Building Psychological Strengths & Improving Outcomes in School Children with Single-Session Interventions

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Abstract

Background:

There is increasing recognition that mental health problems first emerge in childhood and that research and clinical practice should focus on prevention, early intervention and improving young people's access to support. Single-session interventions (SSIs) have shown promise in community health settings, including with youth samples. However, there has been a recent drive to integrate mental health strategies into educational settings such as schools. As such, there is a need to explore how SSIs might contribute to this goal.

Methods:

First, a systematic review and meta-analysis was conducted, drawing papers from three leading databases in psychology, medicine and education. This summarised current evidence of the effectiveness of SSIs, delivered in educational settings, on youth internalizing problems. Second, an empirical study explored how a mindset SSI might be trialled in primary schools. The study explored the intervention's feasibility and acceptability to children in Year 5 and 6 (aged 9-11 years old), their parents and teachers.

Results:

Meta-analyses of 8 studies (n=2,082) estimated a medium effect of SSIs in educational settings for reducing depressive symptoms (g = -0.44, 95% CI -0.93 – 0.05) and for reducing anxiety symptoms (g = -0.62, 95% CI -1.35 – 0.11). The empirical study indicated that a single-session, mindset intervention is feasible to implement in UK primary schools and acceptable to pupils, parents and teachers. It also suggests that the intervention shows promise as a strategy for the prevention of mental health problems in children.

Conclusion:

Taken together, these papers suggest that SSIs may be a viable, cost-effective means of prevention or intervention for youth mental health problems – even when delivered in

educational settings. They highlight the infancy of research in this field, the significant variety between models of intervention and the need for future studies to consolidate or build upon existing evidence.

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Chapter 1. Introduction to the Thesis Portfolio

Single-session interventions (SSIs) have been part of clinical practice in mental health for decades (Bloom, 2001; Cameron, 2007; Hymmen et al., 2013). A common finding has been that within the right context, SSIs could provide an effective treatment for various problems. However, as Hymmen and colleagues (2013) conclude, the design and control of studies needs to be more rigorous in order to evidence the effectiveness of SSIs.

Recently, interest in SSIs for youth mental health problems has grown. This is likely to have been driven by findings from research and practice, which highlight the marked increase in the prevalence of disorders such as anxiety and depression (NHS Digital, 2018) and emphatically clarify that such problems often become established in childhood (Kessler et al., 2005). Single-session interventions are far less burdensome than their full-length equivalents and critically, can be just as effective in addressing youth mental health needs (Schleider & Weisz, 2017; Weisz et al., 2017). However, it is prevention (more than treatment) that has been widely-endorsed as the most sustainable method of addressing these issues (World Health Organization, 2004; Department of Health & Department for Education, 2017).

While a cost-effective response to this growing demand is clearly necessary, there are further obstacles to overcome – namely, access to support. In the UK, too few children and young people in need of intervention appear to actually receive it (25%; NHS Digital, 2018) and for those that do, it is an average wait of 3 months (Abdinasir, 2017). Thus, current directions in research and practice look to improve this through delivery of support in non-clinical settings, such as schools. There is also a sound theoretical basis for this: a systemic perspective would suggest that the systems around the child, such as education, play a significant role in their response to intervention.

As previous reviews have clearly and consistently stated the need for methodological rigour in SSI outcome studies (e.g., Hymmen et al., 2013), it will be important for interventions to be trialled in a more comprehensive manner – and for the current evidence to be evaluated as it emerges. It is hoped that this will lead to a greater understanding of the contexts in which SSIs can be effectively used and the mechanisms by which they affect change. This is a period of time in which resource is being given to the systematic exploration of such interventions; it is critical that this is used efficiently and not wasted.

Therefore, the thesis portfolio aims to develop our current understanding of how we can use SSIs to build psychological strengths and improve outcomes for school children. Chapter 2 describes a systematic review and meta-analysis of the literature regarding SSIs, delivered in educational settings, for youth internalizing problems. The review is intended to evaluate the purported promise of such interventions and moreover, the studies in which they are trialled. Following this, Chapter 4 presents an empirical study in which a single-session, mindset intervention is developed and trialled in primary schools – with a view to exploring the feasibility and acceptability of both the study design and the intervention itself. It is hoped that this will provide a comprehensive foundation for future trials.

Chapter 3 illustrates the clear link between systematic review and empirical study, grounding this in current findings and identified areas of need in research and practice. Chapter 5 and 6 describe any additional methodology and results, for both the systematic review and empirical paper respectively. The text and information contained within these chapters is considered supplementary to (and not necessary for understanding) the main papers. Chapter 7 provides a synthesis of the findings across both papers and a reflection on the overall process of conducting and writing the review, empirical study and thesis portfolio. A discussion of clinical implications and directions for future research is also included.

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Chapter 2: Systematic Review

Single Session Interventions for Youth Internalizing Problems, Delivered in Educational Settings: A Meta-Analysis

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(See Appendix A for Author Guidelines)

Abstract

The prevalence of youth mental health concerns is increasing, particularly with regard to emotional or internalizing problems. In research and clinical practice, various interventions have been developed to meet these evolving needs, but mental health services remain stretched and many children and young people are not receiving timely support. To reduce burden and improve accessibility, focus has shifted to briefer interventions and delivery in non-clinical settings. To that end, this paper presents a meta-analysis of single-session interventions (SSIs), delivered in educational settings, for youth internalizing problems. Three leading databases (one psychological, one medical and one educational) were searched and papers screened for eligibility. This yielded eight randomized-controlled trial studies (2,082 youths) from which findings were synthesized.

Results indicated a medium effect on reducing depressive symptoms (g = -0.44, k=7) and on reducing anxiety symptoms (g = -0.62, k = 4), although neither was statistically significant. This may be a due to using random effects models to accommodate large heterogeneity between studies – which sensitivity analyses were unable to resolve. While it could be said that effects were 'approaching' significance *and* of considerable magnitude, these must be taken with caution given the methodological limitations. We tentatively conclude that SSIs, targeting youth internalizing problems and delivered in educational settings, show promise. Further research is necessary to clarify these findings.

Keywords: Internalizing Problems; Single-Session Interventions; Educational Settings; Children; Youth

Highlights

- Medium effect size estimates for single-session intervention impact on depressive symptoms.
- Medium effect size estimates for single-session intervention impact on anxiety symptoms.
- Despite nonsignificant findings, tentative support for both briefer interventions and intervention delivery in non-clinical settings.
- High heterogeneity between studies – unresolved by sensitivity analyses.
- Varied methodological quality between studies poses a challenge to understanding and reviewing the literature.

Introduction

The mental health of children and young people is a global public health concern, with 10-20% of children and adolescents experiencing mental disorders (Kieling et al., 2011). The economic and social cost of mental ill health is staggering. In England alone, it is estimated at £105 billion annually – and a significant portion of this cost will be attributable to children and young people's mental health, with 50% of all mental disorders established by the age of 14 and 75% by the age of 25 (Kessler et al., 2005). In particular, there has been a notable increase in the prevalence of emotional disorders, such as anxiety and depression, which in the UK rose from 3.9% in 2004 to 5.8% in 2017 (NHS Digital, 2018). These are typically represented by internal distress, although this may lead to more overt negative or disruptive behaviour. The experience of 'internalizing' (affective and often negative symptoms that are directed inwardly, towards the individual) is characteristic of many disorders, but most commonly anxiety and depressive disorders (Regiel et al., 2013).

In response to the increase of poor mental health in children and young people, various interventions have been developed to treat or prevent such problems. Despite strong empirical support for many of these interventions, the prevalence of UK youth meeting diagnostic criteria for at least one mental disorder has risen over the last 15 years (NHS Digital, 2018). Evidence-based interventions tend to involve multiple sessions, which places burden on the patient and clinician(s), as well as a financial cost for the required resources. Thus, the capacity of mental health services to deliver appropriate and timely intervention is limited. In the UK alone, average waiting time for children and young people to receive mental health assessment is 58 days – and a further 41 days for treatment (Abdinasir, 2017). Perhaps more concerning is the finding that only 25% of young people requiring mental health support in 2017 were able to access mental health services (NHS Digital, 2018). It is

evident that access to and cost-effectiveness of youth mental health provision needs to improve.

Single-session interventions (SSIs) may be an appropriate response. The origins of SSIs may be traced back to Freud (Freud & Breuer, 1895) but it was not until work by Talmon (Talmon, 1990), almost a century later, that a cohesive field of research began. This was often linked to 'walk-in' clinical or counselling services (Hymmen et al., 2013). Only recently have SSIs garnered attention as potentially effective, accessible and low-burden means of treating and/or preventing youth mental ill health (e.g., Schleider & Weisz, 2017; Schleider et al., 2019). A small majority appear to employ individual behavioural or cognitive-behavioural models, but non-behavioural (e.g., 'growth mindset'), systemic (e.g., family- or parent- behavioural intervention) and motivational interviewing approaches are also prevalent (Schleider & Weisz, 2017).

Despite outcome studies lacking rigor, the literature indicates that with limited resources, SSIs can lead to improvements in depression, anxiety and various other problems (Cameron, 2007; Hymmen et al., 2013). The promise of SSIs for adults has previously been described in narrative reviews (Campbell, 2012; Cameron, 2007; Bloom, 2001) and a recent meta-analysis found similar effects for youth mental health needs (Schleider & Weisz, 2017). Others have found that the magnitude of treatment effect may be unrelated to the number of sessions (Weisz et al., 2017) or even that in some contexts, brief interventions appear more effective than longer ones (Bakemans-Kranenburg et al., 2003; Tully & Hunt, 2015).

Shortening interventions may reduce clinician caseload and improve waiting times, but does little to improve access to services in the first instance. The need for alternative routes to receiving support has become a key target in recent UK government proposals (Department of Health & Department for Education, 2017) and indeed, evidence suggests that children and young people are already more likely to access professional support from

teachers or primary care professionals than mental health services (NHS Digital, 2018). One promising route may be through the educational settings that children and young people access, with interventions delivered in these environments shown to be effective treatments (Paulus et al., 2016) that receive high levels of engagement and participation (Fazel et al., 2014). However, the current pressure on UK schools, alongside difficulties recruiting and retaining teaching staff, has left many unable to commit time and resources to implement psychological prevention or treatment programmes (Stallard et al., 2014). This arena seems ripe for the application of SSIs.

To date, no known systematic review has explored the potential of SSIs, delivered in educational settings, for the treatment or prevention of youth mental health problems. This is the focus of the present systematic review and meta-analysis. It aims to address the research question: "are single-session interventions, delivered in educational settings, effective for youth internalizing problems?"

Method

This review was registered in an international prospective register of systematic reviews (PROSPERO; CRD42020164146).

Search Strategy

We searched PsycINFO, ERIC and Embase using a combination of search terms for single-session interventions (single session*, one session* or brief intervention*), internalizing problems (anxi*, depress*, worry, panic, phobi*, low mood, sad, sadness, guilt, shame, mental health or internali*), educational settings (school*, college*, sixth form*, universit* or education*) and young people (child*, adolescen*, teen*, student*, pupil*, young person* or young people*), for articles published up until February 8th, 2020. We also hand-searched the reference lists of all identified eligible articles.

Selection Criteria

Only studies of single-session interventions, delivered in an educational setting and with a control group (no treatment, wait-list or active control) as a comparator, were included. Studies were eligible for inclusion if the intervention targeted improved outcomes for children and young people (CYP) (=<25 years of age) and included measured outcomes of internalizing symptoms. Only studies involving randomisation to either intervention or control group (randomised controlled trials – RCTs) were eligible.

CYP were defined as 0-25 years of age, following a move towards better integrated, 0-25 models for youth mental health services in the UK (Department of Health, 2015). Some studies did not report the age range of participants, only the mean and standard deviation. For these, only those with a mean age of 21 years or less and standard deviation smaller than 3.0, were considered eligible for inclusion. Educational settings were defined as institutions whose primary function is education. This included schools and colleges, non-mainstream settings such as pupil referral units, as well as universities.

Studies were excluded if the intended beneficiaries of the intervention were youth with a learning disability, autism spectrum disorder or other developmental condition. This was because such cohorts often require individualised adjustments to interventions (NHS England, 2015), which would render such interventions inappropriate for the wider youth population. However, studies including those with developmental conditions remained eligible if they were part of a larger youth sample, as this is likely to reflect natural variation or prevalence. Studies were also excluded if the single-session intervention was the control condition, as these are typically designed *not* to have experimental effect.

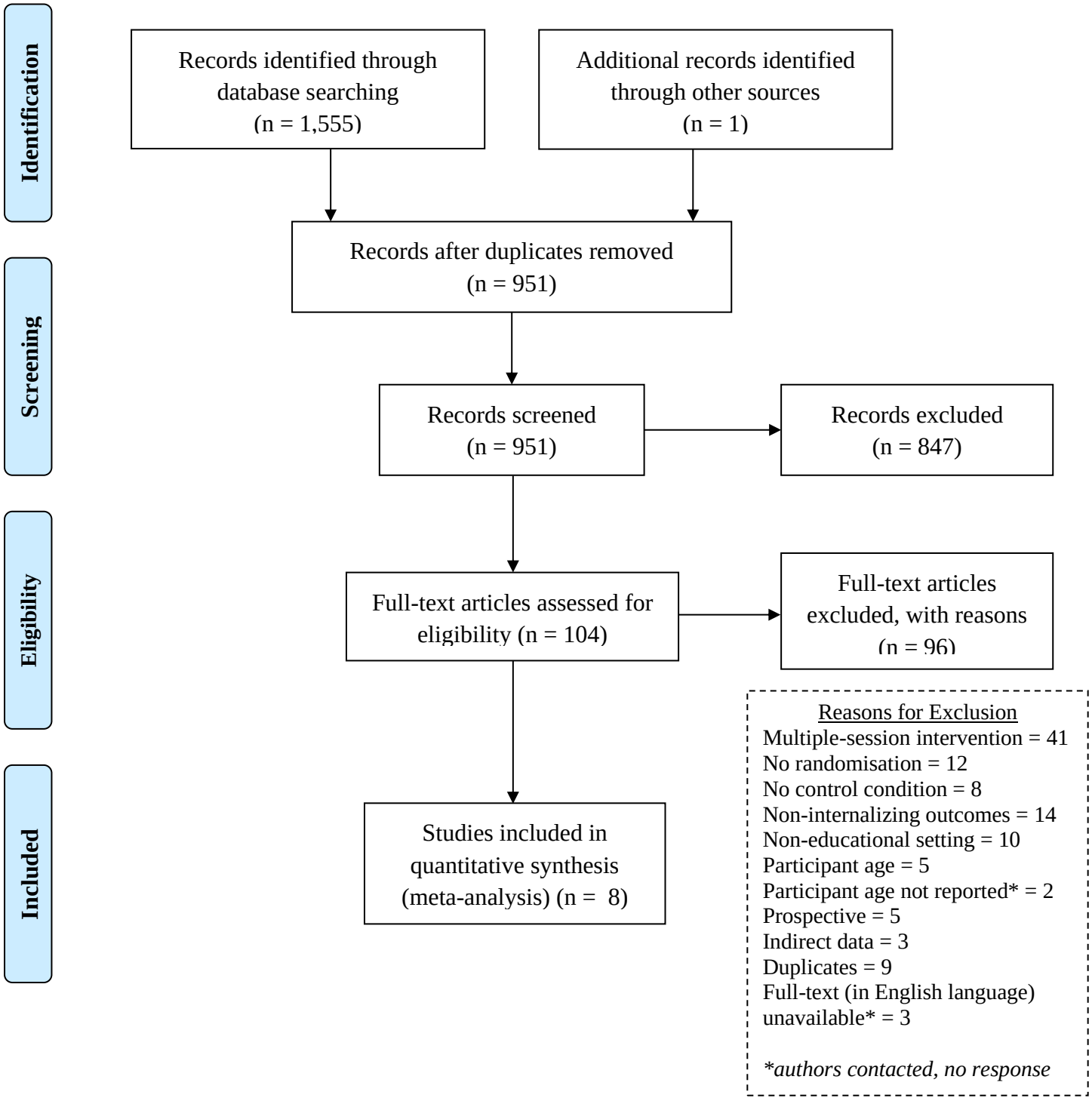
For the purpose of this review, we considered internalising problems as characterized by high levels of negative, affective symptoms that are experienced by the individual rather than directed towards others. Depressive disorders and anxiety disorders are the two most prevalent groups of internalising problems as defined by the Diagnostic and Statistical

Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013), but internalizing problems may also include associated problems such as trauma and stressor-related disorders.

Study Selection

Initial searches returned 1,555 articles, in addition to one article through hand searches of reference lists (950 after duplicates were removed). The primary author (JC) first reviewed titles and abstracts, then the remaining articles at full-text. A second reviewer (KC) independently reviewed a randomly-selected sample of these (20%; 21 articles). The primary and secondary reviewers had 100% agreement on all articles reviewed by both. Where there was shared uncertainty, the perspective of third and fourth reviewers (LP and RMS) were sought. This resulted in 8 studies for inclusion in this meta-analysis (see Figure 1 for study selection process). When it was unclear whether a study met the inclusion criteria, or when a full-text article could not be obtained through library or internet searches, JC contacted the corresponding authors to request additional data or the full-text article.

Figure 1. PRISMA Flow-chart (Study Selection Process)



Data Extraction

An extraction database was used to record and manage items of relevance to the meta-analysis. These were: (a) article details (e.g., title, author, publication year, journal), (b) study setting and recruitment (e.g., sample size, characteristics and attrition), (c) outcomes of interest and measures used, (d) intervention and control condition details (e.g., type, administration, mode, duration, goal) and (e) procedural details (e.g., randomisation blindness, pre-intervention therapist training, follow-up length). The characteristics of each included study are presented in Table 1 and the characteristics of each *intervention* are presented in Table 2.

Table 1. Characteristics of studies included in the meta-analysis

Study	N (Expt. Group, Cont. Group)	Gender	Mean Age (SD)	Ethnicity	Targeted Internalizing Outcome(s)	Relevant Outcome Measure(s)	Setting	Location
Armento et al. (2012)	25, 25	F=62%, M=38%	20.0 (2.75)	Caucasian (88%), Black (8%), Hispanic (2%), Indian (2%)	Depressive symptoms and anxiety symptoms	Beck Depression Inventory; Beck Anxiety Inventory	University	USA
Calvete et al. (2019)	456, 411	F=48.1%, M=51.9%	14.56 (0.97)	Not reported	Depressive symptoms	The Center for Epidemiologic Studies Depression Scale	Secondary/ High School	Spain

Fu et al. (2015)	37, 36	F=49%, M=51%	14.06 (1.61)	Not reported	Negative mood and positive mood	Visual analogue scale	Secondary/ High School	China
Gawrysiak et al. (2009)	14, 16	F=80%, M=20%	18.4 (0.81)	Caucasian (70%), Black (13%), Hispanic (7%), Asian (7%)	Depressive symptoms and anxiety symptoms	Beck Depression Inventory; Beck Anxiety Inventory	University	USA
Geisner et al. (2015)	84, 85*	F=62.4%, M=37.6%	20.14 (1.34)	Caucasian (59.7%), Asian or Pacific Islander (19.4%), Black (1.2%), Mixed (8.4%), Hispanic (7.8%), Native American (<1%).	Depressive symptoms	Beck Depression Inventory	University	USA

Miu & Yeager (2015)	304, 295	F=48%, M=52%	Not reported	Not reported	Depressive symptoms	Children's Depression Inventory - Short Form	Secondary/ High School	USA
Schleider et al. (2019)	115, 107	F=100%	Intervention = 15.2 (0.5) Control = 15.3 (0.5)	Caucasian (37.55%), Hispanic (29.41%), Black (24.43%) and Other (8.59%)	Depressive symptoms and anxiety symptoms	Short Mood & Feelings Questionnaire; Social Phobia Inventory	Secondary/ High School	USA
Zucker et al. (2002)	36, 36	F=68%, M=32%	18.98 (1.06)	Not reported	Anxiety symptoms	State-Trait Anxiety Questionnaire – State Version	University	USA

** = participants from control group and the one intervention group that targeted psychological outcomes (two groups that did not were therefore excluded from the meta-analysis).*

Table 2. Characteristics of interventions (and respective controls) included in the meta-analysis

Study	Intervention Type	Control Type	Intervention Administration	Control Administration	Intervention Mode	Control Mode	Intervention Length	Control Length	Intervention Goal	Follow-Up Length
Armento et al. (2012)	Behavioural activation	Supportive treatment	Clinician	Clinician	Face-to-face	Face-to-face	60 minutes	60 minutes	Treatment	2 weeks
Calvete et al. (2019)	Growth mindset	Education	Self	Self	Paper and/or computer	Paper and/or computer	50-60 minutes	50-60 minutes	Prevention	6 months
Fu et al. (2015)	Cognitive	Cognitive	Self	Self	Computer	Computer	Not reported	Not reported	Treatment	Same day
Gawrysiak et al. (2009)	Behavioural activation	No intervention	Clinician	Clinician	Face-to-face	Face-to-face	90 minutes	90 minutes	Treatment	2 weeks

Geisner et al. (2015)	Personalized feedback	No intervention	Self	Self	Computer	Computer	Not reported	Not reported	Prevention	1 month
Miu & Yeager (2015)	Growth mindset of personality	Growth mindset of athleticism	Self	Self	Paper and/or computer	Paper and/or computer	25 minutes	25 minutes	Prevention	9 months
Schleider et al. (2019)	Growth mindset	Health Education and Relationship Training	Self	Self	Computer	Computer	45 minutes	45 minutes	Treatment	4 months
Zucker et al. (2002)	Cognitive	Education	Clinician	Clinician	Audio and paper	Audio and paper	Not reported	Not reported	Treatment	Same day

Meta-Analytic Method

An effect size (ES) was calculated for each study, using the Meta-Analysis via Shiny (MAVIS, version 1.1.3) software (Hamilton, 2017), which calculated individual Hedge's *g* values, using means and standard deviations from each study. The first post-treatment outcomes were used, as this created the least variation in follow-up length between analysed studies. The overall effectiveness of SSIs for youth internalizing problems was assessed by weighting the study-level ESs and then calculating the average of these for a pooled estimate of effect. Weighting was assigned relative to the sample sizes of studies, so that more weighting was given to studies with larger sample sizes. This was based on the assumption that more precise estimates can be returned from studies with larger sample sizes (Hedges & Olkin, 1985). ESs in the negative range indicate that those receiving SSIs scored lower on the measure(s) of internalizing problems than those in the control condition.

Significant variation in ESs was anticipated, due to the varied methodologies, intervention types and sample characteristics of included studies. Thus, random effects models were used for the meta-analysis. This assumes that the effect to be estimated is not the same in all studies, but reduces power as P-values are larger and confidence intervals wider. Random effects approaches are considered more suitable for meta-analyses in mental health research than fixed effects models (Cuijpers, 2016).

Group-based designs require each value in a group to represent a statistically-independent observation (statistical independence'). Three of the studies included in this meta-analysis used more than one outcome measure of 'internalizing problems'. To include the multiple observations from these studies in the same analysis could lead to an underestimation of error variance and inflation of significance tests (Tabachnick & Fidell, 2001). Instead, separate outcomes were examined in separate analyses and two meta-analyses were carried out: one for anxiety symptoms and one for depressive symptoms.

Moderator Variables

Planned moderator analyses (outlined in the PROSPERO registration) included type of internalizing problem, demographic factors, intervention goal and intervention recipient as moderator variables. However, due to low numbers of studies suitable for the meta-analyses, it was decided that moderator analyses would not be sufficiently powered to provide meaningful outcomes. This is echoed in recommendations for meta-analyses, which suggest that a minimum of five studies are required for categorical analyses to be appropriately-powered (Hedges & Pigott, 2001). To better address the primary research question, sensitivity analyses were performed. These allowed the impact of study quality and risk of bias to be explored.

Methodological Quality

Considered essential components of meta-analyses (Higgins & Green, 2011), assessments of study quality and risk of bias help account for variation in the methodological quality of included studies. In order to accomplish this, evaluations against criteria from the Quality Assessment Tool for Quantitative Studies (Appendix B; National Collaborating Centre for Methods and Tools, 2018) and Cochrane Risk of Bias Tool (Appendix C; Sterne et al., 2019) were independently completed by the primary and secondary reviewers (JC and KC). Both tools provide criteria for generating an overall quality rating (strong, moderate or weak) or risk of bias (low, some concerns, high). Discrepancies were discussed and resolved through joint agreement.

Results

Characteristics of included studies

Seven studies administered a measure of depressive symptoms and were therefore included in the pooled analysis of depressive symptom outcomes. One of these studies (Fu et al., 2015) used a visual analogue scale rather than standardized measures. This enabled

participants to rate the strength and consistency of negative mood experiences (e.g., sad, upset) and generate a summed score for low mood. Where reported, intervention length ranged from 25 to 90 minutes and follow-up periods varied from data collection on the same day, to data collection at 9-months (for both meta-analyses, ES estimates were taken from the first post-treatment outcomes to accommodate this). Of these seven studies, four were carried out in secondary school settings and three at universities. The general trend was for school-based studies to conduct research procedures in place of scheduled lessons, whereas for university studies these were predominantly extra-curricular. Members of staff at participating settings were not involved in the research administration or intervention delivery. The purpose of intervention was treatment in four studies (and prevention in three), all but one of which screened prospective participants for eligibility.

Four studies administered a measure of anxiety symptoms and thus were included in the pooled analysis of anxiety symptom outcomes. The length of single-sessions ranged from 45 to 60 minutes (one study did not report this information). Follow-up periods varied, from data collection on the same day as the intervention, to data collection at 4-months. Three of the included studies were conducted in a university setting and just one at a secondary school. University-based studies had research activities as extra-curricular for participants, whereas the school-based study did not. No members of staff at participating settings were involved in delivery or administration. In all, the purpose of intervention was treatment and all but one screened prospective participants for eligibility.

Notably, none of the studies across either analysis used samples drawn from primary school-age children.

