happy with the number of sessions"; eight participants would have liked "1-2 more"; three "2+ more"; two participants wanting "1-2 less" and one participant saying they would have liked "2+ less".

Adherence

Independent rating of adherence to the intervention model (ICBI or NDST) indicated high adherence to the interventions across all sessions rated (100% on 17 of 21 scales with remaining scales being 89% or above) and there was no evidence of contamination across interventions (i.e. intervention specific components were only found in the appropriate interventions). Competency was at least satisfactory for all therapy components and the average competence score for the vast majority of scales (80%) was above 5 (very good).

Safety of the intervention.

There were no serious adverse events, serious adverse reactions or suspected unexpected serious adverse reactions during the trial. There were no high-risk acts of self-harm (requiring medical attention, but not medical hospital admission). There were some risk issues reported during the trial and safeguarding procedures were followed, including one participant reporting physical abuse by parents; one reporting emotional abuse by parents; and one

reporting non-suicidal self-injury (unrelated to intervention and not requiring medical attention). These events had all began before the participant started the trial but were reported within therapy rather than during the baseline assessment. As none of these events were deemed to be related to the trial by the TSC, continuation rule 4 was met.

**Symptom measures**

Descriptive statistics are presented in **Table 2** and estimates of between-group mean differences in **Table 4**. All symptom measures showed change in the expected direction (i.e. decreases in symptoms of depression, anxiety, PTSS and increases in self-esteem) or no change for both groups.

For depressive symptoms, both groups showed a decrease in depressive symptoms from T1 to T2 and a further decrease at T3. For group differences, there were large effect sizes in favour of ICBI at T2 (d = -1.34, 95% CI [-1.87, -0.80]) and at T3 (d = -0.96, 95% CI [-1.59, -0.33]) with 95% CIs not including zero. The within group effect sizes indicated large effect sizes for decreases in depression score in the ICBI group (T2: d = -1.94 [-2.58, -1.30]; T3: -2.07 [2.73 to -1.42]); the NDST group showed small effect sizes at T2 and large effect size at T3 (T2: d = -0.45 [-1.00 to 0.10]; T3: -0.92 [-1.49 to -0.35]). In the ICBI group, 86% at T2 and 76% at T3 of participants showed reliable change; 72% at T2 and 69% at T3 of participants reduced their scores by ten or more points. In the NDST group, 33% at T2 and 63% at T3 of participants showed reliable change; 19% at T2 and 41% at T3 of participants reduced their scores by ten or more points. Depression scores also decreased in both groups each session according to the Short MFQ questionnaire (**see Figure 2**) with decreases appearing larger in the ICBI group**.**

There was a decrease in anxiety symptoms for both groups across the time points. There was a medium effect (d = -0.51, [-0.89, -0.12]) at T2 and a small effect at T3 (d= -0.40 [-0.88,

0.08]) in favour of ICBI for reducing anxiety symptoms, the 95% CIs at T2 did not include zero but did at T3. Post-traumatic stress symptoms (PTSS) showed a decrease across time points in the ICBI group. There was little change in PTSS from T1 to T2 in the NDST group but a decrease at T3. Self-esteem showed a small increase for both groups across time-points. There was a small group effect, in favour of the ICBI group, for reducing PTSS at both time-points (T2: d = -0.35 [-0.82, -0.12]; T3: d = -0.34 [-0.86, 0.18]) and increasing self-esteem at T2 (d = 0.34 [-0.05, 0.73]), however 95% CIs included zero.

**Measures of cognitive targets**

Please refer to **Table 2** for descriptive statistics and **Table 4** for estimates of between-group mean differences. For memory specificity as measured by the AMT, change was in the expected direction for ICBI (i.e. improvement) with little change in the NDST group. For group differences, there was a medium/large effect at T2 (d = 0.79 [0.35, 1.23]) and a medium effect at T3 (d= 0.63 [0.19, 1.06]) in favour of ICBI for increasing memory specificity. The 95% CIs did not include zero. The within group effect sizes indicated a large increase in memory specificity in the ICBI group (T2: d = 0.91 [0.35, 1.46]; T3: 0.89 [0.34 to 1.44]). The NDST group showed very little change at T2 and a small change at T3 (T2: d = 0.09 [0.46 to 0.63]; T3: 0.23 [-0.31 to 0.78]).

