Cluster-randomised controlled trial of an occupational therapy intervention for children aged 11-13 years, designed to increase participation in order to prevent symptoms of mental illness

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Abbreviated title: CRCT of an occupational therapy intervention

Abstract

Background: The impact of occupational therapy on mental health outcomes for children is largely unexplored. The aim of this study was to investigate an evidence-based occupational therapy intervention designed to increase participation in daily occupations in order to prevent symptoms of mental illness for children and run in schools. **Methods**: The study used a pragmatic, cluster-randomised controlled trial design with two arms. Fourteen clusters (schools), equating to 151 child participants, were stratified by school decile-rank category and block randomised. Blinding of participants post-randomisation was not feasible; however, outcomes assessors were blinded. Outcomes were measured at baseline, after the parallel and crossover phases, and at follow-up; and were anxiety symptoms (primary), depression symptoms, self-esteem, participation and wellbeing. Intention-to-Treat analysis was applied -mixed linear modelling was used to account for clusters and repeated measures, and to adjust for covariates identified. **Results**: This trial found significant positive effects of the intervention on child-rated satisfaction with their occupational performance and teacher-rated child anxiety. No evidence was found to support the effect of the intervention on anxiety and depression symptoms, self-esteem and wellbeing. **Conclusions**: This was the first known cluster-randomised controlled trial to investigate an occupational therapy intervention promoting emotional wellbeing in a non-clinical sample of children. No compelling evidence was found to support the use of the intervention in schools in its current format, however, results were promising that the focus on occupations influenced participation. Recommendations are made to redesign the intervention as an embedded intervention in the classroom, co-taught by teachers and including parental involvement.

Key practitioner message:

- There is a need for interventions promoting mental health and wellbeing in children, aged under 13 years, that focus on participation and not just clinical symptoms.
- There is currently insufficient evidence to roll-out the intervention investigated on a larger scale.
- Modifying the intervention, in the current study, to embed it into the classroom environment may enhance the positive impacts found on participation.
- Occupational therapy presents a viable method for promoting mental health and wellbeing for children.

Introduction

Early intervention is fundamental to achieving better mental health outcomes for children and communities in the future, with childhood mental illness shown to precede and predict mood disorders in adulthood (Kohlboeck, Quadflieg, & Fichter, 2011; Zahn-Waxler, Klimes-Dougan, & Slattery, 2000). The prevalence of specific mental health disorders in children world-wide include anxiety disorders at 6.5% and depression at 2.6% (Polanczyk, Salum, Sugaya, Caye, & Rohde, 2015). There is a clear need to prioritise children's mental health and wellbeing in order to reduce the long-term burden on health care services internationally (Friedberg, Crosby, & Friedberg, 2000; Polanczyk et al., 2015). In order to meet the needs of children clinically impaired by mental health conditions, including those who go undiagnosed and untreated, health services would need to support up to 30% of all children (Polanczyk et al., 2015; Puolakka, Kiikkala, Haapasalo-Pesu, & Paavilainen, 2011; Rijlaarsdam et al., 2015). Secondary mental health services are only funded to support the most severe presentations, the top 3% (Mental Health Commission, 2012), so an alternative is to offer preventative interventions. Schools offer a convenient and feasible location for the widespread delivery of preventative interventions to children (Essau & Gabbidon, 2013; Lavin, Shapiro, & Weill, 1992; Stallard & Buck, 2013). This presents an opportunity to design and evaluate an occupational therapy intervention designed to promote children's mental health outcomes, which is consistent with the profession's research priorities (AOTA Commission on Practice, 2001; Dunford & Bannigan, 2011; Nicholson, 2011).

Mental health promotion in schools

A review of mental health promotion interventions available for children (aged 7-19 years) in the school environment was conducted to determine what is currently available and supported by evidence. More than half the studies reported evaluations that demonstrated varying degrees of effectiveness of Cognitive Behaviour Therapy (CBT) on internal cognitions (Bernstein, Layne, Egan, & Tennison, 2005; Chiu et al., 2013; Dadds, Spence,

Holland, Barrett, & Laurens, 1997; Horowitz, Garber, Ciesla, Young, & Mufson, 2007; Manassis et al., 2010; Possel, Baldus, Horn, Groen, & Hautzinger, 2005). Other interventions investigated building social networks and skills for help-seeking (Aseltine & DeMartino, 2004; Eggert, Thompson, Randell, & Pike, 2002; Thompson, Eggert, Randell, & Pike, 2001), developing life skills (Eggert et al., 2002; Thompson et al., 2001), interpersonal therapy (Horowitz et al., 2007), physical activity (Bonhauser et al., 2005), and information processing (Possel et al., 2005). General conclusions from these studies indicated experimental interventions were more effective at reducing the rates of symptoms of concern than control interventions; in the latter, symptoms typically increased. Evidence was in favour of the need for, and efficacy of, preventative interventions. Interventions focused on making changes to the child's cognitive processing (regardless of treatment modality) and were shown to have benefits for reducing the cognitive symptoms of mental illness or increasing knowledge of mental health.

An occupational therapy perspective could build on the available evidence and directly address the impact of mental health on children's everyday activities and the health-promoting benefits of participation. Despite the well-documented relationship between anxiety, functioning, and participation, evidence for interventions directly targeting functioning and participation, rather than cognitive processing errors alone, and particularly for children younger than 13 years, was limited (Vitiello et al., 2006).Occupational therapy may be viewed as a practical solution to impaired functioning associated with a child's symptoms of anxiety, without the stigma associated with traditional mental health interventions (Barney, Griffiths, Jorm, & Christensen, 2006).

An occupational therapy intervention promoting mental health in children

The occupational therapy intervention evaluated in this study is named Kia Piki te Hauora, which loosely translates from Māori to English as "Uplifting our Health and Wellbeing". The intervention is focused on increasing participation in daily occupations in order to prevent symptoms of mental illness (described in more detail in Tokolahi, Hocking, and Kersten

(2016)). The intervention was delivered by an occupational therapist with groups of 7-12 children from Years 7 and 8 (ages 11-13 years): this is a discrete age bracket in the Aotearoa New Zealand educational system known as 'intermediate'. The intervention was designed to use engagement in developmentally appropriate activities to promote mental health and wellbeing in non-clinical samples of children, by enabling them to understand the relationship between what they do and how they feel and think; to understand how activities in which they engage influence their identity, self-concept, health and wellbeing; to practice and develop strategies for promoting positive wellbeing; and to apply this knowledge in building and designing healthy routines, behaviours and habits in their day-to-day life that support self-esteem and participation.

