Cluster randomised controlled trial of an occupational therapy group intervention for children designed to promote emotional wellbeing

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Abstract

Background: Children's mental health is a growing focus in health promotion. Current treatments focus primarily on modifying internal cognitions with insufficient effect on functional outcomes. Occupational therapists can promote health and wellbeing by enabling children to design and build health-promoting routines and make healthy occupational choices. There was no evidence for the use of occupational therapy as an intervention to promote mental health or increase participation and wellbeing in a preventative context. The aim of the current study was to investigate the effectiveness of a preventative occupational therapy group intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) designed to reduce symptoms of anxiety and depression and improve self-esteem and participation in children aged 11-13 years, by completion of the intervention, and the sustainability of any improvements after a follow-up period of 8-9 weeks.

Methods: The study used a pragmatic, cluster-randomised controlled trial design with two arms: intervention and (waitlist) control. The sample size calculated was 126 participants from 14 clusters, based on a conservatively estimated intra-cluster coefficient (ICC) of 0.05 and a design effect (0.81) to account for the clustering and adjusting for covariates in the analyses. Fourteen clusters (schools), equating to 151 participants, were stratified by school decile-rank category and constrained stratified block randomisation was applied. 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. Data from intervention participants were compared to waitlist-control participants who later went on to receive the intervention: resulting in the crossover phase of the trial. Data were analysed using an intention-to-treat approach to analysis. A mixed design Repeated Measures Analysis of Covariance was conducted to enable adjustment for the clusters and to statistically control for covariates identified. Per protocol, unadjusted and sub-group analyses were also performed.

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. However, there was evidence that the child-rated anxiety and

depression symptoms 8-9 weeks after the intervention were no worse and possibly improved as compared to immediately post-intervention.

Discussion: The current study has provided no new evidence to support the theory that participation in meaningful, positive occupations can impact on mental health symptoms. Strengths of the study included a fully pre-specified statistical analysis plan, robust efforts to minimise biases and sufficient sample size. Limitations included not being able to blind participants and personnel, lack of an attention-control intervention and qualitative data collection. Having a short follow-up period and low parent and teacher response rates also limited findings. Recommendations are made to redesign the intervention as an embedded intervention in the classroom, co-taught by teachers and including parental involvement.

Contribution of new knowledge: 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.

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List of abbreviations

Abbreviation	Full description
AADE	Analysis Adjusted Design Effect
ANCOVA	Analysis of Covariance Analysis
AOTA	American Occupational Therapy Association
ARC	Autonomy Relatedness Competence
CBT	Cognitive Behavioural Therapy
CDI2	Children's Depression Inventory – 2nd Version
CONSORT	Consolidated Standards of Reporting Trials
COPM	Canadian Occupational Performance Measure
CV	Coefficient of Variation
DE	Design Effect
DPA	Dynamic Performance Analysis
EEP	Efficacy End Points
FCS	Full Conditional Specification
GA	Generalised Anxiety
GAS	Goal Attainment Scaling
ICC	Intra-Cluster Correlation Coefficient
ITT	Intention to Treat
MASC10	Multidimensional Anxiety Generalised Scale for Children – Short Version
OPC	Occupational Performance Coaching
PP	Per Protocol
RCADS	Revised Children's Anxiety And Depression Scale
RCT	Randomised Control Trial
RM-ANCOVA	Repeated Measures Analysis of Covariance
RSES	Rosenberg Self-Esteem Scale
RtI	Response to Intervention
SAS	School Anxiety Scale
SAS	Statistical Analysis Software
SENCO	Special Education Needs Coordinator
SEP	Safety End Points
SISES	Single Item Self-Esteem Scale
SLSS	Student Life Satisfaction Scale
SMART	Specific, Measurable, Achievable, Realistic, Time Bound
SOS	Signs of Suicide
SPSS	Statistical Packages for Social Sciences
WHO	World Health Organization

Attestation of authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree of diploma of a university or other institution of higher learning.

Signed:

Date: 25 April 2017

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This 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.

Intellectual property rights

I hereby assert my rights to the intellectual property associated with the Kia Piki te Hauora: Uplifting our Health and Wellbeing© intervention and the copyright to the illustrations used in association with this.

Signature:

Date: 25 April 2017

Chapter 1: Introduction

The aim of this study was to investigate an evidence-based intervention to promote positive mental health and wellbeing for children. The occupational therapy intervention evaluated is named Kia Piki te Hauora, which loosely translates from Māori to English as "Uplifting our Health and Wellbeing". It is an 8 week, school-based, group programme for children aged 11-13 years. Kia Piki te Hauora: Uplifting our Health and Wellbeing©, was designed to reduce symptoms of anxiety and depression, promote self-esteem and increase participation in everyday occupations. It was developed in response to requests from school personnel for an intervention for reducing the impact of anxiety in a broad range of children. Requests were to run an intervention onsite at schools for children experiencing disrupted occupational participation because of sub-clinical mental health issues. School personnel were concerned about students presenting with mild symptoms of anxiety or identified risk factors – in particular low self-esteem and limited participation in school-based occupations – but who were ineligible for secondary mental health services. Kia Piki te Hauora: Uplifting our Health and Wellbeing© takes into account the needs of this population by incorporating a primary health approach focused on mental health promotion and mental illness prevention from an occupational perspective.

In order to ensure provision of this intervention was evidence-based and beneficial for participants, the central question this research 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 11-13 years and are improvements sustained after a follow-up period of 8-9 weeks?*" This thesis reports on the cluster-randomised controlled trial (RCT), undertaken to answer this question, which was completed between April 2014 and November 2015, involving 151 children from 14 schools in the Auckland region of Aotearoa New Zealand. 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. Given the lack of evidence for occupational therapy in children's health promotion generally, the results are likely to be of national and international interest. Results contribute to the limited evidence-base for occupational therapists in this field and identify relevant avenues for future research. This chapter will outline the rationale

behind why the current study was undertaken, situate it within the Aotearoa New Zealand context and close with an overview of the thesis structure.

1.1 Defining constructs

The broad conceptualisation of what constitutes mental health and the client-centred (and complex) nature of occupational therapy contributes to difficulties researchers have in defining and evaluating interventions such as the one in this study. For the purpose of this thesis, mental health is defined as a state of emotional, social and psychological wellbeing; the individual is productive, able to adapt to changes or adversity, able to maintain positive social relationships and has positive self-esteem (Weare & Nind, 2011; Yearwood & DeLeon Siantz, 2010). Occupational therapy focuses on "the nature, balance, pattern and context of occupations … in the lives of individuals, family groups and communities" (Creek, 2003, p. 8). The main aim of therapy is to enable individuals to make occupational choices that maintain, restore and provide benefit in the context of their individual needs, the demands of their daily activities and their environment (Creek, 2003).

1.2 Justification for the research

This study was driven by more than just informal requests for interventions targeting children who were not eligible for secondary mental health services. When I embarked on this PhD in 2013, there was a high degree of legislative support for the evaluation and use of interventions that promoted health and wellbeing, and a foundation of theoretical knowledge that demonstrated the value of such interventions targeting universal populations. Furthermore, the use of a health promotion framework was consistent with an occupational perspective of health and the value of enabling children to participate in everyday occupations. These arguments are outlined below.

1.2.1 Population level interventions to promote health

The *World Health Organization's (WHO) Ottawa Charter* (1986) acted as a catalyst for a change in how healthcare practitioners approached health and wellbeing. The Charter was the culmination of a decade of debate after the Declaration of Alma Ata on Primary Health Care in 1978, which conveyed a different approach to health: "health for all". Increased knowledge and technology available to affect health states and pathologies enabled individuals, communities and nations to strive towards a greater focus on staying well and flourishing; and reduced the focus on recovery, restoration and

rehabilitation (American Occupational Therapy Association, 2013[AOTA]; Wilcock & Hocking, 2015). Examples of successful generic illness prevention and health promotion interventions with children include the use of wellness plans (Kharofa, Copeland, Sucharew, & Meurer, 2015), programmes to promote healthy diet and activity in children (Hoelscher, Moag-Stahlberg, Ellis, Vandewater, & Malkani, 2016), and the use of smartphone applications to promote healthy diets (Coughlin et al., 2015). In order for occupational therapists to adopt a health promotion approach, an understanding of the link between occupational participation and health is required; this is discussed below.

1.2.2 Occupational perspective of health promotion

Fundamental to an occupational perspective of health is the premise that humans are occupational beings and participation in meaningful occupations serves as a determinant of health and quality of life (Stewart, Fischer, Hirji, & Davis, 2016; Townsend & Wilcock, 2004). This standpoint encompasses a salutogenic perspective of health, in which factors that contribute to health and wellbeing are enhanced and prioritised, as opposed to a traditional medical model of health that prioritises minimisation of pathology (Antonovsky, 1987). From an occupational perspective, therefore, health promotion can be understood as participation in meaningful occupations and the health-promoting consequences of doing so (Wilcock & Hocking, 2015). This is consistent with the WHO's (1958) demand for increasing focus on health promotion.

As early as 1966, occupational therapists were responding to the WHO's demand for increasing focus on health promotion (West, 1973) and this was quickly picked-up in several theoretical and conceptual papers written by occupational therapists over the next few decades. Stein (1977) stressed the need for occupational therapy researcher-practitioners to work with healthy populations and identified several areas of potential practice, a list often replicated or added to in later articles. Practice areas included the employment sector preventing workplace accidents and injuries; parenting training to promote early childhood development; informing architectural design and engineering plans to promote universal access; programmes to decelerate the process of senility and aging; and the use of biofeedback in the prevention of mental illness. Stein's proposal was swiftly followed by a commentary from Grossman (1977) who emphasised occupational therapists' understanding of the relationship between occupational participation and health, which placed them in a unique role as an agent for health

promotion. She lamented the lack of commitment in occupational therapy undergraduate education to train students about the health promotion framework. Training was identified by practising therapists as a factor limiting occupational therapy contributions to this area (Grossman, 1977). Undergraduate curricula were reported to have progressed a decade later, when Rider and White (1986) identified that basic health promotion courses were being provided by educational institutions in the United States; however, there was still much room for improvement.

The 1980s saw the acknowledgement of cultural trends towards self-help in the general population and the drive to take increasing responsibility for one's own health habits and environments (White, 1986). It was recognised that occupational therapists were practising in the area of health promotion in the United States and a special issue on the topic was collated in 1986, in which the first examples of preventative occupational therapy intervention evaluations were described (Hollander Kaplan & Burch-Minakan, 1986; Mann, Edwards, & Baum, 1986; Maynard, 1986; Rider & White, 1986; White, 1986). The increasing emphasis on health promotion with populations and communities challenged traditional occupational therapy practice, which typically intervened at the individual level (Mallinson, Fischer, Rogers, Ehrlich-Jones, & Chang, 2009). However, fundamental research to evidence the use of occupations and the nature of occupational participation and its relationship to health and wellbeing is still needed (Dunford & Bannigan, 2011).

1.2.3 Occupational therapy and health promotion

Occupational therapy with a health promotion focus was defined by the American Occupational Therapy Association (AOTA) as "the application of occupational science to prevent disease or disability and promote the health and wellbeing of persons and communities through meaningful engagement in occupation" (AOTA Commission on Practice, 2001, p. 657). In response to this emerging area of practice, occupational therapy associations internationally have produced position statements about the role and scope of occupational therapists practicing with a primary focus on health promotion (American Occupational Therapy Association, 2013; College of Occupational Therapists, 2008).

Occupational therapy's unique contribution to health promotion includes: reducing risk factors and symptoms through engagement in occupation; promoting development and

maintenance of mental functioning abilities through engagement in productive and meaningful activities and relationships; providing training in adaptation to change and coping with adversity to promote mental health; and developing health literacy to promote informed occupational choices (not an exhaustive list) (AOTA Commission on Practice, 2001, 2008; Canadian Association of Occupational Therapists, 2009, 2013a, 2013b; Godfrey, 2000). The complementary and overlapping characteristics of occupational therapy and health promotion are described by Tucker, Vanderloo, Irwin, Mandich, and Bossers (2014) who advocated greater incorporation of health promotion in occupational therapy practice generally. However, evidence to support practice in this area, particularly with children, is needed (Dunford & Bannigan, 2011; Frenchman, 2014). There is evidence that children with disordered mood symptoms participated in a more limited range of occupations than those who had recovered (Merrick, 1992). Such an imbalance of occupational participation was shown to put wellbeing at risk and was correlated with the onset of mental ill-health (Krupa, McLean, Eastabrook, Bonham, & Baksh, 2003; Merrick, 1992). The AOTA makes explicit links between occupational imbalance, occupational deprivation and occupational alienation, and an increase in risk factors for health problems leading to broader health and social problems (AOTA Commission on Practice, 2001; Law, Steinwender, & LeClair, 1998). These concepts are relevant for the health of individuals and groups across the lifespan - including childhood - and across environments, such as at home, school or work and in the community.

Facilitating and enabling participation in a range of occupations is fundamental to health promotion from a school-based occupational therapy perspective: a perspective that needs to promote inclusion, participation and wellbeing for all (New Zealand Association of Occupational Therapists, 2009). Taking an ecological approach that embeds therapeutic strategies into the classroom and school environment has gained traction in recent decades (Bazyk et al., 2015; Bazyk et al., 2009; Bronfenbrenner, 2005; Case-Smith, Weaver, & Holland, 2014; Engelen et al., 2013). The combination of the findings and theory cited above supports the premise that occupational therapists can use knowledge and performance of developmentally appropriate occupations to promote children’s mental health and wellbeing (Canadian Association of Occupational Therapists, 2013a; Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Cramm, Aiken, & Stewart, 2012; Zahn-Waxler, Klimes-Dougan, & Slattery, 2000). Essential to this approach are promoting, maintaining and restoring health through participation in daily

occupations in the environment in which they would normally be performed, ensuring access to occupations that fulfil health needs, leading community development of health promotion initiatives and evaluating outcomes (World Federation of Occupational Therapists, 2016). The current study was consistent with these aims and evaluated a school-based, occupational therapy intervention designed to promote and maintain mental health and wellbeing in children.

1.2.4 The need for further research

Published occupational therapy research has mostly been in the context of secondary healthcare services and focused on treating health conditions, with limited attention paid to the primary health context with healthy populations. The evidence-base underpinning occupational therapy interventions focused on children's occupational participation, health and wellbeing, is sparse and there have been calls from within the profession for this to be addressed (Dunford & Bannigan, 2011). An early example of a primary health, occupational therapy intervention reported in the literature, served school-aged children (6-14 years) and addressed the occupational needs of child survivors of war, aiming to prevent future mental health issues (Simo-Algado, Mehta, Kronenberg, Cockburn, & Kirsh, 2002). This reflective account found the use of meaningful occupations enabled children to connect with their feelings and values, and find meaning in their daily lives.

A later phenomenological study identified that low-income urban youth found participation in leisure occupations, during afterschool care, meaningful and transformative (Bazyk & Bazyk, 2009). This outcome was attributed to being given opportunities to participate in novel and challenging occupations. Participants felt these occupations enabled positive transformations in mood and they valued the opportunity to talk about their feelings and strategies for managing anger in a safe environment. The Sydney Playground Project also upheld an occupational perspective on play. It investigated the impact of environmental (physical and social) modifications on children's physical activity levels, with social skills and self-concept as secondary outcomes (Bundy et al., 2011). The occupationally-driven environmental intervention was found to result in significantly increased levels of moderate physical activity, (Engelen et al., 2013). The results on the secondary outcomes of the Sydney Playground Project have not been reported to date. These studies signpost the potential value and meaning attributed to providing occupational therapy at a primary health level. At the

time of designing the current study, the need for further research validating the effectiveness of occupational therapy interventions utilising a primary health approach, particularly with children, was pressing (AOTA Commission on Practice, 2001; Nicholson, 2011; Wilcock & Hocking, 2015).

1.2.5 Research design to investigate population health

Evaluation of interventions with community populations, at the primary health level, necessitates experimental research designs that are sensitive to change within populations and yet sufficiently robust to accommodate the influences of population members on each other (Eldridge & Kerry, 2012). Primary health research is vulnerable to these and other sources of bias, but it is possible to moderate potential biases through using cluster-RCT designs for the investigation of primary health interventions (Diaz-Ordaz, Froud, Sheehan, & Eldridge, 2013; Eldridge & Kerry, 2012; Isaakidis & Ioannidis, 2003). Therefore, this study utilised a cluster-RCT design that accounted for the clustering of children by school.

1.3 Aotearoa New Zealand context

1.3.1 Bicultural nation

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). Opportunities for occupational therapists to have a role in addressing primary health needs in Aotearoa New Zealand have been clearly documented (Frenchman, 2014; Mace, 2008; Nicholson, 2011). Aotearoa New Zealand is a unique bicultural nation, in which demonstrating the cultural sensitivity of interventions is paramount (New Zealand Association of Occupational Therapists, 2009; Putaiora Writing Group, 2012). The interplay between culture, socioeconomic status and wellbeing needed to be addressed due to significant health disparities that disadvantage Māori in Aotearoa New Zealand (Durie, 1999; Harris et al., 2006). In particular, there is an over representation of Māori in populations of low socio-economic status and high mental health needs (Durie, 1999; Harris et al., 2006). For instance, in a prevalence study drawing data from the 2002/3 New Zealand Health

Survey, odds ratios (95% CI) of the risks of Māori compared to European ethnic groups developing a mental health condition were 1.30 (1.11-1.54), reducing to 1.02 (0.85-1.22) when discrimination and deprivation were adjusted for (Harris et al., 2006). The use of health promotion and community approaches to address health and wellbeing is consistent with Māori health concepts of *taha wairua* (spiritual health), *taha hinengaro* (emotional/mental health), *taha tinana* (physical health) and *taha whānau* (family health) (Durie, 1997).

1.3.2 Aotearoa New Zealand educational system

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. Health Promoting Schools (HPS) was a national innovation that was realised in Aotearoa New Zealand from the late 1990s onwards, modelled on early processes that had been established in Australian schools in the late 1980s (Bassett, Grant, Gwyn, Moffat, & St-Leger, 2001). It was a government funded initiative that involved the collaboration of several service providers including Public Health Nurses (PHNs), schools, healthcare services and the Mental Health Foundation. HPS was a programme designed to integrate concepts of health promotion directly into the educational curriculum, environment and community, and took a 'whole school approach' (Bassett et al., 2001). Specifically, HPS would target common risk factors that undermine resiliency; however, it was not designed to be an independent initiative that would continue indefinitely (Edwards, Ward, & Heald, 2003). Rather, HPS was conceived as an approach that, once assimilated into the school way-of-life, would become a self-sustaining approach to health promotion situated within school populations. HPS targeted mainstream schools and, given about 85% of Māori children receive their education through mainstream schools, this was considered an effective method for supporting the health needs of Aotearoa New Zealand's most disadvantaged populations (Bassett et al., 2001).

The responsibility for organising student wellbeing supports was typically situated with each school's Special Education Needs Coordinators (SENCO), who were responsible for assessing and identifying individual and school needs, allocating resources, developing support programmes and liaising with key staff and agencies to ensure the learning and pastoral needs of the student population were addressed (Education

Review Office, n.d.). Three mental health interventions already available in Aotearoa New Zealand schools, at the time this study was being developed, were the Travellers™, Seasons™ and Mental Health Matters programmes.

1.3.3 Mental health promotion programmes in Aotearoa New Zealand schools

Travellers™ is a school-based intervention designed to build adolescents' resilience in the context of major developmental and life changes. The intervention is run by trained facilitators, from within the school environment, who guide students through fun activities using the metaphor of life as a journey (Dickinson, Coggan, & Bennett, 2003; Skylight., n.d.). Participating schools enrol with the intervention provider and all Year 9 students from that school – aged 13-14 years – are screened. Targeted groups of 8-10 students are invited to participate in a series of 8-10 sessions over a school term, during class time. Sessions reflect on major events and daily hassles, primarily using a cognitive behavioural approach. Short- to medium-term outcomes for participants were evaluated using surveys from 212 students who participated in 2008/2009. Participants reported learning useful strategies that increased resilience when navigating challenging problems, improved relationships and increased help-seeking behaviour; participants also reported reduced subjective distress and improved positive self-perceptions (Robertson, Boyd, Dingle, & Taupo, 2012). The most recent evaluation focused on the intervention content. The study involved an online survey of 32 students, aged 14 years, who had participated in the programme between April and July in 2013 (Term 2 in Aotearoa New Zealand); two focus groups with an additional 14 students, the same age and who participated over the same time-period; and 12 interviews with facilitators who were experienced in facilitating the Travellers™ programme. Overall, participants rated the session content favourably and recommendations to modify the intervention were made by both participants and facilitators (Jasperse, Stevens, van der Meer, & Faculty of Education, 2014). Since its inception the Travellers™ programme has been regularly evaluated (Dickinson, 2004; McCluskey, 2010; Robertson et al., 2012) and has been reported as consistently providing transformative experiences that appeal to a diverse range of students facing major change in their life (Jasperse et al., 2014). Longitudinal research into participant outcomes has been identified as an area of evaluation warranting further attention.

Seasons™ is a peer support programme to help children and young people cope with grief and feelings of loss resulting from separation, divorce or death. The cycle of the

seasons provides a familiar framework within which the children can explore their experiences of grief, using a cognitive behavioural approach. The programme takes an interdisciplinary approach to child development and weaves it with Worden's grief theory (Worden, 2009). The programme was originally developed in 1996 by Anne Graham in collaboration with education, health and welfare professionals through a Catholic service in Melbourne, Australia (Anglican Care, n.d.; Catholic Care, n.d.; Seasons for Growth, n.d.). Newell and Moss (2011) reported over 150,000 children and young people across five countries have participated in the programme with strong, positive effects found for those taking part. In the largest-scale evaluation of the Seasons™ programme to date, 334 children and 40 parents completed online pre-/post-surveys that found high levels of participant and parent satisfaction, emphasised by the low dropout rate (5%). Furthermore, the programme was reported to build understanding and skills, improve emotional wellbeing, and link participants with a supportive network in a diverse student population (Newell & Moss). Recommendations were made to implement the programme more widely, to evaluate longer-term outcomes, review the content and consider the inclusion of a parent component. A repeated measures, mixed methods study was conducted by Riley (2012) with 12 students and found the Seasons™ programme improved self-concept and emotional resourcefulness, and reduced symptoms of anxiety, depression and emotional vulnerability from pre-intervention to post-intervention, with changes continuing at 2-months follow-up. All students reported satisfaction with the programme and some level of having generalised the skills. Minor modifications to the format were recommended (i.e. fewer students per group, longer sessions and no music playing). Overall, the Seasons™ programme was reported to be well-received by students and their parents, and to impact positively on the emotional health and wellbeing of students who had experienced loss.

Mental Health Matters is an intervention resource for teaching staff that provides education and advice related to mental health issues for junior secondary school students (13-14 years) (Mental Health Foundation New Zealand, 2009). A formative evaluation resulted in a teacher development day and published resources (Mental Health Foundation New Zealand, 2001, 2009). Tentative findings from a trial of the programme in three Aotearoa New Zealand schools found it was positively received by teaching staff and students, and recommendations were made for modifications to the programme content – such as reducing the content for each 40-50-minute session and

making pamphlets less sophisticated (Coggan, Disley, & Patterson, 1997). Further evaluation was indicated – however, this was not found in the available literature.

Implementation of these three programmes in schools is dependent on the funding and resources available at each school. Access to Travellers™ and Seasons™ is negotiated between schools and the charitable organisations that facilitate and evaluate the intervention. Mental Health Matters was intended as a sustainable intervention facilitated by teaching staff and embedded into their everyday classroom activities: it was unclear from the evidence found how effectively this was implemented in Aotearoa New Zealand. The studies that reported on these programmes were variable in quality and none appeared to account for clustering of the sample population in the data analysis and interpretation. All three programmes targeted the 14 years+ age-range and, given increasing evidence for the need for early intervention to prevent adverse mental health and academic outcomes longer term, there was an identified need for an intervention targeting a younger age group (Essau & Gabbidon, 2013; Guzman et al., 2011; Lavin, Shapiro, & Weill, 1992; Stallard & Buck, 2013). The development of an occupational therapy mental health promotion intervention in Aotearoa New Zealand must take into account the unique cultural, social and political influences of this context. Acquiring Aotearoa New Zealand and occupational therapy-specific knowledge of interventions for this population is important, both with respect to the individual outcomes for the children, and primary health services in the educational setting. An occupational therapy perspective could build on the evidence already available and provide a missing element to the supports currently in place for promoting the mental health and wellbeing of children.

1.4 Outline of the thesis

This thesis is presented in seven chapters. Chapter one has provided an introduction to the rationale for the study and situates it within the Aotearoa New Zealand primary health and educational contexts. Chapter two provides a more in-depth analysis of the clinical need for an occupational therapy intervention targeting mental health promotion in children; with a fuller justification of the need for the intervention and the trial. Chapter three considers how the intervention was developed and provides a detailed account of the intervention under evaluation.

In the fourth chapter, the methodological framework of the study is outlined, along with the rationale for utilising a cluster-RCT. The quality of comparable cluster-RCT studies are also reviewed. In Chapter five, the methods and study procedure are clearly justified and the rationale for decisions related to design, sample size, outcome measures and analysis are presented. Descriptive and statistical findings are presented in Chapter six, followed by a detailed discussion of the implications of the findings from occupational, primary health, child development and Aotearoa New Zealand educational perspectives in Chapter seven. Recommendations for future research and implementation of the intervention are made.

Chapter 2: Literature review

Children's mental health is of international relevance and concern, and the need for early intervention is fundamental to achieving better outcomes for children and communities in the future. The potential for occupational therapy to positively impact on these outcomes for children, through mental health promotion and prevention, is largely unexplored. This chapter will discuss the progression of normal mental health issues in children, highlight concerns about the prevalence of children's mental health issues, and describe the impact that mental health symptoms can have on participation and occupational performance, and the need for early intervention. A literature review was conducted to determine how the mental health needs of children have previously been addressed followed by a scoping review of the role of occupational therapy in promoting participation, mental health and wellbeing for children. When woven together, these two threads from the literature will demonstrate a need to investigate preventative occupational therapy interventions for children that promote mental health and wellbeing.

2.1 Progression of normal anxiety and low mood

Some level of fears and anxiety are considered normal and are at their highest during the first 11-14 years of a child's life (Field & Davey, 2001). Typically, the developmental progression of these is from behavioural and physical fears, for example, fear of punishment and physical harm, to more psychological and abstract fears, such as shame and humiliation (Silverman & Treffers, 2001). Such anxiety can progress to a clinical level under a variety of circumstances, such as repeated exposure to unrealistic expectations or when a child with age-appropriate fears is in an overprotective environment (Rapee, 1997). Children typically engage in 'risky play' and experience a shifting between positive and negative emotions that push their limits and support healthy development of emotional skills (Sandseter, 2009). Adults around the children (e.g. parents, teachers) can be drawn into a risk-protective mode and constrain children's behaviour in order to keep them safe (Niehues et al., 2013). It is thought an overprotective environment sends the child the message that the world is threatening and they cannot cope (Niehues et al., 2013). In such an environment, the child is also less likely to be given or seek opportunities to test this theory and learn otherwise, thus perpetuating and reinforcing the fears (Rapee, 1997). Subsequently, theory and evidence

support the promotion of children engaging in safe risk-taking and experiencing mastery in unfamiliar environments and activities (Niehues, Bundy, Broom, & Tranter, 2015, 2016; Niehues et al., 2013).

As with anxiety, normal fluctuations in mood are to be expected; typically, these variations are responses to life events and so it is normal to experience periods of depressive symptoms. Low mood can progress to a clinical level for a number of reasons, including disrupted sleep patterns, chemical imbalances in the brain, and repeated exposure to traumatic or stressful situations e.g. abuse or bullying. It has been reported, about a third of children with clinical depression experienced adverse life events or problems with friendships prior to the onset of their illness (Cole, Nolen-Hoeksema, Girgus, & Paul, 2006; Goodyear, 1994). Variations in mood triggered by life events have been shown to present similarly to clinical depression, but do not have the same degree of impairment as a full depressive or mood disorder (Wakefield, Schmitz, First, & Horowitz, 2007).

2.2 Prevalence of mental health issues in children

A robust meta-analysis of 41 prevalence studies from 27 countries, from every world region, identified a world-wide prevalence of diagnosed mental health conditions in childhood and adolescence of nearly 18% (Polanczyk, Salum, Sugaya, Caye, & Rohde, 2015). When the population of children affected by mental health problems was narrowed by the inclusion of impairment in functioning as a criterion for diagnosing mental health conditions, a prevalence of 13.4% was found (Rijlaarsdam et al., 2015). This prevalence rate was consistent with earlier studies also reporting rates between 12-15% (Polanczyk et al., 2015; Roberts, Attkisson, & Rosenblatt, 1998; Stenmark, Bergström, Hägglöf, Öhman, & Petersen, 2015; Verhulst & Koot, 1995). While this prevalence rate is lower than the 18% proposed by Polanczyk et al. (2015), it still equates to approximately 241 million youths affected by various mental health conditions, and their associated negative consequences, around the world at any one time. Over and above this population, there is evidence that there are more children who are clinically impaired by a mental health condition than the 18% previously reported; however, these children may go undiagnosed and untreated. It is suggested that in order to meet the needs of this population, health services should be prepared to support up to 30% of all children (Polanczyk et al., 2015; Puolakka, Kiikkala, Haapasalo-Pesu, & Paavilainen, 2011; Rijlaarsdam et al., 2015).

The highest prevalence identified in any specific group of mental health disorders world-wide was anxiety disorders at 6.5%, followed by depression at 2.6% (Polanczyk et al., 2015). The heterogeneity of the samples that formed the pooled estimates was acknowledged and in other reviews the prevalence of anxiety in middle childhood, approximately ages 10-14 years, was reportedly up to 10.5% (Costello et al., 2003; Zahn-Waxler et al., 2000). Middle childhood is defined differently across the literature (ranging from 6-14years) (Costello et al., 2003; Silverman & Treffers, 2001; Zahn-Waxler et al., 2000) and for the purposes of this study is defined as 10-14 years, which is consistent with the age range of students attending intermediate schools in Aotearoa New Zealand. In a longitudinal community study of 6,674 children aged 9-16 years, the three month prevalence of any disorder resulting in severe emotional disturbance was found to be 6.8% (Costello et al., 2003). Putting these rates into context, when compared to the prevalence of other childhood chronic health conditions, such as obesity (16.8%) (Ogden, Carroll, Curtin, Lamb, & Flegal, 2010) and asthma (8.5%) (Moorman et al., 2007), there is a clear need to prioritise children's mental health and wellbeing in order to reduce the burden on health care services internationally (Friedberg, Crosby, & Friedberg, 2000; Polanczyk et al., 2015).

There is evidence available that illustrates the benefit of earlier intervention in the progression of mental health conditions, as well as earlier in children's lives, in order to reduce the lifetime impact. For example, in a sample of 128 children aged 7-14 years and identified as at risk of anxiety, over half went on to develop a clinical anxiety disorder, compared to around a quarter of those who received treatment (Dadds, Spence, Holland, Barrett, & Laurens, 1997). In another study, mental health screening was conducted with 17,252 children as they entered school in the United States and 11,185 of the same children were followed up four years later. Screening was shown to predict later mental health and educational outcomes, even when student and family risk factors were controlled for (e.g. age of mother, presence of a father, child having a chronic illness etc.) (Guzman et al., 2011). More specifically, a significant relationship between anxiety and depression has been identified (Costello et al., 2003; Silverman & Treffers, 2001), with anxiety disorders in childhood and adolescence shown to precede and predict later mood disorders (Kohlboeck, Quadflieg, & Fichter, 2011; Merrick, 1992; Zahn-Waxler et al., 2000). The relationship between self-esteem and mood conditions has also been documented (Blomfield & Barber, 2011; Fielstein et al., 1985; Wilson & Krane, 1980). Research tracking self-esteem across the lifespan has established it

becomes more stable in adolescence (defined as 12-17 years) and early adulthood (Trzesniewski, Donnellan, & Robins, 2003). This provides additional support to the argument that middle childhood is an optimal time in a child's development for interventions aimed at promoting self-esteem before it stabilises. It is argued that promoting mental health and wellbeing in childhood reduces the personal impact on those individuals in adulthood and the economic burden on the healthcare system longer term (Ministry of Health, 2012; New Zealand Government, 2016).

2.3 Mental health symptoms and participation

Anxiety, functioning and participation are closely related. Children with symptoms of anxiety may present with numerous worries that seem disproportionate or more pervasive than those expressed by their peers; they may be restless, easily fatigued, have difficulty concentrating or be reluctant to participate in the same activities as their peers (American Psychiatric Association, 1994). This reluctance may be fuelled by unhelpful internal cognitions that inhibit the child's participation in meaningful occupations, thereby negatively impacting their level of functioning and development.

Functioning, as defined by the WHO (2007), is the interaction of the body's physiological and anatomical structures and the execution of a task or action by an individual that impacts on his or her ability to participate in life situations. Several studies have been systematically reviewed and found to demonstrate the impact of anxiety on brain functioning in the amygdala (Rauch, Shin, & Wright, 2003) and ventromedial prefrontal cortex (Myers-Schulz & Koenigs, 2012), resulting in increased activity in the parts of the brain that are most responsive to perceived threats. Case-control studies, with children and adolescents, have demonstrated anxiety results in reduced cognitive functioning, in terms of abnormal attention modulation to threat-stimuli (McClure et al., 2007) and reduced emotion recognition (Easter et al., 2005) affecting communication and social interactions. Von Gontard, Moritz, Thome-Granz, and Equit (2015) and Geeraerts et al. (2005) demonstrated relationships between anxiety and physiology, with increased rates of functional gastrointestinal disorders, high rate of sleep-related difficulties (Caporino et al., 2015) and other related self-care complications present in children with anxiety. Furthermore, an 18-year longitudinal study of 224 participants, aged 3-15 years at the time of original data collection, found the presence of a mental health condition in childhood was shown to predict adult mental health issues and poorer psychosocial functioning later in life, as measured by

the Global Assessment of Functioning, when compared to those without a mental health condition in childhood (Kohlboeck et al., 2011). This was a robust study with a high participation rate (82%) after such a long follow-up period that adjusted for age at baseline. However, it was limited by participant self-reports as indicators of diagnoses and no data were collected regarding negative social circumstances that may have influenced participants' mental health.

As indicated in the definition of functioning, impairments in functioning are understood to impact on participation. Participation can be defined as "involvement in a life situation" such as school or play (WHO, 2007, p. 9). Studies have explored the role participation in specific occupations has on mental health. In a large, population-based study of adolescent and adult twins and their families (n=19,288) in the Netherlands, linear regression analysis revealed increased levels of participation, particularly in physical activities, were associated with decreased levels of anxiety (F [2,1]=71.0, p<.0001) and depression (F[2,1]=32.5, p<.0001) (De Moor, Been, Stubbe, Boomsma, & De Geus, 2006). A survey of 1,504 adolescents aged 12-16 years found increased levels of participation in extra-curricular sports and activities were associated with improved mental wellbeing and sense of self-worth, particularly for those from disadvantaged backgrounds (Blomfield & Barber, 2011). Smaller-scale studies have identified the positive benefits of skills-based occupations, such as learning an instrument, on children's self-esteem and wellbeing (Goltz & Brown, 2014; Merrick, 1992). In a study of 65 children (aged 6-14 years), increased participation in sporting occupations was indicated as a potential buffer for reduced levels of anxiety symptoms in children with anxiety and attention deficit/hyperactivity disorder (Kiluk, Weden, & Culotta, 2009; Schumacher Dimech & Seiler, 2011). This evidence supports the argument that increased participation in meaningful occupations may act as a health-promoting mechanism for improving mental health and wellbeing.

Goltz and Brown (2014) hypothesised that less anxious children had more motivation to persist in the absence of positive feedback and had increased tolerance of constructive feedback that developed their performance, hinting at a need for children with anxiety symptoms to have increased opportunities to participate in occupations where they receive frequent positive feedback and develop their persistence, tolerance and self-esteem. However, children with anxiety have also been found to have decreased quality of participation in social relationships, potentially limiting their opportunities for

positive feedback further (Baker & Hudson, 2015). Participation in occupations that promote opportunities for positive feedback may be perceived as a positive coping strategy. Participation in positive coping behaviours was found to mediate symptoms of anxiety (r=-0.32, p<.001) and depression (r=-0.53, p<.001) in a large-scale study across eight cities in China (n=13,512), that also demonstrated a relationship between an adolescent's experience of general stress and school stress (r=0.88, p<.001) (Meng, Tao, Wan, Hu, & Wang, 2011). This is important because there is preliminary evidence that an imbalance in participation in occupations could create an increased risk of decreased wellbeing and increased risk of onset of mental ill-health (Krupa et al., 2003). A notable limitation of these studies was the correlational design and that findings could not predict cause or effect relationships. However, they do constitute support for the theory that participation in meaningful occupations can have significant positive mental health benefits.

2.4 Mental health and early intervention

The section above has shown evidence of high prevalence rates for anxiety and other mental health conditions in children and adolescents. Mental health and wellbeing, and a positive state of functioning is described as being composed of subjective experiences of happiness and wellbeing; positive psychological and social functioning; and being able to cope with adversity and life stressors (Burson, Barrows, Clark, Gupta, & Geraci, 2010). Despite the compelling argument to promote mental health in children and prevent conditions developing, many children remain untreated due to stigma associated with mental health interventions, lack of knowledge about mental health disorders and treatment options, and a reluctance to seek support (Yearwood & DeLeon Siantz, 2010). The drive to seek support may not be present until a condition has escalated to the point it is significantly preventing the child from participating in everyday activities, such as schoolwork, play or family occupations. Interventions available at this level in Aotearoa New Zealand are generally provided in clinic settings that require referral from senior school staff or primary healthcare clinicians and are only available to 3% of the population considered most severely affected by symptoms (Mental Health Commission, 2012; Tokolahi, Em-Chhour, Barkwill, & Stanley, 2013). Subsequently, entry criteria for accessing secondary mental health services are restrictive. Thus, there is a need for interventions at the universal or indicated level, to increase the likelihood of positively impacting on the mental health and wellbeing of children, with anxiety and

low mood, who might otherwise not have access to such services (Ahlen, Lenhard, & Ghaderi, 2015; S. Hall, 2010).

The levels, or tiers, of mental health prevention and promotion are described by Arbesman, Bazyk, and Nochajski (2013) and Bazyk (2011) as:

- Tier 1: Universal or whole-school approach; interventions provided to all children in a class or at a school regardless of health status; aimed at competence enhancement.
- Tier 2: Targeted or indicated interventions; preventative interventions aimed at those with greater needs at baseline, where early or mild symptoms of a disorder are already present; designed to support smaller groups of children from a school who are at risk of developing mental health challenges with an increasing focus on enhancing protective factors.
- Tier 3: Intensive interventions that are individually-focused; aimed at diminishing the effects of identified mental, emotional or behavioural disorders in specific children.

Interventions in the school context, particularly those targeting Tiers 1 and 2, are largely facilitated in group contexts (Stallard, 2009).

The WHO (2013) recommends taking a life-course approach to mental health care, emphasising the role of promoting children's mental health in preventing more significant conditions and the associated mental health burden in adulthood. It was suggested that almost three-quarters of adult mental health conditions have their onset or origin in childhood and, given this, it is unsurprising that mental health promotion and prevention with children is perceived as a global public health concern (Wissow, van Ginneken, Chandna, & Rahman, 2016). Middle childhood (defined in this study as 10-14 years) is a period of substantial physical, emotional and social changes (Centres for Disease Control and Prevention, 2014, 2016). Cognitive changes mean children have the ability for more complex thought, are more able to verbalise their experiences and emotions, and are developing their own sense of right and wrong. Cumulatively, the evidence provided in this section supports middle childhood as a key time for targeting preventative interventions (Dadds et al., 1997; Horowitz, Garber, Ciesla, Young, & Mufson, 2007). However, school-based, preventative interventions currently available in Aotearoa New Zealand (i.e. Travellers™, Seasons™ and Mental Health Matters,

discussed in the previous chapter) are targeted at adolescents aged 14 years or over and preventative interventions targeting younger children are needed.

2.5 Mental health promotion in schools

Schools offer a convenient and feasible location for the widespread delivery of preventative and targeted interventions to children (Essau & Gabbidon, 2013; Lavin et al., 1992; Stallard & Buck, 2013). Furthermore, children are used to being part of a class; therefore, group interactions can provide a safe, familiar environment that normalises common mental health and wellbeing attitudes and experiences (Aseltine & DeMartino, 2004; Possel, Baldus, Horn, Groen, & Hautzinger, 2005). A literature review of quantitative research that explored a range of mental health promotion interventions available for children (aged 7-19 years) in the school environment was conducted to determine what was currently available and supported by evidence. Three Aotearoa New Zealand-based programmes (described earlier, in section 1.3.3) – Travellers™, Seasons™ and Mental Health Matters – were reviewed alongside studies evaluating international programmes. The search strategy is presented in Table 1 (p. 21).

Table 1: Search strategy for school-based, mental health promotion interventions in middle childhood

Databases searched			
Cumulative Index of Nursing and Allied Health Literature (CINAHL) Plus (via EBSCO) Allied and Complementary Medicine Database (AMED) (via OVID) PubMed SCOPUS.			
Search terms			
Population	**Intervention**	**Comparison**	**Outcome**
Child* Elementary	School "Mental health" Prevent* OR promot*	Not specified	Anxiety Depression Self-esteem Participation Wellbeing Life satisfaction
Inclusion criteria		**Exclusion criteria**	
English language Full-text available Peer reviewed journal Intervention: Focused on internalising problems (e.g. mood, anxiety). School-based intervention. Focused on mental health prevention or promotion for non-clinical populations.		Intervention: Focused on externalising problems (e.g. drug/alcohol use, safe sex).	

2.5.1 Current intervention delivery in schools

Ten articles reporting on nine studies were found and reviewed; these are presented in Table 2. The majority of interventions (6/10) reported on evaluations that demonstrated varying degrees of effectiveness of Cognitive Behaviour Therapy (CBT) on internal cognitions. 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).

Table 2: Studies reviewed evaluating school-based, mental health promotion interventions with children

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
Aseltine and DeMartino (2004)	United States	2100 students aged 14-15 years	All consenting students at the five schools	Signs of Suicide (SOS) suicide prevention group psycho-educational programme 2 days integrate into class health curriculum *Control:* Curriculum as usual	Reduction in suicide attempts and no corresponding reduction in suicide ideation No significant change in self-reported help-seeking Increased adaptive attitudes about depression and suicide on the CDS	Experimental design with individual randomisation Post-intervention outcomes collected only – no data obtained to ensure groups were comparable at baseline and no follow-up to evaluate sustainability Same facilitator for active interventions and control, which may have introduced contamination Primary endpoint clearly reported
Bernstein, Layne, Egan, and Tennison (2005)	United States	61 children aged 7-11 years	Screening and nomination by school staff	Friends group programme (CBT) and Friends group programme plus parenting component – provided after school 60 minutes, weekly for 9 weeks, after school *Control:* No treatment	Reduction in proportion of children meeting criteria for anxiety on the ADIS Improvements in clinician ratings on the CGI Parent reported anxiety improved more with the inclusion of parent intervention on the MASC Improved child-rated anxiety on the MASC – greater for the CBT only intervention than the one that included a parent intervention	Experimental design with cluster randomisation Compared two active interventions with a no treatment control Randomised by cluster (school) to prevent contamination, however, clustering not adjusted for in the analysis Obtained outcome measures from multiple respondents Primary hypothesis clearly reported 3-month follow-up data collected and reported elsewhere

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
Bonhauser et al. (2005)	Chile	198 children aged 15 years	All consenting students in the classes selected at random from one school	Group physical exercise sessions following three steps: minimum activity with no weight transfer; weight transfer activities with dynamic large muscle movements; and sports practice 90 minutes, three times per week, over an academic year, integrated into class physical health curriculum *Control:* Standard exercise class	Significantly increased oxygen capacity Speed and jump performance scores improved significantly Decreased self-reported anxiety and increased self-esteem at post-intervention No change in self-reported depression found	Quasi-experimental design with cluster randomisation Randomisation was by cluster; however, this was not accounted for in the analysis due to low numbers of clusters (i.e. 4) Used ITT principles Same facilitator for active interventions and control, which may have introduced contamination
Chiu et al. (2013)	United States	40 children aged 5-12 years	Screening and nomination by school staff	Building confidence individual programme (modular CBT); child, parent, teacher and school nurse modules available 60 minutes weekly, conducted 10-16 times as indicated by symptoms level *Control:* Waitlist	Significant improvements in clinician ratings on the CGI and reduction in clinical level of symptoms on ADIS Significant reduction in parent-rated anxiety, with marginally significant reduction in child-rated anxiety on the MASC No significant differences in internalising scores on CBCL	Experimental design with individual randomisation Modular intervention enabled tailoring of the dose and intervention for participants as indicated No functional outcome measure included No follow-up data collected to evaluate sustainability

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
Dadds et al. (1997)	Australia	128 children aged 7-14 years	Screening and nomination by school staff	The Coping Koala: Prevention Manual for group CBT including parenting component 60 minutes weekly, for 10 weeks *Control:* No treatment	Low convergence between child- and teacher-reported anxiety at baseline No significant differences found at post-intervention Significantly reduced rates of anxiety disorder developed in the treatment group on the ADIS (parent version) at the 6 month follow-up No significant changes in self- or parent reported symptoms on the RCMAS or CBCL	Experimental design with individual randomisation Thorough screening process that established similar rates of anxiety across recruitment methods 6-month follow-up to evaluate sustainability

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
Eggert et al. (2002); Thompson et al. (2001)	United States	341 children aged 14-19 years	Unclear	Counsellors-CARE (C-CARE) – individual crisis intervention Coping and Support Training (CAST) – C-CARE plus group programme aimed at developing social connections C-CARE – one-off, 2 hour assessment/crisis session CAST – C-CARE plus 60 minute group sessions, twice weekly, for 6 weeks *Control:* Usual care- 30 minute support session	Suicide risk and threats reduced in the short-term for all groups, including usual care Mood symptoms (depression, hopelessness, anxiety) reduced over time for all groups, significantly more so for the intervention groups at post-intervention and 9-month follow-up	Experimental design with cluster randomisation Randomised by cluster (school) to prevent contamination; however, clustering not adjusted for in the analysis

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
Horowitz et al. (2007)	United States	380 children aged 13-15 years	All consenting students in three schools	Coping with Stress programme (CBT) or Interpersonal psychotherapy – adolescent skills training (IPT-AST) 90 minute sessions, weekly over 8 weeks *Control:* Usual health curriculum	Small, significant effect for CBT and IPT-AST at post-intervention Larger, significant effects found in the sample sub-group with higher depression scores at baseline No significant difference between the outcomes for the two active interventions No significant differences found between all three groups at 6 months follow-up	Experimental design with individual randomisation Different facilitators for each intervention arm to limit contamination Depression identified as the primary outcome as measured by CDI and CES-D, reported individually (to allow for comparison with other studies) and in combination (as a more robust measure of the construct) Outcome mediators and moderators also investigated
Manassis et al. (2010)	Canada	1139 children aged 8-11 years	Screening of children from 26 schools	The Feelings Club (CBT) group programme, based on the Coping Cat programmes - provided after school 60 minutes, weekly, over 12 weeks, with three parent psycho-educational sessions across that period *Control:* Structured activity group of the same duration, with three parent evenings focused on general child-rearing advice	Improvements on MASC not significantly different between study arms at post-intervention Improvements maintained and tended to have increased at 1-year follow-up Decreasingly significant effects from child-, to parent-, to teacher-reports Exploratory predictors of change included a high degree of structure, positive reinforcement and individualised attention	Experimental design with cluster randomisation Randomised by cluster (groups within a given school) to prevent contamination; however, clustering not adjusted for in the analysis Lack of a no-intervention control Possible ceiling/floor effects due to the non-clinical sample Limited parental engagement observed, potentially attributed to subclinical nature of sample population

Reference	Location	Population	Recruitment	Interventions	Outcomes^	Study strengths and weakness
(Possel et al., 2005)	Germany	342 children aged 13-14 years	All consenting students at six schools	The Universal Primary Prevention: Training the Ease of Handling Social Aspects in Everyday Life – LISA (CBT/social networking training) 90 minutes, weekly, over 10 weeks *Control:* Usual curriculum	Significant positive difference in levels of depression on the CES-D for those with low self-efficacy at post-intervention, maintained at follow-up Network size was significantly larger at 3-months follow-up No significant difference in dysfunctional automatic thoughts Network size and frequency of use were not found to mediate symptoms of depression Self-efficacy indicated as moderating the effect of prevention programmes	Experimental design with cluster randomisation Randomised by cluster (class), which was accounted for in the analysis Mediation analysis included ITT principles not adhered to (drop-outs excluded from analysis) Interventions facilitated with same-sex groups only, unlike facilitation of the curriculum at these schools generally

Notes: ^= Findings describe comparison between treatment group and control group, unless otherwise stated. *Abbreviations:* ADIS=Anxiety Diagnostic Interview Schedule for DSM-IV: Child Version; CBCL=Child Behaviour Checklist; CBT=Cognitive Behaviour Therapy; CDI=Child Depression Index; CDS=Colombia Depression Scale; CES-D=Centre for Epidemiological Studies Depression scale; CGI=Clinical Global Impression; ITT=Intention to Treat; MASC=Multidimensional Anxiety Scale for Children; RCMAS=Revised Children's Manifest Anxiety Scale.

Screening and/or nomination by teaching staff were common methods for identifying participants (used in four studies), suggesting this was an acceptable method of identifying at risk children. Interventions were mostly conducted with students in groups and ranged in duration from 1 to 2 hours per week over a period of 6-12 weeks. Exceptions were studies that provided the intervention over the course of an academic year (Bonhauser et al., 2005) or were contained within a 2-day psycho-educational curriculum (Aseltine & DeMartino, 2004) or a one-off crisis intervention (Eggert et al., 2002; Thompson et al., 2001). Interventions typically targeted children once they had progressed to secondary school, aged 13 years or older. Outcomes of the intervention were generally compared to a control group, with some studies also including comparisons to an alternative intervention or an attention-control group (Bernstein et al., 2005; Eggert et al., 2002; Horowitz et al., 2007; Thompson et al., 2001).

2.5.2 Research designs evaluating interventions in schools

Over half of the studies (6/10) explicitly reported the use of cluster randomisation; although this was not always adjusted for in the analysis plan (Bernstein et al., 2005; Bonhauser et al., 2005; Eggert et al., 2002; Thompson et al., 2001). The remainder randomised participants individually, a design feature that does not account for the increased homogeneity in clustered samples, and increases the risk of making Type I errors (incorrectly rejecting the null hypothesis) (Eldridge & Kerry, 2012). All studies reviewed utilised repeated measures. Outcomes commonly measured were anxiety, depression, internalising behaviours and self-esteem. Participation or level of functioning were infrequently reported as an outcome measured in mental health prevention studies, an observation supported by Chiu et al. (2013).

2.5.3 Outcomes of interventions in schools

The studies reporting on CBT-based interventions in schools were found to significantly modify parent-rated child anxiety symptoms (p=<.001 to .027) (Bernstein et al., 2005; Chiu et al., 2013); children's self-rated anxiety symptoms (p=<.001 to .091) (Chiu et al., 2013; Dadds et al., 1997; Manassis et al., 2010); parent-rated child functioning (p=.02 to .06) (Bernstein et al., 2005); and child-rated depression symptoms (p=.000 to .01) (Horowitz et al., 2007; Manassis et al., 2010; Possel et al., 2005). Of note, two of the studies that included parent involvement in the intervention did not find significant parent- or teacher-rated improvements (Dadds et al., 1997; Manassis et al., 2010), and

another study found significant parent-rated improvements but no significant child-rated improvements (Bernstein et al., 2005) – suggesting CBT is not universally effective as perceived by children and their parents. Furthermore, CBT has been found insufficient in effecting significant change when level of global functioning or life-satisfaction and wellbeing were measured as outcomes (Vitiello et al., 2006).

General conclusions from all the studies indicated experimental interventions were more effective at reducing the rates of symptoms of concern than control interventions; in the latter, symptoms typically increased. A common discussion point was late childhood as a key time for targeting preventative interventions and acknowledgement that universal interventions are typically not universally effective, with greater benefits being measured in those with greater needs at baseline (Dadds et al., 1997; Horowitz et al., 2007). The selected literature found evidence in favour of the need for, and efficacy of, preventative interventions.

Interventions identified in the above review (Bernstein et al., 2005; Chiu et al., 2013; Manassis et al., 2010; Neil & Christensen, 2009; O'Leary-Barrett et al., 2013), and within Aotearoa New Zealand (Anglican Care, n.d.; Dickinson et al., 2003; Mental Health Foundation New Zealand, 2009) 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. From an occupational perspective, the lack of research that investigated or reported any change to levels of participation was of concern. 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, is limited (Vitiello et al., 2006).

2.6 Occupational therapy and health promotion

For children and their families, 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). While occupational therapy in health promotion is the subject of increasing interest, little has been reported about the outcomes of such interventions and no occupational therapy literature was identified using the search

strategy outlined in Table 1 (p. 21). In order to understand more about the focus, design and effectiveness of occupational therapy interventions promoting children's health and wellbeing, and to inform the design of the current study, a scoping review of published academic literature was performed. The question addressed was: *what is known about the outcomes of occupational therapy interventions that address children's health promotion in healthy populations?* This review was accomplished in four steps, as suggested by Arksey and O'Malley (2005): identifying relevant studies, study selection, charting the data and collating, summarising and reporting findings. The search strategy is described in Table 3 below.

Table 3: Search strategy for scoping review of: "What is known about the outcomes of occupational therapy interventions that addressed children's health promotion?"

Databases searched	**Search terms**	**Limits set**
SCOPUS EBSCO GoogleScholar	"public health" OR "primary health" OR "population health" AND OT OR "occupational therapy" AND child* OR adolesc*	Intervention focuses on primary prevention No date limits English only Full-text available

Given the focus of the review question on outcomes, articles were initially included that reported on the quantitative evaluation of occupational therapy interventions with a health promotion or illness prevention focus. Some multi-disciplinary interventions were included if an occupational therapy component was clearly identified and articulated within the article. Inclusion criteria were refined post hoc, based on increasing familiarity with the literature: a process supported by Arksey and O'Malley (2005). As the review progressed it became apparent there was limited quantitative literature to draw from and so the inclusion criteria were broadened to include articles that reported qualitative evaluations. Many of the articles that did not meet the inclusion criteria were conceptual pieces, discussion papers, reviews, editorials or position statements about the relationship between occupational therapy and health promotion, confirming the strength of interest in the topic.

Initially only three articles were found, but hand-searching of references and author searches on GoogleScholar elicited a total of five studies that addressed the review question (Table 4, p.31).

Table 4: Intervention characteristics of studies reporting outcomes of occupational therapy interventions that addressed children's health promotion

Authors	Intervention	Intervention aim	Sample	Location	Frequency	Duration	Facilitator	Measures
Bazyk and Bazyk (2009)	Occupational therapy groups for HOPE (Healthy Occupations, Positive Emotions)	Participation in a range of occupations and self-regulation skills	10	United States	1 hour weekly	9 weeks	Occupational therapy students	In-depth interviews; Observation
Bazyk et al. (2009)	Occupational therapy integrated into a kindergarten curriculum	Emergent literacy and fine motor skills (particularly handwriting)	37	United States	1-2 hours/ month	7 months	Occupational therapist	PDMS-2; VMI; 9-hole pegboard; Pencil grasp; 3 OSELA subtests
Engelen et al. (2013)	Environmental modification to increase physical activity	Physical activity and social skills	226	Australia	Play-breaks, and 2 hours one-off	13 weeks	IDT intervention delivered by an occupational therapist	MVPA
McGarrigle and Nelson (2006)	School skills programme	Performance skills to facilitate gross motor play, fine motor skills (particularly handwriting and scissor skills) and inclusion of cultural themes	16	Australia	80 minutes weekly	6 weeks	Occupational therapy students	VMI; ASQ; Writing Skills I and II; Scissor skills measure
Petersen and Nelson (2003)	Handwriting intervention	Handwriting	59	United States	30 minutes twice weekly	10 weeks	Occupational therapy students	MHT

Notes: ASQ = Conners' Abbreviated Symptom Questionnaire; IDT = InterDisciplinary Team; MHT = Minnesota Handwriting Test; MVPA = Moderate to Vigorous Physical Activity; OSELA = Observation Survey of Early Literacy Achievement; PDMS-2 = Peabody Developmental Motor Scales-2; VMI = Visual-Motor Integration.