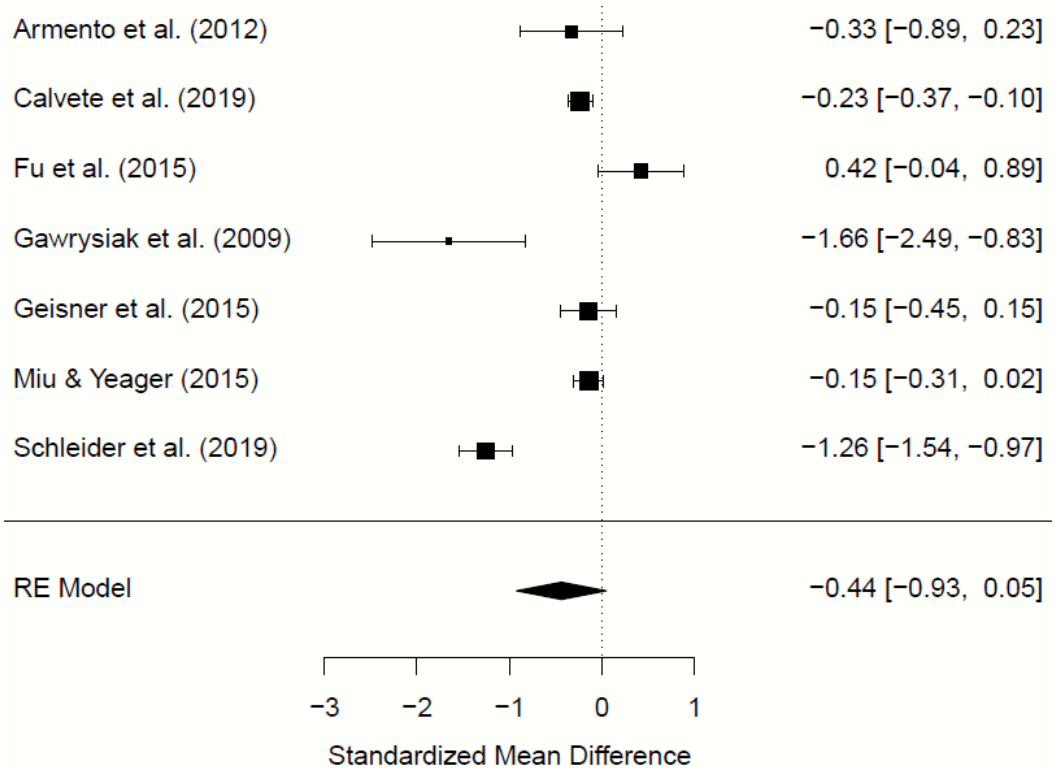
Main Effect for SSIs

A random-effects model was applied to calculate the effect size (ES), confidence intervals and sample variance for each study.

The post-intervention effect of SSIs on depressive symptoms

The weighted mean post-treatment ES for the 7 studies including a depression outcome measure was -0.44, with a 95% confidence interval (CI) of -0.93 – 0.05, p<.078 (see Figure 2).

Figure 2. Forest plot of ES estimates for SSIs with depressive symptom outcomes

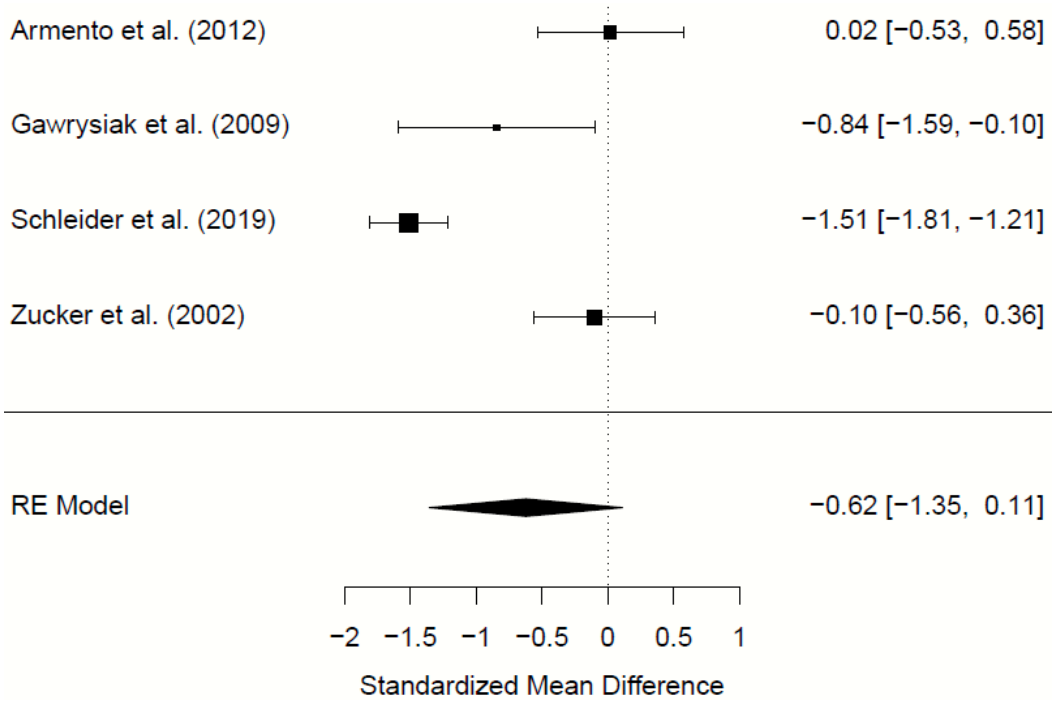


Note: left of dotted line favours intervention.

Post-intervention effect of SSIs on anxiety symptoms

The weighted mean post-treatment ES for the 4 studies including an anxiety symptom measure was -0.62, with a 95% confidence interval (CI) of -1.35 – 0.11, p<.097 (see Figure 3).

Figure 3. Forest plot of ES estimates for SSIs with anxiety symptom outcomes



Note: left of dotted line favours intervention.

Heterogeneity

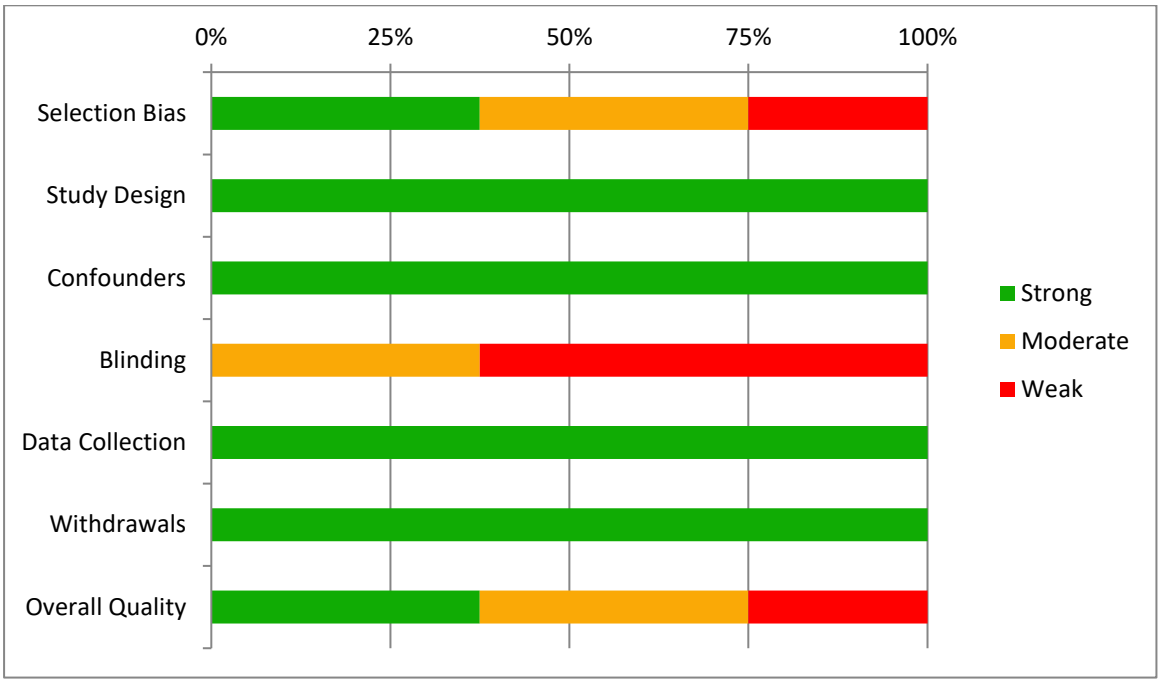
There was significant and large variability in the analysis of SSIs for depressive symptoms ($Q(6) = 67.27$, $p<.0001$, $I^2 = 95.62\%$) and in the analysis of SSIs for anxiety symptoms ($Q(3) = 38.04$, $p<.0001$, $I^2 = 89.18\%$). It is possible that this is an artefact of imprecise studies, indicated by wide confidence intervals that could explain the variability, as opposed to true heterogeneity (innate differences between studies).

Study Quality

The Quality Assessment Tool guides assessors to make judgements of studies across 8 domains of methodological process, with two or more ‘weak’ domains resulting in an overall ‘weak’ rating. Independent reviewers initially had 75% agreement on the overall quality of each study, but largely only one area of discrepancy (what constitutes sufficient evidence to determine if assessors were blind to randomisation). Assessors also discussed

representativeness of samples, relative to populations. Importantly, these minor discrepancies did not alter the proportion of studies rated as 'weak', for which there was 100% agreement. Of the included studies, two met these criteria: Gawrysiak et al. (2009) and Armento et al. (2012). Both samples were judged unlikely to represent the target population, due to participants self-referring (weak on selection bias). Both also failed to provide evidence of researcher blindness to randomisation and participant blindness to the research question (weak on blinding). Overall quality ratings are presented in Figure 4.

Figure 4. The proportion of studies rated strong, moderate or weak quality on each of the assessment domains.

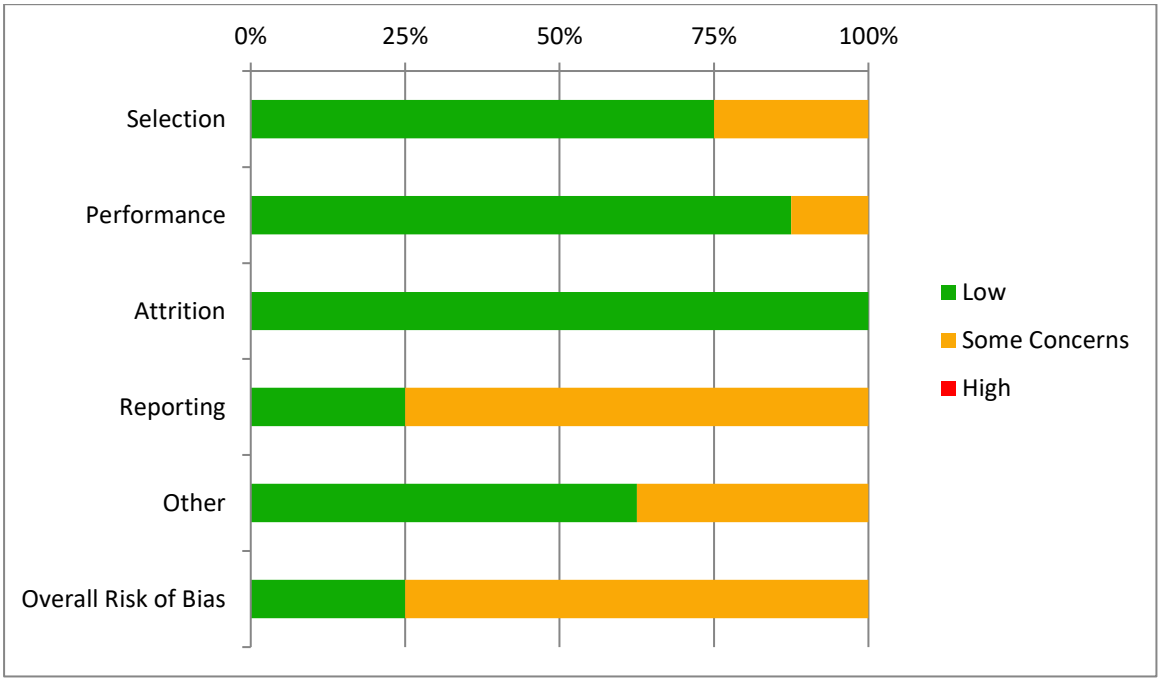


Risk of Bias

The Cochrane Risk of Bias Tool uses an algorithm to denote risk of bias in five different methodological domains, but also allows assessor judgements to be accommodated. According to both assessors' judgements and the Tool's algorithm, no studies were considered to have a high risk of bias. Independent reviewers had 100% agreement on the

overall risk of bias for each study. The proportion of studies rated as low, some or high risk of bias (for each assessed domain) are described in Figure 5.

Figure 5. The proportion of studies rated low, some concerns or high risk of bias on each of the assessment domains.



Sensitivity Analyses

Given the high heterogeneity between included studies, sensitivity analyses were carried out to explore the impact of study quality on effect size estimates. After removing the two studies with 'weak' study quality, heterogeneity was not considerably different for effect on depressive symptom outcomes ($Q(4) = 56.74$, $p<.0001$, $I^2 = 96.29\%$) and the magnitude of effect was reduced (-0.28, CI -0.8 – 0.24, p<.28). The smaller pool of studies yielded a much wider confidence interval, which makes the ES harder to interpret with conviction.

Similarly, study removal did not markedly alter heterogeneity in the analysis of anxiety symptom outcomes ($Q(1) = 25.08$, $p<.0001$, $I^2 = 96.01\%$), although the magnitude of effect was increased (-0.82, CI -2.19 – 0.56, p<.25). The broadening of confidence intervals

is unsurprising, but prevents any authoritative interpretation of the finding. Thus, sensitivity analyses did not resolve the inconsistency identified by heterogeneity tests. Given the small pool of included studies, such a result is not unexpected.

Publication Bias

A regression test for funnel plot asymmetry indicated that there was no publication bias in either the analysis for effects on depressive symptoms ($t(2) = 1.37$, $p<0.31$) or the analysis for effects on anxiety symptoms ($t(5) = -0.71$, $p<0.51$). However, analysis of funnel plots is only recommended for meta-analyses that include ten or more studies. Thus, to further examine the possibility of publication bias, a weight-function model was applied (Vevea & Hedges, 1995). Only the analysis for effects on depressive symptoms contained sufficient number of studies for analysis, which showed no evidence of publication bias ($X^2(1) = 2.59$, $p<.11$).

Discussion

This meta-analytic study summarises the currently available results from what appears to be an area of research in its infancy. Single-session interventions for youth 'psychiatric' problems have been previously reviewed (Schleider & Weisz, 2017), but an extension to this was pertinent, given that the global context of youth mental health continues to shift and governmental directives have targeted improved access through educational settings.

Main Effect of SSIs

Across eight included studies, SSIs demonstrated an effect in the medium range for both depressive symptoms ($g = -0.44$) and for anxiety symptoms ($g = -0.62$). This might suggest that single-session interventions, delivered in educational settings, can generate improvement in youth internalizing problems. However, as confidence intervals cross zero, both pooled ES estimates are numerically promising but non-significant.

These effect sizes are comparable in size to those of full-length interventions for youth psychiatric problems. For instance, Weisz et al. (2017) found a medium ES for interventions targeting anxiety (d = 0.61) and a small ES for those targeting depression (d = 0.29), whereas others have found small effects for interventions that broadly targeted internalizing problems (d = 0.29; Sanchez et al., 2018). Though counter-intuitive and certainly not without critique (e.g., Caldwell et al., 2019), this strengthens the argument that in the right context, less burdensome SSIs may be at least as beneficial as full-length interventions.

It would be useful then, to consider what the "right context" might be. Studies included in the present review vary significantly, despite the specificity of selection criteria. Further, the limited number precluded moderator analyses. However, the current meta-analysis yielded larger effects on anxiety symptoms than depressive symptoms – again, in line with previous findings (Schleider & Weisz, 2017; Weisz et al., 2017). One explanation for this disparity is that youth depression may be less likely to respond to intervention, as it is often characterized by motivational difficulties such as anhedonia (Gabbay et al., 2015). However, it is interesting to note that three of the four studies included in the present 'anxiety' meta-analysis used samples drawn from adolescents at critical periods – either approaching or recently-completing a major transition to university. Fears and anxieties are common during this vulnerable time (West et al., 2010; Grills-Taquechel et al., 2010) and may not necessarily reflect an underlying pathology. However, they are arguably more likely to respond positively to intervention as they may not be accompanied by embedded beliefs or maladaptive behaviours. Indeed, evidence suggests that children's anxiety at times of transition responds well to brief intervention (Cox et al., 2015).

This may explain the absence of prevention-focused studies in the 'anxiety' analysis. Given that symptoms of anxiety are common amongst youth samples, it is therefore easier

but also appropriate to examine *treatment* effects. Conversely, three studies included in the 'depression' analysis were geared towards prevention and individually, they produced small effect sizes. Although this is larger than found in some reviews, the effectiveness of school-based programmes to prevent internalizing problems in children remains an area of uncertainty (Caldwell et al., 2019).

Methodological Issues

Mental health interventions in educational settings are evidently feasible and there appears to be some effects that are worth finding. How well this improves access is difficult to evaluate. In the current review, 37.5% of studies obtained 80-100% participation, a further 50% obtained between 60-79% participation, which suggests that a good proportion of the targeted population are likely to engage with these interventions. However, we cannot easily compare this to SSIs in non-educational settings, for which the 'uptake' of eligible participants is not reported (e.g., Schleider & Weisz, 2017).

Noticeably lacking in studies included in the current review is data regarding race, ethnicity and socio-economic status (SES) of participants. Fifty percent did not contain information regarding race and ethnicity, while 62.5% did not report SES. This is particularly relevant to the issue of accessibility, given that children from economically-disadvantaged or ethnic and racial minority backgrounds are less likely (than middle-to-upper class, nonminority peers) to receive the mental health services they need (Kataoka et al., 2002; Alegría et al., 2015). Known barriers faced by children and families from such backgrounds include stigma, financial cost and transportation (Alegría et al., 2015) and interventions delivered within educational settings could overcome these and decrease disparities in the provision and accessibility of children's mental health care.

High heterogeneity is commonly reported in reviews of mental health interventions in educational settings (Mackenzie & Williams, 2018; Caldwell et al. 2019). In the present

meta-analytic review, random effects models were used to accommodate the large heterogeneity, which generate different pooled estimates than fixed effects models, larger P-values and wider confidence intervals. This may have contributed to the non-significant findings in this review. There are many child outcomes, often linked to mental health, that are of interest to this field of study (e.g., social and emotional comprehension, peer functioning, academic achievement). Inevitably, this means that interventions will vary greatly yet may still generate similar effects (e.g., Sanchez et al., 2018). In the current review, despite large heterogeneity, confidence intervals for pooled effects illustrate that the present findings may be 'approaching' significance, particularly for impact on depressive symptoms.

Strengths and Limitations

To the authors' knowledge, this is the first meta-analytic review of SSIs for youth internalizing problems delivered in educational settings. It adds to the growing literature in this area, both supporting and tentatively extending previous findings. This is particularly important given the diverse nature of interventions that have been (and continue to be) trialled in educational settings. This review demonstrates a need for future research to build on existing findings, to consolidate or improve upon them, so that a more comprehensive evidence base is developed.

Many of the limitations present were due to the methodologies of the included studies. For instance, the large heterogeneity between studies, which sensitivity analyses failed to decrease, weakens the confidence with which we draw conclusions from the present results. The necessary methodological approach was to apply random effects models. While this may increase generalizability, we acknowledge it will also have reduced the power of analysis and may explain the nonsignificant findings.

It was also not possible to analyse data from multiple informants, as the included studies only assessed outcomes from child-report measures. Previous meta-analyses have

demonstrated ‘informant’ to be a pervasive moderator variable (Weisz et al., 2017). Future research should seek to obtain measureable data from multiple informants.

More comprehensive analyses were not viable, given the small pool of included studies. Stringent selection criteria may be responsible this. For instance, interventions were deemed to have multiple sessions if there was any further delivery of content following the initial session, even follow-up contact with clinicians (e.g., Brown et al., 2019). Future reviews might consider the value of examining ‘brief’ interventions, not just SSIs.

Lastly, we only included published, peer-reviewed data and acknowledge that doing so may have produced different results. However, no publication bias was indicated suggesting that the exclusion of smaller studies (often with nonsignificant effects) would not have influenced our interpretation of these findings.

Clinical Implications and Suggestions for Future Research

The results of this review, while tentative, pose implications for both theoretical understanding and clinical delivery of youth mental health interventions. The findings add to an evidence base of SSIs that demonstrate equivalent magnitude of effect to full-length mental health interventions (Weisz et al., 2017) and that educational setting-based interventions are, for some, no less effective than those delivered in community or primary care settings (Mackenzie & Williams, 2018; Sanchez et al., 2018). Not only could SSIs represent a cost-effective alternative or supplement to traditional mental health services, but through delivery in educational settings, they may reduce burden on such services whilst improving accessibility to those in need of support.

To reach a more authoritative conclusion however, there needs to be more randomised controlled trials of SSIs – particularly in non-clinical settings. The current review highlights that existing studies lack rigor in either methodological approach or reporting of data. Key variables such as mean age, ethnicity, socio-economic status will be critical to understanding

how SSIs do or do not work in educational settings. Equally, procedures such as randomisation and blinding could be made more transparent, to aid evaluations of study quality and risk of bias.

Curiously, the present review discovered an absence of studies focused on junior or primary school settings. Given that nearly half of those included were intended as 'preventative' interventions, this is somewhat hard to understand. It may be that intervention content is difficult to adapt for younger audiences, but nonetheless this should form a goal for future research. Of similar importance will be delivery in settings where there is a high proportion of children from low income and/or ethnic and racial minority backgrounds. These are typically resource-strained settings with cohorts who are less likely to access necessary support (Kataoka et al., 2002; Alegría et al., 2015). Demonstrating intervention feasibility, sustainability and effectiveness across different contexts is not only critical to help meet the needs of all youth in education, but may hone the breadth of promising interventions to those that are beneficial to all children and young people.

Conclusion

In sum, SSIs may be an effective means of intervention for youth internalizing problems when delivered in educational settings. Effects were strongest for anxiety symptoms, but larger than previous studies for depressive symptoms. That these findings were nonsignificant means that future research should continue to explore the potential of such interventions. Further and higher-quality studies, investigating SSIs in educational settings are clearly needed.

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Chapter 3. Bridging Chapter

The meta-analytic review described in Chapter 2 presents an overview of the available evidence for single-session interventions (SSIs), delivered in educational settings and targeting youth internalizing problems. To the best of the authors' knowledge, this the first review to deliver a pooled effect size estimate for interventions within this particular context. The findings provide tentative support for existing evidence that SSIs for youth psychiatric problems show promise (Schleider & Weisz, 2017) and further, show that this could extend to SSIs delivered in educational settings.

However, the extremely large amount of heterogeneity, though not uncommon in meta-analytic reviews of psychological interventions in schools (Mackenzie & Williams, 2018; Caldwell et al. 2019), is problematic. It means that for those making decisions about the provision of youth mental health care, especially in light of the recent drive to better embed this in educational settings (Department of Health & Department for Education, 2017), there is no clear picture about what works and for whom. Evidently, there is a need for higher-quality studies in this field. Well-designed and theoretically-sound research can make a significant contribution to the implementation of cost-effective interventions in schools, which in turn may increase access for children, potentially reducing the likelihood that they will need psychological services later in life.

The empirical study, reported in Chapter 4, aims to build a strong foundation in this particular area of research by exploring an intervention's feasibility, acceptability and promise. Furthermore, it seeks to address criticism regarding the risks or potential costs of mindset interventions (Tamir et al., 2007). Through developing and trialling a SSI that integrates additional components with an existing mindset intervention, the study hopes to extend both their theoretical basis and practical application.

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Chapter 4. Empirical Paper

A brief mindset intervention for psychological outcomes in primary school children: A feasibility randomised controlled trial of the Growing Minds Programme

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(See Appendix A for Author Guidelines)

Abstract

There is increasing recognition of the importance of mental health and wellbeing in children and adolescents. Recent UK government proposals highlight the need for school-based interventions to promote wellbeing and resilience. In the USA, researchers have developed a brief 'mindset' intervention that shows promise. The present study involved a pilot randomised controlled trial (RCT), to explore the feasibility and acceptability of testing a modified version of this intervention in UK schools (the 'Growing Minds Programme'). This intervention aimed to also address potential costs of mindset interventions when delivered alone, by adding new elements based on concepts drawn from both Compassion-focused Therapy and Acceptance and Commitment Therapy. Seventy-one participants, aged between 9 and 11 years, were recruited from two UK primary schools and randomised by class into either an intervention or waitlist control group. Outcome measures were collected at baseline, immediate post-intervention, 6-week follow-up and 12-week follow-up. At the end of the study, feasibility questionnaires were administered. Overall, participants reported enjoying and valuing the intervention, while finding the research process acceptable. Moderate effect size estimates were found, indicating improvements in symptomatology and psychological strengths. This suggests preliminary support for the intervention. Larger proportions of clinically-meaningful difference were found in depressive symptoms, psychological flexibility and mindset. However, few of these results represented reliable change. The results indicate that the Growing Minds Programme shows promise as a psychological intervention and that a full-scale trial is both feasible in UK primary schools and acceptable to the target audience.

Keywords: Mindset; Single Session; Primary School; Children; Feasibility; Anxiety; Depression; Self-Compassion; Psychological Flexibility.

Introduction

The mental health and wellbeing of children has become an increasingly popular topic in research, practice and the public understanding. Approximately 50% of mental health difficulties are established by the age of just 14 years (Kessler et al., 2005) and yet, 70% of children and adolescents who experience such problems do not receive appropriate interventions at a sufficiently early stage (Rees et al., 2008). Evidence suggests that "the only sustainable method for reducing burden caused by these disorders is prevention" (World Health Organization, 2004) and national recommendations echo the urgency of this message, with a clear focus on preventative strategies and promotion of healthy behaviours (Department of Health & Department for Education, 2017).

These proposals also highlight schools as key sites for improving access to and 'uptake' of interventions (Department of Health & Department for Education, 2017) – and large-scale pilot programmes are now underway (Ellis et al., 2019). However, there is a clear need to support preventative trials prior to the emergence of mental health problems. These may be most effective in primary schools, as it is understood that the transition to secondary school typically increases children's vulnerability to poor mental health (West et al., 2010).