Setting

The current study was conducted in Auckland, Aotearoa New Zealand. Ensuring early, evidence-based, mental health interventions are available for children to reduce the lifetime impact – on the individual and the healthcare system – is an important focus of the New Zealand Ministry of Health's Blueprint II document (Mental Health Commission, 2012) and the New Zealand Health Strategy 2016 (New Zealand Government, 2016). Furthermore, the New Zealand Educational Review Office: Te Tari Arotake Mātauranga (ERO) (2014) enforces a legal requirement for schools to address the emotional wellbeing and safety of their students. The requirement from ERO was a driver for mental health interventions in schools to be developed and provided. Mental health interventions already available in Aotearoa New Zealand schools, at the time this study was being developed, were inconsistently reported as effective although the studies lacked sufficient rigour (Coggan, Disley, & Patterson, 1997; Dickinson, 2004; Jasperse, Stevens, van der Meer, & Faculty of Education, 2014; McCluskey, 2010; Mental Health Foundation New Zealand, 2014; Newell & Moss, 2011; Riley, 2012; Robertson, Boyd, Dingle, & Taupo, 2012). All programmes targeted the 14 years+ age-range and there was an identified need for an intervention

targeting a younger age group (Essau & Gabbidon, 2013; Guzman et al., 2011; Lavin et al., 1992; Stallard & Buck, 2013).

Aim

The aim of this study was to investigate an occupational therapy intervention run in schools and designed to increase children's participation in daily occupations in order to prevent symptoms of mental illness. The central question addressed was: *"Is Kia Piki te Hauora: Uplifting our Health and Wellbeing© effective in preventing symptoms of anxiety and depression and improving self-esteem and participation in children aged 10-13 years and are improvements sustained after a follow-up period of 8-9 weeks?"*

Methods

Trial design

This trial was a two-arm, pragmatic, cluster-RCT in which schools were the unit of randomisation. Fourteen schools were recruited with a sample of 10-12 students from each school. Inclusion criteria were: children were mainstream students (i.e. no intellectual disability), aged 11-13 years, and able to converse in English. Children were excluded if they reported para/suicidal thoughts or behaviours or they were involved with a secondary mental health service. Further details are available in Tokolahi, Hocking, Kersten, and Vandal (2014). This trial was pragmatic as it measured the effectiveness of an intervention in real-world context (i.e. a school) rather than under ideal conditions (Godwin et al., 2003). The trial employed an open-label, repeated measures, parallel and one-way crossover design. Children were clustered naturally by school and randomised in clusters: this design prevented contamination between trial arms and ensured distribution of confounders was due to chance and not systematic bias. One-way crossover occurred when children allocated to the waitlist for 8 weeks then went on to start receiving the intervention.

Interventions

Experimental intervention

The intervention is a manualised, occupational therapy group intervention: Kia Piki te Hauora: Uplifting our Health and Wellbeing (Tokolahi et al., 2016). The intervention is designed to use engagement in developmentally appropriate activities to promote mental health and wellbeing by enabling students to understand the relationship between what they do and how they feel/think; to understand how activities in which they engage influence their identity, self-concept, health and wellbeing; to practice and develop strategies for overcoming difficult emotions; and to apply this knowledge in building and designing healthy routines, behaviours and habits in their day-to-day life that support self-esteem and participation. The intervention ran for 1 hour per week over a period of 8 weeks of a school term. This timeframe was selected for logistical reasons and to be consistent with evidence-based recommendations for mental health interventions with children and adolescents (Arbesman, Bazyk, & Nochajski, 2013).

Waitlist intervention

The waitlist group did not receive any input during the parallel component of the trial except to complete the baseline and post-intervention outcome measures. In the crossover component of the trial, the waitlist group went on to receive the intervention as described.

Recruitment

All schools in the Auckland region providing mainstream education to children in Years 7 and 8 were invited to participate through a notice in a national teaching magazine. A stratified sample of 50 of those schools from a range of locations in the region were sent personal invitations to participate. Senior staff from schools expressing an interest were offered a meeting with the lead researcher to explain the study process and arrange consent on behalf of the school. Once a school enrolled in the study, a sample of 10-12 students, aged 11-13

years, were recruited by senior personnel from the school (e.g. SENCO, principal) or they volunteered following a presentation at a school assembly. Selection was based on the school personnel's (non-standardised) judgement that the child presented with early symptoms of anxiety along with symptoms of depression, low self-esteem and/or poor participation in typical occupations. Once parental consent and child assent were obtained demographic information about the students was collected.

Randomisation, concealment and blinding

Within each of the three decile strata, low, medium and high, schools were randomly allocated to one of the two study arms (intervention or control) according to a computer-generated procedure coded by the trial statistician (AV), who was unaware of the cluster identifiers, and allocation was revealed in three waves. Each cluster guardian was then informed of their allocation status, in order to facilitate logistical aspects of the intervention. Individual participants (children and parents) were blinded to allocation until after completion of the baseline measures. Further blinding was impractical due to the complex nature of the intervention. Outcome measures were taken at each school by a research assistant blinded to the treatment allocation of each cluster. Trial data were reviewed by A. Vandal, without knowledge of treatment allocation, prior to the final data analyses and after the datasets had been created. The purpose of this review was to finalise the analysis plan.

Sample size

The analysis-adjustment factor of 2(1-*r*) was used erroneously in designing this study to determine a target sample size of 154, instead of the correct factor of (1-r^2) to adjust for the planned ANCOVA analysis. The actual adjusted analysis design effect was 0.81 and the proportion by which the sample size was overestimated was 21%. This conservative sample size yields a power of 87% to detect the target difference under the other design parameters, rather than the nominal 80% originally planned. Therefore, there were no adverse effects from this error on the analysis or the robustness of the findings from the data.

Measures

Child, parent and teacher participants completed all outcome measures on three or five occasions, depending on allocation to intervention or waitlist. The primary outcome was the participant's self-rated anxiety symptoms as assessed with the Multidimensional Anxiety Scale for Children – Short form (MASC-10) (March, 1997). The MASC is psychometrically sound (Langley, Bergman, & Piacentini, 2002), with moderate to excellent test-retest reliability (.75-.86, p<.001) (March & Sullivan, 1999), good internal reliability (Baldwin & Dadds, 2007), excellent internal consistency (n=108, α .70-.85 for subscales and .89 for total) (Muris, Gadet, Moulaert, & Merckelbach, 1998), good discriminant validity (Birmaher et al., 1997), and strong convergent validity (Myers & Winters, 2002). Furthermore, the MASC was shown to be sensitive to treatment effects, with current cut offs discriminating anxious children from non-anxious children, with around 88% accuracy (Birmaher et al., 1997; Myers & Winters, 2002).

The Child Depression Inventory 2nd edition: Self Report [Short form] (CDI2) assessed children's level of depression symptoms (Kovacs, 2011). The CDI2 has been shown to be comparable to the full-version in discriminating between depressed and non-depressed children with high sensitivity and good specificity (Allgaier et al., 2012) with sufficient sensitivity to measure changes over time and following an intervention (Simmons, Wilkinson, & Dubicka, 2015).

Parents rated their child's level of anxiety and depression using the Revised Child Anxiety and Depression Scale – Parent report, short version (RCADS) (Ebesutani et al., 2010; Ebesutani et al., 2012). The RCADS concurrent validity has been demonstrated (Kaat & Lecavalier, 2015); it has good internal consistency (generalised anxiety (GA) α=0.88; and depression, α=0.83) and has been shown to discriminate between children with and without disorders and between children with symptoms of anxiety and those with depression (Ebesutani et al., 2010). A modification of the tool was used (i.e. not all items included), intended to reduce the burden on parents asked to complete a battery of assessments and

thereby increase the likelihood of parent outcome measures being completed. The limitation of this decision was a reduction in reliability and validity of the measure.