As there was a range in study designs for the articles included in this review, the methodological quality of the quantitative studies was judged using a checklist developed for evaluating both randomised and non-randomised trials (Downs & Black, 1998) and the qualitative study was judged against the McMasters critical review guidelines (Letts et al., 2007) (see Appendix 1 and Appendix 2 for the details of these critiques).

2.6.1 Current occupational therapy interventions for promoting children's health

The aims of all the studies were clearly described. Three studies reported on occupational therapy interventions focused on developing school-readiness skills (Bazyk et al., 2009; McGarrigle & Nelson, 2006; Petersen & Nelson, 2003), one reported on modifying the environment to promote physical activity levels (Engelen et al., 2013), and another reported a qualitative evaluation of the perceptions of disadvantaged youth participating in HOPE (Healthy Occupations, Positive Emotions) groups, provided as an after-school programme (Bazyk & Bazyk, 2009).

Interventions typically targeted economically or culturally disadvantaged children at increased risk of health disparities and occupational injustices. Descriptions of interventions were typically minimal, insufficient to facilitate replication or genuine comparison with other occupational therapy interventions. While the children in these studies were without diagnosed neurological, developmental or medical diagnoses, it was noted that their performance was typically behind that of the national standards (Bazyk et al., 2009; McGarrigle & Nelson, 2006; Petersen & Nelson, 2003), thereby placing them at risk of developing physical or mental health conditions longer term.

2.6.2 Measures used to evaluate occupational therapy interventions

The primary outcome measures used in all the studies were valid and reliable, and often accompanied by non-standardised and less robust secondary measures. Given the focus on handwriting in the interventions it is unsurprising that various measures of handwriting performance or component skills featured prominently in the outcome measures reported. The test of Visual-Motor Integration (Beery & Buktenica, 1997) was used in two of the studies and other outcome variables were pencil grasp, writing skills (e.g. form, spacing, legibility), and scissor skills, which were measured differently across each study, making comparison challenging. Literacy was an outcome in only one of the studies, which is interesting given the general emphasis on addressing

handwriting in order to improve literacy and other academic outcomes. Engelen et al. (2013) measured levels of physical activity through the use of accelerometers and Bazyk and Bazyk (2009) explored participant experiences.

2.6.3 Outcomes of occupational therapy interventions promoting children's health

Bazyk and Bazyk (2009) conducted a well-designed, phenomenological evaluation that utilised intensity sampling and established data analysis strategies that were reported clearly. Two forms of triangulation were used to enhance credibility; however, the overall rigour of this study was limited by not reporting on how three of the components of trustworthiness – transferability, dependability and confirmability – were addressed. The study identified two essential elements of the intervention experience: the groups were fun and the participants learned to talk about their feelings and express anger more appropriately. Findings from this study may inform the future development of occupational therapy interventions for low-income, urban youth and provide additional insights into the mental health benefits of occupational participation.

The other occupational therapy interventions resulted in improvements in fine motor skills, emergent literacy skills, handwriting and increased physical activity levels. However, only two of the studies were sufficiently powered to detect clinically important effects (Engelen et al., 2013; Petersen & Nelson, 2003). The methodological quality of the study conducted by Engelen et al. (2013) was superior to the other quantitative studies identified, as their sample was taken from a representative population, the statistical analysis plan and implementation were robust, and sufficient information was provided to assume only low risks of bias were present. The remaining studies had several limitations in these areas. In three of the quantitative studies only pre-post data was collected so these studies were not able to report on the sustainability of any improvements demonstrated. Engelen et al. (2013) measured physical activity level outcomes 2 years after their environmental modification was implemented and the benefits at post-intervention had persisted.

Three of the studies were randomised; however, in one study the randomisation process could have introduced bias as allocation could be predicted (McGarrigle & Nelson, 2006). Bazyk et al. (2009) did not use a control group for ethical reasons so theirs was an outcome study only. Baseline descriptions of potential confounders between the participant groups were only described in the Engelen et al. (2013) study, although one

study did report collecting these data for *ex post facto* analyses of the relationships between these and the main outcome, handwriting (Petersen & Nelson, 2003). This makes it difficult to determine whether or not systematic differences existed between intervention and control participants from the various studies that may have impacted on the outcomes. Furthermore, blinding of participants and researchers was difficult to achieve in all of the studies due to active participant and researcher engagement in the intervention being required; this is a common limitation of studies evaluating complex interventions such as occupational therapy (Medical Research Council, 2008; Tokolahi, Hocking, Kersten, & Vandal, 2016). It was not possible to determine from any of the selected studies whether or not adverse outcomes had been recorded, and if any occurred. This would be important information for future clinical utilisation and research of interventions to ensure safe and effective implementation in practice.

These studies signify the potential value and meaning attributed to providing occupational therapy from a health promotion perspective. However, they also highlight the need for more high quality, empirical evidence on the use of occupational therapy to promote children's mental health and participation. Research with this focus has been identified as a priority for the profession nationally and internationally (AOTA Commission on Practice, 2001; Dunford & Bannigan, 2011; Nicholson, 2011).

2.7 Chapter summary

While prevalence rates vary according to whether or not impairment in functioning is considered, it has been suggested 30% of all children are in need of additional support to address mental health needs, of which only a few will be eligible for specialist services. Anxiety symptoms are the most prominent mental wellbeing concern and are associated with depression and later mental health concerns, as well as concurrent limitations in functioning and participation. The need for early intervention programmes to increase protective factors and minimise mental health concerns is vital in order to lessen the financial and emotional impacts on the population as a whole. While CBT has been found to be somewhat effective at reducing internal cognitions associated with mental health conditions in children, there is limited evidence to suggest it is effective in increasing their functioning and participation. Fundamental to an occupational perspective of health is the premise that humans are occupational beings. It stands to reason, therefore, that with an explicit focus on participation, occupational therapy has a unique contribution towards mental health promotion in children. Occupational therapy

has been shown to have a measurable benefit for children with regards to health promotion. However, the mental health focus of intervention studies so far has been limited and more research is required. The following chapter will describe the development of such an intervention that was evaluated in this study – Kia Piki te Hauora: Uplifting our Health and Wellbeing©.

Chapter 3: Intervention development

This chapter outlines the development of the intervention evaluated in the current study, following a structured process and bringing together the different theories and evidence informing its development. A trial of the intervention format and acceptability is described along with the proposed dynamic changes that occur in response to the intervention. Research into the effectiveness of occupational therapy interventions is a top priority for the profession (College of Occupational Therapists, 2007; The American Occupational Therapy Foundation, 2013). The previous chapter illustrated the need for Aotearoa New Zealand, and occupational therapy-specific, knowledge of school-based mental health promotion interventions for children. Systematic reviews of occupational therapy trials conducted in different settings or with different populations often report interventions are inadequately described, limiting the possibility of synthesising results, replicating studies or generalising findings to practice (Campbell et al., 2000). The steps toward rectifying this situation are to clearly outline and define the theory and evidence underpinning interventions, and provide detailed and accurate descriptions of protocols for their implementation. Therefore, the first step in this research involved clearly outlining the intervention under evaluation in order to be transparent. and promote opportunities for replicating research and generalising findings in the future. A summary of the content from this chapter was published by Tokolahi, Hocking, and Kersten (2016). Kia Piki te Hauora: Uplifting our Health and Wellbeing© is a school-based group intervention for children at risk of developing anxiety, depression, low self-esteem and reduced participation in everyday occupations. The intervention protocol was initially inspired by an intervention developed for use in a secondary mental health setting for children with clinical anxiety and depression (Tokolahi et al., 2013). Components of the original intervention were adapted in response to an identified need, in clinical practice, for a more preventative intervention to be implemented in a school setting.

3.1 Process of intervention development

Weare and Nind (2011) recommended mental health promotion interventions be developed by clinicians, that manualised protocols with clear guidelines be produced and that these should be based on sound theoretical knowledge in order to achieve higher quality intervention protocols. At the time the intervention in the present study

was being developed, there was a range of guidance available about how to develop complex interventions. Guidelines were available from the Medical Research Council (2008) and others (Campbell et al., 2007) on developing complex interventions for health promotion and typically followed a step-wise process of development, piloting, evaluation, reporting and implementation. The focus was primarily on evaluation rather than intervention development and the suggestion was made that further guidance was required on how to structure the first element: development.

In instances when the development and content of occupational therapy interventions had been described, the process typically followed the steps of reviewing evidence, consulting with experts and piloting the protocol (Sackley, Atkinson, & Walker, 2004). Two studies were found that outlined the development of a manual for an occupational therapy intervention (Cook & Birrell, 2007; Maris & Bradshaw, 2004) and one described the development of a framework for practice alongside a suggested frequency, duration and 'dose' of occupational therapy (Sackley et al., 2004); both methods facilitate intervention replication in different contexts. A common theme described by these authors was the challenge of defining occupational therapy interventions with sufficient flexibility to enable therapists to take a holistic, client-centred approach; however, it was asserted that "it is possible to define a specific intervention in a clearly defined group" (Sackley et al., 2004, p. 104). The development process, for the intervention from the current study, occurred in 2013 and followed four-steps similar to that used by Sackley et al. (2004): (1) reviewing the theory (section 3.2); (2) reviewing the evidence (section 3.3); (3) incorporating expert opinion (section 3.4); and (4) trialling (section 3.5). Designing the intervention protocol would ideally occur between steps three and four. However, with the intervention from this study, there was a pre-existing protocol (Tokolahi et al., 2013) that was modified before step four, based on the findings from the initial three steps.

3.2 Step 1: Reviewing the theory

3.2.1 Salutogenic approach

The previous chapter presented evidence of the need for children and their families to have access to evidence-based interventions that promote the child's health and wellbeing and reduce the likelihood of developing mental health problems in the future (Arbesman et al., 2013). Rather than focus specifically on one condition or disorder in

order to prevent mental illness, a salutogenic approach advocates for developing capacities and factors that facilitate wellbeing as more effective and efficient (Antonovsky, 1987). Evidence has shown that engaging in a meaningful balance of occupations is vital to achieving optimal development and to experience health and wellbeing, and promoting this is consistent with taking a salutogenic approach (Bazyk & Bazyk, 2009; Erlandsson, Eklund, & Persson, 2011; Humphry, 2002; Wiseman, Davis, & Polatajko, 2005). It is this foundational belief on the role of participation in occupations for promoting health and wellbeing that serves as the underlying premise of the intervention in this study.

3.2.2 Participation in occupations as a determinant of health

Key to taking a salutogenic approach, alongside an occupational perspective, are opportunities for occupational choices, occupational balance and participation in personally meaningful and satisfying occupations. The range of occupations children choose to participate in, the meaning they attribute to those occupations and the level or intensity with which they choose to, need to, or are expected to, participate in various occupations will all change as they progress through each developmental stage (Davis & Polatajko, 2014; Erlandsson, 2013a). Furthermore, participation in developmentally-appropriate and meaningful occupations has been described as a basic human right that serves as a determinant of health and wellbeing (Townsend & Wilcock, 2004). The use of occupations, in the intervention from the current study, were accompanied by opportunities to engage in occupational self-analysis or reflection to enable children's understanding of the reciprocal relationships between doing, thinking and feeling – similar to how they were used in the Lifestyle Redesign intervention (Bazyk & Bazyk, 2009; Jackson, Carlson, Mandel, Zemke, & Clark, 1998).

3.2.3 Plan, build and design health-promoting routines: Lifestyle (re)design

Lifestyle Redesign focused on embedding health-promoting changes within participants' ongoing routines and lifestyles in the context of changing cognitive, developmental, physiological and social capacities. Methods of intervention delivery in Lifestyle Redesign were didactic presentation, peer exchange, direct experience and personal exploration, as described by Mandel, Jackson, Zemke, Nelson, and Clark (1999). This approach has been clearly demonstrated through a research-generated evidence-base for the Well Elderly Program, the intervention now described as a 'Lifestyle Redesign' programme (Mandel et al., 1999). Cultural adaptations and similar

interventions have been developed for older adults (Craig & Mountain, 2007; Mountain & Craig, 2011; Wenborn et al., 2016) and women of working age (Eklund, Erlandsson, & Wastberg, 2015; Erlandsson, 2013b), which have taken inspiration from the Lifestyle Redesign intervention. When working with children, consideration needs to be given to their developmental stage and their need to increasingly take control of the decision-making for their occupational participation (Townsend & Wilcock, 2004).

The intervention, in the current study, placed value and importance on Lifestyle (Re)Design concepts, and the transformative nature of occupations, as a means of promoting occupational participation (Townsend & Wilcock, 2004). Similar to Lifestyle Redesign, Kia Piki te Hauora: Uplifting our Health and Wellbeing© aimed to provide children with the knowledge to plan, build and design health-promoting routines, habits and occupations into their daily lives. Occupations were used as transformative tools to promote mental health and wellbeing to help shape children's decision-making and to support better mental health outcomes. Given children's developmental stage and emerging self-awareness, it was more appropriate to consider the intervention from the current study as 'Lifestyle Design'.

3.2.4 Patterns of daily occupations: ValMo Model

The Value and Meaning in Occupations (ValMo) Model provides a framework for understanding patterns of occupation that emphasise the role of meaningful participation in promoting health and wellbeing (Erlandsson et al., 2011). Daily occupations are categorised as being *main, hidden, unexpected* and *sleep* occupations (Erlandsson, 2013a). Main occupations are the few occupations that dominate a day, which for a child may include play and schooling. Hidden occupations are those that intertwine with the main occupations and usually receive less attention from the performer despite their importance as they are necessary for maintaining the rhythm of daily occupations. For a child, hidden occupations may include putting their uniform on for school, eating lunch or reading a book before bed. The need to participate in unexpected occupations can result from positive, negative or neutral situations that arise and alter or disrupt the person's usual pattern of occupations. For example, a school sports day requires children to participate in more sporting occupations and different social interactions than typically performed on a regular school day; or illness may induce a child to participate in more restful and solitary occupations in the home environment than if they were well and able to engage in active play occupations with

their peers in a playground. Sleep is understood as a perquisite occupation for the ability to participate in other occupations during waking hours; however, sleep can be interrupted by hidden or unexpected occupations, such as responding to text messages or spending time getting school books ready for the following day. This can result in increased risk of ill-health.

Children, perhaps more so than adults, often lack the knowledge or skills to determine the health-relevant consequences or benefits of the occupations in which they chose to participate (Jackson et al., 1998). As a result, there is an identified need to develop an intervention aimed at educating and encouraging children to "construct daily routines in a manner that would optimise their health and psychosocial wellbeing" and enable them to perform these occupations in real-life environments (Jackson et al., 1998, p. 329). In order to structure the occupational self-analysis or reflection, children participating in Kia Piki te Hauora: Uplifting our Health and Wellbeing© were provided with the framework for describing their patterns of daily occupations taken from the ValMo-Model. Therefore, the intervention used the structure of main, hidden, unexpected and sleep occupations in order to facilitate children's understanding of the connections between their patterns of daily occupations and their mental health and wellbeing.

Patterns of daily occupations are situated within a meaningful context – in the current study, this context is school (Erlandsson et al., 2011). The school environment plays an important role in children's social and educational development (Stallard & Buck, 2013) and provides the context within which to consider the developing child as a whole, with a focus on "strengthening relationships in the life space of a child's family, school, peers and community" (Brendtro & Mitchell, 2011, p. 8). Additionally, the school environment can provide a venue for therapists to work with children who may not otherwise access therapeutic interventions (Arbesman et al., 2013; Stallard & Buck, 2013; Weare & Nind, 2011).

3.2.5 Dynamic Performance Analysis

There is a dynamic, reciprocal interaction between the occupation and the person so that participation in an occupation influences, and is influenced by, individual's beliefs, identities, experiences, goals and life narratives; concepts that are still very much emerging in children (Davis & Polatajko, 2014). Participation, in turn, is impacted by a child's ability to perform developmentally appropriate occupations. The Dynamic

Performance Analysis (DPA) framework for occupational performance assumes healthy occupational performance depends on three, hierarchical levels: motivation to perform; knowledge of how to perform; and the ability to perform (Polatajko, Mandich, & Martini, 2000). Children experiencing anxiety or depressive symptoms may have lower motivation to participate in a range of meaningful occupations, compared to non-anxious or non-depressed peers, as a direct result of the negative internal cognitions associated with the symptoms. This lower motivation may then be exacerbated by reduced opportunities to participate and experience a sense of mastery or occupational competence, that otherwise might encourage them to participate and engage with their environment (Schwammle, 1996). A sense of occupational competence results from the interaction between a person knowing 'how' to act and knowing 'why' to act and this, in turn, can enable participation (Holahan, 2014). This line of reasoning returns our attention to the DPA as a framework for understanding where performance breakdowns are occurring and provide tailored interventions that enable participation in order to promote mental health and wellbeing.

Children can be supported to analyse their own occupational performance and identify specific performance breakdowns in the hierarchy, in order to develop effective strategies for promoting participation in occupations (Rodger & Polatajko, 2010). Integral to the intervention in the current study was enabling participation, and improved mental health and wellbeing outcomes, through increased awareness and understanding of the health-related consequences and benefits of participating in daily occupations. It was proposed that knowledge to make informed occupational choices served as a facilitator for children to feel autonomous and in control, concepts that have been shown to impact on motivation to perform (Poulsen, Ziviani, & Cuskelly, 2013). In this way, children can be enabled to make informed occupational choices that lead to increased engagement in meaningful occupations and greater occupational balance promoting health and wellbeing.

3.2.6 Group theory

Provision of Kia Piki te Hauora: Uplifting our Health and Wellbeing© as a group, was appropriate given the familiarity of group-work for children in the school context and the nature of preventative, school-based interventions needing to target large populations over a short period (Bazyk, 2011; Cole, 2012; Stallard, 2009). Challenges associated with facilitating group work include brevity, unequal participation and

problem-identification. It has been suggested that if a group is too brief there may be insufficient opportunities for the participants to develop meaningful and trusting relationships that can be used to facilitate group outcomes. However, what duration is counted as 'too brief' was undefined (Tschuschke, Anbeh, & Kiencke, 2007). Unequal participation can occur if one (or more) participants are overly dominant or passive, evoking ambivalence or frustration in the other group that blocks their ability to make progress and requires careful facilitation to ensure each member experiences equal opportunities to participate and contribute (Cole, 2012). Over emphasis on problem-identification may deter group members from actively participating, again blocking group progress, which can be minimised by taking a solution-focused or wellness-oriented approach (Schechtman & Gluck, 2005). During the design phase for the current intervention it was important to consult evidence about the appropriate duration for a therapeutic group with children, ensure facilitation enabled all members of the group to participate and contribute and that problem-identification was not a major emphasis within the intervention. Effective groups enable a context for social support from peers, normalisation of experiences and beliefs, exposure to problem-solving from a range of perspectives, and opportunities for developing communication and self-expression skills, which can all promote confidence and boost self-esteem (Cole, 2012). The group format provides the opportunity for modelling and connecting with peers and careful facilitation can promote an atmosphere of non-judgemental acceptance (Sanchez et al., 2007).

3.2.7 Summary of theories

In summary, the intervention in the current study was informed by a range of interwoven theories. A salutogenic approach embodies the drive to focus on building protective factors, such as participation in a balance of meaningful and satisfying occupations, rather than on restoration and recovery. Participation in meaningful occupations is understood to be a determinant of health that can be supported through the planning, designing and building of health-promoting occupations into patterns of daily occupations placed in context. The DPA provides a framework to facilitate children's occupational self-analysis and to better understand where performance breakdowns occur. The theoretical basis for group interventions are drawn upon to provide an environment that can normalise common experiences and promote shared strategies for positive mental wellbeing.

3.3 Step 2: Reviewing the evidence

Evidence was reviewed that directly informed the intervention content and focus as well as evidence that informed the overall format of the intervention.

3.3.1 Health promotion versus mitigation of risk factors

Evidence was described in the previous chapters that supported the role of occupational therapists in promoting children's routines and participation in occupations with beneficial health-related consequences, as part of a health promotion strategy (Persch et al., 2015). Yearwood and DeLeon Siantz (2010) reported "positive mental health is a powerful protective factor against mental illness" (p. 513). Traditionally, occupational therapy outcomes have focused on the mitigation of mental health problems (such as symptoms of anxiety or depression); however, there is increasing focus on building protective factors (such as self-esteem, participation and wellbeing) as a legitimate, if not more effective, method for promoting mental wellbeing and preventing the onset of disease. In the United Kingdom, a review of the most up-to-date evidence for strategies aimed at improving wellbeing in everyday life identified a set of five, simple actions that focus on building protective factors: connection with others; giving; noticing; continued learning; and getting active (The New Economics Foundation, 2011). The intervention in the current study integrated these five principles into the session topics. Emphasis was placed on both promoting participation in occupations with health-related benefits, as well as providing opportunities to reflect on the health-related consequences of participating in occupations that may be detrimental to their mental health and wellbeing.

3.3.2 Evidence supporting session content

As with the evidence guiding the intervention design and focus, much of the literature found surrounding content of the interventions was not occupational therapy-based. However, the literature was deemed relevant as it identified activities or behaviours that facilitated or hindered participation in healthful occupations that could be understood as related to occupational choices and routines. The evidence presented here supports the focus on sleep-related and physically active occupations, communication skills to promote occupational performance and participation, and the use of specific strategies - relaxation, sensory-based strategies and goal-setting - for promoting mental health and wellbeing.

3.3.2.1 Sleep-related occupations

As described earlier, sleep is understood to be a perquisite occupation for the ability to participate in other occupations during waking hours (Erlandsson, 2013a). Several studies advocated the need for sleep to be addressed in the school context given the relationship between sleep and academic, social and mental health outcomes (T. Chen et al., 2014; Kronholm et al., 2015; Persch, Lamb, Metzler, & Fristad, 2015; Spruyt, Alaribe, & Nwabara, 2016). Evidence was found to support occupational choices known to impact on sleep, such as limiting recreational screen-time to 2 hours daily, avoiding device-use immediately prior to sleep, not doing homework shortly before bedtime, engaging in physical occupations during the day and having a regular routine and time for going to bed (American Academy of Pediatrics, 2013; Chen et al., 2014; Council on Communications and Media, 2013; Persch et al., 2015).

Kia Piki te Hauora: Uplifting our Health and Wellbeing©, was designed to provide children with information about the relationship between sleep and mental health issues or behavioural problems and the general importance of sleep-related occupations. Information was shared with the children, who were then encouraged to articulate their performance knowledge of healthful sleep-related occupations (the second level in the DPA hierarchy) and evaluate their current occupational performance more accurately. The intention was to prompt the children to reflect on how sleep-related occupations could result in their own performance successes and breakdowns, potentially motivating them to make healthful changes to their routines and occupational choices. This fits with the first level of the DPA framework that identified motivation as a facilitator or barrier to occupational performance.

3.3.2.2 Active occupations

The use of physically-active occupations has been well documented in interventions for health promotion with children, particularly in relation to childhood obesity (Engelen et al., 2013; Koorts & Gillison, 2015; Murray et al., 2004; Wilson, Magarey, Dollman, Jones, & Mastersson, 2010). Increasing attention has also been paid to the relationship between physically active occupations and mental health and wellbeing (Bonhauser et al., 2005; De Moor et al., 2006; Engelen et al., 2013; Law et al., 2006; Li, Chung, & Ho, 2013). A study involving 120 Chinese adolescents demonstrated a positive relationship between an adventure-based, physical intervention and improvements in their level of symptoms related to depression and anxiety, and self-esteem (Li et al., 2013). This

provided emerging evidence that physical activity incorporated into a complex intervention (i.e. adventure-based activities) was effective in improving mental health outcomes, which is pertinent when developing an intervention using occupations (which are complex) as the medium for facilitating increased physical activity and mental health outcomes.

Increased physical activity levels were found to be associated with significant improvements in anxiety ($p<0.01$) and self-esteem ($p<0.0001$) in a study with 198 adolescent participants from Chile (Bonhauser et al., 2005). As such, the authors concluded the need for schools to encourage children to adopt healthy behaviours, which could be understood as healthy occupational patterns, such as increased physical activity, from a younger age. The argument for early intervention to facilitate physical activity and promote mental health outcomes was supported by studies that examined the relationship between the two. A population-based study of adolescents and adults from the Netherlands ($n=19,288$) found significant relationships between participation in exercise and mental health outcomes (De Moor et al., 2006). Specifically, increased levels of exercise were associated with lower levels of anxiety, depression and neuroticism and higher levels of extroversion and sensation-seeking (all $p<0.00013$).

Kia Piki te Hauora: Uplifting our Health and Wellbeing© aimed to develop children's knowledge on the importance of, and health-related benefits and consequences of, participating in physical occupations. Children were encouraged to reflect on their own occupational patterns, for example, to recognise that physically active occupations may not always be a main occupation (e.g. participating in a sports game) and may at times be hidden (e.g. walking to a friend's house). In this way, children were encouraged to identify which occupations they participated in that already constituted physical activity (e.g. walking to school, playing sports), those which do not (e.g. playing a computer game in their chair), and how their occupational patterns could be modified to be more healthful. This process was facilitated by occupational self-analysis through the use of activity pie charts to track physical activity, shown to be a successful element of the Pizzi Healthy Weight Management Assessment © programme for children with obesity (Kugel, Hemberger, Krpalek, & Javaherian-Dysinger, 2016; Pizzi, 2016).

3.3.2.3 Communication skills

Social skills development, including communication and interaction skills, has been highlighted as a legitimate domain for occupational therapists to target within children's health promotion (Arbesman et al., 2013). Communication is one of three skills recognised under the Model of Human Occupation (the others being processing and motor skills) (Kielhofner, 2002). Unlike sleep-related and physically active occupations, which can be targeted at the performance and participation levels, communication is not a specific occupation but a skill that impacts on occupational performance and participation across several domains. Evidence has demonstrated that children with elevated symptoms of anxiety performed poorly in occupations that were dependent on communication and interaction skills, particularly emotion-recognition in others (Easter et al., 2005).

A particular focus within the communication component of the intervention, advocated for by school personnel during the consultation process and supported by the literature, was cyber communication. It is reported that children aged 8-10 years are in front of screens (e.g. television, phones, tablets etc.) on average about 8 hours per day and more often than not they are using multiple screens simultaneously (American Academy of Pediatrics, 2013; Rideout, Foehr, & Roberts, 2010). Excessive screen-time use has been associated with lower levels of satisfaction at primary school and increased levels of sedentary behaviours, neither of which are indicative of positive mental wellbeing (Rideout et al., 2010). Group interventions provide opportunities for in situ complex interactions and peer cooperation that can been used to facilitate more effective communication and interaction skills amongst children; opportunities a child may be deprived of if they primarily engage in cyber communication (Bazyk, 2011).

Kia Piki te Hauora: Uplifting our Health and Wellbeing© utilised spontaneous interactions that occurred throughout the entire intervention to facilitate opportunities for developing effective communication skills. For example, using praise to positively reinforce demonstrations of pro-social behaviour and modelling conflict resolution skills when disagreements arose. One session utilised a range of games and activities specifically selected to trigger communication challenges and provide opportunities to reflect on patterns of communication, and how these impact on the child's own participation and the participation of others around them. For example, the children completed a group puzzle without any verbal communication and afterwards reflected

on non-verbal strategies that were effective at eliciting positive responses from others and promoted a successful outcome; participants also reflected on how valuable non-verbal communication is when participating in everyday interactions. To enable children to develop more effective communication skills, it is argued here, there is a need to make explicit to children the connection between these skills and daily patterns of occupations (e.g. communication in the friendship role, as part of being a team-player or via a device). Integrating this into the current intervention targeted children's motivation to reflect on and refine their skills, with the intention of increasing their participation, as well as their occupational performance and specific skills (targeting all three layers of the DPA framework).

3.3.2.4 Specific strategies

Specific strategies intended to promote wellbeing and increase children's repertoire of skills for coping with unpleasant emotions or thoughts were integrated throughout the intervention. These strategies included relaxation skills, sensory modulation and goal-setting. The evidence supporting these strategies are described here.

Relaxation strategies were incorporated into the intervention as an evidence-based tool for reducing anxiety and depression symptoms (Van Voorhees, 2010). Relaxation strategies have been reported as being used in many cognitive behavioural therapies (Harden, 2012) and more broadly as part of general stress management and wellbeing programmes (Adi, Killoran, Janmohamed, & Stewart-Brown, 2007). Furthermore, the effective use of relaxation strategies has been associated with significant and sudden gains in treatment and positive future outcomes for children under the care of community mental health teams (Dour, Chorpita, Lee, Weisz, & Research Network on Youth Mental Health, 2013). From this, it could be extrapolated that the use of such strategies could be beneficial for promoting the mental health and wellbeing outcomes of children generally.

Kia Piki te Hauora: Uplifting our Health and Wellbeing© included six (out of a choice of seven) different relaxation strategies (e.g. breathing techniques, progressive muscle relaxation, visualisation) and children were encouraged to participate in and experience each one before making any decisions about whether or not they found it helpful. Relaxation strategies were explicitly associated with sleep-related occupations and occupations that enabled coping.

Sensory processing refers to the way the nervous system receives sensory information from the environment and converts it into responses (Miller, 2014). The deliberate use of sensory stimuli to stimulate specific responses in the nervous system (e.g. calming, activating) can be referred to as sensory modulation, which impacts on emotional and behavioural self-regulation (Hui, Snider, & Couture, 2016) and participation (Miller, 2014). Children experiencing heightened emotional states often respond to ordinary sensory input in intense ways that may negatively influence their emotional state, social interactions, occupational performance and participation (Bazyk, 2011; Mulligan, 2001).

Some children struggle to accurately detect emotions in others due to their own traumatic or impoverished backgrounds; however, heightened emotions can trigger similar challenges that may lead to relationships breaking down because they do not appear to be responding appropriately to the other person's emotional cues (Miller, 2014). As such, there is a benefit to directly teaching emotional recognition and expression while children are in emotionally neutral states, in order to limit the impact of heightened emotions on their social interactions.

The intervention in the current study aimed to facilitate children's understanding of the relationship between sensory experiences and participation in occupations. Children were encouraged to identify their sensory preferences and employ sensory strategies as a tool to lessen the intensity of unpleasant emotional states and promote optimal participation in occupations they wanted, needed or were expected to participate in.

Goal setting is an important strategy for creating focus and direction; however, there are some important factors, informed by self-determination theories, which can promote more effective goal setting with children. Poulsen et al. (2013) described Autonomy, Relatedness and Competence, known as the ARC model, as vital factors influencing motivation for change and achieving goals. When applied to occupational participation, autonomy can be understood as having choices and complements the first level of the DPA framework (motivation to perform) with the need to have the knowledge (second level of the DPA framework) of the health-related consequences and benefits of occupations in order to make beneficial occupational choices. Relatedness is about feeling connected to others, and the occupations participated in and the use of a group intervention, in the current study, provided a social network of individuals working towards goals with the additional incentive of peer support. A sense of competence, or

mastery, of several occupations is important for developing a willingness to work towards more challenging goals.

The ARC model highlights the role of positive relationships to facilitate opportunities for success in meaningful occupations that are sufficiently challenging to interest the participant and at the same time not so challenging for them that they cannot readily be performed or participated in (Christiansen & Townsend, 2004; Poulsen et al., 2013). There are several specific strategies for developing goal-setting skills, including use of the SMART (Specific, Measurable, Achievable, Realistic and Time-bound) framework, which can be challenging even for older youths (Nguyen et al., 2012); Goal Attainment Scaling (GAS) (Cytrynbaum, Ginath, Birdwell, & Brandt, 1979; Cusick, McIntyre, Novak, Lannin, & Lowe, 2006; Graham, Rodger, & Ziviani, 2010); and breaking goals down into manageable steps (Polatajko et al., 2000; Rodger & Polatajko, 2010).

Trialling of Kia Piki te Hauora: Uplifting our Health and Wellbeing© (described in section 3.5) revealed the use of SMART or GAS goals with children in a group context was challenging, as they often struggled to grasp the various components and there was insufficient facilitator time to enable each child to gain sufficient understanding. Subsequently, the intervention most frequently used breaking goals into manageable steps throughout the intervention. Formally, this type of goal setting was used on a weekly basis as part of skills practice, for example, children could choose a relaxation technique they enjoyed and set a goal about how often they would practice it over the coming week and for how long. Informally, goal setting was integrated into group discussions and occupational self-analyses, for example, children who noticed they were not getting enough sleep on their activity pie charts would be supported to develop a goal and a plan for increasing their sleep.

3.3.3 Evidence supporting the intervention format

Identifying interventions that reduce the lifetime impact of mental health issues is an important focus of government policies internationally (DH/Health Improvement Directorate, 2005; Mental Health Commission, 2012; US Department of Health and Human Services, 1990, 2016). Key evidence-based principles for effective interventions aimed at mental health promotion and prevention in schools across all three intervention tiers (see section 2.4) are described here. Several recommendations drawn from the substantial systematic review of systematic reviews and meta-analysis, conducted by

Weare and Nind (2011), were incorporated into the development of Kia Piki te Hauora: Uplifting our Health and Wellbeing© as discussed below. While the systematic review was extensive, it may not have been sufficiently sensitive to identify evidence from newer and less well researched, but promising, interventions not yet evaluated in systematic reviews. Also, although highly relevant, the review findings were not specifically intended for direct translation into an occupational therapy intervention. Despite the review limitations, the evidence reported was sourced from an extensive search of literature reviews and the resulting large numbers of studies to analyse meant that combined quantitative evaluation of the effect of intervention components was robust and reliable.

Given the lack of previously described occupational therapy interventions targeting mental health and wellbeing promotion in children, there was a need to draw from broader literature with an occupational focus. Arbesman et al. (2013) conducted a systematic review of mental health promotion, prevention and intervention literature for children and youth, which largely described occupation- or activity-based interventions published by researchers outside the field of occupational therapy, that fitted within the scope of occupational therapy practice. Interventions focused on: social skills programming; health promotion e.g. stress management, managing obesity, health literacy; and leisure, recreation and play activities. The authors concluded there was strong evidence to support "an occupation- and activity-based approach that can be used with children and youth at all three tiers in a wide range of environments" (Arbesman et al., 2013, p. 125). Examples of such programmes were social-emotional learning interventions, anti-bullying or arts programmes (universal level); life-skills programmes for at risk youth or teenage mothers (targeted level); and social skills programmes for children with an autism spectrum disorder (intensive level).

3.3.3.1 Intervention provider

The provision of interventions, initially developed by clinicians, and delivered by a suitably trained leader was recommended (Weare & Nind, 2011). Oftentimes this would mean the intervention provider in the school context was a teacher, and this was deemed necessary in order for an intervention to become embedded in the school culture. One study reported deliberately excluding teachers during the intervention due to the likelihood students would be socialised to their academic roles and associated achievement orientation (Possel et al., 2005). However, other studies have demonstrated

the positive impact that teachers can achieve when facilitating clinician-developed, mental health promotion interventions (Gillham et al., 2007; Manassis et al., 2010). For the current study, it was decided the facilitator would be a trained clinician (and in this case also the intervention developer) in order to promote consistency in intervention fidelity. Should intervention effectiveness be demonstrated then training of teachers or other co-facilitators would be considered for future research, to ensure the sustainability of the intervention.

3.3.3.2 Intervention duration

It is reported there is a pressing need for greater emphasis on children who fit under the first two tiers of the mental health promotion and prevention hierarchy (Bazyk, 2011): the intervention in the current study, was designed to target the second tier. In a substantial systematic review of systematic reviews and meta-analyses, Weare and Nind (2011) recommended short-term interventions of 8-10 weeks as sufficient for effecting positive outcomes when addressing preventative or mild concerns. For more complex or severe problems, longer-term interventions (9-12 months), were recommended. Given the aim of prevention in the intervention from the current study, and the school-term duration in Aotearoa New Zealand ranging from 8-10 weeks, the decision to facilitate Kia Piki te Hauora: Uplifting our Health and Wellbeing© for 1 hour, weekly, over a period of 8 weeks, was based on both evidence and practical considerations.

3.3.3.3 Group intervention

Service provision via groups has been shown to be as efficient, in terms of time- and cost-effectiveness, as that achieved in individual therapy (Brown & Lewinsohn, 1984; Cole, 2012; Shochet et al., 2001; Wood, Trainor, Rothwell, Moore, & Harrington, 2001). Providing the intervention as a group promotes a sense of connectedness and belonging, with positive interpersonal relationships shown to be one of the most important therapeutic factors for successful therapeutic group-work reported by a sample of 64 children aged 10 years (Schechtman & Gluck, 2005). This potentially counteracts feelings of loneliness, which have been demonstrated to negatively affect treatment outcomes for children with symptoms of anxiety (Alfano et al., 2009). Furthermore, groups provide the most appropriate context for children to develop social skills; with skill-development found to be a key strategy for achieving positive outcomes. Areas for skill development reported to be most successful in the systematic

review by Weare and Nind (2011) were social, emotional, problem-solving and coping skills – with life skills and pro-social behaviour skills receiving a lesser mention.

Bazyk and Bazyk (2009) only reported qualitative outcomes for a study that evaluated a group preventative occupational therapy intervention for children or adolescents. The intervention focused on the needs of disadvantaged, African-American adolescents, through the evaluation of HOPE (Healthy Occupations, Positive Emotions) groups, provided as an after-school programme. Phenomenological interviews elicited themes that illustrated how having fun and self-management of emotions were important for the youth to engage with this intervention in a meaningful way; important concepts to build into Kia Piki te Hauora: Uplifting our Health and Wellbeing©.

3.3.3.4 Intervention delivery methods

In their systematic review of evidence-based principles for effective mental health promotion interventions, Weare and Nind (2011) recommended a combination of behavioural (e.g. games, simulations, group work) and didactic strategies were associated with better outcomes than either approach alone. Kia Piki te Hauora: Uplifting our Health and Wellbeing© utilised a range of activities that required peer exchange to occur (connection), offering positive feedback to others in the group (giving), occupational self-analysis and personal exploration (noticing), didactic presentation (learning), and direct experience of occupations (active).

3.3.4 Summary of evidence

The evidence supporting the content of the sessions focused on sleep-related occupations, physically active occupations, communication and a selection of specific strategies has been described. The discipline-specific evidence for occupational therapy mental health prevention or promotion interventions with children was sparse. However, there was sound evidence for occupation focused components of the intervention and for preventative occupational therapy in other contexts, so a pilot intervention protocol was developed for review in the following two steps.

3.4 Step 3: Incorporating expert opinion

A targeted, preventative-occupational therapy group intervention protocol was developed, based on the reviewed theory and evidence and previous experience of running groups in secondary mental health services for children (Tokolahi et al., 2013).

To ensure the intervention was appropriate in a school setting, consultation occurred with the following groups:

- Children eligible to participate in the intervention: age range 11-13 years (*n*=18).
- Senior teaching staff at eligible schools, such as principals and/or SENCOs (*n*=4).
- Cultural advisors with knowledge of providing culturally sensitive and safe interventions, with a strong mental health component, to children (*n*=3).
- Occupational therapists with knowledge and experience of providing and teaching occupational therapy, with prior experience in working with children and/or in a mental health context (*n*=7).

Consultation with children occurred primarily during the trialling phase described in step 4. SENCOs from four different schools were consulted in the planning of the intervention logistics and overall content. Two SENCOs were from decile 1 schools, one from a decile 6 and one from a decile 10. Aotearoa New Zealand schools are ranked in deciles according to the socio-economic position of a school's student community relative to other schools throughout the country (Ministry of Education, 2015). For example, the 10% of schools with the highest proportion of low socio-economic communities in their zone are ranked decile 1, whereas the 10% of schools with the lowest proportion are ranked decile 10. Each of the SENCOs had a minimum six years of experience teaching in Aotearoa New Zealand and all were female. SENCOs were invited via email - sent by an independent SENCO to a network of eight SENCOs - inviting them to participate in a pilot trial of the intervention offered through a private practice. Four SENCOs expressed an interest and met individually with the researcher. Two SENCOs progressed on to have a pilot trial facilitated at their school, based on practical and logistical considerations. Advice about the amount of time schools would be willing to release children from the standard curriculum during the week, to facilitate their attendance at a wellbeing group, varied (60-120 minutes) and so the duration feasible across them all was selected to ensure consistency i.e. 60 minutes. Furthermore, variability in school-term duration was accommodated: in Aotearoa New Zealand intermediate schools this can vary between 8-10 weeks so the current intervention was limited to 8 weeks. Including parents in the intervention through face-to-face group sessions was considered, given evidence that involving them can significantly increase

an intervention's effectiveness (Arbesman et al., 2013; Khanna & Kendall, 2009; Weare & Nind, 2011). The SENCOs consulted expressed concern that while a parenting component could be helpful, it risked stigmatising the children involved and raised significant practical complications. Parent involvement was therefore not directly included in Kia Piki te Hauora: Uplifting our Health and Wellbeing©; however, parental consent for their child to participate was required and parents were informed their children would be given skills to practice between sessions, so they could support them. Stigma from the participant selection process was also identified as a potential challenge so the SENCOs requested students generally perceived as 'role models' also be selected. Role models were not necessarily students who were less anxious or socially advanced, but children who were perceived by other children as not trouble-makers or as not having special needs in the classroom. This would ensure the group would not be perceived as just for the shy or naughty children. Role models were not explicitly identified, so as not to inadvertently signal the at risk students as being such. Feedback on the intervention protocol from the SENCOs was positive and they suggested additional components to keep the programme consistent with the national curriculum, such as safe participation in cyber occupations.

While the intervention does not target ethnic groups specifically, it was anticipated people from a range of ethnicities would be involved e.g. children, parents/caregivers or school personnel. Three cultural advisors of Māori and Pacific descent were consulted about the design, look and implementation of the intervention protocol; all had a minimum 10 years of experience working in mental health services. After discussions about the content and implementation strategies with the advisors, time was allowed for them to consult with their cultural community before again meeting with the researcher to validate or adjust their feedback. Support was given for the incorporation of Māori motifs and artwork into the design of the manual and materials participants received. Modifications made included the gifting of the intervention name, Kia Piki te Hauora: Uplifting our Health and Wellbeing©, by one of the cultural advisors and the adaptation of an introductory cultural protocol, known as a pepeha[1], that incorporated an occupational focus. Strict adherence to tikanga[2] principles for the opening and closing of sessions with a karakia (prayer) was deemed unnecessary for this intervention, as the

[1] 'Pepeha' refers to a way of introducing one's self in Māori: in this context the pepeha has been modified to have an occupational focus and was developed in consultation with Māori cultural advisors.

[2] 'Tikanga' refers to Maori protocols for performing different rituals and routines.

group opening and closing process already allowed opportunities for each child to feel important and to contribute in some way, with time and space for personal reflection. Karakia were included at the start of the first session and the end of the last session only.

The expert panel of seven occupational therapists all had a minimum of eight years clinical experience. Three therapists were employed in academic roles and two of those were teaching occupational therapy. The other four therapists were employed in two different child and adolescent mental health services, two in senior roles. The panellists were asked if they recognised the intervention protocol as being occupational therapy and what modifications or additions would they recommend. They were also asked to provide feedback regarding the menu options to be used in the Canadian Occupational Performance Measure (COPM): one of the planned outcome measures (discussed in section 5.3). All agreed the intervention was clearly recognisable as occupational therapy, suggesting face validity, and recommended a number of modifications to 'de-clutter' the sessions and improve content clarity and focus. Recommendations included the creation of posters outlining key messages and objectives for each session; the addition and removal of some activities (e.g. added "blowing bubbles" as a breathing activity; removed "Defining problem solving" as an activity); capitalising on the goal-setting required for skills practice within and between sessions rather than focusing on this as a separate topic; modifying hand-outs to support those with handwriting difficulties; the use of rewards to reinforce skills practice completion thus supporting generalisation of skills to other environments; and more consistent terminology.

Feedback provided by the SENCOs, cultural advisors and panel of occupational therapists was incorporated into the intervention protocol resulting in a modified version that was ready for trialling in practice.

3.5 Step 4: Trialling the intervention

The modified version of the intervention protocol was evaluated by trialling it in two different schools, to inform its further development and test how the group format would work in a school environment. The trial was organised through a private occupational therapy practice and offered on a no-cost basis as effectiveness had not been demonstrated. A total of 18 children, aged 10-12 years, from two intermediate schools participated in the pilot trial. The first school was a decile 10 school with a

predominantly New Zealand European student population. The second school was a decile 1 school with a predominantly Pacific Island and Māori student population. It was useful to include participants in the trial from schools ranked at each end of the socio-economic spectrum, in order to get a more accurate idea of acceptability and feasibility within the resources available. The ethnic mix of children who took part in the trial was representative of the schools at which they were enrolled.

Children were invited to participate by a senior teacher at their school; in both instances this was a SENCO. Children selected were identified by the SENCOs as somewhat anxious, low in mood, having low self-esteem or low participation levels but not to a degree warranting referral on to secondary services. At least one role model student was selected from each school to be included. Children were informed that it was their choice to participate and if they agreed to do so then there was an expectation that they would give feedback about what they thought of the group at the end, to inform the development of the group for other children. The session topics are outlined below.

3.5.1 Session topics

3.5.1.1 Introduction to occupation

Children were introduced to each other and the occupational terminology and language used throughout the programme. Through developmentally appropriate play, terms such as ‘occupations’, ‘main occupations’, ‘hidden occupations’ and ‘wellbeing’ were discussed to ensure a preliminary understanding of these concepts.

3.5.1.2 Sleep and rest occupations

After reflecting on their own balance of rest or sleep occupations in relation to other occupations, children were given information about, and encouraged to reflect on, why sleep-related occupations are important. Next they were encouraged to reflect on how occupational choices they made during the day impacted on their participation in sleep or rest occupations (e.g. device use, watching TV, physical activity, routines), and how their own sleep duration compared with national recommendations for their age-group. Strategies were suggested from the literature and integrated with those generated by the children to develop a plan for how to promote sleep-related occupational performance successes.

3.5.1.3 Active occupations

Children reflected on their own balance of active occupations in relation to other occupations and were encouraged to consider why these occupations are important, how occupational choices made during the day inhibited or promoted healthy physical activity and how their own daily physical activity levels compared with national recommendations for their age-group. Each child developed a plan to increase the frequency, intensity or duration of physically active, meaningful occupations in their daily routines. Physical activity was used to explore the immediate impact on the body and was followed by discussion of long-term impacts.

3.5.1.4 Communication in occupations

Games were used to illustrate the differences between verbal, non-verbal and cyber communication, the role and impact of each of these, and ideas shared about how occupations can depend on and be enhanced by effective communication.

3.5.1.5 Occupational disruption

Each child was asked to reflect on how their participation in occupations had been affected by emotional distress and the subsequent impact this had on further occupational engagement e.g. bullying, exams, mental ill-health. Underlying physical, cognitive and affective components that contribute to such disruption were discussed.

3.5.1.6 Coping occupations

A range of occupation-based strategies for overcoming difficult emotions, which could restore or promote occupational participation, were practiced and discussed. These include sensory strategies, having an action plan and relaxation.

3.5.1.7 Values and identity occupations

This is very much an area of development in children, who were encouraged to explore what was important to them personally and how they wished to be perceived by others. They then compared this with the occupational choices they made on a daily basis and their routines.

3.5.1.8 Integrative summary

A review of the previous topics was undertaken to consolidate learning and experiences. Children were actively encouraged to reflect on their personal gains from participating

in the group. The programme concluded with a celebratory ceremony in which children were presented with positive feedback from peers, the programme manual (that contained the content and worksheets from previous sessions) and a certificate of attendance.

3.5.2 Feedback from trial

The presentations of the children who participated suggested the process of using school personnel to identify potential participants was effective for achieving a relevant sample of children. On the whole, feedback from the children was positive – they enjoyed the intervention, in particular the activities, and felt they had learned something in the process. Modifications were made after trialling at each school and based on the children's explicit and implicit feedback based on their comments and observations of how they participated in the intervention (see Table 5, p.59).

Overall, the revisions resulted in a better paced and more cohesive intervention protocol. The SENCO from one of the schools provided unsolicited feedback that the positive response she had received from the children and parents was sufficient for her to consider the intervention successful and expressed interest in offering the intervention at her school in the future.

Table 5: Modifications made to modified version of the intervention protocol following trialling at two schools

Description of original intervention component	Description of modification(s) made
Activity analysis – not all children had the literacy and numeracy skills to be able to construct an accurate analysis of their daily participation pattern in full	Children were only required to identify two to three occupations to include (i.e. sleep, physical activity, school)
Goal setting – the concept of writing a goal proved challenging; furthermore, insufficient time was available to ensure all children understood and were supported to write personalised goals that were relevant to the intervention focus	Session on goal setting and problem solving removed as this was implicitly included in other sessions and skills practice, allowing more time for other topics that were previously rushed
Rest and active occupations – insufficient time to cover content and allow children space to comprehend importance of these topics and how to integrate learning into their real life	These topics were expanded out and given a session each
Healthy drinking - time consuming and rushed, children enjoyed learning about sugar content in typical drinks chosen, however, struggled to make links to how this fitted with other content	Removed activity around healthy drinking
Some children requested that all participants chosen be motivated to attend as those less invested were disruptive for other members of the group	This was not always possible to determine in advance, however, the recruitment process for the trial was intended to identify students most likely to benefit from the intervention and who assented to participate
Requests for video/other media presentations integrated into the intervention	Technology resources available at each school varied so this would not be possible to implement consistently. A 'take-away' CD or MP3 was considered for transferring relaxation skills to other environments (i.e. home), however, this was not able to be resourced
Some children requested more outdoor activities to be included	It was not possible to integrate outdoor activities into sessions at all schools depending on the school environment and weather conditions; no changes made
Parents requested information was shared with them during the course of the intervention to assist in generalising skills and knowledge	Key messages relating to session content were included on skills practice sheets that the children were given at the end of each session and encouraged to share with their parents
Worksheets frequently lost or disposed of	Worksheets combined into a professional booklet to ensure information was readily available for children and parents at the end of the term to review; children were able to review information in one location, worksheets were placed into context, children were more likely to have pride and take care of the information and sheets were less likely to be lost

3.6 Final intervention

Figure 1 depicts the Kia Piki te Hauora: Uplifting our Health and Wellbeing© intervention model, including the session topics (described in the previous section), its methods of delivery, proposed dynamic changes in occupation and the subsequent health related outcomes anticipated.

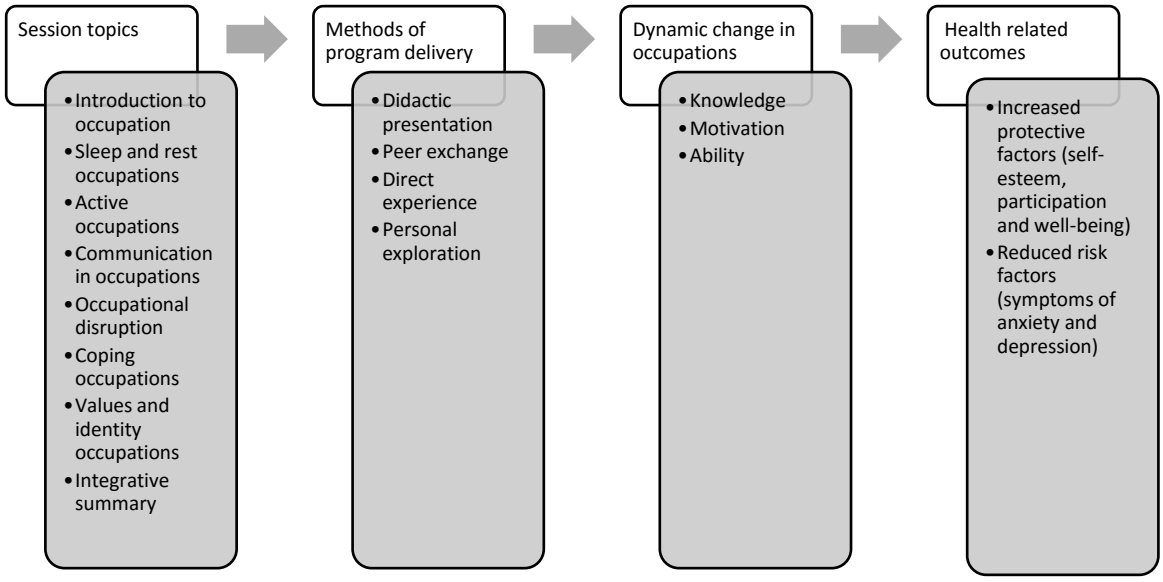


Figure 1: Occupational-science-based Kia Piki te Hauora: Uplifting our Health and Wellbeing© programme model: Recognising the role of occupations in lifestyle design

3.6.1 Methods of intervention delivery

Kia Piki te Hauora: Uplifting our Health and Wellbeing© was manualised based on the protocol developed and described in this chapter (see Appendix 3). The intervention is delivered by an occupational therapist with a group 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 runs for 1 hour a week over a period of 8 weeks of a school term and be located in a self-contained room on the school premises with sufficient space for the number of participants to move around during activities. Each 1 hour session follows a similar format: warm-up activity, skill development, skill practice, discussion about application of skill to real-life, closing round and skills practice for between sessions. Rewards are provided to incentivise participation in the skills practice between sessions and

be related to the session content. Examples of the rewards provided are: stress balls (after doing progressive muscle relaxation using these), bubbles (after doing a breathing exercise using these), and skipping ropes (after doing a physical activity using these). The methods of intervention delivery include: didactic presentation, peer exchange, direct experience and personal exploration. All four delivery modes are integrated into every session to encourage a dynamic and interactive process. Didactic activities include increasing the repertoire of terms, concepts and experiences children are able to name and describe; information sharing e.g. national recommendations regarding duration of hours of sleep or daily physical activity; and skill development for overcoming difficult emotions, such as experiencing different relaxation techniques. Peer exchange is explicitly and implicitly woven into activities to encourage normalisation of experiences, brainstorm ideas and to encourage effective, positive and informative communication. Direct experience involves children actively participating in a range of developmentally-appropriate occupations to highlight concepts and practice skills for managing strong emotions e.g. relaxation, games and planning. Furthermore, participants are encouraged to actively participate in occupational experiences as part of the skills practice between sessions. During personal exploration the children engage in occupational self-analysis, pepeha, and activity scheduling to promote understanding of how their occupational choices impact on their health and wellbeing.

3.6.2 Proposed dynamic changes in occupation and subsequent health related outcomes

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 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. Children participating in this intervention are supported to progress through the framework of the DPA hierarchy in relation to their approach to occupations and occupational choices generally, rather than with regard to a specific occupation (Rodger & Polatajko, 2010). It is proposed this is achieved by providing children with knowledge about what constitutes a health promoting occupation and its benefits (resulting in motivation to participate in more health promoting occupations) and providing information about how to participate in, balance and sustain these occupations. Consequently, it is hypothesised that the

subsequent outcomes are a reduction in risk factors (symptoms of anxiety and depression) and an increase in protective factors (self-esteem, participation and wellbeing).

3.7 Chapter summary

This chapter has described the development and given an overview of Kia Piki te Hauora: Uplifting our Health and Wellbeing©, a manualised, indicated, preventative occupational therapy group intervention. It utilises engagement in developmentally appropriate activities to promote mental health and well-being by enabling students to understand the relationship between what they do and how this influences their identity, self-concept, health and wellbeing; to practice and develop strategies for overcoming difficult emotions; and to apply this knowledge in designing and building healthy routines, behaviours and habits in their day-to-day life. Kia Piki te Hauora: Uplifting our Health and Wellbeing© has been developed from theory and evidence-based practice; it was reported as acceptable and to have content validity as determined by the stakeholders consulted.

Chapter 4: Methodology

It can be argued that no methodology or method are innately superior to another; however, some are more suited to answering particular questions than others (Hyde, 2004; Tse, Blackwood, & Penman, 2000). This study addressed the question: *Is the school-based, occupational therapy intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) effective at reducing symptoms of anxiety and depression and improving self-esteem and participation in children aged 11-13 years*? The study designed to answer this question has been positioned under the post-positivist paradigm. A cluster-RCT design was chosen with efforts made to preserve the integrity of the design and its findings through checks of internal and external validity. The rationale underpinning these decisions is outlined in this chapter. In order to justify the methods selected to answer my research question it is important to first outline the philosophical and theoretical underpinnings that support the decisions made in this study design, then to address how the integrity of the study was protected through addressing issues of validity.