Major barriers to school-based interventions include a lack of resources and scarce evidence base for appropriate strategies (White et al., 2017). Single-Session Interventions (SSIs) typically involve a low level of practical burden and a recent meta-analysis found that SSIs for youth psychiatric problems were significantly effective (g = 0.32), particularly for decreasing the severity of conduct problems (g = 0.52) and symptoms of anxiety (g = 0.59) (Schleider & Weisz, 2017). Promising effects targeting depression were statistically non-significant, but the authors noted that the paucity of trials targeting youth depression (6 of 50 included studies) prohibits any authoritative conclusion. The mean effect size across all SSIs was only slightly smaller than that of full-length psychological interventions (Weisz et al.,

2017) – which present a much greater burden in terms of time and resource. The meta-analysis that accompanies this paper found SSIs to have a similar magnitude of effect even when delivered in educational settings, suggesting that perhaps such interventions offer a cost-effective response to problems such as the current difficulty in accessing youth mental health care owing to demand-capacity strains.

It is also noteworthy that meta-analytic studies have shown that younger children respond better to SSIs than older adolescents (Schleider & Weisz, 2017; Weisz et al., 2017). The authors proposed an explanation for this finding: that this could relate to the length of time it takes for maladaptive beliefs and behaviours to become embedded. So-called 'growth mindset' interventions aim to capitalize on this.

Mindsets and Implicit Theories

Although various definitions exist (French, 2016), mindsets (or 'implicit theories') are generally understood to be sets of assumptions about the origin and malleability of personal traits or abilities. Mindsets fall on a spectrum: fixed mindsets (entity theories) are characterized by beliefs that abilities or traits are mostly innate and unchangeable, while growth mindsets (incremental theories) are characterized by beliefs that abilities or traits can be acquired or changed through effort (Dweck, 2006). Research suggests that mindsets can exist within various domains, such as intelligence and emotion, but also depression, anxiety and personality (Schroder et al., 2016a). For example, a growth mindset of intelligence incorporates the belief that one can increase their intelligence and the understanding that this is accomplished through effort.

Mindset Interventions

The evidence base supports this idea of 'domain specificity', with mindsets found to predict outcomes in a variety of functional areas, including psychological, emotional and academic (Yeager et al., 2014; Romero et al., 2014; Schroder et al., 2016b). For instance,

compared to those who believed emotions were transient, youth who believed them to be fixed experienced more depressive symptoms, recovered more slowly from stressors and used more maladaptive coping strategies (Tamir et al., 2007; De Castella et al., 2013).

Schleider and Weisz (2018) developed a single-session (20-30 minute) 'growth mindset' intervention for use in mainstream schools. The self-administered intervention described the human ability to change our personal traits, incorporating psycho-education about the brain, vignettes and written tasks. Participants were children aged between 12 and 15 years old, for whom a greater level of risk or symptom severity was indicated by anxiety and depression questionnaire scores, school-based accommodations for psychological symptoms, and/or treatment-seeking within the last 3 years. Compared to 'supportive therapy' control (involving similar tasks but designed to encourage emotional identification and expression), recipients of the intervention reported significantly greater improvements in parent-reported depression (d = .60) and anxiety symptoms (d = .28), as well as self-reported depression (d = .29). These benefits were sustained even at a 9-month follow-up. Whilst effects were small-to-modest, the intervention was both deliverable in schools and had a positive impact on mental health and wellbeing outcomes.

Risks and Costs of Mindset Interventions

Researchers have proposed that teaching individuals about their capacity to change may result in them setting higher expectations and striving to reach these, but experiencing self-blame and feelings of incompetence if change is not accomplished (Tamir et al., 2007). Self-criticism has been widely linked to depression in adolescence (Zuroff et al., 1994) and found to predict fewer positive life events than more adaptive modes of self- and interpersonal relatedness (Shahar et al., 2003).

A key process suggested to defend against self-criticism is the ability to be compassionate to oneself (Gilbert et al., 2004; Whelton & Greenberg, 2005). Self-

compassion, offering understanding and kindness to oneself, is the core of Compassion-focused Therapy (CFT; Gilbert, 2009) and is also drawn upon in other 'third wave' cognitive behavioural approaches such as Acceptance and Commitment Therapy (ACT; Hayes et al., 1999). Such models focus less on 'symptom-reduction' than first and second wave CBT (e.g. Beck 2011) and integrate concepts such as acceptance, mindfulness and personal values (Forman & Herbert, 2009). The inclusion of such elements may help to address the potential costs of mindset interventions and could be incorporated alongside traditional components.

The Growing Minds Programme

The present study piloted an adapted mindset intervention in UK primary schools. The intervention was designed by the authors (JC, AP, GB, RMS) and is based on the original (Schleider & Weisz, 2018), with explicit permission. To address potential costs, additional elements of self-compassion, mindfulness and acceptance were incorporated. This adaptation is considered a 'psychological' mindset intervention but for the purposes of the study, was named the 'Growing Minds Programme'.

Owing to the lack of younger children included in existing mindset research, together with the large evidence base for mental health difficulties often starting in childhood (e.g. Kessler et al, 2005), the present study recruited children aged 9-11 years. It was hoped that targeting this age group might have significant potential as a preventative mental health strategy should the intervention be feasible to larger research trials and implementation.

The present study aimed to answer questions about the feasibility and acceptability of running a full RCT – and whether the intervention showed promise. As such, the overarching research question was as follows: "Is a psychological mindset intervention feasible and acceptable as a school-based, mental health intervention?" Further questions included:

a) What are pupils' and teachers' experiences of the intervention?

b) Can the intervention be successfully implemented in a primary school setting?

c) How feasible is recruitment to the study?

d) How appropriate are the data collection methods?

e) Are the study procedures (such as randomisation) acceptable to participants?

f) Can the evaluation plan be implemented as intended?

g) Does the intervention show promise of being successful with a population of primary school children (aged 9-11)?

h) Could a sample size be estimated for a main trial?

Method

Design

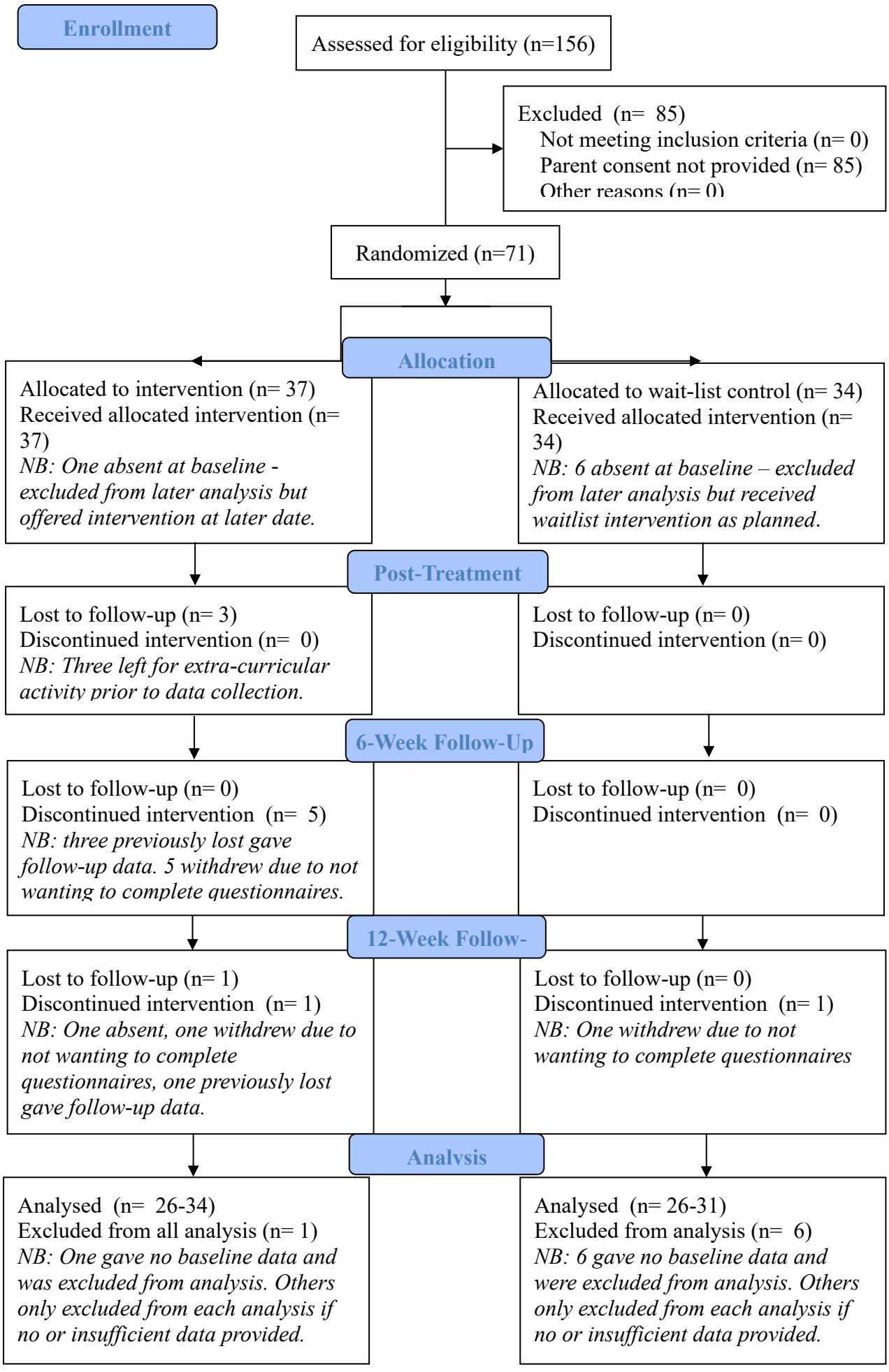
Feasibility studies do not determine whether an intervention is successful (Orsmond & Cohn, 2015), so hypothesis-testing was inappropriate. To answer the research questions, the present study used a feasibility RCT design.

Participants

Participants were children from two different primary schools in the UK. Only children in Years 5 and 6 (aged 9-11 years old) were recruited. Children in this age group are approaching a significant transition between educational settings – and the importance of supportive programmes to help them cope with this is well-documented (West et al., 2010). It was also thought that participants of this age were developmentally 'ready' to understand the intervention. The only exclusion criterion was that pupils unable to read and write in English could not participate (as the intervention has yet to be translated into other languages).

For feasibility studies, a sample size of 50-80 is sufficient to estimate the standard deviation between two groups – which helps determine whether a main trial is worthwhile (Cocks & Torgerson, 2013). The current study recruited a total of 71 participants (Figure 6).

Figure 6. CONSORT Flow Diagram – Participant Recruitment and Retention


Enrollment
Assessed for eligibility (n=156)
Excluded (n= 85)
Not meeting inclusion criteria (n= 0)
Parent consent not provided (n= 85)
Other reasons (n= 0)
Randomized (n=71)
Allocation
Allocated to intervention (n= 37)
Received allocated intervention (n= 37)
NB: One absent at baseline - excluded from later analysis but offered intervention at later date.
Allocated to wait-list control (n= 34)
Received allocated intervention (n= 34)
NB: 6 absent at baseline – excluded from later analysis but received waitlist intervention as planned.
Post-Treatment
Lost to follow-up (n= 3)
Discontinued intervention (n= 0)
NB: Three left for extra-curricular activity prior to data collection.
Lost to follow-up (n= 0)
Discontinued intervention (n= 0)
6-Week Follow-Up
Lost to follow-up (n= 0)
Discontinued intervention (n= 5)
NB: three previously lost gave follow-up data. 5 withdrew due to not wanting to complete questionnaires.
Lost to follow-up (n= 0)
Discontinued intervention (n= 0)
12-Week Follow-
Lost to follow-up (n= 1)
Discontinued intervention (n= 1)
NB: One absent, one withdrew due to not wanting to complete questionnaires, one previously lost gave follow-up data.
Lost to follow-up (n= 0)
Discontinued intervention (n= 1)
NB: One withdrew due to not wanting to complete questionnaires
Analysis
Analysed (n= 26-34)
Excluded from all analysis (n= 1)
NB: One gave no baseline data and was excluded from analysis. Others only excluded from each analysis if no or insufficient data provided.
Analysed (n= 26-31)
Excluded from analysis (n= 6)
NB: 6 gave no baseline data and were excluded from analysis. Others only excluded from each analysis if no or insufficient data provided.

Ethics

Ethical approval was granted by UEA Health Sciences research ethics committee on 27/03/2019 (Appendix D). Please see Appendix E for a copy of the approved application.

Data Collection

The age, gender, ethnicity and school attendance (%) of each participant was recorded. Self-report questionnaires were used to assess various facets of psychological health that the intervention might positively impact upon. These measures had, with the exception of the Implicit Theory Personality Questionnaire, been previously validated for children aged 9-11. Participant and teacher feedback relating to feasibility and acceptability of the intervention was also collected.

The Implicit Theory Personality Questionnaire

The Implicit Theory Personality Questionnaire was used to assess participants' beliefs about the malleability of personality, thus suggesting the type of mindset they have (IPT-Q; Yeager, Miu, Powers & Dweck, 2013). It contains three Likert scale items, on which participants rate their level of agreement with statements about the malleability of personality. Higher scores are indicative of fixed mindsets and lower scores indicative of growth mindsets. The measure has previously demonstrated acceptable reliability (Yeager et al., 2011; Yeager, Trzesniewski, & Dweck, 2013), but has previously only been used with adolescents (aged 14-16).

Self-Compassion Scale for Children

The Self-Compassion Scale for Children (SCS-C; Sutton et al., 2017) assessed the extent to which participants were compassionate to themselves. In a sample of children aged 8 to 12 years old, acceptable internal consistency has been reported ($\alpha = .79$) alongside evidence of convergent validity, with subscales significantly related to all but one correlate of self-compassion (Sutton et al., 2017).

Avoidance & Fusion Questionnaire for Youth

The Avoidance and Fusion Questionnaire for Youth (AFQ-Y8; Greco et al., 2008) was used to measure the rigidity of respondents' beliefs about themselves and their internal experiences, known as psychological inflexibility. This is deemed to be a good outcome measure for both the clinical work of ACT as well as its research (Simon & Verboon, 2016) and in a sample of 8-10 year olds, it has demonstrated adequate-to-good internal consistency ($\alpha = .79$) and good construct validity (Simon & Verboon, 2016).

Revised Children's Anxiety & Depression Scale – Short Version

The Revised Children's Anxiety and Depression Scale (RCADS) – Short Version (Ebesutani et al., 2012) was used to assess the frequency that participants experienced various symptoms of low mood and anxiety. The two incorporated scales (anxiety and depression) have shown acceptable-to-good reliability in school-based samples of children aged 7-14 years ($\alpha = .86$ and $\alpha = .79$, respectively; Ebesutani et al., 2012).

Feasibility Questionnaire

After completing all other aspects of the study, participants were given a brief feedback questionnaire including both open and Likert-scale questions (1-10) in order to capture the respondents' experience of the study. Pupil, self-reported change (in mindset, self-esteem, anxiety, depression and self-compassion) was included to provide an 'anchor' for analysis of clinically-meaningful change in other outcome variables (Johnston et al., 2015). A similar questionnaire was provided to teaching staff involved in recruitment and data collection, with questions regarding the feasibility and acceptability of the intervention and research process, including space for open responses. Both questionnaires were designed by the research team, who drew from those used in comparable feasibility studies (e.g., McAllister et al., 2017).

Procedure

The primary author (JC) contacted 11 local schools to invite them to participate and two agreed. These schools were identified from professional contacts indicating engagement with either clinical or research activities. A teacher at each school (a 'key contact') co-ordinated with other members of staff to gauge interest in, and explore logistics of, the research process. One school requested to exclude their Year 6 pupils, given the pressures of approaching significant examinations. In the other school, both Year 5 and Year 6 pupils took part. There were two classes with 30 pupils each and three with 32 pupils each, a total of 156 children eligible to participate.

Recruitment

Teachers were briefed on the study by the key contact, who had been given a written summary (Appendix F). Teachers introduced the study to pupils in a class setting, before distributing individual information and summary sheets (Appendix G & H) and parent/carer information sheets with consent forms (Appendix I & J). Children were responsible for passing these to parents and despite teachers providing reminders, it is likely that some parents were not given forms at all. Consent forms were requested to be returned to the school within 2 weeks, while child assent forms (Appendix K) were provided immediately prior to the beginning of the study. Parental consent and child assent was specifically for the data collection and not the intervention itself. The intervention was delivered to all children in participating year groups, as per school preference, given that the intervention itself was intended to be beneficial and with little foreseeable risk. Children were offered opportunities to decline the intervention, although none did. Thus, intervention was considered an 'opt-out' process, whilst data collection was an 'opt-in' process. The decision to recruit in this way came from discussion with teachers, and their preference to incorporate the research into the normal school day with as little disruption for students and teachers as possible.

Randomisation

It was agreed (between the research team, key school contacts and the University of East Anglia research ethics committee) that the most appropriate approach to randomisation was to perform it by class rather than individually. This approximates the design of a main trial, which would likely employ cluster randomisation. All classes in participating year groups were randomised to either the intervention group or a wait-list control group, using randomly-generated number sequences. Allocation was carried out by an individual who was independent of the research team.

Baseline Measures

Prior to any data collection, the research team (JC and AP) visited each class to introduce the study to the pupils. All pupils were reminded that neither data collection nor experiencing the intervention was compulsory and that they could opt-out at any time. Those who had parental consent were then asked whether they also gave individual assent, with a member of the research team present to answer questions and counter-sign the assent forms.

Following this, participants were asked to complete baseline self-report measures (Time 1). Experimental groups then undertook the intervention while control groups returned to scheduled lessons.

Intervention

The intervention was a computer-based programme developed by the research team, based on existing mindset interventions (Miu & Yeager, 2015; Schleider & Weisz, 2018). With parental consent, two children (independent of the research team) were asked to read the provisional intervention script and provide feedback. This was used to ‘sense-check’ the intervention content and to make minor adjustments.

The intervention programme consisted of text, audio and animations. First, participants watched and listened to psycho-educational content (drawing upon growth mindset, as well as aspects of CFT, CBT and ACT). This involved a short animated video

and three audio vignettes – a total of 13 minutes. They were then asked to answer three different, multiple-choice questions, presenting short, hypothetical scenarios relating to problems children of a similar age might experience. Afterwards, they read the correct answers (with explanations). Lastly, participants wrote a letter of advice to a hypothetical younger pupil. Together, the multiple-choice questions and writing task were intended to take approximately 15 minutes and this was rarely exceeded. A written transcript and screenshots of the intervention content are provided in Chapter 5 (Additional Methodology).

The intervention programme content was the same for waitlist control groups, but it was delivered only at the end of the study, after all outcome data had been collected at the 12-week follow-up and before administering the feasibility questionnaire. During the allocated time for experimental groups to receive the intervention programme, waitlist control groups returned to scheduled, teacher-led lessons.

Post-Intervention Measures

The outcome measures provided at baseline were repeated at three further time points – immediately after the intervention (Time 2) and at two further follow-ups, intended to be at 6-weeks (Time 3) and at 12-weeks (Time 4). Due to the participating schools' schedules, it was not always possible to secure this precise timeframe (for Time 3 follow-up: 'School A' = 6 weeks, 'School B' = 8 weeks; for Time 4 follow-up: 'School A' = 10 weeks, 'School B' = 12 weeks). The feasibility questionnaire was given to participants only after all groups had completed the intervention, immediately prior to debriefing and the end of participation.

Debriefing

All participants were debriefed at the end of the final follow-up session. This reiterated and summarised the purpose and procedure for the study, as well as giving participants a chance to ask questions or voice concerns.

Data Analyses

Acceptability to pupils and teaching staff was measured by recruitment and retention rates (including reasons given for dropout), and participant and teacher responses to feedback questionnaires.

Outcome measure data were primarily explored through calculation of effect size (ES) estimates. ES however, like statistical significance, does not provide information regarding the intervention's relevance to those affected – an important consideration for future trial design (Sim, 2019). Thus, outcomes were evaluated against 'minimum clinically important difference' (MCID) thresholds. Both anchor- and distribution-based methods were used, with self-reported change scores (as reported in the feedback questionnaire) serving as an anchor for the former and a half standard deviation for the latter. Reliable change indices (RCIs) were also used to determine whether differences over time were significantly greater than could have occurred due to random measurement error.

As a small sample size was anticipated, an a priori decision was made to not summarize (in-text) differences that occurred for =<10% of participants, or where differences between groups was =<10%. This is because change on such a small scale could easily be attributed to non-intervention factors and to account for natural variation between groups.

Missing data for RCADS-25 scores were handled in accordance with the RCADS-25 Child Version Scoring Program 3.1 (UCLA Department of Psychology). This prescribes mean replacement when there are three or fewer missing items on the broad anxiety scale and two or fewer missing items on the depression scale. There is no clear guidance on handling missing data for the SCS-C, AFQ-Y8 and IPT-Q. Following examples set by other studies using such measures (Bratt & Fagerström, 2019), it was decided that mean replacement would be acceptable for <20% missing data (up to two items of the SCS-C and one item of the AFQ-Y8 and IPT-Q). Any instances exceeding this would be excluded from analyses.

Results

Demographic Information

Of the 71 participants, the majority were in Year 5 (55, 77.5%). Forty-two (59.2%) were female, 18 (25.4%) male and for 11 (15.5%), gender was not reported. In terms of ethnicity, 55 (77.5%) were considered White British, three (4.2%) Other White, two (2.8%) Other Ethnicity and for 11 (15.5%), ethnicity was not reported. Forty-nine (69%) had school attendance between 95 and 100%, six (8.5%) had between 90 and 94.9%, and three (4.2%) had between 85 and 89.9%. For 13 (18.3%) participants, attendance was not reported.

While testing for statistical significance of baseline differences is considered inappropriate in RCTs (de Boer et al., 2015), descriptive statistics (Table 3) can help contextualise the findings to some degree.

Table 3. Average Responses to Individual Questionnaire Items

	Intervention Group Mean (SD)	**Control Group Mean (SD)**
RCADS-25	0.63 (0.79)	0.71 (0.81)
SCS-C	1.31 (3.32)	1.30 (3.42)
AFQ-Y8	0.91 (1.12)	0.90 (1.26)
IPT-Q	9.75 (2.99)	10.12 (4.07)

Feasibility and Acceptability

Of the 11 schools approached to participate in the study, 3 responded. One showed initial interest but ultimately stated that they “could not facilitate” the research at this particular time. They did not indicate when would be a better time. Schools were approached in Autumn 2018. The remaining two schools agreed to participate, although one requested that their Year 6 pupils not be included as they felt it would increase their workload later in the year, during a critical examination period. Thus, there were a total of 156 pupils eligible

to participate across both sites. A total of 71 pupils provided both parental/carer consent and individual assent to participate in the data collection. The research team could have taken additional steps to recruit schools (e.g., following up unanswered invitations), but this was not necessary once two schools had agreed to participate.

No children withdrew (or were withdrawn at parental/carer request) from the intervention activity. However, a total of 18 pupils did not complete measures at all time points. The primary reason for this was pupil absence or a conflicting, scheduled activity that teaching staff were unable to re-arrange for them. Five of these 18 pupils withdrew from the study at the 6-week follow-up and another pupil did so at the final follow-up. They all either chose not to give a reason or simply stated that they did not want to do [the questionnaires] anymore. In total, 74.7% of pupils who agreed to participate did so at every available time point. However, as only 8.5% actively withdrew from the study, we may estimate that participant retention rate is between 74.7% and 91.6%.

The 10-point Likert scale feedback questions (1-10, with higher scores indicating greater agreement) indicated that participants thought that the computer activity made sense (M=8.09, SD=2.20), was or will be helpful to them (M=7.07, SD=2.74) and that they would recommend it to a friend or family member (M=7.10, SD=2.50). They did not generally agree that the computer software was hard to use (M=4.12, SD=2.76) or that the activity was boring (M=3.04, SD=2.55). Responses to multiple-choice questions within the intervention demonstrated that participants understood the content. On average, 85.4% of participants identified correct answers. Content analysis of responses to the intervention writing task revealed 5 main themes (example codes in brackets): acceptance of thoughts or feelings (e.g., normalizing and acknowledging transience of experiences), controlling thoughts or feelings (e.g., dismissing and supressing, or focusing on positives), adaptive coping (e.g., emotion regulation and enjoyable activity), making use of relationships (e.g., seeking emotional or

practical support, exploring other friendships or engaging with the difficult relationship) and potential for change (e.g., through action).

Regarding the research process, participants reported being able to understand the questionnaires (M=8.27, SD=1.85) and that they enjoyed taking part in the study (M=7.85, SD=2.42). They generally did not agree that the question sheets took too long to complete (M=4.04, SD=2.90) or that they disliked being randomised to different groups (M=3.32, SD=2.80).

The self-report measure also included space for open responses. These indicated that the majority of pupils had a positive experience of the intervention, finding it broadly helpful (e.g., *"I think everything was helpful because it has told me how to control my actions"*), interesting (e.g., *"it was very interesting and taught me quite a few things"*) and enjoyable (e.g., *"I enjoyed it a lot and loved the questionnaires and activities"*). However, there was a minority of pupils who found parts of the research process tedious (e.g., *"I didn't like answering the questions so many times", "I found it boring"*) or misunderstood procedures (e.g., *"we weren't put into groups"*). Participants' recommendations focused on improving the technology to deliver the intervention (e.g., *"I couldn't really hear what they were saying", "the website was glitching a bit"*), concerns that were observed by the research team during intervention delivery. Some participants noted that it would be a useful activity to offer to others (e.g., *"This study was amazing to the people who needed it, therefore you should carry on to other schools and places"*).

Teaching staff at participating schools were asked to complete a similar feedback questionnaire, to explore whether they felt that the intervention was feasible to run, acceptable to pupils and staff and beneficial to participants. Open response feedback indicated that teachers saw value in the intervention for their pupils, highlighting the universal need for such topics to be present in mainstream education (e.g., *"I feel this is an*

important part of education and would like to see more of this in schools"). Regarding feasibility, teachers noted that the technology used to deliver the intervention required improvements (e.g., *"the activity online was extremely tricky to load on iPads"*) and the need for more support to timetable intervention activities appropriately (e.g., *"timetabling, necessary resources and being made aware of info that needs to be obtained would help with organisation and smooth running"*).