Teachers rated child anxiety using the School Anxiety Scale (SAS) (Lyneham, Street, Abbott, & Rapee, 2008). The SAS has good reliability and internal consistency (total subscale α= .93; GA subscale α=.90; social anxiety subscale α=.92) (Lyneham et al., 2008); and satisfactory test-retest reliability for all subscales after a 4 week period (*ICCs* of .70-.92) (Hajiamini et al., 2012) and a 8 week period (*ICC*=.73-.81) (Lyneham et al., 2008).

Self-esteem was measured using the Rosenberg Self Esteem Scale (RSES) (Rosenberg, 1965) and the Single Item Self Esteem Scale (SISES) (Robins, Hendin, & Trzesniewski, 2001). The RSES to has good test-retest reliability after 1-week (r=.82, p<.001), 2-weeks (r=.85-.87), 7 months (r=.63-.74) and several assessment points over a period of 4 years (r=.69) (Fleming & Courtney, 1984; Revenson, Wollman, & Felton, 1983; Robins et al., 2001; Silber & Tippett, 1965; Torrey, Mueser, McHugo, & Drake, 2000; Wylie, 1989). Several of the RSES items were found to be predictive of self-harm in the future, however, evidence it is sensitive to change in children, following interventions, is limited (Blascovich & Tomaka, 1991; Bowling, 1991; Phillips et al., 2013). The SISES is more reliable when used as a parent, than a child report measure (α=.84 and .77 respectively) (Robins et al., 2001). A moderate correlation was found between the SISES and the Global Self Esteem scale on the Self Perception Profile for Children (rs=.52). To date, no evidence has been found on the sensitivity and specificity of this measure.

Participation was measured using the Canadian Occupational Performance Measure (COPM) (Law et al., 2005). To ensure the occupational participation rated was relevant to the intervention focus for the current study, a menu of 15 occupationally-oriented activities was provided, from which each participant selected two that they considered important and in which they wanted to improve their participation. A menu for activity selection was previously used successfully by Di Rezze, Wright, Curran, Campbell, and Macarthur (2008) and in a personal communication with one of the developers the use of a menu was not

considered a modification of the COPM (M. Law, personal communication, September 10, 2015). The COPM has demonstrated sensitivity to change in client outcomes (Carswell et al., 2004; Eyssen et al., 2011; Law, Anaby, Imms, Teplicky, & Turner, 2015). Parents also rated the menu-items selected by their child on the COPM as a proxy-assessment of participation. Previous uses of the COPM have successfully used parents as proxies to rate child performance and satisfaction (Cusick, Lannin, & Lowe, 2007; Verker, Wolf, Louwers, Meester-Delver, & Nollet, 2006).

Wellbeing was measured using the Student Life Satisfaction Scale (SLSS) (Huebner, 1991a, 1991b, 1994). The Children's Society (2012) and The New Economics Foundation (2012) described the SLSS as sufficiently sensitive to measure changes over time, however, evidence for this is limited (Huebner, 2004).

Ethical considerations

Written assent was obtained from children participating in this trial, along with written consent from their parent/guardian and teachers. The trial was approved by the New Zealand Health and Disability Ethics Committees (14/NTA/13), the Auckland University of Technology Ethics Committee (14/75) and was registered with the Australia/New Zealand Clinical Trials Registry (ACTRN12614000453684) http://www.anzctr.org.au/default.aspx

Data analyses

Analyses on the primary and secondary outcome measures were adjusted for baseline scores, ethnicity, school decile category, and gender by including these as covariates, where indicated by the blind review and where not already adjusted for within the outcome (for example, the MASC-10 adjusts scores for age and gender). The effect of the covariates were allowed to vary depending on time The model accounted for clustering by including it as a random effect, except in three instances where it was not indicated by the blind review, by virtue of the between-cluster variance being estimated at zero (i.e. the two subscales on the RCADS and the SLSS). A participant random effect (nested within cluster, if included)

was also used to account for the repeated measures. An interaction term of intervention indicator crossed with time and phase was also included to enable the desired comparisons between intervention groups. This study utilised an Intention-to-Treat (ITT) approach to analysis, in order to preserve the value of randomisation and to reduce the potential for upward bias in the estimated effect size (Eldridge & Kerry, 2012).

Primary analysis focussed in on the parallel phase of the trial and compared post-intervention and post-waitlist outcomes for participants based on their allocation immediately following randomisation. Secondary analysis utilised information about the intervention from both the parallel phase and data from participants allocated to the waitlist-control when they later went on to receive the intervention. Outcomes were analysed at follow-up assessment (8-9 weeks post-intervention) and compared to immediately post-intervention to assess for non-inferiority of the intervention, using non-inferiority thresholds[i]. The primary outcome for effectiveness of this intervention was the participants' self-rating of anxiety symptoms.

Results

Participants

Fourteen schools and 151 child participants were recruited and randomised (Table 1) between April 2014 and November 2015. Figure 1 shows the flow of clusters (i.e. schools) and participants through the study. The intention had been to recruit schools across the strata of low, medium and high decile categories at the ratio of 4:6:4; however, the ratio actually recruited was 5:2:7. As only two clusters were randomised in the medium decile category, the first two categories were combined to create a single low/medium level for adjustment purposes, such as the use of school decile category as a covariate. The stratified block randomisation was implemented using all three strata, as originally planned. No adverse events or significant harms were reported during the trial.

[Insert Figure 1 about here]

[Insert Table 1 about here]

Baseline data

At baseline, data were available for 89-99% of the child-rated outcome measures, 57-63% of the parent-rated outcome measures and 75-87% of the teacher-rated measures (Table 2). Analysis of differences between the allocation groups at baseline was deemed unnecessary, as the reported variables were included as covariates when the blind review indicated the variable had a significant influence on the outcomes. The data presented in this section represent the baseline data from each study arm as they were randomised. Average baseline scores for anxiety symptoms were in the non-clinical range (<60) for all but one cluster, average baseline scores for depression symptoms were in the clinical range (>60) for all clusters. The other outcome measures do not identify a clinical cut-off for scores.

[Insert Table 2 about here]

Descriptive statistics

The descriptive statistics from the child-, parent- and teacher-rated outcomes are summarised in Table 3, Table 4 and Table 5 respectively. All data were included in the analysis model and no data were removed for the purposes of the ITT analyses. Data at each assessment point were reported in relation to the relative phase: parallel phase, crossover phase or follow-up assessment (as illustrated in Figure 2 above).

[Insert Table 3 about here]

[Insert Table 4 about here]

[Insert Table 5 about here]

Adjusted ITT analyses

Primary analysis

The results of the primary analysis on the ITT dataset are presented in Table 6. There were no significant effects of the intervention on the primary outcome (MASC10) or the other child-, parent- or teacher-rated anxiety, depression, self-esteem, wellbeing and occupational performance in the parallel phase. A statistically significant positive effect of the intervention was found on occupational satisfaction, as measured by the children's COPM satisfaction scale (1.3, *p*=0.009). The average score for the intervention group after the parallel phase changed by +1.6 and for the control group by +0.6; however, a clinically significant score change (of 2) was not achieved.