4.1 Paradigm

Different paradigms for approaching research are typically associated with different methodologies and methods. Epistemologies are generally situated within qualitative or quantitative fields of research, with qualitative findings for a long time being accepted as exploratory only until verified by quantitative research (Leninger, 1992). With greater understanding and attention to how robustly methods are planned and executed across qualitative and quantitative paradigms there are now, more than ever, a variety of genuine choices for researchers in healthcare and social sciences that require consideration when planning research (Angen, 2000; Crotty, 1998). Paradigms considered in relation to the current research study were interpretivism, positivism, post-positivism and mixed methods.

4.1.1 Interpretivism

Interpretivist approaches assume reality is constructed intersubjectively through understandings and meanings developed through one's personal and social experiences (Giddings & Grant, 2002). The assumption is that an interpretation of the truth, relevant to a specific context in space and time, can emerge that is unique to the participants and researchers involved in the research process (Angen, 2000; Leninger, 1992). In order to answer the research question stated, an interpretivist paradigm would not be appropriate as

the question of effectiveness itself assumes an objective state that can be tangibly measured and evaluated.

4.1.2 Positivism

Positivism is concerned with the "positive application of knowledge to assist human progress" (Cruickshank, 2012, p. 71) and evolved from a period when scientists began to reject the explanations of religion and faith as sufficient for explaining various phenomena (Bruce, Pope, & Stanistreet, 2008). Positivism has become embedded in Western society, influencing modern assumptions about what knowledge is and how knowledge can be known (Giddings & Grant, 2002). It takes the epistemological stance of objectivism – truth and meanings are external and independent of the researcher, are empirically measurable, and can be discovered through systematic, logical and methodical procedures of research (Crotty, 1998; Cruickshank, 2012; Neuman, 2014). This is based on the ontological assumptions of realism – that reality is out there, tangible and exists. Positivism assumes that human nature is determined by common laws and eliciting this information means we can explain, control or predict events and responses (Giddings & Grant, 2002; Holden & Lynch, 2004). Positivism has typically been privileged over other paradigms when conducting healthcare research (Breen & Darlaston-Jones, 2010). However, positivism has been criticised for not accounting for researcher biases, assuming them to be value-free and discounting cultural, social, and political beliefs and attitudes that may underlay researchers' decision-making in the research process, thus post-positivism emerged (Giddings & Grant, 2002).

4.1.3 Post-positivism

Post-positivist approaches evolved from the debate about the researcher's (in)ability to remove subjective biases from empirical measurement. While still assuming an objective reality, post-positivism conceded biases are introduced through the research process and assertions are proposed about the need to control for such biases in order to preserve the integrity of the research and obtain findings that are closer to the truth (Kuhn, 1996).

Post-positivism is most relevant to investigating my research question as it calls for the measurement of change in order to demonstrate the intervention's effectiveness. This question contains an assumption that there is a truth that can be discovered, independent of the research process, about the effectiveness of the intervention that can be generalised to a broader population and that this can be measured through systematic and methodical

processes. There is also an acknowledgement of the risk of biases through the research process that need to be controlled for by ensuring robust and transparent methods of investigation. Therefore, the following methodology and methods (described in the next chapter) are situated within the post-positivist realm.

4.1.4 Mixed methods

Adopting a mixed methods study design that included the collection of quantitative data via the RCT and qualitative data from participants via open-ended questionnaires or interviews was considered in the current study. Weaving a qualitative component into the study design offers added value and credibility to RCTs by incorporating participants' lived experiences and providing enhanced opportunities for reflexivity in practice (Hesse-Biber, 2012). This would have facilitated a greater level of depth and understanding about the impact of the intervention and evaluation of how the intervention was implemented (Crotty, 1998). However, including qualitative data collection was beyond the financial and time constraints of the current study.

4.2 Experimental methodology

Methodology refers to the practical approaches to data collection that are associated and affiliated with the relevant paradigm identified for investigating the research question (Giddings & Grant, 2002). Under a positivist paradigm the options available to the researcher are observation or experimental methodologies: the former investigates outcomes for those exposed to a variable of interest and make inferences based on observations; the latter manipulates the presence or absence of the variable of interest before measuring outcomes to determine a causal relationship (Neuman, 2014; Scotland, 2012). Both observational and experimental methodologies take deductive and objective approaches to data collection and interpretation, then formulates laws that allow for predicting or generalising findings to wider populations. These laws are then subjected to rigorous empirical processes and statistical analysis to provide precise evidence for hypothesis verification (Crotty, 1998; Giddings & Grant, 2002; Nelson & Mathiowetz, 2004; Scotland, 2012). For this study, an experimental methodology was deemed more able to effectively investigate the research question, with the intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) being the independent variable and the dependent variables being symptoms of anxiety and depression and levels of self-esteem, participation and wellbeing.

4.3 Randomised controlled trials (RCTs)

Within experimental methodology, a classical design considered the gold standard is the RCT (Hyde, 2004; Nelson & Mathiowetz, 2004). The RCT enables precise manipulation of independent variables between populations considered comparable and balanced as a result of randomisation, in relation to potential known and unknown confounders, to determine the impact on dependent variables (Bruce et al., 2008; Giddings & Grant, 2002). Consequently, the RCT design is highly relevant for health research and ranked second in the hierarchy of evidence - after systematic reviews and meta-analyses - for investigating the effectiveness of interventions and for determining if one intervention is superior, comparable or inferior to another (Hyde, 2004; Tse et al., 2000). In order to ensure accurate reporting, that enables readers to make informed decisions about the relevance and robustness of research conducted, the Consolidated Standards of Reporting Trials (CONSORT) guidelines were developed – these also encourage relevant information to be presented in publications to enable potential meta-analysis of the data in the future (Schulz, Altman, Moher, & CONSORT Group, 2010).

Just over a decade ago it was highlighted that the occupational therapy profession had only recently begun to evaluate its interventions using RCTs and so the scope for conducting robust systematic reviews and meta-analyses was limited (Nelson & Mathiowetz, 2004). While this is gradually changing, there remains an ongoing need for the profession, internationally, to evaluate interventions and practice using more robust methods, such as RCTs (College of Occupational Therapists, 2007; The American Occupational Therapy Foundation, 2013; The American Occupational Therapy Foundation & The American Occupational Therapy Association, 2011).

Though considered the gold standard for investigating the effectiveness of interventions, RCTs are not without their limitations (Giddings & Grant, 2002; Tse et al., 2000). Some complex interventions may be difficult to evaluate using robust RCT methodology as this disrupts the patient-practitioner-intervention dynamic that may be more influential on the outcome of interest than the intervention alone (Medical Research Council, 2008; Milgrom, 2005). Occupational therapy is a complex intervention that may also be considered vulnerable to misrepresentation when evaluated through an RCT (Tse et al., 2000). It has been argued that human nature is more flexible and dynamic than allowed for in an RCT and that what might be deemed a ‘gold standard’ treatment at one time and with one population

may not be considered as effective at another time with another population (Hyde, 2004). Even the initial process of defining a research question for an RCT is potentially hampered by limitations in the breadth of evidence available in which to situate it (Nelson & Mathiowetz, 2004).

For this study, an RCT design was considered to ensure robust evaluation of the school-based, occupational therapy intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) in comparison to no intervention. However, due to the nature of the population a standard RCT was not appropriate and a cluster-RCT design was selected.

4.4 Cluster-RCTs

Growing use of cluster-RCTs in healthcare research has emerged over recent decades as the methodology has gained credibility and prominence (Diaz-Ordaz et al., 2013; Eldridge & Kerry, 2012; Isaakidis & Ioannidis, 2003). Cluster-RCTs are defined as having "groups or clusters of individuals rather than individuals themselves randomised to intervention arms" (Eldridge & Kerry, 2012, p. 3). There are several pragmatic reasons for selecting this design. Randomising by cluster can limit the potential for contamination between study arms. For example, if someone in a therapist-role was given additional training, it would be impractical to randomly allocate his or her patients to receive or not receive the benefits of that training as the new information cannot be 'unlearned'; this scenario would also be ethically questionable (Barbui & Cipriani, 2011). The research question in the present study may be best answered by outcomes analysed at the cluster level (i.e. focus on change within and between clusters), the individual level (i.e. focus on change within and between individuals), or both (Eldridge & Kerry, 2012). Furthermore, there are convenience and cost benefits to investigating an intervention in clusters (Isaakidis & Ioannidis, 2003).

There are several implications of a cluster design for sample size calculations and data analysis. Individuals within clusters are likely to be more homogenous than a sample drawn from the general population. For example, family members are likely to have similar attitudes to health and recovery, shared eating habits, or comparable exposure to environmental factors. These similarities necessitate a greater sample size than individually randomised trials, with adjustments made to the data analysis plan that account for clustering (Campbell, Thomson, Ramsay, MacLennan, & Grimshaw, 2004; Eldridge, Ashby, & Kerry, 2006; Teerenstra, Eldridge, Graff, de Hoop, & Borm, 2012). Failing to account for clustering

increases the risk of Type 1 errors (e.g. finding a significant difference where there is not one). The need to report how these additional considerations have been addressed was formalised in the CONSORT extension to cluster-randomised trials, which highlights key areas to report on when utilising a cluster-RCT design, over and above the reporting guidelines for a standard RCT (Campbell, Elbourne, & Altman, 2004). These reporting requirements are discussed further in the systematic review section below.

4.4.1 Occupational therapy and cluster-RCTs

Occupational therapy focuses on "the nature, balance, pattern and context of occupations and activities in the lives of individuals, family groups and communities" (Creek, 2003, p. 8). The main aim of therapy is to enable the individual, family or community to make occupational choices that "maintain, restore or create a match, beneficial to the individual, between the abilities of the person, the demands of her/his occupations in the areas of self-care, productivity and leisure, and the demands of the environment" (Creek, 2003, p. 8). There is significant potential for occupational therapy interventions to be implemented and investigated using a cluster design, for example, with naturally occurring groups (e.g. children in schools) or with therapists who are randomly allocated to deliver a novel intervention.

Consequently, researchers need to be informed about the conduct of robust cluster-RCTs, to evaluate the quality of current studies and use this information to inform future research design. As part of this thesis, a systematic review was undertaken to investigate the characteristics and quality of conduct and reporting of cluster-RCTs evaluating occupational therapy interventions - this review has been published (Tokolahi, Hocking, Kersten, et al., 2016). This systematic review facilitated a more in-depth understanding of the commonly occurring pitfalls of using cluster-RCTs to evaluate occupational therapy interventions in order to inform the methods used in the current study. Furthermore, the review provided an evidence-based foundation for determining an appropriate correlation co-efficient to use for the sample size calculation in this study.

4.4.2 Cluster-RCTs evaluating occupational therapy: Systematic review

4.4.2.1 Search methods

An extensive search of cluster-RCTs evaluating occupational therapy was conducted in January 2015 and again in July 2015 to ensure completeness, utilising the following

databases: OVID - includes Allied and Complementary Medicine Database (AMED), Cochrane Health Databases, Evidence-based Medicine (EBM) Reviews, Educational Resources Information Centre (ERIC), PsychInfo; EBSCO - includes Cumulative Index of Nursing and Allied Health Literature (CINAHL) Plus, MEDLINE, Health Business Elite, Psychological and Behavioural Sciences Collection; PubMed; and SCOPUS. Specific key words and phrases used were: 'random* control* trial*', 'random* clinical trial*', 'RCT', 'occupational therapy', 'OT', 'cluster*', 'nest*' and 'group' within 3 words from 'random*'. A manual search of all references from included articles was also completed to identify additional reports eligible for inclusion.

4.4.2.2 Eligibility criteria

Studies were included if the research was reported in a peer-reviewed journal, and an occupational therapy intervention had been evaluated. Studies were identified as cluster-RCTs if sufficient detail was provided to determine that participants were randomised by groups (clusters) and the study was not non-randomised or quasi-experimental. Interventions were defined as occupational therapy if explicitly labelled as such or implicitly identifiable as such due to the developer or facilitator being an occupational therapist and/or the underlying theory being drawn primarily from occupational therapy and science literature. Interventions conducted by occupational therapists *or* those from other disciplines were included if the intervention was recognised as a valid occupational therapy intervention. However, interventions that were conducted by an occupational therapist *and* those from other disciplines were considered inter/multi-disciplinary and excluded. Articles reporting protocols and findings were included. Full-text articles available in English were included, no date limits were applied, and no studies were excluded on the basis of quality since one of the review objectives was to provide a description of quality.

4.4.2.3 Quality criteria

To describe the range of trials, and potential moderators of quality (Diaz-Ordaz et al., 2013), data were extracted about the journal, sample and trial design characteristics. To assess the quality of trials five design and analysis recommendations were utilised, as reported and used by Eldridge, Ashby, Feder, Rudnicka, and Ukoumunne (2004) in a systematic review of cluster-RCTs in primary health. The five items were: justifies the use of a cluster design; includes at least four clusters per intervention group; allows for clustering in sample size calculation; uses matching, stratification or an alternative means of reducing chance

imbalances at baseline; and allows for clustering in analysis. Data were extracted to evidence whether or not each recommendation had been satisfied. The original sixth item, 'allows for confounding in analysis' was deemed to be superfluous as there were already recommendations to stratify or match the clusters if potential confounders were predetermined, to account for clustering in the analysis and any further chance confounding would not be specific to the cluster-RCT nature of the design.

To assess the quality of trial reporting, the 12 recommendations from Eldridge et al. (2004) were adopted, which incorporate requirements from the CONSORT extension. Recommendations were: cluster-RCT identified in the title; includes an estimate of an intercluster correlation coefficient (ICC); lists number of clusters randomised; describes baseline comparison of clusters and individuals; lists average cluster size; explains whether analysis is conducted at the cluster or individual level; reports on loss to follow-up of clusters; and reports on loss to follow-up of individuals. The last recommendation from (Eldridge et al.) stipulates reporting loss to follow-up of individuals from *within clusters*. However, a more recent paper is less specific in this regard (Ivers et al., 2011) and the CONSORT extension specifies only reporting of "losses and exclusions for both clusters and individual participants" (Campbell, Elbourne, et al., 2004, p. 10). Therefore, if papers reported on loss to follow-up of individuals *between study arms* then that was considered adequate. Data were extracted to evidence whether or not each recommendation had been satisfied in full, partially or not at all. Furthermore, due to protocol-only reports having limited data available to report, they were reviewed separately with credit given where there was an explicit plan to address the reporting recommendations.

Risk of bias within the trials was assessed using a tool developed by the Cochrane Collaboration to measure low, unclear or high risk of bias within and across trials (Higgins et al., 2011). Data were extracted to evidence these ratings. When the term 'randomised' was absent but a randomisation procedure was referred to, such as 'drawing of lots', this was considered sufficient to confirm a randomisation sequence had occurred. When allocation concealment was difficult to interpret, but it was evident recruitment of individuals within the clusters (not just recruitment of the clusters) was completed prior to randomisation, this was considered a low risk of bias to the trial findings. When therapists providing the intervention were unblinded, but not participants, this was not considered to increase risk of bias as they were part of the intervention. However, when both therapists and participants receiving the

intervention were unblinded, this was considered to contribute to increased risk of bias. Potential risk of bias from incomplete outcome data was considered low if there was limited data loss (<5%) (IBM, 2011), if reasons for missing outcome data were unlikely to be related to the outcome, and if an intention-to-treat (ITT) analysis was conducted.

4.4.2.4 Findings and discussion

Eighteen articles were included reporting on 14 clinical trials from seven different counties, and from a range of allied health, medical and condition-oriented journals (see Figure 2, p. 72). Four were protocols for studies with findings yet to be reported. Studies were published from 2006 onwards, 12 in journals that endorsed the CONSORT statement and 11 studies had statistician involvement (see Table 6 and Table 7, pp. 73-75).

The systematic review identified that occupational therapy researchers have only recently begun to adopt the cluster-RCT design, with trials using this design being conducted and reported only within the last decade and mostly in the last five years (Tokolahi, Hocking, Kersten, et al., 2016). All the studies reviewed post-dated the CONSORT extension, suggesting this may have provided some necessary guidance and direction for researchers. Several interventions were not explicitly labelled as occupational therapy, which creates challenges for combining and reviewing intervention quality and accumulating sufficient evidence of quality to justify occupational therapy interventions. The most common reason stated for selecting a cluster-RCT design was to prevent contamination. Clear justification for the use of a cluster-RCT is important for defending methodological choices and for informing prospective researchers about important considerations of this design (Tokolahi, Hocking, Kersten, et al., 2016).

Describing the baseline comparison between clusters is important for identifying any chance imbalance of confounding factors that could potentially bias the findings (Eldridge et al., 2004). Only five of the 10 full studies reviewed provided this information (Tokolahi, Hocking, Kersten, et al., 2016). It is postulated this omission may have been due to high compliance with the use of stratification or matching to minimise the likelihood of chance imbalances at baseline.

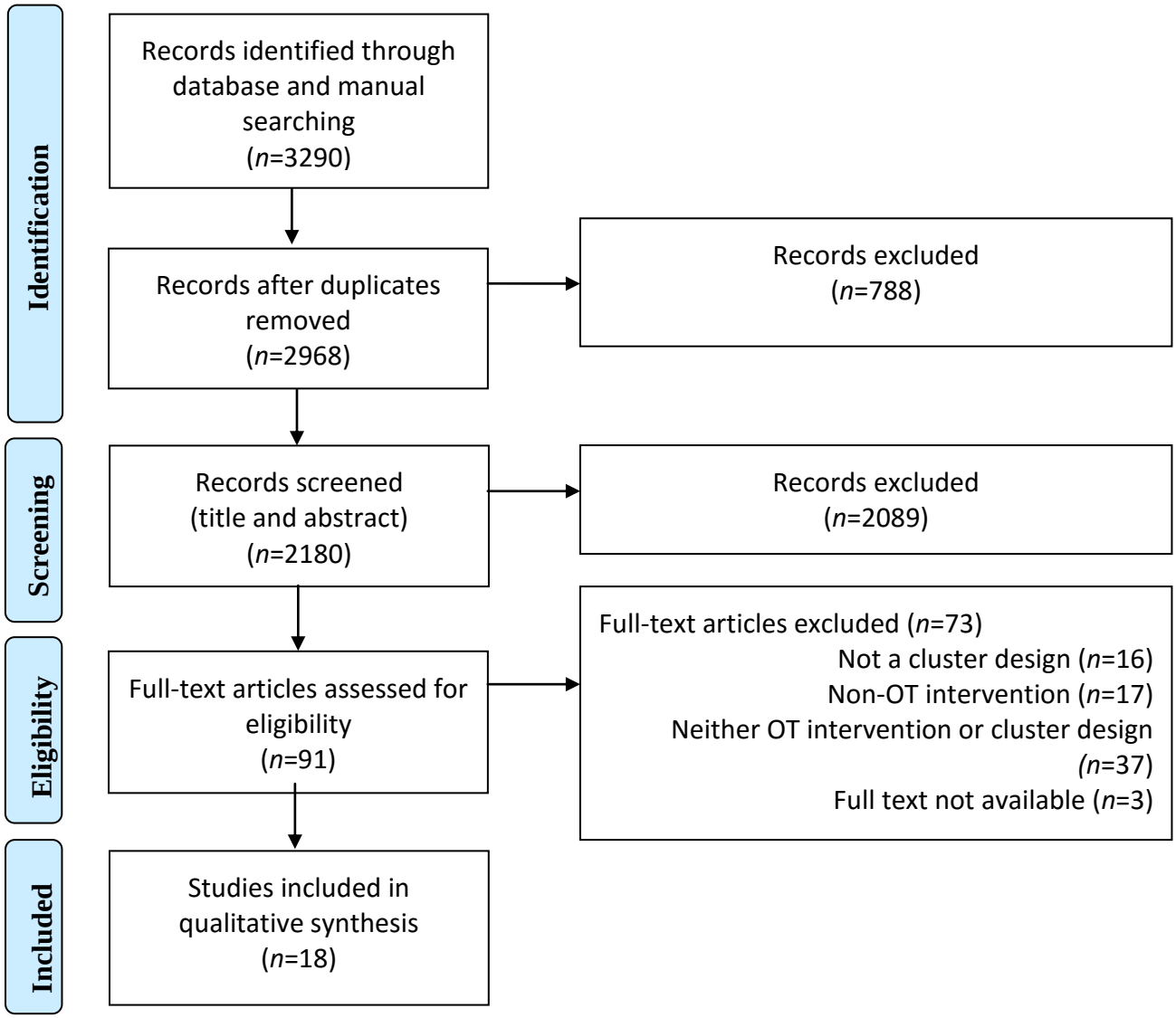


Figure 2: PRISMA flow diagram of the identification process for the sample of 18 articles describing cluster-RCTs included in this review

Table 6: Summary of full studies included in the systematic review and the study characteristics

	Article characteristics				Sample characteristics			Trial design characteristics			
	First Author^	Journal title	Year	Endorsed CONSORT	Location	Clinical problem	Intervention[$]	Cluster units	# Clusters	Cluster size	Statistician involvement
1	Bundy	Australian Occupational Therapy Journal	2013	✓	Australia	Public health Children	Play materials in schools and parent education	Schools	12 (6:6)	18.4*	Yes
	Engelen	Preventative Medicine	2013	✓							
2	Dopp*	BMC Geriatrics	2011	✓	Netherlands	Dementia Older persons	Combined implementation Vs standard COTiD training	Nursing homes; hospitals; mental health services	45 (17 control: 28 intervention)	2.1 *	Yes
	Dopp	Clinical Rehabilitation	2014	✓							
3	Eklund	Scandinavian Journal of Occupational Therapy	2014	✓	Sweden	Mental health Adults	Enriched day programme Vs standard day programme	Psychiatric day centres	8 (4:4)	54?*	No
4	Eyssen	Disability and Rehabilitation	2013	✓	Netherlands	Multiple Sclerosis Adults	Client-centred Vs traditional occupational therapy	Hospital; Rehab centres	13 (7 control; 6 intervention)	19.9*	Yes
5	Law*	BMC Paediatrics	2007	✓	Canada	Cerebral Palsy Children	Child-focused Vs task-focused occupational therapy	Therapist	79	1.8	Yes
	Law	Developmental Medicine and Child Neurology	2011	✓							
6	Mozley	Aging and Mental Health	2007	X	United Kingdom	Depression Older people	Care Home Activity Project	Residential care homes	8 (4:4)	17.9*	No
7	Sackley*	BMC Neurology	2012	✓	United Kingdom	Stroke Adults	Occupational therapy Vs TAU (no occupational therapy)	Stroke-related disability care homes	228 (114:114)	4.6* 4= median	Yes
	Sackley	The BMJ	2015	✓							

8	Sackley	Stroke	2006	✓	United Kingdom	Stroke Adults	Occupational therapy Vs TAU (no occupational therapy)	Stroke-related disability care homes	12 (6:6)	9.8*	Yes
9	Taylor	Clinical Rehabilitation	2012	✓	New Zealand	Stroke Adults	COPM to structure goal-setting Vs traditional goal-setting	Inpatient rehabilitation centres	4 (2:2)	10.3* 9-11.5= medians	No
10	Wenborn	International Journal of Geriatric Psychiatry	2013	X	United Kingdom	Dementia Adults	Enriched day programme	Care homes	16 (8:8)	13.1*	Yes

Notes: * protocol; $versus no intervention unless otherwise stated, ^ alphabetical except where protocol and finding reports are grouped and had different first authors.

Table 7: Summary of protocols included in the systematic review and the study characteristics

	Article characteristics				Sample characteristics			Trial design characteristics			
Study	**First Author**	**Journal title**	**Publication year**	**Endorsed CONSORT**	**Location**	**Clinical problem**	**Intervention[$]**	**Cluster units**	**Number of clusters**	**Cluster size**	**Statistician involvement**
1	Barzel	Trials	2013	✓	Germany	Stroke Adults	HOMECIMT Vs TAU	Practice centres	48 (24:24)	3	Yes
2	Killaspy	BMC Psychiatry	2013	✓	United Kingdom	Mental health Adults	GetREAL staff training	Mental Health Rehabilitation Centres	40 (20:20)	12	Yes
3	McCluskey	International Journal of Stroke	2013	✓	Australia	Stroke Adults	Out and About Programme Vs written clinical guidelines	Community teams	20 (10:10)	15	Yes
4	Tokolahi	BMC Psychology	2014	✓	New Zealand	Public health Children	Kia Piki te Hauora: Uplifting our Health and Wellbeing©	Schools	14 (7:7)	11	Yes

Notes: [$]versus no intervention unless otherwise stated. Abbreviations: TAU=Treatment as usual.

Reasonable quality of the studies reviewed was found, with adherence to quality indicators ranging from 79-86%. The review found over three-quarters of studies accounted for clustering in the sample size calculation (79%), which was a higher proportion than cluster-RCTs conducted over a similar period in other health research (adherence range 36-65%) (Diaz-Ordaz et al., 2013). However, lack of adherence was observed for reporting an ICC or Design Effect (DE), which are required to determine a sample size that accounts for clustering. An ICC is a measure of variability between clusters in a randomised cluster trial and is used in statistical analysis to adjust for variability; a DE is a similar adjustment that is calculated on the basis of the ICC value (Eldridge & Kerry, 2012). Five of the full trials reported an ICC or DE and all of the protocols did. In one protocol the ICC was based on a pilot study (McCluskey et al., 2013); however, for the remainder there was no description of an evidence-based justification for how the ICC had been established. Of the five studies that did not report an ICC or DE, three were pilot or feasibility trials, in which one of the aims was to calculate an ICC for a full trial (Mozley et al., 2007; Sackley et al., 2006; Taylor et al., 2012). Future researchers may benefit from basing their sample size calculations on similar ICCs to those reported in the studies reviewed if the context is similar to their population of interest. There was a wide range of ICCs (0.01-0.37) and the most common ICCs were 0.04 and 0.05. Overall, findings suggested occupational therapy researchers have grasped the importance of ensuring their studies are sufficiently powered for statistical analysis and were largely following recommended guidelines to achieve this.

A priority area for improving future research was accounting for the clustering in the analysis itself, with 79% adherence to this quality criterion falling at the lower range of comparable studies, where adherence ranged between 78-88% (Diaz-Ordaz et al., 2013). Trials most commonly accounted for clustering in the analysis through the use of mixed effects modelling with the cluster as a random effect. One study used tests based on adjusted standard errors (Sackley et al., 2006), which is consistent with the techniques described in a systematic review of cluster-RCTs in stroke (Sutton, Watkins, & Dey, 2013).

All studies reported an average cluster size or provided sufficient information to calculate the average. However, this does not always translate to sufficient information being available to calculate the variation in cluster sizes if these are not fixed. Cluster

size variation is important to consider in relation to sample size as it can significantly impact on the statistical power of data analysed in cluster-RCTs (Eldridge et al., 2006). Stating the range of the cluster sizes and/or providing a coefficient of variation will improve reporting for future studies.

Potential risk of bias in the randomisation process was identified in fewer than half the studies reviewed (43%), primarily due to insufficient information being provided. One of the greatest challenges for occupational therapy, and other complex interventions, is the difficulty of blinding participants and personnel who are actively engaged in the intervention (Eldridge, Ashby, Bennett, Wakelin, & Feder, 2008; Medical Research Council, 2008). The two studies reviewed that overcame this risk either blinded participants to the type of occupational therapy received, client-centred or traditional (Eyssen et al., 2013), or involved only unblinding the cluster guardians who introduced the experimental intervention to therapists as part of implementing best practice guidelines (McCluskey et al., 2013). Participant blinding will continue to challenge researchers of occupational therapy interventions and needs to be acknowledged as a potential bias when the study design cannot overcome this.

Reasonable reporting on loss to follow-up of clusters was found; reporting on loss of individuals between study arms was lower and only one study provided additional information about the loss of individuals from within clusters (Sackley et al., 2015). This additional information is valuable for enabling the reader to understand any patterns or potential bias that may have emerged. For example, if the loss of individuals were all from the same cluster in one arm of the study but evenly spread across the clusters in the other arm.

It is worth noting that while the recommendations that arose from this review were reported separately, on many occasions they were co-dependent. For example, one of the quality recommendations – needing at least four clusters per study arm – was not satisfied in one study due to how randomisation was conducted. Eklund, Gunnarsson, Sandlund, and Leufstadius (2014) reported using drawing of lots – a randomisation procedure with low risk of bias – after combining the eight clusters into two groups and randomising the groups. While the authors acknowledged this was not “strict randomisation” (p. 274), in this systematic review the more significant consequence was on the effective sample size, which became only two clusters (1 per study arm).

4.4.2.5 Limitations of the systematic review

Rigorous searching and data extraction procedures were used to conduct a thorough evaluation of cluster-RCTs evaluating occupational therapy interventions. However, trials not reported as using a cluster-RCT design or as occupational therapy may have been missed. The assessment of trial quality was based solely on information provided in published articles, raising the possibility that omissions were an artefact of limitations in journal space. This may become less of a concern with increasing use of open-access, online journals and publishing of protocols. Open-access journals are still limited in the field of occupational therapy, although many of the articles included were not from occupational therapy-specific journals.

4.4.2.6 Conclusion of the systematic review

Quality of cluster-RCTs of occupational therapy interventions was deemed comparable to those from other areas of health research and to still need improvement. Recommendations considered within the current study, included a need to focus on identifying and justifying the use of a cluster-RCT design and accounting for the clustering in the sample size and analysis. Statistician involvement was associated with better quality and reporting of cluster-RCTs and statisticians were involved in the current study. Increased reporting of ICCs would improve the credibility of published research and aid other researchers in estimating appropriate ICCs for future trials. From this review, it was possible to determine an appropriate range for the ICC to be used in this study. It was also identified as important for researchers to report a comparison of clusters at baseline and provide more detailed information regarding loss to follow-up from within the clusters. To enable systematic reviews and meta-analysis of cluster-RCTs evaluating occupational therapy interventions in the future, more detailed reporting will be required and more interventions must be clearly identified as sitting within the scope of occupational therapy (Tokolahi, Hocking, Kersten, et al., 2016). Therefore, meticulous effort has been made to describe and define the intervention in the current study, in order to facilitate accurate replication in the future (see Chapter 3).

4.5 Chapter summary

This research was designed to answer the question: *Is the school-based, occupational therapy intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) effective at reducing symptoms of anxiety and depression and improving self-esteem and*

participation in children aged 11-13 years? As such, it was situated within the post-positivist paradigm as this question held the assumption that an underlying truth existed that could be discovered through systematic measurement of subjective experiences. The use of a cluster-RCT was deemed the most robust design for evaluating change in a population of school-based children, for whom interactions with each other may have impacted on the outcomes. A systematic review of cluster-RCTs evaluating occupational therapy interventions was conducted and the findings were informative for highlighting design characteristics to focus on in trial design, in order to produce quality research.

Chapter 5: Methods

As outlined in the previous chapter, the current study is situated within a post-positivist paradigm and experimental methodology. The methods utilised within this framework are outlined and justified in this chapter, which describes the design of a cluster-RCT, ethical considerations, the study procedure and statistical analysis plan, and the procedures put in place for monitoring safety.

5.1 Aim

The aim of the current study was to use the rigour of a cluster-RCT to investigate the effectiveness of a preventative occupational therapy group intervention (Kia Piki te Hauora: Uplifting our Health and Wellbeing©) designed to reduce symptoms of anxiety and depression and improve self-esteem and participation in children aged 11-13 years by completion of the intervention and the sustainability of any improvements after a follow-up period of 8-9 weeks.

5.2 Hypotheses

5.2.1 Notation

Descriptions of the notations used are provided here to facilitate interpretation of the equations represented in this thesis.

Table 8: Notation legend

Symbols	Key	Description
q	Outcome measure	Let the superscript q=0,1,2,…,10 denote the outcome measure, with q=1 identifying the MASC-10 primary outcome measure. We also reserve q=0 for the outcome of knowledge about occupation, health and wellbeing
g	Randomisation arm	Let the subscript g=1,2 denote the intervention and waitlist-control groups, respectively
p	Period	Let p=1,2 denote the period, with p=1 corresponding to the parallel period immediately post-intervention and p=2 to the period during which a wait-list control group receives the intervention
tp	Assessment time-point	Let the subscript tp,g=0,1,2 denote respectively the baseline, post-intervention (9 weeks after randomisation) and follow-up assessment time points for (p,g)=(1,1) or (2,2), and t1,2=0,1 denote the baseline and post-intervention assessment time points for the wait-list control group in period 1
s	Cluster	Let the subscript s=1,2,3,… identify the school
i	Participant	Let the subscript i=1,2,3,… identify the individual participant within his or her school s and intervention group g

Let now $Y^{q}_{p,g,t_{p,g},i}$ denote the random measurement of outcome q on participant i in group g at time $t_{p,g}$ in period p and the lowercase version $y^{q}_{p,g,t_{p,g},i}$ the corresponding observed measurements.

5.2.2 Efficacy hypotheses

5.2.2.1 General efficacy model

In the following hypotheses, higher scores represent a favourable outcome. In some cases (e.g. the primary outcome of MASC-10), this direction is reversed (as lower scores indicate lower levels of symptoms), and this fact was taken into account when operationalising the plan. The generic model on which inferences were made was the linear model, adjusted for baseline measurement, given by

$$E[Y^{q}_{p,g,t_{p,g},i}] = \boldsymbol{\theta}^{q\prime}\boldsymbol{x}^{q}_{\boldsymbol{i}} + \alpha^{q}_{t_{p,g}} y^{q}_{p,g,0,i} + \beta^{q}_{p,g,t_{p,g}}$$

(Equation 1)

for p=1,2, g=1,2, and all allowable $t_{p,g}$, where $E[\cdot]$ denotes "expectation" (true mean), $\boldsymbol{x}^{\boldsymbol{q}}_{\boldsymbol{i}}$ is a vector of baseline covariates and $\boldsymbol{\theta}^{q}$ is the vector of coefficients associated with the baseline covariates. Primary and secondary inference targets the $\beta^{q}_{\cdot}$ parameters. Null and alternative hypotheses are denoted H_0 and H_1 respectively.

5.2.2.2 Primary efficacy hypothesis

There will be a difference, in post-intervention child-rated anxiety (primary outcome), self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations, as compared to control period outcomes, when considering only the parallel phase data.

[A] $$\mathrm{H}_0\colon \beta^{\mathrm{q}}_{1,1,1} = \beta^{\mathrm{q}}_{1,2,1} \text{ vs } \mathrm{H}_1\colon \beta^{\mathrm{q}}_{1,1,1} \neq \beta^{\mathrm{q}}_{1,2,1}, \mathrm{q} \geq 1$$

(Equation 2)

5.2.2.3 Secondary efficacy hypotheses

i) There will be a difference in post-intervention child-rated anxiety (primary outcome), self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations, as compared to control period outcomes, when considering both the parallel phase and the crossover phase data.

[B] $\beta^{q}_{2,2,1} = \beta^{q}_{1,1,1} = \beta^{q}_{Tx,1}$ and $H_0: \beta^{q}_{Tx,1} = \beta^{q}_{1,2,1}$ vs. $H_1: \beta^{q}_{Tx,1} \neq \beta^{q}_{1,2,1}, q \geq 1$

(Equation 3)

ii) Longitudinal non-inferiority hypothesis: there will be no marked decrease in favourable outcomes in self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations at follow-up assessment (8-9 weeks post-intervention), as compared to immediately post-intervention.

[C] $\beta^{q}_{2,2,t} = \beta^{q}_{1,1,t} = \beta^{q}_{Tx,t}$ and $H_0: \beta^{q}_{Tx,1} - \beta^{q}_{Tx,2} \geq \delta^{q}$ vs. $H_1: \beta^{q}_{Tx,1} - \beta^{q}_{Tx,2} < \delta^{q}$

(Equation 4)

where $\delta^{q} \geq 1$ is a non-inferiority threshold (non-inferiority thresholds are defined in Table 9, p. 83; and Table 10, p. 85).

iii) Mediation hypothesis: there will be a relationship between change in participant knowledge about occupations, health and wellbeing between pre- and post-intervention and change in the other outcome measures. The mediation model is illustrated in Figure 3 (p. 82) and its analysis detailed in section 5.10.3.

[D]

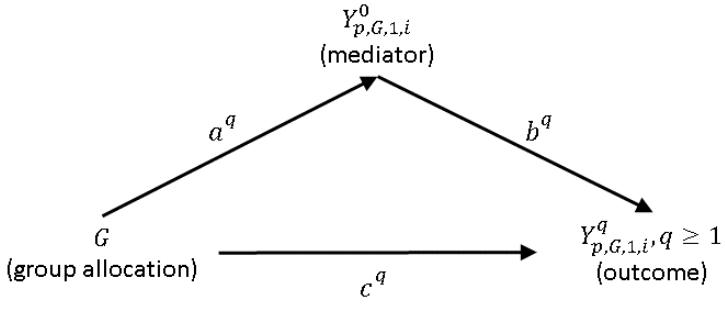


Figure 3: Mediation hypothesis diagram

(Equation 5)

5.3 Outcome measures

Participants completed all outcome measures on three or five occasions, depending on the arm of the trial to which they were allocated (see Figure 5, p. 98). All outcome measures are described in this section.

5.3.1 Primary outcome measure

5.3.1.1 Multidimensional Anxiety Scale for Children – Short form (MASC-10)

The primary outcome for effectiveness of this intervention was the participants' self-rating of anxiety symptoms as assessed with the Multidimensional Anxiety Scale for Children – Short form (MASC-10; see Table 9).

The MASC-10 was selected rather than the full-version (MASC) to reduce the level of burden on participants who were completing a battery of assessments. Alternative measures of anxiety considered were the SCARED (Muris, Merkelbach, van Brakel, Mayer, & van Dongen, 1998), the Revised Children's Manifest Anxiety Scale (RCMAS) (Reynolds & Paget, 1981) and the Spence Children's Anxiety Scale (SCAS) (Spence, 1997). The SCARED has been shown to discriminate between children with and without anxiety disorders – however, does not have a satisfactory factor structure in the general population (Muris, Merckelbach, Schmidt, & Mayer, 1998).

Table 9: Primary outcome measure

Construct	Measure	Description	Scoring	δ^q
Anxiety	Multidimensional Anxiety Scale for Children – Short form (MASC-10) (March, 1997)	Self-rated questionnaire with 10 items measuring the child's thoughts and emotions, specifically related to anxiety. Items were rated on a 4-point Likert scale.	Raw scores are converted to *t*-scores (0-100) adjusted for age and gender. Higher scores indicate higher level of symptoms. <45: below average; 45-55: average; 56-60: slightly above average; 61-65: above average; 66-70: much above average; ≥70: very much above average.	-2.5

Note: δ^q= Non-inferiority threshold[3].

Perrin and Last (1992) demonstrated that the RCMAS, developed on older criteria, could not discriminate between children with varying clinical conditions, suggesting it may not measure a distinct construct but taps into a range of symptoms that add up to a clinical level of dysfunction. While the SCAS is reported to have adequate internal consistency (0.6-0.82), the test-retest reliability was unsatisfactory (Spence, 1998). The MASC-10 was deemed the superior option; it is often the measure that newly developed

[3] 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.

instruments are evaluated against (Muris, Gadet, Moulaert, & Merckelbach, 1998). Its psychometric properties are described below.

The MASC and the MASC-10 are the most widely used measures of anxiety in research with children and the psychometric properties of the MASC-10 have been well researched. In a community sample of 142 children aged 8-18 years, March and Sullivan (1999) found the test-retest reliability of the MASC, over a 3 week period, to be moderate to excellent. Single ICC-means ranged from .78-.88, $p<.001$, where an ICC over .60 is considered satisfactory and over .80 considered excellent (Eldridge & Kerry, 2012). The shorter MASC-10 was also tested at this time and found to have comparable psychometric properties (test-retest reliability of .75-.86, $p<.001$). Test-retest reliability was found to be unaffected by age or gender but was slightly less for an African-American population compared to their white peers. Baldwin and Dadds (2007) also reported good internal reliability of the MASC with a community sample of 499 Australian children aged 8-13 years. Internal consistency was demonstrated to be excellent in a smaller sample of 9-13 year olds ($n=108$, Cronbach alphas of .70-.85 for subscales and .89 for total) (Muris, Gadet, et al., 1998).

Birmaher et al. (1997) demonstrated good discriminant validity with clinical and community populations, which was further support by Myers and Winters (2002) concluding that the MASC has moderate to good validity. They found the MASC to have strong convergent validity supported by its relatively low correlation with the Child Depression Inventory, despite symptoms of anxiety and depression typically overlapping (Myers & Winters). The MASC was shown to have a strong correlation with the SCARED ($r=.72$, $p< .001$) (Muris, Gadet, et al., 1998), to be sensitive to treatment effects, and the current cut offs were able to discriminate anxious children from non-anxious children, with around 88% accuracy (Birmaher et al., 1999; Myers & Winters, 2002).

5.3.2 Secondary outcome measures

Secondary outcomes included child, parent- and teacher-rated symptoms of the child's anxiety, depression, self-esteem, participation in daily occupations, life satisfaction and wellbeing as well as the child's knowledge about occupations, health and wellbeing (see Table 10).

Table 10: Secondary outcome measures

Construct	Measure	Description	Scoring	δ^q
Child-rated measures				
Depression	Children's Depression Index -2 – Self report [short form] (CDI2) (Kovacs, 2011)	Self-rated questionnaire with 12 items measuring the child's thoughts and emotions, specifically related to depression. Each item has three statements and participants select the one that best describes their own experience.	Raw scores are converted to *t*-scores (0-100) adjusted for age and gender. Higher scores indicate higher level of symptoms. <40: below average; 40-59: average; 60-64: high average; 65-69: elevated; ≥70: very elevated.	-2.5
Self-esteem	Rosenberg Self Esteem Scale (RSES) (Rosenberg, 1965).	Self-rated questionnaire with 10 items measuring the child's thoughts about their own abilities and self-worth. Items are rated on a 4-point Likert scale.	Strongly agree (3); Agree (2); Disagree (1); Strongly disagree (0); except items 2,5,6,8,9, which are reverse scored. Total score range 0-30. Higher scores indicate higher level of self-esteem.	1
Participation	Canadian Occupational Performance Measure (COPM)(Law et al., 2005)	Measures self- reported ability to participate in daily activities and satisfaction with one's ability to participate in those daily activities. Two activities are chosen that the individual would like to improve on from a menu of activities pertinent to the intervention goals (see Appendix 4).	Ability and satisfaction are rated on a 10-point Likert scale from 1 to 10 (1=*not at all able* or *not at all satisfied*; to 10=*very able* or *very satisfied*). Performance and satisfaction scores are averaged over both activities and analysed separately. If only one is available, then that one is used. Note: This outcome was singled out for Per Protocol analysis.	2
Wellbeing	Student's Life Satisfaction Scale (Huebner, 1991b)	Self-rated questionnaire with five items measuring a child's sense of wellbeing and life satisfaction. Items are rated on a 5-point scale.	Strongly agree (4); Agree (3); Neither agree or disagree (2); Disagree (1); Strongly disagree (0); except item 3, which is reverse scored. Total score range 0-20. Higher scores indicate higher level of wellbeing and life satisfaction.	1.03

Parent-rated measures				
Anxiety and depression	Revised Child Anxiety and Depression Scale – Parent report, short version (RCADS) (Weiss & Chorpita, 2011) Modification of original measure.	Parent-report questionnaire with 25 items measuring their child's anxiety and depression. Items are rated on a 4-point Likert scale. Original scale had 42 items and this was reduced to the 25 items consistent with the short version of the children's RCADS, in order to minimise the burden on parents and increase the response rate.	Never (0); Sometimes (1); Often (2); Always (3). Scores range from 0-75 with higher scores denoting more symptoms present. Raw scores are converted to *t*-scores (0-100) adjusted for age and gender, specifically for Generalised Anxiety (GA) and Depression (D): <65=non-clinical; 65-69=borderline; >70=clinical.	-2.5
Self-esteem	Single Item Self-Esteem Scale (SISES) (Robins, Hendin, & Trzesniewski, 2001).	Single item parent-rated questionnaire that measures the parent's general evaluation of the child's self-esteem. Parents rate a single 5-point Likert scale.	Scored on a scale from not very true (1) to very true (5). Higher scores indicate higher level of self-esteem.	0.2
Participation	Canadian Occupational Performance Measure (COPM)-modified (Law et al., 2005)	Measures parent- report of child's ability to participate in daily activities and satisfaction with child's ability to participate in those daily activities. Rates the two activities chosen by the child that they would like to improve on from a menu of activities pertinent to the intervention goals.	Ability and satisfaction are rated on a 10-point Likert scale from 1 to 10 (1=not at all able or not at all satisfied; to 10=very able or very satisfied). The performance and satisfaction scores are averaged over both activities and analysed separately. If only one is available, then that one is used.	2
Teacher-rated measure				
Anxiety	School Anxiety Scale (SAS) (Lyneham, Street, Abbott, & Rapee, 2008)	Teacher-rated questionnaire with 16 items that measure the level of anxious behaviours a child is displaying. Behaviours are rated on a 4-point Likert scale.	Never (0); Sometimes (1); Often (2); Always (3). Scores range from 0-48 with higher scores denoting more behaviours present. Scores for items 3,5,7,8,9,10,12,15,16 = subscale for generalised anxiety. Scores for items 1,2,4,6,11,13,14 = subscale for social anxiety (SA).	Total -1.69 GA -0.99 SA -0.89

Note: δ^q= Non-inferiority threshold.

5.3.2.1 Measures of anxiety and depression

5.3.2.1.1 Child Depression Inventory 2nd edition: Self Report [Short form] (CDI2)

The Child Depression Inventory 2nd edition: Self Report [Short form] (CDI2) was selected as the measure of child-reported depression symptoms, rather than the full version, to minimise the burden on participants who were completing a battery of assessments. In a previous study the CDI2 was shown to be comparable to the full-version in discriminating between depressed and non-depressed children with high sensitivity and slightly lower specificity (Allgaier et al., 2012). Furthermore, the CDI2 was chosen as having sound psychometric properties, being widely used in research with children (Kovacs, 2011; Simmons, Wilkinson, & Dubicka, 2015) and being one with which I was familiar. Furthermore, the short version items were found to be more acceptable in school-settings due to the removal of the controversial item "I want to kill myself" (Kovacs, 2011). The CDI2 was reported as sufficiently sensitive to measure changes over time and following an intervention (Simmons et al., 2015). Test-retest reliability was found to be excellent and the evidence available during the design stage of this research found the internal consistency of the CDI2, as reported by the developer, to be acceptable (Cronbach's alpha of .82) (Kovacs, 2011). The discriminative validity of the CDI2 was demonstrated to be strong (Kovacs, 2011) and was supported by moderate correlations with the Beck Depression Inventory (r=.54, p<.001) (Kim et al., 2014) and strong correlations with the Depression Self-Rating Scale for Children (r=.75, p<.01) (Birleson, 1981).

5.3.2.1.2 Revised Child Anxiety and Depression Scale – Parent report, short version (RCADS)

The RCADS is a 25-item parent-report questionnaire of their child's anxiety and depression. This is a modification of the published tool, which is available as either a self-report 25 item questionnaire or a parent-report 47 item questionnaire (Ebesutani et al., 2010; Ebesutani et al., 2012). While there was no published evidence on the psychometric properties of the 25-item version for the parent-report measure, the items chosen were taken directly from the original parent-report version (Ebesutani et al.; Ebesutani et al., 2011; Ebesutani, Tottenham, & Chorpita, 2015) and mirror those used in the 25 item self-report measure. The items from the full version are divided into six DSM-related subscales (Ebesutani et al., 2010) and the selected items on the shortened version map onto the subscales for generalised anxiety and depression, so that age and

gender adjusted *t*-scores can still be calculated for these subscales. The RCADS generalised anxiety (GA) subscale has been demonstrated to have a high magnitude of correlation with the MASC (.86, $p<.001$) (Kaat & Lecavalier, 2015), which was the child-rated measure of anxiety in the present study. Internal consistency of the GA ($\alpha=0.88$) and depression ($\alpha=0.83$) subscales were found to be good; furthermore, the RCADS was shown to discriminate between children with and without disorders and between children with symptoms of anxiety and those with depression (Ebesutani et al., 2010). The decision to modify the measure in this way, for the current study, 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 the reduction in reliability and validity of the measure.

5.3.2.1.3 School Anxiety Scale (SAS)

In a review of the literature Lyneham et al. (2008) found no instruments available to measure child anxiety as observed in a school setting by teachers. Subsequently, they developed the SAS based on items from the Spence Children's Anxiety Scale (SCAS) (Spence, 1998) and evaluated the SAS as a viable option. In a community sample of 240 children aged 5-12 years and a clinical sample of 140 children aged 6-12 years and diagnosed with anxiety ($n=380$), the SAS was demonstrated to have good reliability and internal consistency. Cronbach alpha coefficients of .93 for the total subscale; .90 for the GA subscale and .92 for the social anxiety subscale were found (Lyneham et al., 2008). Satisfactory internal consistency was also found for an Iranian translation of the tool, which was reported to have alpha coefficients of .81, .70, and .92 respectively (Hajiamini et al., 2012). In the study by Lyneham et al. (2008), repeated administration of the SAS after an 8 week period, in the community sample, found satisfactory test-retest reliability across the subscales (*ICC*=.73-.81). Similar results were reported by Hajiamini et al. (2012) with their sample of 200 children aged 6-10 years who reported ICCs of .70-.92 after a four week period. Overall, the SAS was shown to be a reliable and stable measure of teacher-rated child anxiety.

Hajiamini et al. (2012) reported good content validity for the Iranian translation of the SAS and factor analysis confirmed the bi-factor model of the scale: GA and social anxiety. The convergent validity of the SAS total score was demonstrated by significant correlations with the emotional symptoms subscale on the parent-rated Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997) (Pearson correlation coefficient of

.76, $p<.01$) and the social phobia scale on the parent-rated SCAS (Pearson correlation coefficient of .35, $p<.01$) (Lyneham et al., 2008). No significant correlations were found between the SAS and the child-rated SCAS, which is consistent with other research into agreement between multiple informants and highlights the need for collecting data from multiple sources (De Los Reyes & Kazdin, 2005; Lyneham et al., 2008).

When compared to the rate of diagnoses made using an established diagnostic interview, the Anxiety Disorders Interview Schedule for DSM-IV, the SAS was found to correctly identify nearly 70% of anxious children (Lyneham et al., 2008). This level of accuracy is significantly better than the correct identification rate found for the emotional symptoms subscale on the SDQ (less than 20%); however, comparisons should be made tentatively as this study used a different measure, the Development and Well-Being Assessment (DAWBA), for confirming psychiatric diagnoses (Goodman, Ford, Simmons, Gatward, & Meltzer, 2000). As a measure of diagnostic accuracy the DAWBA is gaining emerging support (Simmons et al., 2015). As the community sample in the current study were not assessed for the presence of an anxiety disorder the rate of misclassification will not be reported.

5.3.2.2 Measures of self-esteem

5.3.2.2.1 Rosenberg Self Esteem Scale (RSES)

The Rosenberg Self Esteem Scale (RSES) was selected as the measure of self-esteem (Rosenberg, 1985). It is well established and has previously been used as the measure against which newly developed tools were evaluated (Robson, 2009). There has been some debate regarding whether the RSES is unidimensional, has two factors or is multi-dimensional (Fleming & Courtney, 1984; Owens, 1994; Richardson, 2009; Supple, Su, Plunkett, Peterson, & Bush, 2012). The balance of evidence suggests it is appropriate to be interpreted as unidimensional, which is how it is managed in the current study. The RSES was reported to have 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). Moderate to high internal consistency of the RSES has been reported in adolescents as demonstrated by Cronbach alpha coefficients between .79-.86 (Supple et al., 2012) and adult samples with Cronbach alpha coefficients ranging between .76-.88

(Curbow & Somerfield, 1991; Fleming & Courtney, 1984; Richardson, 2009; Robins et al., 2001; Schmitt & Allik, 2005; Torrey et al., 2000). A study was conducted that compared adolescent (12-17 years) and adult (18-64 years) ratings on the RSES. Strong tests of factorial invariance indicated the scale was comparable for use with adolescents and adults (Whiteside-Mansell & Corwyn, 2003).

In a study involving 259 first year university students, with a mean age of 19 years, Fleming and Courtney (1984) reported the RSES to have good construct validity, with its concept akin to their concept of self-esteem (r=.66, p<.001) and self-regard (r=.78, p<.001). More modest correlations were found with social confidence (r=.51, p<.001), school abilities (r=.35, p<.001), physical appearance (r=.42, p<.001), and physical abilities (r=.42, p<.001). Further support for construct validity was demonstrated by correlations of low self-esteem as measured by the RSES with symptoms of depression (Owens, 1994); a range of psychiatric conditions (p<.001) as measured by the Brief Psychiatric Rating Scale (Torrey et al., 2000); and inverse correlations of positive self-esteem as measured by the RSES with anxiety (-.36, p<.01) and negative affect (-.54, p<.01) (Richardson, 2009). Schmitt and Allik (2005) reported finding the validity of the RSES to be psychometrically sound in their sample of 16,998 college students from 53 nations; and Westaway, Jordaan, and Tsai (2015) also reported the RSES as suitable for use with culturally diverse populations. In a younger population (mean age of 14 years), Phillips et al. (2013) found the RSES to be a valid measure of wellbeing in children and several of the items were predictive of self-harm in the future.

Evidence the RSES is sensitive to change in children, following interventions, is limited (Blascovich & Tomaka, 1991; Bowling, 1991). In a study evaluating a life-skills promotion intervention for girls predisposed to eating disorders, the RSES was used as a measure of global self-esteem (McVey, Davis, Tweed, & Shaw, 2004). The sample was 258 girls with an average age of 11.18 years and measured a significant Time X Group interaction effect of the intervention on self-esteem (F (3, 564) = 2.75, p = .04) at post-intervention, which was 1 week after the 6 week intervention had ended. Torrey et al. (2000) suggested that the RSES was an effective measure of change following an intervention; however, the individual score interpretations were not necessarily clinically meaningful, therefore, cut-off scores indicating distinct levels of self-esteem are not employed.

5.3.2.2.2 Single Item Self-Esteem Scale (SISES)

The SISES is a single item parent-rated questionnaire that measures parents' general evaluation of their child's self-esteem. The SISES was found to be more reliable when used as a parent, than a child report measure (alpha coefficients of .84 and .77 respectively) (Robins et al., 2001). Robins et al. (2001) reported a moderate correlation between the SISES and the Global Self Esteem scale on the Self Perception Profile for Children (*rs*=.52). This correlation was notably lower than those found with adults, further supporting the recommendation that the SISES may be more valid for use with adults than children (Robins et al., 2001). To date, no evidence has been found on the sensitivity and specificity of this measure.

5.3.2.3 Measures of participation

5.3.2.3.1 Canadian Occupational Performance Measure (COPM): Child- and parent-rated

The Canadian Occupational Performance Measure (COPM) was selected as a measure of child participants' self-evaluation of their performance and satisfaction with daily occupations they want to, need to, or are expected to, participate in (Law et al., 2005). Parents were also asked to complete the COPM and rate their perception of their child's performance and satisfaction with daily occupations. The COPM is a client centred measure "recommended as a systematic approach to identify issues and determine client progress in occupational therapy" (Colquhoun, Letts, Law, MacDermid, & Missiuna, 2012, p. 120). It is an explicit measure of occupational performance and reported to facilitate the generation of realistic and client-centred goals (Chen, Rodger, & Polatajko, 2002; Colquhoun, Letts, Law, MacDermid, & Edwards, 2010). The COPM has been used in a large number of studies as the outcome measure for therapy effectiveness as well as being the standard against which the validity of other disease specific measures of client-centred occupational performance have been compared (Carswell et al., 2004).