Preliminary Outcomes

At baseline, the mean scores on outcome measures indicated that overall, the sample was representative of a non-clinical population. Sample mean scores for RCADS-25 subscales were well below clinical or borderline thresholds (M=6.66, SD=4.59 for depression, M=9.94, SD=7.60 for anxiety, M=16.43, SD=11.10 for combined). Clinical cut-off have not yet been determined any of the other measures. SCS-C and AFQ-Y8 scores were comparable to those found in same-aged, non-clinical school samples (Sutton, 2014; Simon & Verboon, 2016). This suggests that the present study involved a population sample with low symptomatology.

From baseline to the final follow-up, the intervention group reported greater improvements across all measured outcomes (Table 4). These estimates indicate that the magnitude of effect exceeded 'small' (0.2) and may be considered at least approaching 'moderate' (0.5) for all measured outcomes. Additionally, the proportion of differences that were considered clinically-meaningful and/or reliable was calculated (Table 5). Although this evidences change occurring for more than 10% of the sample, there are few instances where the difference in change exceeds 10% *between* the intervention and control condition. Those that do exceed 10% are highlighted in bold.

Table 4. Between Groups Effect Sizes (ESs) at Post-Intervention and Follow-Up Assessments

	Post-Intervention				**6-Week Follow-Up**				**12-Week Follow-Up**			
	Intervention			**Control**	**Intervention**			**Control**	**Intervention**			**Control**
	Mean (SD)	**ES (*g*)**	**95% CI**	**Mean (SD)**	**Mean (SD)**	**ES (*g*)**	**95% CI**	**Mean (SD)**	**Mean (SD)**	**ES (*g*)**	**95% CI**	**Mean (SD)**
RCADS-25 - Anxiety Scale	10.17 (7.37)	0.10	-0.41 – 0.61	9.39 (7.98)	8.10 (6.90)	-0.10	-0.61 – 0.41	8.82 (7.65)	6.86 (7.11)	-0.38	-0.90 – 0.14	10.09 (9.51)
RCADS-25 - Depression Scale	5.48 (3.86)	-0.32	-0.83 – 0.19	7.04 (5.73)	4.90 (3.49)	-0.35	-0.86 – 0.17	6.57 (5.59)	4.11 (3.34)	-0.61	-1.14 – -0.08	7.23 (6.21)
RCADS-25 - Combined Scale	15.52 (10.19)	-0.07	-0.57 – 0.44	16.29 (12.82)	12.03 (9.67)	-0.28	-0.79 – 0.23	15.16 (12.05)	11.37 (9.93)	-0.68	-1.21 – -0.15	17.20 (6.86)
SCS-C*	38.01 (13.33)	-0.16	-0.67 – 0.35	39.89 (8.73)	41.19 (12.45)	0.12	-0.39 – 0.63	39.82 (9.44)	42.41 (12.08)	0.42	-0.11 – 0.95	37.73 (10.05)
AFQ-Y8	7.20 (7.03)	-0.05	-0.56 – 0.46	7.54 (6.19)	5.61 (5.73)	-0.38	-0.89 – 0.14	8.46 (8.66)	5.33 (6.75)	-0.43	-0.96 – 0.09	8.90 (9.24)
IPT-Q	9.00 (4.94)	-0.22	-0.74 – 0.29	10.00 (3.63)	10.00 (3.93)	-0.26	-0.79 – 0.27	11.00 (3.65)	7.00 (4.36)	-0.66	-1.19 – -0.12	10.00 (4.64)

Note: RCADS-25 = Revised Children's Anxiety and Depression Scale – Short Version; SCS-C = Self-Compassion Scale for Children;

AFQ-Y8 = Avoidance and Fusion Questionnaire for Youth; IPT-Q = Implicit Theory Personality Questionnaire

**for the SCS-C, positive ES estimates indicate improvement – for all other measures, negative ES estimates indicate improvement*

Table 5. Participants Reporting Clinically Meaningful Differences and Reliable Change

		Anchor-based CMD (% Improved, % Deteriorated)*		**Distribution-based CMD (% Improved, % Deteriorated)***		**Reliable Change (%)**	
		Intervention	*Control*	*Intervention*	*Control*	*Intervention*	*Control*
Post-treatment	*RCADS-25 - Anxiety Scale*	7 (9.09, 12.12)	6 (14.29, 7.14)	17 (30.30, 21.21)	16 (39.29, 17.86)	2 (6.06)	0 (0.00)
	RCADS-25 - Depression Scale	5 (12.50, **3.13**)	7 (10.71, **14.29**)	11 (**21.88**, 12.50)	14 (**32.14**, 17.86)	2 (6.25)	2 (7.14)
	RCADS - Combined			18 (30.30, 24.24)	14 (32.14, 17.86)	3 (9.09)	1 (3.57)
	SCS-C	16 (14.29, **31.43**)	12 (16.22, **16.22**)	10 (**11.43,** 17.14)	13 (**23.08,** 26.92)	4 (**11.43**)	0 (0.00)
	AFQ-Y8	12 (**21.21, 15.15**)	2 (**4.00, 4.00**)	13 (24.24, **15.15**)	12 (20.00, **28.00**)	3 (9.09)	2 (8.00)
	IPT-Q	0 (0.00)	0 (0.00)	19 (**45.16, 16.13**)	13 (**23.08, 26.92**)	5 (16.13)	5 (19.23)
6-Week Follow-Up	*RCADS-25 - Anxiety Scale*	8 (25.00, 3.57)	9 (22.22, 11.11)	15 (39.29, 14.29)	14 (29.63, 22.22)	2 (7.14)	1 (3.70)
	RCADS-25 - Depression Scale	9 (25.00, **7.14**)	12 (25.93, **18.52**)	12 (**28.57**, 14.29)	18 (**40.74**, 25.93)	3 (10.71)	2 (7.41)
	RCADS - Combined			16 (46.67, 6.67)	14 (37.04, 14.81)	3 (10.00)	1 (3.70)
	SCS-C	19 (28.57, **39.29**)	13 (29.63, **18.52**)	18 (**25.00**, 39.29)	19 (**37.04**, 33.33)	4 (14.29)	1 (3.70)
	AFQ-Y8	10 (25.00, **10.71**)	12 (18.52, **25.93**)	11 (25.00, **14.29**)	14 (22.22, **29.63**)	4 (**14.29**)	7 (**25.93**)

	IPT-Q	0 (0.00)	3 (7.69, 3.85)	17 (**42.31**, 23.08)	12 (**15.38**, 30.77)	2 (**7.69**)	9 (**34.62**)
	RCADS-25 - Anxiety Scale	9 (25.00, 7.14)	10 (29.63, 7.41)	15 (**46.43**, 7.14)	10 (**29.63**, 7.41)	3 (10.71)	2 (7.41)
	RCADS-25 - Depression Scale	8 (21.43, **7.14**)	13 (29.63, **18.52**)	9 (25.00, **7.14**)	13 (29.63, **18.52**)	3 (10.71)	2 (7.41)
12-Week Follow-Up	*RCADS - Combined*			14 (40.74, 11.11)	10 (25.93, 11.11)	2 (7.41)	3 (11.11)
	SCS-C	15 (30.77, 26.92)	15 (22.22, 33.33)	15 (30.77, 26.92)	15 (22.22, 33.33)	3 (11.54)	1 (3.70)
	AFQ-Y8	12 (**29.63**, 14.81)	11 (**18.52**, 22.22)	15 (**40.74, 14.81**)	12 (**18.52, 25.93**)	2 (**7.41**)	8 (**29.63**)
	IPT-Q	2 (8.00, 0.00)	4 (11.11, 3.70)	14 (**48.00, 8.00**)	13 (**25.93, 22.22**)	7 (28.00)	10 (37.04)

**percentage reported is relative to sample size for respective condition*

These figures suggest that proportionately, more participants in the intervention group reported positive outcomes. Some differences were sustained across time points and suggest a general trend that in the intervention group, fewer deteriorated in relation to depressive symptoms and psychological flexibility, while a greater number improved in relation to their mindset and psychological flexibility. We did not observe marked differences at baseline.

Discussion

Overall, the findings suggest that a psychological mindset intervention is feasible to implement in UK primary schools, acceptable to pupils and teachers and shows promise.

Study Design Feasibility and Acceptability

The response to our recruitment efforts was encouraging. Two of 11 (18%) schools approached were willing to participate. As most communication was through e-mail, it was important to ensure that invitations reached the appropriate recipients (e.g., the head-teacher or SENCO) and telephoning schools often achieved this. Recommendations from professional contacts (regarding schools with previous engagement in research or clinical activities) may well have also contributed to the response rate. Had unanswered invitations been followed up by the research team, it may have yielded an even larger sample.

For the schools who did not respond to research invitations, one relevant factor may be timing of approach. Subsequent trials would benefit from establishing (a priori) when best to contact schools, which could be accomplished through involvement of education-based stakeholders in trial design. It is also plausible that the current demands on members of school staff mean that research opportunities are not responded to at first enquiry or in a timely fashion and thus, it is recommended that additional follow-up approaches are made.

A good proportion of eligible pupils were recruited to participate (45.5%). A number of factors may have contributed to this. Firstly, having well-designed, approachable information sheets. For instance, images were used to add colour and interest to the text and,

so that children could very quickly understand the key points, a summary page supplement was created. Teacher engagement was critical, too. Communication from key contacts throughout recruitment indicated that, where possible, they were reminding children and parents or carers of the research. However, pupils were responsible for giving these to parents and despite reminders, it is likely that some parents or carers were not given forms at all. A main trial will need to share forms through multiple routes (e.g., by post and/or e-mail, via the school website and/or at school events such as parents' evenings) and consider giving reminders to parents and carers. Notably, more than twice as many girls were recruited. The gender distribution of the year groups approached is not known, but it is understood that male participants are typically less responsive to recruitment (Patel et al., 2003). Study designs may need to include additional considerations of how to encourage boys to participate, as future trials will ideally have more balanced gender representation.

The low rate of dropout (8.45%) indicates an acceptable study design. The majority of missing data (11.2%) was due to school absences or conflicting engagements for pupils. Recently-published research found various benefits to scheduling interventions during the school day, including improved access for prospective participants (Girio-Herrera et al., 2019) – a central motivation behind the drive to increase school-based mental health interventions (Department of Health & Department for Education, 2017). However, Girio-Herrera et al. (2019) reported that conflict between research activities and specific curricular tasks is a major barrier for pupils and teachers. It is therefore recommended that researchers consider alternatives, such as administration during lunch times. Above all, researchers must better liaise with teachers to avoid conflicting commitments or limit the number of sessions missed for a particular class. Focus groups with the wider teaching team, throughout study design and planning, could accomplish this. Indeed, teacher feedback noted that greater communication would enable "smooth running" of study procedures.

The findings suggest that cluster randomisation of classes would be appropriate and effective in any subsequent trials. Feedback indicated that participants did not object to randomisation as part of the study design but also that a small number had not fully understood this process, despite information sheets and direct explanations from researchers. This could reflect poor wording of feedback questions, or a misunderstanding that randomisation would be at an individual level. Primary school children may need additional support to grasp this process, perhaps using school-based examples. This has notable implications for future trials, which should carefully plan how to ensure prospective participants understand all study procedures before providing consent and assent. Teacher feedback suggested very little objection to randomisation for the purposes of research (M=2.2, SD=1.47) and no parents or carers raised concerns.

Outcome measures were successfully administered. Across all time points and measures, there were only two instances (involving separate participants) where the proportion of missing items meant that mean imputation was not possible. However, the multiple questionnaires may have been experienced as tedious and/or too long for the average concentration span of the children recruited, which may be one reason for participant dropout (as indicated by some participants). Although exploration of various outcomes was necessary to evaluate the integration of additional intervention content, guidance for research with children recommends that questionnaires be “as short as possible” (O’Reilly et al., 2013). Future trials may improve participant retention by using fewer outcome measures and data collection points, perhaps also considering incentives to complete questionnaires. Parents and carers did not raise any concerns with the nature of questions being asked.

Data were of a sufficient quality and ‘completeness’ for estimates of effect size, clinically-meaningful difference and reliable change to be calculated. These methods rely on validated measures, with existing estimates of internal consistency. In the absence of such a

measure for a ‘psychological’ mindset (that incorporates components of various mindset domains), the present study used the IPT-Q, which focuses on mindsets of personality. Although the authors were unable to integrate additional questions while retaining internal consistency, there is nonetheless a clear need for a validated, reliable mindset measure that integrates multiple domains. This would be enormously beneficial to subsequent research in this area. In a separate learning point, the research team identified that paper measures were both expensive to print and time-consuming to use. Future trials could decrease this cost by using digital outcome measures, provided this technology works correctly and efficiently.

Intervention Feasibility and Acceptability

Quantitative and qualitative feedback indicates that the vast majority of participants found the intervention useful, interesting and enjoyable. It is possible that this represents a form of response bias, as children may be more vulnerable to this given their variable literacy and linguistic skills (Zeman et al., 2007). However, both the good retention rates and the participant responses to questions within the intervention suggest that they engaged with the content. Open feedback supports this, with comments reflecting an underlying grasp of what the intervention was trying to achieve. Further, teachers were enthusiastic for their pupils to learn about the psychology of mindsets. The technological demands of the intervention were perhaps the main obstacle to efficient delivery. Participants and teachers reported difficulties with the online program, which did not run as smoothly on tablet computers as desktops. Further development of the intervention, with a focus on successful integration with tablet computers, would likely solve this for future trials.

Preliminary Outcomes

Compared with a waitlist control group, those who received the Growing Minds Programme showed markedly greater improvements in symptoms of anxiety and depression, self-compassion, psychological flexibility and mindset. There was a trend for outcomes to

improve over time, with the largest and most consistent improvements at the final follow-up. Intervention effects were mixed at immediate post-treatment and somewhat weak at 6-week follow-up. The ESs at final follow-up were greater than those reported in previous single-session mindset interventions (Schleider & Weisz, 2018; Schleider et al., 2019). It may be that the growth mindset intervention was enhanced by additional components drawn from CBT and 'third wave' cognitive behavioural approaches.

However, while ES estimates may indicate whether an effect *can* be found, clinically meaningful difference provides some indication of whether an effect is *worth finding* and therefore is of significant value to the design of main intervention trials (Leon et al., 2011). Evidence of clinically meaningful change was mixed, but there was a general trend for the intervention group to experience greater improvement in psychological flexibility and mindset, in addition to less deterioration with regard to depressive symptoms and psychological flexibility. Psychological flexibility and growth mindsets represent similar human capacities – that is, our ability to accept present experiences and willingness to adapt in the pursuit of goals. Inflexibility, such as in the 'rigidity' of thoughts, has often been linked to depression (Chawla & Ostafin, 2007; Ruiz, 2010; Schleider et al., 2015). Given the paucity of SSIs targeting youth depressive symptoms (Schleider & Weisz, 2017), the present study gives weight to the suggestion that mindset interventions could address this gap – particularly with a view to the prevention of mental health problems. However, these findings must be taken with caution, as a relatively small proportion of differences were found to be reliable. Moreover, the sample as a whole appeared asymptomatic at baseline, thus any reductions observed may not reflect meaningful *change.*

Limitations

While the current study makes a valuable contribution to a growing area of research, there are a number of limitations that should be acknowledged when interpreting the findings.

It is likely that the recruitment methods biased our sample towards pupils who were more motivated and/or had more engaged parents. While it is predicted that this bias affected both intervention and control groups in a similar way, we cannot suggest that the findings generalize to pupils who did not participate in data collection. Additionally, researchers were not present for initial introduction of the study to pupils, so we cannot exclude the possibility that recruitment was influenced by teacher pressure – although this was not reported in feedback. Having researchers present at this stage would help minimise bias in future trials. While their direct involvement during administration of outcome measures could have influenced participant retention and is known to distort responses (Webster, 1997; Lavrakas, 2008), it may also have safeguarded against participants conferring while completing measures and offered them the opportunity to have their queries answered appropriately.

The methodological approach of the present study would, in a larger trial, equate to a cluster randomised-controlled design. This would therefore require a far larger sample than individual randomized-controlled trials *and* further calculations, due to intra-cluster correlation. However, it facilitates the intervention and study delivery in a real-world setting, where individual randomisation is not feasible. Such approaches appear to work well with weaving research into schools with minimal disruption and are common in school-based intervention research (Stallard et al., 2012; Stallard et al., 2014). Thus, the outcomes explored in this study will enable future researchers to plan accordingly for such a design.

By nature, feasibility studies have limited external validity because we cannot state that the effects found were unlikely to have occurred by chance (as statistical significance was not evaluated). However, feasibility studies are an essential part of developing and trialling interventions, so it is simply that conclusions ought to be made with caution.

Lastly, in the absence of a reliable, validated measure of a psychological mindset, the current study can only report participants' change in mindsets of personality.

Clinical Implications and Suggestions for Future Research

Taken together, the results from the present study strengthen the case for a brief mindset intervention in response to current challenges of addressing youth mental health and wellbeing. They illustrate the high acceptability and feasibility of both the intervention and the study design(s) required to evaluate these. Participants reported a positive experience, highlighting interest in and helpfulness of new learning, as well as enjoyable aspects such as the animated video. Teachers too, noted the importance of these psychological concepts being introduced to schoolchildren, and no parents raised any concerns about the content or process. The findings also indicate that the mechanisms targeted by the additional components of the Growing Minds Programme show post-intervention differences between groups (i.e., in self-compassion and psychological flexibility).

In addition to specific recommendations made in this paper, future study of mindset interventions would benefit significantly from the development and validation of a measure for mindsets across various domains (e.g., 'psychological' mindset). Researchers may also wish to collaborate with teachers to develop a brief guide for how to deliver the Growing Minds Programme. This could include effective involvement and implementation strategies, intervention content and rationale. This would help reduce practical and technological barriers (which are critical barriers to overcome), minimise biases in recruitment or responding and contribute to the development of a scalable SSI to meet the current demand.

Conclusion

In conclusion, this study demonstrates that a trial of the Growing Minds Programme is feasible to conduct in UK primary schools and acceptable to children in Year 5 and Year 6. Further, there is some indication that it may prove beneficial across a variety of psychological domains and that the addition of content from 'third wave' psychotherapies may be useful.

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Chapter 5. Additional Methodology

This chapter describes additional methodological processes from the systematic review (Chapter 2) and the empirical study (Chapter 4). The main chapters present all information that is critical to understanding study processes – the information contained in this chapter is considered supplementary.

Additional Methodology: Systematic Review

Contacting Authors

After the primary researcher (JC) had screened article titles and abstracts, 104 articles remained and were subject to full-text assessment of eligibility. Among these, five could not be accessed as full-text, English language articles. As such, JC contacted each paper's author(s) and received two replies. These two studies did not meet the inclusion criteria and were excluded. The remaining three were excluded due to lack of sufficient data.

Additional Methodology: Empirical Paper

Demographic Data

Demographic data were collected at the end of the study, so data for participants who dropped out were not recorded. It was not requested for pupils who were absent at baseline or who did not provide consent until only after Time 1 or Time 2 – this was an oversight by the lead researcher (JC). Lastly, one school did not provide attendance data for two participants and follow-up requests by JC were not responded to.

Reliability of Instrument to Measure Mindset

The research team designed three questions to supplement the Implicit Theory Personality Questionnaire (IPT-Q; Yeager, Miu, Powers & Dweck, 2013). This was intended to encompass beliefs about internal experiences (e.g., thoughts and feelings), as they are important components of psychological mindsets (e.g., Tamir et al., 2007; Schroeder et al., 2016). The additional questions were as follows: (a) you can completely control your thoughts, feelings and urges, (b) the things our brains do make sense, (c) your thoughts, feelings and urges come and go. As with the IPT-Q, these questions were provided on a 6-point Likert scale, with higher scores indicating a greater level of agreement with statements. It was decided a priori, to protect the validity of the original IPT-Q, that these original items would be evaluated separately. However, this revealed that the internal consistency was poor ($\alpha = 0.03$) and the additional questions were not used for analyses.

Randomisation Procedure

The randomisation procedure, which in a main trial would equate to cluster randomisation, was carried out as follows (once for each participating school):

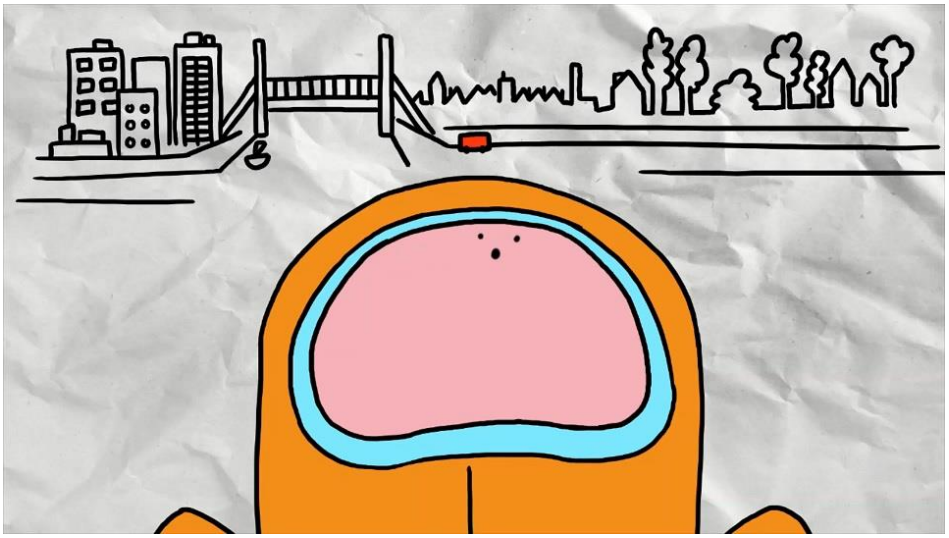
1. A random numerical value was assigned to each class in each participating year group.

2. An instance of ‘T1’ was generated for half the classes and an instance of ‘T2’ was generated for the remaining half. For example, if a school had 4 classes available for the study, two instances of ‘T1’ and two instances of ‘T2’ would have been generated.
3. These were then arranged in a single column, in a systematic order (i.e., T1, T2, T1, T2 etc.).
4. A second column, alongside the first, was populated with numbers generated at random by computer software.
5. These random numbers were sorted according to size or value. This created a random and unpredictable order of T1s and T2s.
6. In a third column, the random values that were earlier assigned to each class or form, were added. These were entered in numerical order, thus allocating each class or form randomly to either the intervention (T1) or control (T2) group.

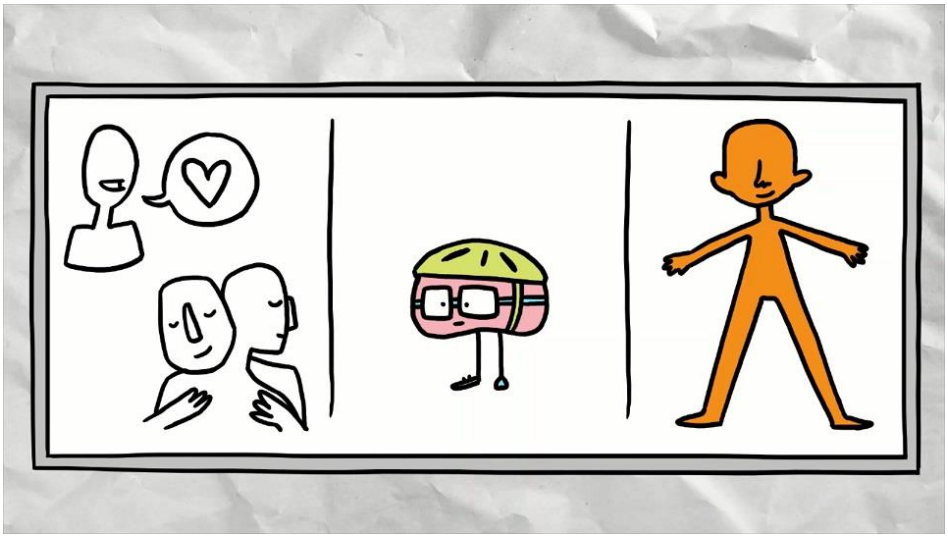
Intervention Transcript

Narrator:

Our brains are very complicated. They are made from billions of little parts (called ‘nerve cells’). These nerve cells work together to make us think, feel and act. When you wake up in the morning, your brain tells you to move your arms and legs. But it is also making you think and feel. Maybe you think “Oh, I need to get ready for school”. How would this make you feel? Happy? Excited? Nervous? Annoyed? So you see, what we think and feel is connected. We can think something and that makes us feel a certain way. When you walk towards a road, your brain might think “that car is going quite fast”. This might make you feel worried. Of course, your brain then tells you not to cross the road!



There is a part of your brain whose only job is to look after you. Let's call it the 'safety' brain. Human beings have been around for millions of years – that's because our safety brain has done a great job! Sometimes it keeps us safe from physical danger… and sometimes it keeps us safe from things we imagine are dangerous – even if these aren't really things to worry about. Our safety brain learns what is dangerous from the things that happen in our lives. Imagine other people were really nice to you every day. Your brain might learn that other people are fun and friendly! It might tell you to keep spending time with friends. Now imagine you had been bullied. Other people might seem really frightening after that! Your brain might tell you to keep away from other people. Our brain learns from all the different things that happen in our lives: going to school, moving house, being looked after by grown-ups… These are just some examples of things that affect what our brain learns.



What does all this mean? Well, it means that everything our brain does is for a reason. Even if it does things we don't like, such as making us feel scared or angry, these things are completely normal. They happen because of all the things that are affecting our brains and all those things that our brains have learned from.

Summary Text:

- Our brain makes us think, feel and act.
- What we think and feel is connected.
- A part of our brain tries to keep us safe.
- This 'safety brain' learns from things that happen to us.
- So everything our brain does is for a reason.

Narrator:

Sometimes, people say we should just stop thinking or feeling something – but this never really works. Let's try it now. In the next ten seconds, whatever you do, *don't* think about a pink elephant. See? Not only did you think about a pink elephant, you probably thought about it more than ever before! Why do you think this happens? Well, scientists think that the brain sends millions of messages *every single* second. Imagine trying to control all of this… it's almost impossible!