[Insert Table 6 about here]

Secondary analysis

The results of the secondary analysis are presented in Table 7. There was no significant effect of the intervention on the primary outcome (MASC10) once information about the intervention from the crossover phase was also taken into account. A positive effect of the intervention found on the children's COPM satisfaction scale was approaching significance (0.6, *p*=0.076); however, the score change was sub-threshold for clinical significance. Significant positive effects of the intervention were found on the teacher-rated outcome (SAS) for the total score and both of its subscales (GA and Social anxiety) (Total: -3.2, *p*=0.001; GA: -1.5, *p*=0.017; SA: -1.6, *p*=0.011). Clinically significant change scores for the SAS, or its subscales, are not reported in the literature. However, if the values used for the non-inferiority threshold were substituted as score changes indicative of clinically significance (SAS= 1.7; SAS-GA= 1.0; SAS-SA= 0.9), then it may be suggested that clinically significant positive change was achieved post-intervention in comparison to the control period.

[Insert Table 7 about here]

Post intervention follow up assessment

Findings from the analysis of the longitudinal effects of the intervention on the outcome measures at the post-intervention follow-up assessment point are presented in Table 8. Comparison was between post-intervention and post-intervention follow-up assessment points and not between the study arms. There was sufficient evidence to reject the null hypothesis and conclude that measurements were non-inferior for one secondary outcome: the CDI2, for which the average baseline score was in the clinical range. The interpretation of this result is that this outcome was no worse, and possibly improved for participants at post-intervention follow-up, as compared to post-intervention. Therefore, the effects of the intervention on CDI2could be considered sustainable. Regarding the primary outcome, the average MASC10 score was in the non-clinical range at baseline and remained in the non-clinical range at post intervention follow-up. For this and the remaining outcomes there was insufficient evidence to determine whether or not the impact of the intervention was non-inferior at post-intervention follow-up as compared to post-intervention.

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[Insert Table 8 about here]

Intra-cluster correlation coefficients (ICCs)

For the current study, an a priori estimate of the ICC of 0.05 was used to account for variances between- and within-clusters (i.e. schools) for the purposes of sample size computation. ICCs for the current study ranged between 0.00-0.71. The estimated ICC was within the actual range calculated, which facilitated a more conservative adjustment than was indicated for 12 of the 14 measures. Therefore, it can be considered to have been a reasonable estimate to use in the sample size calculation. The ICCs reported in Table 9 may be considered in future estimates for similar research designs with these outcomes.

[Insert Table 9 about here]

Efficacy of blinding

At the end of each period of intervention or waitlist the outcome assessors were asked to indicate which randomisation group they thought the schools they had collected data from had been allocated to. Two outcome assessors were unblinded, each on one occasion, by child participants. Excluding the incidents of unblinding, out of 11 guesses, they correctly identified the randomisation group once (waitlist) and 10 times they declined to guess because they reported being unable to do so.

Discussion

Kia Piki te Hauora was not found to significantly impact child- and parent-rated anxiety, depression, self-esteem or wellbeing outcomes, as compared to the control, however, teacher-rated symptoms of anxiety were shown to significantly reduce. The primary analysis found participation in the intervention significantly improved children's satisfaction with their performance when participating in everyday occupations they had wanted to improve, as compared to the control.

This trial provided no new evidence to support the theory that improved participation in daily occupations can significantly impact on preventing symptoms of mental illness. It is acknowledged that participation in an intervention may not be considered a meaningful occupation in itself. It may be hypothesised that improvements in participation need to become more established before they impact symptoms of mental illness and wellbeing or that establishing healthier routines and occupational choices earlier in the child's development enables them to be more resilient in response to future adversities and challenges to their mental health and wellbeing. Evaluating these hypotheses would require a longer follow-up of the outcomes than was feasible in the current study and may warrant further investigation.

Baseline measures

The process of teacher nominations, in the current study, produced a sample of children rated as anxious by the teachers, but whose self-report and parental report indicated experiencing significant depression, not anxiety, symptoms. A possible explanation for the non-significant findings could have been the baseline anxiety levels were low, creating a floor effect – with limited scope for level of symptoms to reduce. Future research may benefit from including anxiety levels as an eligibility criteria. Elevated depression symptoms at baseline was unexpected and may suggest that teachers were more likely to identify children who perceived themselves as experiencing low mood as highly anxious. Similarly, another study reported teacher-rated child anxiety symptoms were a robust predictor of child self-reported depression symptoms (Snyder et al., 2009). It may be that greater emphasis on strategies for managing low mood, rather than anxiety, could have achieved more positive outcomes in the current study. In practice, facilitators would have access to baseline data in order to more accurately tailor the intervention to the needs of the participants (Hall et al., 2014), however, for this cluster-RCT, access to baseline outcome data was not feasible for the facilitator who was also the primary investigator and needed to remain blinded until study completion (Moher et al., 2010).

Participation measure

A measure of mental health symptoms was chosen as the primary outcome measure (MASC10) rather than the occupationally-based outcome measure used (COPM), due to it being widely used and having strong psychometric properties. The aim of the intervention was to prevent symptoms of anxiety and depression symptoms through improving children's occupational choices and participation, rather than targeting cognitions alone. It is promising that child-rated satisfaction of their participation improved significantly and raises the question of whether or not an occupational measure would have been a more appropriate primary outcome measure. A precedent has recently been set, with a study including occupational participation as the primary outcome (Law et al., 2015). Additionally, clinically

significant change as measured by the COPM is a change score of 2 (Law et al., 2005). However, the COPM was developed and evaluated for use with clinical populations or those with chronic conditions and its use with community populations to measure the efficacy of preventative interventions has not been formally established. It may be that a value less than 2 would be appropriate as a measure of clinically significant change for a preventative intervention focused on health promotion rather than recovery or remediation. However, the psychometric properties of using the measure in this way have not been evaluated and require further investigation.

Study strengths and limitations

The cluster-RCT reported here was an ethically sound, well-designed study with a fully pre-specified statistical analysis plan (Tokolahi et al., 2014). Features of the study design that minimised the risk of biases included randomisation at the cluster level, allocation concealment, blinding of participants until after the collection of baseline measures, blinding of outcome assessors, and the use of a control group for comparison during the parallel phase. The sample recruited was large enough to ensure the analysis was sufficiently powered and the outcome measures used were psychometrically sound. Furthermore, the blinding of outcome assessors was assessed to be largely effective. Given the complex nature of the intervention under evaluation, blinding of participants and personnel (other than outcome assessors) was not feasible, nor was comparison to an attention-control intervention or the collection of qualitative data. Two key limitations were the lack of comparison at follow-up, the short follow-up period, and missing data/low response rates (particularly from parents).

Reconsidering the intervention

Reflecting on the promising findings, it is worth considering the redesign of Kia Piki te Hauora: Uplifting our Health and Wellbeing© as a universal intervention. If the intervention was embedded into the daily routine of the classroom and co-facilitated by a teacher,

opportunities for the children to practice the skills in the context of their everyday lives would increase (Bean, Kendellen, & Forneris, 2016; Blackwell & Dunn, 2016). Studies have concluded that integrating interventions into the curriculum achieved greater and longer lasting positive effects on children's mental health (Adi, Killoran, Janmohamed, & Stewart-Brown, 2007; Berkowitz & Bier, 2007; Rones & Hoagwood, 2000).