In order 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. The parent forms were pre-printed with the two items from the menu chosen by their children in order to enable comparison between the child- and parent-rated scores on the same outcomes. Previous modifications 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). The use of 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 was reported as a valid, reliable and clinically useful outcome measure for clinicians and researchers (Carswell et al., 2004). Strong test-retest reliability was reported in the COPM manual (Law et al., 2005). This was supported by later studies reporting correlation coefficients of 0.89 ($p<0.001$) for performance ratings and 0.88 ($p<0.001$) for satisfaction ratings in a Dutch version of the COPM when re-administered after a 1 week period (Cup, Reimer, Thijssen, & van Kuyk-Minis, 2003) and intra-class coefficients of 0.81 ($p<0.001$) for performance ratings and 0.76 ($p<0.01$) for satisfaction ratings (Sewell & Singh, 2001). In a systematic review of the literature on the psychometric properties of the COPM, Carswell et al. (2004) summarised that it was found to have sound construct and criterion validity across a range of populations. Of the 11 articles reviewed that assessed the COPM validity, only one focused on its use with children and none reported a sample with mental health issues or a community sample (Carswell et al., 2004). The COPM has demonstrated sensitivity to change in client outcomes (Carswell et al., 2004; Eyssen et al., 2011; Law, Anaby, Imms, Teplicky, & Turner, 2015).

5.3.2.4 Measure of wellbeing

5.3.2.4.1 Student Life Satisfaction Scale (SLSS)

The Student Life Satisfaction Scale (SLSS) was initially intended for use in large-scale surveys of children's wellbeing and was used in the present study as a concise measure of children's perception of their global wellbeing (Huebner, 1991b, 1994). Adequate internal consistency (alpha coefficient .82) and moderate test-retest reliability of the SLSS, at 2-weeks (.74) (Huebner, 1991b) and 4-weeks (.64) (Gilman & Huebner, 1997) were demonstrated. The ratings on the SLSS were shown to be positively correlated with positive life events, internal locus of control (Ash & Huebner, 2001), global self-esteem (Dew & Huebner, 1994) and negatively correlated with neuroticism (Fogle, Huebner, & Laughlin, 2002), anxiety (Huebner, Drane, & Valois, 2000) and depression (Huebner & Alderman, 1993). The SLSS ratings were shown to differentiate from those

of affect (Huebner, 1991a, 1991b) and self-esteem (Terry & Huebner, 1995). The Children's Society (2012) and The New Economics Foundation (2012) evaluated a range of evidence for better understanding children's wellbeing and how to measure it: the SLSS was identified as a first step to achieving this and is purported to be sufficiently sensitive to measure changes over time (Huebner, 2004).

5.3.3 Mediator

5.3.3.1 Measure of knowledge change

A knowledge survey was developed for the current study with specifically constructed items and focused on the content of each session from the intervention (see Appendix 5). Sub-sets of questions pertinent to the session content were completed at the start of each session and the full set of questions were repeated during the final session of the intervention (see Table 11). Trialling of the intervention and this survey resulted in the removal of fill-in-the-blank formats as these were poorly received and understood. Questions with multiple-choice or True/False response options were most readily accepted during the trialling and thus used in the final survey.

Table 11: Mediation outcome measure

Construct	Measure	Description	Scoring
Knowledge	Knowledge survey	Seven sets of two-three questions - one set for each week - in multiple choice and True/False formats. Measured change in participant knowledge of concepts and strategies covered in the intervention.	One point was allocated for each correct answer (some questions could achieve more than one point if more than one answer could be selected) with a total possible score of 26. Higher scores indicated greater knowledge.

5.3.4 Baseline covariates

Socio-demographic data consisting of age, gender, total-response ethnicity, and year of education were collected at baseline. To accommodate total response ethnicity (participants being able to select more than one ethnicity with which they identified), non-mutually exclusive indicator variables for each of Māori, Pasifika, Asian and European-and-others were created. This indicator variable enabled participant data to be modelled more efficiently, in order to determine separate effects for each ethnicity. The decile category of the school was also collected. The decile categories used to stratify randomisation were "Low", "Medium" and "High". Since only two schools were randomised in the "Medium" category, the first two categories were aggregated to a

single “Low/Medium” level. The aggregation was carried out to uphold balance between the two resulting strata.

5.4 Interventions

5.4.1 Experimental intervention

The intervention was a manualised, occupational therapy group intervention, Kia Piki te Hauora: Uplifting our Health and Wellbeing©, which is described in Chapter three and summarised in Tokolahi, Hocking, and Kersten (2016) (see Appendix 3). The intervention ran for 1 hour a week over a period of 8-weeks of a 10-week school term. Occupational patterns addressed included participation in sleep occupations, active occupations, communication, the impact of occupational disruption and occupation-based strategies for coping. Outcomes were measured at the individual level although the intervention was provided in a group context.

5.4.1.1 Treatment fidelity

Treatment fidelity was scored by the facilitator using a fidelity implementation checklist based on those designed and used by Forgatch et al. (2005). The checklist records delivery of the intervention and student responsiveness per session. Each achieved item scores 1, giving a total possible score of 14 per session or 112 per cluster (Table 12, p. 95). Participant fidelity was measured through attendance and completion of homework tasks.

5.4.2 Waitlist-control

The waitlist group did not receive any input during the parallel component of the trial and only completed 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.

Table 12: Intervention fidelity checklist

Intervention component	**Achieved (Y/N)**
Adherence	
Objectives and plan posters up	
Key purpose identified (verbal)	
Activities conducted	
Materials used	
Key messages reviewed (quiz)	
Duration and exposure	
Between 55-60 minutes spent on session content	
Quality of delivery	
Facilitator comes prepared	
Facilitator encouraging and enthusiastic	
Explicit instructions given	
Constructive and positive feedback to students given	
Pacing and transitions effective	
Programme specificity	
Adheres to activities as designed	
Shows knowledge of content and intervention strategies	
Student responsiveness	
Most students are actively engaged or willingly compliant	
Total score = total number of 'Yes's (max 14)	

5.5 Trial design

This trial was a two-arm, pragmatic, cluster-RCT in which schools were the unit of randomisation (see Figure 4, p. 96). This trial was pragmatic as it measured the effectiveness of an intervention in real clinical practice rather than under ideal conditions (Godwin et al., 2003). The trial employed an open-label, repeated measures, parallel and one-way crossover design. Analysis of the parallel phase of the trial compared post-intervention and post-waitlist outcomes for participants based on their allocation immediately following randomisation (i.e. intervention or waitlist-control, respectively). One-way crossover occurred when children allocated to the waitlist crossed-over to start receiving the intervention after a set time. Analysis of the crossover phase combined data from the parallel phase with data from participants allocated to the waitlist-control who later went on to receive the intervention. The analyses of crossover phase data did not enter into the primary analyses. Children were clustered naturally by school and this design prevented contamination between trial arms (intervention and waitlist).

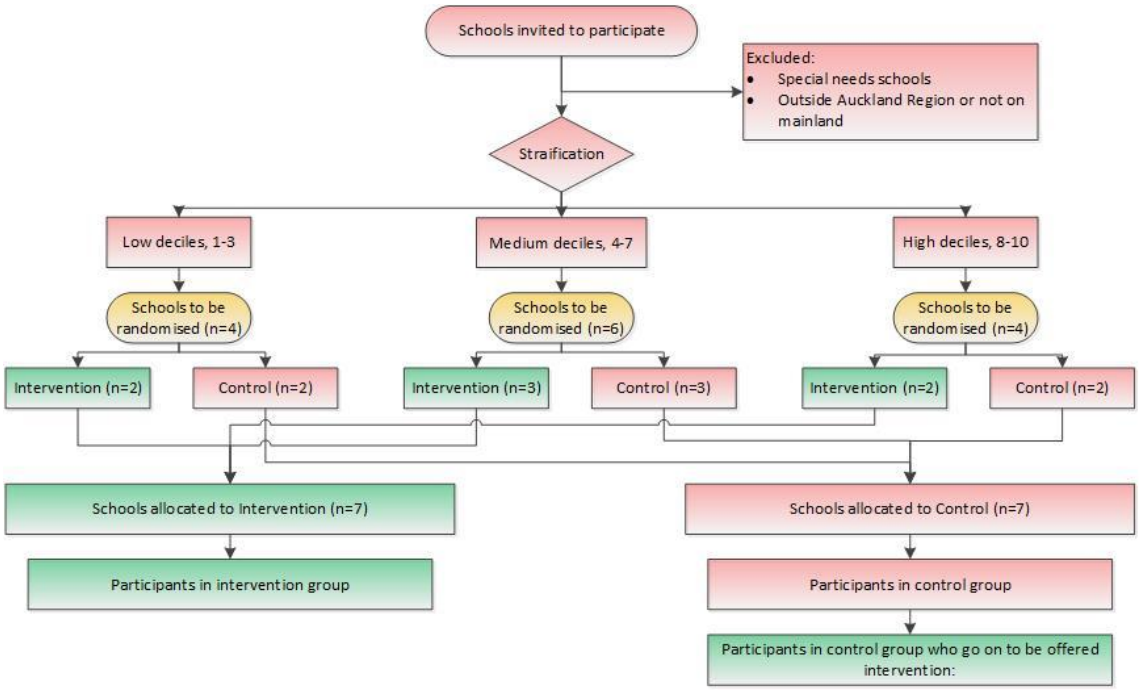


Figure 4: Planned study flow diagram

5.6 Participants

5.6.1 Cluster participants

In Aotearoa New Zealand, intermediate school is a 2-year segment in years 7-8 of a child's academic education between primary and secondary schools. Across 13 electoral wards within the Auckland Region, the Ministry of Education identified 253 schools providing education to over 42,000 intermediate students in 2013 (Ministry of Education, 2013a, 2013b). School types that incorporate the intermediate years include full primary (Years 1-8), stand-alone intermediate schools (Years 7-8) and composite schools (Years 1-13). The Ministry of Education has typically grouped the deciles into broader categories for research purposes: low (deciles 1-3), medium (deciles 4-7) and high (8-10) (Ward & Thomas, 2013). While the decile rank of a school does not necessarily reflect the socio-economic status of the students on its roll, nor the quality of the school, it does enable the government to target funding and enable schools to minimise barriers to learning that children from low socio-economic communities may face. From a research perspective, obtaining a sample of schools from a range of decile ranks was important for ensuring the student population were representative of the general population.

Each cluster was a discrete school providing education to students aged 11-13 years from the Auckland Region. Schools were recruited and stratified by decile, in order to achieve a representative proportion of schools across deciles groupings.

5.6.1.1 Cluster inclusion criteria

- School provided education for Year 7 & 8 students.
- School was located in Auckland region.
- The school's principal consented to participate.

5.6.1.2 Cluster exclusion criteria

- School provided education exclusively for special needs group e.g. English for Speakers of Other Languages (ESOL) school, schools for children with intellectual disabilities.
- School was located outside of Auckland region or not on the mainland.

5.6.2 Individual participants

Participants were children, aged 11-13 years and enrolled in Years 7 or 8 at one of the clusters recruited. Students were nominated by school personnel or the research and intervention were presented to the children in a school assembly and they volunteered. In order to minimise stigma potentially associated with the intervention, sometimes students generally perceived as 'role models' were also included, so the group would not be perceived as just for the shy or naughty children. Role models were not explicitly identified as such, not even to the facilitator, so as not to inadvertently signal the at risk students as being such. Participating children generally presented with symptoms of anxiety or depression, low self-esteem or low levels of participation in typical school-based occupations, as determined by the judgements of school personnel. Repeated measures were taken from the same participants at multiple time points to determine how the intervention changed individual-level outcomes (see Figure 5, p. 98).

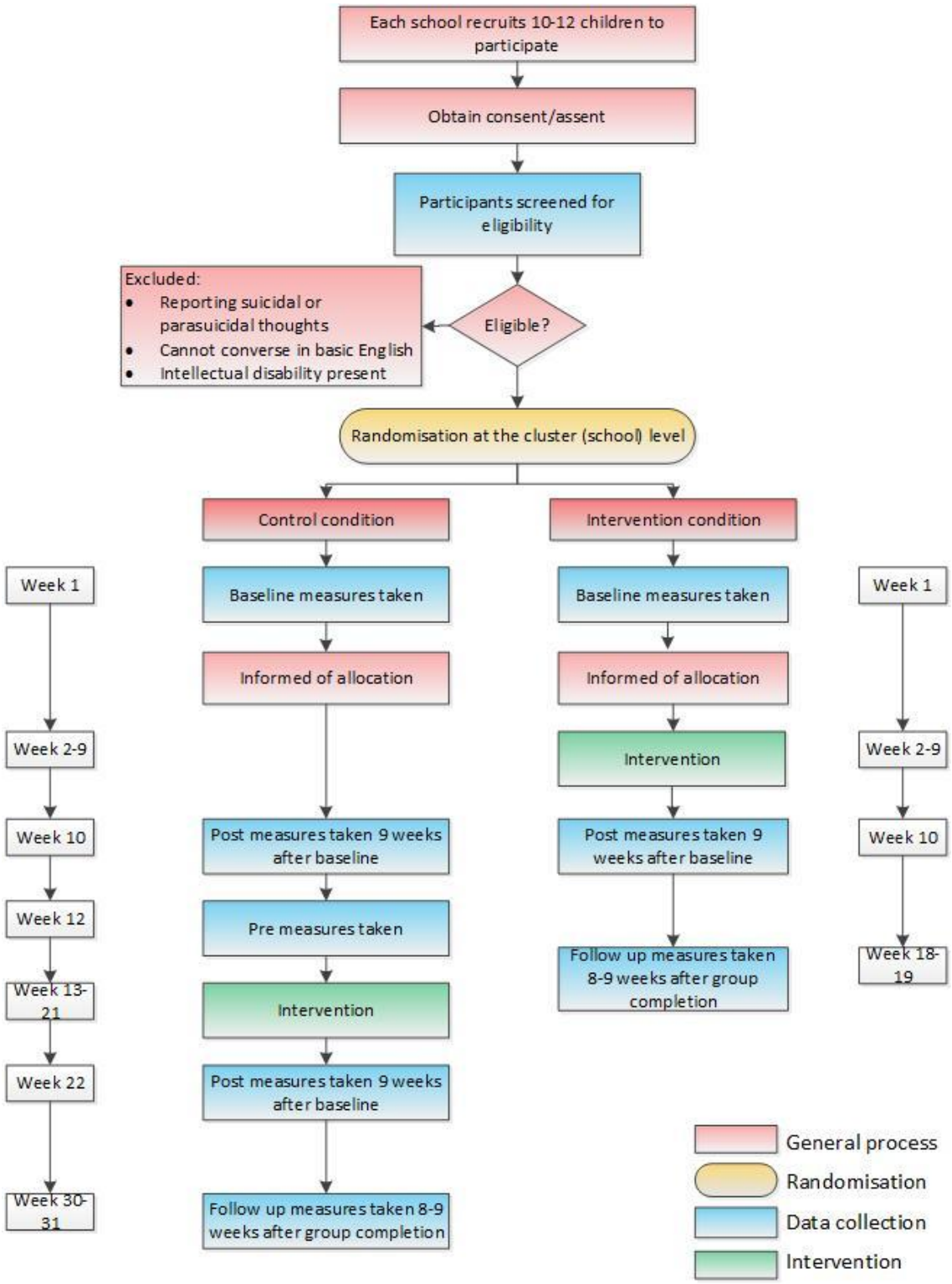


Figure 5: Participant flow diagram

5.6.2.1 Participant inclusion criteria

- Aged 11-13 years
- Able to converse in basic English
- A mainstream student (i.e. no intellectual disability)

5.6.2.2 Participant exclusion criteria

- Participant self-, teacher- or parent-report indicated suicidal or para-suicidal thoughts/behaviours
- Participant was already involved with secondary mental health services to address anxiety or depression

The plan was to exclude students from the study if it was identified that their needs were sufficiently high to warrant more intensive support. These students would have been identified through self-reporting of the above exclusion criteria and would then have been given information about relevant support services in their area, compiled by a clinician familiar with child and adolescent mental health services, and a referral made, where appropriate, by the intervention facilitator. No students were excluded from this study on the basis of these criteria.

5.7 Ethics and registration

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 (see Appendix 6 and Appendix 7).

5.7.1 Commitment to the principles of the Treaty of Waitangi

As the current study was conducted in Aotearoa New Zealand, it was important to demonstrate active commitment to the principles of the Treaty of Waitangi, outlined by the Health Research Council of New Zealand (2010). The core principles of the Treaty of Waitangi guide legislation, healthcare and research in Aotearoa New Zealand and are represented by the terms: partnership, participation and protection. While this study did not target Māori populations specifically, children who identified as Māori were part of the sample population. Given health disparities between Māori and non-Māori in Aotearoa New Zealand, it is important to ensure the mental health and wellbeing needs

of Māori are actively targeted. In the current study, the adoption of a Te Reo Māori[4] name for the intervention and inclusion of Māori-inspired artwork in the intervention materials were specifically intended to be inclusive of Māori cultural meanings and aesthetics and appeal to children who identified as Māori.

5.7.1.1 Partnership with Māori

In this study, benefits were anticipated for all children, regardless of ethnicity. Culturally safe practices were included in the study process and intervention. To ensure this, consultation was conducted in partnership with Māori and Pacific cultural advisers, from mental health service settings, to review the cultural sensitivity of the intervention and the study process. As a direct result of this consultation a number of components of the intervention were modified and are described in Chapter three.

5.7.1.2 Participation of Māori

Ethnicity was neither an exclusion or inclusion criteria for this study and although Māori children were not directly targeted by this intervention it was intended to be beneficial for children from a range of backgrounds and ethnicities. Key stakeholders for this study (children, parents, teaching staff, Māori cultural advisors, and occupational therapists) participated in a consultation process during the design of the intervention and the research study. The intervention was gifted the name, Kia Piki te Hauora: Uplifting our Health and Wellbeing©, by Māori cultural advisors consulted during the intervention development. The intervention name and materials, which used multicultural imagery, were used with the intention to increase the appeal to participants from a range of backgrounds. The study was reviewed by a Māori cultural advisor who expressed confidence that it was sensitive to the cultural needs of Māori participants and their whānau[5]/family. Children, and their whānau were encouraged to all participate in the decision-making process regarding whether or not they took part in the study – they were invited to do this in the 'participant information sheets'. In order to promote participation of populations potentially hindered by lower levels of literacy (e.g. Māori, Pacific, immigrant populations; Statistics New Zealand, n.d.) a freephone number was provided for participants to contact the researcher directly to ask questions; and the options of completing outcome measures over the phone or in person were also

[4] Te Reo Māori is the Māori language.

[5] Whānau is a Māori term for family that is typically more inclusive and extended than the traditional Western definition of family.

available. Two participating parents opted to complete the outcome measures over the phone and on 4-5 occasions parents used the freephone number to ask practical questions about their surveys, such as clarifying timeframes for returning these or checking the return address when their child had lost the stamped, return-addressed envelope in transit.

5.7.1.3 Protection of Māori

Respect for diversity was a general principle within this research. In order to specifically protect Māori culture, cultural concepts, values and norms it is important to demonstrate how these align (or potentially conflict) with the purpose and focus of planned research. This study investigated a school-based, occupational therapy intervention promoting mental health and wellbeing in children in the community. The use of health promotion and community approaches to addressing health and wellbeing needs are consistent with Māori health concepts (Durie, 1997). Though it was not raised as a concern in the consultation process, Māori participants may have been concerned by the limited inclusion of formal kaupapa Māori[6] protocols in the intervention and the study. Participants were made aware that participation was voluntary and that should they chose not to participate, or chose to participate and later change their mind, they could withdraw at any point without adverse consequences.

5.7.2 Vulnerable population

Children are a vulnerable population and the following precautions were taken to protect them during their participation in this study. Though children essentially have the same basic human rights as adults they are often dependent on adults to give effect to their rights, partly due to their developmental needs. This protection is seen primarily as a parental duty; however, there is also a State obligation to ensure institutions protect children's rights (e.g. schools) (Human Rights Commission: Te Kahui Tika Tangata, 2013). Consequently, senior school personnel were asked to provide informed consent for students from their school to participate in this study and to nominate students they felt would benefit from the intervention. School personnel were asked not to exclude students on the basis of their gender, socio-economic status, or relationship with the school, to ensure equitable access opportunities for all students. School personnel were provided with information sheets written in plain English and outlining the school and

[6] Kaupapa Māori research seeks to identify and uphold Māori views, solutions and ways of knowing through challenging the concept of normal as constructed by the dominant culture.

researcher's responsibilities. Informed assent was sought from the children, and their parents were contacted to obtain informed consent. Participant information sheets were written in plain English and at a level evaluated to be easily understood by 11+ year olds for the student versions and 14+ year olds for the parent and teacher versions as measured by the Flesch-Kincaid reading scale (McClure, 1987). Both parent and child consented/assented for the child to participate – if either one declined the child did not go on to be a study participant. The physical and emotional safety of the children was protected at all times and is discussed in more depth in section 5.13.

5.7.3 Consent

Detailed information about the study and participant responsibilities were provided to potential participants (clusters and individuals) prior to recruitment. Please refer to Appendix 8, Appendix 9 and Appendix 10 for child, parent/caregiver and school participant information sheets and consent forms. Information was provided about the voluntary nature of participation; the potential benefits and risks of participation; the right to withdraw; and how data would be collected, used and stored. Reassurances were also provided that the study adhered to key elements of the Code of Health & Disability Services Consumers' Rights 1994. Written consent from the school principal was required before recruitment of participants occurred. Once parents consented to their child participating, the children were invited to assent. The *Participant information sheet: Student version* was reviewed by potential participants in a meeting with the lead researcher and children were offered the opportunity to ask any questions they had before signing the assent form. Informed consent was obtained from senior school personnel from all participating schools (clusters); and assent and consent obtained from all participants and their parent/guardians.

5.7.4 Confidentiality

Clusters were informed that data collection and reporting would be conducted in accordance with the Privacy Act (1993). That is, data would only be used for the purpose for which it has been collected and reported in such a way that identification of schools or students would not be possible. Participants were also informed that most information collected about students from that cluster would not be shared directly with school personnel. The exception to this was participant attendance, which school personnel were informed of to ensure student safety and accountability.

Participants were informed that information collected about them would be kept confidential. The only exceptions to this were 1) attendance, and 2) if participants had reported anything concerning risk that required a parent/guardian being informed. On no occasions were concerning disclosures made by a child participant during the intervention and so no parents were contacted as a result.

Information collected, including data and participant contact details, will be stored securely at AUT for up to 10 years from November 2015, after which it will be destroyed. Clusters and participants were informed of this.

5.7.5 Truthfulness and limiting deception

Participants had full knowledge of the study aim and their allocation for the main part of the study; however, individual participants (not cluster guardians for logistical reasons) were blinded to their allocation at the point of completing the baseline measurements. This was intended to minimise bias in the study and participants were informed this process would occur prior to enrolling into the study.

5.7.6 Conflict of interest

No participants were approached or recruited who had a direct or dependent relationship with myself. The intervention was initially developed based on theory, evidence, consultation with colleagues and clinical experience, then trialled through a private practice at no cost to participants. This study was funded by grants from the Vice Chancellor Scholarship through Auckland University of Technology (AUT), the Oakley Mental Health Foundation, the Lotteries Translational Research fund, Centre for Person Centred Research at AUT and a donation from The Warehouse Ltd. None of these funding organisations gained or lost financially from this study, nor did they have a role in influencing its design or how it is reported. Financial support gained at the time of recruitment was openly declared to all participants.

5.8 Procedure

Following informal ethical approval of the study, in April 2014, schools were approached and notified that the study was planned. Formal ethical approval was granted in early May 2014 and recruitment of those, and more, clusters was completed and participant recruitment was undertaken and continued until March 2015. The first round of baseline measures were taken in May 2014 and were closely followed by the

intervention being facilitated in the first schools. Interventions were facilitated between May 2014 and September 2015: the intervention ran in terms 2, 3 and 4 of 2014 and terms 2 and 3 in 2015. The final 8-9 week follow-up outcome measures were collected by the end of November 2015.

5.8.1 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 the Education Gazette, a national teaching magazine (see Appendix 11). A stratified sample of 50 of those schools from a range of locations in the Auckland region were sent personal invitations to participate and expressions of interest were received from 16 of those schools (the remaining schools did not respond). Schools were stratified by decile ranking proportionate to their representation nationally (i.e. low, medium, and high). A convenience sample of 14 schools for recruitment was targeted, with stratification targets of 4 for each the low and high decile schools, and 6 for the medium decile schools. 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. This process was repeated until 14 schools were recruited. In total, 16 schools expressed an interest in having the intervention facilitated with their students. After an initial meeting, two of the schools – both parochial establishments, one a high decile the other a low decile school – decided not to enrol in the study, reporting an already busy schedule for their students and concerns about the logistical commitments required if randomised to the control arm of the study.

A sample of 10-12 students aged 11-13 years at each of the enrolled schools were recruited by senior personnel from the school (e.g. SENCO, principal). Selection was based on the school personnel's 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. An invitation to participate in the research, the *Participant information sheet: Parent version, Parent consent form,* the *Participant information sheet: Child version* and the *Participant assent form* were sent home with children nominated by school personnel (Appendix 8, Appendix 9 and Appendix 10). Schools were offered the opportunity for me to describe the research process and requirements to potential participants at a school assembly, parent evening or similar forum, or to have information given to them to convey this information themselves. One

cluster (low decile school) chose to have me present this information at a meeting with the nominated children and their parents present where they would ask questions as needed. Another cluster (high decile school) requested this information to be presented at a school assembly for all potential child participants to hear and ask questions about. The information sheet included contact details in case potential participants and their parents or caregivers had wanted to contact me for more information at any point. Participants were asked to return *Parent consent forms* to the identified school personnel or directly to me. Children with signed parental consent met with me as a group to receive information about the study process and the intervention; providing this information as a group reduced the focus on any one individual and enabled each child to make a decision about their participation, informed by who they might be participating with. They were then invited to participate in the study and given the opportunity to ask any questions. Once parental consent and child assent were obtained demographic information about the students was collected.

5.8.2 Randomisation

Schools were allocated unique identifiers. 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 (A.Vandal, supervisor), who was unaware of the cluster identifiers. Allocation was revealed in three waves, after the recruitment of all participating schools was completed for a given school term. Provision for an arbitrary number of waves as needed was made, in case recruitment was low.

5.8.3 Allocation and concealment

The randomisation scheme aimed to maintain balance within each decile stratum while keeping my workload as intervention provider manageable. Schools were recruited several at a time, at three time points, corresponding to intervention inception in the second term of 2014, the third term of 2014 and the second term of 2015. Constrained stratified block randomisation was applied with decile-based strata, using blocks of size two. The recruited schools were randomly ordered within strata, and randomisation blocks generated. The constraint that no more than five schools be under intervention (including interventions carried out on wait-list control schools) during any given semester was applied. A block configuration for all strata at each recruitment time point was generated randomly. Any configuration failing to meet the constraint was rejected

and an alternative configuration produced randomly until constraint satisfaction. For the third term of 2014, the rejection criterion took into account wait-list interventions planned in that term for schools recruited in the previous term. All details of the randomisation process, including the block size and the rejection method to uphold the constraint, were kept from all other investigators by the trial statistician until the end of the trial follow-up, to uphold concealment.

Once each school had nominated the students - and they had consented/assented to participate - each cluster's allocation was revealed. The school was then informed of their allocation status, in order to facilitate logistical aspects of arranging times and venues for 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.

5.8.4 Blinding

Outcome measures were taken at each school by a research assistant/outcome assessor blinded to the treatment allocation of each cluster. Multiple research assistants were used to ensure they could not guess study allocation by the number of times they had conducted testing at a school. Efficacy of blinding is reported in the next chapter.

Blinding of myself, as facilitator of the intervention; the schools (clusters); or individual participants, after baseline measures were taken, was not possible. This was due to the pragmatic trial design and the nature of the experimental intervention that required active participation and interaction from participants compared to the control, which required no involvement or participation. Blinding participants is notoriously difficult in complex and non-pharmacological interventions, by nature of them requiring significant participant interaction; the difficulty is increased when the comparison group is a waitlist-control group (Boutron, Tubach, Giraudeau, & Ravaud, 2004). Offering an attention-control intervention was considered to counter-act this; however, including this was beyond the scope, budget and timeframe of this study and had ethical implications for removing children from their standard curriculum.

5.8.5 Efficacy End Points (EEP)

The primary EEP for this study was the post-intervention time-point, which occurred one-week after completion of the intervention and used the primary outcome measure,

the MASC-10. Secondary EEPs for this study were at 8-9 weeks follow-up after completion of the post-intervention outcome for the primary outcome measure (MASC-10), and post-intervention and 8-9 weeks follow-up after completion of all of the other outcome measures.

5.8.6 Safety End Points (SEP)

A record was kept of any adverse events linked to the study intervention or assessments. Adverse events that occurred onsite at any of the schools would initially require relevant school policies to be adhered to or a response as outlined in section 5.13 below. Study termination would have been considered if the intervention was observed to increase the level of distress in several participants resulting in their withdrawal from typical social, educational or family activities. Previous trialing of the intervention in practice indicated this was unlikely. This situation did not occur; if it had, there would have been discussion with the AUT supervisors and consultation with stakeholders involved (as appropriate) to decide whether it was appropriate for the study to continue.

5.8.7 Data management

Data were entered into an Access database by a research assistant to maintain blinding of the primary investigator/intervention facilitator. Range and logic checks were built-in to assist with data cleaning. A data monitor, a statistician who was not associated with the study or part of the supervisory team, was assigned to review the quality and completeness of data collected. The data monitor conducted an unblinded review of the data at two time points:

- On completion of the first round of intervention and waitlist groups being implemented (July, 2014)
- On completion of the first year of the trial (February 2015)

These reviews had the scope to inform recommendations about data quality and collection, data completeness, changes to the sample size and to review the adverse event log for safety issues. The trial statistician involved in randomisation and myself remained blinded to the data to prevent potential bias in intervention delivery and the analysis. As this was a low risk, short-term intervention, no interim analyses were planned and no stopping rules were in place, as recommended by Stallard, Whitehead, Todd, and Whitehead (2001).

5.9 Statistical analysis plan

Data were analysed using the Statistical Package for the Social Sciences (SPSS version 20), SAS version 9.4 and R version 3.2.

5.9.1 Descriptive statistics

Means, standard deviations and frequencies were used to describe demographic and outcome variables at the individual level. Variability in the descriptive statistics at the cluster level were reported using the within-cluster sample standard deviation estimate, and estimates of the between-cluster and within-cluster standard deviations for each arm and overall. Estimates were produced using restricted maximum likelihood. In a normal model fitting only an intercept, the estimated standard deviation of normally distributed random effects associated with the clusters was used as the between-cluster standard deviation estimate and the residual standard deviation estimate was the within-cluster standard deviation estimate. Analysis of descriptive statistics also allowed variables to be checked for any violations of assumptions underpinning the statistical techniques planned, such as checking for normality, outliers, and missing data.

5.9.2 Datasets for analysis

As a pragmatic trial, this study utilised an Intention-to-Treat (ITT) approach to analysis to reduce the potential for upward bias in the estimated effect size (Eldridge & Kerry, 2012). The result was that data from all randomised participants were used, with allocation corresponding to their allocation following randomisation, regardless of adherence to treatment allocation as this more accurately reflects real-life conditions. No distinction was made between child, parent and teacher analysis sets.

5.9.2.1 Primary ITT dataset

The primary ITT dataset consisted of all the data from the parallel phase of the trial based on participants' original allocation to one of the two study arms, i.e. intervention or waitlist-control. Allocation for this dataset represented the study arm the participant was allocated to at randomisation regardless of treatment received.

5.9.2.2 Secondary ITT dataset

The secondary ITT dataset consisted of all the data from the primary ITT group, plus the additional data from the crossover phase – those originally allocated to the waitlist-

control group in the parallel phase of the trial who later went on to receive the intervention.

5.9.2.3 Per Protocol dataset

The Per Protocol (PP) dataset consisted of all the data from the primary ITT set with allocation reflecting the actual treatment received. Minor deviations did not affect participant inclusion in the PP dataset. Major protocol violations that resulted in participant data being excluded from the PP dataset were:

- Eligibility violation
- Out-of-window assessments
- Unplanned incomplete intervention or exposure to intervention

5.9.2.3.1 Eligibility violation

Eligibility violation refers to participants identified as not meeting the eligibility criteria after randomisation into the study. This protocol violation was not known to occur for any participants.

5.9.2.3.2 Out-of-window assessments

Pre-determined criteria were set to identify data as in-window and any observations taken out-of-window were treated as missing from the PP analysis set. In order to define in-window data, a 'ghost intervention' indicator was created. The 'ghost intervention' represented the 8 week period, during which participants in the control group were on the waitlist. In-window data were defined by the following rules:

- Assessment date was available
- Baseline date was between -10 and 0 working days prior to the start of the 'ghost intervention' for the waitlist group
- Baseline date was between -10 and 0 working days prior to the start of the intervention for the intervention group
- Pre-intervention date was between -10 and 0 working days prior to the start of the intervention for the waitlist group who went on to receive the intervention
- Post-intervention date was between 0 and 10 working days following completion of the intervention for the intervention group

- Post-intervention date was between 0 and 10 working days following completion of the ‘ghost intervention’ for the waitlist group
- Follow-up date was between 35 and 60 working days following completion of the intervention
- Dates for parent-rated outcomes were after all child-rated outcome dates
- Dates for teacher-rated outcomes were after or equal to all the child-rated outcome dates from the same cluster, and no more than 10 actual days before all child-rated outcome dates from the same cluster

In practice, these rules only applied to the outcomes that were analysed in the PP analysis (i.e. MASC10, COPM child performance and COPM child satisfaction ratings).

5.9.2.3.3 Unplanned incomplete intervention and exposure to intervention

Participants in the PP set were assigned to the study arm based on the treatment they actually received. A participant originally allocated to the intervention arm who attended fewer than 4 sessions was thus assigned to the wait-list control arm for the purposes of the PP analyses. No participants in the control arm of the study were inadvertently exposed to the intervention.

5.9.3 Blind review

Trial data were reviewed by A. Vandal (supervisor) 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. The review had the scope to change three components of the statistical plan: selection of covariates to be included in the final analyses to increase statistical efficiency; description of transformations required or selection of alternative regression families and management of missing data.

For continuous outcomes, a normal model adjusted for the outcome at baseline, child gender, child ethnicity, and dichotomised school decile category (Low/Medium vs High) were assessed for normality of the residuals and of the random effects. The base model was a linear mixed effects model with time-point entered as a factor in the case of longitudinal data. The focus was on qualitative appraisal of the parametric assumptions by graphical means such as qq-plots and measures of association between mean outcome and residual variance, rather than testing. The selection of an appropriate generalised linear model and link was preferred to data transformation. In the instances

where the data displayed residual leptokurtosis and/or skewness (i.e. RCADS – Depression subscale, SISES), these departures from normality were deemed insufficient to introduce bias strongly (Judkins & Porter, 2016). Therefore, all outcomes were analysed using least-squares (normal) models and no transformations of the data were performed.

The final selection of covariates from among those listed above was the result of the blind review and independent of their allocation, as the covariates were collected pre-randomisation and the reviewer was blind to the allocation. Each outcome was subjected to regression analysis. The appropriateness of adjusting the model for the preselected covariates was assessed primarily on the basis of the partial R^2. Covariate assessments were based on complete case analysis of a mixed model, involving clusters as random effects.

Frequency of missing data in selected baseline covariates was assessed and in all cases where baseline data were missing, multiple imputation was used to create five imputed datasets based on the joint distribution of the baseline covariates. Possible outliers were investigated during the blind review as validation for data entry, but no observation was to be removed from the analysis sets as a result of this investigation.

5.10 Data analysis plan

A Repeated Measures Analysis of Covariance (RM-ANCOVA) analysis of the data allowed comparisons of between-subject (intervention versus waitlist-control) and within-subject (repeated measures on outcomes) factors and their interactions, while statistically controlling for baseline scores, dichotomised cluster's decile rank and other covariates that were identified as the result of the blind review (see Table 13, p. 21). A mixed model, RM-ANCOVA was applied to the primary ITT, secondary ITT and PP datasets. To maximise statistical efficiency, parallel phase, crossover phase, and follow-up assessment measurements were included in all regressions for a given outcome, with fixed effects appropriately set-up for parallel or crossover analysis and specific contrasts used to isolate results at any time point. The PP analysis consisted of data from the primary outcome (MASC10) and the child COPM (performance and satisfaction scales) only.

5.10.1 Unadjusted analysis

This section applies to the analyses of hypotheses [A]. The intervention effect was assessed for all outcomes after the parallel phase and the outcome mean and standard error by arm, the difference of means between the arms with a *t*-distribution-based 95% confidence interval were reported. In practice the unadjusted analyses were carried out using a simple unadjusted mixed model on the ITT dataset, accounting for clusters (schools) using a normally distributed random effect, and reported summary results in each arm.

5.10.2 Adjusted analysis

This section applies to the analyses of hypotheses [A], [B] and [C]. All tests of significance of hypotheses concerning treatment effect parameters were carried out using a level of significance of 5% and two-sided alternatives, with the exceptions of the one-sided longitudinal non-inferiority alternatives. There was only one planned comparison for testing the primary hypothesis so no adjustment for multiplicity was required. Given the need to make multiple comparisons for the secondary hypotheses, the False Discovery Rate control was applied to protect against Type I errors (Benjamini & Hochberg, 1995). Sub-hypotheses thus retained would be deemed statistically significant.

All estimates were produced as point estimates and as 95% confidence intervals. Predetermined covariates specified for this study were:

- Baseline scores on outcome measures
- Dichotomised school decile (low/medium vs. high)
- Child gender
- Child ethnicity
- Time from baseline to assessment (treated as categorical data) for repeated measures analyses

Covariates were included in the model in order to reduce residual variance in the regression. Baseline values were included in the model in all cases, except the COPM measures, which are defined as differences from baseline. Final covariate selection was determined by a blind review; selected covariates are reported in Table 13 (p. 113). All analyses (except where the blind review indicated otherwise), including the unadjusted

analyses, accounted for clustering by entering the school as a random effect. The participant was accounted for as a (nested) random effect in all but the unadjusted analyses, which were effectively carried out as univariate analyses. The association between repeated measures was accounted for by a participant-specific, normally distributed, random effect.

Table 13: Covariate included in the analyses for each outcome

Outcome	**Baseline included**	**Covariates other than baseline value**
MASC-10	Yes	School decile category, Māori, Pasifika, Asian, European/Others
RCADS - GA	Yes	None (also no cluster random effect needed)
RCADS - D	Yes	School decile category, Māori, Pasifika, Asian, European/Others (also no cluster random effect needed)
SAS Total	Yes	Māori, Pasifika, Asian, European/Others
SAS GA	Yes	School decile category, Māori, Pasifika, Asian, European/Others
SAS Social anxiety	Yes	None
CDI-2	Yes	School decile category
RSES	Yes	School decile category, Māori, Pasifika, Asian, European/Others
SISES	Yes	Māori, Pasifika, Asian, European/Others
COPM (Child) Performance	No	Gender, school decile category
COPM (Child) Satisfaction	No	Gender, school decile category
COPM (Parent) Performance	No	School decile category, Māori, Pasifika, Asian, European/Others
COPM (Parent) Satisfaction	No	School decile category, Māori, Pasifika, Asian, European/Others
Wellbeing	Yes	School decile category, Māori, Pasifika, Asian, European/Others (also no cluster random effect needed)

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.

5.10.3 Mediation analyses

Mediation analyses were carried out under the assumption of no interaction between the intervention allocation and the mediator, and the assumption of sequential ignorability of the mediator. Theoretically, sequential ignorability assumes the mediator was randomly assigned given baseline covariates and the randomised allocation (Small, 2013). In practice the assumption was equivalent to the mediator value depending only

on baseline covariates and the treatment arm, and not on post-randomisation confounders.

To carry out the mediation analysis of outcome Y ($= Y_{1,1}^{1}$, or MASC-10 at post-intervention) on the allocation G mediated by variable M ($Y_{1,1}^{0}$, or the Knowledge survey score at post-intervention) adjusted for covariates X, M was regressed on G and X (via the model $M \sim aG + k_1X$), then Y regressed on G, M and X (via the model $Y \sim c'G + bM + k_2X$). The direct effect of G on Y (from the model $Y \sim c'G + bM + k_2X$) was presented as the estimate of c', and the indirect mediation effect as $a \times b$. The total effect was presented as $c = c' + a \times b$ (see Figure 3, p. 82).

In practice *c*', the direct effect, was taken as the estimate of the contrast *p1:g1:t1 - p1:g2:t1* from the model:

$$Y_{p,g,t} \sim \boldsymbol{x}^{q} + Y_{p,g,0} + \mathrm{M} + \ p{:}\, g{:}\, t,$$

(Equation 6)

In practice the indirect effect *a*b*, was estimated by multiplying the estimate of 'b' (the coefficient of *M* in Equation 6), by the estimate of 'a' given by *p1:g1:t1 - p1:g2:t1* in the model:

$$M \sim p{:}\, g{:}\, t + \boldsymbol{x}^{q}\ .$$

(Equation 7)

5.10.4 Sub-groups for analysis

A floor effect may have affected the outcomes measured for participants with subclinical symptoms, for whom *substantial* change was not anticipated. In order to mitigate the potential dilution of significance incurred by a floor effect, sub-groups for analysis were defined as:

- Participants with total *t*-scores on the baseline MASC-10 of <56 (average levels of anxiety)
- Participants with total t-scores on the baseline MASC-10 of ≥56 (high average to elevated levels of anxiety)

5.10.5 Missing data

It was assumed that missing covariate data were missing at random (i.e. missingness depended on observed information only). For the inferential analyses, five complete imputed datasets were created from independent imputations of the missing baseline and pre-intervention (for the control group) data. Imputed values were constrained to lie within the observed bounds of the available data. Baseline data were imputed using a full conditional specification (FCS) algorithm on a core set of variables (i.e. available covariates and baseline data) with the exception of SAS SA, SAS GA and the parental COPM performance scores. These three measures could not be made part of the core set as it proved impossible to generate them within the stipulated bounds: therefore, they were imputed separately on the basis of a distribution condition on the core set. The same approach was used for imputation of pre-intervention data (for the control group), with SAS SA, SAS GA, SISES, child COPM performance, child COPM satisfaction scores, and parental COPM performance scores being excluded from the core set of variables. For descriptive purposes, no imputation was used and missing values were reported separately.

5.11 Sample size

A difference of ±5 in the *t*-score on the primary outcome measure (Multidimensional Anxiety Scale for Children- Short form: MASC10) after an 8 week period can be considered clinically significant (March, 1997). To detect a difference of ±5 in the MASC with a power of 80% and a significance level of 5%, against a two-sided alternative, 64 children are needed per study arm when randomisation occurs at the participant level. However, the sample size calculation and data analysis needed to account for the reduced efficiency of the cluster design used in this study. This efficiency reduction is due to possible between-cluster variability (Eldridge & Kerry, 2012). Estimates of the ICC, and cluster-size coefficient of variation (CV) needed to be obtained first in order to estimate the so-called DE and obtain the sample size required for the Effective Sample Size (ESS) to equal that of an individually randomised design. A further adjustment for the Analysis of Covariance Analysis (ANCOVA) was also applied to the sample size (Teerenstra et al., 2012).

5.11.1 Intra-cluster correlation coefficient (ICC)

The ICC is a relative measure of variability between clusters in a clustered sample and is used in statistical analysis to account for this component of variance, in addition to within-cluster variability. Without a pilot study to calculate the ICC, it was estimated at 0.05, based on a conservative average of the recommendation to use 0.03 from Campbell, Fayers, and Grimshaw (2005) who analysed ICCs used in clinical trials, and ICCs ranging from 0.00 to 0.09 used in similar studies (Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; Murray et al., 2004; Patel et al., 2010; Tol et al., 2008). Data from the current study, were used to calculate ICCs using the formulae suggested by Stanish and Taylor (1983):

$$\text{cluster variance}/(\text{cluster variance} + \text{residual variance}) \quad \text{(Equation 8)}$$

Variance estimates and ICCs for each outcome measure were calculated from the non-imputed efficacy analysis data.

5.11.2 Coefficient of variation (CV)

The CV describes the variability in cluster sizes if these are not fixed. The CV is important to consider when calculating sample size as it can significantly impact on the statistical power of cluster randomised trial data analysis. Eldridge et al. (2006) defined CV as the ratio of the standard deviation of cluster sizes to the mean cluster size. One method they described for calculating the CV requires investigators to estimate the likely range of cluster sizes, from which the CV is in turn estimated by (likely range/4)/mean cluster size. The denominator of 4 is based on the width of the 95% confidence interval of a normal distribution. If CV is <0.23, the effect of adjustment for the variable cluster size on calculating the sample size is considered negligible. For the present study, it was estimated *a priori* the range of cluster sizes to be five (minimum 6, maximum 11) and the mean cluster size to be nine, yielding

$$CV = (5/4)/9 = 0.14 \quad \text{(Equation 9)}$$

and indicating that cluster size variability would have a negligible effect on sample size.

5.11.3 Design effect (DE)

The DE is a coefficient applied to the sample size calculated under independent sampling (hereafter the "raw sample size") in order to account for the design (Eldridge & Kerry, 2012). The DE is calculated as follows:

$$1 + (m\text{-}1)\,\rho = \text{DE}$$

(Equation 10)

where m=Average cluster size; ρ=Intracluster correlation coefficient; DE=Design effect.

For this study, as the DE was estimated *a priori* as:

$$1 + (9\text{-}1)0.05 = 1.4$$

(Equation 11)

5.11.4 Analysis-adjusted design effect (AADE)

The AADE assumes analysis to be conducted on the unadjusted follow-up scores between two intervention arms. In order to include baseline outcomes as covariates and conduct an ANCOVA, the sample size calculation was further adjusted under independent sampling by a factor of $(1\text{-}r^2)$ to obtain what is referred to here as the AADE:

$$\text{AADE} = (1\text{-}r^2) / (1 + (m\text{-}1)\,\rho)$$

(Equation 12)

where r= Reliability coefficient of primary outcome (Teerenstra et al., 2012). An error at design stage resulted in the use of an analysis-adjustment factor of $2(1\text{-}r)$ instead of the correct factor of $(1\text{-}r^2)$. The implications of this error are discussed at the end of this section on sample size determination.

The primary outcome measure the MASC10, and MASC from which it is derived, have several reliability coefficients (r) available for test-retest reliability; however, many of these were for shorter time-periods than those required for this study. These ranged from .75-.86 over 2-3 week periods (Greenhill, Pine, March, Birmaher, & Riddle, 1998; March & Sullivan, 1999; Muris, Gadet, et al., 1998). One study investigated the test-retest reliability of the MASC10 over an 8 week period, consistent with the time frame

of this study, and test-retest reliability was found to be excellent (r=.0.83, p<0.001) (Osman et al., 2008). Subsequently, using the conservative reliability coefficient of 0.65, the $AADE_{used}$ for this study was calculated as:

$$AADE_{used} = (2 \cdot (1\text{-}0.65)) / (1 + (9\text{-}1)0.05) = 0.98$$

(Equation 13)

5.11.5 Effective sample size (ESS)

The ESS takes into account the cluster design to indicate the comparative sample size to if the study was randomised at the individual level. It is related to the number of clusters, mean cluster size and AADE by the formula:

$$mk/AADE_{used} = ESS$$

(Equation 14)

where m = mean cluster size; k = number of clusters; $AADE_{used}$ = Analysis-Adjusted Design Effect used. The ESS having been identified as 64 participants per arm, and the average cluster size at 9, the recruitment target was calculated as:

$$k = ESS \times AADE_{used}/m = 64 \times 0.98/9 = 6.97 \lessapprox 7 \text{ schools per arm}$$

(Equation 15)

5.11.6 Recruitment target

The sample size requirement for this study was 63 per study arm, a total of 126 children from 14 schools. Cluster attrition was considered unlikely, but to account for an intra-cluster attrition of up to 20% the target mean cluster size was increased to 11, yielding a target sample of 154 participants.

5.11.7 Correction to the analysis-adjustment coefficient

The analysis-adjustment factor of 2(1-r) was used erroneously in designing this study, instead of the correct factor of (1-r^2) to adjust for the planned ANCOVA analysis (the factor of 2(1-r) is used when unadjusted score differences from baseline are used as the dependent variable). It can be shown that (1-r^2) < 2(1-r) for any $r \neq 1$, which implies that the error was conservative, and resulted in a target sample size that was larger than required for the nominal significance level and power. The actual AADE was

$$AADE_{actual} = (1-0.65^2)\ (1 + (9-1)0.05) = 0.81$$

(Equation 16)

The proportion by which the sample size was overestimated was $[1-2(1-0.65)/(1-0.65^2)]\times 100\%=21\%$. This conservative sample size yields a power of 87% to detect the target difference under the other design parameters, rather than the nominal 80%. Therefore, there were no adverse effects from this error on the analysis or the robustness of the findings from the data.

5.12 Validity

Given the pragmatic nature of this cluster-RCT, and that it measured effectiveness rather than efficacy, it was important to ensure both internal and external validity (Eldridge et al., 2008).

5.12.1 Internal validity

Internal validity refers to the 'reliability or accuracy of the results' to determine if "differences between the intervention and control groups can be confidently attributed to the intervention and not due to some alternate explanation" (Godwin et al., 2003, p. 30). Threats to internal validity of a clinical trial can be minimised through having a sufficient sample size, use of randomisation and allocation concealment, a cluster design to limit contamination and ensuring fidelity (Eldridge et al., 2008; Godwin et al., 2003). A sample size calculation was conducted, and recruitment targets identified prior to recruitment ensured that this study was sufficiently powered for appropriate statistical analysis that accounted for clustering (this is described in more detail in section 5.11). Randomisation, allocation concealment, blinding of outcome assessors and clustering of participants were addressed in this study and are described in more detail in the next chapter. How fidelity was measured in this study is described in detail below.

5.12.1.1 Fidelity

Fidelity refers to the degree to which a treatment or programme was implemented as intended. It is important to measure fidelity in a study so researchers can feel confident that variability in treatment implementation was not a moderator of the study outcomes (Carroll et al., 2007). Carroll et al. (2007) outlined a framework for implementation fidelity and how it should be measured: this framework includes adherence (to content, coverage, duration and frequency), moderators (implementation complexity, facilitator

strategies, quality of delivery and participant responsiveness), and identification of essential components.

Adherence: The intervention was manualised to provide structure and uniformity of facilitation and administration. The intervention manual described the session by session guidelines and strategies for facilitation and administration. Each intervention session ran for 1 hour per week over 8 weeks – this standardisation of duration and frequency was based on the maximum allowance some schools could accommodate the programme (i.e. some were prepared to offer more time but this would have introduced variability in implementation).

Participant adherence was measured through attendance and completion of skills practice (homework tasks). Participants who did not attend all of the intervention were still included in the final analysis as per the ITT approach. Researcher adherence was monitored through self-rating of implementation on a fidelity implementation rating scale based on the scales designed and used by Forgatch, Patterson, and DeGarmo (2005) in a study evaluating the implementation fidelity of a parenting programme and Mellard (2010) and the American Institutes for Research (2016) in their Response to Intervention (RtI) framework (see Table 12, p. 95). Audio-recording of a random selection of sessions was considered to enable researcher adherence to be monitored by an independent clinician; however, as only one facilitator ran the intervention this seemed less necessary and was considered too intrusive for the participants and likely to change both researcher and participant behaviour.

Moderators: Implementation fidelity is influenced by a number of factors, defined by Carroll et al. (2007), that are in turn likely to be moderated by each other. 'Intervention complexity' refers to whether the intervention was detailed or vague, simple or complex. To minimise the impact of complexity as a moderator, the Kia Piki te Hauora: Uplifting our Health and Wellbeing© intervention was manualised. This ensured clear, detailed instructions were provided, enabling consistency across intervention groups, while still allowing a degree of flexibility and discretion for the facilitator to personalise the content for participants. The manual provided clear 'facilitation strategies' assisting with uniform delivery across intervention groups. However, such uniformity was highly likely for this study anyway, as the same facilitator provided the intervention across all clusters. 'Quality of delivery' refers to whether the intervention was provided in a manner appropriate to achieving the intended outcome. For this study, the facilitator

was also the intervention developer, so a high level of intervention familiarity and understanding was assumed. While no checks of the quality of delivery were directly planned, the consultation process described in chapter three was, in part, an effort to assess the facilitator's intentions with the intervention design. The consultation process resulted in positive feedback about the purpose and implementation of the intervention from an expert panel of occupational therapists experienced in working with children and adolescents. The final moderator proposed by Carroll et al. (2007) was 'participant responsiveness', which was measured and recorded by facilitator observation on the fidelity implementation rating scale (see Table 12, p. 95). During piloting of the intervention, acceptability of the intervention was considered reasonable given the consistent attendance of child participants and the high level of observed participation.

Identification of essential components: The intervention manual (see Appendix 3) clearly stipulated the process and content for each session. The 'key messages' for each session were discussed during the session and printed at the start of each section of the manual, on a poster visible to the group during the intervention, and on the skills practice sheets that were taken home by participants, ensuring this information was explicitly conveyed and available to participants.

5.12.2 External validity

External validity is pivotal for a pragmatic study and refers to the generalisability of a study's results to the population of interest, which in this study was students with early indicators of mental distress, low self-esteem or poor participation (Godwin et al., 2003). The external validity of a cluster randomised study is more complicated than for an individually randomised study as "results may be generalisable to the clusters, to the individuals in those clusters or both" (Campbell, Elbourne, et al., 2004, p. 707). Threats to external validity can be minimised through having few exclusion criteria to enable obtaining a representative sample (Godwin et al., 2003), minimising attrition and conducting the research across different time periods (Campbell, Elbourne, et al., 2004).

5.12.2.1 Exclusion criteria

In this study, a representative metropolitan sample of clusters were obtained through stratification of schools by decile ranking. Minimal exclusion criteria for clusters and individuals were applied to increase the relevance to the wider population and preserve

external validity. Inclusion and exclusion criteria are described in section 5.6 in more depth.

5.12.2.2 Minimising attrition

Regular communication with senior school personnel promoted easier reconnection with participants at data collection points, particularly at the follow-up. Follow-up occurred 8-9 weeks post-intervention and involved a repeat of all outcome measures in order to track any change over time. A 2-week period was allowed for data collection at follow-up to create flexibility intended to improve retention. Of the four school terms, terms two and three (May-July and July-September) were deliberately chosen for the parallel trial to increase the likelihood participants would still be affiliated with the same school at the 8-week follow-up and be contactable through that channel.

5.12.2.3 Different time periods

The parallel study was conducted across four terms (the crossover trial across five terms) over the course of two years, limiting time-specific influences but not eliminating them: the intervention for the parallel trial was only implemented during terms two and three so may not be generalisable to terms one or four.

5.13 Safety monitoring

The safety of the participants, the researcher and the data was considered for this research study. Below is a description of how the following were attended to: emotional and physical safety of the participants, and safety of the researcher and research assistants/outcome assessors.

5.13.1 Emotional and physical safety of the participants

At two schools, a staff member was present at all times during the data collection and interventions: in both instances this was because of school policies around children's safety and the need for supervision of and support for external staff. Staff members took the role of managing unruly behaviour that occurred and oftentimes they would sit away from the group and attend to their own paperwork.

The emotional and physical safety of the child participants was crucial at all times and there were differing levels of planned responses to issues that could have arisen. Children were not forced to participate in any activities they did not feel comfortable

doing. They were informed from the start (and reminded every session) that they did not need to share any information about themselves they did not want to and that any information shared by the participants was to be kept confidential within the group (see section 5.7.4 above on confidentiality for more information about and exceptions to this).

Planned responses to any emotional concerns participants presented with during the sessions are outlined in Table 14 (p. 124). On several occasions low levels of concern were raised in the group requiring careful management and problem-solving within the session. This was expected given the nature and the content of the intervention. On one occasion, an incident of serious bullying was disclosed by several members of the group and a school staff member, who was already present, agreed to take the information on board and address the issue directly.

Children were not asked to participate in physical activities beyond the sort they typically performed in a school environment. They were also informed (and reminded sporadically) that if they did not feel comfortable completing any activities they could request to not participate in that activity directly and to take on a less active role. On a few occasions participants chose to sit out of some activities (one participant sat out of most physical activities having broken her foot the week prior to the first session) and invariably the participants returned to participate in the following activity.

Safety instructions were given prior to any physical activities (e.g. stay within a safe location, no touching/hitting of others, listen to instructions, stop immediately if instructed to do so by the facilitator). In the event of an injury the standard school protocol was followed for accessing medical assistance and informing parents. On one occasion a child was mildly injured (one finger pushed awkwardly) when playing an active game and he was supported to seek attention by the school nurse. No further input was required and this did not impact on his participation at school or in the intervention beyond the session.