So our thoughts and feelings come from our brains. But once we have a thought or feeling, does it get stuck in our brain? Well, the answer is no! Thoughts and feelings come and go, every day. We might be feeling happy until something happens, and then we feel worried. Has something like this ever happened to you? Although thoughts and feelings don't last forever, we *can* have certain thoughts and feelings coming up again and again. Why does this happen? Well, when our brain sends the same message lots of times, that message can become stronger. A bit like your muscles – the more they 'work out', the stronger they get. For example, when we fall off a bike, our brain sends messages to be careful of riding bikes. If we fall off a bike three times, this message can grow so strong that we become scared of bikes. But if we get back on the bike and *don't* fall off, that 'scared' message might get weaker and we might not feel so frightened of bikes in the future. So you see, it is really important for the brain to change. It helps us learn!

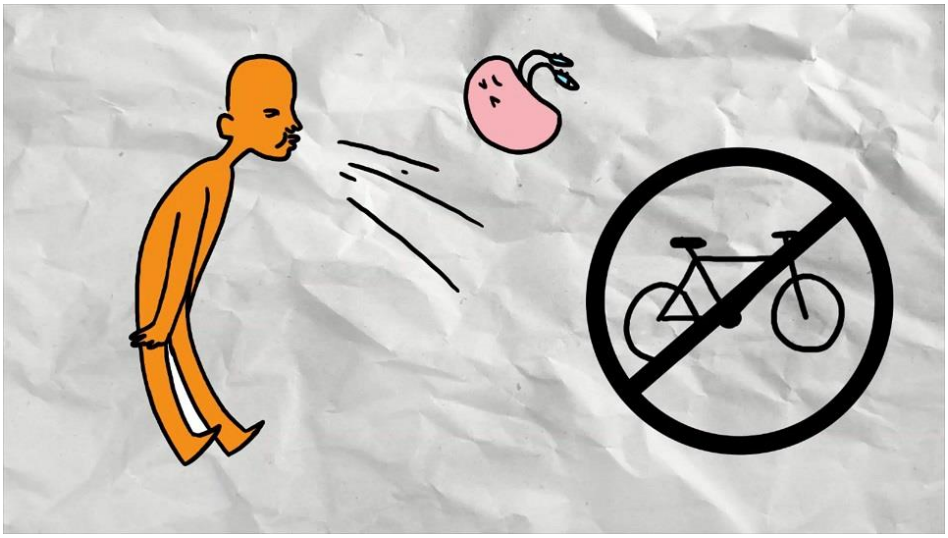
These messages in your brain are part of what makes you, you. Your brain might send strong or weak messages about being shy, being clever, being funny, being good at sport, being good at school work… these are just some examples. Together, these messages make patterns of how we think, feel and act. We call this our 'personality'.

Summary Text:

- It is almost impossible to control what we think and feel.
- But thoughts and feelings do change. They come and go all the time.
- Some thoughts and feelings come up more often. Some might be nice, some may not be.
- These ‘messages’ get stronger the more they are sent.
- Together, all of this makes your ‘personality’.

Narrator:

Our personality comes from our experiences and our biology (that’s our bodies). So it isn’t our fault which messages develop, get stronger or get weaker – the things that happen to us are often outside our control. We don’t always like our personality! For example: some people might like feeling clever, but other people might hate it. We all have things we like and don’t like about ourselves. Many people believe that our personality is fixed – that it can’t change. But we know that this isn’t true. Our brains and our personality can change over time. A bit like Play-Doh, it can be re-shaped. We don’t have to stay the same; we can grow and change. Remember what we said earlier? It is almost impossible to control all our thoughts and feelings. But we *can* control how we react to them. We can change what we do and how often we do it. This is how the brain learns new ways of doing things. Sometimes, we can even change bits of our personality! For example, we don’t have to listen to our brain when it tells us not to ever ride a bike. It might be scary, but that’s our safety brain giving us that feeling. If riding the bike is important to us, we can do it anyway… and hey, it could be loads of fun!



Choosing new ways to react… trying to make changes… it isn't easy! There are things in the world that we can't control – and these things can make changing more difficult. We can't do something impossible (like staying calm when we have been punched, or being happy when we don't get picked for the netball team). It also takes lots of time to change. This means that we need to be kind to ourselves and not expect too much. It could be helpful to imagine that the brain is like a garden. Like all gardens, you have to try to look after it even though it takes lots of time, or things happen that make it more difficult for plants to grow. Just like you can't control the weather, we can't control all the events in the world around us – or how these will affect our brains. However, we can try to respond in a way that is helpful to us. So, what have we learned?

Summary Text

- Humans have all sorts of thoughts and feelings, coming and going everyday. Some we like, some we don't like.
- These thoughts and feelings can come up because of our past experiences and our biology. It is our brain's way of looking after us.
- We can't fully control these thoughts or feelings, but we can choose how to respond when they come up.
- Sometimes, our reactions help our brain learn new ways of doing things.
- It often means that we get to do more of the things that are important to us.

Audio Vignettes

To help you see how young people think about all these things, we have asked them for some examples. Let's hear from them now.

"Noah" (Actor)

Hi, my name is Noah. I get really nervous when we have sports lessons at school. Sometimes, I actually feel sick. It's horrible and makes me not want to come to school at all. I think I am like this because my Dad and my teachers are always saying that I'm really good at school subjects. But I don't feel very good at sports. I don't want to let anyone down. All these worries stop me from doing nice things. They even stop me concentrating in other lessons when I know we have sports later. I used to try and ignore these thoughts and tell myself to stop thinking that way. But it never really works. Like, if I told you 'don't think about a pink elephant for the next 30 seconds', I bet you can't do it… I bet you're thinking of pink elephants even more than normal, right?

Now I know my safety brain is trying to look after me. It's making me worried because being good at lessons is important to me! So I'm trying to be kind and remember that these thoughts will come and go. It's normal. You know, my brain probably thinks it has to

be good at everything, all the time. But thoughts and feelings change from moment-to-moment. I guess this means I don't have to be good at everything, all the time. I can just be me.

I still get worried about exams. But now I'm happier being me: sometimes clever, sometimes silly.

"Ava" (Actor)

Hi, I'm Ava. School is hard for me. I get in trouble for shouting and fighting. My teacher said that I'm angry a lot, too. I know I feel angry when school work is too hard, when people don't listen to me, when my sister is being annoying… I don't like it, but it feels like I can't control it.

It really makes sense that this all comes from my brain. My brain might have learned to be angry for all sorts of reasons, so I know this feeling is normal. I also know that sometimes feelings come up when they don't need to, because the brain is just 'making sure'. When this happens, it helps to remember that even though a feeling can be really strong, it can't actually hurt me. Now I know that feeling angry is normal, I also know that feeling this way does not make me a bad person. The things that make me angry are not nice things! My brain is just trying to protect me. I am still going to try changing things, though. I will try different ways to react when I feel angry. Maybe it will help my brain learn it doesn't need to be angry to keep me safe.

I'm not in trouble as much at school now. I don't always get it right, but I'm trying and I feel better.

"Levi" (Actor)

I'm Levi. I don't have many friends at school – probably because I get really embarrassed to talk. I never know what to say! Mum said that I'm just shy. I wish I wasn't. In

my last school, some of the other kids made fun of me. I ignored it, but I did feel lonely. I didn't know what I could do to change things.

It's difficult to remember sometimes, but being shy now, doesn't mean I will always be shy. I know that my brain can change, but that I have to do something to help it to change. So even though it's really scary, I am now trying to speak to people even if I don't know what to say. It does help! I also learned something new: just because I don't like it, doesn't make shyness a bad thing. I practiced being brave the other day and spoke to my classmate. Do you know what he said? He said he likes sitting next to me <u>because</u> I'm quiet. Now, we sit together at lunch.

I don't think I'm a shy person anymore. I'm quiet, but I definitely speak to people – everyday!

Multiple Choice Questions

Question 1

Alfie didn't get the grade he wanted on a class exam. He felt disappointed and embarrassed, believing he was not a smart person. Based on what you have learned today, what response do you think would be helpful for Alfie? Tick the answer or answers you believe could help.

A. He could control his emotions. If he doesn't want to feel disappointed or embarrassed, he can just focus on feeling better instead.
B. He can notice that feeling this way is normal – of course he didn't like getting a low grade. He can also be brave and share his result with a friend, then ask himself 'does this really mean I can't be smart?'

Q1: Post-Answer Summary

It is almost impossible to control our emotions. Remember how complicated your brain is?! It would be good for Alfie to remember that it's normal to feel disappointed

sometimes. If he shares his score with a friend, he might feel less embarrassed. Alfie can remind himself that a low score just means he hasn't done enough to get a high score… *yet.*

Question 2

Maya felt angry and upset when she heard someone saying something horrible about her. She thought "there must be something wrong with me." Based on what you have learned today, what response do you think would be helpful for Maya? Tick the answer or answers you believe could help.

A. It is normal to be upset and angry hearing something like this – and even if Maya sometimes has thoughts that there is something wrong with her, this does not make it true.
B. Maya might have lots of worries and it would help her to focus hard on feeling better.

Q2: Post-Answer Summary

It would be good for Maya to remember that feeling angry and upset is a totally normal response. She might think that there is something wrong with her, but having this thought doesn't make it true. It is easy to confuse "trying to change" with "trying hard to feel better". We can't control how we feel or think, so we should focus our effort on choosing more helpful actions.

Question 3

Lily forgot her lines in the school play. She heard her parents say that she "is just a very nervous girl". Lily felt upset, thinking she might not be able to become a teacher as it meant standing in front of people and talking. Based on what you have learned today, what response do you think would be helpful for Lily? Tick the answer or answers you believe could help.

A. Lily should accept that she is nervous and that this is probably her fault. She could think about doing a different job, instead.

B. Lily should accept that she is nervous, but that it doesn't mean she can't be a teacher. She could think about learning ways to cope with this.

Q3: Post-Answer Summary

It would be good for Lily to accept that she feels nervous sometimes, but this really isn't her fault. There are lots of reasons our brain makes us think or feel things! Lily could still be a teacher, even if she gets nervous. If she wants to, she can try learning new skills that help her talk to people.

Letter Writing Activity

We would like you to write a letter of advice to a younger pupil. Imagine it is their first day at a new school. They are hanging out in the playground. They see a friend from last year. They don't know many other kids, so they say hello and wave their hand. But their friend turns around and talks to someone else. How would you feel about this? What kinds of thoughts do would you have? Please write in the box below.

What could you say to help them cope with thoughts and feelings in a different way? How could this help them over time? Using the information you have learned about today (e.g., thoughts and feelings, personality, the brain and how to change), please write a letter to this younger pupil.

Content Analysis

This followed an inductive approach, whereby a structure emerged from the analysis, rather than applying a pre-determined framework. This was selected as the measure and questions were unique to this evaluation. The process involved multiple steps: first, the primary author (JC) familiarised themselves with the data, reading through participant responses multiple times and recording their initial impressions. Four reflective questions were answered, based on published guidance for qualitative content analysis (Erlingsson & Brysiewicz, 2017):

- What is the text talking about?
- What stands out?
- How did I react reading the text?
- What message was I left with?

Following this, JC sought to condense individual statements into smaller units. This was a repetitive process, involving revisions, to ensure each unit retained the original meaning and could then be considered a ‘meaning unit’. Meaning units were subsequently attributed ‘codes’ to concisely describe them and allow connections between units to be more easily identified. JC then sought to organize the codes into broader categories; appraising them to determine which codes appear to belong together, thereby creating a category.

Clinically-Meaningful and Reliable Change Calculations

Two approaches to determining the MCID exist. Anchor-based methods, which compare the difference in outcome scores to an external measure of change, are regarded as preferential (Johnstone et al., 2015). Anchor-based MCIDs were determined from participants’ scores on a self-reported measure of change. This ‘anchor’ measure had been designed by the research team for the purpose of analysis and included five items on a 7-point Likert scale. Each item corresponded to a different standardized measure used across the

study (Johnstone et al., 2015). The mean difference in outcome measure scores was taken for those that reported small change on the 'anchor' measure, thus defining the MCID (Revicki, Hays, Cella & Sloan, 2008).

However, given that participants only completed the self-report measure of change at the final follow-up, it was considered appropriate for additional, distribution-based methods to be performed. This compares the difference in outcome scores to a measure of variability and in the present study, the MCID was represented by a half SD (Revicki et al., 2008).

Lastly, the reliability of any changes was assessed through calculating the reliable change index (RCI) for each set of mean differences. The RCI is used to assess whether difference in scores over time is significantly greater than could have occurred due to random measurement error. It is calculated by dividing a mean difference score by the standard error of this difference. An RCI that is >= +/-1.96 is considered not likely to be due to measurement error alone (as 1.96 corresponds to the 5% tail of a normal distribution).

Sister Study

A 'sister' study, carried out by another trainee clinical psychologist at the University of East Anglia (AP), ran alongside the empirical study presented in this thesis. AP's study explored the feasibility and acceptability of a similar intervention but with 16-18 year olds. This point of difference reflected an underlying theoretical assumption that the age groups represented children experiencing developmental change and transition (e.g., in roles, social groupings, identity, relationships) – and that during this time, they are more vulnerable to mental health stressors (West et al., 2010; Grills-Taquechel et al., 2010). However, there is no consensus about which age or developmental period would most benefit from mindset interventions, only that negative, psychological experiences (e.g., anxiety) can respond better to intervention during periods of transition (Cox et al., 2015). As the proportion of young

children who experience difficulties with their mental health increases (Kessler et al., 2005), it is clear that intervention and preventative strategies should be provided at an earlier age.

The trainees drafted the study design (e.g., follow-up times, analysis plan) and intervention together, in addition to supporting each other to deliver the intervention and collect outcome or feedback data. However, the intervention content was subsequently and individually adapted by each trainee, so that it was appropriate for the relevant age group. Differences were minimised where possible. The trainees also individually adapted study designs, including randomisation procedures and outcome measures.

The following processes were conducted entirely individually: recruitment of and communication with host sites, creating information sheets, consent forms and assent forms, storing and handling data, conducting analyses and reporting the study as an empirical paper.

Chapter 5: References

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Chapter 6. Additional Results

This chapter presents additional results for both the systematic review (Chapter 2) and the empirical study (Chapter 4).

Additional Results: Systematic Review

Study Quality and Risk of Bias Assessment

As described in Chapter 2, assessments of study quality were carried out for each paper included in the review. Overall ratings of quality and risk of bias are presented in the main chapter, but a detailed consideration of these assessments is provided in Table 6 and Table 7 below. For study quality, green represents a score of 1, which indicates that this was an area of strength; orange represents a score of 2, which reflects an area of moderate quality; and red represents a score of 3, indicative of weak quality. For risk of bias, these same colours represent similar constructs: green represents an area that was well-addressed by the study, orange denotes an area that was partially-addressed and red an area that was poorly-addressed by the study.

Table 6. Quality ratings of individual assessment items for all studies included in the review

	Study Quality Criteria						
Study	**Selection Bias**	**Study Design**	**Confounders**	**Blinding**	**Data Collection**	**Withdrawals**	**Overall Quality**
Armento et al. (2012)							
Calvete et al. (2019)							
Fu et al. (2015)							
Gawrysiak et al. (2009)							
Geisner et al. (2015)							
Miu & Yeager (2015)							
Schleider et al. (2019)							
Zucker et al. (2002)							

Table 7. Risk of bias ratings of individual assessment items for all studies included in the review

	Risk of Bias Criteria					
Study	**Selection**	**Performance**	**Attrition**	**Reporting**	**Other**	**Overall Risk of Bias**
Armento et al. (2012)						
Calvete et al. (2019)						
Fu et al. (2015)						
Gawrysiak et al. (2009)						
Geisner et al. (2015)						
Miu & Yeager (2015)						
Schleider et al. (2019)						
Zucker et al. (2002)						

Additional Results: Empirical Paper

Participant Responses to Intervention Tasks

Participants were asked to complete a set of multiple-choice questions, described in the Additional Methodology (Intervention Script). Of the 71 participants consented to data collection, 55 had their answers to intervention questions recorded. This discrepancy is partially explained by pupil absence. Further, researchers (JC and AP) noted that some pupils had not correctly submitted their answers at the end of the intervention. Although we offered support to pupils who experienced difficulties, it is possible that some did not submit their data. The technology to deliver the intervention was designed to not allow participants to progress past a question unless they had provided an answer. Despite this, four participants' responses were not recorded, which suggests there may have been a technological fault.

On average, 85.4% of participants gave correct responses across the three multiple-choice questions. Regarding each individual question, 35 (63.6%) gave correct responses to question one, while 51 (92.7%) and 55 (100%) gave correct responses to questions two and three, respectively. Notably fewer participants responded correctly to the first question. On reflection, we wonder whether the available answers were not clearly defined as 'correct' or 'incorrect'. For instance, one response is deemed incorrect because it suggests we can control our emotions. Although the intervention tried to clarify that we can control our actions, not our feelings, this wording of this question may have been too subtle for participants to apply their learning to. Additionally, the 'correct' answer implies sharing concerns with a friend, which may not be perceived by pupils as a positive strategy. Overall, this suggests that multiple-choice questions are a good way to help participants embed learning, but their success relies on well-formulated, appropriate questions. Future trials should consider this.

Open responses to the letter-writing task were analysed using simple content analysis, following published guidance for this method (Erlingsson & Brysiewicz, 2017). The primary

author (JC) first familiarised themselves with the data, reading through participant responses multiple times and then answering four reflective questions (Table 8). Following this, the JC condensed individual statements into ‘meaning units’ and attributed these to ‘codes’ that could concisely describe them. For instance, “your thoughts and feelings come and go, so it is alright to feel that way – but it doesn’t mean that you can’t do anything about it”, was condensed into three meaning units: “thoughts and feelings are transient”, “feelings are normal” and “you can change things”. Similarly, “you could go and talk to your friend from last year and see what they are up to – try not to feel empty” was condensed into two units of meaning: “could seek other friendships” and “try to avoid a negative feeling”.

Through organizing the codes into broader groups, five categories emerged: acceptance of thoughts or feelings (e.g., normalizing and acknowledging transience of experiences), controlling thoughts or feelings (e.g., dismissing and supressing, or focusing on positives), adaptive coping (e.g., emotion regulation and enjoyable activity), making use of relationships (e.g., seeking emotional or practical support, exploring other friendships or engaging with the difficult relationship) and potential for change (e.g., through action).

Table 8. Researcher’s Initial Impressions of Qualitative Feedback

Question	Researcher (JC) Response
What is the text talking about?	The participants reflected on how they might feel in the given situation and then made various suggestions for how the hypothetical ‘younger pupil’ could respond (in a helpful way).
What stands out?	Lots of acknowledgement of sadness, disappointment or anger. Helpful comments about coping strategies, seeking support and making new friends. Perhaps less helpful (but common) statements

	about controlling emotions.
How did I react reading the text?	Encouraged to notice lots of compassionate responses, feeling grateful to the pupils. Frustrated by suggestions to supress or dismiss thoughts and feelings.
What message was I left with?	Generally, pupils recommend seeking support and/or making new friends as a strategy. This may be complemented by adaptive coping (e.g., calming or enjoyable activity, normalizing) or occasional less adaptive coping (e.g., controlling thoughts or feelings).

Participant Feedback

Quantitative data were collected from 14 questions regarding participant experience of the study. For the purpose of analysis, these were split into three categories: "experience of the intervention", "experience of the research process" and "self-reported change". Responses ranged from "strongly disagree" (1) to "strongly agree" (10) for the first two categories. For the latter category, responses ranged from "much less" (1) to "much more" (7) for the first three questions, then "much worse" (1) to "much better" (7) for the latter two questions. Table 9 presents mean responses, alongside standard deviations and interquartile ranges. Qualitative feedback was captured in open-ended "comments" sections of feedback questionnaires (Table 10).

Table 9. Mean Responses to Feedback Questionnaire - Participants

Experience of the Intervention	Mean	SD	IQR	N
The computer activity made sense to me	8.09	2.20	3	45
The computer software was hard to use	4.12	2.76	4	45
I think the computer activity has been/will be helpful for	7.07	2.74	3.5	45

me				
I would recommend the computer activity to a friend or family member	7.10	2.50	4	45
I found the computer activity boring	3.04	2.55	4	45

Experience of the Research Process	**Mean**	**SD**	**IQR**	**N**
I understood what the question sheets were asking me	8.27	1.85	3	47
The question sheets took too long to complete	4.04	2.90	5	47
I did not like being put in different groups at random	3.32	2.80	4	39
I enjoyed taking part in this study	7.85	2.42	3	47

Self-Reported Change	**Mean**	**SD**	**IQR**	**N**
How sure I am that my thoughts and feelings come and go	4.98	1.27	2	46
How sure I am that the way my brain works can change over time	5.40	1.34	1.5	45
How kind I am to myself, including when I have difficult thoughts and feelings, or notice things I don't like about myself	5.02	1.35	2	45
How worried or nervous I feel	4.80	1.25	2	45
How sad or low I feel	4.75	1.42	2	45

Table 10. Qualitative Feedback – Participants

Participant #	Q1	Q2	Q3
1	I found it boring. Very boring.	I really didn't enjoy the videos. I don't want to do it again.	I haven't changed at all.
8	I was interested and I enjoyed the video clip we watched about the brain.		
13	It was very useful and I would do it again.		
14	I enjoyed doing the task.		
15	It was very interesting and taught me quite a few things that I didn't already know.		
20	It was quite a good video but on the audio I couldn't really hear what they were saying so I found some of the questions hard.	It was OK but I didn't like answering the questions so many times.	It was OK.
21	The website was glitching a bit.		
23	It was very interesting	It felt good explaining	I felt this study

	and made me think a lot.	myself.	changed me a bit.
24	The video was fun but you learn something as well.	It was good but some questions I didn't get or understand.	
26	It was fun and you got to learn a lot it just took a long time.	It took a bit of a long time and it was fun answering all of the questions.	The questions were weird and I liked how you put the scales of 1-10.
27	I found interesting and I learnt a bit.	It was fun.	
41	I cannot remember it.	I can't remember.	
45	The computer was fun and I learned a lot from it.	The studying was fun and I have learned a lot about the brain and how it works.	
49	It was fun and I liked it.	It was also fun and interesting.	
52		It was quite fun and I know it will be good for my future.	
55	It was very good.		
62	I think the computer scheme was quite hard because when I was typing, it kept coming up	I think the study was good and I have no comments about it except for saying that it	

	with the next thing/slide and if you went off the typing, it would be hard to get back on it. Other than that, I found it quite interesting and fun. I liked the video because it was fun but also educational.	made me think through which was good!	
63	Why did we have to do it?		
66	I wouldn't use any tablets to do the task because they play up so I would use a computer.	I think it would help more children in the future by doing the study.	I also think you could help teenagers by doing the tasks and also grownups.
67	It was very funny.	We weren't put into groups!	We weren't put into groups!
69	It was quite hard to write a letter.	We didn't be put into groups. Why were we not put into groups?	
73		We did not get put into groups.	
75	I found it very fun and helped me a lot but some of this I already knew.	The study was very fun to me and the sheets were quite easy to do	

	The computer software was very hard to see it kept coming up with the next slide and very hard to type. It is bad quality. Otherwise I enjoyed it a lot and loved the questionnaires and activities. Loved the video!!!	but some I did not really understand. They didn't take long to complete and I didn't mind that we were split into groups. I really liked it.	
78	It was very enjoyable.		
79	I think the video was very informative.	It was very helpful.	
81	I really like the video because it has told me how to control my thoughts and feelings and it was very helpful to me.	I think the study was helpful because people can see how I react to things.	I think everything was helpful because it has told me how to control my actions.
82		I think it was fun and I would recommend it for my brother to do.	I think watching the video helped me.
83	I think it was a great animation to describe the troubles people have with their brain.	This study was amazing to the people who needed it, therefore you should carry on to other	

	schools and places.

Teacher Feedback

Teachers were also invited to provide feedback, using a similar measure in which responses (to ten questions) ranged from "strongly disagree" (1) to "strongly agree" (10). Table 11 presents mean responses, alongside standard deviations and interquartile ranges. Qualitative feedback was captured in open-ended "comments" sections of feedback questionnaires (Table 12).

Table 11. Mean Responses to Feedback Questionnaire - Teachers

Experience of the Intervention	**Mean**	**SD**	**IQR**	**N**
I feel like the pupils/students struggled to engage with the intervention	4.17	3.02	3	6
I think the intervention has benefitted the pupils/students who completed it	7.33	1.70	3	6
It would be useful to have this intervention in schools	8.33	1.70	1.75	6
It was difficult to get the resources to run the computerised intervention in school	3.17	3.08	0	6
This intervention could fit within the school timetable	7.33	1.60	1.75	6
Experience of the Research Process	**Mean**	**SD**	**IQR**	**N**
It was easy to get parents involved/responses from parents	7.00	1.22	1.5	4
There was adequate support for pupils/students and staff during the research process	9.50	0.50	1	4
The measures used seemed appropriate	8.75	1.09	0.75	4
The research study consumed too much time	2.80	0.75	1	5

I did not like that pupils/students were randomly allocated to either the intervention or control	2.20	1.47	1	5

Table 12. Qualitative Feedback – Teachers

Teacher #	Q1	Q2
1	The children have been introduced to BLP and Growth Mindset in the school so are aware of the ideas already. The activity online was extremely tricky to load on iPads – children typing in the web address and form didn't sync well on iPads. Some more info in advance would be useful (e.g., timetabling, necessary resources and being made aware of info that needs to be obtained would help with organisation and smooth running).	
2	I think if we had it set up as an intervention across the school it would be useful. We know that growth mindsets and & understanding how the brain works can be one of the biggest impacts on children's progress. I think it may need to be a more	Some of the children didn't want to repeat the questionnaire as they found the questions about death upsetting.

	regular intervention for it to be successful.	
3	I feel this is an important part of education and would like to see more of this in schools.	I put maybe for parent response as I'm not too sure about how much involvement they had. Good study and helpful for children.
4	This is a <u>really</u> important area in schools and <u>all</u> schools should do this!	Some children would need tremendous support if chosen and would not have been able to do this without a reader for Year 5. Also children need lots of time to answer questions and would give or put anything if they felt there was a time element. Those who were not involved need to be given something to do at the same time.
5	In terms of timetabling it would depend on the length/frequency of sessions.	