Teacher involvement in the facilitation of the intervention may lead children to experience a greater sense of social support from their teachers, which a previous study identified as one of several factors associated with enhanced wellbeing in adolescents (Armstrong & Boothroyd, 2007). Additionally, an embedded intervention would prevent children missing enjoyed subjects scheduled at the same time as the intervention, something children reported impacting on their participation in the current study (McCoy, 2014). Parental involvement could enable children to generalise knowledge and experiences from the intervention into the home environment and support the development and sustainability of routines that promote participation in health-promoting occupations. Targeting routines and habits has been found to have a positive impact on children's and parents' occupational choices to participate more frequently in health-promoting occupations (Kugel, Hemberger, Krpalek, & Javaherian-Dysinger, 2016).

Conclusions

Insufficient evidence was found for Kia Piki te Hauora: Uplifting our Health and Wellbeing© to promote mental health and wellbeing in children aged 10-13 years in its current format. A positive, significant impact of the intervention on teacher-rated anxiety and child-rated performance and their satisfaction with their performance was found; however, the latter did not appear to correspond to similar improvements in child-rated mental health outcomes. Redesigning Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded intervention is indicated.

Implications for practice and research

The current study was the first known cluster-RCT to investigate an occupational therapy intervention promoting mental health and wellbeing in a non-clinical sample of children. The discussion above highlighted how the intervention could be modified to enhance the effectiveness on targeted outcomes. Recommendations are to deliver the intervention as an embedded intervention, in collaboration with teachers, and introducing parent involvement to increase opportunities for children to generalise skills into more environments and support their ability to build health-promoting routines into their pattern of daily occupations.

Future research may be warranted on the modified intervention as an embedded intervention, using an occupationally focused measure of participation as the primary outcome. The current study was a standalone cluster-RCT and further study may benefit from being part of a unified programme of research, including multiple pilot studies to identify appropriate occupationally-focused outcome measures and to ensure the most effective delivery models are used (Miller, Schoen, James, & Schaaf, 2007). In order to elicit meaningful outcomes from these pilot studies it is recommended that a mixed methods approach be taken that would incorporate the collection of quantitative and qualitative data. A longer follow-up period with a controlled comparison group was beyond the scope and resources of this study but would be important to consider when planning similar studies in the future.

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Authors contributions

ET conceived of the intervention, was the primary researcher, led the study design and wrote the initial grant applications and this manuscript. AV, PK and CH all contributed significantly to the study design and grant applications, with JP contributing significantly to data analysis and interpretation. All authors contributed to, read and approved the final manuscript.

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Table 1: Characteristics of the clusters and participants at baseline

	Cluster characteristics				Participant characteristics			Ages			Ethnicities***				
Cluster (School)	**Year enrolled**	**Baseline term***	**Decile ranking**	**Decile group**	***n***	**♀**	**♂**	**Mean age (SD) (years)**	**Age min**	**Age max**	**NZE**	**Māori**	**Pacific ******	**Asian**	**Other**
Control															
01NCH	2014	3	10	High	8	5	3	12.5 (0.7)	11.5	13.2	2	3			4
02KRL	2014	2	1	Low	12	8	4	12.1 (0.6)	11.2	12.8	1	9	2		
04WMH	2014	2	10	High	13	8	5	11.7 (0.7)	11.0	12.8	12				1
07SHH	2014	2	8	High	12	6	6	11.8 (0.6)	11.1	12.8	10				2
10MPL	2015	2	1	Low	8	6	2	12.1 (0.7)	11.0	13.0		5	7	2	2
13GPL	2015	2	1	Low	11	6	5	12.5 (0.5)	11.4	13.0		2	9	1	1
14PIM	2015	2	6	Medium	9	7	2	12.0 (0.7)	11.2	13.3			2	4	4
				Total	*73*	*46*	*27*	*12.1 (0.3^, 0.6$)*	*11.0*	*13.3*	*25*	*19*	*20*	*7*	*14*
Intervention															
03CPH	2014	2	10	High	10	2	8	12.3 (0.4)	11.6	12.9	6	1			3
05WIM	2014	2	6	Medium	10	4	6	12.2 (0.6)	11.0	12.8	5	4	1		4
06AIL	2014	2	3	Low	9	7	2	12.0 (0.6)	11.1	12.6		1		7	1
08GEH	2014	3	8	High	10	3	7	12.3 (0.6)	11.2	13.2	9		1		1
09KTH	2014	3	10	High	11	7	4	12.2 (0.6)	11.2	13.2	5		2	3	3
11MCL	2015	2	2	Low	11	0	11	12.2 (0.8)	11.0	13.0	2	2	5		6
12DGH	2015	2	10	High	8	8	0	11.4 (0.3)**	11.1	11.8	6		1		1
				Total	*69*	*31*	*38*	*12.1 (0.3^, 0.6$)*	*11.0*	*13.2*	*33*	*8*	*10*	*10*	*19*
			Totals for all schools		*142*	*77*	*65*	*12.1 (0.2^, 0.6$)*	*11.0*	*13.3*	*58*	*27*	*30*	*17*	*33*

Notes: *There are 4 terms in the New Zealand academic calendar; **Ages for two participants in this cluster were missing; ***totals do not always match *n* as participants may have identified with more than one ethnic group; ****includes Cook Island Māori, Niuean, Samoan and Tongan; ^=between cluster variance; $=within cluster variance.

Abbreviation: NZE=New Zealand European; SD=standard deviation.