Table 14: Levels of potential presenting concerns and planned facilitator responses

Level of concern	Presenting concern	Planned response
Low	Common 'concerning issues', such as reports of occasional times when participant felt sad, lonely or tearful.	Managed carefully within the group and normalised. This may have included supporting the child to find a solution and how to access the relevant assistance (e.g. teacher, school nurse, parent).
Moderate	Concerns raised around bullying.	Discussed with the participant after the group and agreement gained of which teacher could be approached and informed. In negotiation with the participant this may have been led by the researcher or the child with the researcher's support.
Moderate	Ongoing concerns raised about significant emotional wellbeing, such as persistent low mood.	Discussed with the participant after the group and agreement gained of how parents (and teachers if appropriate) would be informed. Initially, the child would have been supported to find a solution and how to access the relevant assistance (e.g. teacher, school nurse, or parent). If this was not sufficient then coping strategies would be discussed and a safety plan put in place. A safety plan may have included coping skills the child could use, actions the facilitator would take, who would be informed, and where the child could seek additional assistance if the situation escalated.
Severe	Imminent concerns raised about risk to self, such as suicidal ideation/thoughts or self-harm, or abuse.	Discussed with the participant after the group and agreement gained of which teacher would be approached and informed by the researcher and how parents would be informed. Informing other agencies may also have been appropriate e.g. Child Youth and Family services, and decided on a case-by-case basis. In the event of suspected or actual abuse being disclosed the Ministry of Education (2009) protocol would be followed. The child would be supervised, kept informed and supported while their parents were made aware as soon as possible. Coping strategies would be discussed and a safety plan put in place with the child and their parents/caregivers (and school if appropriate). A safety plan may have included coping skills the child could use, actions the facilitator would take, who would be informed, and where the child could seek additional assistance if the situation escalated. The recommendation to discuss this issue further with their family doctor would be made and a referral on to relevant secondary mental health services could be made by the facilitator if the family chose this option.

5.13.2 Safety of the researchers

The following procedures were adhered to at all times and in each of the different schools in which the study was conducted to ensure the safety of my own and the study research assistants'/outcome assessors' safety, referred to collectively from hereon as the researchers.

Researchers' whereabouts were always known:

- A colleague/family member of the researchers were notified of which school was being visited and details of the expected return time were given.
- Researcher carried a charged cell phone preloaded with home, office and colleague contact numbers.
- Researchers' mobile phone was turned on (silenced to avoid disturbances).
- Researchers showed respect to the school by dressing appropriately for the school environment and observed school health and safety protocols.

Researchers informed the school when onsite:

- Researchers signed the visitors' book on arrival and departure at each school.
- Researchers had a planned schedule of visits agreed with a senior staff member (e.g. principal, SENCO) in advance.
- Researchers followed any health and safety procedures required by the school (e.g. in case of fire/emergency).

Going to areas that were considered unsafe:

- Researchers checked the map and knew where to go before reaching the area and ensured sufficient petrol was in the fuel tank.
- Valuables were not left on display in the car and personal documents, e.g. purse were kept on the researcher's person at all times.
- Researchers arranged for someone to call / text shortly after the scheduled end of visit to check all was okay.
- Researchers acted confidently and ignored provocative comments or behaviours: hands were kept free.

If the researchers were uneasy during a school visit:

- Researchers immediately reported any dangerous or threatening incidents to senior staff at the school and the AUT supervisors.
- If a participant/family member/school employee became violent or abusive the researchers would respond calmly with "I" messages; keep statements matter of fact, simple and direct; keep a physical distance; would not reach out and touch the person; would not get up from the chair while the person was sitting, and not leave too abruptly.

Safety plans were adhered to and on no occasion were the researchers' safety compromised: the need to implement these last two actions did not arise.

5.14 Chapter summary

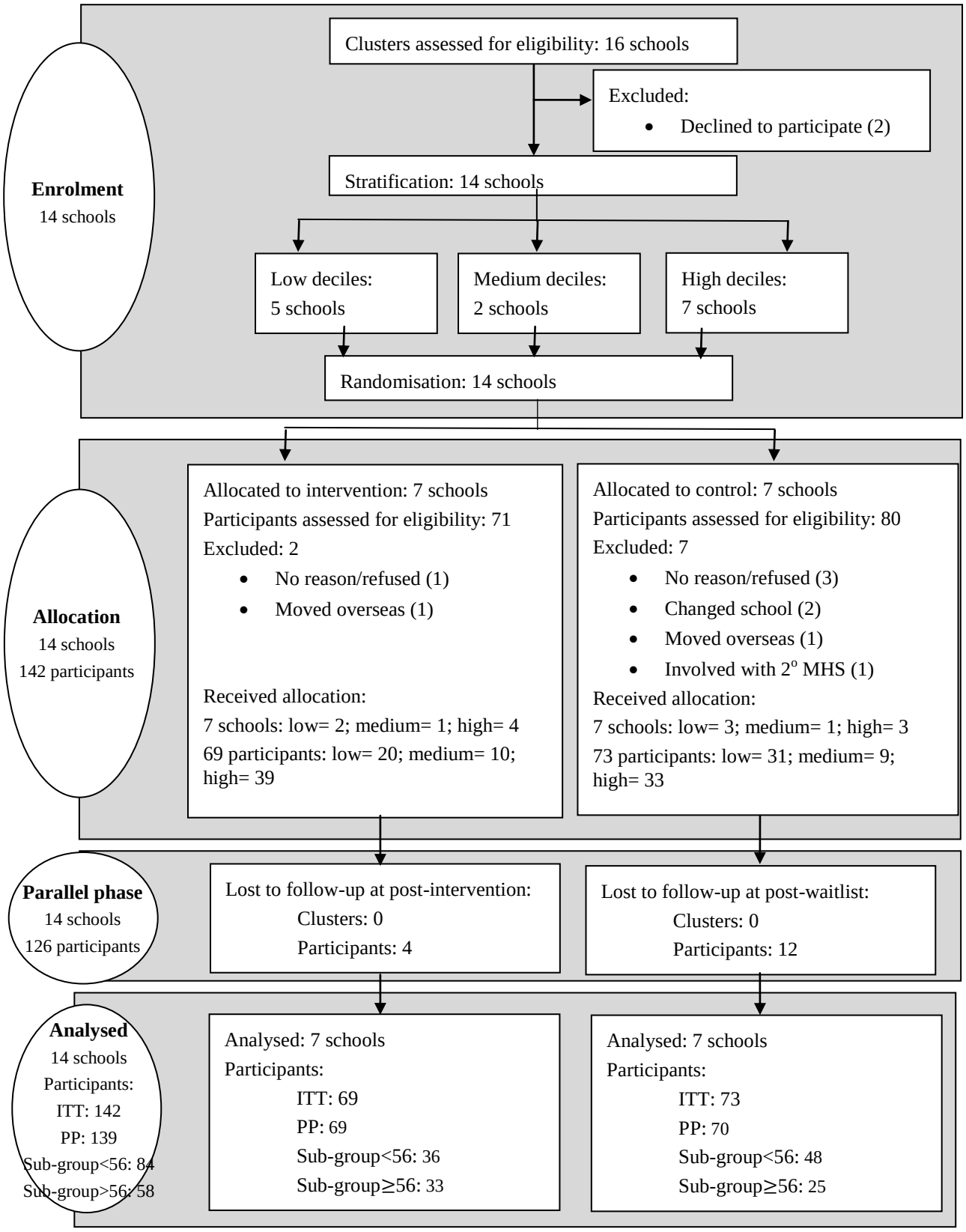
This chapter has outlined, in-depth, the planned and implemented methods for the cluster-RCT conducted for the current study, which were summarised in the protocol article by Tokolahi, Hocking, Kersten, and Vandal (2014). As a pragmatic trial, it was vital that external validity was maximised; however, this should not be at the expense of internal validity, which is typically the focus of efficacy studies (Godwin et al., 2003). Plans to preserve internal and external validity have been described, such as the use of randomisation and fidelity checklists. The next chapter will describe the outcomes from the planned statistical analysis and the findings from this trial.

Chapter 6: Results

The results presented in this chapter describe the findings from the study in this thesis, a cluster-RCT that evaluated a preventative occupational therapy intervention for promoting mental health and wellbeing in children aged 11-13 years: Kia Piki te Hauora: Uplifting our Health and Wellbeing©.

6.1 Participants

Fourteen schools and 151 child participants were recruited and randomised. Figure 6 (p. 128) shows the flow of clusters (i.e. schools) and participants through the study.



Notes: 2^{o} MHS=secondary mental health service; ITT=Intention to treat analysis dataset; PP=Per Protocol analysis dataset; Sub-group<56 refers to dataset of participants with lower self-rated anxiety at baseline (MASC10 *t*-score was below 56) and Sub-group≥56 refers to dataset of participants with higher self-rated anxiety at baseline (MASC10 *t*-score was 56 or above).

Figure 6: Study flow diagram showing cluster and participants related to the primary outcome

6.1.1 Clusters

Schools were recruited from eight of the 13 electoral wards in Auckland (see Figure 7). Of the 16 schools invited to participate in the study, 14 agreed to take part and were deemed eligible to participate based on the predetermined criteria. The two schools that declined to participate were both parochial schools that cited busy educational schedules as the reason for not participating in the current study.

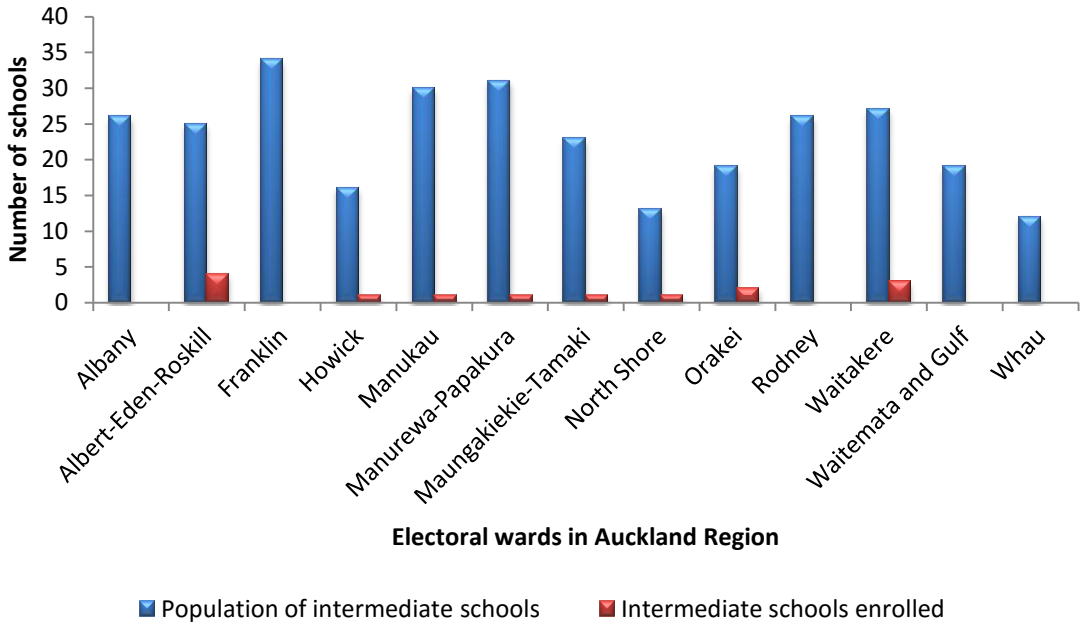


Figure 7. Number of intermediate schools across electoral wards in Auckland Region and number of schools enrolled into the current study

Baseline characteristics of the clusters (i.e. schools) are reported in Table 15 (p. 130). The average cluster size was 10.14 children per school (range 8-13 children per school). Variations in cluster sizes needed to be accounted for if the variation was calculated to be significant (Eldridge et al., 2006). Based on the actual data collected the CV was calculated as

$$CV = (6/4)/10.14 = 0.15 \quad \text{(Equation 17)}$$

and within the range deemed to have negligible impact, so was not used for adjustment purposes. Twelve of the 14 clusters were state-funded public schools, one was a private school and one a state-integrated Catholic school. Twelve of the 14 clusters were co-educational, one was an all-girls school and one school nominated a class that consisted of boys-only to participate.

Table 15: 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: *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.

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 use of school decile category as a covariate. The stratified block randomisation was implemented using all three strata, as originally planned.

6.1.2 Participants

Each of the clusters nominated children, based on the criteria outlined in section 5.6, to potentially take part and a total of 151 children were recruited. Nine children withdrew from the research before baseline outcome measures were collected (see Figure 6, p. 128). The baseline characteristics of the 142 participants who provided baseline data are described in Table 15 (p. 130). In total, 77 females and 65 males took part; participant ages ranged from 11.0-13.3 years, with a mean age of 12.09 years (SD 0.6). The relative gender and ethnic distributions in relation to the general population, as reported by Statistics New Zealand (2013, 2014), are outlined in Figure 8 and Figure 9.

a) b)

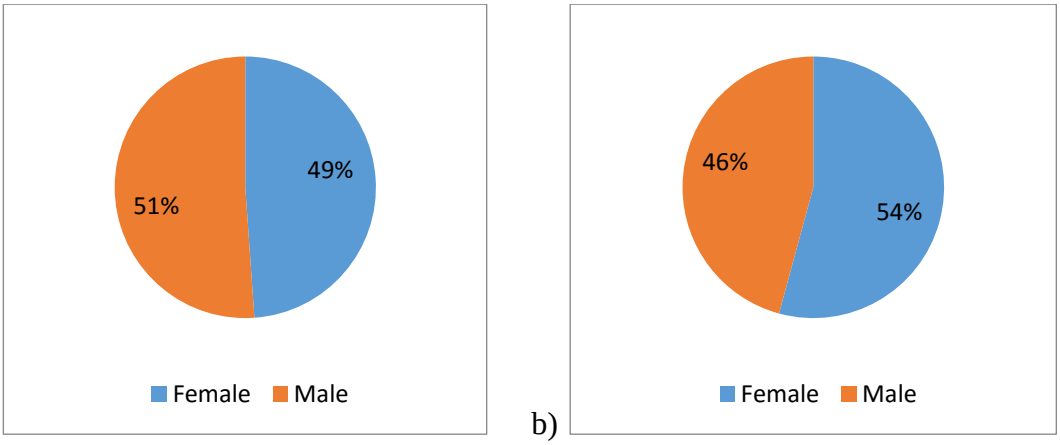
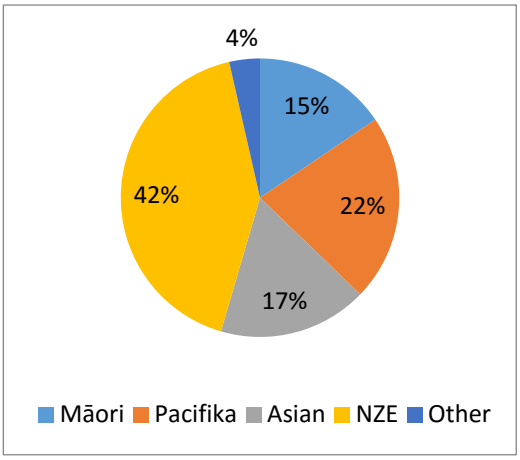
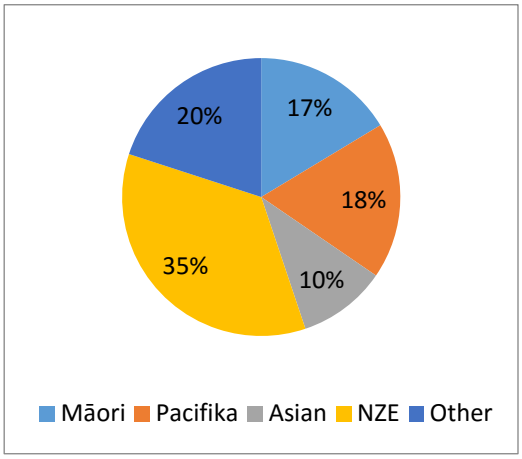


Figure 8. a) Gender distribution of intermediate school students in Auckland Region; b) Gender distribution of participants in the current study

a)



b)



Abbreviation: NZE=New Zealand European.

Figure 9. a) Ethnic distribution of intermediate school students in Auckland Region; b) Ethnic distribution of participants in the current study

Figure 8 illustrates that a higher proportion of females were recruited than that found in the general population of intermediate school students in the Auckland region. Similar proportions of Māori were represented in the sample as in the general population (see Figure 9). Fewer children identifying with Asian and New Zealand European ethnicities were recruited in relation to the general population and there were notably more participants identifying with the 'other' category included in the study, which predominantly consisted of children identifying as South African. A chi-square test of homogeneity was conducted (see Appendix 12) and overall, the gender and ethnicity distributions in the sample were not found to be significantly different from the general population the participants were drawn from.

6.1.3 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 the children. On both occasions, unblinding occurred when a child mentioned his or her participation in the intervention to the outcome assessor (despite being prompted not to). 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 they had absolutely no idea.

6.2 Baseline data

6.2.1 Missing data at baseline

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. A summary of the missing data at baseline is presented in Table 16 (p. 133). Missing data at baseline, as well as missing covariate data, were managed through multiple imputation, as stipulated in the statistical analysis plan (see section 5.10.5).

Table 16: Summary of missing outcome measure data at baseline

Outcome measure	***n* missing at baseline**	***n* available (out of a possible 142)**
Child-rated outcomes		
MASC10	4	138
CDI2	7	135
RSES	10	132
COPM Performance	10	132
COPM Satisfaction	11	131
Wellbeing	11	131
Parent-rated outcomes		
RCADS GA	60	82
RCADS D	60	82
COPM Performance	60	82
COPM Satisfaction	60	82
SISES	64	78
Teacher-rated outcomes		
SAS	37	105
SAS GA	37	105
SAS SA	37	105

Data completeness at baseline for each measure and within each analysis varied. In order to clearly and accurately present information about missingness in the data, each table reports the number of observations available for each outcome, for each hypothesis, at each timepoint and for each analysis set. In all cases, 142 observations would have been available at baseline had no data been missing. Multiple imputation was used to reduce the risk of selection bias due to missingness.

6.2.2 Baseline outcomes

The baseline data for child-rated outcomes, by cluster and allocation status, are presented in Table 17 (p. 135); the parent- and teacher-rated baseline measures are presented in Table 18 (p. 136) and Table 19 (p. 137) respectively. 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.

6.2.3 Baseline anxiety

Across all of the clusters, the average *t*-score on the primary outcome, the Multidimensional Anxiety Scale for Children – Short form (Multidimensional Anxiety Scale for Children – Short form: MASC10) – at baseline, was 52, which sits squarely in the non-clinical range. At baseline, the average scores across both study arms for the parent- and teacher-rated measures of anxiety – Revised Child Anxiety and Depression Scale: General Anxiety subscale (RCADS-GA) and the School Anxiety Scale (SAS), respectively – were in the non-clinical range. The SAS was the only measure of anxiety where some of the clusters scores at baseline were in the clinical range (four out of seven clusters in both the control and intervention arms).

Table 17: Baseline data for child-rated measures, by cluster and study arm

		Child-rated measures: Mean (standard deviation)[7]									
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; SD=standard deviation; SLSS=Student Life Satisfaction Scale; ^=between cluster variance; $=within cluster variance.

[7]Non-clinical range for measures: MASC10=<56; CDI2=<59 – lower scores indicate lower levels of symptoms. RSES, COPM Performance, COPM Satisfaction and SLSS – higher scores indicate higher levels of self-esteem, performance, satisfaction and wellbeing.

Table 18: Baseline data for parent-rated measures, by cluster and study arm

	Parent-rated measures: Mean (standard deviation)[8]									
Cluster ID	***n***	**RCADS–GA**	***n***	**RCADS-D**	***n***	**SISES**	***n***	**COPM Performance**	***n***	**COPM Satisfaction**
Control										
01NCH	4	41.5(4.1)	4	64.8(15.1)	4	2.0(1.2)	4	5.8(3.2)	3	6.6(3.2)
02KRL	2	57.0(2.8)	2	55.5(16.3)	2	2.5(0.7)	2	7.5(2.1)	2	7.0(2.8)
04WMH	13	41.6(5.3)	13	55.6(10.2)	10	3.2(0.9)	11	7.19(1.9)	11	6.5(2.0)
07SHH	12	42.4(4.0)	12	52.8(7.0)	12	3.4(1.8)	12	5.4(2.4)	12	5.6(2.3)
10MPL	3	40.0(3.0)	3	50.7(12.5)	3	3.0(2.0)	3	7.3(4.6)	3	7.0(5.2)
13GPL	2	44.5(2.1)	2	44.0(0.0)	2	4.5(0.7)	2	10.0(0.0)	2	10.0(0.0)
14PIM	4	41.5(3.9)	4	62.0(6.2)	4	3.5(1.0)	4	7.8(1.7)	4	7.8 (2.1)
Total	*40*	*43.3 (1.4^, 5.2$)*	*40*	*54.7 (6.0^, 9.4$)*	*37*	*3.4 (0.6^, 1.0$)*	*38*	*7.4 (1.0^, 2.0$)*	*37*	*7.3 (0.8^, 2.1$)*
Intervention										
03CPH	7	42.6(9.0)	7	61.9(13.8)	7	3.0(1.0)	7	7.3(3.2)	7	7.3(2.3)
05WIM	10	46.1(8.8)	10	60.2(11.6)	10	2.6(0.8)	10	4.8(2.5)	10	4.8(2.5)
06AIL	3	40.6(4.7)	3	49.3(7.6)	3	3.7(1.2)	3	7.7(2.5)	3	7.0(2.7)
08GEH	9	41.6(5.8)	9	65.3(9.4)	9	3.0(1.2)	9	6.8(2.8)	9	5.9(2.8)
09KTH	10	40.8(5.2)	10	58.3(8.8)	9	3.2(1.2)	9	6.1(2.7)	9	6.2(2.6)
11MCL	5	41.4(10.4)	5	47.8(12.5)	3	3.3(0.6)	5	5.4(3.2)	5	7.8(1.9)
12DGH	6	44.2(5.2)	6	53.0(8.0)	6	2.5(1.2)	6	6.5(2.8)	6	6.7(2.4)
Total	*50*	*42.7 (1.3^, 7.0$)*	*50*	*57.0 (5.8^, 10.2$)*	*47*	*3.0 (0.2^, 1.0$)*	*49*	*6.0 (0.6^, 2.5$)*	*49*	*6.2 (0.7^2.1$)*
Total – all schools	*90*	*42.9 (1.0^, 6.2$)*	*90*	*55.9 (5.7^,9.8$)*	*84*	*3.2 (0.5^, 1.0$)*	*87*	*6.7 (0.9^, 2.1$)*	*86*	*6.7 (0.9^,2.1$)*

Notes: ^=between cluster variance; $=within cluster variance; *.n*=number of observations available. *Abbreviations*: COPM=Canadian Occupational Performance Measure; RCADS – GA= Revised Child Anxiety and Depression Scale – Parent report – Generalised Anxiety subscale; RCADS – D= Revised Child Anxiety and Depression Scale – Parent report – Major Depression subscale; SISES=Single Item Self-Esteem Scale; ^=between cluster variance; $=within cluster variance.

[8] Non-clinical range for RCADS (GA and D)=<65 – lower scores indicate lower levels of symptoms; SISES, COPM Performance, and COPM Satisfaction – higher scores indicate higher levels of self-esteem, performance and satisfaction.

Table 19: Baseline data for teacher-rated measures, by cluster and study arm

		Teacher-rated measures: Mean (standard deviation)[9]		
Cluster	***n***	**SAS**	**SAS-GA**	**SAS-SA**
Control				
01NCH	8	18.3(10.2)	11.5(7.2)	7.0(3.6)
02KRL	12	19.3(4.4)	8.9(2.2)	10.3(2.8)
04WMH	13	7.0(7.8)	4.3(4.2)	2.6(4.1)
07SHH	12	12.3(6.8)	7.4(5.2)	4.8(3.5)
10MPL	8	18.4(8.2)	9.0(4.3)	9.4(5.7)
13GPL	0	-	-	-
14PIM	8	22.6(7.9)	13.6(3.1)	9.0(6.1)
Total	*61*	*15.2*	*8.5*	*6.6*
		(5.2^, 6.7$)	*(3.0^, 4.2$)*	*(2.7^, 3.7$)*
Intervention				
03CPH	10	21.2(11.0)	12.2(6.1)	9.0(5.6)
05WIM	10	22.2(6.0)	12.7(3.1)	9.5(4.6)
06AIL	8	12.4(10.6)	6.1(5.8)	6.3(4. 9)
08GEH	7	20.6(11.8)	12.3(6.9)	8.4(5.2)
09KTH	10	15.2(6.3)	9.2(5.4)	6.0(2.6)
11MCL	11	12.5(7.0)	7.1(3.8)	5.4(4.3)
12DGH	8	25.8(12.6)	15.1(6.0)	10.6 (7.0)
Total	*64*	*18.5*	*10.7*	*7.9*
		(4.7^, 9.1$)	*(3.0^, 5.1$)*	*(1.7^, 4.8$)*
Total – all schools	*125*	*16.9*	*9.7*	*7.3*
		(5.1^,7.9$)	*(3.1^, 4.7$)*	*(2.2^, 4.2$)*

Notes: ^=between cluster variance; $=within cluster variance; *n*=number of observations available. *Abbreviations*: SAS=School Anxiety Scale; SAS-GA=School Anxiety Scale-Generalised Anxiety subscale; SAS-SA=School Anxiety Scale-Social Anxiety subscale; ^=between cluster variance; $=within cluster variance.

6.2.4 Baseline occupational participation

The COPM performance and satisfaction scales were completed by the children in relation to two occupational menu items they identified as wanting to improve in. Their parents also rated the child's performance and satisfaction of the same items, without explicit knowledge of how their child rated themselves. Table 20 (p. 139) presents the frequency with which each menu item was selected by child participants as something

[9] SAS (total, SA and GA) – lower scores indicate lower levels of anxiety symptoms.

they wanted to improve over the course of the intervention. The most commonly selected items were being able to set goals and work towards them (12.5%), physically active occupations (11.7%) and occupations that enabled them to rest and relax (9.6%).

Distinct cut-off scores indicating levels of performance or satisfaction are not used in the COPM so evaluation is determined by change scores. At baseline the scores varied considerably across clusters (child-rated COPM: performance range= 4.0-9.0; satisfaction range=3.6-9.1; parent-rated COPM: performance range=4.8-10.0; satisfaction range=4.8-10.0) and between study arms (child-rated COPM: performance=6.1 and 5.8; satisfaction=6.2 and 5.3; parent-rated COPM: performance=7.4 and 6.0; satisfaction=7.3 and 6.2, control and intervention groups respectively) (see Table 17, p. 135; and Table 18, p. 136). One cluster had an average baseline score of 10 for parent-rated performance and satisfaction, at the upper end of the scale, thus allowing no scope for improvements to occur in parent ratings.

Table 20: Frequency of items selected as part of the Canadian Occupational Performance Measure (COPM)

COPM menu items (in order of most to least selected in total)	Frequency count			Proportion of participants who selected item
	First activity	Second activity	Combined total	
I am able to set goals and work towards them	17	18	35	24.6%
I participate in activities that are physically active	18	15	33	23.2%
I am able to participate in activities that help me to rest and relax	12	15	27	19.0%
I communicate well with others (in person)	10	13	23	16.2%
I take an active role in my learning	14	9	23	16.2%
I cope with strong emotions and am still able to participate in my daily occupations	9	12	21	14.8%
I cope with unhelpful thoughts and am still able to participate in my daily occupations	8	13	21	14.8%
I participate in activities that are important to me	11	7	18	12.7%
I participate in activities that support me getting a good night's sleep	9	6	15	10.6%
I participate in social activities with friends	7	7	14	9.9%
I have a routine I am happy with	9	4	13	9.2%
I participate in activities that express my identity	5	7	12	8.5%
I participate in calm activities	4	5	9	6.3%
I participate in social activities with my family	4	5	9	6.3%
I communicate well with others (via a device)	4	4	8	5.6%
Totals	*141*	*140*	*281*	*200%**

*represents participants ability to choose two items.

6.2.5 Baseline depression, self-esteem and wellbeing

Child-rated depression, as measured by the Children's Depression Inventory – 2nd version (CDI2) was in the highly elevated range for all clusters at baseline, regardless of allocation to the intervention or control. This indicates a level of clinical depression was present in the participating children.

At baseline, the average scores across both study arms for the parent-rated measure of depression symptoms - Revised Child Anxiety and Depression Scale: Depression scale (RCADS-D) were in the non-clinical range. However, two clusters in the control arm of the study and three clusters in the intervention arm of the study had an average RCADS-D score in the elevated range (≥60); with one of those in the clinical range (≥65) indicating the presence of probable depression as reported by parents.

Child-rated self-esteem was measured using the Rosenberg Self-Esteem Scale (RSES), which does not use distinct cut-offs to determine levels of self-esteem: scores range between 0-30 with higher scores denoting higher levels of self-esteem. Variability in the RSES baseline scores was evident across both arms of the study (intervention: 12.4-22.9; control: 13.6-22.7); however, the mean scores were similar.

The average parent-rated measure of their child's self-esteem, the Single Item Self-Esteem Scale (SISES), was reasonably consistent across the study arms at baseline (control=3.4; intervention=3.0). The SISES is a single-item scale with 5 points from 1-5 with higher scores indicating higher self-esteem.

The Student Life Satisfaction Scale (SLSS), a child-rated measure of wellbeing, similarly does not use distinct cut-offs to determine levels of wellbeing: scores range from 0-20 and higher scores denote greater levels of wellbeing. At baseline, the average scores across the arms of the study were similar (control=14.5; intervention=14.1).

6.3 Process evaluation

As part of the cluster-RCT a number of measures were included to evaluate the implementation process of the intervention, Kia Piki te Hauora: Uplifting our Health and Wellbeing©. Intervention adherence and fidelity were both measured and are reported on here.

6.3.1 Intervention adherence

Intervention adherence was assessed by participant attendance and completion of skills practice tasks between sessions: it is not a representation of the number of participants followed-up who completed the outcome measures. The number of participants who attended each session, from each cluster, is presented in Table 21 (p. 141). Nine of the 14 clusters had ≥80% attendance (range 64-94%) and the overall attrition was 18%. Each session was well attended; overall attendance ranged from 77-90% with no marked drop-off in attendance as the intervention progressed. The number of participants who completed the skills practice between each session, from each cluster, is presented in Table 22 (p. 142). Many of the clusters completed less than half of the skills practice with only four completing ≥54% (overall range 10-66%). Completion rates of skills practice between sessions ranged from 40% (session 6) to 69% (session 8), with an overall completion rate of 40%.

Table 21: Summary of participant attendance at each session, by cluster

			Number of participants attending each session								*Attendance*
Cluster ID	**Cluster size**	***n****	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	***overall (%)***
01NCH	8	8	8	8	6	5	5	8	5	6	*51 (80%)*
02KRL	12	11	10	11	10	11	10	4	11	11	*78 (89%)*
03CPH	10	10	10	10	10	7	9	10	10	9	*75 (94%)*
04WMH	13	12	10	10	8	11	11	10	10	11	*81(84%)*
05WIM	10	10	9	10	6	6	5	7	7	6	*56 (70%)*
06AIL	9	9	9	9	8	9	9	9	6	8	*67 (93%)*
07SHH	12	12	5	11	11	12	10	12	11	10	*82 (85%)*
08GEH	10	10	7	8	7	7	7	6	5	5	*52 (65%)*
09KTH	11	10	10	9	8	9	10	10	9	9	*74 (93%)*
10MPL	8	8	7	7	8	4	7	6	4	7	*50 (78%)*
11MCL	11	11	9	11	9	7	10	7	11	9	*73 (83%)*
12DGH	8	8	8	5	7	8	2	4	7	6	*47 (73%)*
13GPL	11	10	10	8	10	10	9	9	7	9	*72 (90%)*
14PIM	9	7	4	5	5	4	4	3	6	5	*36 (64%)*
Totals (%)	*142*	*136*	*116 (85)*	*122 (90)*	*113 (83)*	*110 (81)*	*108 (79)*	*105 (77)*	*109 (80)*	*111 (82)*	*82%*

Note: *n*=observations available; *Data for some participants was missing due to either withdrawal from the intervention or administrative error.

Table 22: Summary of skills practice completion each session, by cluster

			Number of completed skills practice**							*Skills practice*
Cluster ID	**Cluster size**	***n****	**2**	**3**	**4**	**5**	**6**	**7**	**8**	***completed overall (%)***
01NCH	8	8	5	4	3	1	1	4	4	*22 (34%)*
02KRL	12	11	3	5	4	3	4	6	7	*32 (36%)*
03CPH	10	10	3	6	6	2	4	4	8	*33 (41%)*
04WMH	13	12	8	8	10	9	7	10	11	*63 (66%)*
05WIM	10	10	5	3	4	3	1	2	3	*21 (26%)*
06AIL	9	9	7	7	7	5	5	2	6	*39 (54%)*
07SHH	12	12	6	7	12	10	9	10	8	*62 (65%)*
08GEH	10	10	2	0	1	1	0	0	4	*8 (10%)*
09KTH	11	10	5	5	4	9	7	5	9	*44 (55%)*
10MPL	8	8	4	0	2	3	3	4	5	*21 (33%)*
11MCL	11	11	3	3	4	6	6	3	5	*30 (34%)*
12DGH	8	8	5	5	5	2	2	3	5	*27 (42%)*
13GPL	11	10	3	1	1	3	0	3	6	*17 (21%)*
14PIM	9	7	3	4	2	4	0	2	5	*20 (36%)*
Totals (%)	*142*	*136*	*62 (47)*	*58 (45)*	*65 (51)*	*61 (49)*	*49 (40)*	*58 (48)*	*86 (69)*	*40%*

Notes: *n*=observations available; *Data for some participants was missing due to either withdrawal from the intervention or administrative error; **No skills practice was expected in preparation for session 1.

6.3.2 Intervention fidelity

Within 24 hours of each session from the intervention being completed, the facilitator (the primary investigator for this study/the doctoral candidate) completed a 14-item self-rated fidelity checklist to rate programme delivery and fidelity to the intervention protocol (see Table 12, p. 95). Facilitator compliance with the content and delivery of the intervention was generally high. Table 23 (p. 143) presents the data on fidelity scores by session, cluster and in total. The reasons for reduced fidelity scores are presented in Table 24 (p. 144) and were predominantly the result of disruptive behaviour (e.g. talking over the facilitator giving instructions requiring them to be repeated or provoking negative reactions from peers) or the facilitator forgetting to administer the knowledge quiz.

Table 23: Intervention fidelity scores for each session, by cluster

			Fidelity score[10] for each session								***Total score/cluster***
Cluster	**Year**	**Term**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	***(out of 112)***
01NCH	2014	4	14	14	14	13	14	14	13	13	*109*
02KRL	2014	3	14	14	14	14	14	14	14	14	*112*
03CPH	2014	2	14	13	12	14	13	14	14	14	*108*
04WMH	2014	3	14	14	14	14	14	14	14	14	*112*
05WIM	2014	2	14	14	14	13	14	14	14	14	*111*
06AIL	2014	2	14	14	14	14	14	13	13	13	*109*
07SHH	2014	3	14	14	14	14	14	14	14	14	*112*
08GEH	2014	3	14	14	13	14	14	13	14	14	*110*
09KTH	2014	3	14	14	13	13	14	14	13	14	*109*
10MPL	2015	3	14	12	12	14	14	11	14	13	*104*
11MCL	2015	2	14	13	14	13	9	10	12	13	*98*
12DGH	2015	2	14	14	14	14	14	14	14	13	*111*
13GPL	2015	3	14	12	14	14	13	13	14	13	*107*
14PIM	2015	3	14	14	13	14	14	14	14	14	*111*
Total/session(out of 196)			*196*	*190*	*189*	*192*	*189*	*186*	*191*	*190*	

[10] Fidelity score was out of 14 for each session.

Table 24: Frequency and reasons for reduced intervention fidelity

Item where points lost	Frequency	Reasons for infidelity
Adhered to activities as designed	10	Disruptive behaviour – 5 Adapted to better meet needs of the group – 3 Accommodate shorter session due to timetable change - 2
Pacing and transitions	9	Disruptive behaviour – 5 Shorter sessions due to timetable change – 2 Students attending medical appointments - 2
Key messages reviewed	9	Forgot to complete knowledge quiz (at either start or end) - 9
Activities all conducted	8	Ran out of time – 5 Disruptive behaviour – 2 Forgot - 1
Students actively engaged	6	Disruptive behaviour – 4 Unknown – 2
Facilitator encouraging	1	Illness - 1

6.4 Descriptive statistics

The descriptive statistics from the child-, parent- and teacher-rated outcomes are summarised in Table 26 (p. 147), Table 27 (p. 148) and Table 28 (p. 149) respectively. All data were included in the analysis model and no data were removed for the purposes of the ITT analyses. The PP dataset included the data from participants where there were no eligibility violations. Eligibility violations occurred when data were deemed to have been collected out-of-window (p. 109), participants allocated to the intervention did not attend a minimum of four sessions (out of a possible eight) and participants allocated to the control had been exposed to two or more sessions of the intervention. The numbers of participants in the various datasets used are presented in Table 25 (p. 146). Data at each assessment point were reported in relation to the relative phase: parallel phase, crossover phase or follow-up assessment, as defined below (see Figure 10, p. 145).

6.4.1 Parallel phase

The parallel phase refers to data collected at baseline (pre-randomisation) and at the same assessment point for both study arms (in other words, the post-intervention for the intervention group and post-waitlist for the control group). The data from the parallel phase informs the primary analysis, focusing on hypothesis A.

6.4.2 Crossover phase

On completion of the parallel phase of the trial, the control group completed crossover phase baseline measures (in other words, pre-intervention measures completed post-randomisation for the control group), went on to receive the intervention and then completed crossover phase assessments (i.e. post-intervention for the control group). This crossover phase only applies to the control arm and its data, added to the parallel phase data, and informs key secondary analyses, focusing on hypothesis B. The data were managed in this way to increase the statistical power of the analysis and improve the efficiency of the model by reducing the variance of the effect size estimates.

6.4.3 Follow-up assessment

The follow-up assessment point was defined as occurring 8-9 weeks after completion of the intervention for both the intervention and control groups. It informs the longitudinal analysis focusing on hypothesis C.

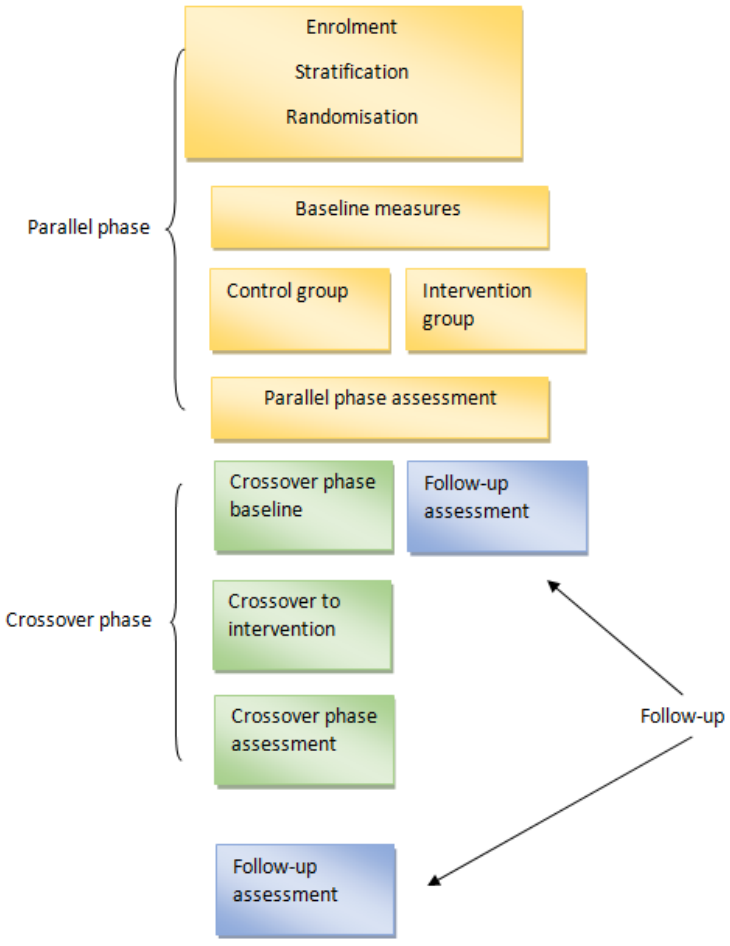


Figure 10: Study flow diagram illustrating study phases

Table 25: Number of participants included and excluded from each dataset

Dataset	***N* expected**	***n* included**	***n* intervention**	**+ *n* 1**	***n* control**	**+ *n*2**	***n* lost to follow-up/missing**	***n* out-of-window**
Intention-to-treat (ITT)								
Parallel phase	142	142	69		73			
Crossover phase	215	215	142		73			
Follow-up	142	131	131		0		11	
Sub-group: MASC10 *t*-score <56	-	84	36		48			
Sub-group: MASC10 *t*-score ≥56	-	58	33		25			
Per protocol (PP)								
Parallel phase	142	104	59	0	39	6	10	28
Crossover phase	215	165	118	0	39	8	22	28
Follow-up	142	120	120	0	0	10	11	1

Notes: *n*1=participants switched from control to intervention due to protocol violations; *n*2=participants switched from intervention to control due to protocol violations.

Table 26: Means and standard deviations for child-rated outcomes at each assessment point

Child-rated outcomes	Study arm	Baseline (pre-randomisation) *n*	Mean (bcv, wcv)	95% CI	Parallel phase assessment point *n*	Mean (bcv, wcv)	95% CI	Crossover phase baseline *n*	Mean (bcv, wcv)	95% CI	Crossover phase assessment point *n*	Mean (bcv, wcv)	95% CI	Post-intervention follow-up *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: *scores are already adjusted for age and gender; + 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 (for the intervention and control groups) or pre-intervention (for the crossover group). *Abbreviations*: bcv=between-cluster variance; CDI2=Children's Depression Inventory (2nd Ed); CI=confidence interval; COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; *n*=observations available; RSES=Rosenberg Self-Esteem Scale; SLSS=Student Life Satisfaction Scale; wcv=within-cluster variance.

Table 27: Means and standard deviations for parent-rated outcomes at each assessment point

Parent-rated outcomes	Study arm	Baseline (pre-randomisation) *n*	Mean (bcv, wcv)	95% CI	Parallel phase assessment point *n*	Mean (bcv, wcv)	95% CI	Crossover phase baseline *n*	Mean (bcv, wcv)	95% CI	Crossover phase assessment point *n*	Mean (bcv, wcv)	95% CI	Post-intervention follow-up *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: *scores are already adjusted for age and gender; [+] =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 (for the intervention and control groups) or pre-intervention (for the crossover group). *Abbreviations*: CI=confidence interval; *n*=observations available; COPM=Canadian Occupational Performance Measure; MASC10=Multidimensional Anxiety Scale for Children – Short form; *n*=observations available; 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 28: Means and standard deviations for teacher-rated outcomes at each assessment point

Teacher-rated outcomes	Study arm	Baseline (pre-randomisation) *n*	Mean (bcv, wcv)	95% CI	Parallel phase assessment point *n*	Mean (bcv, wcv)	95% CI	Crossover phase baseline *n*	Mean (bcv, wcv)	95% CI	Crossover phase assessment point *n*	Mean (bcv, wcv)	95% CI	Post-intervention follow-up *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: *scores are already adjusted for age and gender; $^{+}$ =average score is defined as the average of the scores for both activities if present or the score of one if one was missing. *Abbreviations*: CI=confidence interval; *n*=observations available; SAS=School Anxiety Scale; SAS GA=School Anxiety Scale – Generalised Anxiety subscale; SAS SA=School Anxiety Scale – Social Anxiety subscale.

6.4.4 Estimated intra-cluster correlation coefficients

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 (see section 5.11.1). Accurate reporting of ICCs require sufficient description of the dataset (including the sample, outcomes measured and nature of the intervention – described for this study in section 6.4); the method of calculation (see section 5.11.1); and the precision of the ICC (Campbell, Grimshaw, & Elbourne, 2004). Calculated ICCs are reported in Table 29 (p. 150); no adjustments were made for covariates in these analyses. Given the low variation in cluster sizes within the current study (*cv*=0.14, p. 116), it can be assumed the precision of the ICCs calculated was reasonable.

Table 29: Intra-cluster correlation coefficients 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

ICCs for the current study ranged between 0.00-0.71. The estimated ICC was within that actual range calculated and facilitated a more conservative adjustment than was indicated for 12 of the 14 measures, therefore, can be considered to have been a reasonable estimate to use in the sample size calculation. The ICCs reported in Table 29 may be considered in future estimates for similar research designs with these outcomes.

6.5 Efficacy 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. 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. An interaction term of intervention indicator crossed with time was also included to account for the repeated measures (parallel and crossover phases, as well as follow-up assessment).

6.5.1 Adjusted ITT analyses

6.5.1.1 Analyses of the parallel phase data

Hypothesis A: There will be a difference in post-intervention child-rated anxiety (primary outcome), self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations, as compared to control period outcomes, when considering only the parallel phase data.

The results of the primary analysis on the ITT dataset, including covariates and whether clustering was accounted for, are presented in Table 30 (p. 152). 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 change of ± 2 was not achieved. The change estimate for the primary outcome measure (MASC10) after the parallel phase went counter to the anticipated direction: the intervention group average MASC10 score increased slightly (+1.5), whereas the average scores for the control group remained relatively static (-0.4). The score change for this outcome was not clinically or statistically significant: a change of ± 5 would have been required to achieve clinical significance, with higher scores denoting higher levels of symptoms.

Table 30: Hypothesis A: Adjusted analyses from the parallel trial

		Covariates*					Hypothesis A: Adjusted – differences between study arms at the primary end-point			
Outcome	***n* available (*N*=142)**	**Baseline score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Estimated difference**	**Standard error**	**95% CI[a]**	***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 Performance	130			✓	✓	✓	0.8	0.5	-0.2-1.8	0.117
COPM Satisfaction	130			✓	✓	✓	1.3	0.5	0.3-2.3	0.009***
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 Performance	59		✓	✓		✓	1.2	0.9	-0.5-3.0	0.171
COPM Satisfaction	58		✓	✓		✓	0.2	1.1	-1.9-2.3	0.851
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: [a] Confidence Interval; *covariates 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.

6.5.1.2 Analysis of the crossover phase data

Hypothesis B: There will be a difference in post-intervention child-rated anxiety (primary outcome), self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations, as compared to control period outcomes, when considering both the parallel phase and the crossover phase data.

The results of the secondary analysis of hypothesis B are presented in Table 31 (p. 154). There was no significant effect of the intervention on the primary outcome (MASC10) based on both the parallel phase and the crossover phase data. A positive effect of the intervention found on the children's COPM satisfaction scale was approaching significance (0.3, 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 non-inferiority threshold values were substituted as score changes indicative of clinically significance (SAS=$\pm$1.7; SAS-GA=$\pm$1.0; SAS-SA=$\pm$0.9), then it may be suggested that clinically significant positive change was achieved post-intervention in comparison to the control period.

Table 31: Analysis of hypothesis B (intervention effect from the parallel and crossover phases combined)

		Covariates*					Hypothesis B – differences between study arms at post-intervention			
Outcome	***n* available (*N*=215)**	**Baseline score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Estimated difference**	**Standard error**	**95% CI[b]**	***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 Performance	189			✓	✓	✓	0.4	0.3	-0.3-1.0	0.258
COPM Satisfaction	189			✓	✓	✓	0.6	0.3	-0.1-1.3	0.076
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 Performance	82		✓	✓		✓	-0.6	0.4	-1.4-0.3	0.208
COPM Satisfaction	81		✓	✓		✓	-0.7	0.5	-1.6-0.3	0.146
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: [a] Standard error; [b] Confidence Interval; *covariates 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.

6.5.1.3 Sub-group analyses

The data from the parallel phase were divided into participants with lower child-rated anxiety (MASC10 *t*-score <56) and participants with higher child-rated anxiety (MASC10 *t*-score ≥56) at baseline. Analysis of hypothesis A was conducted on each sub-group of the data, in relation to two outcome measures (MASC10 and COPM performance and satisfaction scales) and adjusted for the same covariates as in the primary analysis: the results are presented in Table 32 (p. 155). Conducting the sub-group analysis on the COPM scales was a deliberate amendment to the statistical analysis plan and decided upon prior to conducting the analysis but after unblinding. This decision was made as participation was a primary target of the intervention and the COPM is an occupational therapy outcome measure deemed sufficiently important to include in this analysis. A positive effect of the intervention was found on the children's COPM performance and satisfaction scales (1.6, p=0.035) after the parallel phase, for the more anxious sub-group (MASC10 *t*-score ≥56) that was significant at the 0.05 level. However, due to the significance threshold of $p \leq 0.025$ not being met, as determined by the False Discovery Rate for hypotheses in the same family, this result was not deemed significant at the nominal 0.05 level.

Table 32: Sub-group analysis of hypothesis A

	Hypothesis A: Sub-group analysis – differences between study arms at post-intervention (lower anxiety <56)				**Hypothesis A: Sub-group analysis – differences between study arms at post-intervention (higher anxiety ≥56)**			
Outcome	**Estimate**	**SE**	**95% CI[a]**	***p*-Value**	**Estimate**	**SE**	**95% CI[a]**	***p*-Value**
MASC10	2.9	2.2	-1.4-7.1	0.190	3.1	2.6	-2.0-8.2	0.234
COPM Performance	0.4	0.6	-0.8-1.6	0.495	1.3	0.7	-0.1-2.6	0.059
COPM Satisfaction	1.1	0.6	-0.1-2.4	0.069	1.6	0.7	0.1-3.0	0.031*

Notes: SE=standard error; [a] Confidence Interval; *significant at p<0.05.

6.5.2 Adjusted PP analyses

The results of the PP analysis for hypotheses A and B are presented in Table 33 (p. 157). A statistically significant positive effect of the intervention was found on the child-rated COPM satisfaction scale (1.1, p=0.038) after the parallel phase. Statistically significant positive effects of the intervention were found on the child-rated COPM performance and satisfaction scales after the crossover phase (0.7, p=0.034 and 0.8, p=0.045 respectively). These estimates of difference between the study arms, on the child-rated COPM scales, were not clinically significant for either phase. The significant positive effects of the intervention on the child-rated COPM performance and satisfaction scales, after the crossover phase, were not present in the ITT analysis. The presence of these significant results in the PP analysis indicate that the protocol violations (primarily complete, in-window outcome data and attending four or more sessions) may have been important factors in achieving a positive effect for participants.

Table 33: Hypothesis A and B using PP dataset

	Covariates*					Hypothesis A: Adjusted: Differences between study arms after the parallel phase				Hypothesis B: Differences between study arms after the crossover phase			
Outcome	**Baseline outcome score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Estimated difference**	**Standard error**	**95% CI[a]**	***p*-Value**	**Estimated difference**	**Standard error**	**95% CI[b]**	***p*-Value**
MASC10**	✓	✓	✓		✓	3.2	2.0	-0.6-7.0	0.102	-0.7	1.5	-3.5-2.2	0.637
COPM Performance			✓	✓	✓	0.4	0.5	-0.2-1.7	0.135	0.7	0.3	0.1-1.4	0.034***
COPM Satisfaction			✓	✓	✓	1.0	0.5	0.1-2.1	0.038***	0.8	0.4	0.0-1.6	0.045***

Notes: *covariates determined by the blind review; **scores are already adjusted for age and gender; ***significant at $p<0.05$ level.

6.5.3 Unadjusted analyses

Unadjusted analyses are presented here as recommended in the CONSORT guidelines (Moher et al., 2010): adjustments were made for selected variables, nominated *a priori* and adjusted for using analyses of covariance as reported in section 6.5.1. The results of the unadjusted analysis of the primary and secondary outcomes are presented in Table 34 (p. 160). A significant negative effect of the intervention on the primary outcome (MASC10) was found (7.2, p=0.011) suggesting a greater increase in anxiety for the intervention group than for the control group. However, this finding was no longer significant once the analysis was adjusted for by the relevant covariates. In order to understand this discrepancy, the estimated coefficients for the covariates were reviewed and higher anxiety at baseline (i.e. mean MASC10 *t*-score) was found to significantly contribute to higher anxiety at post-intervention by a coefficient of 0.7 for each unit of increase in the MASC10 *t*-score (p<.0001), along with being Māori by a coefficient 4.6 (p=0.027) or Asian by a coefficient of 7.0 (p=0.004), as compared to belonging to the reference category of New Zealand European. The baseline data presented in Table 15 (p. 130) show a higher proportion of Māori participants were included in the control group as compared to the intervention group and a slightly higher proportion of Asian participants were present in the intervention group as compared to the waitlist control group. Table 17 (p. 135) shows a higher mean anxiety score for the intervention group at baseline as compared to the control group. These data support the conclusion that higher anxiety in the intervention group after the parallel phase, in the unadjusted analysis, was partly the result of higher anxiety in that group at baseline and was likely to have been affected by an uneven distribution of Māori and Asian participants across the study arms.

A statistically significant positive effect of the intervention was found on the children's COPM satisfaction scale (1.2, p=0.007) for participants in the intervention group compared with those in the control group; the positive effect was upheld in the adjusted analysis (1.3, p=0.009).

In the unadjusted analyses, non-significant effects of the intervention were found on the SAS, SAS-GA and SAS-SA; however, in the adjusted analyses of hypothesis B these were found to be significant. These inconsistencies may be understood in the context of the covariates found to have the most significant effect in the adjusted analyses, which for all three scales was the baseline score by a coefficient of 0.1 (p<.0001). A review of

the baseline data presented in Table 19 (p. 137) shows the intervention group had higher scores at baseline, which in the unadjusted analysis will have masked the significant effects of the intervention that were found in the adjusted analysis.

Similarly, a non-significant increase in parent-rated child depression, as measured by the RCADS-D, shifted to a non-significant decrease in depression in the adjusted analysis. This was again attributable to the baseline scores for this outcome (coefficient 0.5, $p<.0001$) that were found to be slightly higher for the intervention group at baseline (with higher scores indicating higher levels of symptoms), as compared to the control group (see Table 18, p. 136), potentially masking the positive direction of change.

The unadjusted analysis found a non-significant increase in wellbeing, as measured by the Student Life Satisfaction Scale (SLSS) that shifted to being a non-significant decrease in wellbeing in the adjusted analysis. A review of the estimated coefficients for the covariates were reviewed and revealed baseline wellbeing had a significant effect on this outcome after the parallel phase, by a coefficient of 0.7 ($p<.0001$). Baseline wellbeing scores for the intervention group were slightly lower for the intervention group, as compared to the control group, with higher scores indicating improved wellbeing (see Table 17, p. 135). However, the difference between the unadjusted and adjusted estimates was minimal (0.0) so this discrepancy does not warrant further investigation.

Table 34: Hypothesis A: Unadjusted analyses from the parallel trial

		Hypothesis A: Unadjusted – differences between study arms at the primary end-point		
Outcome	***n* available (*N*=142)**	**Unadjusted estimated difference**	**Standard error**	***p*-Value**
Child-rated outcomes				
MASC10*	132	7.2	2.4	0.011**
CDI2*	124	1.4	1.8	0.456
RSES	129	0.4	2.1	0.861
COPM Performance	130	0.5	0.4	0.231
COPM Satisfaction	130	1.2	0.4	0.007**
SLSS	129	0.0	1.1	0.990
Parent-rated outcomes				
RCADS GA*	66	-0.4	1.4	0.793
RCADS D*	66	0.2	3.6	0.950
COPM Performance	59	1.1	0.8	0.176
COPM Satisfaction	58	0.3	0.7	0.726
SISES	65	0.1	0.2	0.750
Teacher-rated outcomes				
SAS	104	-1.3	3.0	0.670
SAS GA	104	-0.1	1.9	0.967
SAS SA	105	-1.3	1.5	0.427

Notes: *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.