Chapter 6: References

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Chapter 7. Discussion and Critical Evaluation

This chapter offers a 'synthesized' discussion of the findings from both the systematic review (Chapter 2) and empirical study (Chapter 4). A critical reflection on the thesis process is also included.

Systematic Review and Meta-Analysis

The meta-analytic review explored the potential of single-session interventions (SSIs), delivered in educational settings, to address youth internalizing problems. The current, relevant literature was systematically reviewed and analysed, producing an estimate of impact on depressive symptoms and impact on anxiety symptoms. These effect size estimates indicated a medium effect on depressive symptoms (g = -0.44, 95% CI -0.93 to 0.05) and on anxiety symptoms (g = -0.62, 95% CI -1.35 to 0.11). While this does reflect an improvement in symptomatology, these findings were nonsignificant. It is plausible that this was due to large heterogeneity between studies. Sensitivity analyses for study quality could not resolve this.

Both pooled effect sizes were comparable to those reported for full-length interventions for youth anxiety and depression (d =0.61 and d = 0.29; Weisz et al., 2017) and larger than others for more broad internalizing problems (d = 0.29; Sanchez et al., 2018). This suggests that SSIs may, in the right context, be at least as beneficial as full-length interventions. However, the "right context" is difficult to determine – amongst the small number of studies reviewed, there were large differences between study designs and interventions. The analyses yielded greater effects on anxiety symptoms than depressive symptoms, in line with previous reviews (Schleider & Weisz, 2017; Weisz et al., 2017). Notably, the anxiety meta-analysis included more studies with participants at 'transitional' periods in life, which are marked by common fears and anxieties (West et al., 2010; Grills-

Taquechel et al., 2010) but are also times in which anxieties may respond best to brief intervention (Cox et al., 2015).

Overall, the results strengthen the claim that SSIs may be an effective response to the growing demands of youth mental health (Schleider & Weisz, 2017) – even when delivered in educational settings. The review also draws attention to areas of methodological weakness amongst studies in this field of research.

Empirical Study

Following the systematic review, the empirical paper described the pilot randomised controlled trial (RCT) of a single-session, 'mindset' intervention (The Growing Minds Programme) in primary schools. This aimed to support a potential main trial by exploring the intervention's feasibility, acceptability and promise. In order to address concerns about the risks or costs of mindset interventions, the Growing Minds Programme integrated additional components drawn from cognitive-behavioural and 'third wave' psychotherapies.

Seventy-one participants, aged between 9 and 11 years, were recruited from two different schools and randomised to either an intervention or waitlist control group. The findings suggest that the intervention is both feasible to run in primary school settings and acceptable to the target audience. Recruitment was encouraging at both school- and individual-level, whilst participant dropout was only 8.45%. Feedback from participants and from teachers was positive, highlighting various strengths – particularly elements of the intervention. The main obstacles identified were technological demands and length or tediousness of multiple questionnaires. Post-intervention outcomes revealed medium effect size estimates, indicating improvements in symptomatology and psychological strengths.

These preliminary results were comparable to those of the meta-analytic review. Further, there was a trend for outcomes to improve over time and by the 12-week follow-up, effect size estimates were larger than those reported in previous studies of single-session

mindset interventions (Schleider & Weisz, 2018; Schleider et al., 2019). It may be that the intervention was enhanced by additional psychotherapeutic components. Taken together, the two papers have yielded interesting findings and these, it is hoped, will make a useful contribution to a burgeoning field of psychological study.

Strengths and Limitations

Systematic Review and Meta-Analysis: the process of searching, screening and assessing eligibility of studies for the systematic review was not done in isolation. The primary researcher (JC) was supported by a second reviewer (KC) for a proportion of articles. This was good practice, as it reduces the risk of selection bias and also human error, such as eligible papers being missed (Cuijpers, 2016). In addition, two further members of the research team (LP and RMS) were available to resolve queries raised between JC and KC. This reflects a typical research process, in which each member of the team has a clearly defined role. It is acknowledged that the benefit gained from having a second reviewer could have been improved by having KC assess more than 20% of full-text articles.

A further strength was the rigor applied to evaluating methodological quality and risk of bias for included studies. KC completed the same evaluative process, independent of JC, which reduces the risk of biases in judgement. Furthermore, consideration was given to both study quality and risk of bias, both of which were reported in the main paper – a practice that is often overlooked but remains vital to the meta-analytic process (Cuijpers, 2016).

One of the main limitations of the present review is the sample – at both a review- and study-level. The small pool of eligible studies may be a result of particularly stringent inclusion criteria, but it does indicate that this field of research is in its infancy. Notably, although the selection criteria did not exclude studies that were not written in the English language, a small number that may have been eligible were excluded because they could not be translated. Ultimately, the small pool of included studies meant that moderator analyses,

which could otherwise have explored variables of interest, were not possible. Of those that were included, none took samples of younger children (e.g., primary school age).

There were methodological problems with included studies, too. All studies only used child-informant outcome measures, despite previous meta-analyses demonstrating 'informant' to be a pervasive moderator variable (Weisz et al., 2017). Equally, others have found poor agreement between parent and child with regard to the child's functioning (Meiser-Stedman et al., 2017b). In addition, the methodologies and interventions were considerably varied amongst studies. Such large heterogeneity is common in psychological meta-analyses (Cuijpers, 2016) but nonetheless represents a limitation. In the present review, it will have reduced the power of the analysis.

Empirical Study: in contrast to the methodological quality of certain studies included in the meta-analytic review, the empirical study was comprehensive in its design and reporting of this. Feasibility studies should predominantly answer questions about procedures and intervention acceptability (Orsmond & Cohn, 2015) and in doing so, provide a solid foundation for main trials. Elements that added to this strength included cluster randomisation, multiple follow-up points, use of participant self-reported change and multiple outcome measures. Another strength was the sample size, which was reasonably large for feasibility studies and is sufficient to estimate the standard deviation between two groups – a necessary step in determining the value of a main trial (Cocks & Torgerson, 2013).

As with the meta-analytic review, the empirical study lacked outcome measures from multiple informants and although this may not have formed a significant part of the analysis, would nonetheless have been useful to evaluate in terms of feasibility and acceptability. The study was also unable to use a reliable, validated measure of a 'psychological' mindset. The Implicit Theory Personality Questionnaire (IPT-Q) is intended to assess mindset in relation to personality, which is only partially relevant to the Growing Minds Programme. The research

team attempted to extend this measure but their additions were found to have poor internal consistency and were not used.

Reflections on the Thesis Portfolio Process

The systematic review and meta-analysis had to be revised following initial screening of titles, abstracts and full-text articles, as there were insufficient papers for review. This was communicated to PROSPERO and a minor adjustment to the search terms and inclusion criteria was accepted – that being to include studies in university settings. There was initial frustration amongst the research team, particularly the primary author, as scoping searches had appeared promising. However, this was a learning experience that may be useful in future research endeavours.

There were a number of challenges to the empirical project. The application to the Research Ethics Committee was declined on multiple occasions, as revisions were requested to make the content appropriate for a younger audience. Later, liaising with schools was successful but communication was inconsistent and caused delays to data collection. This was likely due to demand on teachers at the time.

Clinical and Theoretical Implications

Taken together, the results suggest that there is considerable, unexplored potential with regard to SSIs for youth mental health. The systematic review and empirical study both represent, to the best of the authors' knowledge, a 'first' in research: that is, an exploration of SSIs for mental health in educational settings and a trial of a *modified,* mindset-based SSI. The consistent, medium effect sizes found justify the interest shown by researchers and illustrate that this is an area of considerable promise.

The findings suggest that SSIs may have an equivalent effect to full-length interventions, if delivered at the right time, in the right setting or through the right medium. The largest effect reported from the meta-analyses was for anxiety, which primarily included

studies of children experiencing a period of transition. Interestingly, a similar magnitude of effect was observed in the empirical study, which took a sample of children approaching a significant developmental, transitional period of life. It may be that, consistent with previous findings (e.g., Cox et al., 2015), children are vulnerable during these periods but equally, are receptive to intervention. Given that the empirical study suggests children as young as 9 years old can make sense of and utilise learning from a mindset intervention, this provides some indication of the age at which preventative strategies can be applied.

With regard to setting, the meta-analytic review findings indicate that interventions are no less effective in educational settings than those delivered in the community or primary care sites. This is a particularly pertinent finding in light of the recent drive to better integrate positive mental health strategies with school curriculums (Department of Health & Department for Education, 2017). The empirical study illustrates that mindset interventions are both feasible and acceptable to deliver in schools and with young children. If the promise it shows as a preventative strategy can be upheld, this may be an effective way of improving children's access to support while reducing burden on mental health services.

The meta-analytic review does not provide much clarity as to the "right medium" for intervention. Indeed, there was large heterogeneity between a small pool of included studies. However, the empirical study suggests that the content and administration of a single-session mindset intervention may generate a marked, positive effect. Furthermore, the mechanisms targeted by additional components (i.e., those drawn from 'third wave' psychotherapies) showed post-intervention differences, indicating that it may be possible to enhance such interventions and address potential costs.

Directions for Research

Both papers highlight a need for more randomised-controlled trials of SSIs in non-clinical settings. In particular, trials in primary school settings may help us better understand

the promise of SSIs as a preventative strategy. Trials in settings that predominantly cater for children with low income and/or from ethnic and racial minority backgrounds will provide evidence for (or against) the extension of this promise to resource-strained settings and cohorts who are less likely to access necessary support (Kataoka et al., 2002; Alegría et al., 2015). The meta-analytic review also illustrates the variable methodological quality and rigor in reporting of studies, both of which must be improved in future research. The empirical paper contributes to this and more feasibility studies may help achieve such a goal.

With regards to mindset intervention research, it is clear that a valid and reliable measure of mindsets across multiple 'domains' is needed. As research continues to expand the scope of mindsets and implicit theories (e.g., Tamir et al., 2007; De Castella et al., 2013), the validity of measured change in mindset will depend on an appropriate tool. Lastly, the empirical study has laid a solid foundation for a main trial of the Growing Minds Programme, which would be appropriate given the potential shown.

Overall Conclusion

Taken together, the meta-analysis and empirical study offer complementary findings – they both provide support for existing evidence (e.g., Schleider & Weisz, 2017; Schleider & Weisz, 2018) but moreover, make meaningful additions that have implications for both research and practice. They suggest that SSIs may be an effective intervention for youth internalizing problems, their impact consistent in size even when delivered in educational settings. In particular, mindset interventions not only show similar promise, but are evidently feasible and acceptable to primary school settings. This may be important as attention is given to earlier intervention and prevention.

Chapter 7. References

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Appendices

Appendix A. Journal of Abnormal Child Psychology Author Guidelines

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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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.

Cover Letter

Per APA guidelines, all submissions must include a cover letter that provides information about:

- Any previous presentation of the data.
- The existence of any closely related manuscripts that have been submitted for simultaneous consideration to the same or to another journal.

Of particular note, the cover letter must describe any previous publications or manuscripts being submitted for simultaneous consideration in which the main variables of interest overlap with the variables being examined in the current JACP submission. If the publication is using a publicly available data set, authors must provide a link to a list of other publications using the data set and list previous publications using the same variables. Finally, the cover letter needs to include a statement describing how the current results add significantly to previous publications with the same sample to warrant publication as a separate paper.

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, and telephone number(s) of the corresponding author
- If available, the 16-digit ORCID of the author(s)

Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

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.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).
- Manuscripts with mathematical content can also be submitted in LaTeX.

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.

MANUSCRIPT FORMAT

All JACP manuscripts should be submitted to Editorial Manager in 12-point Times New Roman with standard 1-inch borders around the margins.

APA Style

Page length: 35 pages; Text must be double-spaced; APA Publication Manual standards must be followed.

Terminology

- 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.

Scientific style

- Please always use internationally accepted signs and symbols for units (SI units).
- Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.
-

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).

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.

Tables

- All tables are to be numbered using Arabic numerals.
- Tables should always be cited in text in consecutive numerical order.
- For each table, please supply a table caption (title) explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

Artwork and Illustrations Guidelines

Electronic Figure Submission

- Supply all figures electronically.
- Indicate what graphics program was used to create the artwork.
- For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
- Vector graphics containing fonts must have the fonts embedded in the files.
- Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art

- Definition: Black and white graphic with no shading.
- Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
- All lines should be at least 0.1 mm (0.3 pt) wide.

- Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.
- Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art

- Definition: Photographs, drawings, or paintings with fine shading, etc.
- If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.
- Halftones should have a minimum resolution of 300 dpi.

Combination Art

- Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.
- Combination artwork should have a minimum resolution of 600 dpi.

Color Art

- Color art is free of charge for online publication.
- If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.
- If the figures will be printed in black and white, do not refer to color in the captions.
- Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

- To add lettering, it is best to use Helvetica or Arial (sans serif fonts).
- Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).
- Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.
- Avoid effects such as shading, outline letters, etc.
- Do not include titles or captions within your illustrations.

Figure Numbering

- All figures are to be numbered using Arabic numerals.
- Figures should always be cited in text in consecutive numerical order.
- Figure parts should be denoted by lowercase letters (a, b, c, etc.).
- If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures, "A1, A2, A3, etc." Figures in online appendices (Electronic Supplementary Material) should, however, be numbered separately.

Figure Captions

- Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.
- Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.
- No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.
- Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.
- Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

- Figures should be submitted separately from the text, if possible.
- When preparing your figures, size figures to fit in the column width.
- For most journals the figures should be 39 mm, 84 mm, 129 mm, or 174 mm wide and not higher than 234 mm.
- For books and book-sized journals, the figures should be 80 mm or 122 mm wide and not higher than 198 mm.

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If you include figures that have already been published elsewhere, you must obtain permission from the copyright owner(s) for both the print and online format. Please be aware that some publishers do not grant electronic rights for free and that Springer will not be able to refund any costs that may have occurred to receive these permissions. In such cases, material from other sources should be used.

Accessibility

In order to give people of all abilities and disabilities access to the content of your figures, please make sure that

- All figures have descriptive captions (blind users could then use a text-to-speech software or a text-to-Braille hardware)
- Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)
- Any figure lettering has a contrast ratio of at least 4.5:1

Electronic Supplementary Material

Springer accepts electronic multimedia files (animations, movies, audio, etc.) and other supplementary files to be published online along with an article or a book chapter. This feature can add dimension to the author's article, as certain information cannot be printed or is more convenient in electronic form.

Before submitting research datasets as electronic supplementary material, authors should read the journal’s Research data policy. We encourage research data to be archived in data repositories wherever possible.

Appendix B. Quality Assessment Tool for Quantitative Studies

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

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** 1	**MODERATE** 2	**WEAK** 3
B STUDY DESIGN	**STRONG** 1	**MODERATE** 2	**WEAK** 3
C CONFOUNDERS	**STRONG** 1	**MODERATE** 2	**WEAK** 3
D BLINDING	**STRONG** 1	**MODERATE** 2	**WEAK** 3
E DATA COLLECTION METHOD	**STRONG** 1	**MODERATE** 2	**WEAK** 3
F WITHDRAWALS AND DROPOUTS	**STRONG** 1	**MODERATE** 2	**WEAK** 3

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. Cochrane Risk of Bias Tool

Preliminary considerations

Study Design

- ☐ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: _____ Comparator: _____

Specify which outcome is being assessed for risk of bias _____

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed. _____

Is the review team's aim for this result…?

- ☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s)
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist

Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Elaboration	Response options
1.1 Was the allocation sequence random?	Answer 'Yes' if a random component was used in the sequence generation process. Examples include computer-generated random numbers; reference to a random number table; coin tossing; shuffling cards or envelopes; throwing dice; or drawing lots. Minimization is generally implemented with a random element (at least when the scores are equal), so an allocation sequence that is generated using minimization should generally be considered to be random. Answer 'No' if no random element was used in generating the allocation sequence or the sequence is predictable. Examples include alternation; methods based on dates (of birth or admission); patient record numbers; allocation decisions made by clinicians or participants; allocation based on the availability of the intervention; or any other systematic or haphazard method. Answer 'No information' if the only information about randomization methods is a statement that the study is randomized. In some situations a judgement may be made to answer 'Probably no' or 'Probably yes'. For example, , in the context of a large trial run by an experienced clinical trials unit, absence of specific information about generation of the randomization sequence, in a paper published in a journal with rigorously enforced word count limits, is likely to result in a response of 'Probably yes' rather than 'No information'. Alternatively, if other (contemporary) trials by the same investigator team have clearly used non-random sequences, it might be reasonable to assume that the current study was done using similar methods.	Y/PY/PN/N/ NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Answer 'Yes' if the trial used any form of remote or centrally administered method to allocate interventions to participants, where the process of allocation is controlled by an external unit or organization, independent of the enrolment personnel (e.g. independent central pharmacy, telephone or internet-based randomization service providers). Answer 'Yes' if envelopes or drug containers were used appropriately. Envelopes should be opaque, sequentially numbered, sealed with a tamper-proof seal and opened only after the envelope has been irreversibly assigned to the participant. Drug containers should be sequentially numbered and of identical appearance, and dispensed or administered only after they have been irreversibly assigned to the participant. This level of detail is rarely provided in reports, and a judgement may be required to justify an answer of 'Probably yes' or 'Probably no'. Answer 'No' if there is reason to suspect that the enrolling investigator or the participant had knowledge of the forthcoming allocation.	Y/PY/PN/N/ NI

1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	*Note that differences that are compatible with chance do not lead to a risk of bias. A small number of differences identified as 'statistically significant' at the conventional 0.05 threshold should usually be considered to be compatible with chance.* Answer 'No' if no imbalances are apparent or if any observed imbalances are compatible with chance. Answer 'Yes' if there are imbalances that indicate problems with the randomization process, including: (1) substantial differences between intervention group sizes, compared with the intended allocation ratio; or (2) a substantial excess in statistically significant differences in baseline characteristics between intervention groups, beyond that expected by chance; or (3) imbalance in one or more key prognostic factors, or baseline measures of outcome variables, that is very unlikely to be due to chance and for which the between-group difference is big enough to result in bias in the intervention effect estimate. Also answer 'Yes' if there are other reasons to suspect that the randomization process was problematic: (4) excessive similarity in baseline characteristics that is not compatible with chance. Answer 'No information' when there is no *useful* baseline information available (e.g. abstracts, or studies that reported only baseline characteristics of participants in the final analysis). The answer to this question should not influence answers to questions 1.1 or 1.2. For example, if the trial has large baseline imbalances, but authors report adequate randomization methods, questions 1.1 and 1.2 should still be answered on the basis of the reported adequate methods, and any concerns about the imbalance should be raised in the answer to the question 1.3 and reflected in the domain-level risk-of-bias judgement. Trialists may undertake analyses that attempt to deal with flawed randomization by controlling for imbalances in prognostic factors at baseline. To remove the risk of bias caused by problems in the randomization process, it would be necessary to know, and measure, all the prognostic factors that were imbalanced at baseline. It is unlikely that all important prognostic factors are known and measured, so such analyses will at best reduce the risk of bias. If review authors wish to assess the risk of bias in a trial that controlled for baseline imbalances in order to mitigate failures of randomization, the study should be assessed using the ROBINS-I tool.	Y/PY/PN/N/NI

Risk-of-bias judgement	See algorithm.	Low / High / Some Concerns

Optional: What is the predicted direction of bias arising from the randomization process?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Elaboration	Response options
2.1. Were participants aware of their assigned intervention during the trial?	If participants are aware of their assigned intervention it is more likely that health-related behaviours will differ between the intervention groups. Blinding participants, most commonly through use of a placebo or sham intervention, may prevent such differences. If participants experienced side effects or toxicities that they knew to be specific to one of the interventions, answer this question 'Yes' or 'Probably yes'.	Y/PY/PN/N/NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	If carers or people delivering the interventions are aware of the assigned intervention then its implementation, or administration of non-protocol interventions, may differ between the intervention groups. Blinding may prevent such differences. If participants experienced side effects or toxicities that carers or people delivering the interventions knew to be specific to one of the interventions, answer question 'Yes' or 'Probably yes'. If randomized allocation was not concealed, then it is likely that carers and people delivering the interventions were aware of participants' assigned intervention during the trial.	Y/PY/PN/N/NI

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	For the effect of assignment to intervention, this domain assesses problems that arise when changes from assigned intervention that are inconsistent with the trial protocol arose because of the trial context. We use the term **trial context** to refer to effects of recruitment and engagement activities on trial participants and when trial personnel (carers or people delivering the interventions) undermine the implementation of the trial protocol in ways that would not happen outside the trial. For example, the process of securing informed consent may lead participants subsequently assigned to the comparator group to feel unlucky and therefore seek the experimental intervention, or other interventions that improve their prognosis. Answer 'Yes' or 'Probably yes' **only** if there is evidence, or strong reason to believe, that the trial context led to failure to implement the protocol interventions or to implementation of interventions not allowed by the protocol. Answer 'No' or 'Probably no' if there were changes from assigned intervention that are inconsistent with the trial protocol, such as non-adherence to intervention, but these are consistent with what could occur outside the trial context. Answer 'No' or 'Probably no' for changes to intervention that are consistent with the trial protocol, for example cessation of a drug intervention because of acute toxicity or use of additional interventions whose aim is to treat consequences of one of the intended interventions. If blinding is compromised because participants report side effects or toxicities that are specific to one of the interventions, answer 'Yes' or 'Probably yes' only if there were changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context. The answer 'No information' may be appropriate, because trialists do not always report whether deviations arose because of the trial context.	NA/Y/PY/PN/N/NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	Changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context will impact on the intervention effect estimate if they affect the outcome, but not otherwise.	NA/Y/PY/PN/N/NI

2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	Changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context are more likely to impact on the intervention effect estimate if they are not balanced between the intervention groups.	NA/Y/PY/PN/N/NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Both intention-to-treat (ITT) analyses and modified intention-to-treat (mITT) analyses excluding participants with missing outcome data should be considered appropriate. Both naïve 'per-protocol' analyses (excluding trial participants who did not receive their assigned intervention) and 'as treated' analyses (in which trial participants are grouped according to the intervention that they received, rather than according to their assigned intervention) should be considered inappropriate. Analyses excluding eligible trial participants post-randomization should also be considered inappropriate, but post-randomization exclusions of ineligible participants (when eligibility was not confirmed until after randomization, and could not have been influenced by intervention group assignment) can be considered appropriate.	Y/PY/PN/N/ NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	This question addresses whether the number of participants who were analysed in the wrong intervention group, or excluded from the analysis, was sufficient that there could have been a substantial impact on the result. It is not possible to specify a precise rule: there may be potential for substantial impact even if fewer than 5% of participants were analysed in the wrong group or excluded, if the outcome is rare or if exclusions are strongly related to prognostic factors.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See algorithm.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Elaboration	Response options
2.1. Were participants aware of their assigned intervention during the trial?	If participants are aware of their assigned intervention it is more likely that health-related behaviours will differ between the intervention groups. Blinding participants, most commonly through use of a placebo or sham intervention, may prevent such differences. If participants experienced side effects or toxicities that they knew to be specific to one of the interventions, answer this question 'Yes' or 'Probably yes'.	Y/PY/PN/N/NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	If carers or people delivering the interventions are aware of the assigned intervention then its implementation, or administration of non-protocol interventions, may differ between the intervention groups. Blinding may prevent such differences. If participants experienced side effects or toxicities that carers or people delivering the interventions knew to be specific to one of the interventions, answer 'Yes' or 'Probably yes'. If randomized allocation was not concealed, then it is likely that carers and people delivering the interventions were aware of participants' assigned intervention during the trial.	Y/PY/PN/N/NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	This question is asked only if the preliminary considerations specify that the assessment will address imbalance of important non-protocol interventions between intervention groups. Important non-protocol interventions are the additional interventions or exposures that: (1) are inconsistent with the trial protocol; (2) trial participants might receive with or after starting their assigned intervention; and (3) are prognostic for the outcome. Risk of bias will be higher if there is imbalance in such interventions between the intervention groups.	NA/Y/PY/PN/N/NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	This question is asked only if the preliminary considerations specify that the assessment will address failures in implementing the intervention that could have affected the outcome. Risk of bias will be higher if the intervention was not implemented as intended by, for example, the health care professionals delivering care. Answer 'No' or 'Probably no' if implementation of the intervention was successful for most participants.	NA/Y/PY/PN/N/NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	This question is asked only if the preliminary considerations specify that the assessment will address non-adherence that could have affected participants' outcomes. Non-adherence includes imperfect compliance with a sustained intervention, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention. Consider available information on the proportion of study participants who continued with their assigned intervention throughout follow up, and answer 'Yes' or 'Probably yes' if the proportion who did not adhere is high enough to raise concerns. Answer 'No' for studies of interventions that are administered once, so that imperfect adherence is not possible, and all or most participants received the assigned intervention.	NA/Y/PY/PN/N/NI

2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	Both ‘ naïve ‘per-protocol’ analyses (excluding trial participants who did not receive their allocated intervention) and ‘as treated’ analyses (comparing trial participants according to the intervention they actually received) will usually be inappropriate for estimating the effect of adhering to intervention (the ‘per-protocol’ effect). However, it is possible to use data from a randomized trial to derive an unbiased estimate of the effect of adhering to intervention. Examples of appropriate methods include: (1) instrumental variable analyses to estimate the effect of receiving the assigned intervention in trials in which a single intervention, administered only at baseline and with all-or-nothing adherence, is compared with standard care; and (2) inverse probability weighting to adjust for censoring of participants who cease adherence to their assigned intervention, in trials of sustained treatment strategies. These methods depend on strong assumptions, which should be appropriate and justified if the answer to this question is ‘Yes’ or ‘Probably yes’. It is possible that a paper reports an analysis based on such methods without reporting information on the deviations from intended intervention, but it would be hard to judge such an analysis to be appropriate in the absence of such information. If an important non-protocol intervention was administered to all participants in one intervention group, adjustments cannot be made to overcome this. Some examples of analysis strategies that would not be appropriate to estimate the effect of adhering to intervention are (i) ‘Intention to treat (ITT) analysis’, (ii) ‘per protocol analysis’, (iii) ‘as-treated analysis’, (iv) ‘analysis by treatment received’.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See algorithm.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Risk of bias due to missing outcome data