For all other measures, the CIs included zero. Positive image detail and frequency was expected to increase whilst negative image detail and frequency to decrease. For positive image detail, the ICBI group showed an increase from T1 to T2 (and little difference between T1 and T3) whereas the NDST group showed little change. For positive image frequency, the ICBI group showed a small increase across the time points whilst the NDST showed a small decrease. At T2, there was a small group effect in favour of ICBI for positive image vividness (d = 0.44 [-0.03, 0.92]) and for positive image frequency (d = 0.31, [-0.14, 0.77]).

Change was also in the expected direction for negative imagery with (small) decreases in negative image detail and frequency for both groups from T1 to T2 and from T1 to T3. There were small group effects in favour of ICBI for reducing negative image frequency at T2 (d = -0.37 [-0.85, 0.11]) and at T3 (d = -0.23 [-0.77, 0.31]).

Self-concept clarity showed increases (as expected) for both groups across time-points and no between group effects were observed. For more adaptive responses to low mood, it is considered to be positive to see decreases on the rumination scale and increases on the distraction and problem-solving scales. Rumination showed a decrease for both groups at both time-points. There was little change for distraction or problem-solving in either group. There was a medium between-group effects at T3 (d = -0.45 [-0.94, 0.04]) for rumination in favour of ICBI. For distraction, there were small between-group effects at T2 (d = -0.20 [-0.52, 0.11]) in favour of the NDST group. There was a small between-group effect for use of problem-solving at T3 (d = 0.30 [-0.10, 0.70]) in favour of the ICBI group.

**Feasibility and acceptability of incorporating technology**

For the memory recall task, at T1 all participants completed the subjective mood ratings (n=56) and heart rate data was collected for 52 of these participants. At T2, subjective mood ratings were collected for 49 participants (equipment failure meant data was not collected for one participant). Heart rate data was obtained for 46 participants. At both time points, the heart rate equipment did not work for three participants and one participant did not consent to wear the monitor. For the daily ratings of mood at T1, 52 participants (27 in ICBI and 25 in NDST) completed at least 3 days of ratings and 46 completed at least 5 days of ratings (25 in ICBI and 21 in NDST). At T2, 31 participants (15 in ICBI and 16 in NDST) completed at least 3 days of ratings and 23 completed at least 5 days of ratings (10 in ICBI and 13 in NDST).

585 Compliance with completing the memory specificity training on the mobile application
586 was highly variable ($\bar{x}$=12.52; SD= 7.95; range 0-21). The mobile application was not
587 compatible with several of the participant's phones (n=10 in IBCI group). These participants
588 were provided with a phone to complete these tasks on, but this may have impacted on
589 compliance (participants completing MEST on their own phone $\bar{x}$=14.65; SD= 5.82; range 2-
590 21; participants completing MEST on trial phone: $\bar{x}$=8.9; SD= 9.48; range 0-21).

591 ## Discussion

592 The primary aim of this early-phase RCT was to investigate the feasibility, acceptability
593 and safety of the trial methodology and two interventions (imagery-based cognitive
594 behavioural intervention, ICBI, and non-directive supportive therapy, NDST). Our key
595 criteria for proceeding to a definitive RCT were satisfied: we recruited 100% of the target
596 sample in eleven months; retention rates were high (89% at T2 and T3); average acceptability
597 of the interventions was above satisfactory and; there were no indications of harm arising
598 from the trial or interventions. Another key aim was to estimate the likely effect size of ICBI
599 on depressive symptoms, relative to a matched control intervention currently endorsed in
600 NICE guidelines for adolescent depression. The results suggest that ICBI, relative to NDST,
601 may have a large effect on reducing depressive symptoms and in leading to changes in a key
602 risk factor for relapse (OGM; Sumner et al., 2011; Sumner, Griffith, & Mineka, 2010). The
603 depression score at T2 (primary clinical endpoint) suggests large effect size superiority at
604 both the lower and upper end of the 95% CI. Encouragingly, this large effect was maintained
605 at follow-up. These differences suggest that the intervention has clinical potential as d (and
606 the lower band of the 95% CI) was greater than the minimum clinically important difference
607 identified in previous literature (0.24-0.5; Bell et al., 2018; Cuijpers et al., 2014) In general,
608 changes in the symptoms and in the cognitive mechanism were in the expected direction from

pre to post intervention. Finally, incorporating technology into assessment and treatment garnered mixed success with further consideration of how to best deliver these techniques required. The results suggest that the intervention has clinical potential and now requires evaluation in a definitive trial.