6.6 Longitudinal analyses: Assessment phase data

Hypothesis C: There will be no marked decrease in favourable outcomes in self-, parent- and teacher-rated symptoms of anxiety and depression, child self-esteem and participation in typical occupations at follow-up assessment (8-9 weeks post-intervention), as compared to immediately post-intervention.

Analysis of secondary hypothesis C, using the ITT dataset, evaluated the longitudinal effects of the intervention on the outcome measures at the follow-up assessment point using the same covariates as specified in the previous analyses. Comparison was between post-intervention and follow-up assessment points and not between the study arms. The results are presented in Table 35 (p. 162). There was sufficient evidence to accept the null hypothesis and conclude that measurements were non-inferior for the primary outcome (MASC10) and one secondary outcome (CDI2). The interpretation of

these results is that these outcomes were no worse, and possibly improved for participants at follow-up, as compared to post-intervention. Therefore, the effects of the intervention on the MASC10 and CDI2 (had they been significant) could be considered sustainable. For the remaining outcomes there was insufficient evidence to determine whether or not the impact of the intervention was non-inferior.

Further analyses of hypothesis C were conducted on the PP dataset and adjusted for the same covariates and interactions effects as the previous analysis (see Table 36, p. 163). There was insufficient evidence found for either the MASC10 or the two child-rated COPM scales to be able to accept the null hypothesis for hypothesis C; therefore non-inferiority could not be concluded. In other words, there was no evidence to determine whether or not the change in the outcome measures evaluated was sustainable between post-intervention and follow-up, which was consistent with the above findings on the ITT dataset.

Table 35: Analysis of hypothesis C - longitudinal change between post-intervention and follow-up assessments

		Covariates*					Hypothesis C - differences between post-intervention and follow-up			
Outcome	***n* available (*N*=284)**	**Baseline outcome score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**One-sided 95% CI**	**Outcome delta**	**Delta relationship to lower bound**	**Status of H_a (non-inferiority)**
Child-rated outcomes										
MASC10**	257	✓	✓	✓		✓	-0.3	-2.5	<	Accept
CDI2**	240	✓		✓		✓	-24.3	-2.5	<	Accept
RSES	252	✓	✓	✓		✓	-4.7	1	>	Reject
COPM Performance	252			✓	✓	✓	-0.6	2	>	Reject
COPM Satisfaction	252			✓	✓	✓	-0.6	2	>	Reject
Wellbeing	253	✓	✓	✓			-3.2	1.0	>	Reject
Parent-rated outcomes										
RCADS GA**	129	✓					-10.7	-2.5	>	Reject
RCADS D**	129	✓	✓	✓			-4.6	-2.5	>	Reject
COPM Performance	121		✓	✓		✓	-2.3	2	>	Reject
COPM Satisfaction	121		✓	✓		✓	-2.4	2	>	Reject
SISES	122	✓	✓			✓	-0.9	0.2	>	Reject
Teacher-rated outcomes										
SAS	160	✓	✓			✓	-5.0	-1.7	>	Reject
SAS GA	161	✓	✓	✓		✓	-4.2	-1.0	>	Reject
SAS SA	163	✓				✓	-1.1	-0.9	>	Reject

Notes: *covariates determined by the blind review; **scores are already adjusted for age and gender. *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 36: Hypothesis C using PP dataset

	Covariates*					Hypothesis C: Non-inferiority – longitudinal differences between post-intervention and follow-up (crossover data)			
Outcome	**Baseline outcome score**	**Ethnicity**	**School decile category**	**Gender**	**Clustering**	**Lower bound of a 90% CI**	**Outcome delta**	**Delta relationship to lower bound**	**Status of H_a (non-inferiority)**
MASC10**	✓	✓	✓		✓	-8.4	-2.5	>	Reject
COPM Performance			✓	✓	✓	-0.9	2	>	Reject
COPM Satisfaction			✓	✓	✓	-1.3	2	>	Reject

Notes: *covariates determined by the blind review; **scores are already adjusted for age and gender; *** significant at $p<0.05$

6.7 Mediation analyses

Knowledge gain, as a potential mediator, was evaluated using a questionnaire about the content of the intervention. Analysis of the mediation effect of knowledge gain on the outcome measures (hypothesis D) was adjusted for the same covariates and interaction effects as for the first three hypotheses. The mediation model is illustrated below (see Figure 11) and the results are presented in Table 37 (p. 166). It is worth noting that almost a quarter (24.7%) of data relating to knowledge gain were missing (due to incomplete data available or the facilitator forgetting to administer the knowledge quiz on occasions), so the findings below should be interpreted with caution. Knowledge gain for the group allocated to the control arm of the study was not measured, and was assumed to be zero; therefore, it was unsurprising that the relationship between the intervention and the mediator (path 'a') was highly significant across all of the outcome measures.

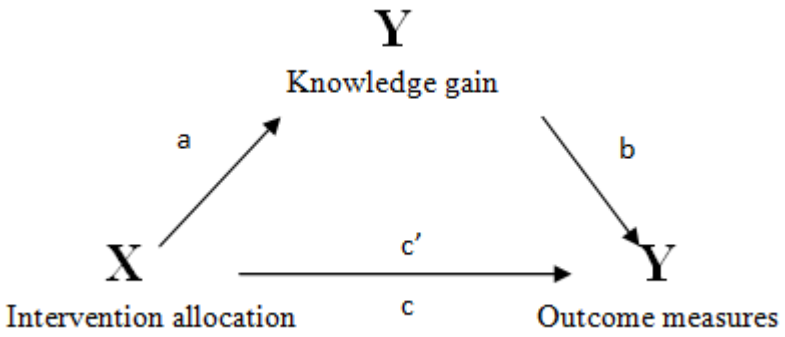


Figure 11: Model of mediation analysis

A significant total effect of the intervention on the child-rated COPM satisfaction scale score was found (+1.3, 95%CI=0.1-2.4, *p*=0.03), consistent with the findings from the primary analysis. The direct path for this outcome measure was also significant (+1.3, 95%CI=0.0-2.6, *p*=0.04). However, the indirect effect was not significant; indicating the impact of the intervention on participation was not mediated by knowledge gain. Significant relationships between the mediator (knowledge gain) and outcome measures (path 'b') were found for the CDI2 (-0.3, 95%CI=-0.6-0.0, *p*=0.03) and the Rosenberg Self-Esteem Scale (RSES; +0.3, 95%CI= 0.1-0.5, *p*=0.00). Significant effects were also found in the indirect paths for the same outcome measures (CDI2: -1.9, 95%CI= -3.7--0.1, *p*=0.04; RSES: +1.5, 95%CI= 0.3-2.8, *p*=0.01), showing a significant effect of the intervention on depressive symptoms and self-esteem via knowledge gain. However, in

both instances, the sign for the direct effect was opposite to that for the indirect effect, which is suggestive of inconsistent mediation having occurred. The effect of the intervention via knowledge gain was a small but significant decrease in depressive symptoms and a small but significant increase in self-esteem. In each case, the effect of the intervention appeared to be counterbalanced by an effect independent of knowledge gain (i.e. the 'direct effect') going in the opposite direction and resulting in a non-significant total effect overall.

6.8 Summary of results

The results from this cluster-RCT 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. However, there was evidence that the child-rated anxiety and depression symptoms 8-9 weeks after the intervention were no worse and possibly improved as compared to immediately post-intervention.

Table 37: Effects from mediation analysis of the intervention effect by knowledge

Outcome measure	Effect from mediation analysis														
	a			b			Direct effect (c')			Indirect effect (a*b)			Total effect (c)		
	Estimate [1]	95% CI	p-value	Estimate [2]	95%CI	p-value	Estimate [2]	95%CI	p-value	Estimate [2]	95%CI	p-value	Estimate [2]	95%CI	p-value
Child-rated outcomes															
MASC10	5.1	2.6-7.6	0.00*	0.1	-0.3-0.5	0.60	2.6	-2.1-7.2	0.28	0. 6	-1.6-2.8	0.62	3.1	-1.0-7.2	0.14
CDI2	5.7	4.0-7.3	0.00*	-0.3	-0.6--0.0	0.03*	2.5	-1.2-6.3	0.19	-1.9	-3.7--0.1	0.04*	0.6	-2.6-3.8	0.71
RSES	4.9	2.5-7.4	0.00*	0.3	0.1-0.5	0.00*	-1.7	-4.2-0.9	0.20	1.6	0.4-2.8	0.01*	-0.1	-2.3-2.2	0.95
COPM Performance	5.7	4.0-7.3	0.00*	0.0	-0.1-0.1	0.46	0.9	-0.4-2.2	0.19	0.2	-0.4-0.8	0.47	1.1	-0.1-2.3	0.08
COPM Satisfaction	5.7	4.0-7.3	0.00*	0.0	-0.1-0.1	0.83	1.4	0.1-2.7	0.04*	0.1	-0.6-0.7	0.83	1.5	0.3-2.6	0.02*
SLSS	5.0	2.5-7.5	0.00*	0.0	-0.2-0.2	0.97	-0.0	-1.6-1.6	1.00	0.0	-0.8-0.8	0.97	-0.0	-1.4-1.4	0.98
Parent-rated outcomes															
RCADS-D	5.2	2.6-7.7	0.00*	-0.4	-1.0-0.1	0.12	0.8	-5.0-6.6	0.79	-2.2	-5.3-0.9	0.16	-1.4	-6.4-3.5	0.57
RCADS-GA	5.9	3.9-7.9	0.00*	-0.1	-0.4-0.1	0.33	0.5	-2.4-3.4	0.74	-0.8	-2.5-0.9	0.35	-0.3	-2.6-2.0	0.79
COPM Performance	5.2	2.7-7.6	0.00*	-0.1	-0.2-0.1	0.39	1.0	-1.2-3.2	0.36	-0.4	-1.3-0.5	0.41	0.6	-1.3-2.5	0.53
COPM Satisfaction	5.1	2.6-7.6	0.00*	-0.0	-0.2-0.1	0.60	0.2	-1.9-2.3	0.85	-0.2	-1.1-0.7	0.62	0.0	-1.8-1.8	0.98
SISES	4.6	2.1-7.1	0.00*	0.0	-0.0-0.1	0.25	0.0	-0.6-0.6	0.95	0.2	-0.1-0.4	0.29	0.2	-0.3-0.7	0.47
Teacher-rated outcomes															
SAS	4.8	2.2-7.5	0.00*	0.2	-0.2-0.5	0.44	-3.3	-9.8-3.2	0.32	0.78	-1.3-2.7	0.46	-2.6	-8.7-3.6	0.41
SAS-GA	4.7	2.2-7.2	0.00*	-0.1	-0.3-0.2	0.51	-1.3	-5.2-2.6	0.51	-0.4	-1.5-0.8	0.53	-1.7	-5.3-2.0	0.38
SAS-SA	6.0	4.0-7.9	0.00*	0.2	-0.1-0.4	0.18	-2.6	-5.6-0.4	0.09	0.9	-0.5-2.2	0.20	-1.7	-4.2-0.7	0.17

Notes [1]estimate of knowledge change; [2]estimate of change in anxiety score; *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.

Chapter 7: Discussion

The findings presented in the previous chapter suggest Kia Piki te Hauora: Uplifting our Health and Wellbeing© is a promising intervention for promoting increased participation in children aged 11-13 years. An overview of the study findings regarding the impact of the intervention on anxiety, occupational participation, depression, self-esteem and wellbeing will be presented here.

7.1 Overview of findings

7.1.1 Impact of the intervention on anxiety

The adjusted, ITT analyses provided no evidence that the intervention impacted more positively on child-rated anxiety symptoms than no intervention, after the parallel phase as measured by the primary outcome measure: the Multidimensional Anxiety Scale for Children – Short form (MASC10). Following the crossover phase, the average MASC10 score for the intervention group decreased, as compared to the control group, but differences were not significant. The PP analyses were consistent with the results from the ITT analyses after the parallel and crossover phases, and again did not achieve statistical or clinical significance. The unadjusted analysis showed a clinically and statistically significant increase in child-rated anxiety symptoms for the intervention group, compared to the control group, after the parallel phase (i.e. a change of ± 5); however, this was not sustained when baseline covariates were adjusted for. The findings from the sub-group analysis demonstrated that the impact of the intervention on anxiety for children with lower anxiety levels at baseline was not significantly different than for those with higher levels of anxiety at baseline: in both instances there was a non-significant (statistically and clinically) increase in anxiety. The longitudinal hypothesis found sufficient evidence to determine that child-rated anxiety at 8-9 weeks follow-up was no worse, and possibly improved, as compared to assessment at post-intervention.

Findings from the RCADS-GA and School Anxiety Scale (SAS) consistently found decreases in anxiety reported for the intervention group when compared to the control group, in the adjusted (and unadjusted) analyses, after the parallel and crossover phases. Changes in the mean RCADS-GA scores were insufficient to be deemed clinically or statistically significant. Changes in mean SAS total and subscale scores were clinically

significant when baseline covariates were adjusted for in the ITT analysis of the parallel phase and became statistically significant after the crossover phase. For both the RCADS-GA and the SAS, there was insufficient evidence available to conclude non-inferiority of the intervention at the follow-up assessment.

Overall, there was no evidence to suggest the intervention resulted in a significant change for participants on the primary outcome compared to those in the control group. Anxiety impacts internal cognitions as well as external behaviours that impact participation (Chiu et al., 2013). As the primary outcome measure predominantly focused on internal cognitions, it may be that the impact of the intervention was more on the external behaviours. This hypothesis is tentatively supported by the trend towards improvement reported by parents and significant improvements reported by teachers (i.e. raters other than the children) and improvements found in the child-rated participation measure discussed below.

7.1.2 Impact of the intervention on occupational participation

Estimates of change for child-rated performance on the Canadian Occupational Performance Measure (COPM) were found to increase, non-significantly, more for the intervention group, after the parallel phase, than for the control group in the adjusted (and unadjusted) ITT analyses. This positive trend was maintained after the crossover phase data was included in the analysis; however, did not reach clinical or statistical significance after either phase (clinical significance would have required a change of ± 2). Consistent with the ITT analyses, non-significant improvements were also found in the PP analyses of child-rated COPM performance for the intervention group, as compared to the control group. However, in the PP analysis, after inclusion of the crossover phase data the positive trend of the intervention effect on child-rated COPM performance was found to be statistically significant, as compared to the control period data. This finding suggests that attendance at a minimum number of sessions may have increased the positive impact of the intervention on children's participation and performance. The findings from the sub-group analysis demonstrated that the impact of the intervention on child-rated performance, for children with lower anxiety levels at baseline, was not significantly different than for those with higher levels of anxiety at baseline: in both instances there was a non-significant trend showing improvement in performance.

Average parent-rated performance scores on the COPM were found to increase non-significantly for the intervention group after the parallel phase, in the adjusted (and unadjusted) ITT analyses, as compared to the control group. The trend for parent-ratings of their child's performance suggested a decrease in the intervention group, as compared to the control group, after inclusion of the crossover phase data; however, this change was not statistically or clinically significant.

Child-rated satisfaction with their performance, as measured by the COPM, was found to have significantly improved for the intervention group after the parallel phase in the adjusted (and unadjusted) ITT analysis, when compared to the control group. This finding was promising given the preventative nature of the intervention. Following inclusion of the crossover phase data the improvement associated with the intervention was no longer statistically significant when compared to the control period data, although it approached significance (p=0.076). The results of the PP analyses were consistent with the ITT analyses, except that the statistical significance of child-rated COPM satisfaction was maintained after inclusion of the crossover phase data, further suggesting attendance at a minimum number of sessions may have contributed to improved outcomes for participants. None of these improvements for child-rated COPM satisfaction achieved clinical significance (clinical significance would have required a change of ± 2).

The parent-rated satisfaction of their child's performance, measured by the COPM, was shown to increase, non-significantly, for the intervention group after the parallel phase in the adjusted (and unadjusted) ITT analyses, when compared to the control group. After inclusion of the crossover phase data the average score change for parent-rated satisfaction with their child's performance was found to decrease after the intervention when compared to the control period data; however, this was neither statistically or clinically significant.

Overall, the intervention was found to produce a positive trend in child-rated performance and a positive, significant impact on child-rated satisfaction with their performance. The impact on parent-rated child performance and satisfaction with their child's performance was inconsistent. This finding was not dissimilar to findings from other studies evaluating school-based cognitive behaviour therapy interventions, where parents and children reports often differed (Bernstein et al., 2005; Dadds et al., 1997;

Manassis et al., 2010). Given the focus of the intervention in this study on participation and external behaviours, it is promising to see a positive trend related to children's participation performance and their satisfaction with this. It is interesting that this finding did not consistently flow through into the parent-rated measures of participation. Parents were not directly involved in the intervention and, although informed of the overall intervention focus, would have been less aware of the intervention content and strategies unless explicitly informed by their child. This may have influenced their expectations about the level of change realistically anticipated, which in turn may have impacted their ratings. Furthermore, no teacher-rated measure of participation was included and this could have provided interesting feedback about whether children were able to generalise skills learned into the school setting (i.e. the environment in which the intervention took place) more or less than into the home environment. This would also have created further opportunities to evaluate whether the improvements were primarily experienced by the children or if they were also objectively observable (i.e. in the classroom setting).

7.1.3 Impact of the intervention on depression, self-esteem and wellbeing

Depressive symptoms were measured using the Children's Depression Inventory – Short form, version 2 (CDI2: child-rated) and RCADS-D (Depression subscale: parent-rated). A non-significant increase in depression symptoms on the CDI2 were found for the intervention group, as compared to the control group, after the parallel phase in the adjusted (and unadjusted) ITT analyses. After inclusion of the crossover phase data, the direction of change altered and a non-significant decrease in symptoms after the intervention was found, as compared to the control period data. Although inconsistent, this result from the crossover phase data is promising given the elevated levels of depression found in the sample as a whole, at baseline; however, does not warrant undue emphasis given the change in the parallel phases data was non-significant. The longitudinal hypothesis analysis found sufficient evidence to determine that child-rated depression at 8-9 weeks follow-up was no worse, and possibly improved, compared to post-intervention. Results for the RCADS-D were also inconsistent, with a non-significant decrease in symptoms post-intervention found after the parallel phases in the adjusted ITT analyses and a non-significant increase in symptoms found after inclusion of the crossover phase data, when compared with the control period data.

Self-esteem was measured using the Rosenberg Self-Esteem Scale (RSES: child-rated) and Single Item Self-Esteem Scale (SISES: parent-rated). Both measures showed a non-significant improvement in the intervention group, as compared to the control group, after the parallel phase in the adjusted (and unadjusted) ITT analyses. After inclusion of the crossover phase data the RSES change score after the intervention indicated a slight (non-significant) decrease in child-rated self-esteem when compared to the control period data; however, the parent-rated SISES maintained a non-significant increase. A marginal decrease in self-reported wellbeing, measured by the Student Life Satisfaction Scale (SLSS), was found after the parallel and crossover phases in the adjusted ITT analysis, after the intervention when compared to the control period data.

For all the outcome measures related to depression, self-esteem and wellbeing, there was insufficient evidence to accept the null hypothesis for the longitudinal hypothesis, meaning it was not possible to conclude non-inferiority of the intervention on these outcomes at 8-9 weeks follow-up when compared to post-intervention. In other words, it was not possible to conclude whether these outcomes at the follow-up assessment were any worse (or better) than at post-intervention. Overall, there was no evidence found to conclude the intervention impacted significantly on child- or parent-rated symptoms of depression, self-esteem or wellbeing.

7.1.4 Summary of findings

Four main conclusions were drawn from the results:

- The intervention did not significantly impact child- and parent-rated anxiety, depression, self-esteem or wellbeing outcomes, as compared to the control, based on the data from the parallel and crossover phases.
- 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, based on the parallel phase data.
- Higher attendance of the intervention (e.g. four or more sessions) was related to a significant improvement in child-rated performance in everyday occupations they had wanted to improve, based on data from the parallel and crossover phases.

- The intervention had a significantly positive impact on teacher-rated child anxiety, when compared to the control, after the crossover phase.

Previously reviewed interventions were shown to primarily target the cognitive symptoms of mental illness or increase knowledge of mental health (see Chapter 2). Evidence already supports the impact of mental health symptoms, anxiety and depression, in particular, on participation; and preliminary evidence was reported that found participation in positive and meaningful occupations was correlated with improved mental health symptoms (Blomfield & Barber, 2011; De Moor et al., 2006; Goltz & Brown, 2014; Kiluk et al., 2009; Schumacher Dimech & Seiler, 2011). The intervention in the current study focused primarily on children learning to design and build healthy routines, behaviours and habits into their day-to-day life, with the intention of this impacting positively on mental health symptoms (Tokolahi, Hocking, & Kersten, 2016). However, the current study has provided no new evidence to support the theory that participation in meaningful, positive occupations can have a causal impact on mental health symptoms, although participation in an indicated 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 mental health 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.

7.2 Impact of baseline measures on outcomes

7.2.1 Baseline anxiety measures

The level of anxiety symptoms in the sample at baseline was in the average range so it is possible there was a floor effect – limited scope for level of symptoms to reduce – that impacted on the non-significant findings for these outcome measures. A similar limitation was identified in studies reviewed by Weare and Nind (2011), whereby it was hypothesised that for populations where there were no overt problems there was not the same scope for improvement. In anticipation that this may occur, the statistical analysis plan included testing the interaction of two sub-groups on predetermined outcome measures: MASC10 and the children's COPM subscales. The two sub-groups were

categorised as those with lower levels of anxiety (as measured by a MASC10 *t*-score of less than 56: normal range) and those with higher levels of anxiety (as measured by a MASC10 *t*-score of equal to or more than 56: from high average upwards). Inclusion of an interaction effect (of the sub-group on the outcomes) and determining sub-groups *a priori* were strengths in this analysis plan (Assmann, Pocock, Enos, & Kasten, 2000; Pocock, Assmann, Enos, & Kasten, 2002). However, no statistically significant results were found once the nominal significance threshold was adjusted for by the False Discovery Rate control (Benjamini & Hochberg, 1995). Additionally, the size of each sub-group was small and the subgroup analyses were not sufficiently powered to reject a false null hypothesis (Assmann et al., 2000).

Future research investigating the efficacy of Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an indicated intervention, (or, more appropriately, a modification of the current intervention), may benefit from including anxiety levels, measured by the MASC10 (or another anxiety measure), as an eligibility criteria to ensure the sample does not contain either overly anxious participants (who would be eligible for intensive support through secondary mental health services) or consist solely of non-anxious participants (for whom minimal change would be anticipated). Alternatively, it may be that the MASC10 was not the most appropriate variable from this study upon which to determine the sub-groups or that the cut-off between lower and higher levels of anxiety was too arbitrary and did not produce sufficiently distinct groups to enable meaningful comparison (i.e. the cut-off selected was at the cusp between average and high-average levels of anxiety; however, it may have been more appropriate for the cut-off to have been at the cusp between high-average and clinically elevated levels of anxiety). Other studies investigating outcomes with children employed sub-groups based on gender, race, age and socio-economic status (De Craemer et al., 2014; Kintner & Sikorskii, 2008); however, in the current study, these variables were already adjusted for as covariates in the analyses. One of the COPM subscales as a measure of participation, or the CDI2 as a measure of depression symptoms, may have been more appropriate choices for determining sub-groups for analysis. No studies were found using sub-groups of COPM or CDI2 data in this way, so doing so would likely result in similar limitations to those described for the MASC10 – any cut-off between the sub-groups would be largely arbitrary.

7.2.2 Baseline depression measures

The process of teacher nominations, in the current study, produced a sample of children rated as anxious by the teachers, but who self-reported experiencing more depression than anxiety symptoms. Unlike the baseline scores for child-rated anxiety, the baseline scores for child-rated depression were in the elevated range. Similarly, parent-ratings indicated parents thought their children displayed more symptoms of depression than anxiety. Finding elevated depression symptoms in the children 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. Alternatively, this may have been a product of the measure of depression, the CDI2, having low discriminant validity for distinguishing between symptoms of anxiety and depression (Klein, Dougherty, & Olino, 2005). Thus, it could be argued that what the teachers were observing and perceiving as anxiety symptoms the children were experiencing as depression symptoms or were experiencing as anxiety that was more effectively evaluated by the depression outcome measure. This is consistent with a previous study by Prakash and Coplan (2007), which found children who were withdrawn and self-reported greater depressive symptoms were more likely to be rated by teachers as more 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 mood, rather than anxiety, could have achieved more positive outcomes in the current study. In clinical practice, it would be useful for intervention facilitators to have access to baseline data in order to more accurately tailor the intervention to the needs of the participants (Hall et al., 2014). In the context of this cluster-RCT, access to baseline outcome data was not feasible for the intervention facilitator (PhD candidate) who was also the primary investigator and needed to remain blinded to this information until study completion, in order to reduce the risk of bias in the study conduct (Moher et al., 2010).

7.3 Triangulation of perspectives in the data

The use of teacher nomination to identify children perceived as more anxious was found to be reasonably successful, as evidenced in the data from eight of the 14 clusters, where teacher-rated child anxiety scores were in the elevated range. This increased potential for change (e.g. from the elevated range into the non-clinical range) may have been a factor in the statistically and clinically significant positive outcomes found on the

teacher-rated anxiety measure. Of note, baseline anxiety as reported by the teachers (and parents to a lesser extent) was higher than that reported by the children. Research has previously found that teachers consistently have a different perspective of children, particularly given their opportunities to observe many children of the same age simultaneously, each year (for comparison with), and the different expectations within the classroom (Stranger & Lewis, 1993; van der Ende, Verhulst, & Tiemeier, 2012). This different perspective adds to the value of including teachers as informants of children's mental health and wellbeing in clinical practice and research.

Kolko and Kazdin (1993) found correlations between parents and teacher reports were generally stronger (though not significantly so) than between teachers and children, or parents and children, and it was suggested that children may under-report internalising problems. Inconsistent patterns of symptoms reporting, between different informants, were found in the literature. Some studies reported children potentially reported more concerns in comparison to their teachers and parents (Stranger & Lewis, 1993; van der Ende et al., 2012). However, others found low levels of agreement about child anxiety symptoms between parents and children and the pattern of children reporting fewer symptoms than parents (Choudhury, Pimentel, & Kendall, 2003; Kolko & Kazdin, 1993).

Informant agreement was investigated by Kolko and Kazdin (1993) in a sample of 162 children (with a mean age of 9.1 years), their parents and their teachers on both internalising and externalising behaviours. Ninety-eight children from this sample were from a community sample with no identified behavioural or mental health problems. Low-to-moderate correlations were found in the outcomes between children, parents and teacher reports (Kolko & Kazdin, 1993). Disagreement between multiple informants has been identified as a common challenge for measuring outcomes in children and one of the reasons why triangulation of perspectives is so valuable (Choudhury et al., 2003).

7.4 Outcome measurement

7.4.1 Measures of participation

7.4.1.1 Primary vs. secondary outcome measure

The main purpose behind the design of the intervention was to effect change in children's occupational choices and participation, in order to enhance mental health and

wellbeing. The literature review, reported in Chapter two of this thesis, highlighted the overwhelming focus of current preventative interventions on changing children's internal cognitions in order to minimise mental ill-health symptoms (e.g. anxiety, depression) and the lack of research measuring participation and functioning as outcomes. In the design of the current study, a mental health outcome was chosen as the primary outcome measure (MASC10) rather than the occupationally based outcome measure used (COPM). This decision was based on the intervention targeting mental health and wellbeing, and the MASC10 being widely used and having strong psychometric properties. At the time of designing the current study, few examples were found in the literature of participation measures being used as a primary outcome. The aim of the intervention was to impact anxiety and depression symptoms through participation in meaningful occupation, so it is promising that child-rated satisfaction of their participation improved significantly. Given the intervention was not primarily designed to target internal cognitions, this raises the question of whether or not an occupational measure would have been a more appropriate primary outcome measure. More recently, research is emerging about the validity and reliability of using measures of participation as a primary outcome (Anaby, Law, Teplicky, & Turner, 2015; Law, Anaby, Imms, Teplicky, & Turner, 2015). It is hypothesised that if the intervention had a clinically and statistically significant impact on participation (not just satisfaction with performance) then the mental health outcomes may also have been impacted more positively. The developers of the COPM had not intended for it to be used as a measure of participation (Law et al., 2005); although it is regularly reported and described as such (Sakzeqski, Boyd, & Ziviani, 2007; Tam, Teachman, & Wright, 2008). While the COPM has found promising results in the current study and measured an effect of the intervention, another measure might be appropriate to use alongside the COPM in the future.

7.4.1.2 Alternative measure of participation

Finding an alternative, suitable measure of participation that is psychometrically robust, flexible enough to be individualised for each participant and yet focused on the intervention aims will be a challenge. Several alternative measures were considered and rejected: the School Functioning Assessment (SFA) as it takes a time-consuming 1-2 hours to administer (Coster, Deeney, Haltiwanger, & Haley, 1998); the Children's Assessment of Participation and Enjoyment/Picture Activity Cards Sort (CAPE/PACS)

system as it was specifically designed to measure participation outside of the school curriculum (King et al., 2004); the Children's Assessment of Participation (CASP) as it was developed for use with children with brain injury (Bedell, 2009); and the Perceived Efficacy and Goal Setting (PEGS) as it was not designed for children as old as those targeted by the intervention in this study (Missiuna, Pollock, & Law, 2004).

Measures of participation that may be worthy of further consideration in future evaluations of Kia Piki te Hauora: Uplifting our Health and Wellbeing© are Goal Attainment Scaling (GAS) (Kiresuk & Sherman, 1968), Participation and Environment Measure for Children and Youth (PEM-CY) (CanChild., 2016) and time-use diaries. GAS was developed as a criterion-referenced evaluation tool that has been evaluated with a wide age range of children (Tam et al., 2008), has been evaluated in a variety of settings – including schools – and has been shown to have good responsiveness to meaningful clinical change (Sakzeqski et al., 2007). In their review of several measures of participation, Sakzeqski et al. (2007) reported the validity of the GAS was shown to be variable and reliability was rated as adequate to excellent (ICCs reported ranged between 0.51-0.98). However, there were limitations to how the GAS was being used as goals were predominantly set by clinicians/researchers and evaluated by the same people or the children's caregivers, thus raising questions about how client centred its implementation had been. However, Steenbeek, Gorter, Ketelaar, Galama, and Lindeman (2015) described how children's therapists often scored the goals lower than independent therapists and so there have been some reassurances regarding possible therapist bias. Children were assumed to be unable to identify their own goals; however, a recent RCT used the GAS as one of two measures of participation/change (the other being the COPM) reported that children could be trusted to identify their own goals for therapy using the GAS (Vroland-Nordstrand, Eliasson, Jacobsson, Johansson, & Krumlinde-Sundholm, 2016). There are similarities between the COPM and the GAS although they are reported to evaluate different aspects of goal evaluation, "that is, GAS facilitates operationalisation and observation of specific behaviours whereas the COPM provides the client's perspective of accomplishment of a broadly or specifically defined goal" (Tam et al., 2008, p. 293). Future studies should determine whether one, both, or neither of these measures of participation are most appropriate for evaluating the current intervention.

PEM-CY was developed from the International Classification of Functioning (ICF) framework as a parent-rated measure of children's participation across home, school and the community (Coster et al., 2012). Three dimensions of participation are measured: frequency, intensity of involvement and desire for change. The measure was reported to have moderate to good internal consistency (ICCs 0.59+) and test-retest reliability (0.58+) over a 1-4 week period (Coster et al., 2011). Using a measure that could be rated by both children and parents was an important factor in selecting the COPM for the current study. No literature was found evaluating the PEM-CY as a child-rated measure, so further investigation into the psychometric properties of the measure used in this way may be warranted.

A recent scoping review by Hunt and McKay (2015a) described time-use diaries as "the most established research technique used to explore aspects of human occupation" (p. 1). While most studies compared the time-use of different populations, 16% (*n*=61 studies) did examine the relationship between health and time-use (Hunt & McKay, 2015a). In a review of studies only focused on an adolescent population, a similar proportion of studies focused on the relationship between health and time-use (i.e. 18%, *n*=33 studies) and recommendations were made for the use of time-use diaries with adolescents (defined as aged 10-19 years) in the future (Hunt & McKay, 2015b). Recommendations included: capturing data from full 24 hour periods; analysing overall activity patterns rather than discrete activities; and using robust, valid, reliable, sensitive and age-appropriate instruments to investigate the relationship between time-use, health and wellbeing. However, no specific instruments were suggested. Sanders, Shaw, Guez, Baur, and Rudd (2009) effectively used time-use diaries in a cohort of 4,983 children participating in a longitudinal study in Australia, to evaluate the relationship between green space, physical activity and screen-time use. The time-use diaries captured data from 24 hour periods. The initial waves elicited information from parent-reports using pre-determined activity codes and later waves used child-reports of sequential activities over a single day. The children's diaries were then coded according to a framework to enable comparison between participants, which illustrates a potential template for how to administer, code and analyse time-use diaries in future research. These reviews did not comment on the validity and reliability of time-use diaries with children; however, one notable limitation to using time-use diaries in the context of the current study is the lack of time-use data for well populations aged 11-13 years for comparison against (Hunt & McKay, 2015a). Given the current evidence available, future evaluation of the

impact of the intervention in the current study on participation may be best measured by a combination of the COPM or GAS and a time-use diary, which are both completed with the children and the parents to promote accuracy and ensure multiple perspectives are included.

7.4.1.3 Determination of clinical significance in a community sample

Score changes of clinical significance on the COPM were determined by the developers as 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 measuring 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, as evaluation of the psychometric properties of the measure being used in this way have not been investigated, consideration of an alternative threshold for clinical significance does not influence the conclusions from the current study.

7.4.1.4 Menu item selection

In the current study, children chose two items from a menu of 15 occupational performance and participation issues (menu items) they might want to improve and that were relevant to the content of the intervention. Items included, for example: communicating with others (in person); participating in social activities with friends; taking part in activities that express my identity; having a routine I am happy with (see Table 20, p. 139, for complete list). Previous studies have demonstrated the effectiveness of using programme-specific menus to enable individualisation of goals while retaining a focus on the intervention aims (Di Rezze et al., 2008). Although the use of the programme-specific menu items was supported by the expert panel of occupational therapists and trialled during the intervention development, the specific items have not been formally validated for use with the intervention. It may be that some of the menu-items provided were more pertinent than others and there may have been other relevant occupations that were not included in the list. Further investigation may be warranted to elicit participant experiences about what performance and participation outcomes they feel were achieved on completion of the intervention and if these were covered in the menu options.

From the 15 menu items available, almost a quarter (24.6%) of participants identified that they would like to be more able to set goals and work towards them. Based on the finding that a large proportion of children identified goal-setting as a skill worth developing in order to increase their participation, it clearly had relevance to the participants in the study. Children may have felt disempowered about how to set goals as they were used to adults setting goals for them based on adult-led priorities (Wiart, 2015). During the consultation process, explicit, didactic teaching about goal-setting was removed, based on the recommendations of the expert panel because it was considered an integrated component of many of the other activities and less engaging material to present. Goal-setting with children has recently been described as challenging due to the difficulty children have comprehending the concepts or feeling sufficiently autonomous in their actions to pursue a goal (Robertson, Jepson, Macvean, & Gray, 2016). However, some literature has suggested children as young as 5 years can actively engage in the goal setting process (Missiuna, Pollock, Law, Walter, & Cavey, 2006), fostering "greater feelings of autonomy and control over their own successes" (Wiart, 2015, p. 296). Post hoc analysis of the data from the current study is recommended, to investigate whether there was a relationship between improvements in participation and participants who identified goal-setting as a skill to improve. Findings of such analysis could reveal whether or not the intervention was successful at addressing children's sense of improved goal-setting abilities in particular and their impact on performance and participation.

7.4.1.5 Parent ratings for comparison with child-ratings

After selecting two items from the menu list, child participants self-rated their own performance and satisfaction, before the two selected items were added to the parent-rated forms for them to rate their child's performance and their satisfaction with their child's performance. Various modifications have been reported in the literature that have successfully utilised parents as proxy raters for their children (Carswell et al., 2004; Cusick et al., 2007; Verker et al., 2006; Wallen & Ziviani, 2012). It could be argued that in the current study the process described was more robust as both parents and children completed the COPM. Despite this triangulation process, there were discrepancies between parent and child ratings on the COPM. Parents' average ratings of their children's performance and satisfaction with their children's performance were higher at baseline than how children rated themselves, on average (6.72 and 6.74; 5.95

and 5.73 respectively) and the impact of the intervention on the average change score was not consistent across raters. Discrepancies between child- and parent-reported COPM findings could be interpreted from several perspectives: COPM administration, limited generalisation of skills and lack of parental involvement in the intervention.

Firstly, neither children nor parents completed the COPM as an interview. The COPM is intended as an occupationally focused interview in which the therapist elicits (from the client or their proxy) the areas of occupational performance a client is struggling with, identifies the client's priorities for change and then rates these areas in terms of the client's ability and satisfaction with his or her ability (Law et al., 2005). In the present study, children completed their ratings in a group setting and it is unknown what impact this may have had on the accuracy of the COPM administration, compared to administering it as an individual interview (see section 7.6.2 below for further discussion on this point). A search for studies evaluating the psychometric properties of the COPM administered in a group context elicited no results, indicating a gap in the research literature investigating the appropriateness of administering the measure in this way. Parents independently completed the COPM as a paper-based survey and returned it via post. The lack of discussion with the researcher around the choice of menu options (and alternative options not selected) may have impacted on parents' ratings on the COPM.

Secondly, it may be that the children rated their perceived satisfaction with their performance as higher because they experienced improvement during the intervention and school environments, which were not generalised into the home environment. If changes in performance were not transferred into the home environment there would have been less improvement for the parents to observe and rate, which may have impacted on the level of parental satisfaction of their child's performance. No equivalent outcome measure was completed by the teachers to support or refute this suggestion; however, teacher-rated anxiety was found to improve significantly, thus hinting that school-based changes were more positive and more noticeable than home-based changes. Thirdly, the lack of direct parental involvement in the intervention may have meant that parental expectations of change did not match the intentions of the intervention. Modifications to the intervention are recommended that incorporate parental involvement and are discussed further in section 7.8.2 below.

7.4.2 Measures of depressive symptoms

7.4.2.1 Use of the CDI2

In this study, child-rated symptoms of depression were measured using the CDI2. At the time of designing the current study there was a lack of consensus about the most suitable measures of depression in children; however, the CDI2 was selected as it was shown to have robust psychometric properties and was widely used (Allgaier et al., 2012; Birleson, 1981; Kim et al., 2014; Kovacs, 2011). A more recent systematic review of 15 measures of depression in children, published after data collection had commenced in the current study, reported that although the CDI2 is sensitive to change it has unsatisfactory internal consistency (Simmons et al., 2015). This conclusion was drawn from a number of studies reporting diverse alpha coefficients ranging from low (0.36) (Ivarsson, Svalander, & Litlere, 2006) to high (0.80) (Smucker, Craighead, Craighead, & Green, 1986). Factor analysis studies reported the structure to vary depending on whether children (aged 8-12 years) or adolescents (aged 13-16 years) were being measured and factor models explained no more than one third of the variance (for children and adolescents) casting further doubt on the CDI's internal consistency (Brooks & Kutcher, 2001). Furthermore, the CDI was reported to have questionable discriminant validity with regards to its ability to distinguish between anxiety and depression in clinical and community populations (Klein et al., 2005). An alternative measure may be indicated if this study were repeated. The review by Simmons et al. (2015) recommended the RCADS – self-report form as a suitable tool for monitoring progress over time, due to it having reasonable psychometric properties and greater correspondence to diagnostic syndromes (Chorpita, Moffitt, & Gray, 2005). Furthermore, the child-rated RCADS also has a shortened version (10 items) that would minimise the burden on participants, another reason why the CDI2 (short form) was selected. The current study did not require (nor expect) formal diagnoses to be made for the participants and the focus was more on level of symptomology so the CDI2 was sufficient. However, given the evidence from the recent review and the current use of the parent RCADS in this study, use of the child-rated RCADS in the future is now more strongly supported in the literature and would promote greater consistency between the parent- and child-rated tools (Simmons et al., 2015).

7.4.2.2 Modification of the RCADS

The parent RCADS was selected as a measure of a parent's perception of his or her child's level of anxiety and depression; the original measure has 45 items and was deemed too long for use in the current study. A meta-analysis by van Horn, Green, and Martinussen (2009) reported a non-significant effect of survey length on response rates (r=.06, p=.56, length in items; r=−.13, p=.37, length in pages). However, it was acknowledged that information about survey length was only reported in 55% of the articles reviewed and so this conclusion should be interpreted with some caution (van Horn et al., 2009). Given the number of other assessments parents were expected to complete in the current study, the parent form was shortened in order to be less burdensome (see section 5.3.2.1.2 above for rationale). Items on the parent RCADS correspond directly to items on the children's RCADS, which has an established short form with 25 items. The items selected for the modified parent measure were based directly on the items included in the children's RCADS short form. It was not apparent until after data collection that this resulted in a few items not being included that contributed directly to the subscales of interest (GA and depression). Subsequently, the RCADS subscale scores were derived from fewer items than the developers had intended, meaning that these outcomes may not have been measured as effectively as they could have been and the results should be interpreted with some caution.

7.5 Process evaluation

Aspects of how the intervention in the current study was designed and implemented were reviewed and evaluated to better understand the role the process had on the outcomes found. Quantitative data were collected about participant adherence to the intervention, facilitator fidelity to the intervention and knowledge gain as a potential mediator of the intervention. Evaluation of these factors in relation to the RE-AIM framework is explored, along with how they may have impacted on the evaluation of the intervention effectiveness.

7.5.1 Quality intervention development

The development of Kia Piki te Hauora: Uplifting our Health and Wellbeing© followed a four-step process, similar to that used by Sackley et al. (2004) and informed by the Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (MRC, 2008). The MRC guidance has recently been criticised

for being primarily evaluation focused and a more in-depth, six-step process for developing quality interventions has been suggested (Wright, Wimbush, Jepson, & Doi, 2015). The six steps are to 1) define and understand the problem and its causes; 2) identify causal and contextual factors that are modifiable; 3) identify relevant mechanisms for change; 4) clarify delivery methods; 5) test and adapt the intervention; and 6) collect sufficient evidence of effectiveness to progress to rigorous evaluation. This more robust process was adhered to and described in a study by Robertson et al. (2016) in the evaluation of a health promotion exergame (a video game that requires physical activity). An iterative process of planning, execution, evaluation and analysis occurred that involved the trialling of multiple prototypes and the collection of quantitative and qualitative data to inform the intervention development. A logic model was created to represent the intervention assumptions, inputs, mechanisms for change and anticipated outcomes (Robertson et al., 2016). Evaluation of the protocol trials determined which aspects of the model worked as intended and this provided the focus for future analysis and planning, with regard to whether or not intervention design and/or contextual factors were more significant in achieving the desired outcomes. Had this framework been available at the outset of the current study it would have been useful to invest more time focused on steps 1-3 in a more systematic and rigorous manner. For example, conducting qualitative investigations with children, parents and teachers to identify what they perceived as problematic and the causal factors that could be modified, or a pilot study that investigated multiple potential mechanisms for change. Potential mechanisms for change may have included the impact of changes in participation on mood and the impact of changes in mood on participation. Qualitative data were not collected as part of the current study so is not available to inform this type of evaluation and analysis; however, would be important to consider in future studies.

7.5.2 Intervention adherence

The high attendance rates (82%) over the course of the intervention were similar to those reported by Dadds et al. (1997) and Jones et al. (2010) (81% and 77% respectively), although reporting of attendance rates was less common in many of the studies than reporting completion rates. Manassis et al. (2010) and Gillham et al. (2007) did not report specific attendance rates for their interventions but did conduct exploratory analysis and found a correlation between attendance and change in outcome. In the current study, there was evidence in the findings from the PP analyses

of child-rated scores for their performance of everyday occupations and their satisfaction with these, that attending a minimum of four sessions was sufficient to impact positively on these outcomes. Analysis of the correlation between attendance and the outcome measures was not included in the analysis plan for the current study but may be useful to include in future analysis and studies. Data about barriers to attending the intervention sessions in the current study were not formally collected; however, from informal information recorded the most common reasons were acute illness resulting in non-attendance at school or a conflict with a special event at school.

Page and Persch (2013) reported risk of bias was unlikely for studies with attrition less than 20%. Attrition in the current study was 18%. However, students may have felt obliged to attend the intervention as if it was a compulsory lesson or because of power imbalance present between teachers and students when the teacher advised it was time for them to attend. Efforts were made to counteract this and students were regularly reminded that their participation was voluntary. On occasions, a number of students exerted their right not to participate and requested to miss a session due to a timetable clash with a special event at school (e.g. class performance), which was always supported. Further, there was no notable change in levels of attendance across the 8 weeks of the intervention. Participants' regular attendance without marked evidence of changing attendance over time, suggested students understood they had control over their own participation. In this context, it may be reasonable to consider attendance as having been an indicator of acceptability and that the intervention was positively received.

Skills practice tasks to be completed between sessions were incorporated into Kia Piki te Hauora: Uplifting our Health and Wellbeing© and incentives were provided to promote engagement with this transfer training. However, these tasks were not consistently completed and adherence to skills practice ranged between 64-94% across the clusters. It has been suggested that children's difficulty transferring skills beyond an intervention may be linked to them not selecting skills to learn and transfer based on the same priorities as the adults around them (Royer, Desbiens, Bitaudeau, Maltais, & Gagnon, 1999). Therefore, the skills they opt to practice may be less likely to be reinforced. An argument has been made that the transfer of skills is not immediate and therefore measurement of change beyond the intervention needs to account for this (Allen, Rhind, & Koshy, 2015; Petitpas, Cornelius, van Raalte, & Jones, 2005). In other

words, children need the opportunity to practice skills in real-life situations beyond the intervention setting, indicating the need to embed the intervention into the classroom curriculum and daily routine. Furthermore, a paper reporting on the Mental Health Awareness Action programme in England reported that one of the key ingredients for reducing stigma associated with mental health issues is direct contact with others who express emotional challenges and hearing their testimonies of how they felt and coped (Pinfold, Thornicroft, Huxley, & Farmer, 2005). Embedding the intervention into the classroom curriculum for all children would increase opportunities for testimonies about personal experiences and strategies to be shared, build the capacity of the whole class and, it could be argued, increase the impact of the intervention as a whole.

7.5.3 Intervention fidelity

Intervention fidelity assessments provide useful information about the degree to which an intervention was implemented as intended (Carroll et al., 2007). Not all studies report intervention fidelity rates, which can be a limitation of the conclusions drawn, and they were noted as more commonly reported in newer studies (Horowitz et al., 2007). In the current study, intervention fidelity across the individual sessions ranged between 64-100%. The lower fidelity scores were primarily from one cluster where there were several unplanned changes to the scheduling and duration of the sessions due to last-minute timetable changes at the school. Overall, these rates are somewhat comparable with intervention fidelity rates reported elsewhere. Gillham et al. (2007) reported fidelity rates between 86-91% for an after-school, clinic-based intervention and Schaaf, Benevides, Kelly, and Mailloux-Maggio (2012) reported rates between 63-97% for an individual, clinic-based intervention. However, neither of these studies were pragmatic trials that needed to accommodate the realities of clinical practice. In studies conducted in a clinic setting, it may be expected that pragmatic realities are less prominent and intervention fidelity may be more readily achieved. Chiu et al. (2013) evaluated a school-based modular CBT intervention, administered with the child participant and their caregiver or the child alone. Intervention fidelity was reported for the caregiver and child modules as 90.2% and 89.2% respectively. These are higher rates than those reported in the current study; however, the intervention in Chiu et al. (2013) was delivered on an individual not a group basis, which may have contributed to facilitators achieving higher fidelity rates. Facilitating the intervention in the current study as a group was associated with particular challenges to implementation fidelity, in

particular disruptive behaviour on the part of a small number of participants that impeded the intervention process and students not engaging.

Disruptive participant behaviour was the most commonly cited reason for facilitator non-compliance with the intervention protocol. Responding to disruptive participant behaviour required adaptations to the way activities were implemented and management of the behaviours took time away from covering the content, resulting in sessions that were more rushed. It could be argued that managing such behaviour impacted on the facilitator's therapeutic relationship and interactions with participants, elements of group processes that have previously been shown to be correlated with intervention outcomes (Manassis et al., 2010). In a study of a school-based, group CBT intervention, data about elements of the group process were recorded rather than intervention fidelity (Manassis et al., 2010). For example, data were collected about therapist-initiated and therapist-responsive interactions with the child and use of positive reinforcement. Specific data about the extent to which these elements were present were not reported; however, exploratory analysis was conducted to evaluate any correlation between these and therapeutic change. Group process elements were found to be correlated with a range of outcomes (e.g. depression, anxiety and problematic behaviours) at both post-intervention and 1 year follow-up. With this in mind, future versions of the intervention from the current study will need to balance the need for managing disruptive participant behaviour and preserving positive group process elements, such as positive reinforcement.

The challenge of students not always engaging with the intervention appeared to occur more in schools where a significant proportion of the curriculum was delivered via a device or through digital learning, although no information was collected to confirm these impressions. Access to technology and multi-media materials was anticipated to be unfeasible across all schools (which was confirmed during the consultation process while the intervention was under development). In order to maintain the consistency of intervention implementation across all schools, a decision was made at the outset not to include digital delivery methods. Incorporating such strategies into future versions of the intervention might enhance student engagement, particularly at schools where digital learning is an integral feature of the school culture.

Challenges with intervention fidelity, from the current study, may be overcome through a different model of delivery that embeds the intervention into the classroom

curriculum. Embedding the intervention into the classroom curriculum could reduce the intensity of time restrictions, increase intervention flexibility to better meet the needs and culture of children within the classroom, improve access to resources the children are already familiar with (e.g. technology devices) and enable a co-teaching approach. Co-teaching would enable inclusion of the teacher's knowledge and understanding of the children's interests and behavioural histories, thus increasing the children's engagement and limiting the extent of disruptive behaviour.

7.5.4 Mediation

It was proposed (in Chapter three) that changes to the outcomes might be mediated by knowledge gained about what constitutes health promoting occupations, their benefits and how to participate, balance and sustain these. A questionnaire, developed to measure knowledge gain, was completed at the start of each session (to evaluate baseline knowledge) and during the final session of the intervention (to evaluate post-intervention knowledge). A positive mediation effect of knowledge gain was identified on depression symptoms and self-esteem, suggesting that gaining knowledge from the intervention could have facilitated improvements in these outcomes. Further investigation would be required to determine which areas of knowledge gain translated into improvements in mental health and wellbeing.

Positive mediation effects of knowledge gain on depression symptoms and self-esteem were counterbalanced by an independent effect resulting in an overall non-significant effect. No other potential mediators were evaluated in the current study and so no conclusions can be drawn about what these independent effects were, although on reflection a number of suggestions might be hypothesised as potential mediators: completion of skills practice between sessions and removing students from class.

7.5.4.1 Potential mediators

Completion of skills practice was discussed in section 7.5.1 above; however, this was not included in the statistical analysis plan as a variable for formal evaluation in the mediation analyses. Post hoc analysis of participant skills practice completion rates as a potential mediator may have yielded useful information about the role this had in facilitating or inhibiting the impact of the intervention on various outcomes. Participating in an intervention outside the context of their everyday classroom environment and routines may have meant some children incurred challenges with how

to implement strategies beyond the session context (Royer et al., 1999). Statistically and clinically significant improvements found in the teacher-rated anxiety symptoms may have occurred as a result of the intervention being provided in the school-environment and this being the setting in which children were more readily able to generalise the skills and experiences from the intervention. An embedded intervention would ensure more adults around the children are familiar with all the skills the children are being encouraged to develop and can be aware of and reinforce the practice and transfer of skills beyond the intervention context that occur spontaneously (discussed further in section 7.8.3 below).

It is possible that removing children from the classroom environment resulted in them inadvertently feeling stigmatised or singled-out (Weare & Nind, 2011). Measuring children's feelings of inclusiveness or of being stigmatised may have provided useful information to include in the model as a potential mediator of the intervention on child-rated outcome measures. Barney et al. (2006) found many adults reported they would feel embarrassed about seeking help from a professional and it may be extrapolated from this that children might feel similarly. Children may have experienced worries about the negative perceptions of others about them being removed from their class to attend a mental health and wellbeing group (although not overtly identified as such). In anticipation of this, in the current study, the group title deliberately did not include any reference to mental health and the teachers were asked to nominate role models to participate alongside those they identified as having an indicated need for the intervention[11].

7.5.5 Process evaluation and the RE-AIM framework

The current study was not designed to comprehensively evaluate the implementation of Kia Piki te Hauora: Uplifting our Health and Wellbeing©, however, did investigate some domains within the RE-AIM framework. The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) was designed as "a conceptual model for the planning, implementation, evaluation, review, and reporting of implementation science and dissemination research" (Kessler et al., 2012, p. 46). Few studies are reported to assess factors related to intervention delivery and uptake that can

[11] Participants were aware from the participant information sheets and assent process that mental health and wellbeing was a focus of the intervention; however, this was not communicated to any non-participants.

limit the transfer of conclusions into real-world settings (Koorts & Gillison, 2015). The components of the RE-AIM model are reflected on here, where data were available, to facilitate transfer of knowledge to other settings.

Reach was tentatively reported in terms of the number of clusters in the sample population (i.e. 14 schools) compared to the general population (i.e. 301 schools in the Auckland Region), and by reporting exclusion criteria (and clusters/participants excluded) in the recruitment process. However, characteristics of non-participants were not collected and only informal qualitative information was collected to understand the reasoning behind non-attendance during the intervention after enrolment.

Effectiveness was attended to at a basic level as a primary outcome was identified in the current study (i.e. MASC10), broader outcomes were measured and sub-group analyses were performed for one potential moderator (i.e. level of anxiety). However, these outcomes were not compared to a public health goal, differential attrition rates were not investigated further and qualitative methods of research were not employed to understand the outcomes further. While such investigations would have provided valuable information they were beyond the scope of the current study.

Adoption at the setting (i.e. cluster) level was briefly reviewed in terms of the number of settings approached, exclusion criteria applied and description of the characteristics of the settings that participated. Adoption at the staffing level was not applicable in the context of this study. Qualitative research methods were not applied to understand adoption at either level.

Implementation of the intervention was reviewed to some degree, in terms of intervention adherence (see section 7.5.1), intervention fidelity (see section 7.5.3) and adaptations made when implementing the study (concerning data collection, not the intervention: see section 7.6 below). However, these discussions did not address all the elements of this domain as stipulated in the RE-AIM framework (Kessler et al., 2012). For example, data about the cost of the intervention and potential cost savings resulting from the intervention were not collected.

In a separate study an occupational therapy student conducted a basic qualitative descriptive review of children's engagement in the intervention with a small sample of three children who had participated in Kia Piki te Hauora: Uplifting our Health and

Wellbeing© early on in the trial (McCoy, 2014). A focus group with the children elicited five factors that those children reported as significant in promoting their engagement in the intervention: sharing, doing, working together, solving and missing. 'Sharing' related to the experience of participants sharing information about themselves and their occupational experiences, and may be linked to 'peer exchange', which was an intended intervention delivery method. 'Doing' related to participants' engagement in group activities, games and tasks as part of the intervention or as part of skills practice between sessions, and may be linked to 'direct experience', which was another intended delivery method. 'Working together' described children's experiences of collaborating and communicating with others in order to achieve goals and participate in the intervention activities. This factor, along with the next one, 'Solving', did not relate directly onto any of the intended delivery methods. Solving described children's perceptions about who might benefit from the intervention, skills they had developed from participating and helping others to learn the skills they had developed. The final factor identified was 'missing', which reflected on the impact of the intervention occurring during the school day and how this affected the children's occupational engagement in other school occupations. This impact was perceived both positively and negatively e.g. missing-out on boring or enjoyed subjects. Overall, the role of 'doing', occupational identity as an influencer of occupational decisions, and opportunities to help others were revealed as integral to the engagement of and benefit for children participating in the intervention (McCoy, 2014). It should be noted this was a small-scale study that included only 2% of the population exposed to the intervention; however, it does provide emerging qualitative evidence for understanding how implementation impacted on children's engagement in the intervention.

Given Kia Piki te Hauora: Uplifting our Health and Wellbeing© was only available to clusters as part of the research there was no expectation that it would continue beyond the current study. Therefore, it was not applicable to consider the final domain of the RE-AIM framework, maintenance. Future investigations into Kia Piki te Hauora: Uplifting our Health and Wellbeing© may benefit from employing a review of all elements from the RE-AIM framework in order to gain a greater understanding of the effectiveness of its implementation and the impact this may have had on the outcomes measured.