Table 2: Baseline data for child-rated measures, by cluster and study arm

	Child-rated measures: Mean (standard deviation)											
Cluster ID	***n***	**MASC10**	***n***	**CDI2**	***n***	**RSES**	***n***	**COPM Performance**	***n***	**COPM Satisfaction**	***n***	**SLSS**
Control												
01NCH	8	60.3(7.3)	8	76.4(9.8)	8	12.4(3.9)	8	4.6(2.1)	8	4.3(2.9)	8	6.9(6.0)
02KRL	12	52.0(11.1)	12	72.9(7.2)	12	15.4(4.3)	12	6.7(2.2)	12	6.1(3.6)	12	14.2(4.0)
04WMH	13	45.9(9.5)	13	72.5(5.3)	13	22.3(3.8)	13	5.2(1.7)	13	5.6(2.6)	13	17.2 (2.9)
07SHH	12	49.0(8.8)	12	71.3(7.8)	12	21.2 (4.5)	12	4.8(1.6)	12	4.9(1.9)	12	13.8(4.4)
10MPL	8	39.5(14.9)	8	70.4(9.3)	8	22.9(4.6)	8	9.0(2.8)	8	9.1(2.5)	8	15.0(9.9)
13GPL	10	49.7(12.7)	11	70.7(8.8)	11	20.8(5.2)	11	7.7(2.7)	11	7.7(2.8)	11	16.8(2.7)
14PIM	8	50.4(13.2)	8	73.6(9.0)	8	17.6(6.4)	7	4.0(2.6)	7	4.3(4.3)	8	11.6(6.7)
Total	*71*	*50.0 (7.1^, 11.1$)*	*72*	*72.8 (2.9^, 7.7$)*	*72*	*19.9 (3.7^, 4.2$)*	*71*	*6.1 (1.1^, 2.0$)*	*71*	*6.2 (1.6^, 2.5$)*	*72*	*14.5 (3.0^, 4.3$)*
Intervention												
03CPH	10	58.8(14.3)	10	79.7(7.5)	10	13.6(6.4)	10	5.8(2.5)	10	5.1(2.8)	10	10.8(6.4)
05WIM	10	54.2(8.2)	10	77.1(8.8)	10	19.2(6.7)	10	4.3(2.0)	10	3.6(2.5)	10	14.8(5.6)
06AIL	9	54.6(7.4)	9	72.3(6.9)	9	22.7(6.4)	9	6.1(1.1)	9	6.0(1.2)	9	16.6(4.1)
08GEH	10	55.9(11.1)	10	74.0(5.2)	10	19.2(4.1)	10	5.8(2.3)	10	4.7(1.8)	10	14.8(2.9)
09KTH	11	53.4(7.6)	11	75.8(8.5)	11	17.1(7.4)	11	6.0(2.7)	11	5.1(3.5)	11	12.1(5.4)
11MCL	11	52.0(10.7)	10	70.8(6.8)	11	18.4(2.8)	11	6.3(2.3)	11	6.4(2.7)	10	14.0(5.1)
12DGH	8	55.1(12.9)	6	75.0(7.2)	8	22.6(4.4)	8	6.0(1.8)	7	5.4(2.2)	8	15.9(2.8)
Total	*69*	*54.9 (0^, 10.2$)*	*66*	*74.9 (2.6^, 7.2$)*	*69*	*18.9 (2.9^, 5.6$)*	*69*	*5.8 (0.7^, 1.8$)*	*68*	*5.3 (1.0^, 2.1$)*	*68*	*14.1 (1.7^, 4.7$)*
Total for all schools	*140*	*52.4 (5.3^, 10.7$)*	*138*	*73.8 (2.8^, 7.5$)*	*141*	*19.4 (3.2^, 4.8$)*	*140*	*6.0 (0.9^, 2.0$)*	*139*	*5.7 (1.3^, 2.3$)*	*140*	*14.3 (2.3^, 4.5$)*

Notes: ^=between cluster variance; $=within cluster variance; *n*=number of observations available.

Abbreviations: CDI2=Children's Depression Inventory – 2nd edition; COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RSES=Rosenberg Self-Esteem Scale; SLSS=Student Life Satisfaction Scale.

Table 3: Means and standard deviations for child-rated outcomes at each assessment point

		Baseline (pre-randomisation)			Parallel phase assessment point			Crossover phase baseline			Crossover phase assessment point			Post-intervention follow-up		
Child-rated outcomes	**Study arm**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**
MASC10	Intervention	69	54.8 (0,10.2)	51.8 - 57.9	65	56.3 (3.0, 11.3)	51.9 - 60.8	-	-	-	-	-	-	67	54.4 (0, 12.6)	50.6-58.1
	Control	71	49.5 (4.7,11.1)	44.1 - 54.9	67	49.1 (1.5, 11.6)	45.3 - 52.8	69	50.1 (6.5, 11.5)	43.0 - 57.3	61	49.0 (5.6, 12.9)	42.3-55.6	64	46.7 (5.9,11.8)	40.1-53.3
CDI2	Intervention	66	74.9 (2.1, 7.4)	72.0 - 77.9	59	74.9 (1.8, 7.8)	71.8 - 77.9	-	-	-	-	-	-	63	74.2 (0, 7.4)	72.0-76.5
	Control	72	72.4 (0, 7. 9)	70.1 -74-7	65	73.5 (1.9, 8.4)	70.3 - 76.6	69	72.94 (2.7, 7.9)	69.5 - 76.4	57	72.8 (2.0, 7.8)	69.6-76.0	61	70.3 (0.8, 6.7)	68.1-72.6
RSES	Intervention	69	18.9 (2.5, 5.7)	16.0 - 21.8	65	19.2 (2.6, 6.4)	16.1 - 22.3	-	-	-	-	-	-	65	19.7 (3.0, 5.9)	16.3-23.0
	Control	72	19.0 (3.6, 4.7)	15.4 - 22.6	64	18.9 (4.1, 4.4)	14.8 - 22.9	63	20.85 (3.0, 4.0)	17.8 - 23.9	59	19.5 (3.3, 5.9)	15.8-23.2	63	21.3 (3.6, 4.9)	17.6-24.9
COPM Performance[+]	Intervention	69	5.7 (0.6, 1.8)	5.0-6.5	64	1.1* (0.6, 1.4)	0.4-1.8	-	-	-	-	-	-	65	1.4* (0.8, 1.9)	0.5-2.4
	Control	71	6.0 (1.7, 1.8)	4.3-7.7	66	0.8* (0, 1.8)	0.3-1.3	63	6.3 (0.5, 2.2)	5.5-7.1	59	1.4** (0.8, 1.9)	0.5-2.4	64	1.5** (0.9, 2.4)	0.4-2.6
COPM Satisfaction[+]	Intervention	68	5.3 (0.9, 2.1)	4.2-6.3	64	1.6* (0.45 1.9)	0.9-2.4	-	-	-	-	-	-	65	1.9* (0.7, 2.2)	0.9-2.9
	Control	71	6.0 (1.6, 2.6)	4.4-7.6	66	0.6* (0, 2.0)	0.0-1.2	63	6.3 (1.3, 2.5)	4.9-7.8	59	1.3** (0.7, 2.0)	0.4-2.2	64	1.4** (1.0, 2.3)	0.3-2.6
SLSS	Intervention	68	14.1 (1.3, 4.8)	12.2 - 16.0	65	14.3 (1.5, 5.0)	12.3 - 16.4	-	-	-	-	-	-	65	14.0 (1.2, 5.3)	12.0-16.0

	Control	72	13.7 (3.1, 4.7)	10.5 - 16.9	64	14.35 (0.6, 5.4)	12.6 - 16.1	63	15.7 (0.9, 4.2)	14.1 - 17.3	59	14.8 (0, 4.7)	13.3-16.4	64	15.3 (2.1, 3.6)	13.1-17.6

Notes: bcv=between-cluster variance; wcv=within-cluster variance; CI=confidence interval; *n*=observations available; + average score is defined as the average of the scores for both activities if present or the score of one if one was missing; *change in score from baseline; **change in score from crossover phase baseline.
Abbreviations: CDI2=Children's Depression Inventory (2nd Ed); COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RSES=Rosenberg Self-Esteem Scale; SLSS=Student Life Satisfaction Scale.