Primarily, our results indicate that the trial methodology and interventions are feasible to deliver in a school-setting, acceptable to participants and that there were no safety concerns associated with the trial or interventions. Therapy compliance was similar for both interventions with all participants who completed the interventions attending at least three sessions. Adherence to the therapy model by the therapist was at least satisfactory with no evidence of contamination. Acceptability ratings for both interventions were also good, and participants were mostly satisfied with the number of therapy sessions. This is encouraging as most school-based prevention and early intervention programs for depression are significantly longer (Calear & Christensen, 2010; Werner-seidler, Perry, Calear, Newby, & Christensen, 2017).

Both interventions produced reductions in depressive symptoms, however there were large between group effect sizes indicated for ICBI relative to NDST. These large beneficial effects were maintained at follow-up. On average, the ICBI group demonstrated an 11-point decrease on the depression measure (MFQ) relative to the NDST group. Previous studies have considered a difference of ten points clinically meaningful and important (Smith et al., 2015) and other studies have stipulated that only five points on the MFQ represents a clinically important difference (Goodyer et al., 2016). Treatment effect sizes for early interventions for depression range greatly (e.g. a review of school-based early intervention programmes for depression identified that around half of the trials demonstrated a significant reduction in depressive symptoms, and these trials had effect sizes of between d = 0.21 and d = 1.40; Calear & Christensen, 2010) and the vast majority of these trials have employed only

a wait-list control group. The effect sizes in the current study are at the top end of this spectrum and relative to an active control. This is important as a large study comparing CBT with a brief psychosocial intervention found no superiority effect on depressive symptoms (Goodyer et al., 2016) and some suggest that much of the effect of therapy for (adult) depression is due to non-specific factors (Cuijpers et al., 2012). There was also a reduction in symptoms of anxiety in both groups, with a medium effect at T2 and a small effect at T3, both in favour of ICBI. It would perhaps be unsurprising if the intervention had trans-diagnostic effects. Having an excess of negative past images and higher vividness of negative images has been linked with anxiety in adults (Hirsch, Clark, Mathews, & Williams, 2003; Morina, Deeprose, Pusowski, Schmid, & Holmes, 2011) and adolescents (Pile & Lau, 2018, 2020) and imagery procedures have also successfully been used to target self-images in adults with social anxiety (Wild et al., 2008).

The within group effect sizes give some indication of whether the results from the case series (Pile et al., 2020) can be replicated and whether symptoms of depression decrease with NDST, although these should be interpreted with caution as within group effects may be subject to confounding. For the ICBI group, the within group effect sizes at T2 for reducing depressive symptoms in the trial (d = -1.94, 95% CI [-2.58, -1.30]) were in keeping with the large effect found in the case series (d= -1.32, , 95% CI [-2.41, -0.22]) and large effects were found for increasing memory specificity in both (trial, d = 0.91, 95% CI [0.35, 1.46]; case series: d = 1.80, 95% CI [0.62, 2.98]). For NDST, there was a small/large within group effect on depression symptoms (T2: d = -0.45, 95% CI [-1.00 to 0.10]; T3: -0.92, 95% CI [-1.49 to -0.35]) but a much smaller effect of memory specificity (T2: d = 0.09 [0.46 to 0.63]; T3: 0.23 [-0.31 to 0.78]). This suggests that NDST reduces depressive symptoms and is a valid active control yet does not ameliorate a key cognitive mechanism targeted in ICBI. However, identifying the most appropriate control intervention is challenging. NDST was chosen as it is

recommeneded by NICE guidelines, is as close as possible to what youth with depression would receive in schools and controls for non-specific therapist factors. There is the possibility that it under-performed, especially given that the number of sessions of NDST (i.e. four sessions) was determined by the format of the experimental intervention. Given the huge range of effect sizes generated by previous studies (e.g. d = 0.21 to d = 1.40; Calear & Christensen, 2010), it is difficult to know what effect size to expect from the control group. There is the possibility that we might find smaller between-group effect sizes if we had compared the imagery treatment to another therapy that targetted specific cognitive mechanisms (e.g. CBT).