Signalling questions	Elaboration	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The appropriate study population for an analysis of the intention to treat effect is all randomized participants. "Nearly all" should be interpreted as that the number of participants with missing outcome data is sufficiently small that their outcomes, whatever they were, could have made no important difference to the estimated effect of intervention. For continuous outcomes, availability of data from 95% of the participants will often be sufficient. For dichotomous outcomes, the proportion required is directly linked to the risk of the event. If the observed number of events is much greater than the number of participants with missing outcome data, the bias would necessarily be small. Only answer 'No information' if the trial report provides no information about the extent of missing outcome data. This situation will usually lead to a judgement that there is a high risk of bias due to missing outcome data. Note that imputed data should be regarded as missing data, and not considered as 'outcome data' in the context of this question.	Y/PY/PN/N/ NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Evidence that the result was not biased by missing outcome data may come from: (1) analysis methods that correct for bias; or (2) sensitivity analyses showing that results are little changed under a range of plausible assumptions about the relationship between missingness in the outcome and its true value. However, imputing the outcome variable, either through methods such as 'last-observation-carried-forward' or via multiple imputation based only on intervention group, should not be assumed to correct for bias due to missing outcome data.	NA/Y/PY/PN/N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	If loss to follow up, or withdrawal from the study, could be related to participants' health status, then it is possible that missingness in the outcome was influenced by its true value. However, if all missing outcome data occurred for documented reasons that are unrelated to the outcome then the risk of bias due to missing outcome data will be low (for example, failure of a measuring device or interruptions to routine data collection). In time-to-event analyses, participants censored during trial follow-up, for example because they withdrew from the study, should be regarded as having missing outcome data, even though some of their follow up is included in the analysis. Note that such participants may be shown as included in analyses in CONSORT flow diagrams.	NA/Y/PY/PN/N/NI

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	This question distinguishes between situations in which (i) missingness in the outcome could depend on its true value (assessed as 'Some concerns') from those in which (ii) it is likely that missingness in the outcome depended on its true value (assessed as 'High risk of bias'). Five reasons for answering 'Yes' are: 1. Differences between intervention groups in the proportions of missing outcome data. If there is a difference between the effects of the experimental and comparator interventions on the outcome, and the missingness in the outcome is influenced by its true value, then the proportions of missing outcome data are likely to differ between intervention groups. Such a difference suggests a risk of bias due to missing outcome data, because the trial result will be sensitive to missingness in the outcome being related to its true value. For time-to-event-data, the analogue is that rates of censoring (loss to follow-up) differ between the intervention groups. 2. Reported reasons for missing outcome data provide evidence that missingness in the outcome depends on its true value; 3. Reported reasons for missing outcome data differ between the intervention groups; 4. The circumstances of the trial make it likely that missingness in the outcome depends on its true value. For example, in trials of interventions to treat schizophrenia it is widely understood that continuing symptoms make drop out more likely. 5. In time-to-event analyses, participants' follow up is censored when they stop or change their assigned intervention, for example because of drug toxicity or, in cancer trials, when participants switch to second-line chemotherapy. Answer 'No' if the analysis accounted for participant characteristics that are likely to explain the relationship between missingness in the outcome and its true value.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See algorithm.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Elaboration	Response options
4.1 Was the method of measuring the outcome inappropriate?	This question aims to identify methods of outcome measurement (data collection) that are unsuitable for the outcome they are intended to evaluate. The question *does not* aim to assess whether the choice of outcome being evaluated was sensible (e.g. because it is a surrogate or proxy for the main outcome of interest). In most circumstances, for pre-specified outcomes, the answer to this question will be 'No' or 'Probably no'. Answer 'Yes' or 'Probably yes' if the method of measuring the outcome is inappropriate, for example because: (1) it is unlikely to be sensitive to plausible intervention effects (e.g. important ranges of outcome values fall outside levels that are detectable using the measurement method); or (2) the measurement instrument has been demonstrated to have poor validity.	Y/PY/PN/N/NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Comparable methods of outcome measurement (data collection) involve the same measurement methods and thresholds, used at comparable time points. Differences between intervention groups may arise because of 'diagnostic detection bias' in the context of passive collection of outcome data, or if an intervention involves additional visits to a healthcare provider, leading to additional opportunities for outcome events to be identified.	Y/PY/PN/N/NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Answer 'No' if outcome assessors were blinded to intervention status. For participant-reported outcomes, the outcome assessor is the study participant.	NA/Y/PY/PN/N/NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Knowledge of the assigned intervention could influence participant-reported outcomes (such as level of pain), observer-reported outcomes involving some judgement, and intervention provider decision outcomes. They are unlikely to influence observer-reported outcomes that do not involve judgement, for example all-cause mortality.	NA/Y/PY/PN/N/NI

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	This question distinguishes between situations in which (i) knowledge of intervention status could have influenced outcome assessment but there is no reason to believe that it did (assessed as 'Some concerns') from those in which (ii) knowledge of intervention status was likely to influence outcome assessment (assessed as 'High'). When there are strong levels of belief in either beneficial or harmful effects of the intervention, it is more likely that the outcome was influenced by knowledge of the intervention received. Examples may include patient-reported symptoms in trials of homeopathy, or assessments of recovery of function by a physiotherapist who delivered the intervention.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See algorithm.	Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Elaboration	Response options Y/PY/PN/N/ NI
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	If the researchers' pre-specified intentions are available in sufficient detail, then planned outcome measurements and analyses can be compared with those presented in the published report(s). To avoid the possibility of selection of the reported result, finalization of the analysis intentions must precede availability of unblinded outcome data to the trial investigators. Changes to analysis plans that were made before unblinded outcome data were available, or that were clearly unrelated to the results (e.g. due to a broken machine making data collection impossible) do not raise concerns about bias in selection of the reported result.	
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	A particular outcome domain (i.e. a true state or endpoint of interest) may be **measured** in multiple ways. For example, the domain pain may be measured using multiple scales (e.g. a visual analogue scale and the McGill Pain Questionnaire), each at multiple time points (e.g. 3, 6 and 12 weeks post-treatment). If multiple measurements were made, but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result. Attention should be restricted to outcome measurements that are eligible for consideration by the RoB 2 tool user. For example, if only a result using a specific measurement scale is eligible for inclusion in a meta-analysis (e.g. Hamilton Depression Rating Scale), and this is reported by the trial, then there would not be an issue of selection even if this result was reported (on the basis of the results) in preference to the result from a different measurement scale (e.g. Beck Depression Inventory). Answer 'Yes' or 'Probably yes' if: There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a domain was measured in multiple eligible ways, but data for only one or a subset of measures is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results can arise from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception, or vested interest in showing, that an	Y/PY/PN/N/ NI

	experimental intervention is beneficial may be inclined to report outcome measurements selectively that are favourable to the experimental intervention. Answer 'No' or 'Probably no' if: There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all eligible reported results for the outcome domain correspond to all intended outcome measurements. or There is only one possible way in which the outcome domain can be measured (hence there is no opportunity to select from multiple measures). or Outcome measurements are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results. Answer 'No information' if: Analysis intentions are not available, or the analysis intentions are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome domain could have been measured.	
5.3 ... multiple eligible analyses of the data?	A particular outcome measurement may be analysed in multiple ways. Examples include: unadjusted and adjusted models; final value vs change from baseline vs analysis of covariance; transformations of variables; different definitions of composite outcomes (e.g. 'major adverse event'); conversion of continuously scaled outcome to categorical data with different cut-points; different sets of covariates for adjustment; and different strategies for dealing with missing data. Application of multiple methods generates multiple effect estimates for a specific outcome measurement. If multiple estimates are generated but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result. Attention should be restricted to analyses that are eligible for consideration by the RoB 2 tool user. For example, if only the result from an analysis of post-intervention values is eligible for inclusion in a meta-analysis (e.g. at 12 weeks after randomization), and this is reported by the trial, then there would not be an issue of selection even if this result was reported (on the basis of the results) in preference to the result from an analysis of changes from baseline. Answer 'Yes' or 'Probably yes' if:	Y/PY/PN/N/NI

	There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a measurement was analysed in multiple eligible ways, but data for only one or a subset of analyses is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results arises from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception or vested interest in showing that an experimental intervention is beneficial may be inclined to selectively report analyses that are favourable to the experimental intervention. Answer 'No' or 'Probably no' if: There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all eligible reported results for the outcome measurement correspond to all intended analyses. or There is only one possible way in which the outcome measurement can be analysed (hence there is no opportunity to select from multiple analyses). or Analyses are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results. Answer 'No information' if: Analysis intentions are not available, or the analysis intentions are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome measurement could have been analysed.	
Risk-of-bias judgement	See algorithm.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable / NA

Overall risk-of-bias judgement	**Criteria**
Low risk of bias	The study is judged to be at **low risk of bias for all domains** for this result.
Some concerns	The study is judged to raise **some concerns** in at least one domain for this result, but not to be at high risk of bias for any domain.
High risk of bias	The study is judged to be at **high risk of bias** in at least one domain for this result. Or The study is judged to have **some concerns** for **multiple domains** in a way that substantially lowers confidence in the result.

Appendix D. Letter of Ethical Approval from UEA Research Ethics Committee

Joseph Cassidy
MED

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

27 March 2019

Dear Joseph

Project Title: Feasibility and Acceptability of a Brief Mindset Intervention in UK Primary Schools

Reference: 201819 - 050

Thank you for your response to the recommendations from the FMH Ethics Committee to your proposal. I have considered your amendments and can now confirm that your proposal has been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely

Professor M J Wilkinson

Chair, FMH Research Ethics Committee

Appendix E. Application for Ethical Approval

Application Form for Ethical Approval of a Health Related Research Project

IMPORTANT: PLEASE READ BEFORE COMPLETING THIS FORM:

1. Please refer to the guidelines for Applicants conducting Research Projects in FMH when completing this form. The link to this is on the FMH Ethics intranet page.

2. **It is ESSENTIAL that you do not use complex/technical language.** This is to ensure that the objectives of your project/research and the procedures to be conducted can easily be understood by non-specialists and lay members of the Committee.

3. **All submitted applications must include an electronic version of all relevant documents.** All hard copies must be collated and fixed together in the top left hand corner.

4. **Please include your supervisor when emailing the application if you are a student.**

5. **If the project involves the use of drugs, or testing of new equipment, or research on NHS patients** it MUST be referred to an NHS Research Ethics Committee for approval.

6. **Applications cannot be accepted after the deadline** so please ensure that you read the information above and complete the checklist at the back of this form. To avoid delays it is essential that you ensure you have provided all of the required information in the requested format, on or before the deadline.

If this is related to a Research project please include the following information (if student, you may need to ask your supervisor for this):

REN project number:…….....

Name of REN Project Officer:……..

If the project is a resubmission, please provide the FMH Ethics Reference Number:

…….....

For standard applications. Please send 2 hard copies of the application form, proposal and all other supporting documents to: FMH Research Ethics, c/o FMH RIN Administration, Research & Innovation Office, The Registry 1.14, University of East Anglia, Norwich NR4 7TJ. **Please also e-mail ONE copy of all documents to** fmh.ethics@uea.ac.uk on or before the deadline shown on the following intranet page. (https://portal.uea.ac.uk/faculty-school-intranets/fmh-intranet/ethics-committee).

If you are submitting a **Service Evaluation/Audit or Human Tissue application,** please tick one of the following relevant boxes:

1. **If the project involves the use of Human Tissue**, please complete this form and email **ONE** signed copy (if student) including all supporting documents to fmh.ethics@uea.ac.uk. These can be emailed at any time and do not usually need to go to a Committee meeting. **We do not need hard copies of Human Tissue applications.** ☐

2. **If the project is a Service Evaluation or Audit within the NHS**, please complete this form and email **ONE** signed copy (if student) including all supporting documents to fmh.ethics@uea.ac.uk. **The Chair will also require evidence of acceptance by the relevant host NHS Trust with your submission.** These can be emailed at any time and do not usually need to go to a Committee meeting. **We do not need hard copies of Service Evaluations/Audits.** ☐

For any queries please email: fmh.ethics@uea.ac.uk

Please ensure that you have completed the checklist at the end of the form before submitting and have provided all of the required information, as the Committee will return your application if the required information is not provided.

Application form

1. Name of applicant: JOSEPH CASSIDY…….....
   (Block letters)

2. Academic address for correspondence (please do not use your home address:

   UNIVERSITY OF EAST ANGLIA
   NORWICH RESEARCH PARK
   NORWICH……..

   ……..Post code: NR4 7TJ……..

3. Tel No: 01603 591258……..

4. Academic (UEA) E-mail address:

   joseph.cassidy@uea.ac.uk.....……..……

5. School: Norwich Medical School…….…….

6. Status of applicant (Staff, UG or PG student - and year of course): PG Student, Y2...

7.
8. Supervisory arrangements for **STUDENT PROJECTS ONLY:**

   Is this study being carried out to fulfil a required part of your course? Yes

   Degree/Course Doctorate in Clinical Psychology.....

   School Norwich Medical School…..…….

   N**ame and contact details of UEA supervisor:**

   Supervisor Name: Dr Gemma Bowers…….……

   Supervisor Email: gemma.bowers@uea.ac.uk.…… … … ……..

Please ensure that your supervisor signs the declaration on page 4 of this document

9. Has this application gone to an Ethics Committee elsewhere? No

   If YES, please indicate where and **provide copies of correspondence**:

……

Project details (**sections 9, 10 and 11 must be limited to a combined maximum of 3000 words**).

10. **Full title:**
    Feasibility and Acceptability of a Brief Mindset Intervention in UK Primary Schools

11. **Purpose of project:**
    I want to explore whether a brief mindset intervention is both feasible and acceptable to primary school children and teachers in the UK. I also want to explore whether this intervention shows promise in improving mental health and well-being outcomes in primary school children.

    Recent government proposals highlight the need for school-based interventions to promote well-being and resilience (Department of Health & NHS England, 2015). This preventative approach aims to improve the emotional well-being of children and young people, and also to reduce the demand on children's mental health services in the UK.

    UK schools have struggled to implement these changes, with a lack of resources and appropriate, evidence-based interventions a key issue (White et al., 2017). In the USA, researchers developed a brief, computer-based intervention that shows promise. This 'mindset' intervention teaches children about our ability to change our personal traits, incorporating psycho-education about the brain, vignettes and written tasks (Schleider & Weisz, 2018). Compared to an active control group, recipients of this intervention reported greater and more rapid improvements in parent-reported depression and anxiety, as well as greater and more rapid improvements in youth reported depression. These were sustained even at a 9-month follow-up. The effects were modest, but the intervention was both deliverable in schools and had a positive impact on mental health and well-being outcomes.

    There does seem to be value in this approach. Research indicates that mindset type predicts outcomes in various domains, including psychological (Yeager et al., 2014; Romero, Master, Paunesku, Dweck & Gross, 2014) and emotional (Yeager, Miu, Powers & Dweck, 2013; Schroder et al., 2017). For instance, those who held beliefs about emotions being fixed were recovered more slowly from stressors and used maladaptive coping strategies more often than adaptive ones (Tamir, John, Srivastava & Gross, 2007; Schroder et al., 2015). Schleider & Weisz (2018) focused their intervention solely on 'personality', but it is argued that incorporating elements relating to psychological and emotional experiences may have further benefit.

    Moreover, a critique of teaching individuals about their capacity to change has been that this may result in higher expectations and striving, plus self-blame and feelings of incompetence if change is not accomplished (Tamir et al., 2007). Self-criticism in particular has widely been linked to depression in adolescence (Zuroff, Koestner & Powers, 1994) and found to predict fewer positive life events (Shahar, Henrich, Blatt, Ryan & Little, 2003).

    A key process involved in self-criticism is the relative inability to 'self-soothe' and be compassionate to oneself (Gilbert, Clarke, Hempel, Miles & Irons, 2004; Whelton & Greenberg, 2005). Developing self-compassion is inherent in a number of so-called 'third wave' psychotherapies; most notably Compassion-focused Therapy (CFT; Gilbert, 2009; 2010) but also Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) (Hayes, Luoma, Bond, Masuda & Lillis, 2006; Neff & Tirch, 2013). These have emerged from more traditional Cognitive-Behavioural Therapies (CBT) but move away from key assumptions (e.g., to improve wellbeing, distressing thoughts must be altered in content or in frequency), focus less on 'symptom-reduction' and integrate new concepts such as acceptance, mindfulness, personal values and self-compassion (Forman & Herbert, 2009).

    To address the potential costs of current mindset interventions, future methods could include elements that promote self-compassion, acceptance and mindfulness. For instance (Neff, 2003):

- Self-kindness in place of self-judgement.
- Common humanity (the realization that suffering, failure and inadequacies are a normal part of human experience).
- Mindfulness in place of over-identification (acceptance of difficult thoughts and feelings).

This could be incorporated alongside components of a growth mindset intervention. Such concepts provide a framework through which psychological and emotional experiences (rather than just personality) can be explored. For instance:

- Understanding these difficult experiences as an evolved function.
- Promoting acceptance of these through recognition that they are universal, transient and ultimately harmless.
- Exploring how our personal histories and individual factors can understandably bias what psychological and emotional experiences we have, as well as our responses to these.
- Promoting agency in our choice of response, even if we cannot control the experiences themselves – and linking this to effecting change over time.

The proposed study will explore the possibility of testing an adapted mindset intervention in UK schools. This has been designed by the research team and is based on the original intervention (Schleider & Weisz, 2018) (with permission from the authors). To address potential psychological and emotional costs, additional elements of self-compassion, mindfulness and acceptance are incorporated. This adaptation will be termed a 'psychological' mindset intervention. However, there are many unknown factors that could influence the results of a main trial. Therefore, the proposed study will answer questions about the feasibility of running a full trial and the acceptability of this intervention to participants. These are as follows:

1. Is a 'psychological' mindset intervention feasible and acceptable as a school-based, mental health intervention in the UK?
    a. What are pupils' and teachers' experiences of the intervention?
    b. Can the intervention be implemented in a primary school setting?
    c. Does the intervention show promise of being successful with a population of 9-11 year olds?
2. Is the proposed design for evaluating this intervention both feasible and acceptable to participants and teachers?
    a. How feasible is recruitment to this study?
    b. How appropriate are the data collection methods and measures?
    c. Are study procedures (such as randomisation) acceptable to participants and to teachers?
    d. Can the evaluation plan be implemented as intended?
    e. What sample size might be required for a full-scale trial?

12. **Methodology, Procedure and Analysis:**

<u>Design</u>

Feasibility studies explore the practicalities of implementation and evaluation, as well as the acceptability of the intervention to its target audience (Orsmond & Cohn, 2015). From this, the research team, research sponsor or commissioning bodies can make informed decisions about whether or not to pursue a full-scale trial.

They do not determine whether an intervention is successful or not, so hypothesis-testing is deemed inappropriate for this design. Instead, research questions aim to explore implementation practicality, acceptability and indications of efficacy (Bowen et al., 2009). To answer these, it is necessary to deliver the intervention and collect measures as in a main trial. Therefore, the study will adopt an experimental design with participant randomisation to either an intervention group or a wait-list control.

Participants

The participants will be children from two different primary schools in the UK. These two schools have each provided written confirmation of their desire to participate in the research. Children in years 5 and 6 will be recruited. This is because participants must be developmentally 'ready' to understand and make use of the intervention. Furthermore, children in this age group are approaching a significant transition, between primary and secondary education. The importance of programmes to promote wellbeing and resilience to help children cope with the stress of these transitions has been well-documented (West, Sweeting & Young, 2010).

There will be few exclusion criteria. Pupils unable to read and write in English cannot participate, as the intervention has not been developed in other languages. The inclusion and exclusion criteria are deliberately broad as it is hoped that the intervention will be helpful for all pupils, not just those who have been identified as 'at risk' or who already experience mental health difficulties. This corresponds with the recent government proposals for preventative interventions in schools.

There is no consensus in the existing literature regarding appropriate sample size for feasibility studies, but guidance suggests that between 50 and 80 are necessary to estimate the main study's standard deviation (Cocks & Torgerson, 2013). As such, the proposed study will aim to recruit between 25 and 40 participants for each group – a total of between 50 and 80 children. A "sister-study" by another UEA trainee will run concurrently, recruiting a further 50–80 participants to assess feasibility of the intervention with 16-18 year olds. This age group also encompasses a key transition for young people – entering adulthood.

Measures

Immediately before undertaking the mindset intervention, participants will be asked to complete a number of self-report measures, in order to record baseline data.

Feasibility

A structured questionnaire will be used to capture feedback from participants and from teaching staff at the school. Using both open and Likert-scale questions (1-10), these aim to capture the respondents' experience of the study. Student, self-reported change (in mindset, self-esteem, anxiety, depression and self-compassion) is included to support other outcome measures in feasibility studies (Johnstone et al., 2015). The questionnaire has been designed by the research team, who have based it on those used in comparable feasibility studies (e.g., McAllister et al., 2017).

The following data will be recorded:

- Demographic information (age, gender and ethnicity) for all participants.
- Participant recruitment and retention rates, including reasons given for any dropout.
- Time taken for each participant to complete the intervention.
- Completion rates for both the intervention and each of the outcome measures.
- School attendance rates for all participants. This may provide useful information relevant to participant retention and dropout rates, but could also indicate whether the intervention shows promise, as maladaptive self-beliefs have been linked to poor school attendance (Kearney, 2008; Rivers, 2010).
- The research team will also record their experiences of the research process, including participant engagement, plus the barriers and facilitators to intervention delivery.

Mindset

The first outcome measure has been partially designed by the research team. It will include the three-items used by Schleider & Weisz (2018) to assess the beliefs that respondents hold about the malleability of personality. However, it will introduce three additional questions, to capture beliefs about internal experiences such as thoughts and feelings. This is because these are key constructs within a 'psychological' mindset, but no measure currently exists to assess these. This does compromise the statistical robustness of the measure as a whole, but the three 'original' items will be analysed separately in order to protect the validity of the personality mindset measure.

Furthermore, due to the lack of alternatives, all research (to date) that involves mindset assessment has adapted existing mindset measures to capture additional or different constructs (e.g., Tamir et al., 2007; Schroder et al., 2015).

Self-Compassion

Participants will also complete the Self-Compassion Scale for Children (SCS-C) (Sutton, Schonert-Reichl, Wu & Lawlor, 2017), a measure of self-compassion, adapted from the Self-Compassion Scale – Short Form (Raes, Pommier, Neff & Van Gucht, 2010). The authors of the SCS-C tested the factor structure, reliability and validity of their scale; they found acceptable internal consistency for a single factor model (Cronbach's alpha = .79) and good internal consistency for a two-factor model (Cronbach's alpha = .81 and .83); the authors also found evidence of convergent validity, with subscales significantly related (in the expected directions) will all but one correlate of self-compassion. Although the authors recommended that further validation research is undertaken, they acknowledged that the SCS-C *"fills a substantial gap in the toolbox of social and emotional assessments currently available for children and early adolescents"* (Sutton et al., 2017).

Psychological Inflexibility

In addition, participants will complete the Avoidance and Fusion Questionnaire for Youth (AFQ-Y8; Greco, Lambert & Baer, 2008), which measures 'psychological inflexibility' – the rigidity of respondents' beliefs about themselves and their internal experiences. This is "the hallmark feature and main outcome of ACT" (Simon & Verboon, 2016). Examination of the factor structure, construct validity and reliability of this measure was conducted with a sample of 8-10 year old. The authors found that the internal consistency of the measure was adequate-to-good (Cronbach's alpha = .79) and there was a positive relationship between psychological inflexibility and anxiety symptoms – indicative of good construct validity (Simon & Verboon, 2016).

Anxiety and Depression

Lastly, participants will complete the Revised Children's Anxiety and Depression Scale (RCADS) – Short Version (Ebesutani et al., 2012). The RCADS – Short Version is a self-report checklist that measures frequency of various symptoms of low mood and anxiety. It has been found to have acceptable reliability; the anxiety scale corresponding significantly with anxiety-related diagnostic groups and the depression scale corresponding significantly with clinic-referred and school-based samples (Ebesutani et al., 2012).

Procedure

Two primary schools have formally agreed to participate in the study and a 'key contact' has been identified at each of these sites. The 'advertisement' of the study will be through direct and indirect conversations with members of school staff. The key contact can share information about the study and gauge interest of fellow teachers and potentially, of parents.

Recruitment

Researchers will engage teaching staff through direct meetings but also indirectly, via the key contacts. Teachers will introduce the study to pupils, then send information sheets and consent forms home with them – to be delivered to parents or carers. Completed forms can then be returned to the teaching staff/key contacts. Child assent forms will be collected immediately prior to the intervention. This would provide sufficient opportunity for parents or carers to discuss the study with their child and for the child to decline involvement prior to the intervention. Parental consent and child assent relates to the research (baseline and outcome measures, as well as other feedback forms) and not the mindset intervention. Consent to participation in the intervention is at school level.

The research team will assign a random numerical value to each pupil. Subsequent measures will be distributed by participant number rather than name, to ensure anonymisation.

Randomisation

All pupils in Year 5 and Year 6 will be randomised to either the intervention group or a wait-list control group. After additional discussion with schools and supervisors, it has been strongly recommended that the most appropriate and useful design would be to randomise participants by school class/form. This enables the feasibility study to approximate the design of a future main trial. It is acknowledged that in a full-scale trial, this would equate to a cluster randomised-controlled design and would therefore require a far larger sample and further calculations (of the intracluster correlation coefficient). However, the outcomes explored in this study will enable future researchers to plan accordingly for such a design. Such approaches are common in school-based intervention research (Stallard et al., 2012; Stallard et al., 2014). The process of randomisation is explicitly detailed in the accompanying research protocol.

The intervention group will undertake the computer-based task at the earliest opportunity (the next available Personal, Social Health and Economic [PSHE] lesson), while the wait-list control group will receive the intervention at the 16-week follow-up of the intervention group (in another scheduled PSHE lesson).

Baseline Measures
Following randomisation and immediately prior to undertaking the intervention, individuals whose parents have consented to completing questionnaires will complete a battery of formal outcome measures, in order to assess baseline scores.

Intervention
The intervention will be delivered to all Year 5 and Year 6 pupils at the participating schools as part of the standard school curriculum (during a timetabled PSHE class).