Table 4: Means and standard deviations for parent-rated outcomes at each assessment point

		Baseline (pre-randomisation)			**Parallel phase assessment point**			**Crossover phase baseline**			**Crossover phase assessment point**			**Post-intervention follow-up**		
Parent-rated outcomes	**Study arm**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**	***n***	**Mean (bcv, wcv)**	**95% CI**
RCADS GA	Intervention	50	42.7 (0, 7.2)	40.2 - 45.2	34	41.4 (0, 6.8)	38.6 - 44.3	-	-	-	-	-	-	41	41.7 (1.6, 5.9)	39.0-44.4
	Control	40	43.7 (4.6, 4.5)	38.9 - 48.5	32	41.8 (0, 4.3)	39.6 - 43.7	32	43.4 (0, 5.4)	41.1 - 45.7	25	40.8 (0, 4.17)	38.7 - 43.0	29	40.5 (0, 5.0)	38.3-42.8
RCADS D	Intervention	50	57.4 (4.6, 10.6)	51.7 - 63.1	34	55.6 (2.3, 9.9)	51.0 - 60.3	-	-	-	-	-	-	41	52.9 (4.9, 9.1)	47.1-58.6
	Control	40	55.6 (2.6, 10.0)	50.8 - 60.4	32	55.4 (4.9, 12.1)	47.9 - 62.9	32	54.9 (3.2, 10.4)	49.2 - 60.6	25	55.0 (3.0, 13.2)	47.2 - 62.8	29	52.3 (3.9, 11.8)	45.5-59.1
COPM Performance+	Intervention	49	6.0 (0.2, 2.3)	5.2-6.8	31	2.1* (0, 2.5)	1.0-3.3	-	-	-	-	-	-	38	2.3* (0, 2.3)	1.4-3.2
	Control	38	6.9 (1.0, 2.0)	5.6-8.2	28	1.8* (0.5, 3.5)	0.2-3.5	33	7.3 (0, 2.1)	6.4-8.2	23	2.0** (0, 3.2)	0.3-3.7	29	1.9** (0, 3.3)	0.4-3.4
COPM Satisfaction+	Intervention	49	6.1 (0.5, 2.2)	5.2-7.0	31	1. 9* (0, 2.7)	0.7-3.1	-	-	-	-	-	-	38	1.8* (0, 2.5)	0.8-2.8
	Control	37	6.6 (0.4, 2.2)	5.6-7.6	27	2.5* (1.5, 3.5)	0.2-4.8	33	7.2 (0, 2.2)	6.3-8.1	23	2.1** (0, 3.2)	0.3-3.8	29	1.8** (0, 3.2)	0.3-3.2

SISES	Intervention	47	3.0 (0, 1.1)	2.6-3.3	34	3.5 (0.3, 0.8)	3.1-4.0	-	-	-	-	-	-	40	3.5 (0.2, 0.8)	3.2-3.9
	Control	37	3.2 (0.2, 1.1)	2.7-3.7	31	3.5 (0, 1.0)	3.0-3.9	31	3.5 (0.3, 1.0)	2.9-4.1	21	3.3 (0.8, 0.9)	2.2-4.4	27	3.5 (0.3, 0.9)	2.9-4.1

Notes: bcv=between-cluster variance; wcv=within-cluster variance; CI=confidence interval; *n*=observations available; [+] average score is defined as the average of the scores for both activities if present or the score of one if one was missing; *change in score from baseline; **change in score from crossover phase baseline.

Abbreviations: COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RCADS D=Revised Children's Anxiety and Depression Scale – Depression subscale; RCADS GA=Revised Children's Anxiety and Depression Scale – Generalised Anxiety subscale; SISES=Single Item Self-Esteem Scale.

Table 5: Means and standard deviations for teacher-rated outcomes at each assessment point

Teacher-rated outcomes		Baseline (pre-randomisation)			Parallel phase assessment point			Crossover phase baseline			Crossover phase assessment point			Post-intervention follow-up		
	Study arm	*n*	Mean (bcv, wcv)	95% CI	*n*	Mean (bcv, wcv)	95% CI	*n*	Mean (bcv, wcv)	95% CI	*n*	Mean (bcv, wcv)	95% CI	*n*	Mean (bcv, wcv)	95% CI
SAS	Intervention	64	18.5 (4.1, 9.4)	13.7-23.3	43	13.3 (5.0, 9.4)	6.0-20.7	-	-	-	-	-	-	41	12.4 (4.6, 7.8)	5.7-19.1
	Control	61	16.1 (5.2, 7.5)	10.1-22.2	61	14.7 (3.6, 6.6)	10.3-19.1	41	11.9 (3.5, 6.2)	5.4-18.4	29	9.4 (4.3, 6.2)	1.0-17.9	47	11.4 (5.2, 5.2)	5.4-17.4
SAS GA	Intervention	64	10.6 (2.7, 5.3)	7.6-13.6	43	8.0 (2.6, 5.2)	4.1-11.9	-	-	-	-	-	-	41	8.0 (3.2, 4.6)	3.6-12.5
	Control	61	9.0 (2.9, 4.5)	5.6-12.4	61	8.1 (2.8, 3.8)	4.9-11.4	41	6.7 (1.8, 4.0)	3.2-10.3	29	5.0 (1.4, 3.7)	1.6-8.4	48	6.3 (3.1, 2.8)	2.8-9.8
SAS SA	Intervention	64	7.8 (1.2, 4.9)	5.9-9.7	43	5.3 (2.41, 4.82)	1.6-8.9	-	-	-	-	-	-	42	4.4 (1.7, 3.8)	1.7-7.1
	Control	61	7.1 (2.7, 4.2)	3.9-10.4	62	6.6 (1.8, 3.7)	4.3-8.8	41	5.1 (2.1, 3.3)	1.3-8.9	29	4.2 (2.5, 3.6)	-0.6-9.1	49	4.9 (1.9, 3.2)	2.4-7.3

Notes: bcv=between-cluster variance; wcv=within-cluster variance; CI=confidence interval; *n*=observations available.

Abbreviations: SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale.

Table 6: Adjusted analyses examining the parallel phase

		Covariates*					Adjusted – differences between study arms at the primary end-point			
Outcome	***n*** **(*N*=142)**	**Baseline score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Estimated difference**	**Standard error**	**95% CI**	***p*-Value**
Child-rated outcomes										
MASC10**	132	✓	✓	✓		✓	3.0	1.7	-0.4-6.3	0.082
CDI2**	124	✓		✓		✓	0.2	1.4		0.880
RSES	129	✓	✓	✓		✓	0.2	0.9	-1.6-2.0	0.827
COPM	130			✓	✓	✓	0.8	0.5	-0.2-1.8	0.117
Performance										
COPM	130			✓	✓	✓	1.3	0.5	0.3-2.3	0.009***
Satisfaction										
SLSS	129	✓	✓	✓			-0.0	0.7	-1.3-1.2	0.958
Parent-rated outcomes										
RCADS GA**	66	✓					-0.5	1.1	-2.7-1.7	0.632
RCADS D**	66	✓	✓	✓			-1.2	2.3	-5.7-3.2	0.591
COPM	59		✓	✓		✓	1.2	0.9	-0.5-3.0	0.171
Performance										
COPM	58		✓	✓		✓	0.2	1.1	-1.9-2.3	0.851
Satisfaction										
SISES	65	✓	✓			✓	0.3	0.2	-0.2-0.7	0.265
Teacher-rated outcomes										
SAS	104	✓	✓			✓	-2.69	2.55	-7.68-2.30	0.290
SAS GA	104	✓	✓	✓		✓	-1.42	1.54	-4.44-1.59	0.356
SAS SA	105	✓				✓	-1.80	1.11	-4.00-0.41	0.110

Notes: *n*=observations available; N=sample size; CI=Confidence Interval; *determined by the blind review; **scores are already adjusted for age and gender; ***significant at $p<0.05$.