In terms of cognitive targets, results indicated improvements in memory specificity for the ICBI group and a medium/large between-group effect size in favour of ICBI. The changes in the self-rated measures of negative and positive imagery vividness (and frequency) were small but in the expected direction for the ICBI group. There were some group differences observed for improving positive imagery (vividness and frequency at T2) and reducing negative imagery frequency (at T2 and T3) in favour of the ICBI group but these were small (with the 95% confidence intervals including zero). A future trial would benefit from careful consideration of how best to measure and observe changes in these complex psychological processes in adolescents, for example evaluation may benefit from the development of an experimental measure of imagery vividness (Pearson, Deeprose, Wallace-hadrill, Burnett, & Holmes, 2013). We have not investigated associations between changes in symptomatology and changes in cognitive targets as this was a feasibility RCT and so statistical testing is considered not appropriate and is likely to be underpowered (Eldridge et al., 2016). Similarly, we adopted an integrative approach to developing this intervention, so do not know which techniques or mechanisms are driving the observed symptom changes. Meta-analyses in adults have indicated that memory specificity alone only produces small effects on depression

(Hitchcock, Werner-Seidler, Blackwell, & Dalgleish, 2017). Imagery rescripting has demonstrated much larger effects on symptoms across different disorders (Morina et al., 2017) although there has been no prior research in adolescent depression (except our case series (Pile et al., 2020)). OGM and dysfunctional emotional mental imagery are inherently linked and likely to have a reciprocal relationship [e.g. many ascribe a central role of imagery-based processes in remembering specific autobiographical events (Conway & Pleydell-Pearce, 2000; Holmes et al., 2016)]. They, therefore, may influence each other to maintain symptoms of depression. We suggest that using IR and MEST in combination may target dysfunctional mental imagery and OGM more powerfully than either used in isolation. We also suggest value in targeting both negative and positive imagery, rather than either alone. For example, to first use imagery rescripting to reduce the impact of intrusive images and free up cognitive capacity to imagine a positive future, which is then enhanced in therapy. A future trial would benefit from including a more extensive embedded mechanism study to clearly clarify the underlying processes contributing to therapeutic change.

A third aim was to incorporate technology to enhance assessment and intervention. Unfortunately, technology complicated the assessment with it being difficult to fit the heart rate monitors and the mobile application sometimes being incompatible with participants' phones. Almost all participants consented to wear the heart rate monitor and complete the daily mood ratings. However, compliance for the mood ratings with mixed and much lower post intervention (46% of those finishing therapy completed at least 5 days of ratings) than pre-intervention (82% completed at least 5 days). Completing the homework tasks on mobile phones may be of benefit, with most participants completing over half of the memories and some participants reporting finding the process valuable. However, several adjustments need to be made to the technology in order to enhance the user experience. The relationship between compliance and therapy outcomes would be interesting to explore in a future study,

given that some research in youth with anxiety disorders suggests no link between them (Arendt, Thastum, & Hougaard, 2016).

A major limitation is that both interventions were delivered by the same person who developed ICBI and this represents a risk of allegiance. Another risk is contamination as the therapist may employ additional techniques, for example cognitive behavioural techniques in response to risk issues. To reduce the risk of allegiance bias and of contamination, sessions were recorded and a random sample of sessions were independently rated by a clinical psychologist for adherence to each protocol and for competence of delivery. Furthermore, contact time and participant rated acceptability was similar for the interventions. This methodology is appropriate as a first test of efficacy, as it enabled us to reduce any heterogeneity that may be introduced by having several therapists and increase sensitivity by delivering the interventions optimally (Ioannidis, 2016). However, future trials should have a broader range of therapists and ultimately replication by an independent group would be useful. The intervention also needs to be delivered by the target workforce to see whether similar effects can be generated. Whilst, the workbook and therapist manual style of the intervention lends itself to delivery by individuals without extensive training in psychological therapy, this remains to be tested. Another limitation is that we do not know whether participants would meet diagnostic criteria for depression. Participants were required to be scoring above clinical cut-off for depression for two weeks before starting the intervention, but a diagnostic interview was not completed. This decision was made following consultation with lived experience representatives and teachers and reflects clinical services in the UK, where self-reported symptom severity rather than diagnoses guide clinical decision making (e.g. https://cypiapt.com/; Gyani, Shafran, Layard, & Clark, 2013).