The intervention is a computer-based program developed by the research team. It is based on existing mindset interventions (Miu & Yeager, 2014; Schleider & Weisz, 2018). Each researcher has had clinical training and experience in relevant psychological interventions for children and in the evidence-based, psychotherapeutic approaches that the intervention content is drawn from. Feedback was sought from children and teachers to ‘sense-check’ the intervention and allow for appropriate amendments. There will be no substantial changes to the content or meaning of the script following ethical approval.

The intervention program consists of text, audio and animations. All activities will be self-administered and delivered via a desktop computer. First, participants will read, watch and listen to psycho-educational content. This will take about 15 minutes. Then, they will answer three different, multiple-choice questions before reading through the answers. These questions are based on short, hypothetical scenarios relating to problems children of a similar age might experience. Lastly, participants will complete a written task, which involves writing a letter of advice to a hypothetical younger pupil. The latter stages should, together, take a further 15 minutes. Each of these ‘stages’ is detailed in the intervention script (attached to this application). This script describes the intervention content in text format. However, for the completed intervention, this content will be presented by audio (read aloud) and complimented by animations. Only ‘core’ messages will be provided as text, so that the intervention is simple enough for the target age group.

Post-Intervention Measures
The same measures provided at baseline will also be administered immediately after completing the computer task and again at 6-week and 16-week follow-ups. Participants will answer feasibility measures at the 16-week follow-up interval only. At this interval,after both groups have completed the final set of measures, the waitlist control group will be offered the intervention.

Debriefing
All participants will be provided with a debriefing session at the end of the 16-week follow-up session. As with the other group components of this study, at least two members of the research team will be present, as well as one member of the school teaching staff.

Analysis Plan

Feedback questionnaires, which capture information about the feasibility and acceptability of the intervention and research process, will be subjective to descriptive analysis. Frequencies, percentages and measures of central tendency, will be reported alongside standard deviations and interquartile ranges. Content analysis (Morgan, 1993) will be used to code, count and numerically-describe responses to open-ended questions, in addition to the written summaries of notable events and themes from the researchers' diaries.

Other indications of feasibility and acceptability will be reported: the percentage of correct answers given to multiple-choice questions, the average time taken by participants to complete the intervention, and researchers' reflections on responses to the written task. In addition, recruitment and retention rates will be compared to recommended standards for clinical trials and presented alongside the time taken to recruit participants. Lastly, participant demographics will be reported in percentages.

Descriptive statistics and estimation should be used to assess evidence of the intervention's impact, as feasibility studies lack sufficient power to carry out rigorous hypothesis-testing (Lancaster, Dodd & Williamson, 2004; Orsmond & Cohn, 2015). Individual and mean differences, considered across time points and between groups, will be used to explore the potential effects of the intervention and what these suggest about the suitability and sensitivity of outcome measures. Clinically-meaningful differences will be calculated using distribution- and anchor-based methods, while reliable change indices will be calculated to determine whether the magnitude of any difference (between pre- and post-intervention) is statistically reliable or a result of measurement error (Orsmond & Cohn, 2015). For the formal outcome measures, standard deviations and confidence intervals can infer the size and direction of treatment effect and thus inform decisions such as whether to undertake a full-scale trial (Lee et al., 2014). Lastly, any difference in school attendance rates (between pre- and post-intervention) will be calculated for each group and presented in terms of percentages.

13. Resources required:
    a. Paper and printing resources for: information sheets, consent forms and assent forms, feasibility questionnaires and outcome measures.
    b. Microsoft Office.
    c. IBM SPSS Statistics.
    d. Envelopes and stamps for parent/carer information sheets and consent forms.
    e. A research mobile phone (including credit).
    f. An encrypted USB flash drive.
    g. Two animators have supported the development of the intervention.
    h. The necessary desktop computers will be provided at the participating school sites.

14. Source of Funding:

    University of East Anglia (UEA)

15. Has this project been peer reviewed? If yes, please include details of who the project has been peer reviewed by.

    This project has been reviewed by two staff members from the Doctoral Programme of Clinical Psychology at the University of East Anglia: Dr Jo Hodgekins, a research tutor, and Dr Kiki Mastroyannopoulou, a clinical lecturer.

16. Ethical issues:

The two primary schools who expressed interest in the study were provided with clear and comprehensive information about the research; including the rationale, design and ethical considerations. Following this, a gatekeeper at each school gave consent to participate in the research. A copy of the letter detailing gatekeeper consent is included in this ethics application.

Individual consent will be sought from parents/guardians, who will be provided with a clear summary of the rationale and procedure of the study, including ethical considerations. In accordance with the General Data Protection Regulation (GDPR; European Parliament and Council, 2016), the information sheet describes what data is collected and how it will be handled. It also states that participation is voluntary and participants can withdraw from the study at any time, without consequence. In addition, contact details for the research team are detailed on the information sheets, should parents/guardians wish to enquire further or discuss concerns. These sheets can be returned to members of the school staff, and subsequently to the research team. Pupils whose parents have consented will also receive an age-appropriate information sheet. This will be given to them alongside the assent form, prior to collecting baseline data. Data will not be collected from pupils who do not assent. At each data collection interval (including follow-up sessions), participants will be reminded of their right to refuse participation or withdraw at any time. It is important to note that after the second data collection interval, researchers will begin data analysis. This means that data already collected and included in the analysis cannot be withdrawn, given that the research team are working to a strict completion deadline and it would not be feasible within this to repeat analyses for each instance of withdrawal. However, further data will not be collected from participants who withdraw after the second data collection interval.

Parental consent and child assent relates to the research (baseline and outcome measures, as well as other feedback forms) and not the mindset intervention. Consent to participation in the intervention is at school level. The research team felt that this method puts fewer demands on members of the teaching staff and allows all pupils, not just those whose parents consent, to receive a potentially-beneficial intervention.

An alternative approach was considered: to request individual parental consent for both the intervention and the data collection. However, the research team felt that this would put a greater demand on school staff as it requires specific pupils to take time out of the standard curriculum activities in order to participate. Further, it would mean that a number of pupils (whose parents did not consent) would miss out on a potentially-beneficial intervention.

The key contacts from each school have provided letters of support for this method. Copies of these letters are included in this ethics application. Notably, providing an intervention within an existing PSHE curriculum has been successfully applied in a recent, national study of mindfulness training in schools (MYRIAD; Kuyken et al., 2017).

Participant data will be kept anonymous through collection, handling and storage (UEA Management of Personal Data Policy, 2017). Each school site will keep a record of the pupils whose parents have consented and a random numerical value (participant number) will be assigned to each of these pupils. The research team will be blind to this process, so that they will only ever be able to discern individual pupils by their randomly-assigned numerical value (rather than any identifying information). Only the parental consent forms will contain the participants' names – all other documents will be assigned by participant number.

In line with GDPR (European Parliament and Council, 2016), all paper documents containing participant data will be stored in locked filing cabinets, in locked office space at the UEA. Data in digital media format will be stored on a password-protected computer and transferred using an encrypted USB flash drive. This data will be kept in the anonymised format throughout the process, only the minimum personally-identifiable data will be collected and it will only be accessible to members of the research team.

The main applicant will retain responsibility for management of this data (the data custodian) until graduation from the UEA, at which point this responsibility will transfer to a research supervisor.

Following publication, all data collected will be held for at least ten years, in a repository at the UEA, before being destroyed (UEA Research Data Management Policy, 2017). No personally-identifiable data will be presented in any publications or reports about the research.

To protect confidentiality where possible, the research team will implement the following:

- Participants will be asked to complete measures independently of one-another, with the researchers stating the importance of this to the validity and confidentiality of the research data.
- Although participants will complete measures in a classroom, alongside their peers, the research team and school will set up the classroom so that participants have some privacy and space from others.
- Completed measures will be returned to the research team in a sealed, unmarked envelope.

Individual assent forms will be completed with at least one researcher present, whilst at least two researchers will be present for all parts of the research process involving groups (intervention, data collection intervals and debriefing). The research team members will answer questions from pupils and support the management of any situations that may occur. There is potentially risk of participant distress, as the intervention or measures may prompt them to reflect on difficult personal experiences (such as emotions, self-esteem, or personal history). In such instances, a researcher will gently reiterate the right to withdraw. In line with the UEA Participant and Research Safety Policies (2017), participants will be informed of this potential risk prior to consenting, via the information sheet. This document also provides contact details for the research team and information sign-posting young people to supportive services (such as their GP and mental health charities).

If the research team are significantly concerned about the risk to someone, confidentiality may be overridden (British Psychological Society, 2014). In such instances, the team would inform a senior member of staff at the school so that the school's safeguarding policies and procedures can be followed – although they would endeavour to inform the pupil first, provided this is not expected to escalate the risk. This process is explained in both the parent and child version of the information sheet. It has also been considered that participants might approach researchers for advice relating to personal issues. In such instances, they will be advised to speak to a trusted member of the school staff team and/or directed to contact a supportive service – their GP or mental health charities, for example. Researchers will be required to explain that they are present for the purposes of the study and not to provide treatment.

In line with UEA policies (Reporting Adverse Events and Amendments, 2017), adverse or unexpected events that may indicate risk or harm to anyone involved in the research will be reported to the Chair of the approving ethics subcommittee.

A wait-list group will be used as a control to the intervention group. This means that the control group will receive the intervention only after all data has been collected. Thus, although the control group may experience delay in receiving the intervention, they are not withheld from its benefits. These potential benefits include:

- Improved psychological and emotional well-being.
- More adaptive beliefs about malleability of personal traits.
- More adaptive beliefs about the nature of internal experiences.
- Increased understanding of psychological concepts, such as thoughts, feelings, and the biological basis for these.
- Improved school attendance.

The research team identified the main burden of the intervention and data collection being the time taken from school activities – estimated to take up to three hours of participant time. However, this is minimised by providing the intervention as part of a PSHE curriculum and the use of short-form outcome measures. Further, an integral part of the liaison between the research

team and the key contacts will be to prepare for study procedures so that they minimise the impact on each pupil's regular school schedule. In short, the research team have and will take steps to maximise the benefits to pupils and minimise the burden or risk to pupils (International Conference on Harmonisation, 1996).

No deception is involved in the proposed study. However, in line with best ethical practice guidelines (British Psychological Society, 2014), a debriefing session will be held at after both groups have completed the intervention. The research team will provide clear information about the study and allow participants to ask questions or raise any concerns. Participants who wish to speak to a member of the research team in private will be given the opportunity to do so. All researchers have up-to-date DBS certificates to enable them to work with children.

Teaching staff at the participating schools will complete a brief and anonymous feedback questionnaire. These will be distributed by the key contacts at their respective school sites and made available in communal areas that are restricted to staff members only. The questionnaires will include sufficient information for potential respondents to make an informed decision as to whether they wish to provide this feedback. According to the Health Research Authority (2017), it is therefore appropriate that separate information sheets and consent forms are not provided (for teaching staff). The feedback questionnaires will be returned via the key contacts (further ensuring anonymity) and the collected data will be handled and stored in the same way as pupil data. Teaching staff may reflect positively on contributing to research, but otherwise there are few benefits or risks to their participation.

No risks to the research team (as a result of carrying out this study) are anticipated. The components of the procedure that directly involve participants will be conducted exclusively at the two school sites, with at least one member of the teaching staff (ideally, the key contact) present at all times. At data collection intervals, the research team plan to have two researchers present. Lone working policies (UEA, 2017) will be followed if ever required, though it is not predicted to be necessary. In addition, a participant log will be used to record contact with participants. Research supervision will be provided on a regular basis by the primary research supervisor (UEA, 2015). All members of the research team have completed training on good research practice (International Conference on Harmonisation, 1996) and have experience of carrying out psychological research.

Planned dissemination includes submission of a research paper to a relevant, psychological journal and sharing summaries of findings with participants – both individuals and the schools as a whole. Other opportunities to publicize the research include the annual research conference hosted by the UEA and social or national media. In line with UEA guidance (2015), should other researchers request our data, we may share anonymised data with them if deemed appropriate. This is described in participant information sheets.

The researchers declare no conflicts of interest.

17. Proposed start and finish dates:

    Start date: February 2019…… Finish date: March 2020…….

18. Where will the research be carried out?

    This research will be carried out at two local primary schools.

18. Information sheets and consent forms must be appended (c.f. NRES site for models, http://www.hra-decisiontools.org.uk/consent/ Please ensure that participants are requested to initial the boxes on the consent forms.

19. Checklist - **please check and complete before submitting your application as incomplete applications will be returned by the Committee. Many applications come in very close to the deadline and if we have to return it you may miss that month's meeting:**

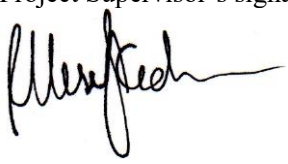
	Yes / No / N/A
Have you completed all sections of the application in language which will be understood by lay people?	Yes
If student, has your supervisor signed the form?	Yes
If student, please provide name and email address for your supervisor	Yes
Have you included your academic address (not your home address)?	Yes
Have you included a header and footer on each page with your name, date of submission, version number and page number?	Yes
Have you included the following documents, if applicable?	
• Protocol. It is recommended that a protocol is always submitted as it facilitates a comprehensive review of the project	Yes
• Gatekeeper consent	Yes
• Participant information sheets (using NRES format)	Yes
• Consent forms	Yes
• Letters to participants	N/A
• Copies of questionnaires	Yes
• Copies of correspondence from other ethics committees	N/A
• Copies of all recruitment letters, emails, posters and adverts	Yes
• Research Safety Checklist **(please complete even if no risks are identified)**	Yes
Have you proof-read your application to check for typographical and grammatical errors?	Yes
Have you included 5 hard copies of your application and all supporting documents (**collated and attached together**) and e-mailed a copy of all documents to fmh.ethics@uea.ac.uk?	Yes
If this is a Service Evaluation/Audit have you emailed ONE signed copy of your application and all supporting documents to fmh.ethics@uea.ac.uk?	N/A
If this is a Service Evaluation have you included the evidence of acceptance by the relevant host NHS Trust with your submission?	N/A
If this is a Human Tissue application have you emailed ONE signed copy of your application and all supporting documents to fmh.ethics@uea.ac.uk?	N/A

Academic Supervisor Declaration – for STUDENT PROJECTS ONLY:

I have read this application and can confirm that I am taking supervisory responsibility for this project.

In the case of a student research outside the normal course requirements I confirm that I am happy to take responsibility for the quality of protocol design, the provision of necessary resources, statistical support and usual supervision and governance of the student.

Project Supervisor's signature: Date:



30/11/2018

Post Held: Professor of Clinical Psychology, Norwich Medical School

Appendix F. Study Summary for Key Contacts

Brief Mindset Intervention in UK Schools

Background

Recent government proposals highlight the need for school-based interventions to promote well-being and resilience. In the USA, researchers have developed a brief, computer-based intervention that shows promise. This 'mindset' intervention aims to teach children about our ability to change our personal traits. However, it can be criticized for not addressing potential costs, such as setting expectations too high, or feelings of blame if one fails to change. In addition, it was tested with a very limited sample of teenage children, from middle- to high-income families in the USA.

What Is The Study?

The proposed study will explore the possibility of testing a modified version of this intervention in a UK primary school. This intervention will also aim to address potential costs by adding new elements based on the idea of self-compassion. Participants will be children aged between 9 and 11 (Years 5 and 6), recruited from Primary schools in the UK.

What Is The Intervention?

The intervention involves completing a set of computer-based tasks, lasting about 30 minutes in total. These tasks include reading and listening to information, watching animated video clips, completing an interactive worksheet and writing a short letter. The content will explain about thoughts, feelings, personality and the human brain, as well as ways to be more kind and compassionate to ourselves. The study will also involve collecting questionnaires from participating pupils at four different time points – immediately prior to the intervention, immediately after the intervention, then again at 6- and 16-week follow-ups.

How Will Participating Schools Be Involved?

We would like to offer the intervention to everyone in Year 5 and Year 6 at participating schools. One way in which this could be done is to provide it within a PSHE lesson. It would be up to the participating schools to agree with this, but the research team felt this method puts fewer demands on the school staff. The research team would provide letters to be handed out to parents (via pupils) explaining the study and whether they wish to consent to their child filling out questionnaires. These letters would also explain that the intervention would run as part of the PSHE programme and their child will receive this unless they specifically wish them not to.

Appendix G. Information Sheets for Children

INFORMATION SHEET FOR CHILDREN

To be given to parent/carer as well as the child

What is the 'Growing Minds Programme'?

We have worked with animators to develop a short computer programme, which we have called the 'Growing Minds Programme'. It shares information about: how our brains work, how we think, and how we feel. It aims to help young people notice how they think about themselves, and hopefully discover some useful skills. The Growing Minds Programme is for young people to complete on a computer on their own. It should take around 30 minutes.

Why is this study being done?

Research is important to keep improving our health and wellbeing. Our study hopes to help young people find healthy ways of coping with difficult situations, feelings and thoughts. We are trying to find out if the Growing Minds Programme can be used in schools, and whether it is helpful for children.

How will it happen? What will I need to do?

The Growing Minds Programme will happen as part of a normal day at your school. Some classes will do the Growing Minds Programme sooner than other classes, but the whole school year will have the chance to do it before the end of July 2019. If you choose to take part, we will decide at random when your class will do the Growing Minds Programme (like picking a name out of a hat). After you have completed it, there will be some questions for you to answer. There are no 'right or wrong' answers. All the answers will help us know how helpful the activity is. If you decide not to take part, you will be in the same room as your classmates, but will be given a different piece of school work to do. This means your friends will only know you didn't do it if you tell them.

What might happen if I take part?

It can sometimes be hard to think about feelings or difficult situations, but you may learn some helpful skills. If you need help with anything about the study, you can ask a teacher or

your parent or carer. If we are worried about you or someone else, we may talk to one of your teachers. This is to make sure you and other people are safe.

Who will know I am taking part?

We will know, as well as your parent or carer, teachers and the other children from your school who are doing the study. No one else will know unless you tell them.

Do I have to take part?

You do not have to take part. It is your choice and you can just say "no". No one will be cross and you will not be treated differently. If you do want to take part, your parent or carer will need to write their name on a form and send it back to us. You can change your mind at any time.

What happens with the information I give?

We keep it in a safe and locked place, where only we can look at it. We will write about the study and what we found out. A short summary of this will be given to the school and to any parents or carers who want it. You will not be named in the report.

Did anyone else check the study is OK to do? How can I find out more about it?

This study has been checked by lots of people, including some of your teachers, to make sure it is OK. Your parent, carer or teacher may be able to answer any questions you may have. They can also ask us any questions.

Thank you for reading this!

Appendix H. Summary Sheet for Children

The Growing Minds Programme

Summary Sheet for Children

- The Growing Minds Programme is a short computer activity. It explains about how our brains work, how we think and how we feel. There are 15 minutes of videos and sound clips, plus 15 minutes to answer some questions.

- We are doing a study of the Growing Minds Programme. We are trying to find out if it can be used in schools. We would also like to know if it can help young people find healthy ways of coping with difficult situations, feelings and thoughts.

- The Growing Minds Programme will happen as part of a normal day at your school. Some classes will do it sooner than others, but everyone will get a chance to do the activity. We will decide who goes first at random.

- If you and your parent or carer agrees to it, we will give you some question sheets after the activity. Your answers will help us know how helpful the programme is.

- You don't have to take part if you don't want to and you can stop taking part at any time.

- If you would like to know more about this research, please see the 'full' information sheet.

Thank you for reading this.

Appendix I. Information Sheet for Parents/Carers

Participant Information Sheet for Parents
The Growing Minds Programme: Piloting a Computer-Based Wellbeing Activity in UK Primary Schools

Why are we carrying out this research?
Children's mental health and well-being is an important topic in schools at the moment. The research team has developed a brief computerised programme – the 'Growing Minds Programme'. The aim of this research study is to find out if it can be useful in a school setting.

What does the study involve? Does my child have to take part?
This Growing Minds Programme study lasts approximately 30 minutes. It includes reading and listening to information, watching video clips, answering questions and writing a short letter. The activity will explain about thoughts, feelings, personality and the human brain. Your child will be eligible for this study if they are in Year 5 or 6 and able to read and write in English. Taking part is optional. It will not affect your child's education, healthcare or other rights if they do not participate.

The Growing Minds Programme will run as part of the school's Personal, Social, Health and Economic (PSHE) lessons and will be provided to all pupils in your child's year group. As such, you and your child will not be asked to give consent to this activity and your child's participation will be assumed. If you do not wish your child to complete the Growing Minds Programme, please contact the school and they can arrange for your child to withdraw from the activity. Half of your child's year group will complete the programme in April, and the other half will complete it 12 weeks later. This helps us look at the difference between the two groups.

The consent form for this study relates only to the collection of data about your child, for the purpose of evaluating the Growing Minds Programme. Your child will meet with the research team at school and will be asked if they wish to take part. If they wish to take part, and if you also consent to your child taking part, your child will be asked to complete questionnaires at three time points: after completing the activity, 6 weeks after the activity, and 12 weeks after the activity. In short, your child will do the programme as part of PSHE *unless* you contact the school to say you do not wish them to take part. Your child will *only* complete the questionnaires for the purpose of research if you sign and return the consent form.

What information will be collected?
The research team will collect the following information to help improve the Growing Minds Programme.

- Your child's age, gender and ethnicity.
- If your child withdraws from the study, the reason for withdrawal.
- Your child's belief in their ability to change, levels of anxiety, depression, self-compassion and the flexibility of their beliefs about themselves.
- Your child's rates of school attendance.
- Children will also be asked to complete a feedback questionnaire about their views and experiences of the intervention and the study. As part of this, your child will be asked to rate change in their emotional well-being.

What are the possible benefits, disadvantages and/or risks of taking part?
It is not possible to predict all disadvantages or risks. It is possible that parts of the programme (e.g., thinking about feelings and thoughts) might cause distress. There may be unforeseen disadvantages, as the Growing Minds Programme is newly-developed. However, we hope that those who take part might gain:

- Improved understanding of thoughts, feelings, personality and the human brain.
- Improved understanding of how to be more self-compassionate and why this is helpful.
- Positive changes in mental health and wellbeing.
- Improved resilience to stress.

What will happen to data / information about your child?
The University of East Anglia (UEA) is the sponsor and the data controller for this study. We will use information from your child and their school records in order to undertake this study and will act as the data controller. This means that we are responsible for looking after your child's information and using it properly.

The information gathered during the study will be treated as confidential and handled in accordance with the EU General Data Protection Regulation (GDPR) (2018). Once consent has been given, participants will be assigned a number and this will be used in place of their name. If collected data were to be shared as part of research publication, all identifiable information will remain confidential. Confidentiality may be breached and the relevant authorities informed if the research team are significantly concerned about the risk to your child or others.

Once your child has started completing the second batch of questionnaires, data will be put together for analysis. This means it would not be possible to withdraw information your child has already provided. However, if your child withdraws from the study, they will not be asked to provide further information. Research data will be stored in either locked cabinets or on encrypted password protected media. Beyond the conclusion of the study, research data will only be accessed by research supervisors, who will be its custodians. After ten years, all data will be destroyed. You can find out more by contacting those listed at the end of this document.

Where and when will the study occur?
The study will happen at your child's school. It will begin in March/April 2019. The study will last for 12 weeks, although your child will only be asked to participate on three separate occasions.

What will happen to the results of the study?
The research team intend to publish the study and its findings in a psychological journal and to share this at a research conference. Participants and their parents/carers can request a summary of the research.

What if I have a concern or complaint?
If you have a concern about any aspect of this study, you can speak to the research team. If you wish to complain formally, you can do this by contacting the UEA. Contact details are listed below.

Who has reviewed this study?
All research at the UEA is looked at by an independent group of people, called a Research Ethics Committee, to protect those involved in the study. This study has been reviewed by the UEA Faculty of Medicine and Health Sciences Research Ethics Committee, who have agreed that it can take place. Teachers are your child's school have also reviewed the study and have agreed for it to take place at the school.

Contact Details
Joseph Cassidy (Primary Investigator, UEA) (joseph.cassidy@uea.ac.uk).
Dr Gemma Bowers (Research Supervisor, UEA) (gemma.bowers@uea.ac.uk).
Professor Niall Broomfield (Head of Department, UEA) (niall.broomfield@uea.ac.uk).

Appendix J. Consent Form for Parents/Carers

A Brief 'Mindset' Intervention for School Children: Is It Feasible in UK Primary Schools?

Name of Lead Researcher: Joseph Cassidy, University of East Anglia

Contact Information: joseph.cassidy@uea.ac.uk

	Please initial box
1. I confirm that I have read the information sheet dated 09/01/2019 for the above study. 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 he/she is free to withdraw at any time without giving any reason, without his/her education, healthcare or legal rights being affected.	☐
3. I understand that if I withdraw my child from the study (or he/she chooses to withdraw) after returning the second batch of questionnaires, his/her contribution up until that point cannot be withdrawn, but they will not be asked to give any further information.	☐
4. I understand that relevant sections of my child's school records (e.g., attendance) may be looked at by individuals working at the University of East Anglia, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.	☐
5. I understand that the information gathered during the study will be treated as strictly confidentialand handled in accordance with the EU General Data Protection Regulation (GDPR) (2018). I understand that confidentiality may be breached and the relevant authorities may need to be informed if the research team are significantly concerned about risk to your child or to others.	☐

6. I consent to the storage and processing of personal information and data for the purposes of this study. ☐

7. I agree for my child to take part in the above study. ☐

8. I would like to receive a copy of the study's findings. ☐ **YES / NO**

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix K. Assent Form for Children

ASSENT FORM – FOR CHILD/YOUNG PERSON

Title: Can we use our computer activity in a primary school? Is it helpful?

Please circle all that you agree with:

1. Do you understand what this study is about?

YES NO

2. Have you asked all the questions you want?

YES NO

3. Have you had your questions answered in a way you understand?

YES NO

4. Are you happy to take part?

YES NO

If <u>any</u> answers are ‘no’, or you don’t want to take part, don’t sign your name!

If you <u>do</u> want to take part, you can write your name below.

Your Name: _____

Date: _____

The researcher who explained this study to you needs to sign, too:

Print Name: _____

Signature: _____

Thank you for your help!