7.5.6 Summary of process evaluation

In the future, redesign of the intervention from the current study should be informed by the six steps for designing quality interventions suggested by Robertson et al. (2016). Participant adherence to Kia Piki te Hauora: Uplifting our Health and Wellbeing© was inconsistent. Attendance was regular, comparable with attendance at interventions from other studies, and attending four or more sessions of the intervention (out of a possible eight) was linked with significant improvement in child-rated COPM performance and satisfaction with participation in everyday occupations. However, participants did not regularly complete the skills practice tasks between sessions that were intended to facilitate their generalisation of knowledge and skills. Facilitator fidelity to the intervention was acceptable given the pragmatic nature of the study, although variability between clusters was evident and the environmental conditions at certain schools often presented reoccurring challenges to achieving fidelity to the implementation each week (e.g. conduct of the children, unscheduled timetable changes). Knowledge gain was evaluated as a potential mediator that effected the impact of the intervention on some of the outcomes measured. Significant impacts of knowledge gain were found on depression symptoms and self-esteem; however, these were counterbalanced by the impact of factors independent of knowledge gain. It was hypothesised that these independent factors, described as potential mediators, may have been completion of skills practice and perceptions associated with being removed from the classroom to attend an intervention.

While elements of the RE-AIM framework were evaluated, further investigation of these would have elicited additional information for identifying significant implementation factors that may have impacted intervention effectiveness. Limitations in how the intervention was implemented may be overcome by reconsidering the delivery method for Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded intervention.

7.6 Data collection

There were several challenges inherent in the process of collecting data from multiple informants in this school-based research. While rigour and consistency were always aimed for, there were some discrepancies between the anticipated and implemented methods of data collection for a variety of unexpected reasons. Reliability of data

collected about individual-level changes, in a community-based intervention, is reported to be one of the biggest challenges faced in studies of this type (Koorts & Gillison, 2015). Rather than being suggestive of poor research practices, Kirk (2007) argued research with children generates a genuine need for flexibility and creativity in data collection methods. The methodological issues that arose in this study are considered in some detail here and fall into five categories: communication and relationships; children's behaviour; the physical environment; (un)predictability; and legislation.

7.6.1 Communication and relationships

Early consultation with cluster guardians and stakeholders, such as teachers, was important for establishing cooperation and effective lines of communication (Okello et al., 2013). In this study, a key contact was identified at each school; however, sometimes they were not available at the times scheduled for data collection, or they informed the outcome assessors of other events at the last minute that would limit the time for data collection. School personnel appeared to appreciate and benefit from a call on the morning of an arranged data collection session (often scheduled a week in advance) to assist with arranging the children to be available in a timely manner. Children often noticed the added pressure created by having less time and this typically triggered either increased problematic behaviours or children rushing to complete their outcome measures.

Tension arose with some teachers not directly involved with children in the research, for example, when data collection was occurring in a shared space that they partially occupied. Okello et al. (2013) suggested it was not uncommon that discussions about the research that occurred with key contact people were not always disseminated to wider teaching staff, which was sometimes the experience of the outcome assessors in the current study. Furthermore, in this study, the key contact person did not always introduce the outcomes assessor to the teacher whose space was being used for data collection and this sometimes created tension and hostility that the assessors had to resolve.

Sensitivity to children's willingness to participate needed close observation. Although consent forms had been signed, the child's behaviour at times indicated dissent (e.g. running away), which was important to respect regardless of whether or not the teachers/parents wanted them to take part (Okello et al., 2013). In such cases, children

exhibiting dissent were re-advised that participation was voluntary and their participation was not pursued. The use of a small gift is often recommended in the literature for achieving a higher response and completion rate (Schilpzand, Sciberras, Efron, Anderson, & Nicholson, 2015; Wilson et al., 2010). However, such incentives were not used in the current study to avoid the risk of children feeling coerced. Instead, an unannounced small koha was offered on completion of outcomes at some assessment points (i.e. one wrapped sweet per child) in gratitude for their time and patience in completing these.

Parents/caregivers were contacted to ensure their child had remembered to take the parent questionnaires home from the data collection session, to remind the parent to complete the forms and to answer any questions they may have had. The relationship with parents was limited to these brief interactions and, in some cases, the parents did not have a sense of any relationship with the researchers, having returned their consent by post and not in person. Challenging responses encountered by the outcome assessors included being hung-up on during phone calls, parents not speaking English, parents reporting no knowledge of the research project (despite having signed a consent form) or having incorrect contact information provided. These challenges were not dissimilar to those reported in the literature by McDonald and Rosier (2011). On some occasions, the person contacted would report the child having moved to live with another relative and several calls were required to locate the appropriate respondent and review the consent process. On other occasions, parents were delighted to be contacted and were keen to seek advice or give feedback about the programme – in one instance unblinding the outcome assessor to the participant's allocation status (and therefore the cluster's allocation status).

7.6.2 Children's behaviour

Management of children's behaviour during data collection (and the intervention) has been noted in the literature as challenging at times (Wilson et al., 2010) and the experiences of the outcomes assessors in the current study reflected this. Problematic behaviours typically observed included children being distracted by bumping into each other on purpose, not attending to the instructions or other off-task behaviour that disrupted others. On rare occasions, the outcome assessors were confronted by aggressive behaviours, such as accusatory language, having the paperwork thrown towards them or passive-aggressive comments like "*I don't care*". Feedback from

teachers reassured the outcomes assessors that this was not unusual behaviour for those children and most of those children asserted they still wanted to participate in the study. Outcome assessors reported it was common for children to rush through their responses, without appearing to give due consideration to how they were rating their experiences on each outcome measure. Ramifications of this might be that outcomes collected are not representative of the child's lived experiences and therefore may not accurately measure the impact of the intervention. Problematic behaviours observed were considered to be more intense or frequent when children were involved in data collection during preferred lesson times (e.g. elective topics, such as art or music) or when data collection points were scheduled immediately prior to or over a lunch break. However, as guests in the schools it was not always possible to dictate the timing of data collection sessions.

During data collection sessions, which were completed with each cluster as a group, children would sometimes group together around one table so their elbows were touching or overlapping. Prompting was required for them to spread-out and sit at separate tables so they could complete the questionnaires with more privacy (Kovacs, 2011; March, 1997). While privacy was discussed and encouraged, some children actively shared their responses with peers or offered suggested responses to questions other participants had about the items on the outcome measures. On the occasions when this occurred in the current study, it was unknown to what extent this impacted on how children rated their experiences. This also provides an illustration of why clustered data is more likely to be homogenous, thus reinforcing the need for clustering to be accounted for in the data analysis (Eldridge & Kerry, 2012).

In general, the outcome assessors would read each question aloud for the children to follow (regardless of some rushing ahead) and this assisted those with literacy difficulties, as well as positively impacting on participant behaviour. However, the low literacy levels of some of the children resulted in an increased need for support from the outcome assessors, which was more labour intensive and meant less attention could be directed towards managing other children's behaviour (Wilson et al., 2010). In one school, this was inadvertently overcome by a teaching assistant being present, as per the school policy with external visitors (elaborated on further in section 7.6.5 below), who circulated around the children to aid in reading the paperwork and on one occasion to mark the responses on the participant's behalf (with the child's permission). If this

study were to be replicated in the future, it will be worth balancing the increased (financial and time) costs associated with individual administration of the outcome measures with the potential for higher quality responses and data collected. When participants were seen individually, for example if they had been absent on the scheduled day for data collection and the outcome assessor had returned a day or two later, their behaviour was noticeably more cooperative and calm than the behaviour of participants in the group, and completion of the outcomes progressed more quickly. Unfortunately, this was not possible to do in the present study due to financial constraints and the impact this would have had on the organisational abilities of each school's key contact person to arrange.

7.6.3 The physical environment

Provision of a suitable space for conducting data collection has been reported by Wilson et al. (2010) as often problematic. In this study, data collection typically occurred in a classroom or a staff boardroom. The latter often elicited better behaviour from the children, which was presumed to be their acknowledgement of being privileged to be in the 'adult space'. Collection of data in classrooms was typically more problematic: issues that arose included prior activities in the room not having been cleared up in a timely manner, inappropriately sized furniture (e.g. chairs and tables at heights for much younger children), and being moved from one classroom to the next because data collection took longer than the room was available for (typically due to data collection starting late after getting the participants organised). Some schools were situated on large grounds and the process of locating participants could be time-consuming – this further impacted on the time available to complete data collection, and the behaviour of children who arrived early and were becoming restless.

7.6.4 (Un)predictability

Outcome assessors had not been involved in the school recruitment process so were often unfamiliar with the location, staff and physical environments of the various schools. Managing the unpredictability of what to expect at each cluster location created some anxiety regarding logistical issues, for example, access to the school, parking, where to go on arrival, how to navigate the grounds, and what sort of personalities to expect (staff and students). These matters were discussed with the primary researcher in advance and on an on-going basis in individual supervision. Furthermore, participant absences from school or changes to the school timetable required a flexible schedule for

data collection (Wilson et al., 2010). Aside from general absences due to sickness, it was also found that data collection sessions were scheduled at times when child participants were offsite on fieldtrips or doing other 'fun' and novel activities that necessitated the outcome assessors to return and meet with these children at a later date.

7.6.5 Legislation

An Act that came into power part-way through the study, determined that all researchers who would come into contact with children were required to undertake thorough police vetting checks (Vulnerable Children's Act, 2015). This was undertaken by all outcome assessors; however, the process needed to be repeated for each school visited and due to delays in the vetting process these reports were often not returned quickly enough. This necessitated the presence of a staff member at all times during data collection, putting additional, unexpected strain on the schools' resources and introducing a different element to the data collection process not previously encountered. The presence of a staff member generally had a positive impact on the behaviour of participants during data collection. However, at times the staff member present would appear to get bored and get into a discussion with participants about an unrelated topic and need to be redirected away from this behaviour. The need for supervision from a staff member also had an impact on the selection of non-ideal physical environments (discussed earlier) for conducting data collection so that staff could continue their teaching commitments while visually monitoring the data collection process.

7.6.6 Recommendations to address data collection challenges

Given the challenges encountered in the data collection process for the current study, several recommendations are made for conducting similar research in the future. The primary researcher should make concerted efforts to present the research to all teachers who may have contact with the research (and participants) and parents, not just the key contact people at the school (Schilpzand et al., 2015). This step is intended to foster greater investment from the teaching staff as a whole, improving response rates, and also providing opportunities for connecting with secondary contact people if the key contact is unavailable or away on the day data collection is scheduled. Although it could be useful to involve the outcomes assessors in these initial meetings too, for the current study that was not possible as the timing of such meetings would have resulted in them being unblinded to the allocation status of the school. Presentations to more than key contacts at the school were offered in the current study, however, rarely taken up. Staff

at one school requested a presentation to students during assembly, staff at another requested a presentation to parents at an afterschool meeting.

The timing of data collection sessions is also worthy of consideration. Avoiding times immediately prior to or during break times was preferable in the current study; however, there was no literature found to suggest whether or not after-school data collection may or may not be more effective than times during the school day. Benefits of an after-school time slot include: not interrupting the child's school day or preventing them from attending preferred lessons; less restrictions on physical environments available, so that data collection can occur in a more comfortable environment where children are able to have their own space and more privacy; and the possibility of parental involvement so they can complete their outcomes simultaneously. These benefits may be outweighed by the children still wanting to rush their questionnaires to leave for home, children forgetting to attend and going off-site and parents not being available for after-school meetings.

Completing the data collection with children individually may overcome many of the behavioural management issues reported but needs to be considered within the financial and practical limitations of the study. If collecting the data as a group, having a teaching assistant present to manage the behaviour may be beneficial. The expectations of the teaching assistant's role would need to be made explicit, including how they are not to engage the participants in conversation during data collection, beyond responding to task-related enquires.

7.7 Strengths and limitation of this study

7.7.1 Study strengths

The cluster-RCT reported here was an ethically sound, well-designed study with a fully pre-specified statistical analysis plan. 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. The blind review of the data prior to conducting the analysis and after the datasets had been created,

ensured that covariates were selected on the basis of the blind review without regard to allocation. Subsequently, accounting for clustering in the analysis of two of the outcome measures (RCADS and SLSS) was deemed unnecessary; however, for the other measures clustering was accounted for.

7.7.2 Study limitations

Given the complex nature of the intervention under evaluation, blinding of participants and personnel (other than outcome assessors) was not feasible in the current study. Also, due to the financial and time parameters of the study, it was not possible for comparison to an attention-control intervention or for qualitative data to be collected and analysed. The addition of qualitative data would have provided a valuable contribution to enriching understanding of both the impact of the intervention and the effectiveness of the implementation processes (Crotty, 1998). Some qualitative analysis of participant experiences was conducted in a separated study conducted by McCoy (2014) and is discussed in section 7.5.5 above. Two key limitations to the design and implementation of the current study are elaborated on below: the lack of comparison at follow-up and short follow-up period, and missing data and response rates.

7.7.2.1 Assessment at follow-up

In order to facilitate recruitment, and due to pragmatic factors related to the timing of school terms, the protocol stated the crossover component of the trial required participants in the control arm of the study to receive the intervention without a follow-up assessment point. Given the limited potential for change from the baseline scores, it is unfortunate that there was no comparison at follow-up for determining a more accurate impact of the intervention over time; however, this was beyond the scope of this trial.

The follow-up period for the current study was only 8-9 weeks (2 months) in total and it could be suggested that over such a short period, children may not have encountered sufficiently challenging situations that triggered the need to use some of the skills developed in the intervention. Other studies investigating preventative interventions with children reported following up nonclinical samples at 3, 6, 12 and 24 months to determine whether positive effects were sustained or perpetuated (Bernstein, Bernat, Victor, & Layne, 2008; Dadds et al., 1997; Engelen et al., 2013; Gillham, Hamilton, Freres, Patton, & Gallop, 2006; Manassis et al., 2010). Most studies reported that

positive effects were sustained over time. However, Horowitz et al. (2007) reported the effects of a CBT intervention for preventing depression were short-term and not sustained at a 6 month follow-up. One study reported a 10 week follow-up period was used after a brief intervention (<60 minutes) and was sufficient for detecting effects over time (Eggert et al., 2002).

In the current study, a longer follow-up period, for example 3-6 months, may have been more useful for determining the true impact of the intervention over time, particularly given the duration and preventative nature of the intervention. One of the CBT interventions evaluated for the prevention of depression symptoms, the FRIENDS programme, included a booster session that was shown to support outcomes at up to a 12 month follow-up (Neil & Christensen, 2007). Booster sessions were not within the scope of the intervention in the current study; however, they may be a useful element to consider for ensuring positive effects are sustained in the longer term. If Kia Piki te Hauora: Uplifting our Health and Wellbeing© were to be embedded into the classroom curriculum, as recommended, then teachers familiar with the intervention content could reinforce positive strategies and promote mental health and wellbeing on an ongoing basis beyond the therapist involvement. This ongoing reinforcement could act as frequent boosters potentially perpetuating the positive effects of the intervention and promoting generalisation of skills to broader contexts.

7.7.2.2 Missing data and response rates

School-based research requires the researcher to "engage and maintain the goodwill and participation of a variety of stakeholders", such as school personnel, parents, children and interested community members, in order to facilitate effective recruitment and response rates (Schilpzand et al., 2015, p. 2). In the current study, data available for ITT analysis were incomplete and the inclusion of multiple imputations was required. Approximately 7% of the primary outcome data from the children were missing and less than 13% of the other child-rated outcomes. Missingness was assumed to be random and most frequently occurred because a child was off-school with acute illness.

Parent and teacher response rates were much lower. The response rate for the parent-rated outcome measures in the present study was 63% at baseline, 42% after the parallel phase and 49% at follow-up assessment. Teacher response rates were 88% at baseline, 51% after the parallel phase and 64% at follow-up assessment. These response rates are

comparable to, if not higher than, the average response rate of 49.6% reported in a systematic review of studies utilising surveys as a method of data collection (van Horn et al., 2009). The level of missingness across parent and teacher responses increases the risk for Type 1 errors (Gaugler & Akritas, 2012), and the conclusions for these outcome in the current study should be interpreted conservatively.

Although associated with higher costs and slower response times, mail surveys have been found to yield higher response rates than email surveys (Shih & Fan, 2009). Greenlaw and Brown-Welty (2009) found in their study, comparing web-based, paper-based and mixed-methods for administering surveys that, although the more costly option, the mixed-methods yielded significantly higher response rates. In the current survey, parent and teacher participants had the option of completing the outcome measures as a paper-based survey or online. At baseline, 17% and 8% of responses from parents and teachers, respectively, were completed online; 7% and 0% were completed online after the parallel phase; and at follow-up assessment 4% and 14% were completed online (parents and teachers, respectively). These web-based responses may have represented a proportion of the participants who would otherwise not have responded using the paper-based method only. Thus, having the online survey in the current study appeared to have resulted in a higher response rate than might have been achieved with outcome measures only collected via paper-based surveys.

In line with suggestions for school-based research by Fletcher and Hunter (2003), efforts were made to improve response rates from parents that included: promoting the research to schools, parents and children through flyers, handouts and assembly presentations; having dedicated outcome assessors organise the data collection (and not leaving this to teachers); and reminding parents on up to four occasions to return their questionnaire. Other strategies suggested by Fletcher and Hunter (2003), such as direct communication (face-to-face) were not always practical and the use of incentives was not considered appropriate. Parents were provided with written recruitment information taken home by their child and the only direct contact with the researchers occurred as reminders to the parents to complete the outcome measures or specific questions from the parents. In these instances, parents (and teachers) were provided with a freephone number and email address they could use to contact the primary researcher.

All parent participants were contacted directly by an outcome assessor in the process of data collection, either by phone or email (depending on which method they had

indicated as their preference on the consent form). Parents were provided with prepaid envelopes to return the questionnaires or given the opportunity to complete it online if preferred. Despite these efforts, the response rate was still low with 54-59% of the parent-rated data missing. Multi-level strategies suggested by Schilpzand et al. (2015) and found to be effective in increasing parent response rates were: pre-notification postcards forewarning parents that the outcome measures were being sent out and personalised cover letters with the study and school logos, co-signed by the researcher and the school principal. In the current study, no notifications of upcoming data collection were sent out and cover letters included the study logo only- these would be useful strategies to consider if this study were replicated in the future.

Over a quarter (27%) of teacher-rated data was missing from the current study. Effective relationships were developed and maintained with the key contact person at each school; however, this was rarely the classroom teacher(s) of the children taking part in the study and in some instances no direct contact with the classroom teacher of the children occurred. Strategies that might have improved teacher response rates include direct communication with classroom teachers, study posters in the schools, email updates for all teachers, distribution of graphs reporting response rates across the region and incentives for schools with the highest response rates (Schilpzand et al., 2015).

7.8 Reconsidering the intervention delivery methods

When reflecting on the findings and above discussion, it is worth considering whether or not Kia Piki te Hauora: Uplifting our Health and Wellbeing© should remain a tier 2 (indicated) intervention or if it should be modified into a tier 1 (universal) intervention. It is noted that universal interventions have not always been found to be universally effective, with the greatest benefits found for children with the greatest needs at baseline (Dadds et al., 1997). Furthermore, a review of universal interventions for preventing depression in children and adolescents found insufficient evidence for their implementation and cautioned that without environmental changes, universal interventions targeting individual level changes may be insufficient to produce change (Spence & Shortt, 2007). However, 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). 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 adolescent girls, along with having an internal locus of control, experiencing fewer negative life events and perceived parental social support (Armstrong & Boothroyd, 2007). Additionally, an embedded intervention would prevent children missing enjoyed subjects that the rest of their class get to participate in, a factor identified in the qualitative evaluation by McCoy (2014) as significantly impacting on children's participation in the intervention from the current study (see section 7.5.5 above for fuller discussion of this evaluation). Furthermore, implementation as an embedded intervention would address the time-consuming practicalities of gathering children from multiple classrooms, which resulted in less time to focus on what was typically already a busy intervention schedule. This time pressure may have resulted in sessions feeling unnecessarily rushed and prevented some participants from having sufficient time to process the key concepts.

Therefore, the recommendation is to redesign Kia Piki te Hauora: Uplifting our Health and Wellbeing© as a universal intervention, rather than pursuing further research on it as an indicated intervention. Given the preliminary evidence supporting the impact of the intervention – on child-rated performance and satisfaction and teacher-rated child anxiety – it may be worth redesigning Kia Piki te Hauora: Uplifting our Health and Wellbeing© into an embedded classroom intervention to investigate whether this can further improve the outcomes achieved for participating children.

Redesigning Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded intervention would require environmental changes to be included in order to be effective, such as changes in teacher responses for managing issues related to mental health and wellbeing. This would enable facilitation of skill transfer into the everyday context as promoted through the use of implicit and explicit approaches. Bean et al. (2016) suggested an implicit approach involves the coaching of skills in the moment without overtly linking this to other situations or environments, for example, using a relaxation technique to facilitate the transition between lessons and not discussing other applications of this skill. The explicit approach was described as making overt to participants how skills can be transferred to different environments, for example, playing a game that involves high levels of communication and following this with a discussion about the communication strategies that were effective and how these

strategies can be used in everyday conversations. (Bean et al.) also promoted the use of key words that can be repeated and reinforced, peer modelling in groups and taking advantage of "teachable moments" (p. 275) to highlight connections with other situations (Walsh, Ozaeta, & Wright, 2010). This complements the identified desire of children to help others and share their newly developed skills (McCoy, 2014), as they apply this knowledge into broader classroom contexts, while using a language shared by others in their class.

The qualitative review by Bean et al. (2016) found taking an explicit approach to facilitate transfer of skills was most effective. The first two elements (key words and peer modelling) were incorporated into Kia Piki te Hauora: Uplifting our Health and Wellbeing© from the outset; the last (use of teachable moments beyond the intervention) would require the intervention to be embedded into the daily classroom routine in order to effectively facilitate such moments. Embedding the intervention into the classroom or school culture would require consideration of a co-teaching delivery model, parental involvement and consideration of the embedded-explicit model, each described below.

7.8.1 Co-teaching as a potential delivery model

In the substantial literature review by Weare and Nind (2011), the balance of evidence suggested that delivery methods are highly influential of intervention effectiveness. Three of the studies reviewed concluded that integrating interventions into the curriculum achieved greater and longer lasting positive effects on children's mental health (Adi et al., 2007; Berkowitz & Bier, 2007; Rones & Hoagwood, 2000). The systematic review recommended the use of a range of delivery modes (e.g. didactic, interactive) and that to successfully embed an intervention into a school culture the teachers needed to be adequately trained (and supported) in how to facilitate interventions developed by clinicians (Weare & Nind, 2011). Increased collaboration with teaching staff would be vital for embedding a programme such as Kia Piki te Hauora: Uplifting our Health and Wellbeing© into the school curriculum, to achieve a change in classroom culture as well as to provide support for teachers to implement intervention strategies.

Blackwell and Dunn (2016) suggested an embedded-explicit model for achieving naturalistic, meaningful and contextualised exposure to therapeutic interventions at a

universal level. The embedded-explicit model incorporates daily opportunities to participate in routines and occupations associated with the core concepts of the intervention (embedded) and therapist implementation of core concepts delivered to small groups or the whole class, two to three times a week (explicit). Therefore, children are exposed to more frequent opportunities to participate in and practice strategies over a longer period of time than if they received more traditional pull-out therapy and it is proposed that as a result fewer children will require more intensive intervention (Blackwell & Dunn, 2016).

7.8.2 Parental involvement in the intervention

Beyond involving teachers in the intervention, integration of parents into the embedded approach 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. A recent study by Kugel et al. (2016) evaluated a health promotion intervention targeting obesity in children that was designed to actively engage children and parents in modifying habits and routines to promote healthier choices about diet and occupational choices. Semi-structured interviews conducted with 10 children, aged 8-9 years, and their parents, were analysed using an iterative process of cyclic coding. Targeting routines and habits was found to have a positive impact on children's and parents' choices to participate in more frequent health-promoting occupations and time was identified as a barrier to participation in more health-promoting occupations (Kugel et al., 2016). It is anticipated that targeting routines and habits through Kia Piki te Hauora: Uplifting our Health and Wellbeing© would also have a positive impact on children and parents' occupational choices and that time may still be a barrier. Time may be a barrier to even including parents and embedding the intervention concepts beyond school. However, if strategies can be used to overcome or minimise time barriers, such as integrating parental involvement in the intervention with current parent involvement with their child's academic participation, then this might result in a greater positive impact on the children's participation, mental health and wellbeing overall.

7.8.3 Embedded-explicit framework

The embedded-explicit framework developed by Blackwell and Dunn (2016) was developed from the qualitative data collected during a feasibility study. Their feasibility study investigated an occupational therapy-led classroom intervention for developing

children's self-regulation skills, facilitated by teachers, therapists and researchers (Blackwell, Yeager, Mische-Lawson, Bird, & Cook, 2015). The study found that embedding self-regulation strategies into the daily classroom routine enhanced children's emotional vocabulary and their capacity to recognise emotions.

In the embedded-explicit framework, three key ingredients were identified that had successfully facilitated embedding an intervention into an early childhood environment: relates, translates and investment/insight. "Relates" refers to the therapist's ability to build an effective partnership with the classroom teacher, to genuinely respect their perspective and actively collaborate in decision-making and planning. In Aotearoa New Zealand, the regulatory body for occupational therapists identifies "building partnerships and collaborations" as one of five key competencies that therapists need to demonstrate in order to fulfil the requirements for registration (Occupational Therapy Board of New Zealand, 2015, p. 1). Therefore, relating to the teacher should be an ingredient that therapists in Aotearoa New Zealand are able to competently incorporate when aiming to embed interventions into the classroom environment. By developing a positive relationship with the classroom teacher, the therapist would be more able to accurately gauge the needs of a class for an intervention such as Kia Piki te Hauora: Uplifting our Health and Wellbeing©, build teacher capacity when needed and work alongside the teacher to co-teach key concepts.

The second key ingredient identified was "translates", which refers to the therapist's ability to modify or adapt materials from the intervention to a particular classroom environment or culture, or the children's skill level. This would include the therapist bringing to the teacher's attention elements of the teacher's current practice, strategies or the class/school routines that already facilitate and enable core concepts from the intervention and where there is room for further development (Blackwell & Dunn, 2016). The Occupational Therapy Board of New Zealand (2015) competencies 'applying occupational therapy knowledge, skills and values' and 'practising appropriately for a bicultural Aotearoa New Zealand' would be accounted for here. Therapists intending to implement Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded intervention would need to translate the core occupational components to enable them to be integrated into a busy curriculum with a culturally diverse population of students in a culturally safe manner.

The third and final ingredient identified by Blackwell and Dunn (2016) was "investment/insight" and involves the teacher taking ownership of the intervention and utilising core language or strategies from the intervention, beyond interactions with the therapist. This ingredient was reported to be facilitated by empowering teachers in a collaborative process (relates) and translating therapy into the classroom and building teacher capacity (translates). In order to facilitate Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded classroom intervention, teachers and therapists would need to collaborate about the key concepts from the intervention that need to be prioritised within a specific classroom environment, and modify and adapt strategies and teaching to fit the current culture and demands of the classroom. Additionally, teachers would need to feel empowered to implement these strategies whether or not the therapist was present.

The embedded-explicit model for incorporating interventions in the classroom is consistent with the approach taken by Bazyk et al. (2009), who investigated integration of occupational therapy services into a kindergarten. This involved both direct (e.g. planned group activities, co-teaching) and indirect (e.g. observations, coaching, consultation) occupational therapy services to enable improved literacy skills for children both with and without disabilities. Another successful example of an embedded-explicit occupational therapy intervention in the classroom was investigated by Case-Smith et al. (2014). This study evaluated the Write-Start programme, which involved explicit co-teaching (therapist and teacher) of handwriting skills and strategies that the teacher could embed and use beyond the sessions in other written work with the children. This intervention was shown to improve handwriting legibility and speed and adds to the evidence that co-teaching can enable teachers to integrate therapeutic strategies into the curriculum and provide opportunities for more responsive feedback and adaptation of strategies. It is therefore apparent that evidence is emerging to support occupational therapists implementing interventions using an embedded-explicit or integrated approach.

7.8.4 Evaluation of alternative delivery methods

The current study has provided preliminary evidence that the intervention impacted on children's occupational performance and satisfaction, as measured by the COPM. Experience of facilitating the intervention across 14 schools has revealed that while the content was positively received, the delivery model needed more flexibility and greater

integration into the classroom routine. This was supported by the results from the mediation analysis, which found significant effects of knowledge gain (one delivery method) on depression symptoms and self-esteem that were counterbalanced by an independent and unmeasured effect. The independent effect may have been the result of delivery methods that were not defined or measured in this study, such as removing children from their regular classes to facilitate their participation in the intervention. By evaluating the intervention using alternative delivery methods, such as embedding it into the classroom routine, more information could be provided about the effectiveness of the intervention under pragmatic conditions.

7.9 Intervention in the context of the national health strategy

The intervention in the current study was specifically designed to target participation. Kia Piki te Hauora: Uplifting our Health and Wellbeing© aimed to enable children to make informed choices about their routines and patterns of daily occupations, in order to promote mental health and wellbeing. The aim of the intervention from the current study has a good fit with the recently released *New Zealand Health Strategy 2016*. The *New Zealand Health Strategy 2016* tagline, "live well, stay well, get well", fits with the focus of Kia Piki te Hauora: Uplifting our Health and Wellbeing© on participation, mental health and wellbeing (New Zealand Government, 2016). The five strategic factors put forth in the New Zealand Health Strategy 2016 are: *people-powered, closer to home, value and high performance, one team,* and *a smart system*. The intervention in the current study relates to the first three strategic factors in particular. The *people-powered* strategic theme envisions people as more health literate, able to make informed choices about their own health and having access to "practical, evidence-based health advice from a range of service providers", including occupational therapists (p. 18). Developing health literacy in this way is seen as essential to promoting health equality, enabling people to make informed life-style choices, and facilitating their ability to navigate health services (Canadian Association of Occupational Therapists, 2013a). By providing an occupational perspective on health, the intervention from the current study was designed to increase children's ability to make informed occupational choices with greater understanding of the health-related consequences and benefits of those decisions. Findings that the intervention improved child-rated performance, and satisfaction with that performance, provided promising evidence that Kia Piki te

Hauora: Uplifting our Health and Wellbeing© promoted occupational health literacy to enable more satisfying and healthful occupational habits and routines for participants.

The second strategic theme strategic theme, *closer to home,* reflects the need to more effectively integrate health services (e.g. in the school setting for children), provide services closer to where people live, and promote wellness through population-based and targeted initiatives focused on children, young people and families and whānau (New Zealand Government, 2016). While the intervention in the current study achieved this to a basic extent, embedding the intervention into the classroom routine and culture and involving parents more would have enabled wider access to the mental health and wellbeing promotion intervention. It is widely recognised that taking a family-centred approach to work with children and whānau /families is best practice (Graham, Rodger, & Ziviani, 2009). Parental involvement in Kia Piki te Hauora: Uplifting our Health and Wellbeing© could have taken the form of psychoeducation for parents about the content of the intervention and the developmental needs of children to engage in a range of meaningful occupations. In particular, risk-reframing of occupations involving positive risk-taking may have been a useful facilitator to increase children's participation and performance beyond the intervention context (Niehues et al., 2015, 2016). Positive risk-taking, or risky-play may include trying an unfamiliar occupation where there is no guarantee of success or engaging with unfamiliar peers when it is unknown how their approach will be received etc. Risky play is argued to be a contributor to the development of children's health, happiness and wellbeing (Bundy et al., 2013; Niehues et al., 2016; Niehues et al., 2013). An observational study of preschoolers' play reported that risky play consisted of both environmental and individual characteristics that challenged the player and incorporated potential risks to the play (usually physical in nature) (Sandseter, 2009). Children's participation in everyday play occupations with elements of risky play are often constrained by the adults around them, who may be fearful of adverse events while a child is under their care or of harsh judgements made by other adults about the 'right' approach to take (Niehues et al., 2016).

During the consultation process for the intervention development, school personnel indicated parental involvement would likely act as a barrier to recruitment and child participation, so was not incorporated into the current intervention protocol. Furthermore, involving whānau /families lay beyond the financial and practical scope of the current study. As the intervention was facilitated in the school environment, actively

involving teachers would have been a more achievable and sustainable approach to take. A recent study of school-based occupational therapy evaluated occupational performance coaching (OPC) with teachers (Hui et al., 2016). This study found improvements in teacher-rated performance and satisfaction of their classroom management, as measured by the COPM. This study found clinically significant progress towards goals was achieved for 64% of participants (n=11) and that improvements were sustained at follow-up, 7 weeks later. Although this study focused on the teacher's classroom management of behavioural problems, it could be extrapolated that OPC is a potential method for facilitating children's participation through promoting mental health and wellbeing. Therefore, OPC has the potential to be an effective strategy to facilitate embedding Kia Piki te Hauora: Uplifting our Health and Wellbeing© into the classroom curriculum.

The third strategic theme from the New Zealand Health Strategy 2016 reflected in the intervention from the current study is *value and high performance* (New Zealand Government, 2016). This theme describes the plan to ensure services take an investment or early intervention approach to address health and social issues and measure performance of services, with that information openly available to enable informed decision-making and better performance. As such, Kia Piki te Hauora: Uplifting our Health and Wellbeing© was designed as an evidence-based programme, to be available in the school setting as an early intervention for children aimed at promoting mental health and wellbeing. Furthermore, the outcomes of this intervention were evaluated in order to provide information for children, parents, teachers and therapists to make informed decisions about supports available in the future for children in Aotearoa New Zealand.

7.10 Conclusions and implications for practice

7.10.1 Conclusions

Insufficient evidence was found for Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an intervention to promote mental health and wellbeing in children aged 11-13 years. A positive, significant impact of the intervention on child-rated performance and their satisfaction with their performance was found; however, this impact was not clinically significant and did not appear to correspond to similar improvements in the mental health outcomes. Knowledge gain was found to moderate

the effect of the intervention on child-rated depression symptoms and self-esteem, supporting the use of didactic teaching and knowledge sharing as an element of future versions of the intervention. Redesigning Kia Piki te Hauora: Uplifting our Health and Wellbeing© as an embedded intervention is indicated.

7.10.2 Implications for practice and significant contribution to knowledge

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 results contribute evidence of the positive impact of an indicated occupational therapy intervention for promoting participation in children aged 11-13 years. However, the evidence from the current study does not support the widespread use of Kia Piki te Hauora: Uplifting our Health and Wellbeing©, in its current format, for promoting mental health and wellbeing in children. The discussion above highlighted elements of the programme delivery that could be modified to enhance the effectiveness of the intervention on the targeted outcomes. In particular, delivering the intervention as an embedded intervention, in collaboration with teachers and incorporating more elements of the school culture (e.g. digital learning). Furthermore, it is anticipated that parental involvement would increase the opportunities for children to generalise skills into more environments and support their ability to build health-promoting routines into their pattern of daily occupations.

7.11 Future research

Evidence from the current study demonstrated a positive impact of the intervention on children's participation, in terms of their performance, and their satisfaction with their performance, and this is worthy of further investigation. Elements of how the intervention was implemented are worth reconsidering and modifying to facilitate an embedded, whole-class approach, with the intention of minimising stigma and disruption for the participants and to increase opportunities for enhanced participation. Furthermore, this would create more scope for tailoring the intervention to the needs and cultures of participants in each classroom. It may still be beneficial to measure mental health outcomes, such as anxiety and depression, in which case the RCADS child and parent versions might provide a consistent and robust measure that enables reasonable comparisons across informants. Use of an occupationally focused measure of participation might be more appropriate as the primary outcome measure.

The current study was a standalone cluster-RCT and future research may benefit from being part of a unified programme of research. This unified programme might include multiple pilot studies to identify appropriate occupationally focused outcome measures sensitive enough for measuring change over a variety of time periods and facilitate modifications to the intervention ensuring 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, with increased emphasis on data relevant to process evaluation within the RE-AIM framework. Factors independent of knowledge gain counterbalanced the impact of the intervention and warrant further investigation; it is currently hypothesised that these factors may have included removal of children from their daily routines (causing disruption and possible stigma) and non-completion of skills practice between sessions, which could be further investigated through a qualitative study design.

A longer follow-up period was beyond the scope and resources of this study and would be important to consider when planning similar studies in the future. A pilot study with a smaller sample of participants may be used to determine the rate at which changes in participation occur in those allocated to a control versus those allocated to an active intervention. Having a comparison group at the follow-up period will be important for determining the longer-term impact of the intervention on the outcome measures.

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Appendices

Appendix 1: Critique of quantitative studies

Down's and Black rating criteria (Downs & Black, 1998).

ALL CRITERIA DESCRIPTION OF CRITERIA (with additional explanation as required, determined by consensus of raters) POSSIBLE ANSWERS

1 Is the hypothesis/aim/objective of the study clearly described? Must be explicit

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	The aim of this study was to describe what full integration of occupational therapy services would look like in an emergent literacy kindergarten curriculum and to document fine motor and emergent literacy outcomes for children with and without disabilities.
Engelen et al. (2013)	Yes	The objective of this study was to increase children's physical activity during break time at school through active free play, coupled with an adult directed intervention aimed at reframing risks often associated with free play.
McGarrigle and Nelson (2006)	Yes	This study was designed to evaluate the occupational therapy 'school skills' programme provided by the University of Queensland's Children's Life Skills Clinic…. It was also hypothesized that the experimental group would show greater improvements in these areas, compared to a comparison group receiving regular schooling only.
Petersen and Nelson (2003)	Yes	The purpose of this study was to evaluate whether an occupational therapy intervention improved an academic outcome (D'Nealian printing) in a school setting.

2 Are the main outcomes to be measured clearly described in the Introduction or Methods section? If the main outcomes are first mentioned in the Results section, the question should be answered no. ALL primary outcomes should be described for YES

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	Instruments described in methods section.
Engelen et al. (2013)	Yes	The primary outcome measure, children's physical activity, was measured with Actigraph accelerometers…The available play space per child on the playground as expressed in m2 was obtained by dividing the available playground area
McGarrigle and Nelson (2006)	Yes	Two standardized tests and two non-standardized measures were administered.
Petersen and Nelson (2003)	Yes	The MHT (Reisman, 1993) was used in the current study to measure outcome.

3 Are the characteristics of the patients included in the study clearly described? In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given. Single case studies must state source of patient

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	A convenience sample of 37 children, with and without disabilities, from two integrated kindergarten classrooms participated in this study. The age range of the sample at the beginning of the study was 60 to 83 months, with a mean age of 71.5 months. Twelve children had identified disabilities (6 in each class) and received special education, occupational therapy, speech–language pathology, adapted physical education, music therapy, and physical therapy, as needed. Children with disabilities all qualified for special education and presented with a variety of developmental disabilities, including Down Syndrome (n=3), cerebral palsy (n=1), mental retardation (n=4), and undiagnosed developmental delays (n=4). Only one of the children with disabilities was nonambulatory and used a wheelchair. Although the remaining 25 children were identified as typically developing peers, many were at risk of fine motor and academic delays because of their low-income urban status (Lee-Corbin & Evans, 1996). For example, on the basis of the pretest scores, the typically developing peers demonstrated an average of 18 months of delay in visual–motor skills based on the VMI.
Engelen et al. (2013)	Yes	At baseline, participating children were 6.0 (SD 0.6) years of age (range 4.7–7.3 years). Of the 119 boys and 102 girls, 0.5% were underweight, 78.5% were healthy weight, 14.5% were overweight and 6.5% were obese. ICSEA ranged from 980 to 1170. Almost all children were born in Australia, but half of the children had a least one parent born overseas. The participants' backgrounds were very diverse with parents originating from 35 different countries, the most originating from Australia (n=280), the Philippines (n=22), Italy (n=22), China (n=16), India (n=16) and New Zealand (n=15). This was representative of the diversity in the schools from which children were recruited.
McGarrigle and Nelson (2006)	Yes	Participants in the experimental group included three males and five females with ages ranging from 66 to 84 months (mean = 74.1). The comparison group comprised three males and two females with ages ranging from 64 to 77 months (mean = 73.0). Of the 13 participants, four were repeating grade one. These four children were evenly distributed between the two groups.
Petersen and Nelson (2003)	Yes	There were no significant differences between the two randomly assigned groups in terms of age, gender, race, or absences from the 20 planned group sessions….The original sample consisted of 62 first-grade children. Three subjects relocated before the study was completed, resulting in a final sample size of 59. Included were 30 Caucasian students, 25 African-American students, and 4 Hispanic students. Completing the study were 31 girls and 28 boys. Mean age was 7.1 years (SD = 0.4). Inclusion criteria for participants in the study were: (a) enrollment in one of three first-

	grade classrooms in a school served by a federally funded school-based health center for economically disadvantaged children; (b) informed consent; and (c) maintenance in the school until the end of the study and attendance for at least 10 of 20 planned group sessions.

4 Are the interventions of interest clearly described? Treatments and placebo (where relevant) that are to be compared should be clearly described.

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	Indirect and direct occupational therapy services described.
Engelen et al. (2013)	Yes	The intervention had two components: (1) a 13-week playground-based intervention and (2) a 2-hour adult intervention administered 2 to 3 weeks after the initiation of the playground intervention. Post-testing took place during the final week of the playground-based intervention. Children at the control schools participated in standard break times. They did not have access to the intervention materials and adults received no intervention.
McGarrigle and Nelson (2006)	Yes	The grade-one 'school skills' programme consisted of six, 80-minute sessions conducted within the school once a week, for six weeks… Within one week of pre-testing of all participants, the programme was provided to the experimental group in term one, while the comparison group was exposed to regular schooling only.
Petersen and Nelson (2003)	Yes	The children were randomly assigned to either an experimental (handwriting intervention) or control (no handwriting intervention) condition….The 30 children randomly assigned to the intervention group were scheduled to receive 20 sessions of occupation-al therapy….Each child in the intervention group followed an individualized daily plan that was reflective of a general plan applied to all participants (e.g., certain equipment and space were made available for the day)…. Classroom teachers were not informed about the content of the interventions until debriefings were held after the conclusion of the study.

5 Are the distributions of principal confounders in each group of subjects to be compared clearly described? A list of principal confounders is provided. YES = age, severity

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	See Table 1.
McGarrigle and Nelson (2006)	No	
Petersen and	No	

Nelson (2003)

6 Are the main findings of the study clearly described?

Simple outcome data (including denominators & numerators) should be reported for all major findings so that the reader can check the major analyses & conclusions.

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	See Tables. Results section provides description of OT service provided, comparison of pretest and posttest fine motor performance and emergent literacy skills and analysis of improvements demonstrated beyond maturation.
Engelen et al. (2013)	Yes	See Table 2.
McGarrigle and Nelson (2006)	Yes	Pre-to-post data from the experimental and comparison groups were pooled, after establishing no significant discrepancy between the groups' initial measures… Statistical comparisons are presented in Table 2.
Petersen and Nelson (2003)	Yes	Primary and secondary analyses described. See Tables.

7 Does the study provide estimates of the random variability in the data for the main outcomes?

In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	SDs provided in Tables.
Engelen et al. (2013)	Yes	See Table 2.
McGarrigle and Nelson (2006)	Yes	Means and standard deviations for pre- and post-intervention scores are presented in Table 1.
Petersen and Nelson (2003)	Yes	See Table 1.

8 Have all important adverse events that may be a consequence of the intervention been reported?

This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events (COMPLICATIONS BUT NOT AN INCREASE IN PAIN).

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	UTD	Presence/absence or measurement of adverse events not reported.
Engelen et al. (2013)	UTD	Presence/absence or measurement of adverse events not reported.
McGarrigle and Nelson (2006)	UTD	Presence/absence or measurement of adverse events not reported.
Petersen and Nelson (2003)	UTD	Presence/absence or measurement of adverse events not reported.

9 Have the characteristics of patients lost to follow-up been described?

If not explicit = NO. RETROSPECTIVE – if not described = UTD; if not explicit re: numbers agreeing to participate = NO. Needs to be >85%

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	UTD	"…written parental consent and the students' written assent were obtained from **all** of the invited participants". Assumed no loss to follow-up but not explicit.
Engelen et al. (2013)	No	Fig. 1 represents the flow of schools and participants through the study and shows a 95% participant retention rate.
McGarrigle and Nelson (2006)	Yes	Of the 16 children who initially entered the study, 13 completed the end programme testing; two left the school and one was unavailable at the time of testing…The three children who did not complete post-programme testing had been members of the comparison group, leaving an imbalance of group sizes.
Petersen and Nelson (2003)	Yes	The original sample consisted of 62 first-grade children. Three subjects relocated before the study was completed, resulting in a final sample size of 59.

10 Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

Yes/No

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	See Tables.
Engelen et al. (2013)	Yes	See Table 2.
McGarrigle and Nelson (2006)	Yes	See Table 2.
Petersen and Nelson (2003)	Yes	See Table 2.

11 Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

The study must identify the source population for patients and describe how the patients were selected. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	No	Students with and without disabilities enrolled in two integrated kindergarten classrooms with fully integrated occupational therapy services were invited to participate in this study.
Engelen et al. (2013)	Yes	The Catholic school system was chosen for convenience but it was known *a priori* that the schools vary widely in terms of socio-economic status and culture… we sought to recruit a random sample of 19 five to seven-year old children per school (total n=226), representative of young primary school children in those schools. T
McGarrigle and Nelson (2006)	UTD	Participants were a purposive sample of 16 grade-one Indigenous children currently enrolled at an urban Indigenous school…The children had no known neurological, developmental or medical diagnoses. In addition to parent/guardian consent, inclusion criteria for the sample required that they be of Australian Indigenous background, enrolled in grade-one at the school, and had received three or more of the six occupational therapy sessions
Petersen and Nelson (2003)	No	Eighty percent of students attending this school were considered homeless according to federal guidelines, and two residential centers for victims of abuse were within the school boundaries for attendance. The school neighbourhood continues to have the highest crime rate, the highest assault rate, and the highest domestic violence rate in the city, which has a population of approximately 100,000. The school turnover rate each academic year is approximately 40 percent, and the school has the highest percentage of students on free or reduced lunch of all 18 elementary schools in the district.

12 Were those subjects who were prepared to participate representative of the entire population from which they were recruited?

The proportion of those asked who agreed should be stated. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	No	A convenience sample of 37 children, with and without disabilities, from two integrated kindergarten classrooms participated in this study
Engelen et al. (2013)	Yes	This was representative of the diversity in the schools from which children were recruited.
McGarrigle and Nelson (2006)	Yes	Participants were a purposive sample of 16 grade-one Indigenous children currently enrolled at an urban Indigenous school…The children had no known neurological, developmental or medical diagnoses. In addition to parent/guardian consent, inclusion criteria for the sample required that they be of Australian Indigenous background, enrolled in grade-one at the school, and had received three or more of the six occupational therapy sessions
Petersen and Nelson (2003)	UTD	

13 Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?

For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. Must state type of hospital and country for YES. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	Conducted in US. Novel intervention. Standard curriculum described. …sample of kindergarten-age children attending an inner city urban school who received fully integrated occupational therapy services.
Engelen et al. (2013)	Yes	Conducted in Australia. Novel intervention – environmental modification so staffing representative.
McGarrigle and Nelson (2006)	Yes	The Life Skills Clinic has provided a six week programme to grade-one students at an urban Indigenous school, each year since 1998.
Petersen and Nelson (2003)	UTD	

14 Was an attempt made to blind study subjects to the intervention they have received?

For studies where the patients would have no way of knowing which intervention they received, this should be answered yes. Retrospective, single group = NO; UTD if > 1 group and blinding not explicitly stated. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	Schools and researchers were blinded to the intervention allocation until the completion of baseline testing.
McGarrigle and Nelson (2006)	No	Intervention required active participation.
Petersen and Nelson (2003)	Yes	Classroom teachers were not informed about the content of the interventions until debriefings were held after the conclusion of the study.

15 Was an attempt made to blind those measuring the main outcomes of the intervention? *Must be explicit Yes/No/UTD*

Reference	Rating	Evidence
Bazyk et al. (2009)	No	A battery of six assessments was administered by the research team to all participants
Engelen et al. (2013)	Yes	Children's physical activity, was measured with Actigraph accelerometers Objective measurement tool.
McGarrigle and Nelson (2006)	Yes	The VMI was administered as a group within the classroom and scored by a single blinded assessor, experienced in scoring the VMI. Observations for the ASQ were carried out in the classroom over a period of four hours in the morning of a usual school day and completed by trained occupational therapy students independent of

		the study and blinded to group allocation. T
Petersen and Nelson (2003)	No	The principal investigator administered the MHT to control group subjects, and 14 occupational therapy students administered the MHT to the intervention group subjects.

16 If any of the results of the study were based on "data dredging", was this made clear?

Any analyses that had not been planned at the outset of the study should be clearly indicated. Retrospective = NO. Prospective = YES Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	No	Results report on outcomes stipulated in the methods
Engelen et al. (2013)	Yes	Only primary outcome and potential predictor variables reported.
McGarrigle and Nelson (2006)	No	NA
Petersen and Nelson (2003)	No	NA

17 In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case control studies, is the time period between the intervention and outcome the same for cases and controls?

Where follow-up was the same for all study patients the answer should yes. Studies where differences in follow-up are ignored should be answered no.

Acceptable range 1 yr follow-up = 1 month each way; 2 years follow-up = 2 months; 3 years follow-up = 3months.....10 years follow-up = 10 months. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	Pre-post only and no control group.
Engelen et al. (2013)	Yes	Same time period. Children at the control schools participated in standard break times. They did not have access to the intervention materials and adults received no intervention.
McGarrigle and Nelson (2006)	Yes	Within one week of completion of the six week programme both the experimental and comparison groups were post-tested, using the same battery of assessments. The programme was then provided to the comparison group in term two, while the experimental group received only regular schooling. Again, within one week of completion of the six week programme, both the experimental and the comparison group were post-tested using the same battery of assessments.
Petersen and Nelson (2003)	Yes	Same time period. In the pretesting and posttesting of the actual study, the children were removed from the classroom for administration of the MHT. The principal investigator administered the MHT to control group subjects, and 14 occupational therapy students administered the MHT to the intervention group subjects.

18 Were the statistical tests used to assess the main outcomes appropriate?

The statistical techniques used must be appropriate to the data. If no tests done, but would have been appropriate to do = NO Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	To determine clinical significance, the Proportional Change Index (PCI) was calculated for tests yielding age equivalent scores (PDMS–2 [FM] and VMI). Comparisons using two-way ANOVAs …
Engelen et al. (2013)	Yes	Mixed-effects multi-level linear regression was used for each outcome, taking clustering and repeated measurement into account.
McGarrigle and Nelson (2006)	Yes	Due to a small sample size and the use of raw scores for comparisons, a more conservative, non-parametric approach to data analysis was utilized. To determine whether a participant improved over the course of the programme, a Wilcoxon-Z repeated measures test was computed, comparing pre-test and post-test scores for each assessment. To compare the gains of the experimental group with those of the comparison group, a Mann Whitney U-Test was completed. Alpha was set at 0.05.
Petersen and Nelson (2003)	Yes	A multivariate analysis of variance (MANOVA) on the difference scores (gain scores) generated by the five variables of interest (legibility, space, line, size, and form) was planned to compare the gains made by the intervention group with those of the control group.

19 Was compliance with the intervention/s reliable?

Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. Surgical studies will be YES unless procedure not completed. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	Emerging role so not standardised. Role conducted clearly described as one of the outcomes.
Engelen et al. (2013)	Yes	Environmental intervention.
McGarrigle and Nelson (2006)	Yes	Intervention plans were reviewed prior to each session by the supervising therapist to ensure appropriateness and fidelity of treatment….The supervising therapist closely observed and provided 'hands on' supervision during the intervention sessions to help maintain fidelity of treatment between the groups.
Petersen and Nelson (2003)	UTD	Each child in the intervention group followed an individualized daily plan that was reflective of a general plan applied to all participants (e.g., certain equipment and space were made available for the day)… the intervention condition is necessarily somewhat open-ended.

20 Were the main outcome measures used accurate (valid and reliable)?

Where outcome measures are clearly Yes/No/UTD described, which refer to other work or that demonstrates the outcome measures are accurate = YES.

ALL primary outcomes valid and reliable for YES

Reference	Rating	Evidence
Bazyk et al. (2009)	Yes	Fine motor performance was measured by the Fine Motor (FM) scale of the Peabody Developmental Motor Scales–2 (PDMS–2), a norm-reference standardized test for children birth through 72 months (Folio & Fewell, 2000)…. Visual–motor skills were measured using the Visual–Motor Integration test (VMI; Beery & Buktenica, 1997)…. In-hand manipulation was measured using five small pegs from a nine-hole pegboard…. Last, pencil grasp was assessed using the developmental sequence described by Schneck (1991) and Schneck and Henderson (1990)…. Three subtests of Clay's (1993) Observation Survey of Early Literacy Achievement (OSELA) were used. Since the 1960s, Clay has engaged in in-depth research and analysis of literacy development.
Engelen et al. (2013)	Yes	A researcher attached the accelerometers at 9.00 AMand removed them at 3.00 PM on five consecutive school days, at baseline and post-test. Data were recorded in 5 second epochs but reintegrated to 15 s to fit the cut-off point algorithm. Accelerometers provided total activity counts as well as estimates of time spent in sedentary, light or moderate–vigorous intensity physical activity (MVPA) using existing cut-off points for children (Evenson et al., 2008). Although accelerometer cut-off points have well-documented limitations, the algorithm we used was recently recommended for this age group (Trost et al., 2011).
McGarrigle and Nelson (2006)	Yes	The Beery-Buktenica Developmental Test of Visual Motor Integration, 4th Edition, Revised, (VMI; Beery, 1997), for children aged 3–7 years was used…. Children's general classroom behaviour was evaluated using the Conners' Abbreviated Symptom Questionnaire (ASQ; Conners, 1990)…. Two measurement tools were developed specifically for this study to formally observe the functional skills of handwriting and scissor use.
Petersen and Nelson (2003)	Yes	An interrater reliability study was also conducted on the scoring of the MHT. Fourteen occupational therapy students received training to administer and score the MHT, but three did not attain acceptable levels of interrater agreement on test samples. The remaining eleven raters were tested on 20 examples randomly drawn from those used in the test-retest reliability study. ICCs for the five main variables used in this study ranged from .73 to .99 (from good to almost perfect). The ICC for speed was .65.

21 Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?

Patients for all comparison groups should be selected from the same hospital. The question should be answered UTD for cohort and case control studies where there is no information concerning the source of patients. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.

Engelen et al. (2013)	Yes	Different groups. Twelve Catholic co-educational primary schools in Sydney, Australia participated in the study and were randomised to the control or intervention groups in equal numbers.
McGarrigle and Nelson (2006)	No	Both the experimental and comparison group were exposed to the intervention method, but at different times.
Petersen and Nelson (2003)	Yes	Different groups. The children were randomly assigned to either an experimental (handwriting intervention) or control (no handwriting intervention) condition.

22 Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same time?

For a study which does not specify the time period over which patients were recruited, the question should be answered as UTD. Surgical studies must be <10 years for YES, if >10 years then NO. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	Data were collected from June 2009 to December 2010 by research assistants and trained student researchers.
McGarrigle and Nelson (2006)	Yes	The experimental group received the six week occupational therapy programme in term one of the school year, while the comparison group received only regular schooling.
Petersen and Nelson (2003)	Yes	The children were randomly assigned to either an experimental (handwriting intervention) or control (no handwriting intervention) condition. Randomization procedures ensured that each child was assigned in an unbiased way.

23 Were study subjects randomised to intervention groups?

Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	Twelve Catholic co-educational primary schools in Sydney, Australia participated in the study and were randomised to the control or intervention groups in equal numbers.
McGarrigle and Nelson (2006)	No	Participants were randomly assigned to either an experimental or comparison group through an odd/even selection process according to their name order on the class roll.
Petersen and Nelson (2003)	Yes	The children were randomly assigned to either an experimental (handwriting intervention) or control (no handwriting intervention) condition. Randomization procedures ensured that each child was assigned in an unbiased way. Each child was assigned a number from

	1 to 62; number slips were drawn from an opaque container and alternately assigned to group 1 or group 2. Assignment of groups to the intervention or control condition was also random.