In terms of clincal implications, this feasibility RCT suggests that ICBI could be an effective brief intervention for those experiencing high symptoms of depression (e.g. scoring

above clinical cut-off and meeting criteria for child and adolescent mental health services). As the intervention targets robust maintaining factors for depression (e.g. intrusive imagery, overgeneral memory) and both the case series and current RCT included young people with a range of depression severity (i.e. there was no exclusion criteria for high severity), it may also be usefully deployed as a adjunct to other therapies or as standalone intervention for more severe depression. However, this requires further investigation and future studies could investigate whether depression severity at baseline is a predictor of treatment response.

Here, we have demonstrated feasibility, acceptability and safety of the methodology and interventions. Initial estimates of the effect size in reducing depressive symptoms suggest that the intervention has clinical potential. This was an early stage trial aiming to estimate likely effect sizes to adequately power a larger later stage trial which would determine the statistical and clinical significance of treatment effects. The range of effect size estimates may now be used alongside other considerations to inform power calculations for a fully powered definitive RCT evaluating the efficacy of ICBI as an early intervention for adolescent depression. This mental imagery-based intervention (tackling both negative and positive future imagery, in a relatively brief and simple way that can be delivered in a school setting) has been translated from basic science and informed by current frontline interventions to provide an alternative to current interventions for adolescent depression.

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1068

1069 **Table 1:** Baseline sample characteristics and measures of intervention compliance

| | **ICBI (n=29)** | **NDST (n=27)** |
|---|---|---|
| **Age** | $\bar{x}$=17.093 (SD = 0.570) | $\bar{x}$=17.044 (SD = 0.512) |
| **Percentage female** | 62.1% | 59.3% |
| **Percentage Caucasian** | 27.6% | 22.2% |
| **Number of sessions completed** | $\bar{x}$=3.66 | $\bar{x}$=3.59 |
| Range | 0-4 | 0-4 |
| **Number of sessions offered** | $\bar{x}$= 4.24 | $\bar{x}$= 4.37 |
| Range | 0-6 | 3-6 |
| % of offered sessions attended | 86.18% | 84.07% |
| **Average contact time (minutes)** | $\bar{x}$=215.83 | $\bar{x}$=200.19 |
| Range | 0-306 | 0-305 |

**Table 2: ITT Means and standard deviations for measures of clinical symptoms and cognitive targets (n=29 for ICBI; n=27 for NDST)**

| | T1 | | | | T2 | | | | T3 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ICBI | | NDST | | ICBI | | NDST | | ICBI | | NDST | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| **MFQ** | 33.69 | 7.58 | 32.78 | 8.60 | 19.00 | 11.05 | 28.93 | 11.21 | 17.97 | 11.77 | 24.88 | 12.17 |
| **SCARED** | 40.86 | 12.73 | 36.55 | 12.10 | 32.68 | 14.44 | 34.95 | 14.71 | 30.38 | 15.86 | 32.06 | 12.66 |
| **RIES-C*** | 39.59 | 15.44 | 34.95 | 11.32 | 32.24 | 15.28 | 34.59 | 12.80 | 25.34 | 15.55 | 27.59 | 14.24 |
| **RSES** | 23.10 | 4.81 | 22.52 | 4.27 | 25.17 | 4.74 | 23.19 | 4.70 | 25.38 | 4.56 | 24.33 | 3.52 |
| **AMT** | 5.55 | 2.40 | 5.56 | 2.53 | 7.72 | 1.77 | 5.78 | 2.83 | 7.69 | 1.63 | 6.15 | 2.82 |
| **PIT Positive** | 23.29 | 5.01 | 23.47 | 4.09 | 24.79 | 6.21 | 22.93 | 5.70 | 23.69 | 5.51 | 24.07 | 5.55 |
| **PIT Negative** | 25.54 | 5.81 | 24.81 | 2.77 | 23.95 | 5.48 | 23.67 | 3.58 | 24.33 | 5.88 | 23.06 | 3.89 |
| **PIT Freq Positive** | 20.80 | 4.32 | 22.41 | 4.31 | 20.91 | 5.73 | 21.20 | 6.23 | 21.29 | 5.92 | 21.98 | 5.65 |
| **PIT Freq Negative** | 22.60 | 4.61 | 21.81 | 3.14 | 20.05 | 4.97 | 21.04 | 3.36 | 19.94 | 4.62 | 20.38 | 4.51 |
| **SCCS** | 29.79 | 6.43 | 30.63 | 5.53 | 31.48 | 7.30 | 33.11 | 6.92 | 32.34 | 8.07 | 32.85 | 7.06 |
| **Rumination** | 37.93 | 6.89 | 37.13 | 6.22 | 35.62 | 8.45 | 35.70 | 6.75 | 32.38 | 8.42 | 34.85 | 5.63 |
| **Distraction** | 15.24 | 3.83 | 15.41 | 3.26 | 14.72 | 3.51 | 15.56 | 2.68 | 15.55 | 3.74 | 16.30 | 4.27 |
| **Problem solving** | 10.69 | 3.36 | 11.37 | 2.48 | 10.38 | 3.20 | 10.96 | 2.67 | 11.52 | 3.39 | 11.11 | 2.62 |