Abbreviations: CDI2=Children's Depression Inventory (2nd ed); COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RCADS D=Revised Children's Anxiety and Depression Scale – Depression subscale; RCADS GA=Revised Children's Anxiety and Depression Scale – Generalised Anxiety subscale; RSES=Rosenberg Self-Esteem Scale; SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale; SLSS=Student Life Satisfaction Scale; SISES=Single Item Self-Esteem Scale.

Table 7: Adjusted analysis examining the crossover and parallel phases

		Covariates*					Differences between study arms at post-intervention			
Outcome	***n* (*N*=215)**	**Baseline score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Estimated difference**	**Standard error**	**95% CI**	***p*-Value**
Child-rated outcomes										
MASC10**	193	✓	✓	✓		✓	-0.3	1.2	-2.6-2.1	0.835
CDI2**	181	✓		✓		✓	-0.8	1.0		0.385
RSES	188	✓	✓	✓		✓	-0.0	0.6	-1.2-1.2	0.958
COPM	189			✓	✓	✓	0.4	0.3	-0.3-1.0	0.258
Performance										
COPM	189			✓	✓	✓	0.6	0.3	-0.1-1.3	0.076
Satisfaction										
Wellbeing	188	✓	✓	✓			-0.3	0.5	-1.3-0.8	0.640
Parent-rated outcomes										
RCADS GA**	91	✓					-1.4	0.9	-3.2-0.3	0.108
RCADS D**	91	✓	✓	✓			0.4	1.4	-2.3-3.1	0.788
COPM	82		✓	✓		✓	-0.6	0.4	-1.4-0.3	0.208
Performance										
COPM	81		✓	✓		✓	-0.7	0.5	-1.6-0.3	0.146
Satisfaction										
SISES	86	✓	✓			✓	0.0	0.1	-0.2-0.3	0.757
Teacher-rated outcomes										
SAS	133	✓	✓			✓	-3.2	1.0	-5.1- -1.3	0.001***
SAS GA	133	✓	✓	✓		✓	-1.5	0.6	-2.7- -0.3	0.017***
SAS SA	134	✓				✓	-1.6	0.6	-2.9- -0.4	0.011***

Notes: *n*=observations available; N=sample size; CI=Confidence Interval; *determined by the blind review; **scores are already adjusted for age and gender, ***significant at $p<0.05$.

Abbreviations: CDI2=Children's Depression Inventory (2nd ed); COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RCADS D=Revised Children's Anxiety and Depression Scale – Depression subscale; RCADS GA=Revised Children's Anxiety and Depression Scale – Generalised Anxiety subscale; RSES=Rosenberg Self-Esteem Scale; SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale; SISES=Single Item Self-Esteem Scale.

Table 8: Adjusted analysis of follow-up phase

Outcome	*n* (*N*=284)	Covariates*					Differences between post-intervention and follow-up			
		Baseline outcome score	Ethnicity	School decile category	Gender	Clustering	Non-inferiority threshold (NIT)	NIT relationship to bound from CI	Relevant bound of one-sided^ 95% CI	Status of alternative hypothesis (non-inferiority)^
Child-rated outcomes										
MASC10**	257	✓	✓	✓		✓	-2.5	<	13.51	Reject
CDI2**	240	✓		✓		✓	-2.5	>	-2.92	Accept
RSES	252	✓	✓	✓		✓	1	>	-4.7	Reject
COPM Performance	252			✓	✓	✓	2	>	-0.6	Reject
COPM Satisfaction	252			✓	✓	✓	2	>	-0.6	Reject
Wellbeing	253	✓	✓	✓			1.0	>	-3.2	Reject
Parent-rated outcomes										
RCADS GA**	129	✓					-2.5	<	4.24	Reject
RCADS D**	129	✓	✓	✓			-2.5	<	16.17	Reject
COPM Performance	121		✓	✓		✓	2	>	-2.3	Reject
COPM Satisfaction	121		✓	✓		✓	2	>	-2.4	Reject
SISES	122	✓	✓			✓	0.2	>	-0.9	Reject
Teacher-rated outcomes										
SAS	160	✓	✓			✓	-1.7	<	4.24	Reject
SAS GA	161	✓	✓	✓		✓	-1.0	<	1.83	Reject
SAS SA	163	✓				✓	-0.9	<	0.92	Reject

Notes: *n*=observations available; N=sample size; CI=Confidence Interval; *determined by the blind review; **scores are already adjusted for age and gender; ^if an increase in outcome would be unfavourable, decision is to accept H_A if NIT> upper bound of a lower one-sided 95% CI, otherwise if an increase would be favourable, decision to accept H_A is if NIT< lower bound of an upper 95% CI.

Abbreviations: CDI2=Children's Depression Inventory (2nd ed); COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RCADS D=Revised Children's Anxiety and Depression Scale – Depression subscale; RCADS GA=Revised Children's Anxiety and Depression Scale – Generalised Anxiety subscale; RSES=Rosenberg Self-Esteem Scale; SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale; SISES=Single Item Self-Esteem Scale.

Table 9: Intra-cluster correlation coefficients (ICC) calculated from non-imputed efficacy analysis data

Outcome	Between-cluster variance	Within-cluster variance	ICC estimate
Child-rated outcomes			
MASC10	0	50.0	0.00
CDI2	1.2	32.6	0.04
RSES	1.1	10. 5	0.10
COPM Performance	0.4	2.9	0.12
COPM Satisfaction	0.3	3.0	0.09
SLSS	2.9	9.6	0.23
Parent-rated outcomes			
RCADS-GA	4.8	10.5	0.31
RCADS-D	37.2	15.5	0.71
COPM Performance	0	3.7	0.00
COPM Satisfaction	0	4.1	0.00
SISES	0	0.3	0.00
Teacher-rated outcomes			
SAS	7.2	16.3	0.31
SAS-GA	3.0	6.3	0.32
SAS-SA	2.4	5.0	0.32

Abbreviations: CDI2=Children's Depression Inventory (2nd ed); COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; RCADS D=Revised Children's Anxiety and Depression Scale – Depression subscale; RCADS GA=Revised Children's Anxiety and Depression Scale – Generalised Anxiety subscale; RSES=Rosenberg Self-Esteem Scale; SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale; SISES=Single Item Self-Esteem Scale.

[i] Non-inferiority thresholds were calculated from published information regarding values for clinically significant change and standard deviations (SD) for each outcome. Non-inferiority thresholds are reported here as the change scores required before clinical significance has occurred. These have been calculated as "delta = *es* x SD" with the effect size (*es*) being consistently valued at 0.25 for the normed outcomes that are converted to *t*-scores and 0.2 for all others.