24 Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	Schools and researchers were blinded to the intervention allocation until the completion of baseline testing.
McGarrigle and Nelson (2006)	UTD	Before commencement, the project gained ethical clearance from the Ethics Committee of the School of Health and Rehabilitation Sciences at the University of Queensland and approval from the Indigenous school board. The children were then randomly allocated to two approximately equal sized groups. Within one week of pre-testing of all participants, the programme was provided
Petersen and Nelson (2003)	UTD	Assignment of groups to the intervention or control condition was also random.

25 Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

In non-randomised studies, if the effect of the main confounders was not investigated or no

adjustment was made in the final analyses the question should be answered as no. If no significant difference between groups shown then YES. Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	NA	For ethical and service delivery reasons, a control group was not obtained. Consequently, this was an outcome study rather than a clinical trial.
Engelen et al. (2013)	Yes	Mixed-effects multi-level linear regression was used for each outcome, taking clustering and repeated measurement into account. Each model included eight fixed factors: treatment (control/intervention), phase (baseline/post-test), interaction between treatment and phase (effect of treatment over time, i.e. the difference between groups in change from baseline), sex, year (kindergarten/year 1), BMI and ICSEA values, and two random effects: school and participant ID. The interaction between treatment, phase and sex was tested to check whether the effect of treatment over time differed by sex.
McGarrigle and Nelson	No	NA

(2006)		
Petersen and Nelson (2003)	Yes	Data collected also provided opportunities for ex post facto analyses of the relationships between age, gender, race, and number of school absences on the one hand and performance on the MHT on the other hand.

26 Were losses of patients to follow-up taken into account?

If the numbers of patients lost to follow-up are not reported = unable to determine.

Yes/No/UTD

Reference	Rating	Evidence
Bazyk et al. (2009)	UTD	Loss to follow-up not reported.
Engelen et al. (2013)	Yes	Minimal loss. Fig. 1 represents the flow of schools and participants through the study and shows a 95% participant retention rate.
McGarrigle and Nelson (2006)	Yes	The three children who did not complete post-programme testing had been members of the comparison group, leaving an imbalance of group sizes. Small sample analysed non-parametrically to accommodate this.
Petersen and Nelson (2003)	Yes	Minimal loss. The original sample consisted of 62 first-grade children. Three subjects relocated before the study was completed, resulting in a final sample size of 59.

27 Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance <5%?

Sample sizes have been calculated to detect a difference of x% and y%.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	No	No sample size or power calculation reported. A convenience sample of 37 children, with and without disabilities, from two integrated kindergarten classrooms participated in this study. T
Engelen et al. (2013)	Yes	Based on *a priori* power analysis (Bundy et al., 2011) we sought to recruit a random sample of 19 five to seven-year old children per school (total n=226), representative of young primary school children in those schools.
McGarrigle and Nelson (2006)	No	Due to a small sample size and the use of raw scores for comparisons, a more conservative, non-parametric approach to data analysis was utilized.
Petersen and Nelson (2003)	Yes	The estimated effect size ($\eta 2$) was .378, with an observed power of .994. This is a very large effect, indicating a substantial difference between the occupational therapy intervention group and the control group (Cohen, 1988).

Appendix 2: Critique of qualitative studies

Critical Review Form – Qualitative: Studies (Version 2.0) (Letts et al., 2007)

CITATION:

Bazyk, S., & Bazyk, J. (2009). Meaning of occupation-based groups for low-income urban youths attending after-school care. *American Journal of Occupational Therapy, 63*(1), 69-80. doi:10.5014/ajot.63.1.6

STUDY PURPOSE:

Was the purpose and/or research question stated clearly?

 yes

 no

Outline the purpose of the study and/or research question.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Using a phenomenological approach, the purpose of this qualitative study was to identify and describe the meaning of occupational therapy groups focusing on engagement in structured leisure occupations, group process, and social–emotional learning as experienced by low-income urban youths attending after-school care.

LITERATURE:

Was relevant background literature reviewed?

 yes

 no

Describe the justification of the need for this study. Was it clear and compelling? How does the study apply to your practice and/or to your research question? Is it worth continuing this review?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Situates intervention in the context of occupational science with a focus on occupational deprivation for disadvantaged youth. Describes occupational participation need of low income urban youth and impact of afterschool programmes on academic and social-emotional outcomes.

STUDY DESIGN:

What was the design?

 phenomenology

 ethnography

 grounded theory

 participatory action research

 other

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Phenomenology	Using a phenomenological approach, the purpose of this qualitative study was…

Was the design appropriate for the study question? (i.e., rationale) Explain. When doing critical reviews, there are strategic points in the process at which you may decide the research is not applicable to your practice and question. You may decide then that it is not worthwhile to continue with the review. Was a theoretical perspective identified?

 yes

 no

Describe the theoretical or philosophical perspective for this study e.g., researcher's perspective.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Phenomenology is the study of the individual's experience from her or his perspective (Finlay, 1999; Gray, 1997). Using a phenomenological approach, the purpose of this qualitative study was to identify and describe the meaning of occupational therapy groups focusing on engagement in structured leisure occupations, group process, and social–emotional learning as experienced by low-income urban youths attending after-school care.

Method(s) used:

□ participant observation

□ interviews

□ document review

□ focus groups

□ other

Describe the method(s) used to answer the research question. Are the methods congruent with the philosophical underpinnings and purpose?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	In-depth interviews Participant observation	All phenomenological approaches focus on how people make sense of experience and transform it into consciousness, which requires capturing and describing how people experience the phenomenon - "how they perceive it, describe it, feel about it, judge it, remember it, make sense of it, and talk about it with others" (Patton, 2002, p. 104). To achieve this perspective, a combination of interviews and participant observations were used (Patton, 2002).

SAMPLING:

Was the process of purposeful selection described?

□ yes

□ no

Describe sampling methods used. Was the sampling method appropriate to the study purpose or research question?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	A purposeful sample of 10 children (4 boys, 6 girls) was interviewed after Investigational Review Board approval, written parental consent, and children's assent. Intensity sampling guided the selection and consisted of those children who represented "excellent or rich examples of the phenomenon of interest" (Patton, 2002, p. 234). For this study, "excellent cases" were defined as those children who consistently attended the HOPE groups.

Was sampling done until redundancy in data was reached?2

□ yes

□ no

□ not addressed

Are the participants described in adequate detail? How is the sample applicable to your practice or research question? Is it worth continuing?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Not addressed	NA

Was informed consent obtained?

□ yes

□ no

□ not addressed

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	A purposeful sample of 10 children (4 boys, 6 girls) was interviewed after Investigational Review Board approval, written parental consent, and children's assent.

DATA COLLECTION:

Descriptive Clarity

Clear & complete description of site: □ yes □ no

participants: □ yes □ no

Role of researcher & relationship with participants: □ yes □ no

Identification of assumptions and biases of researcher: □ yes □ no

Describe the context of the study. Was it sufficient for understanding of the "whole" picture?

What was missing and how does that influence your understanding of the research? Throughout the form, "no" means the authors explicitly state reasons for not doing it; "not addressed" should be ticked if there is no mention of the issue.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	On the basis of children's inherent needs for structured leisure occupations, social–emotional learning, and close human connections, preventive occupation-based groups for low-income urban youths attending after-school care the Occupational Therapy Groups for HOPE—was developed and conducted. This 9-week program, embedded in a faith-based after-school setting in a large Midwestern city, has been offered yearly as a service-learning initiative since 2003. Under the supervision of Susan Bazyk (an occupational therapy faculty member), groups of graduate occupational therapy students coplan and facilitate the 1-hr weekly groups, each made up of 8–10 children. After-school care providers also participate in the group activities to learnhow to simultaneously engage children in meaningful occupations and attend to social–emotional learning needs (Bazyk, 2005)…. The HOPE groups were provided to 70 children attending an inner-city faith-based after-school program. Under the supervision of Susan Bazyk, 22 graduate occupational therapy students, assigned in groups of 2 or 3, co-facilitated the weekly groups. The children were placed in 9 groups—5 groups of boys and 4 groups of girls. The average group size was 7–8 children. All group participants were African American, ranging in age from 7 to 12 years and living within the low-income range or near the poverty level. Approximately 70% of the children lived in single, female-headed households (Bazyk, 2005).

Procedural Rigour

Procedural rigor was used in data collection strategies?

 yes

 no

 not addressed

Do the researchers provide adequate information about data collection procedures e.g. gaining access to the site, field notes, training data gatherers? Describe any flexibility in the design & data collection methods.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Process for indepth interviews and participation observations described clearly.

DATA ANALYSES:

Analytical Rigour

Data analyses were inductive?

□ yes □ no □ not addressed

Findings were consistent with & reflective of data?

□ yes □ no

Describe method(s) of data analysis. Were the methods appropriate? What were the findings?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Giorgi's (1985) data analysis strategies, as described by Polkinghorne (1989), were closely followed to understand the essence of the group experience from the subjective perspective of the participants (see Appendix).

Auditability

Decision trail developed?

□ yes □ no □ not addressed

Process of analyzing the data was described adequately?

□ yes □ no □ not addressed

Describe the decisions of the researcher re: transformation of data to codes/themes. Outline the rationale given for development of themes.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Partially	Giorgi's (1985) data analysis strategies, as described by Polkinghorne (1989), were closely followed to understand the essence of the group experience from the subjective perspective of the participants (see Appendix)…. After reading the interviews, identifying meaning units, and transforming the meaning units using an occupational science perspective, it became apparent that a synthesis of the meaning units could be presented in terms of occupational meaning, form, and function.

Theoretical Connections

Did a meaningful picture of the phenomenon under study emerge?

□ yes

□ no

How were concepts under study clarified & refined, and relationships made clear? Describe any conceptual frameworks that emerged.

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	After reading the interviews, identifying meaning units, and transforming the meaning units using an occupational science perspective, it became apparent that a synthesis of the meaning units could be presented in terms of occupational meaning, form, and function….Two major themes describing the essential elements of the group experience emerged from the data: "The HOPE groups are fun" and "the children learned to talk about their feelings and express anger in appropriate ways."

OVERALL RIGOUR

Was there evidence of the four components of trustworthiness?

Credibility □ yes □ no

Transferability □ yes □ no

Dependability □ yes □ no

Confirmability □ yes □ no

For each of the components of trustworthiness, identify what the researcher used to ensure each. What meaning and relevance does this study have for your practice or research question?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Partial	To enhance credibility, two forms of triangulation were used—multiple qualitative methods and multiple data analysts. Other components not addressed.

CONCLUSIONS & IMPLICATIONS

Conclusions were appropriate given the study findings?

□ yes □ no

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	Groups are fun – form, function and meaning. Social-emotional learning – how to manage anger.

The findings contributed to theory development & future OT practice/ research?

□ yes □ no

What did the study conclude? What were the implications of the findings for occupational therapy (practice & research)? What were the main limitations in the study?

Reference	Rating	Evidence
Bazyk and Bazyk (2009)	Yes	The findings have implications for how therapists and therapy assistants can design and implement groups to address the occupational and social–emotional needs of children. Moreover, findings may be used to articulate the mental health benefits of participation in occupation-based groups. By applying an occupational science perspective, the occupational therapy groups for HOPE were designed to help low-income urban youths “find pleasure in the right things” (Csikszentmihalyi, 1993, p. 39). Findings of this study contribute to an understanding of the role of occupational therapy in a relatively new practice arena—after-school programs in low-income urban contexts. Limitations: small sample

Appendix 3: Kia Piki te Hauora: Uplifting our Health and Wellbeing© intervention manual

Kia Piki te Hauora was designed by Ema Tokolahi who has sole copyright to the intervention resources, format and imagery. Research into the effectiveness of Kia Piki te Hauora is supported by Auckland University of Technology (AUT).

Illustrations by Charity Russell.

Printed in Auckland, New Zealand, 2013.

Kia Piki te Hauora

Kia Piki te Hauora means to Uplift Our Health and Wellbeing.

A well-being group for intermediate students

Purpose

Kia Piki te Hauora is an 8 week course for intermediate students that aims to increase knowledge of how what we DO impacts on our health, well-being, how we connect with others and how we feel about ourselves. Kia Piki te Hauora provides skills and knowledge that can help us feel able to cope, now and in the future.

Contents

Yellow highlighted text are direct instructions to be given to the group.

Green highlighted text are suggested questions to prompt discussion with group.

Full manual removed to protect copyright.

Appendix 4: Canadian Occupational Performance Measure (COPM) menu items

Get ready for a good night's sleep (e.g. calming bed time routine)

Take part in physical activities (e.g. sports, washing car, play park, skateboarding, swimming)

Take part in calm activities (e.g. reading, board games, watching TV)

Take part in social activities with friends (e.g. parties, going to the mall, hanging out)

Take part in social activities with family (e.g. family gatherings, meal times, day trips)

Rest and relax (i.e. doing things that help me feel calm and not stressed)

Taking part in activities that express my identity

Take an active role in my learning (e.g. doing homework, answering questions in class, asking questions, group-work).

Communication with others well (in person)

Communicate with others well (via a device)

Cope with strong emotions so I can still do what I want to or need to

Cope with unhelpful thoughts so I can still do what I want to or need to

Setting goals and knowing how to work towards them

Taking part in activities that are important to me

Have a routine I am happy with (e.g. where I can do the activities I need to and want to, without feeling stressed out)

Appendix 5: Knowledge survey

Week 1

When we talk about 'occupations' in Kia Piki te Hauora, we mean: **(Circle one)**	The job a person has, such as being a teacher.	The everyday activities we do, such as going to school and brushing our teeth.	When one country takes over another country.	None of the above

Wellbeing is about: **(Circle one)**	Not being sick.	Feeling we are able to cope with life's stressors.	Feeling happy and healthy.	All of the above.

Week 2

Circle your response to indicate whether you believe the following statements to be True or False:	*Sleep helps me grow*	True	False
	Sleep helps me concentrate	True	False

To be healthy, children aged 10-14 years need to sleep for how long each night? (Circle one)	6-8 hours	8-10 hours	10-12 hours

Week 3

Circle your response to indicate whether you believe the following statements to be True or False:	*Physical activity improves sleep*	True	False
	Physical activity improves mood and reduces stress	True	False

To be healthy, children and adolescents need to participate in how much physical activity each day? (Circle one)	30 minutes	60 minutes	90 minutes

Week 4

Circle your response to indicate whether you believe the following statements to be True or False:	*We use verbal communication more than non-verbal*	True	False
	Communication is important for my social relationships	True	False

Cyber communication relies on… (Circle one)	Verbal communication	Non-verbal communication	No communication

Week 5

When the fight of flight response is triggered our body will… **(Circle all that apply)**	Increase our heart rate and breathing	Sweat more	Relax our muscles

Circle your response to indicate whether you believe the following statements to be True or False:	*The relaxation response is the opposite of the fight or flight response*	True	False
	There is nothing we can do to trigger the relaxation response	True	False

Week 6

Which of the following are bodily senses?	Seeing and hearing	Tasting and smelling	Touching and moving

(Circle all that apply)			

Circle your response to indicate whether you believe the following statements to be True or False:	*Telling myself "I can do it" can help me do what I want /need to do*	True	False
	Going home and not doing the thing that makes me scared/ angry/upset is the best way to manage strong emotions	True	False

Week 7

Circle your response to indicate whether you believe the following statements to be True or False:	*Values are something we think are important*	True	False
	Everyone shows their values in the same way	True	False

Asking for help is… **(Circle all that apply)**	A sign of weakness and should be avoided at all costs.	A brave and strong coping skill that everyone needs to do at one time or another.	A difficult thing to do sometimes.

Appendix 6: Health and Disability Ethics Committee (HDEC) approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

07 May 2014

Mrs Emma (Ema) Tokolahi
15a Jesmond Terrace
Mt Albert
Auckland 1025

Dear Mrs Tokolahi

Re:	Ethics ref:	**14/NTA/13/AM02**
	Study title:	Cluster randomised controlled trial of an indicated occupational therapy group intervention for children aged 11-13 years, designed to reduce symptoms of anxiety and depression and improve self-esteem and participation

I am pleased to advise that this amendment has been approved by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	Version	Date
Survey/questionnaire: Child Depression Inventory - 2 (CDI-2)	1	24 April 2014
Post Approval Form	1	25 April 2014

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

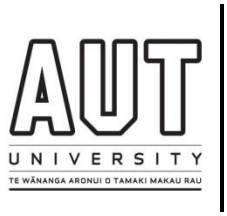
- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of International good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Karen Bartholomew	Non-lay (intervention studies)	01/07/2013	01/07/2016
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Dr Christine Crooks	Non-lay (intervention studies)	01/07/2013	01/07/2015
Mr Kerry Hilni	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Etuate Seafi	Non-lay (intervention studies)	01/07/2012	01/07/2014
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2014

http://www.ethics.health.govt.nz

Appendix 7: Auckland University of Technology Ethics Committee (AUTEC) approval



A U T E C

S E C R E T A R I A T

1 April 2014

Clare Hocking
Faculty of Health and Environmental Sciences

Dear Clare

Ethics Application: **14/75 Cluster randomised controlled trialof an indicated occupational therapy group intervention for children aged 11-13 years, designed to reduce symptoms of anxiwty and depression and improve self-esteem and participation.**

Thank you for submitting your application for ethical review. I am pleased to advise that the Chair of the Auckland University of Technology Ethics Committee (AUTEC) and I approved your ethics application, subject to the following condition:

1. Provision of the approval letter from North A Health and Disability Ethics Committee.

The Chair and the Executive Secretary wish to commend the researcher and yourself on the quality of the Information Sheet for the children.

Please provide me with a response to the points raised in these conditions, indicating either how you have satisfied these points or proposing an alternative approach. AUTEC also requires copies of any altered documents, such as Information Sheets,

surveys etc. Once your response is received and confirmed as satisfying the Committee's points, you will be notified of the full approval of your ethics application. Full approval is not effective until all the conditions have been met. Data collection may not commence until full approval has been confirmed. If these conditions are not met within six months, your application may be closed and a new application will be required if you wish to continue with this research.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

I look forward to hearing from you,

Yours sincerely

Kate O'Connor

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: Ema Tokolani etokolah@aut.ac.nz

Appendix 8: Participant information sheet/Consent form: For schools

Room AB114
Centre for Person-Centred Research
AUT University, Private Bag 92006
Auckland 1142, New Zealand
Telephone: 0800 KIA PIKI
0800 542 7454
Email: etokolahi@aut.ac.nz

Participant information sheet: For school principals

Kia Piki te Hauora

A wellbeing group for intermediate school students

Students, their parents and teachers from your school are invited to take part in a study of a wellbeing group for intermediate school students. School personnel will be asked to provide an appropriate venue for a group intervention to be held, recruit 10-12 students to participate, and have the teachers of those students complete a questionnaire about them on 3-5 occasions. Whether or not your school takes part is your choice. This Information Sheet will help you decide if you would like your school and students from your school to take part. Before you decide you may want to talk about the study with other people, such as other school personnel or the Board of Trustees. Feel free to do this. If you agree to take part in this study, please sign the Consent Form on the last page of this document (page 5) and return it to the lead researcher, Ema Tokolahi.

(1) What is the study about?
This study is investigating the benefits of a group-based programme that aims to support students to feel good about themselves and promote mental wellbeing in intermediate school students. There is currently little evidence for interventions of this sort. Completing research to evaluate school-based interventions for children is important for our children's future health and wellbeing.

Your school has been identified as providing education for students in Years 7 and 8. It is anticipated some Year 7 and 8 students may have a tendency to worry, have negative thoughts and/or they often do not feel good about themselves. The aim of the wellbeing group is to prevent a problem in these areas developing.

(2) Who is carrying out the study?
The wellbeing group was designed by Ema Tokolahi, NZROT, who is the Lead Investigator for this study. Ema is carrying out the study as part of her Doctoral Studies at Auckland University of Technology (AUT). This pilot study has received ethical approval from HDEC (Ref: 14/NTA/13) and the AUT Ethics Committee.

(3) What does the study involve?
The study requires 10-12 students to be recruited from each school involved, who assent to take part and whose parents consent to them taking part in the wellbeing group and the study. Information sheets will be provided (electronic and paper copies) to be sent home with children identified as potentially benefiting from the group. If requested I will present the

study to the Year 7 and 8 students at an appropriate forum. If a venue is provided I can also present to parents. This will be at the school's discretion. Additionally, I can also provide written information to include in a school newsletter, if applicable. A key contact between the school and the researcher will need to be identified to assist with organising these practicalities.

The wellbeing group involves brainstorming, relaxation, quizzes, learning skills and games. The group will be run on site at school, during school time. There needs to be an area for students to sit in a circle and a small area to move around freely (it is fine if this just requires chairs being moved to the edge of the room).

Students will initially be asked to complete a questionnaire to screen for eligibility to take part in the study. This can be done via post, the key contact at school or during class time and will be negotiated between the researcher (Ema) and the key contact. The school will then be randomly allocated to receive the wellbeing group in the next term or to go on a waiting list. IT IS IMPORTANT THAT STUDENTS AND PARENTS ARE NOT INFORMED OF THIS ALLOCATION UNTIL LATER.

One teacher for each participating student will be asked to complete a brief, one-page questionnaire in the first and last week of the next term. It is important to collect this information even if your school is on the waiting list. If your school is on the waiting list the wellbeing group will be offered the following term and one teacher for each participating student will again be asked to complete a brief, one-page questionnaire in the first and last week of that term. The teachers will be asked to complete the questionnaire one final time eight weeks after the group has finished. In total, the teacher will be asked to complete the questionnaire up to five times (maximum) per student. Teachers will be able to complete their questionnaire at their own convenience within a one-week period. This allows the researcher to track changes over time.

Parents and students will also be asked to complete questionnaires at the same time points. A research assistant will need a quiet room in which to complete the questionnaires with the students identified as study participants. After the initial round of questionnaires have been completed then students and parents can be informed whether the school has been allocated to having the group run in the next term or if it is on the waiting list for the group to run the following term.

(4) How much time will the study take?

The wellbeing group will involve students being out of their normal classes for one hour a week, over eight weeks. Completion of the student questionnaires in the first and last week of term will take up to 45 minutes (each time). These will be administered by a research assistant. Teacher questionnaires will take approximately 5 minutes per student.

(5) Can my school withdraw from the study?

If your school decides to no longer take part in the study it can withdraw at any point, although you will be encouraged to consider the timing of withdrawing to allow children to complete the programme if they have started it. This can be agreed in discussion with the lead researcher (Ema). You do not have to give a reason, and it will not affect your relationship with AUT.

(6) Will anyone else know the results?

Information collected about your school and students will have identifying details removed and be combined with information from other schools and students. It will be used to investigate the benefits of a wellbeing group for intermediate school students. Information will be kept confidential and stored securely at AUT for up to 10 years at which point it will be destroyed. Any reporting of this study will not include individual information that could identify your school or individual students. Reporting may include summaries of group information all together and the running of the group.

(7) Will the study benefit my school?

- Taking part in this study is consistent with the Health Promoting Schools philosophy.
- Teachers often have less time than they would like to commit to promoting student health and wellbeing, due to many other responsibilities. Finding evidence for school-based interventions to address student wellbeing will improve outcomes for students and potentially ease the pressure off teachers.
- Taking part in this study will support research into the wellbeing group so that its usefulness for other students in schools can be investigated.
- The wellbeing group has been designed to decrease worrying or negative thoughts, increase student's self-esteem and support them to take part in a range of activities typically expected of students their age. In turn, this is intended to support student participation in educational activities and therefore promoting educational achievements also.

(8) Are there any potential risks involved?

- Taking part in this study will require students to be away from their standard curriculum for one hour a week, over eight weeks.
- The wellbeing group will identify common challenges students face with their emotions, self-esteem and activities they take part in. For some students this may unexpectedly trigger a distress response. Ema will be available after each session to talk with any students who have become distressed in the course of the group, if needed.
- Some of the sessions involve physical activity. This will be of a similar nature to activities typically carried out in schools, thereby not expected to increase the physical risk to the students.

(9) What if something goes wrong?

If any student is injured while taking part in this study, which is unlikely, s/he would be eligible for compensation from ACC just as s/he would be if s/he were injured in an accident at school or at home.

(10) What are my school's rights?

- Taking part in this study is your choice. If your school does not want to take part, you do not have to give a reason, and it will not affect your relationship with AUT. If your school does want to take part now, but you change your mind later, you can pull out of the study at any time.
- Any reporting of this study will not include individual information that could identify your school or the students taking part.
- You will be informed of any adverse events that may impact on your school or students in the course of taking part in this study.

(11) What are the students' rights?

- If a student does not want to take part, they do not have to give a reason and it should not affect their input at school. If they decide to take part now, but change their mind later, they can pull out of the study at any time.

- The student and their parent/caregiver are able to access information collected about him/her as part of this study. The school will not be privy to this information without the explicit consent of the parent/caregiver.
- Information collected about the students will be kept strictly confidential. If any student responses are of concern, their parent/caregiver will be informed directly. Responses of concern would be if the student was rating their level of worries or negativity as significantly above the norm for their age group. If this were the case, the parent/caregiver has the choice to inform the school and/or to have their child referred on for additional assessment or support. Ema can assist with this process. Or they may decide no further action is required.

(12) Are there any costs to taking part in this study?
There is no cost to take part in this study. The cost of running the wellbeing group is covered by a Scholarship.

(13) What if I require further information?
The lead investigator, Ema Tokolahi, is available to answer any questions you may have about the project. Ema can be contacted at etokolah@aut.ac.nz or 0800 KIA PIKI/0800 542 7454. On completion of the study, you will be invited to access a one-page summary of the study findings: this study will occur over a 2.5 year period so the summary will not be available till late 2016.

(14) What if I have a complaint or concern?
If you have any questions, concerns or complaints about the study at any stage, you can contact Ema at etokolah@aut.ac.nz or 0800 KIA PIKI/0800 542 7454. Or you can contact her supervisors at AUT: Clare Hocking on (09)9219162 or clare.hocking@aut.co.nz and Paula Kersten on (09)9219180 or pkersten@aut.ac.nz.

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on 0800 555 050 or at advocacy@hdc.org.nz.

You can also contact the health and disability ethics committee (HDEC) that approved this study on 0800 4 ETHICS or at hdecs@moh.govt.nz.

Room AB114
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Consent form: For schools

A wellbeing group for intermediate school students

Please tick to indicate you consent to the following:

I have read and I understand the Participant Information Sheet.	Yes	No
I have been given sufficient time to consider whether or not to participate in this study.	Yes	No
I have had the opportunity to use a legal representative or other school personnel to help me ask questions and understand the study.	Yes	No
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes	No
I understand that my school taking part in this study is voluntary and my school may withdraw from the study at any time without this affecting our relationship with AUT.	Yes	No
I consent to the research staff collecting and processing student information, including information about their health, provided this is done with the consent of the parent/caregiver and child.	Yes	No
If my school decides to withdraw from the study, I agree that the information collected about students up to the point when my school withdraws may continue to be processed.	Yes	No
I understand parents/caregivers will be informed if any information collected about their child is of concern. If this is the case it is the parent/caregiver responsibility to choose what action is appropriate to take.	Yes	No
I understand that my school's participation in this study is confidential and that no material, which could identify my school or individual students, will be used in any reports of this study.	Yes	No
I know who to contact if I have any questions about the study in general.	Yes	No
I understand my school's responsibilities as a study participant.	Yes	No
I wish to receive a summary of the results from the study.	Yes	No

If you circled Yes to 'receive a summary of the results from the study', please provide your email address.

Email:

Declaration

I, _____(print your name and title), give consent for my school,

_____(print your school's name) to take part in this research.

Signature: Date:

Appendix 9: Participant information sheet/Consent form: For parents

Room AB114
Centre for Person-Centred Research
AUT University, Private Bag 92006
Auckland 1142, New Zealand
Telephone: 0800 KIA PIKI
0800 5427454
Email: etokolah@aut.ac.nz

Participant information sheet: For parents

Kia Piki te Hauora: A wellbeing group for intermediate school students

You and your child are invited to take part in the study of a wellbeing group for intermediate school students. This will involve you completing two questionnaires about your child and your child completing questionnaires about themselves and participating in a group during school time. Whether or not you and your child takes part is up to you and your child. This Information Sheet will help you decide if you would like to take part. Before you decide you may want to talk about the study with other people, such as family/whānau, friends, or teachers. Feel free to do this. If you agree to your child taking part in this study, please sign the Consent Form on the last page of this document (page 4) and return it to the nominated teacher at school. Please keep a copy of this Participant Information Sheet and the Consent Form for your records.

(1) What is the study about?
This study will investigate the benefits of a group for promoting emotional wellbeing in intermediate school students. There is currently little evidence for interventions of this sort. Completing research to evaluate school-based interventions for children is important for our children's future health and wellbeing.

(2) Who is carrying out the study?
The wellbeing group was designed by Ema Tokolahi, a registered occupational therapist, who is the Lead Investigator for this study. Ema is carrying out the study as part of her Doctoral Studies at Auckland University of Technology (AUT). This study has received ethical approval from HDEC (Ref: 14/NTA/13) and the AUT Ethics Committee.

(3) What does the study involve?
This study is investigating the benefits of a group-based programme that aims to support students to feel good about themselves. Students will develop skills to be more able to cope with strong emotions and to have more confidence in doing things they would normally do. Activities will include brainstorming, relaxation, quizzes, learning skills, and games. Your child is invited to take part in the wellbeing group with up to 10 other students from the same school. Your child has been chosen because they are in Years 7 or 8 and his/her teacher thought s/he would benefit.

Your child will be asked to complete an initial questionnaire to screen for eligibility to take part in the study. S/he will be randomly allocated to join the group in the next term or to go on a waiting list and join the group the following term. You may request feedback about your child's responses and general comments can be provided. If your child is not eligible to participate because their responses indicate a particularly high level of anxiety or depression symptoms you will be informed

and offered the option of a referral being made to a relevant service to access additional support. If your child's responses indicate there is a risk to him/her from him/herself, from others or to others, then you or another responsible adult (e.g. teacher, social worker) will be informed.

You will be asked to complete a short, one-page questionnaire at the start and end of the next term. It is important to collect this information even if your child is on the waiting list. If your child was on the waiting list you will be asked to complete the same questionnaire again at the start and end of the following term also. You will be asked to complete the questionnaire one final time about eight weeks after the group has finished. In total, you will be asked to complete the questionnaire up to five times (maximum). This allows the researcher to track changes over time.

In the first and last week of term your child will be asked to complete four short questionnaires and card sort. These ask about their thoughts, feelings and behaviours. It is important to collect this information even if your child is on the waiting list. If your child is on the waiting list they will be asked to complete the questionnaires again at the start and end of the following term, when they get to take part in the group. They will be asked to complete the questionnaires one final time about eight weeks after the group has finished. In total, your child will be asked to complete the questionnaires up to five times (maximum). This allows the researcher to track changes over time.

(4) How much time will the study take?
The wellbeing group will involve your child being out of their normal classes for one hour a week, over eight weeks. Completion of questionnaires in the first and last week of term will take up to 45 minutes (each time). These will be done with a research assistant and will happen during school time.

(5) Can my child withdraw from the study?
If you, or your child, change your mind about taking part in the study s/he can withdraw at any point. You do not have to give a reason, and it will not affect the input your child receives at school or your relationship with AUT.

(6) Will anyone else know the results?
Information collected about your child will have identifying details removed and be combined with information from other children. It will be used to investigate the benefits of a wellbeing group for intermediate school students. Information will be kept confidential and stored securely at AUT for up to 10 years at which point it will be destroyed. Any reporting of this study will not include individual information that could identify you or your child. Reporting may include summaries of group information all together and the running of the group.

(7) Will the study benefit my child?
Potential benefits
- The wellbeing group has been designed to decrease worrying or negative thoughts your child may experience. It is intended to increase children's self-esteem and support them to take part in a range of activities typically expected of children their age.
- The aim of the wellbeing group is to increase your child's ability to cope with strong emotions and to ask for help when needed. It normalizes that some distress is OK and s/he can cope.
- Taking part in this study will support research into the wellbeing group so that its usefulness for other students can be investigated.

(8) Are there any risks involved?
Potential risks
- Taking part in this study will require your child to be away from their standard curriculum for one hour a week, over eight weeks.

- The wellbeing group will identify common challenges children face with their emotions, self-esteem and activities they take part in. For some students this may unexpectedly trigger a distress response. Ema will be available after each session to talk with any children who have become distressed in the course of the group, if needed.
- Some of the sessions involve physical activity. This will be of a similar nature to activities typically carried out in schools, thereby not expected to increase the physical risk to your child.

(9) What if something goes wrong?
If your child were injured while taking part in this study, which is unlikely, s/he would be eligible for compensation from ACC. This is just as s/he would be if s/he were injured in an accident at school or at home. Your child will have to have a claim lodged by yourself with ACC, which may take some time to assess. If your child's claim is accepted, s/he will receive funding to assist in his/her recovery. If your child has private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect his/her cover.

(10) What are my child's rights?
- Taking part in this study is your choice. If you, or your child, do not want your child to take part, you do not have to give a reason, and it will not affect the input your child receives at school. If your child agrees to take part and you do not then your child will not be enrolled into the group. If your child does want to take part now, but changes his/her mind later, your child can pull out of the study at any time.
- You and your child are able to access information collected about him/her as part of this study.
- Information collected about your child will be kept strictly confidential. If your child's responses are of concern, you will be informed directly. Responses of concern would be if your child rates their level of worries or negativity as significantly above the norm for their age group. If this were the case, you may choose to have your child referred on for additional assessment or support and Ema can assist with this process. Or you may decide no further action is required.
- Any reporting of this study will not include individual information that could identify you or your child.
- You will be informed of any adverse events that may impact on your child in the course of taking part in this study.

(11) Are there any costs to my child taking part in this study?
There is no cost to take part in this study. The cost of running the wellbeing group is covered by a Scholarship.

(12) What if I require further information?
The lead investigator, Ema Tokolahi, is available to answer any questions you may have about the project. Ema can be contacted at etokolah@aut.ac.nz or 0800 542 7454. On completion of the study, those taking part will be invited to access a one-page summary of the study findings, if they are interested: this study will occur over a 2.5 year period so the summary will not be available till late 2016.

(13) What if I have a complaint or concern?
If you have any questions, concerns or complaints about the study at any stage, you can contact Ema at etokolah@aut.ac.nz or 0800 542 7454. Or you can contact her supervisors at AUT: Clare Hocking on (09)9219162 or clare.hocking@aut.co.nz and Paula Kersten on (09)9219160 or pkersten@aut.ac.nz.

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on 0800 555 050 or at advocacy@hdc.org.nz.

You can also contact the health and disability ethics committee (HDEC) that approved this study on 0800 4 ETHICS or at hdecs@moh.govt.nz.

AUT

Consent form: For parents

A wellbeing group for intermediate school students

Please tick to indicate you consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes	No
I have been given sufficient time to consider whether or not to participate in this study.	Yes	No
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	Yes	No
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes	No
I understand that my child taking part in this study is voluntary (the choice of me and my child) and that my child may withdraw from the study at any time without this affecting their input at school.	Yes	No
I consent to the research staff collecting and processing my child's information, including information about his/her health, provided this is done with the assent of my child.	Yes	No
If I, or my child, decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes	No
I understand I will be informed if any information collected about my child is of concern and that if this is the case it is my responsibility to choose what action is appropriate to take.	Yes	No
I understand that my child's participation in this study is confidential and that no material, which could identify me or my child personally, will be used in any reports on this study.	Yes	No
I know who to contact if I have any questions about the study in general.	Yes	No
I understand mine and my child's responsibilities as a study participant.	Yes	No
I wish to receive a summary of the results from the study.	Yes	No

Please write your contact details below (for preferred method of contact) so we can contact you if needed regarding your child's participation in the study.

Phone number:

Email/Address:

Parent declaration

I, _____(print your name), give consent for my child,

_____ (print your child's name) to take part in this research.

Signature: Date:

☐ Please tick this box if you are OK to be contacted about further research related to Kia Piki te Hauora. Whether or not you tick this box it will not affect your rights as described above.

Appendix 10: Participant information sheet/Assent form: For children

Room AB114
Centre for Person-Centred Research
AUT University, Private Bag 92006
Auckland 1142, New Zealand
Telephone: 0800 KIA PIKI
0800 5427454
Email: etokolah@aut.ac.nz

Participant information sheet: For students

Kia Piki te Hauora: A wellbeing group for intermediate school students

You are invited to take part in a study of a well-being group. This will involve completing some questionnaires and taking part in an 8 week group for 1 hour a week, over a term. Whether or not you take part is your choice. This sheet gives you information to help you decide if you would like to take part. You can ask questions about the study at any time. You do not have to decide today if you will take part or not. You may like to talk it over with your family or whānau first. Your parents have also been given an information sheet similar to this and they must agree to you taking part too. If either of you do not agree to taking part you will not be enrolled into the study. If you do agree to take part in this study, please sign the Assent Form on the last page and hand it to the person who has talked you through this information.

(1) What is the study about?
This study will investigate the benefits of a group for promoting emotional wellbeing in intermediate school students. There is currently little evidence for groups of this sort. Completing research to evaluate school-based wellbeing groups for children is important. We need to know what works and what does not work.

(2) Who is carrying out the study?
The person running the group and this study is Ema Tokolahi. This study has received ethical approval. This means people have checked I am not planning to lie to you or do anything that might hurt you.

(3) What does the study involve?
This study is investigating the benefits of a group-based programme that aims to support students to feel good about themselves. Students will develop skills to be more able to cope with strong emotions and to have more confidence in doing things they would normally do. Activities will include brainstorming, relaxation, quizzes, learning skills, and games. You have been chosen because you are in Year 7 or 8 at your school. Your teacher thought you might find the group useful or interesting. Up to 10 other students from your school have also been invited. It does not mean your teacher thinks you have a problem. It is not that sort of group. It is the sort of group that might stop you having a problem later on.

Firstly, you will be asked to complete a questionnaire to check it is OK for you to take part. Then it will be decided if you will take part in the group in the next term or if you will wait until the term after before you take part in the group. You will be asked to complete four short questionnaires and a card sort in the first and last week of next term. Questions are about your thoughts, feelings and actions. It is important to collect this information even if you are on the waiting list. If you are on the waiting list, you will get to take part in the group the following term. Then you will be asked to complete the same questionnaires in the first and last week of that term too. You will be asked to complete the questionnaires one last time about eight weeks after the group has finished. This allows the researcher

to check for changes over time. Your parents may ask for feedback about your responses and general comments can be provided. If your responses indicate there is a risk to you from yourself, from others or to others, then a parent/caregiver or other responsible adult (e.g. teacher, social worker) will need to be informed. If this is the case, you will be told before this happens.

(4) How much time will the study take?
The group will involve you being out of your normal classes for one hour a week, for eight weeks. In the first week and last week of term you will also be asked to spend up to 45 minutes (each time) with a research assistant to complete the questionnaires.

(5) Can I withdraw from the study?
If you change your mind about taking part in the study you can stop at any point. You do not have to give a reason, and it will not affect you at school.

(6) Will anyone else know the results?
I am going to tell people about this study in general. At no point will I tell them anything that will mean they know that you took part. Nor will they be able to find out your individual responses. The rules set by the government say I have to keep your information for a long time. It will be kept private, safe and secure. After 10 years it will be destroyed.

(7) What are some of the good things about taking part?
- Taking part in the group might help you learn skills to feel good about yourself. You may learn to cope with strong emotions better. Hopefully you will feel more confident about the everyday things you normally do.
- You might find it interesting to hear about other students experiences. You will hear how they cope and feel good about themselves.
- Taking part in this study will help me investigate the wellbeing group. Then I can find out how useful the group is for lots of students, like you.

(8) Are there any not-so-good things about taking part?
- Taking part in this study will require being away from your normal classes for one hour a week, for eight weeks.
- Sometimes talking about emotions or thoughts can be a little embarrassing or upsetting. No one is expected to share anything about themselves they do not want to. If you do feel upset after a group, I (Ema) will be around to talk it over.
- Some of the sessions involve moving around. No more than you would move around in some other classes though. If you do not feel you can do any of the activities, you do not have to.

(9) What are my rights?
- Taking part in this study is your choice. If you do not want to take part, you do not have to give a reason, and it will not affect you at school. If you do want to take part now, but change your mind later, you can pull out of the study at any time.
- You and your parents/caregivers are able to access information collected about you as part of this study.
- All information collected about you will be kept strictly confidential (private) and is not shared with the school. If I am worried about any of your responses I will have a quick talk with your parents/caregivers. If that is going to happen I will let you know first!

(10) Is there a cost?
No – it is free!

(11) What if I have a concern or want to know more?
If you have any questions, concerns or complaints about the study, you can contact Ema at etokolah@aut.ac.nz or 0800 542 7454. Or you can talk to your teacher or parent/caregiver and ask them to do so.

Room AB114
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School of Rehabilitation & Occupation Studies
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Auckland 1142, New Zealand
Telephone: 0800 KIA PIKI
0800 5427454
Email: etokoiah@aut.ac.nz

Assent form: For students

A well-being group for intermediate school students

Please tick to indicate you consent to the following:

I have read and I understand the Participant Information Sheet.	Yes	No
I have been given enough time to consider whether or not to take part in this study.	Yes	No
I have had the opportunity to get help to ask questions so I can understand the study.	Yes	No
I have a copy of this assent form and information sheet.	Yes	No
I understand taking part in this study is voluntary (my choice) and that I can withdraw from the study at any time without this affecting me at school.	Yes	No
I agree to the research staff collecting and processing my information, provided this is done with the consent of my parent/caregiver.	Yes	No
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes	No
I understand my parent/caregiver can request feedback about my responses on questionnaires and that they will be informed if any information collected about me indicates there is a risk of harm. If this is going to happen I will be told first.	Yes	No
I understand that my information will be kept confidential and that any sharing of information about the study will not identify me personally.	Yes	No
I know who to contact if I have any questions about the study in general.	Yes	No
I understand what is expected of me taking part in this study.	Yes	No
I agree not to share information about other people that I find out as a result of taking part in this study	Yes	No

Declaration

I, _____(print your name), agree to take part in this research.

Signature: Date:

☐ Please tick this box if you are OK to be contacted about further research related to Kia Piki te Hauora. Whether or not you tick this box it will not affect your rights as described above.

Appendix 11: Recruitment adverts

Thank you for your Education Gazette notice submission Research x

no-reply@confirmations.edgazette.govt.nz 2/17/14
to me

Hello Ema Tokolahi

Thank you for submitting your notice to *Education Gazette*.
Here is a preview of the text you have submitted. All notices may be subject to editing.

Notice number: 616086

Wellbeing group for Intermediate school students - invitation to Auckland schools to participate

FREE wellbeing group intervention for intermediate school students in the Auckland region. Available to 14 mainstream schools providing education to Years 7&8, who would like to participate in research investigating the benefits of the wellbeing intervention. Schools from a range of deciles required. Please contact Ema Tokolahi at AUT on 02102315654 or ematokolahi@gmail.com for more information.

We are checking your notice and will publish it as soon as we can.

Regards
Education Gazette
www.edgazette.govt.nz

Appendix 12:Statistical testing to evaluate representativeness of the sample against the population (Stat Trek, 2016)

Gender

Data:

Populations/Observations	**Males (1)**	**Females (2)**	**Totals**
Population (1)	3335	3190	6525
Sample (2)	65	77	142
Totals	3400	3267	6667

Null hypothesis:

The proportion of females in the population is identical to the proportion of girls in the sample.

H0 = $N_{females}$ in population = $N_{females}$ in sample

Alternative hypothesis:

The distribution of females differs between the populations.

Analysis plan:

Chi-square test for homogeneity with the significance level set at 0.05.

Analysis:

Degrees of freedom (DF): is equal to:

DF = (r - 1) * (c - 1)

where r is the number of populations, and c is the number of levels for the categorical variable. For the current study this translates to r=2 and c=2, which is equal to:

DF = (2-1)*(2-1) = 1

Expected frequency counts: are calculated separately for each population, at each level of the categorical variable as:

$E_{r,c} = (n_r * n_c) / n$

where $E_{r,c}$ is the expected frequency count for population r at level c of the categorical variable, n_r is the total number of observations from population r, n_c is the total number

of observations at treatment level c, and n is the total sample size. For the current study this translates to:

$E_{1,1}$ = (6525*3400)/6667 = 3327.58

$E_{1,2}$ = (6525*3267)/6667 = 3197.42

$E_{2,1}$ = (142*3400)/6667 = 72.42

$E_{2,2}$ = (142*3267)/6667 = 69.58

Test statistic: the chi-square random variable (X^2) defined as:

$X^2 = \Sigma [(O_{r,c} - E_{r,c})^2 / E_{r,c}]$

where $O_{r,c}$ is the observed frequency count in population r for level c of the categorical variable, and $E_{r,c}$ is the expected frequency count in population r for level c of the categorical variable. For the current study this translates to:

$X^2 = \Sigma [(3335-3327.58)^2 /3327.58 = 0.0165] + [(3190-3197.42)^2/3197.42 = 0.0172] + [(65-72.42)^2/72.42 = 0.7602] + [(77-69.58)^2/65.58 = 0.8395]$

$X^2 = 1.6334$

Interpretation:

Using a chi-square distribution calculator (Stat Trek, 2016) the *p* value was calculated as 0.8, which is above the predetermined significance level of 0.5. Therefore, we cannot reject the null hypothesis and can conclude the gender distribution in the sample was not significantly different to that in the population as a whole.

Ethnicity

Data

Populations/Observations	**Maori (1)**	**Pacific (2)**	**Asian (3)**	**NZE (4)**	**Other (5)**	**Totals**
Population (1)	6525	9107	7273	17606	1495	42006
Sample (2)	27	30	17	58	33	165
Totals	6552	9137	7290	17664	1528	42171

Null hypothesis:

The proportion of each of the ethnic groups is identical to the proportion of each of the ethnic groups in the sample.

H0 = $N_{females}$ in population = $N_{females}$ in sample

$H0 = N_{Maori}$ in population = N_{Maori} in sample

$H0 = N_{Pacific}$ in population = $N_{Pacific}$ in sample

$H0 = N_{Asian}$ in population = N_{Asian} in sample

$H0 = N_{NZE}$ in population = N_{NZE} in sample

$H0 = N_{Other}$ in population = N_{Other} in sample

Alternative hypothesis:

The distribution of at least one ethnicity differs between the populations.

Analysis plan:

Chi-square test for homogeneity with the significance level set at 0.05.

Analysis:

Degrees of freedom (DF) is equal to:

$DF = (r - 1) * (c - 1)$

where r is the number of populations, and c is the number of levels for the categorical variable. For the current study this translates to r=2 and c=5, which is equal to:

$DF = (2-1)*(5-1) = 4$

Expected frequency counts: are calculated separately for each population, at each level of the categorical variable as:

$E_{r,c} = (n_r * n_c) / n$

where $E_{r,c}$ is the expected frequency count for population r at level c of the categorical variable, n_r is the total number of observations from population r, n_c is the total number of observations at treatment level c, and n is the total sample size. For the current study this translates to:

$E_{1,1} = (42006*6552)/42171 = 6526.36$

$E_{1,2} = (42006*9137)/42171 = 9101.25$

$E_{1,3} = (42006*7290)/42171 = 7261.48$

$E_{1,4} = (42006*17664)/42171 = 17594.89$

$E_{1,5} = (42006*1528)/42171 = 1522.02$

$E_{2,1} = (165*6552)/42171 = 25.64$

$E_{2,2}$ = (165*9137)/42171 =35.75

$E_{2,3}$ = (165*7290)/42171 =28.52

$E_{2,4}$ = (165*17664)/42171 =69.11

$E_{2,5}$ = (165*1528)/42171 =5.98

Test statistic: the chi-square random variable (X^2) defined as:

$X^2 = \Sigma [(O_{r,c} - E_{r,c})^2 / E_{r,c}]$

where $O_{r,c}$ is the observed frequency count in population r for level c of the categorical variable, and $E_{r,c}$ is the expected frequency count in population r for level c of the categorical variable. For the current study this translates to:

$X^2 = \Sigma [(6525-6526.36)^2/6526.36 = 0.0002] + [(9107-9101.25)^2/9101.25 = 0.0036] + [(7273-7261.48)^{2/}7261.48 = 0.0183] + [(17606-17594.89)^{2/}17594.89 = 0.0070] + [(1495-1522.02)^2/1522.02 = 0.4797] + [(27-25.64)^2/25.64 = 0.0721] + [(30-35.75)^2/35.75 = 0.9248] + [(17-28.52)^2/28.52 = 4.6532] + [(58-69.11)^2/69.11 = 1.7860] + [(33-5.98)^2/5.98 = 122.0870]$

$X^2 = 130.8149$

Interpretation

Using a chi-square distribution calculator (Stat Trek, 2016) the *p* value was calculated as 1, which is above the predetermined significance level of 0.5. Therefore, we cannot reject the null hypothesis and can conclude the gender distribution in the sample was not significantly different to that in the population as a whole.

Appendix 13: Front pages of three articles published from the current study to date

Tokolahi *et al. BMC Psychology* 2014, 2:16
http://www.biomedcentral.com/2050-7283/2/16

BMC Psychology

STUDY PROTOCOL Open Access

Cluster-randomised controlled trial of an occupational therapy group intervention for children designed to promote emotional wellbeing: study protocol

Ema Tokolahi[1*], Clare Hocking[2], Paula Kersten[2] and Alain C Vandal[3,4]

Abstract

Background: Symptoms of anxiety and depression are common in childhood, as are risk factors that undermine wellbeing: low self-esteem and limited participation in daily occupations. Current treatments focus primarily on modifying internal cognitions with insufficient effect on functional outcomes. Occupational therapists have a role in measuring and enabling children's functional abilities to promote health and wellbeing. To-date there is no evidence for the use of occupational therapy as an intervention to promote mental health or increase self-esteem, participation and wellbeing in a preventative context. The aim of this cluster-randomised controlled study is to investigate the effectiveness of an 8-week occupational therapy group intervention (Kia Piki te Hauora) at reducing symptoms of anxiety and depression and improving self-esteem, participation and wellbeing in children aged 11–13 years.

Methods/design: In this two-arm, pragmatic, cluster-randomised controlled trial, 154 children will be recruited from 14 schools. All mainstream schools in the region will be eligible and a convenience sample of 14 schools, stratified by decile ranking (i.e. low, medium, and high) will be recruited. Eight to twelve students aged 11–13 years from each school will be recruited by senior school personnel. Following consent, schools will be randomised to either the intervention or waitlist control arm of the trial. The study will employ a parallel and one-way waitlist-to-intervention crossover design. Each cluster's involvement will last up to 19 or 31 weeks depending on allocation to the intervention or waitlist respectively. The primary outcome is symptoms of anxiety and secondary outcomes are: symptoms of depression, self-esteem, participation in daily occupations and wellbeing. Outcome measurement will be repeated at baseline, post-intervention and again at 8–9 weeks follow-up. Planned statistical analyses will utilise repeated measures analysis of covariance. The primary analysis will be based on an intention-to-treat analysis set and include only parallel data. The crossover data will only be used in secondary analyses.

Discussion: This is the first cluster-randomised controlled trial to investigate an occupational therapy intervention promoting emotional wellbeing in a non-clinical sample of children. Results will contribute to the limited evidence base for occupational therapists in this field and potentially support investment in these services.

Trial registration: Australia/New Zealand Clinical Trials Register: ACTRN12614000453684.

Keywords: Occupational therapy, Health promotion, Anxiety, Depression, Self-esteem, Participation, Wellbeing, Children, Schools

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Article

Quality and Reporting of Cluster Randomized Controlled Trials Evaluating Occupational Therapy Interventions: A Systematic Review

OTJR: Occupation, Participation and Health
2016, Vol. 36(1) 14–24

DOI: 10.1177/1539449215618625
otj.sagepub.com
SAGE

Ema Tokolahi[1], Clare Hocking[1], Paula Kersten[1], and Alain C. Vandal[1,2]

Abstract

Growing use of cluster randomized control trials (RCTs) in health care research requires careful attention to study designs, with implications for the development of an evidence base for practice. The objective of this study is to investigate the characteristics, quality, and reporting of cluster RCTs evaluating occupational therapy interventions to inform future research design. An extensive search of cluster RCTs evaluating occupational therapy was conducted in several databases. Fourteen studies met our inclusion criteria; four were protocols. Eleven (79%) justified the use of a cluster RCT and accounted for clustering in the sample size and analysis. All full studies reported the number of clusters randomized, and five reported intercluster correlation coefficients (50%). Protocols had higher compliance. Risk of bias was most evident in unblinding of participants. Statistician involvement was associated with improved trial quality and reporting. Quality of cluster RCTs of occupational therapy interventions is comparable with those from other areas of health research and needs improvement.

Keywords

cluster randomized controlled trials, methods, occupational therapy, research design, systematic review

Background

There is growing use of cluster randomized control trials (RCTs) in health care research, with systematic reviews of cluster RCTs emerging over recent decades as the methodology gained credibility and prominence (Diaz-Ordaz, Froud, Sheehan, & Eldridge, 2013; Eldridge & Kerry, 2012; Isaakidis & Ioannidis, 2003). No one has reviewed the quality and reporting of cluster RCTs within occupational therapy, although methodological evaluations of occupational therapy RCTs have been published (Bennett, Hoffmann, McCluskey, Coghlan, & Tooth, 2013; Bennett et al., 2007; Kim, Yoo, Jung, Park, & Park, 2012; Moberg-Mogren & Nelson, 2006; Norton-Mabus & Nelson, 2008). It is important to evaluate the quality of current studies to ensure robust research of this kind is being conducted within the occupational therapy profession, to identify the unique challenges and opportunities created by the evaluation of occupational therapy interventions using this design and to inform future research design.

Cluster RCT Design

Cluster RCTs are defined as having "groups or clusters of individuals rather than individuals themselves . . . randomized to intervention arms" (Eldridge & Kerry, 2012, p. 3). There are several pragmatic reasons for selecting this design. In interventions or population studies, randomizing by cluster can limit the potential for contamination between study arms. For example, if someone in a helper role was given additional training, it would be impractical to randomly allocate their clients to receive or not receive the benefits of that training as the new information cannot be "unlearned"; this scenario would also be ethically questionable (Barbui & Cipriani, 2011). Researchers may be interested in outcomes at the cluster level (i.e., focus on change within and between clusters), the individual level (i.e., focus on change within and between individuals), or both (Eldridge & Kerry, 2012). Furthermore, there are convenience and cost benefits to investigating an intervention in clusters (Isaakidis & Ioannidis, 2003).

Cluster designs have several implications for sample size calculations and data analysis. The individuals within clusters are likely to be more homogeneous than those from a

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Routledge
Taylor & Francis Group

Development and Content of a School-Based Occupational Therapy Intervention for Promoting Emotional Well-Being in Children

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ABSTRACT

The development and content of an occupational therapy intervention promoting emotional well-being, for children with subclinical anxiety, is described. Development and trialing followed a four-step process: (1) reviewing theory, (2) reviewing evidence, (3) incorporating expert opinion, and (4) trialing. The intervention consists of eight group sessions, led by an occupational therapist, over 8 weeks of an academic term. Its proposed outcomes will be achieved by providing children with knowledge about health promoting occupations and how to participate in, balance, and sustain these. This article offers a guideline for the development and description of similar interventions to facilitate more robust evaluation of clinical practice.

KEYWORDS

Health promotion; mental health; occupational therapy; school-based; well-being

Introduction

Anxiety disorders in childhood and adolescence are common, with studies from Australasia, Europe, and North America indicating a period prevalence between 5% and 31% of whom only 10% fulfill criteria for a mental health disorder (Essau & Gabbidon, 2013; Weare & Nind, 2011). Anxiety symptoms include excessive levels of unhelpful internal cognitions that impact on the individual's participation in educational, social, and family occupations and are associated with increased rates of anxiety and depression in early adulthood (Cresswell, Waite, & Cooper, 2014). Subsequently, the burden of anxiety conditions on public health is significant, yet despite this many children remain untreated due to stigma associated with mental health interventions, lack of knowledge about mental health disorders and treatment options, and a reluctance to seek support (Yearwood & DeLeon Siantz, 2010). This highlights the need for preventative and early interventions in this population, with schools offering a convenient and feasible location for the widespread delivery of preventative and targeted interventions to children (Essau & Gabbidon, 2013; Stallard & Buck, 2013).

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