*Please note that for RIES-C, n=28 for ICBI and n=26 for NDST. T1 = assessment point prior to intervention; T2 = assessment point after intervention; T3 = three months following the post assessment. ICBI = Imagery –based cognitive behavioural intervention; NDST = non-directive supportive therapy. SD = standard deviation. MFQ = Mood and Feelings Questionnaire; SCARED = Screen for Child Anxiety Related Disorders; RIES-C = Child Revised Impact of Event Scale: child version; RSES = Rosenberg Self Esteem Scale; AMT = Autobiographical Memory Task; PIT = Prospective Imagery Task; Pos = Positive; Neg= Negative; Freq = Frequency; SCCS = Self-Concept Clarity scale.

**Table 3:** Quantitative feedback on the acceptability of the intervention (means and standard deviations). Data is only from participants who completed T2 (ICBI, n=27; NDST, n=23). The scales are 1-5 with 5 being the most positive answer (e.g. very satisfied) unless otherwise specified.

| | **Satisfaction** | **Extent to which intervention has helped** | **Recommend to a friend** | **Number of sessions** Alterative scale used[1] |
|---|---|---|---|---|
| **ICBI** | 4.26 (0.66) | 4.26 (0.59) | 3.96 (0.90) | 3.04 (0.59) |
| **NDST** | 3.96 (0.88) | 4.04 (0.71) | 4.17 (0.58) | 3.44 (0.99) |

1. For this scale, 3 is the most positive answer indicating that they are happy with the number of sessions. 1 and 2 indicate preference for fewer sessions and 4 and 5 indicate preference for more sessions. ICBI = Imagery – based cognitive behavioural intervention; NDST = non-directive supportive therapy.

**Table 4:** Effect of group for clinical and cognitive measures using intention-to-treat analysis. Unstandardized parameter estimates from the ANCOVA and Cohen's d for each variable are reported.

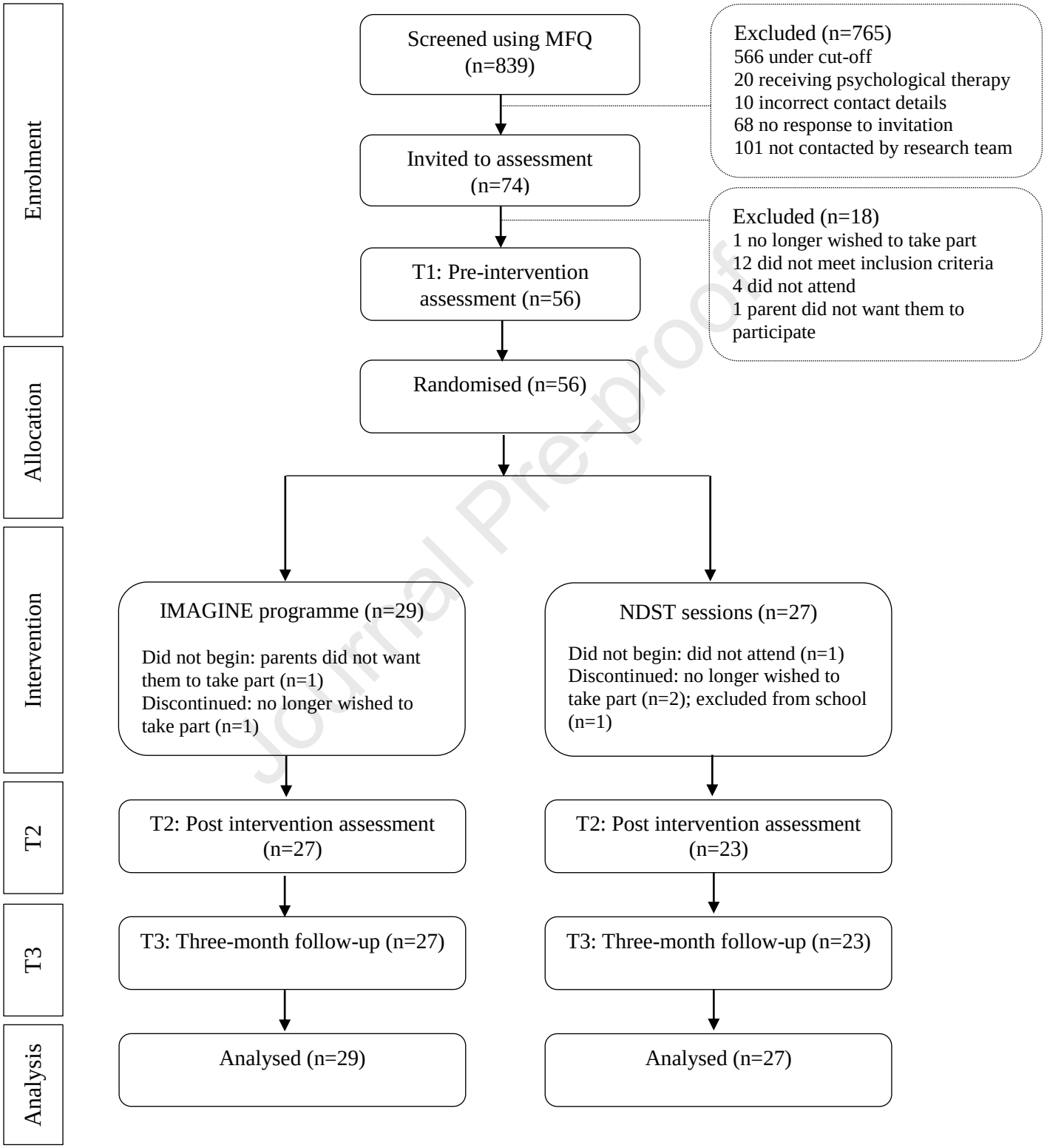
| | T2 | | | | | | T3 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **B** | **95% CI of B** | | **d** | **95% CI of d** | | **B** | **95% CI** | | **d** | **95% CI of d** | |
| **MFQ** | -10.80 | -15.13 | -6.48 | -1.34 | -1.87 | -0.80 | -7.75 | -12.83 | -2.67 | -0.96 | -1.59 | -0.33 |
| **SCARED** | -6.33 | -11.12 | -1.55 | -0.51 | -0.89 | -0.12 | -4.98 | -10.92 | 0.96 | -0.40 | -0.88 | 0.08 |
| **RIES-C** | -4.74 | -11.17 | 1.70 | -0.35 | -0.82 | 0.12 | -4.61 | -11.68 | 2.46 | -0.34 | -0.86 | 0.18 |
| **RSES*** | 1.56 | -0.24 | 3.35 | 0.34 | -0.05 | 0.73 | 0.76 | -1.11 | 2.64 | 0.17 | -0.24 | 0.58 |
| **AMT** | 1.95 | 0.87 | 3.03 | 0.79 | 0.35 | 1.23 | 1.54 | 0.47 | 2.62 | 0.63 | 0.19 | 1.06 |
| **PIT Pos** | 2.03 | -0.15 | 4.21 | 0.44 | -0.03 | 0.92 | -0.24 | -2.36 | 1.89 | -0.051 | -0.51 | 0.41 |
| **PIT Neg** | -0.25 | -1.97 | 1.50 | -0.055 | -0.43 | 0.33 | 0.71 | -1.18 | 2.60 | 0.15 | -0.26 | 0.56 |
| **PIT PosFreq** | 1.44 | -0.65 | 3.53 | 0.31 | -0.14 | 0.77 | 0.90 | -1.29 | 3.08 | 0.19 | -0.28 | 0.67 |
| **PIT NegFreq** | -1.47 | -3.37 | 0.43 | -0.37 | -0.85 | 0.11 | -0.91 | -3.05 | 1.23 | -0.23 | -0.77 | 0.31 |
| **SCCS** | -0.98 | -3.90 | 1.94 | -0.16 | -0.65 | 0.32 | 0.27 | -2.51 | 3.06 | 0.046 | -0.42 | 0.51 |
| **Rumination** | -0.65 | -3.95 | 2.65 | -0.099 | -0.60 | 0.40 | -2.97 | -6.20 | 0.26 | -0.45 | -0.94 | 0.04 |
| **Distraction** | -0.72 | -1.84 | 0.40 | -0.20 | -0.52 | 0.11 | -0.64 | -2.39 | 1.12 | -0.18 | -0.67 | 0.31 |
| **Problem solving** | -0.16 | -1.43 | 1.10 | -0.056 | -0.48 | 0.37 | 0.89 | -0.30 | 2.08 | 0.30 | -0.10 | 0.70 |

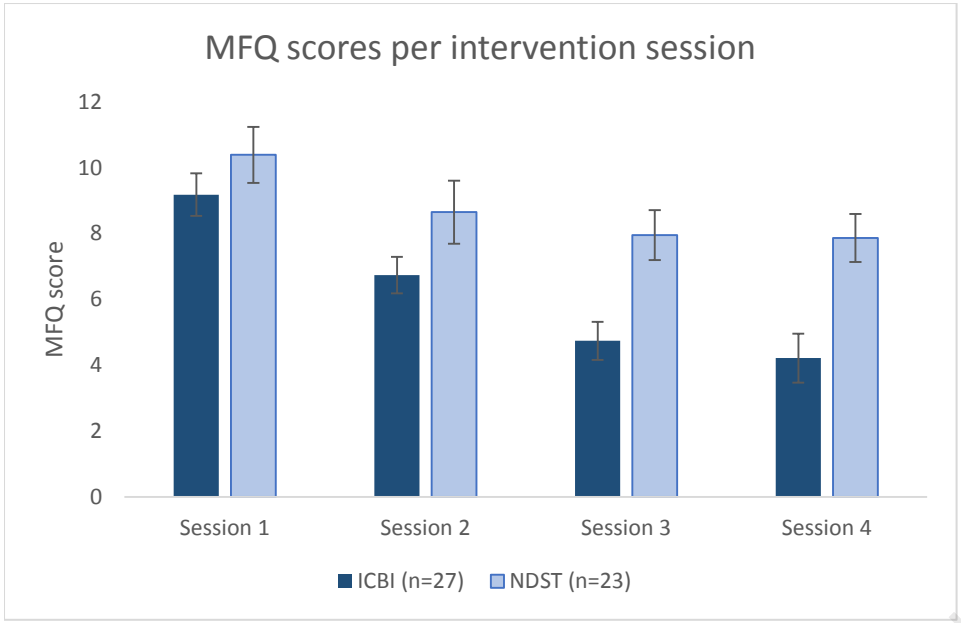
*Please note that for RIES-C, n=28 for ICBI and n=26 for NDST. T2 = assessment point after intervention; T3 = three months following the post assessment. MFQ = Mood and Feelings Questionnaire; SCARED = Screen for Child Anxiety Related Disorders; RIES-C = Child Revised Impact of Event Scale: child version; RSES = Rosenberg Self Esteem Scale; AMT = Autobiographical Memory Task; PIT = Prospective Imagery Task; Pos = Positive; Neg= Negative; Freq = Frequency; SCCS = Self-Concept Clarity scale.

**Figure 1:** Flow through trial in CONSORT diagram

**Figure 2:** Mean MFQ scores for each group (ICBI, n=27; NDST, n=23) for those completing the intervention session with error bars indicating standard error (please note that n=23 for ICBI in session 4). The MFQ was completed at the beginning of each intervention session.

**Figure 1: Flow through trial in CONSORT diagram**





**Highlights**

- Trial evaluated a mechanistically focused intervention for adolescent depression.
- Imagery-based intervention (ICBI) compared to non-directive supportive therapy.
- All continuation rules were met for feasibility and acceptability.
- Large between group differences in depressive symptoms and memory specificity.
- Definitive trial indicated to determine treatment efficacy of ICBI.

**Declaration of interests**

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: