The Effectiveness, Acceptability and Practicality of a CBT-Sensory Modulation Intervention for Children 4-7 Years Old Presenting with Anxiety

A thesis written in partial fulfilment of the requirements of the Doctor of Health Sciences degree at the Auckland University of Technology, Auckland, New Zealand.

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Abstract

Background

Childhood anxiety is associated with long-term consequences, including the development of mood disorders and functional challenges, if not treated early. However, literature shows that young children do not receive timely interventions due to long waiting lists, a shortage of psychologists, and an inability to complete interventions that are between 9 and 20 sessions, due to their parents' competing commitments. Cognitive Behavioural Therapy (CBT) is the main non-pharmacological intervention used for the treatment of anxiety. CBT is a talking-based therapy which helps people explore and manage unhelpful thoughts to reduce distressing emotions or problematic behaviours. While often recommended, CBT alone may not be effective in treating childhood anxiety and is not always developmentally appropriate for younger children. Sensory modulation is a clinical intervention that uses sensory-based strategies to help with emotion regulation and can be adapted for young children. To address a gap in early intervention for younger children with anxiety, a modified CBT plus sensory modulation intervention was developed, which could potentially be delivered by a wide range of clinicians.

Study Design

The current study tested the effectiveness, acceptability, and practicality of a 6-session modified CBT plus sensory modulation anxiety intervention developed for children aged 4 to 7 years old presenting with anxiety. The study used a multiple baseline single case experimental design. Six children with clinically significant anxiety were admitted to the study. Four therapists delivered the intervention with the children and their mothers (n=6) at a Child, Adolescent, and Family Service and a Child and Family Care Trust. The six children received the intervention during the study phase, where the intervention was delivered in a staggered fashion. Data, including the levels of each child's anxiety and functioning, were collected at multiple baseline points, then during and post-intervention and 1-month follow-up. Visual and statistical analyses of data were completed to determine the effectiveness of the intervention. Subjective feedback from the mothers and therapists were also collected. Content analysis was used to analyse the subjective feedback to determine the acceptability and practicality of the intervention.

Results

Quantitative findings and visual analysis of data provided evidence supporting the effectiveness of the intervention in treating childhood anxiety. Subjective feedback data showed that the intervention was received as an acceptable and practicable intervention for

younger children with anxiety. One month post-intervention data showed that gains were maintained, with four children not meeting the threshold for a primary diagnosis of anxiety with which they were diagnosed upon entering the study.

Implications

This study was the first to combine CBT and sensory modulation for younger children presenting with anxiety. The study findings provide preliminary evidence that the intervention was effective, acceptable, and practicable. However, larger randomised clinical trials are required to confirm the effectiveness of the intervention. The results contribute to the further understanding of how to develop age-appropriate interventions for the management of childhood anxiety, including the use of sensory-based strategies for younger children. The manualised intervention has the potential to help address childhood anxiety by providing non-psychology professionals, with a framework for supporting younger children early.

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Attestation of Authorship

I hereby declare that this submission is my 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: Tafadzwa Mavhunga

Date: 1 April 2024

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Ethical Approval acknowledgement

This study was approved by the Health and Disability Ethical Committees (HDECs) on December 15, 2020 (study number 20NTA165), and by Auckland University of Technology Ethics Committee (AUTEC) in March 2021. Local ethics approval was granted by the Hawkes Bay Hospital Clinical Trials Committee on April 4, 2022.

Intellectual Property Rights

I hereby assert my rights to the intellectual property associated with the Ngā Timatanga Toa © intervention and the copyright to the illustrations used in association.

Signature: Tafadzwa Mavhunga

Date: 1 April 2024

List of Abbreviations

AACAP	American Academy of Child and Adolescent Psychiatry
ACT	Acceptance and Commitment Therapy
ADHD	Attention Deficit Hyperactivity Disorder
ASD	Autism Spectrum Disorder
ASEBA	Achenbach System of Empirically Based Assessment
BLA	Baseline Average
BTD	Behaviour Tracking Diary
CALIS	Child Anxiety Life Interference Scale
CALIS-C	Child Anxiety Life Interference Scale Child form
CALIS-P	Child Anxiety Life Interference Scale Parent form
CALIS-PV	Child Anxiety Life Interference Scale Pre School Version
CAMHS	Child and Adolescent Mental Health Services
CBCL	Child Behaviour Checklist
CBT	Cognitive Behavioural Therapy
CORS	Child Outcome Rating Scale
CSRS	Child Session Rating Scale
DBT	Dialectical Behaviour Therapy
DHB	District Health Board
DSM 5	Diagnostic and Statistical Manual of Mental Disorders, 5th edition
ES	Effect Size
FTE	Full Time Equivalent
FU	Follow-up
GAD	Generalised Anxiety Disorder
ICAMHS	Infant, Child, and Adolescent Mental Health Services
MI	Mid Intervention
NCCIH	National Center for Complementary and Integrative Health
NESP	New Entry to Specialist Practice
NGO	Non-Government Organisation
NZ	New Zealand
OCD	Obsessive Compulsive Disorder
ODD	Oppositional Defiance Disorder
ORS	Outcome Rating Scale
PHO	Primary Health Organisation
PI	Post Intervention
PISCF	Participant Information Sheet and the Consent Form

PSQ	Parents' Satisfaction Questionnaire
PTSD	Post Traumatic Stress Disorder
RCT	Randomised Control Trial
SAD	Separation Anxiety Disorder
SAS-TR	School Anxiety Scale - Teacher Report
SCARED	Screen for Child Anxiety and Related Emotional Disorders
SCAS	Spence Children's Anxiety Scale
SCED	Single-Case Experimental Design
SMART	Sensory Motor Arousal Regulation Therapy
SNRI	Serotonin-Norepinephrine Reuptake Inhibitor
SRS	Session Rating Scale
SSRI	Selective Serotonin Reuptake Inhibitor
TBRI	Trust-Based Relational Intervention
TRF	Teacher Report Form
TSQ	Therapist Satisfaction Questionnaire
YCORS	Young Child Outcome Rating Scale
YCSRS	Young Child Session Rating Scale

Chapter 1:

Introduction

This thesis presents research completed as part of the Doctor of Health Science programme at Auckland University of Technology, New Zealand (NZ). The research investigated the effectiveness, acceptability, and practicality of a novel intervention for young children experiencing clinically significant anxiety. The intervention was a manualised 6-session programme based on Cognitive Behavioural Therapy (CBT) and sensory modulation principles. The study used a single-case multiple baseline experimental design methodology, with qualitative feedback from parents and therapists. This first chapter briefly introduces the thesis and the study presented within it. Why and how the study was conducted, the aim, and the context are all briefly outlined. Justification for the study is provided, and the chapter concludes with an outline of how the thesis is structured.

The Study Aim

The aim of the current study was to evaluate the effectiveness, acceptability, and practicality of a 6-session CBT-sensory modulation intervention delivered to young children (4- to 7-years), presenting with clinically significant anxiety. The manualised intervention (Ngā Timatanga Toa- see Appendix A) was developed by combining simple CBT and sensory modulation strategies. It was designed to be delivered to children and their parent(s) across six sessions. Four mental health clinicians were trained to deliver the intervention with the study participants. The overall intent of the intervention was to provide strategies for children and their parent(s) to reduce anxiety symptoms and the extent to which these interfere with daily life. The study also aimed to understand if this intervention was acceptable to the parents, children, and therapists; and if it was practical to be delivered in NZ child and adolescent mental health settings.

Childhood Anxiety and Limitations in Current Service Delivery

Childhood anxiety refers to anxious presentations in young children characterised by excessive worry and fear that significantly affect their functioning, independence and overall wellbeing (American Psychiatric Association, 2013). Anxiety is a normal automatic and adaptive response to perceived threats or in anticipation of feared situations (Chand & Marwaha, 2023; Quek et al., 2019; Ströhle et al., 2018). However, when anxiety persists, causes distress and affects daily functioning it becomes clinically significant, with the potential to lead to an anxiety disorder (American Psychiatric Association, 2013). Anxiety disorders are some of the most commonly experienced mental health conditions diagnosed in children, often

manifesting in excessive worry, somatic issues, such as stomach aches, fear of separation from caregivers and avoidance of anxiety-provoking situations (Venta et al., 2021). Anxiety disorders that begin in childhood often have serious long-term consequences if left untreated, including further mental health and addiction issues, and disrupted social and occupational functioning (Catania et al., 2011; Cobham et al., 2017; Freidl et al., 2017; Grieshaber et al., 2023; Mutluer et al., 2022; Swan et al., 2018). In NZ, the prevalence of anxiety is 3.9% for children aged 2 to 14 years of age (Ministry of Health, 2020). One in five children will be diagnosed with anxiety by 19 years of age (Mental Health Foundation, 2014). International data show similar patterns, with 6.9% of children under eighteen years in Australia experiencing anxiety (Australian Institute of Health and Welfare, 2020; Danchin et al., 2019; Sicouri et al., 2022), and 9.4% of American children aged between 3 and 17 years diagnosed with an anxiety disorder (Centre for Disease Control, 2022; Lebrun-Harris et al., 2022).

Despite the prevalence and long-term consequences of childhood anxiety disorders, there are issues with the timely provision of effective treatments. While evidence-based psychological therapies to help children and young people with anxiety exist, many young children are not able to access these treatments (Creswell et al., 2014; Green et al., 2012; Meringakas et al., 2010; Mutluer et al., 2022; Reardon et al., 2018). This is due to several barriers such as a shortage of suitably trained professionals, including psychologists, and long waiting times (Abrams, 2023; Bringewatt & Gershoff, 2010; O'Brien et al., 2016; Rucklidge et al., 2018; The NZ Psychological Society, NZ College of Clinical Psychologists and NZ Psychologists Board, 2023). In response to increasing mental health issues in children and issues with access to treatment, the wellbeing of children and young people is being given increased attention in NZ (The Werry Workforce: Whāraurau, 2021). This has led to the rollout of service improvement activities to increase access to mental health services for children, young people, and their families. The present study aligns with the ambition of the NZ Government's vision for mental health services, 'Kia Manawanui Aotearoa' (Ministry of Health, 2021). A key element of the vision is to grow and support new and existing mental healthcare professionals and transform how mental health services are accessed and delivered in NZ (The Werry Workforce: Whāraurau, 2021).

Intervention Approaches Used in this Study

Cognitive Behavioural Therapy (CBT) is a talking-based therapy in which individuals are supported to identify maladaptive beliefs, thoughts, and behaviours, and replace them with more adaptive ones, resulting in greater coping skills and improved functioning (Gatchel & Rollings, 2008; Hofmann et al., 2012). CBT is the non-pharmaceutical treatment of choice for childhood anxiety, but like other psychological treatments, it can be difficult to access in a

timely manner (Babatunde et al., 2019; Comer & Barlow, 2014; Hansen et al., 2021; O'Brien et al., 2016). Although CBT is the most evidence-based approach for treating anxiety, most of the relevant research does not include studies undertaken with children under 7 years of age (Creswell et al., 2014; Rapee et al., 2023). Additionally, younger children may not have adequate cognitive abilities to engage in full CBT (Cobham et al., 2017; Halder & Mahato, 2019). This highlights a gap in the literature on published interventions or approaches for children under 7-years living with anxiety. Hence, there is a need to adapt the use of CBT for younger children and develop and evaluate other age-appropriate interventions.

In the present study, CBT techniques were combined with sensory modulation strategies, with the aim of better meeting the needs of young children with anxiety. Sensory modulation refers to the regulation of sensory input from one's environment and body, including visual, auditory, olfactory, gustatory, proprioceptive, vestibular and interoceptive input (Brown et al., 2019). The processing and regulation of stimuli occurs neurologically within the central nervous system, as well as through behavioural responses, such as seeking or avoiding specific sensations (Brown et al., 2019). Sensory modulation intervention was developed within occupational therapy practice and is a relatively new approach within mental health services, with an emerging evidence base (Craswell et. al., 2020). The intervention emphasises the use of sensory-based strategies to manage emotions via the autonomic nervous system by dampening or arousing the neurological system (Moore, 2005; Moore, 2016). It utilises the application of one or more sensory modalities such as deep pressure, massage, rocking, aromatherapy items, music, stress balls, fidget items, calming audio sounds, or visual images (Champagne, 2006; Lloyd et al., 2014; Moore, 2016). This sensory-based approach is practical, with limited cognitive demand and can be easily adapted for use by young children (Miller, 2014a). The evidence related to CBT and sensory modulation interventions is discussed in Chapter Two.

Researcher Motivation to Develop a New Intervention

My interest in sensory modulation originated during undergraduate studies, particularly in courses focused on paediatrics and child health. This early fascination deepened over time and eventually prompted me to implement sensory modulation techniques with children between the ages of 8 and 12 who experienced difficulties with emotion regulation, specifically anger management. Over the span of one year, I conducted group sessions as part of a service improvement initiative, and these efforts culminated in a presentation at a health improvement conference held in Australia. This experience marked my initial adventure into intervention research. Several years later, I expanded my involvement in sensory modulation by participating in a project to create an e-learning training programme for mental health

professionals that is still being used today. The objective of this training was to enhance staff knowledge and application of sensory modulation within clinical settings. In line with my commitment to enhancing practice, I subsequently carried out an organisational service-level audit at a specific hospital to identify the obstacles and facilitators of successful sensory modulation implementation in mental health settings. The findings from this audit were subsequently published in the New Zealand Occupational Therapy Journal. Throughout my career, I have consistently pursued my passion for sensory modulation and intervention research. Through continuous improvement activities, I have tested and refined concepts across diverse contexts, contributing valuable insights and advancements to the field. I received consistent and robust support from my colleagues, which included counsellors, nurses, social workers, psychologists, psychiatrists, and psychotherapists. These professionals acknowledged the significance of sensory modulation as a useful non-pharmacological intervention for children with various mental health conditions. They displayed enthusiasm towards the potential of sensory modulation and expressed a desire to see it widely implemented in clinical practice. Their strong belief in the intervention's efficacy fostered a collective endeavour to incorporate it into standard care. Colleagues frequently collaborated with me, contributing their insights and expertise to refine and expand the utilisation of sensory modulation. This shared dedication played a pivotal role in driving my motivation to establish sensory modulation as a trusted and promising intervention within the team.

The idea of developing an intervention specifically for young children living with anxiety presented itself when I worked as an occupational therapist at a Te Whatu Ora Health New Zealand Mental Health Service. It was observed that there were limited developmentally appropriate interventions for young children with anxiety that involved the young child and their parent(s). Interventions provided at that time mainly involved the parent(s)/guardian(s) only, and sometimes parents were referred to online self-help materials/resources. Some parents were unhappy about being referred to self-help materials and insisted on wanting in-person therapy that involved themselves and their children. The lack of access to in-person therapy was due to systemic problems that exist across NZ as outlined above. These included a lack of training in psychological therapies for non-psychology healthcare professionals, a shortage of psychologists, difficulty accessing psychological treatment, and long waiting times to access psychological therapies. The parents' feedback led to the idea of developing a novel intervention that would involve the parent(s)/guardian(s) and the child, be cost-effective, and easy to access. This gave birth to the 6-session Ngā Timatanga Toa (or 'Being Brave') intervention. The name of the programme was adapted from the work of Dr Hirshfeld-Becker an American psychologist.

I envisioned an opportunity to use sensory modulation and modify the standard CBT approach to develop an intervention that would be appropriate for younger children. I am an occupational therapist with over twenty years of continuous practice experience and was knowledgeable and experienced in the use of sensory modulation in mental health practice and was familiar of its benefits with adults and children. The intervention was developed to include both the child and parent, knowing that active child/family participation and engagement in therapy increases the likelihood of success (Creswell et al., 2014). It was envisioned that the involvement of the children in the therapy would allow them to learn age-appropriate strategies to manage their emotions. Parents would be involved as coaches and co-therapists, with opportunities to learn about their child's anxiety and further help their child identify anxiety triggers and strategies to alleviate it. Further details about the intervention and its development are provided in Chapter 3.

How the Study was Conducted

The current enquiry set out to examine if the Ngā Timatanga Toa programme was effective, acceptable, and practical. A single-case multiple baseline experimental design was used to guide the enquiry. Six children aged 4- to 7-years, experiencing clinically significant anxiety, and their parents, were recruited to participate in the intervention with a trained clinician. The intervention was delivered to participants in NZ, between July 2020 and December 2022.

As participants entered the study, they were randomly allocated to a 3-week, 4-week, or 5-week baseline period. Standardised measures of anxiety and anxiety interference were administered on entry into the study, during the baseline period, at mid- and post-intervention (PI), and at 4-weeks follow-up (FU). Qualitative feedback related to the acceptability and practicality of the intervention was collected from the therapists and parents using questionnaires developed for the study. Data collected were analysed using visual analysis and effect size (ES) calculations to determine the effectiveness of the intervention. General themes were drawn from parental and therapist feedback to understand the acceptability and practicality of the intervention in an NZ child and adolescent mental health context.

Impact of COVID-19

The intervention and data collection occurred during the peak of the COVID-19 pandemic, which resulted in significant disruptions that had a major impact on the study. These challenges are analysed and discussed in Chapters 5 and 6, where the specific effects of COVID-19 on the research are detailed. The disruptions caused by the pandemic had profound implications for both the implementation of the intervention and the collection of data.

However, the study persevered and made necessary adjustments to overcome these obstacles. The findings presented in these chapters provide valuable insights into how the pandemic influenced the research process and ultimately shaped the study's results.

Justification for the Study

As outlined above, there are limited interventions that have active involvement of young children under the age of 7-years presenting with anxiety. Although there are well-evidenced CBT interventions for children over 7-years-old living with anxiety, the limited number of interventions for children under 7-years presented a gap in service delivery. To address this gap, an age-appropriate intervention was developed, combining modified CBT with sensory-modulation strategies. The intention was to create a manualised programme that non-psychology clinicians could apply with relatively limited training requirements. At the start of this doctoral study, much of the evidence for using sensory modulation in mental health practice was from adult mental healthcare settings. There was a clear gap in the evidence base related to the use of sensory strategies with children experiencing mental health issues. Additionally, the evidence for CBT-based interventions with children under 7-years was limited. Therefore, to address these evidence and practice gaps, this study was designed to test a novel intervention for younger children living with anxiety, which combined CBT and sensory modulation. Results from the study have the potential to open new avenues of practice, theory, and research in the treatment of childhood anxiety.

Outline of the Thesis

This thesis is presented in seven chapters. Chapter 1 presented an introduction to the study, the problem in context, an overview of the study design, and a justification for the study. Chapter 2 presents further literature related to the context and focus of the study. It includes evidence related to childhood anxiety, current treatments, and barriers to accessing treatment for younger children living with anxiety. Chapter 3 discusses the development of the CBT-sensory modulation intervention manual. Chapter 4 presents the methodological framework that underpins the study and the rationale for using a single-case multiple baseline experimental design. Chapter 4 also outlines the methods and details how the study was carried out, including the tools and data analysis methods used. Chapters 5 and 6 present the research results, while Chapter 7 discusses the results and identifies implications for practice and recommendations for future research.

Conclusion

A novel CBT-sensory modulation intervention for young children with clinically significant anxiety was developed in response to a perceived gap in service delivery. The research presented in this thesis was designed to investigate the effectiveness, acceptability, and practicality of this intervention using a single-case multiple baseline experimental design, along with qualitative feedback. The following chapter provides a review of relevant literature to further analyse the study context and examine the current evidence base related to interventions for childhood anxiety.

Chapter 2:

Literature Review

Introduction

This chapter presents a review of the literature relevant to the study context and existing interventions for young children with anxiety. It includes an overview of the NZ mental health service context in which children with anxiety are seen; followed by literature related to childhood anxiety, its prevalence, and current treatments. Limitations of the current interventions for younger children living with anxiety are discussed. Finally, sensory modulation theory and evidence are reviewed to justify the intervention tested in the current study.

Literature Search Strategy

To find literature relevant to the current study, a literature search was completed using major health-specific and general databases, including EBSCO Host (CINAHL and Medline), Cochrane, PsychINFO, and Scopus, as recommended by Bramer et al. (2018). A hand search was also completed of relevant journals focussing on the management of childhood anxiety and different treatment modalities. The search strategy aimed to comprehensively explore literature related to CBT and sensory modulation interventions for children with anxiety with a specific focus on the 4 to 7-year age range. The search utilised combinations of relevant search terms, including: "cognitive behavi* therapy", OR "cognitive behaviour~ therapy", OR "CBT", combined with keywords pertaining to the target population AND ("child*", "young children", "infants"), AND the specific condition ("anxiety"), ("childhood anxiety"), ("anxious children"), AND age ranges ("4-7 years", "4-12 years"). Additionally, terms related to treatment approaches ("treatment", "intervention", "management", "therapy", "manual*") were included to encompass various types of interventions. Over 40 articles relevant to the study were identified that focused on the treatment of childhood anxiety. The same approach was also used to find sensory modulation literature, and combinations of search terms including: "sensory modulation", OR "sensory integration", OR "sensory approaches", OR "sensory-based interventions", OR "sensory processing" were used.

A hand search was also executed to find literature relating to the context of the study. This included searching NZ and international government websites, such as the Ministry of Health and their partner organisations' websites. The search terms used were: "prevalence of childhood anxiety", "funding for child and adolescent mental health services", "staffing", "barriers to treatment with anxiety", "access", "staff training", and "workforce challenges".

An initial search was done at the beginning of the doctoral programme in 2018. A second search was done in 2024 to update the literature, wherein new relevant literature found was incorporated into the thesis.

Child and Adolescent Mental Health Services (CAMHS) in NZ

In NZ, mental healthcare services for children between 0 and 19 years are provided by Primary Health Organisations (PHOs), Non-Government Organisations (NGOs), community-based CAMHS, and in-patient services (Mental Health Commission, 2012; Minister of Health, 2005; Ministry of Health, 2000, 2004; Quin, 2009). While PHOs and NGOs provide services to children with mild to moderate mental health challenges, specialist CAMHS services provide treatment for those with moderate to severe mental health challenges.

Improving mental healthcare service delivery has been a government focus over the last 30 years. The focus has led to two major inquiries—the Mason Inquiry in 1996 (Ministry of Health, 1996) and the more recent one completed in November 2018 (Minister of Health, 2018; Ministry of Health, 2017, 2018a). The focus of the Mason Inquiry was to review the availability of mental healthcare services in New Zealand and findings indicated that CAMHS were underdeveloped, understaffed, and had an unskilled workforce (Ministry of Health, 1996). The recently completed inquiry sought to identify how to intervene early, respond better, and promote well-being (Minister of Health, 2018). These areas are relevant to the effective and timely delivery of mental healthcare services to children in NZ.

The Need for Earlier Intervention

The age of diagnosis for many mental health disorders is between the ages of 16 and 25 years; however, the emergence of disorders often starts in childhood, in the context of early trauma, stress and distress (Bayer & Beatson, 2013; Children's Commissioner, 2017; Dougherty et al., 2015; Health and Disability Commissioner, 2018). Research into brain development indicates that early identification and intervention for childhood stressors and trauma can sharply improve health outcomes (Colizzi et al., 2020; Fusar-Poli, 2019; Ismail et al., 2017; Miller, 2014b), including children's mental health (Costello, 2016). Studies have shown this to be the case for children presenting with anxiety (Bayer & Beatson, 2013; Morgan et al., 2016). With the evidence that anxiety emerges early in childhood and is associated with significant impairment, it is logical that interventions should be accessible early to at-risk children and their families.

However, due to various service pressures, the current healthcare system is delayed in providing services to children with mental health challenges and their presentations worsen

before being seen, often leading to more severe health consequences for the children and their families (Children's Mental Health Ontario, 2020; Hansen et al., 2021; Semovski et al., 2021). The He Ara Oranga report (Ministry of Health, 2018a) argued that concerns about focussing on people with severe mental health problems without a parallel focus on early intervention is detrimental to those individuals whose presentations do not meet the eligibility criteria for specialist mental health services. If not treated early, mental health problems become more complex and difficult to manage as children and young people progress into adulthood (Neufeld et al., 2017; Ramage et al., 2005; The Werry Workforce - Whāraurau, 2017). The need to address and promote good mental health of children and adolescents has long been recognised as vital to prevent future serious mental health challenges (Ramage et al., 2005; Wainberg et al., 2017). The development of services and interventions that promote mental wellbeing as early as possible has been identified as critical to future population health (Clinton et al., 2016; Colizzi et al., 2020; Connor, 2017; Kim et al., 2022; Miller, 2014b).

Barriers to Early Intervention

The majority of children who present with anxiety disorders do not have access to appropriate and timely mental health care due to several factors, including lack of services, stigma, long waiting times, lack of trained professionals, lack of information to know where to go, and competing commitments for families (Creswell et al., 2022; Hansen et al., 2021; Iskra et al., 2018; Moroz et al., 2020; Oostermeijer et al., 2021; Shing et al., 2021; Stafford et al., 2020). Difficulty accessing services early has been identified as a barrier to preventing young children from getting help when needed (Lawrence et al., 2015; Ministry of Health, 2016b; Williams et al., 2017). In New Zealand, rates of access to mental healthcare services for young children and adolescents up to 19 years old remain low, with only 4.5% of the population in this age group getting mental health support (The Werry Workforce - Whāraurau, 2021). This is below the 5% target set by the second Blueprint for New Zealand Mental Health Services (Mental Health Commission, 2012). For the 0 to 9-year-olds, access decreased from 1.51% to 1.47% (The Werry Workforce - Whāraurau, 2021). International studies show that only a fraction of children with significant mental health challenges access CAMHS (Costello et al., 2014), showing evidence of severe mental health issues for young children. In a study by Lempinen et al. (2018), only half of children with multiple mental health challenges were in contact with services in Australia, and fewer than one in four children who identified as having mental health challenges saw a professional (Hiscock et al., 2020).

Even when children and families do have access to services, barriers to engagement with service providers is another major problem identified in the current system (Appleby & Phillips, 2016), with high rates of 'did not attend' and 'lost to follow up' being reported

(Rankin, 2011). This may be related to financial or transport issues, inability to commit to long interventions, and other family and/or parental work commitments (Appleby & Phillips, 2016; Ministry of Health, 2004; Rankin, 2011). Furthermore, the stigma associated with mental illness and mental health services, and not knowing where to get help, have also been identified as barriers to accessing mental health support (Goldie et al., 2016; Hansen et al., 2021; Iskra et al., 2018; Miller, 2014b).

Workforce Challenges

Although the Child and Adolescent Mental Health Services (CAMHS) workforce grew by 2% between 2018 and 2020/21, workforce deficiencies continue to be a problem (The Werry Workforce - Whāraurau, 2021). This was first identified in the Mason Inquiry (Ministry of Health, 1996) and the first 'Blueprint for Mental Health Services' (Mental Health Commission, 1998); hence, a workforce development plan was implemented. However, understaffing has continually been reported in several subsequent documents (Ministry of Health, 2012, 2018b; Ramage et al., 2005; The Werry Centre, 2011; The Werry Workforce - Whāraurau 2017; The Werry Workforce - Whāraurau, 2021). Ongoing shortages of mental health professionals appear to be a product of complex issues including funding, recruitment, retention, burnout, stress, and lack of specialist training (Hatcher et al., 2005; Lambie & Stewart, 2010; Ministry of Health, 2016a; The Werry Workforce - Whāraurau, 2021). The government and the District Health Boards (DHBs) have acknowledged the shortage of mental healthcare clinicians as one of the factors that affect service delivery (Mental Health Commission, 2011; The Werry Workforce - Whāraurau, 2021). Despite the need for increased mental health services for children and young people, there were approximately 1.0 full-time equivalent (FTE) child and adolescent psychiatrists per 100,000 population in NZ public mental health services in 2019 (Royal Australian and New Zealand College of Psychiatrists [RCANZP], 2019). This is short of the recommended 2.0 to 4.0 FTE per 100,000 population (RANZCP, 2019; Thabrew et al., 2017).

A further workforce issue is the training and skill level of staff (The Werry Workforce - Whāraurau, 2021). The child and adolescent mental healthcare workforce is comprised of a range of professionals, including occupational therapists, psychotherapists, nurses, social workers, counsellors, alcohol and drug clinicians, psychiatrists, and psychologists (Bernard & Turk, 2009; National CAMHS Support Service, 2011; Royal College of Psychiatrists, 2018; Sergeant & Barret, 2009). Of these professionals, non-psychology allied healthcare professionals and nurses make up the bulk of the workforce but receive inadequate training in child and adolescent mental healthcare at the undergraduate level (Gupta et al., 2019; Hipol & Deacon, 2012; Peters, 2003). The Werry Workforce National Survey of Infant, Child, and

Adolescent Mental Health Services (ICAMHS) (The Werry Workforce - Whāraurau, 2021) reported significant findings from DHBs that inform the workforce's current skills. The DHBs indicated a shortage of specialist staff and a lack of specific training and funding to undertake specialist training. The greatest need is to develop specialist skills such as the delivery of specific interventions such as CBT, Dialectical Behaviour Therapy (DBT), and Acceptance Commitment Therapy (ACT) (The Werry Workforce - Whāraurau, 2021). Therefore, a skilled workforce is required to improve service delivery, including early intervention in the child and adolescent mental healthcare sector.

The shortage of clinical psychologists and other qualified CBT therapists is one of the reasons the wait time is extended, with not enough trained clinicians to manage the increased referrals (Creswell et al., 2010; Lambie & Stewart, 2010; The NZ Psychological Society et al., 2023). Allied health and nursing clinicians report a lack of confidence in providing psychological therapies, such as CBT, because they are not adequately trained (Tingleff & Gildberg, 2014; Wolitzky-Taylor et al., 2018). Staniforth and Appleby (2022) found that the provision of extra training to newly graduated clinicians in a New Entry to Specialist Practice (NESP) programme increased the confidence of new graduates in general mental health practice. However, the training did not focus on specific therapeutic interventions in-depth, and Appleby et al. (2020) highlighted the importance of teaching new graduate clinicians therapeutic modalities for working in mental health. Therefore, as recommended in the Werry Workforce - Whāraurau (2021) report, the development of psychological interventions and training for non-psychology allied healthcare clinicians would assist in addressing this gap. This includes interventions to address the growing number of children presenting with anxiety.

Childhood Anxiety

Anxiety is a normal automatic and adaptive response to perceived threats or in anticipation of feared situations (Chand & Marwaha, 2023; Quek et al., 2019; Ströhle et al., 2018). Anxiety is different from fear, and different brain regions mediate these responses (Daniel-Watanabe & Fletcher, 2021). Fear is an emotional response to real or perceived imminent danger; whereas anxiety is the anticipation of future threats produced by the sustained anticipation of an aversive event (American Psychiatric Association, 2013; Daniel-Watanabe & Fletcher, 2021). Anxiety helps detect threats and fosters survival mechanisms (Dhabhar, 2018; Lewis & Rudolph, 2014).

Anxiety becomes clinically significant when it persists and causes distress and/or affects daily functioning (American Psychiatric Association, 2013). Clinically significant levels of anxiety in children are characterised by an ongoing sense of fear expressed in various ways including

difficulty separating from parents or caregivers, excessive crying, frequent and severe tantrums, avoidance of feared situations, needing constant reassurance, and freezing responses (Venta et al., 2021). These responses are disproportionate to the identified fear stimulus and are associated with other physiological responses such as increased heart rate, sweating, headaches, muscle tension, and tummy aches (Chand & Marwaha, 2023; Tyrer, 2018). If clinically significant anxiety persists, an anxiety disorder may be diagnosed (American Psychiatric Association, 2013). There are several types of anxiety disorders, including separation anxiety disorder (SAD), selective mutism, specific phobia, panic disorder, agoraphobia, and generalised anxiety disorder (GAD) (American Psychiatric Association, 2013). The characteristics of these types of anxiety are described in the American Psychiatric Association's (2013) *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5) and are summarised in Table 1.

Table 1

Types of Anxiety Disorders

Type of anxiety disorder	Characteristic symptoms
Separation anxiety disorder	Developmentally inappropriate, excessive worry or distress associated with separation from a primary caregiver or major attachment figure.
Selective mutism	Absence of speech in certain social situations despite the presence of speech in other situations (usually at home).
Social anxiety	Excessive fear or worries about being negatively evaluated by others in social situations.
Specific phobia	Excessive fear or worries about a specific object or situation.
Panic disorder	Recurrent unexpected panic attacks with physical and cognitive manifestations (i.e., an abrupt surge of intense fear or discomfort).
Agoraphobia	Excessive fear or worries about being in situations (e.g., crowds, enclosed spaces) in which the individual may be unable to escape or get help should panic-like or other overwhelming or embarrassing symptoms occur.
Generalised anxiety disorder	Excessive, uncontrollable worries regarding numerous everyday situations or activities.
Substance/medication-induced anxiety or anxiety due to another medical condition	Anxiety occurring in the context of substance/medication use or a physical illness.

(American Psychiatric Association, 2013)

The Prevalence, Nature, and Impact of Childhood Anxiety Disorders

Anxiety disorders in children are common (Creswell & Waite, 2016; Seligman et al., 2011) and have a period prevalence between 9% and 27%, with separation anxiety being the most frequently diagnosed (American Psychiatric Association, 2013). In NZ, the prevalence of anxiety disorders in children 2- to 14-years-old is 3.9% (The Werry Workforce - Whāraurau, 2021). It is estimated that around 4% of children in this age range have been diagnosed with an emotional and/or behavioural problem at some point in their lives (Health and Disability Commissioner, 2018).

Anxiety is expressed differently at different developmental stages through childhood, adolescence, and adulthood (Lewis & Rudolph, 2014). Literature suggests that, typically, anxieties appear and disappear in a predictable pattern consistent with the developmental stages, which has been described as an 'ontogenic parade' (Marks, 1987). For example, separation from parents or guardians is a key factor that causes anxiety in infants; while school, personal, and health concerns cause anxiety in school-aged children, and social issues and performance concerns cause anxiety in older children (Broeren & Muris, 2009; Christie & MacMullin, 1998; Manicavasagar & Silove, 2020; Silverman et al., 1995). While these various anxieties are typical through the developmental stages, early identification of symptoms which persist or reach clinically significant levels is important to prevent negative impact and the development of debilitating long-term anxiety disorders (Bhatia & Goyal, 2018; Griffiths & Fazel, 2016).

Childhood anxiety is associated with impairments in social and academic functioning (Afshari et al., 2014; Bennett et al., 2015; Chiu et al., 2013; Creswell et al., 2010; Galla et al., 2012; Ginsburg et al., 2011; Ialongo et al., 1995; Langley et al., 2004; Minde et al., 2010; Scainia et al., 2016). Additional consequences may include poor academic achievement, social isolation, poor cognitive development, unemployment, more serious anxiety disorders, alcohol and drug misuse, mood disorders, and higher chances of depression and suicidal behaviour (Afshari et al., 2014; Alyahri & Goodman, 2008; Barrett et al., 1996; Breinholst et al., 2012; Chiu et at., 2013; Creswell et al., 2010, 2014, Creswell & Waite, 2016; Drake & Ginsburg, 2012; Hirschfeld-Becker, Masek, Henin et al., 2010; Scainia et al., 2016; Van Steensel & Bögels, 2015; Waddel et al., 2007; Wergeland et al., 2015; Woodward & Fergusson, 2001). Additionally, childhood anxiety disrupts family life through parental stress (Afshari et al., 2014; Gilbertson et al., 2017; Minde et al., 2010; Van der Bruggen et al., 2008). Several studies have established an association between socioeconomic status, anxiety, and health outcomes (Elgar et al., 2015; Phelan et al., 2010; Reiss et al., 2019). Findings indicate that people from disadvantaged backgrounds have a higher risk of developing mental health problems,

including anxiety disorders, which are, in turn, associated with poorer general health outcomes (Elgar et al., 2015; Phelan et al., 2010; Reiss et al., 2019). Not only are children from low socioeconomic families two to three times more likely to develop mental health problems, they are also less likely to access services due to barriers such as parents' inability to pay (Reiss, 2013). Despite the significant negative health and social outcomes, anxiety disorders often go undiagnosed and untreated in young children (Creswell et al., 2014). The prevalence and significant impact of childhood anxiety strongly reinforces the need to increase access to effective treatments for this condition.

Co-occurring Disorders

Childhood anxiety disorders rarely emerge in isolation; they usually co-occur with conditions such as Attention Deficit Hyperactivity Disorder (ADHD), Autism Spectrum Disorder (ASD), Oppositional Defiance Disorder (ODD), and depression (Mobach et al., 2019). For example, research has found that anxiety and ADHD are comorbid in 15 to 50% of cases (Barkley, 2006; D'Agati et al., 2019; Gümüş et al., 2015). In Gümüş et al.'s (2015) study, amongst 170 children diagnosed with anxiety, a comorbidity of 27.6% was evident between anxiety and ADHD. Anxiety is also comorbid with other anxiety disorders; one-third of children and adolescents diagnosed with an anxiety disorder met the criteria for a diagnosis of one or more further anxiety disorders (Rapee et al., 2009). Mood disorders are also highly co-morbid with anxiety disorders, with depression being adolescents' most common comorbid condition (Copeland et al., 2014; Costello et al., 2011; Hankin et al., 2016). In preschool children, Spence et al. (2018) reported that SAD, social phobia, and GAD were highly co-morbid with depression. However, Predrescu et al. (2018) found comorbidity increased with age; thus, adolescents experienced higher levels of comorbidity between anxiety and depression compared to young children. In children 3 to 5-years-old, ODD was found to be comorbid with anxiety disorders, and a diagnosis of ODD at 3 years of age was a predictor for separation anxiety at 5 years of age (Martín et al., 2016). Consideration of concurrent disorders is essential when treating anxiety in clinical practice because other disorders may affect the treatment responsiveness and outcomes (Nilsen et al., 2013; Ollendrick et al., 2008). Melton et al. (2016) stated that *"children and adolescents with comorbid anxiety and depression have unique presentations, greater symptom severity, and treatment resistance compared with those who have either disease in isolation"* (p. 1). This suggests that these children may have poorer outcomes (Walczak et al., 2018) and, therefore, require comprehensive assessment and treatment strategies to synergistically manage symptoms of their primary diagnosis and co-morbidities (Melton et al., 2016).

Neuro-Physiological Aspects of Anxiety

Anxiety is characterised by the ‘flight, fight, and freeze’ response, in which the body is physiologically mobilised and ready for action in response to perceived threats or danger (Chu et al., 2022; Godoy et al., 2018; McCarty, 2016). The conscious or unconscious perception of threat initiates a cascade of central and sympathetic nervous system responses which stimulate increased heart rate, breathing, sweating, and muscle tension, while reducing activity in digestive, sexual, and other systems that are not required in an emergency (Fink, 2016; McCarty, 2016). Individuals with anxiety disorders are hypersensitive to potential threats (Barry et al., 2015; Grillon et al., 2017; Mogg & Bradley, 2018; O’Donovan et al., 2013) and have a stronger and more prolonged sympathetic response once a threat is perceived. For example, people with GADs have been reported to have chronic physiological arousal, deficient amygdala recruitment, dysregulated fear circuitry, and dysregulated neuroendocrine system resulting in hypervigilance (McTeague & Lang, 2012; Patriquin & Mathew, 2017). The dysfunction of the prefrontal-amygdala-based circuits has been implicated in the pathophysiology of fear-based anxiety (Bouras et al., 2023; Kenwood et al., 2021; Kredlow et al., 2021). Brain imaging studies have found that the neural circuits between the amygdala (known as the brain’s ‘alarm system’) and the prefrontal area of the cortex (which helps regulate responses to threats) do not function as effectively in people with anxiety disorders (Madonna et al., 2019; Shackman & Fox, 2021; Terpou et al., 2019). Research has found that the amygdala is overactive in initiating fear responses in children with anxiety disorders (Wehry et al., 2015). Increased noradrenergic systems and low serotonin levels have also been identified in people with anxiety disorders (Liu et al., 2019; Yamamoto et al., 2013) and has led to the use of selective serotonin-reuptake-inhibitors (SSRIs) and serotonin-norepinephrine-reuptake-inhibitors (SNRIs) as treatments for anxiety (Munir & Takov, 2022). Non-pharmaceutical interventions that target the neuro-physiological aspects of anxiety include sensory-based strategies and will be discussed in more detail later in the chapter.

Cognitive Aspects of Anxiety

Cognitive responses in childhood anxiety include repetitive negative thoughts and images, with constant appraising of potential danger or anticipated negative outcomes that may be associated with a future event (Songco et al., 2020). Additional responses involve a pervasive sense of uncertainty, poor emotional regulation, and maladaptive beliefs (Grupe & Nitschke, 2013; Mahoney et al., 2018; Mennin et al., 2009; Ruan et al., 2023). As children’s cognitive abilities advance with age, their capacity to evaluate and appraise threatening situations using deductive reasoning increases (Songco et al., 2020). Therefore, the greater the child’s ability to predict a negative outcome of a future event, the greater their capacity to worry over such

an event (Songco et al., 2020). Logically, worries become more prominent in adolescents due to their increased ability to foresee multiple negative outcomes (Songco et al., 2020) and have the propensity to make more cognitive errors (Pereira et al., 2012). It has also been hypothesised that negative metacognitive beliefs (Songco et al., 2020), cognitive errors (Pereira et al., 2012), and faulty information processing contribute to the development of pathological worries in children (Hirsh & Matthews, 2012). However, it is important to note that very little is known about the defining characteristics of worries in children (Songco et al., 2020), so the models discussed here are adult models that have been adapted and applied to children and youth.

A study by Songco et al. (2020) provided preliminary evidence indicating that some cognitive functions (i.e., biased information processing, interpretation, judgement, memory bias, and attention) play a significant role in the development and maintenance of anxiety in children and youth. Songco's findings are consistent with those by Ishikawa (2015), who stated cognitive errors and negative self-statements contributed to the development of anxiety in children, when they tested their cognitive-behavioural model of anxiety in Japan. Understandings related to the cognitive framework of anxiety are important because they highlight the significance of including cognitive components in assessing and treating childhood anxiety disorders (Ishikawa, 2015; Pereira et al., 2012).

Behavioural Aspects of Anxiety

Childhood anxiety involves a range of behavioural aspects including avoidance (Eaton et al., 2018; Hofmann & Hay, 2018; Olatunji et al., 2010; Whiteside et al., 2013), somatisation (Biedel et al., 1991; Crawley et al., 2013), and challenging behaviours at home and school that impact a child's ability to participate in daily activities. These aspects also manifest as excessive worry, physical symptoms like restlessness and difficulty with social interactions, clinging to parents/caregivers, excessive crying, constantly complaining about being picked on, and sleep difficulties (Aktar et al., 2017; Rapee et al., 2000).

Anxious children will go to great lengths to evade anxiety-provoking situations or stimuli they perceive as threatening. Avoidance can lead to impaired academic and social functioning (Russell & Topham, 2012) and has been reported as a predictor of more significant mental health challenges in children (Crawley et al., 2013; Shanahan et al., 2014). Additionally, heightened arousal and vigilance are common behavioural responses, with anxious children displaying increased sensitivity to potential threats, resulting in chronic alertness (Crawford et al., 2023; Robinson et al., 2013). Cognitive-behavioural approaches have proven effective in managing the behavioural and cognitive aspects of anxiety (Kreuze et al., 2018;

Sigurvinsdóttir et al., 2019). Strategies include teaching children appropriate coping strategies and promoting realistic appraisal of perceived threats, followed by exposure therapy, which helps children confront and gradually overcome feared situations, reducing avoidance behaviours (Patriaca et al., 2022).

Assessment of Anxiety Disorders in Children

According to the American Academy of Child and Adolescent Psychiatry (AACAP), anxiety disorders should be diagnosed after a thorough clinical assessment of the anxiety symptoms, functional impairment, syndromal symptom combinations, symptom frequency, severity, onset, duration, physical signs, and presence of co-morbid disorders, including medical conditions that may mimic anxiety (Walter et al., 2020). The anxiety diagnosis should be made as per the Diagnostic and Statistical Manual (5th ed.) (DSM 5, American Psychiatric Association, 2013), and distinguish between age-appropriate worries and fears and normal responses to stressors (Walter et al., 2020). The assessment should also consider the presenting symptoms and severity of anxiety to determine other factors that may be contributing to the maintenance of anxiety (Connolly & Bernstein, 2007). Information should be gathered from multiple sources, including the child, the family, the parents/guardians, the school, and other professionals involved (Connolly & Bernstein, 2007; Walter et al., 2020). In addition to a clinical interview, anxiety psychometric tools should be used to gather more information about the child's anxiety (Walter et al., 2020). Several assessment tools have been developed, tested, and used in clinical practice to assess and manage anxiety. These include the Multidimensional Anxiety Scale for Children (March et al., 1997), Screen for Child Anxiety and Related Emotional Disorders (SCARED) (Birmaher, 1999), Spence Children's Anxiety Scale (SCAS) (Spence, 1997, 1998), Paediatric Anxiety Rating Scale (Edwards et al., 2010), Children's Anxiety Life Interference Scale (CALIS) (Lyneham et al., 2013), and School Anxiety Scale Teacher Report (SAS-TR) (Lyneham et al., 2008). The CALIS and SAS-TR were used in the present study, along with a clinical assessment of anxiety symptoms, as discussed in Chapter 4.

Management of Anxiety Disorders in Children

As outlined previously, it is important to provide early intervention for children presenting with anxiety and increase access to psychological treatments for those identified as at risk of developing an anxiety disorder. A case study with two toddlers aged 26 and 35 months evidenced that early interventions delivered to toddlers with anxiety can be beneficial (Hirshfield-Becker, Henin, Rapoport et al., 2019). An RCT study with 385 children aged

between 3 and 6 years (Morgan et al., 2015) showed that a CBT intervention can reduce anxiety symptoms and mitigate the likelihood of more serious mental health issues developing in the future (Baughman et al., 2020). A multimodal approach to treating childhood anxiety is increasingly common, and includes a combination of medication, psychological therapy, and environmental interventions (Patel et al., 2018; Piacentini et al., 2014). In terms of medication, SSRIs and SNRIs are the recommended first and second-line treatments for managing childhood anxiety (Pettitt et al., 2022), and treating depression and some anxiety disorders (Yuan & Deban, 2021). These medications have demonstrated efficacy and are generally safe, albeit with some recognised side effects such as gastrointestinal issues, changes in appetite, and sleep disturbances (Ipser et al., 2009; Leonte et al., 2022). SSRIs are preferred as the first choice over SNRIs because they have fewer side effects (Leonte et al., 2022). However, Read et al. (2014) and Sharma et al. (2016) stated that young children are more likely to experience more side effects when taking anti-depressants than adults. Furthermore, Bagshaw and Thabrew (2016) reported that anti-depressive medication significantly increased the rate of suicidal ideation in children and young people. The potential side effects of medication in children make the development of non-pharmaceutical options for managing anxiety critical.

Several non-pharmaceutical interventions have been evaluated with children, adolescents, youths and adults experiencing significant anxiety with promising results. These include traditional forms of in-person CBT (Hofmann et al., 2012), as well as computer-based CBT (Calear & Christensen, 2010; Hollis et al., 2016; Pennant et al., 2015; Richardson et al., 2010; Rooksby et al., 2015; Storch et al., 2015; Vigerland et al., 2016) and school-based CBT (Haugland et al., 2020; Mychailyszyn et al., 2012). These are discussed further in the following paragraphs.

Further studies have explored the use of Acceptance and Commitment Therapy (ACT) for anxiety mainly with adults (Coyne et al., 2011; Halliburton & Cooper, 2015; Swain, Hancock, Dixon et al., 2013; Swain, Hancock, Hainsworth et al., 2015). ACT is a talking-based intervention that focuses on helping people develop psychological flexibility by accepting their thoughts and feelings instead of wanting to control them, to help reduce the impact of anxiety and move beyond it towards valued goals.

Some studies incorporated mindfulness practice for anxiety, one in the context of an acceptance-based intervention (Vøllestad et al., 2012), and several with cognitive-based therapy (Chiesa & Seretti, 2011; Evans et al., 2008; Kim et al, 2009; Malboeuf-Hurtubise eta al., 2017; Semple et al., 2010). Mindfulness practices are believed to assist with anxiety by allowing individuals to pay attention to their present moment without judgement, allowing them to be aware of their feelings, thoughts and bodily sensations and recognising the early

signs of anxiety and intervening before they escalate. Similarly, yoga (Weaver & Darragh, 2015) helps reduce anxiety through the interconnectedness of the physical, mental and emotional systems by promoting relaxation, emotional balance, and increasing resilience.

A small number of studies reported positive findings from child-centred play therapy (Li, Chung, Ho et al., 2016; Stulmaker & Ray, 2015), Triple P (Özyurt et al., 2015; Wilson et al., 2012), and resilience-based group programmes (Watson et al., 2013). Triple P is a positive parenting intervention that focusses on equipping parents with the knowledge and skills to manage behaviour problems in children and adolescents. Child-parent and family-focused interventions have also been demonstrated to be effective in treating childhood anxiety (Brendel & Maynard, 2013; Brendel & Maynard, 2014; Kennedy et al., 2009), and these will be discussed further under parental involvement in CBT.

Among the various interventions for anxiety, CBT interventions have the strongest evidence base, with the individual and combined sample sizes and experimental designs in the CBT studies being more robust than the small sample sizes and quasi-experimental designs in many of the other intervention studies. It can be concluded that CBT is the most evidenced and widely used psychological therapy for managing childhood anxiety (James et al., 2020; Seligman et al., 2011; Sigurvinsdóttir et al., 2019). Many of the other interventions are not well-researched; some were only tested in adults, and most do not have strong evidence for their effectiveness with younger children.

CBT for Anxiety

Cognitive Behavioural Therapy is a form of psychotherapy, which was developed by Ellis (1962) and Beck (1970) and combines behavioural and cognitive interventions to alter or reduce dysfunctional thinking patterns and unhelpful responses to situations (Beck et al., 1987; Brewin, 1996; Dryden & Branch, 2012; Fenn & Byrne, 2013; Knapp & Beck, 2008). The underlying assumption is that prior learning affects current behaviour, resulting in unwanted behaviours and maladaptive thinking patterns (Brewin, 1996; Dummett, 2010; Fenn & Byrne, 2013; Knapp & Beck, 2008). The primary goal of the intervention is to identify maladaptive beliefs, thoughts, and behaviours, and replace them with more adaptive ones, resulting in greater coping skills and functioning (Gatchel & Rollings, 2008; Hofmann et al., 2012). CBT is based on collaborative empiricism, which establishes collaborative therapeutic relationships between a patient and a therapist (Fenn & Byrne, 2013). Behavioural techniques are used to test the patient's catastrophic thinking and predictions about feared situations (Knapp & Beck, 2008). For example, a patient may be involved in a behavioural experiment to leave the house if they have anxiety about going into public places because they think something terrible will

happen to them. In this instance, behavioural techniques will be combined with cognitive techniques to disconfirm the patient's dysfunctional assumptions and negative thoughts (Brewin, 1996; Fenn & Byrne, 2013; Knapp & Beck, 2008). As outlined previously, behavioural strategies, such as diaphragmatic breathing and graded exposure, may be used to manage autonomic nervous system arousal and challenge thinking (Fink, 2016; McCarty, 2016).

CBT-Based Interventions for Children

The efficacy of CBT for childhood anxiety has been established through RCTs, systematic reviews, and meta-analysis studies (Cartwright-Hatton et al., 2004; Compton et al., 2004; Fisak, et al., 2018; Guo et al., 2021; Hofmann et al., 2012; In-Albon & Schneider 2006; James et al., 2020; Öst & Ollendick 2017; Sawyer & Nunez, 2014; Scainia et al., 2016; Tse et al., 2023). Gains have been reported to be maintained for up to five years post-treatment (Barrett et al., 1996; Brown et al., 2018; Creswell et al., 2014; Kendall, 1994). CBT can be delivered in a stepped care model - with varying depth and intensity, depending on the child's anxiety levels; it can also be delivered electronically, in a group format, and with a parental focus (Barrett et al., 2015).

Twenty-eight studies were found that investigated CBT for children aged 2 to 14-years, with 2984 participants (Anticich, Barrett, Silverman et al., 2013; Barrett et al., 2015; Bayer, Beatson, Bretherton et al., 2017; Breinholst et al., 2021; Carlyle, 2014; Cobham, 2012; Creswell et al., 2017; Donovan & March et al., 2014; Esbjørn et al., 2019; Hirshfeld-Becker et al., 2008; Hirshfield-Becker et al., 2010; Hirshfield-Becker et al., 2011; Infantino et al., 2016; Kendall et al., 2008; Khanna & Kendall, 2010; Lawson et al., 2023; Lundkvist-Houndoumadi & Thastum, 2013; March et al., 2009; Minde et al., 2010; Monga et al., 2015; Pahl & Barrett, 2010; Ruocco et al., 2016, Salari et al., 2018; Scaini et al., 2022; Spence et al., 2006; Thirlwall et al., 2013; Villabø et al., 2018; Waters et al., 2009). These studies examined various formats (i.e. parents only, child and parents, groups and online) for delivering CBT to anxious children, and all were based solely on CBT principles without blending other approaches. The number of sessions ranged from two to twenty sessions and the content included psychoeducation, cognitive restructuring, and relaxation techniques. Sixteen studies utilised an RCT design, nine used quasi-experimental designs, and three were case studies. The overall quality of the studies and robustness of the designs were considered strong, enhancing the credibility of the findings. Most studies included children over seven years old. Overall, the evidence from these studies showed that CBT interventions were effective for children, however, it must be noted that children under seven years old were underrepresented in these studies. The interventions led to significant reductions in anxiety symptoms, which were sustained for up to 5-years post-intervention (Brown et al., 2018). These findings suggest

that CBT is an effective approach for addressing anxiety in children despite potential limitations in the evidence and intervention options for younger children, as discussed below.

Manualised CBT Interventions for Children

An extensive search of databases and online information resulted in the identification of six existing anxiety intervention manuals for children. These interventions include the Coping Cat programme (Kendall & Hedtke, 2006a; Kendall & Hedtke, 200b; Khanna & Kendall, 2008), the Coping Kiwi programme (Girling-Butcher & Ronan, 2002), the Cool Kids programme (Rapee et al., 2006), the Cool Little Kids programme (Bayer et al., 2011; Rapee, 2013), the Fun Friends Program (Barrett et al., 2015), and the CBT based manual for children (Minde et al., 2010). These existing intervention manuals are all based on CBT principles and have a similar focus and target population as the intervention in the present study, as presented in Table 2. However, no anxiety treatment manuals specific for children aged 4 to 7-years that combined CBT and sensory modulation were found.

The core principles of these manuals are skills training including homework, psychoeducation, cognitive restructuring, and parent training (Garber et al., 2016; Sauter et al., 2009). Several studies evaluated the effectiveness of the Coping Cat (Kendall & Hedtke, 2006a; Kendall & Hedtke, 2006b; Khanna & Kendall, 2008), Cool Kids (Rapee et al., 2006), and Cool Little Kids (Bayer et al., 2011; Rapee, 2013) manualised programmes and showed they were effective in reducing anxiety in children (Albano & Kendall, 2002; Arendt et al., 2015; Barrett et al., 1996; Djurhuus & Bikic, 2019; Hudson et al., 2015; Rapee et al., 2006). In addition, the studies were successfully conducted in different settings and regions, yielding results that support providing CBT-based intervention as beneficial in school, home, service settings and research/laboratory contexts. The Cool Kids, Cool Little Kids, and the Coping Cat programmes are the most well-researched intervention manuals for children with anxiety, with strong evidence gathered through RCTs and in different countries (Arendt et al., 2015; Bayer et al., 2011; Breinholst et al., 2012; Kennedy et al., 2009; Lenz, 2015; Mihalopoulos et al., 2015; Morgan et al., 2015; Rapee et al., 2005; Wuthrich, 2015; Zikopoulou et al., 2021). The Coping Kiwi programme was evaluated by Girling-Butcher and Ronan in 2009 in NZ. It was found to reduce anxiety in children, with gains maintained for 3 to 12-months post-treatment (Girling-Butcher & Ronan, 2009).

Although these manualised interventions have largely been proven effective, they have some limitations relevant to the current study (see Table 2). Three of the interventions, with the strongest evidence, were developed for and tested with children older than 7yrs (Girling-Butcher & Ronan, 2009; Khanna & Kendall, 2008; Rapee et al., 2006). Of the remaining interventions one was a school-based preventative programme, focused on building resilience,

rather than managing significant anxiety issues (Barrett et al., 2015); another was parent-focused and did not directly involve the children in developing strategies (Bayer et al., 2011) and the third CBT manual for children, had promise, but limited evidence of efficacy (Minde et al., 2010). The Cool Little Kids intervention manual was developed for children with emotional disorders and was not specific for children with clinically significant anxiety (Bayer et al., 2011). Additionally, all these interventions were group-based programmes, except for Minde et al. (2010) and the Coping Kiwi (Girling-Butcher & Ronan, 2009).

Table 2

Existing Intervention Manuals for Childhood Anxiety

Manual Name	Age (years)	Features & strengths	Limitations
Cool Little Kids programme	3-6	Group based preventative programme for children with emotional challenges. Extensively tested with good evidence base. Delivered over six sessions.	Parent focused and does not include children. Not specifically for children with significant anxiety.
CBT manual for children	3-7	An individual treatment for anxious children. Involves the participation of parents and children. Delivered in eight sessions on average.	Has not been extensively tested.
Fun Friends program	4-7	Play-based group intervention to prevent anxiety and increase social and emotional strength in schools. Involves parents at regular intervals. Delivered in12 to 16 sessions.	Preventative programme rather than a treatment for clinically significant anxiety.
Coping Kiwi programme	8-11	Developed/tested in NZ for anxious children. Delivered to individual participants in eight sessions.	Does not include children under seven.
Coping Cat programmes	7-17	Three programmes for anxious children: (a) for 7-13yr olds only. (b) for parents/caregivers of children 7-13yrs old. (c) for adolescents 14-17yrs. Extensively tested with good evidence base. The programme has 16 sessions delivered to individuals or in groups.	Does not include children under seven.
Cool Kids programme	7-17	Group programme for anxious children. Involves the participation of both children and their parents. Tested extensively and has good evidence. Delivered between six and ten sessions.	Does not include children under seven.

Parent Involvement in CBT

CBT with younger children often focuses on the family unit or parents, with no direct intervention for the child (Creswell & Waite, 2016). However, CBT has been found to be more effective when the intervention includes both the parent and child's active involvement (Halder & Mahato, 2019; Teubert & Pinquart, 2011). Recognition that parents play a critical role in modifying their child's thinking and behaviour has led to the development of parent-focused CBT interventions (Creswell et al., 2014). These are particularly relevant for supporting younger children who may not have the verbal and cognitive capacity for elements of CBT (Grave & Blissett, 2004; Minde et al., 2010). The inclusion of parents has benefits such as incorporating parental knowledge of the child's anxiety and level of functioning, integrating treatment into the child's routine, and parents using their relationship with the child to support the therapy process (Anticich et al., 2012; Infantino et al., 2016; Vallis et al. 2020). Six CBT intervention studies (Cartwright-Hatton et al., 2011; Donovan & March 2014; Hirshfield-Becker et al., 2010; Hirshfield-Becker et al., 2011; Monga et al., 2015; Waters et al., 2009) were found that tested parent-only and parent-child interventions. The ages of the child participants ranged from 2 to 9-years-old. Four of the studies were RCTs with waitlist control; one was a prospective longitudinal study with repeated measures, and the other was a case study. The studies produced evidence supporting the use of CBT for young anxious children with marked improvements at follow-up; and supported the inclusion of parents in treatment. Five studies indicated that parental inclusion led to superior outcomes, except for one study (Waters et al., 2009), which found no difference between the groups. However, both treatment conditions were superior to waitlist control, and gains were maintained for up to 12-months, suggesting parental involvement may still have been helpful (Waters et al., 2009).

Limitations and Considerations in using CBT With Younger Children

Despite its proven effectiveness in older children and adolescents, the evidence for CBT has some limitations, which suggests that it may not be as effective for children younger than 8-years (Cartwright-Hatton et al., 2004; Compton et al., 2004; Creswell et al., 2014; Kurniawan, 2018; Moreno-Peral et al., 2017; Pegg et al., 2022; Stulmaker & Ray, 2015; Vallis et al., 2020; Wang et al., 2017). In a 2015 meta-analysis, Pennant et al. (2015) stated there was uncertainty around the effectiveness of CBT in children aged 5 to 11-years-old. Similarly, Vallis et al. (2020) stated that key questions about the efficacy and appropriate formats for using CBT with preschool children with anxiety remain unanswered. It has been identified that children under 8-years were not represented in most CBT research, particularly in the larger RCTs (Cartwright-Hatton et al., 2004; Compton et al., 2004; Hirshfeld-Becker et al., 2010; Wergeland et al., 2015). Therefore, it cannot be firmly concluded that CBT is effective in younger children, as is evidenced in adolescents and adults. Halder and Mahato (2019) argued

that CBT is more suited to mid-childhood or older children. This is because younger children may have limited language and lack the meta-cognition and communication capacity required to identify automatic thoughts and distinguish emotional states (Halder & Mahato, 2019). Similarly, Garber et al. (2016) stated that some children may respond poorly to CBT treatment because they do not yet have the cognitive, social, or emotional maturity needed to understand and apply the skills being taught in therapy.

According to Piaget (1962), younger children use more concrete modes of thinking, with children aged 3 to 8-years at the preoperational stage of development. This stage of cognitive development is associated with limited abstract thinking, restricted conceptualisation skills, and a lack of fluent language (Grave & Blissett, 2004; Halder & Mahato, 2019; Minde et al., 2010). As higher-order cognitive processes are yet to be developed in younger children, high-intensity formal CBT may be ineffective in this population (Garber et al., 2016; Stulmaker & Ray, 2015). Therefore, if low-intensity or less formal CBT is used with younger children, it needs to be adapted to suit their developmental level, and the literature indicates that greater engagement in treatment can be achieved when games, activities, stories, and multi-sensory approaches are used (Cheng et al., 2019; Horne-Moyer et al., 2014; Johnson, 2020; Swank, 2008). Halder and Mahato (2019) suggested making adaptations targeting behavioural changes with fewer cognitive requirements. Pegg et al. (2022) stated that CBT can be efficacious with younger people, with appropriate adaptations and modifications.

As outlined previously, many children with anxiety disorders have co-existing issues, including difficulties with attention, sensory processing, developmental delay, and emotional dysregulation. This indicates that, along with adaptations of CBT, there is a need for more comprehensive interventions than CBT alone (Afshari et al., 2014; Carthy et al., 2010; Southam-Gerow & Kendall, 2000; Suveg & Zeman, 2004). Combining CBT principles with other developmentally age-appropriate, child-friendly approaches may result in more effective treatments for younger children living with co-existing issues along with anxiety.

An additional issue with current CBT offerings is that they are often seen as a specialist form of treatment delivered mainly by psychologists, who are in short supply within the public healthcare system (Madden-Smith, 2021; Rucklidge et al., 2018; The NZ Psychological Society et al., 2023). Waiting lists for psychological interventions result in children not receiving early treatment as required; and, for many families, CBT is expensive to fund (Thase et al., 2020). Furthermore, formal CBT follows a manualised protocol delivered in 60 to 90-minute sessions across 9 to 20-weeks (Barrett et al., 1996; Cumba-Avilés, 2017; Głuszek-Osuch, 2016; Luberto et al., 2017). Many parents cannot commit to this number of sessions due to other life demands (Creswell et al., 2014). These issues highlight the need for further

interventions that are low-intensity and can be delivered by a wider range of mental health clinicians with a manageable level of involvement for parents.

Sensory Modulation: An Emerging Intervention

Sensory modulation is defined as the capacity to regulate and organise the degree, intensity, and nature of responses to sensory input in a graded and adaptive manner (Miller et al., 2001). This regulation of sensory input occurs neurologically in the central nervous system, as well as behaviourally (e.g. seeking out or avoiding sensations). Sensory modulation intervention was pioneered by the occupational therapist Jean Ayres (1972), who explored sensory integration and processing in the 1960s and 1970s, mostly with children living with developmental issues. It was then applied and championed in adult mental healthcare services by another occupational therapist, Tina Champagne (Champagne & Stromberg, 2004, Champagne, 2010, 2011a). The premise of sensory integration is that all sensory input from multiple environmental sources converge in the brain, where it is processed and integrated to allow people to respond appropriately to their environmental demands (Ayres, 1972). Sensory modulation is the regulatory component of sensory integration, through which less important stimuli is filtered out and habituated to, and important information is processed further and actively responded to (Ayres, 1972). Champagne and Sayer (2003) advanced these ideas and applied them to adult mental health and addiction settings to help patients regulate their emotions and behaviour to deal with emotional distress (Champagne & Sayer, 2003).

Sensory Modulation Theory

Sensory modulation intervention emphasises the use of sensory-based strategies to manage emotions via the autonomic nervous system by dampening or arousing the neurological system (Moore, 2005; Moore, 2016). It utilises the application of one or more sensory modalities such as deep pressure, massage, rocking, aromatherapy items, music, stress balls, fidgety items, calming audio sounds, or visual images (Champagne, 2006; Lloyd et al., 2014; Moore, 2016). In most interventions for childhood anxiety, including CBT, relaxation training is used to help reduce a child's physiological response to anxiety (Kim & Kim, 2018; Hamdani et al., 2022; National Center for Complementary and Integrative Health [NCCIH], 2021). Relaxation strategies allow children to modify their physiological arousal; decreasing the activity of the sympathetic nervous system and supporting emotional regulation (Afshari et al., 2014). In sensory modulation intervention, this is achieved using sensory strategies, such as listening to calming sounds, specific odours, such as lavender, massage and other forms of deep pressure, and movement against resistance to promote relaxation through activation of the vagus nerve

of parasympathetic nervous system (Champagne, 2010, 2011a; Champagne & Stromberg, 2004; Moore, 2005, 2016; Porges, 2009).

To understand how sensory modulation approaches assist with emotion and behaviour regulation, one must understand the relationship between sensory processing and emotional arousal. Kaplan and Sadock (1991) asserted that human emotions are an expressed response to the external or internal environment. Developmental theorists claim humans respond innately to environmental stimuli and, through experience, learn to self-regulate their responses (Peil, 2014). Failure to self-regulate and respond to sensory stimuli appropriately can result in functional problems (Gomez et al., 2021; Miller et al., 2009; Peil, 2014). This is where sensory modulation strategies are used to assist patients with self-regulation to enhance their ability to adapt to sensory stimuli, and is consistent with the polyvagal theory (Porges, 2001) which states activation of the vagus nerve through sensory approaches, such as deep breathing, results in a relaxation response for individuals with anxiety.

A key component of anxiety disorders is an overactive physiological response, which is targeted by sensory modulation interventions (Champagne, 2008; Fink, 2016; Knapp & Beck, 2008; McCarty, 2016). Sensory modulation interventions activate the senses (visual, auditory, tactile, vestibular, olfactory, gustatory, and proprioceptive), resulting in calming or alerting responses (Champagne, 2008; Machingura et al., 2017). Activation of the parasympathetic nervous system results in a calm state, and activation of the sympathetic nervous system results in alert states or the 'flight and flight' or 'freeze' response (Champagne, 2008). For example, light touch and cold temperature activate the sympathetic nervous system and are considered alerting (Champagne & Kroomar, 2012). This type of sensory input can be used with patients who are depressed.

Information presented earlier indicates that people with anxiety have heightened arousal, emotions, and sympathetic systems, and are hypervigilant (Chu et al., 2022; Godoy et al., 2018; McCarty, 2016). In that regard, treatment that promotes self-regulation, self-soothing, and emotional regulation may be critical in managing these symptoms in childhood anxiety. Sensory modulation interventions are a self-discovery process that involves exploring sensory needs and preferences and providing children with calming strategies to teach regulation of arousal and improve emotional and behavioural responses to stimuli. They provide opportunities to help recognise and regulate sensory experiences, identify sensory preferences, and begin to heal the mind through sensations of the body (LeBel & Champagne, 2010). Sensory approaches can involve the use of single sensory modalities (e.g. listening to music), multi-sensory kits or strategies, and dedicated sensory rooms or environments, all of which can be used in times of distress (Champagne, 2011a). A further preventative approach is the

use of sensory 'diets', which involves the intentional application of calming or alerting stimuli through one's daily routines, to manage arousal levels and prevent under or over stimulation (Kinnealey et al., 1995).

Evidence for Sensory Modulation Intervention

Sensory modulation intervention has an emerging evidence base, which indicates it is effective in emotional regulation. However, most of the research involving people with mental health issues has been conducted with adults (e.g. Blackburn et al., 2016; Chalmers et al., 2012; Champagne, 2011b; Champagne & Stromberg, 2004; LeBel & Champagne, 2010; Lloyd et al., 2014; Moore, 2005; Sutton & Nicholson, 2011; Te Pou, 2011). These studies have found that sensory-strategies can be used to promote calm states, improve self-regulation, and increase engagement in activities of daily living (Champagne, 2011a&b; Engel-Yeger & Dunn, 2011; Porges, 2009; Sutton & Nicholson, 2011; Te Pou, 2011; Wallis et al., 2017). Studies also report that sensory modulation empowers and improves clients' repertoire of skills to deal with distressing situations (LeBel & Champagne, 2010; Sutton & Nicholson, 2011).

The evidence for sensory modulation intervention can be divided into single modality research and multimodal sensory strategies including sensory rooms. There is a range of evidence to support the use of single sensory modalities. For example, evidence suggests that slow rhythmic sensory input, such as a rocking chair, activates the parasympathetic nervous system via the vestibular system, resulting in a calming effect (Watson et al., 1998). Deep-pressure massage has also been reported to be calming and beneficial for reducing arousal symptoms associated with anxiety (Heard et al., 2012; Mollo et al., 2008; Spira, 2014; Streeter et al., 2010). The use of weighted modalities (e.g. heavy blankets or soft toys) to stimulate deep pressure receptors, has also been found to have some benefits in reducing anxiety (Becklund et al., 2021; Champagne, 2015; Eron et al., 2020; Mullen et al., 2008). Other research has found that the inhalation of specific aromas and scented oils has been found to stimulate the parasympathetic nervous response and enhance relaxation (Buckle, 2007; Maddocks-Jennings & Wilkinson, 2004). Listening to music for at least 30-minutes has successfully been used to induce relaxation in patients presenting with anxiety (Lin et al., 2011). Additionally, other forms of auditory input have been widely used to regulate mood (Canbeyli, 2013, 2021; Champagne & Koomar, 2012; Lepage et al., 2001).

Many of the studies evaluating multi-sensory interventions have been conducted in inpatient mental health units (Cameron et al., 2020; Doroud et al., 2024; Haig & Hallet, 2023), including a few with children (Garzotto et al., 2020; Unwin et al., 2021). Multisensory rooms have

shown promising results in assisting patients with emotion regulation and reducing distress across ages groups and diagnoses (Cameron et al., 2020; Haig & Hallet, 2023). In a pilot study undertaken within inpatient mental health units in NZ, sensory rooms reduced arousal, facilitated calm, supported self-management, and enhanced interpersonal connection (Sutton et al., 2013). Drawing attention to bodily sensation and/or the immediate environment, sensory modulation provided a distraction from intrusive cognitions such as anxious thoughts, delusional ideas, and auditory hallucinations (Sutton et al., 2013).

In addition to the use of multisensory strategies and rooms in inpatient mental health settings, multi-sensory interventions have successfully been applied in a group format and individually in community and outpatient settings (Champagne, 2011a; Champagne, 2011b; Champagne et al., 2010; Dempsey, 2016; Forsberg, et al., 2024; Pfeiffer, 2012; Wallis et al., 2017). In these exploratory studies, participants were supported to identify and apply a range of individualised sensory strategies to manage their anxiety. In addition to reduced anxiety symptoms, some of the studies reported improved functioning.

Multisensory interventions have also been combined with other therapeutic approaches, including CBT. For example, a case study by Champagne (2011b) tested a sensory modulation program for an adult with post-traumatic stress disorder (PTSD) and depression that combined CBT and sensory modulation. During the intervention, the patient created a customised sensory diet and a sensory kit of prescribed tools and strategies that were easily accessible to implement during distress (Champagne, 2011b). The study showed that the sensory diet significantly and positively impacted the patient's ability to work, reduced nightmares, and improved concentration (Champagne, 2011b). While the research related to using sensory modulation with adults is promising, there are very limited studies on the use of sensory modulation with younger children in mental health settings. However, some studies have explored the application of sensory strategies with children in different health contexts, and these are reviewed below.

Application of Sensory-Based Strategies with Children

While there are no studies that have explored the application of sensory strategies for younger children with clinically significant anxiety, several exploratory studies have tested interventions for children with self-regulation issues following trauma (Da Silva, 2011; Finn et al. 2017; Purvis et al., 2013; Raider et al., 2008; Ryan et al., 2017; Taylor, 2019). These interventions incorporated a range of sensory strategies and achieved positive outcomes. For example, Purvis et al. (2013) described gains made by children with a history of trauma who completed the Trust-Based Relational Intervention (TBRI), a therapeutic model that trains

caregivers to provide effective support and treatment for at-risk children. Purvis's study was a pre- and post-measure study with 18 participants aged from 3-18. The intervention included sensory-rich activities that promoted calming and self-regulation and were shown to be helpful. Similarly, Ryan et al. (2017) described a case study of a 4-year-old who received a multidisciplinary model for treating complex trauma in early childhood. The intervention had a strong neurodevelopmental base with an emphasis on relationship-building and regulation-enhancing activities. The authors described the successful application of sensory modulation and the benefits of using sensory diets to promote self-regulation. Finn et al. (2017) described the application of the Sensory Motor Arousal Regulation Therapy (SMART) programme with a 7-year-old traumatised boy. The programme aimed to enhance sensory-motor engagement and promote affective, behavioural, and physiological regulation using somatic regulation and sensory integration techniques (Finn et al., 2017). It was specifically designed for traumatised children who may have limited capacity for engaging in talking-based therapies (Finn et al., 2017). The result of the intervention indicated the child had improved communication of emotions, increased self-regulation capacity, and increased connection with his parents. However, no firm conclusions can be drawn about the efficacy of these interventions due to methodological limitations, including small sample sizes (Finn et al., 2017; Purvis et al., 2013; Ryan et al., 2017). Finn et al.'s (2017) study lacked post-intervention measures of the symptoms targeted by the intervention, and Ryan et al. (2017) lacked pre- and post-measures to assess progress and only gathered parent and therapist feedback. Nonetheless, the studies provide preliminary evidence to support the use of sensory and somatic-based interventions for emotional and self-regulation.

Despite these studies being targeted at children with experience of trauma, the successful use of sensory-based strategies has relevance for children with anxiety because hypersensitivity to potential threats and a strong sympathetic nervous system response are common in both anxiety disorders and trauma (O'Donovan et al., 2013). Two separate studies by Da Silva (2011) and Taylor (2019) also highlighted the benefits of sensory approaches with self-regulation and grounding in children with trauma. Da Silver (2011) completed an exploratory qualitative study with four social workers who used sensory treatment in combination with other approaches to treat children with histories of trauma. Findings from Da Silva (2011) indicate that the sensory treatments were effective and were rated highly by the participants. Taylor (2019) explored the use of a combination of sensory and trauma focussed CBT for maltreated children in New Zealand. Taylor's (2019) findings showed promising results of the combined intervention in the treatment of maltreated children. Raider et al. (2008) completed an RCT of the Youth Structured Sensory Therapy for Traumatized Adjudicated Adolescents in Residential Treatment (SITCAP-ART) and found evidence to support the use of sensory

strategies to reduce trauma symptoms. The SITCAP-ART was designed to treat terror symptoms in traumatised individuals from pre-schoolers to adults. Raider et al.'s study had 23 children aged 15 to 18-years, and the results demonstrated the programme was effective in reducing trauma-related symptoms and improving mental health symptomatology. These six studies Purvis et al. (2013), Ryan et al. (2017), Finn et al. (2017), Da Silva (2011), Taylor (2019), and Raider et al. (2008), highlighted the benefits of sensory strategies in improving self-regulation, challenges that are also evident in children with anxiety.

Keehn et al. (2012) modified the Coping Cat programme by making sensory and motor adaptations for the treatment of anxiety in 8 to 14-year-old children with Autism. The results provided preliminary evidence to support the use of a modified anxiety programme to reduce clinically significant levels of anxiety in children with high-functioning Autism. Two further studies evaluated the uses of sensory strategies to help children manage surgical and dental anxiety (Ahmed et al., 2011; Reynolds et al., 2023). In peri-operative care, sensory-based strategies (deep breathing exercises, tactile toys, videos, touring the facility, play, diversion, and books) were shown to be helpful in reducing anxiety in children before surgery (Ahmed et al., 2011). McTee et al. (2019) found that visual approaches may reduce stress in children 4 to 12-years-old with Autism during audiological testing. In medical needle procedures, the use of visual distractions and breathing techniques was found to be helpful in reducing pain in a Cochrane review (Birnie et al., 2018). Similar results were reported in systematic reviews (Bodison & Parham, 2018; Reynolds et al., 2023), which highlighted the use of sensory strategies, including various visual, tactile, and auditory adaptions, to effectively reduce anxiety before dental procedures. From the limited research into using sensory strategies for self-regulation and management of anxiety in children, it can be postulated that sensory strategies may be beneficial to promote emotional regulation and dampen the sympathetic response in children with clinically significant anxiety.

Summary of Evidence on the Use of Sensory Modulation for Anxiety

The sensory modulation intervention literature reviewed showed promising results in the treatment of anxiety (Champagne, 2011a&b; Champagne & Stromberg, 2004; Champagne et al., 2010; Dempsey, 2016; Pfeiffer, 2012; Wallis et al., 2017). Sensory modulation intervention uses sensory-based strategies to reduce the physiological responses (or 'flight and fight') associated with anxiety and provides an alternative or complementary modality to CBT. While CBT has the most evidence for its effectiveness, it has been argued that it may not be appropriate for everyone (Månsson et al., 2020) hence, alternative strategies such as sensory modulation have started to gain more recognition. While several studies have shown that the use of sensory modulation strategies can reduce anxiety and associated distress in adults

(Champagne, 2011b; Champagne & Stromberg, 2004; Champagne et al., 2010; Dempsey, 2016; Pfeiffer, 2012, Sutton et al., 2013; Wallis et al., 2017), no intervention studies have been conducted with younger children experiencing clinically significant anxiety.

Studies involving children have established a relationship between sensory processing disorder and anxiety and how sensory modulation interventions can assist with reducing anxiety and distress (Houghton et al., 2020; Lane et al., 2012; MacLennan et al., 2021; MacMahon et al., 2019). MacLennan et al (2021) states that their findings suggest that sensory sensitivity is a key early factor in the development of anxiety. Based on the findings of these studies (Houghton et al., 2020; Lane et al., 2012; MacLennan et al., 20201; MacMahon et al., 2019) it is evident that helping young children manage their sensory sensitivity may have a significant impact on their anxiety. In adult studies, the relationship between anxiety and sensory modulation has been established with findings showing the benefits of using sensory approaches in reducing anxiety (Champagne, 2011b, Dempsey, 2016; Wallis et al 2017). In that regard, it could be argued that since all human beings have the same basic anatomical and physiological architecture, sensory modulation strategies should also work for children since sensory modulation intervention targets the physiological system to reduce anxiety. For example, a young child can be calmed down by a rocking motion, which also calms down an adult through the use of a hammock. Sensory modulation may benefit children because it is body-based and has fewer cognitive requirements, utilising simple sensory toys and strategies (Halder & Mahato 2019; Garber et al., 2016; Grave & Blissett, 2004). Even young children can be empowered to learn sensory strategies they can use to regulate their emotions (Steele & Kuban, 2013). In the current study, two sessions based on sensory modulation were integrated into the intervention. These focused on educating the child and family on how sensory modulation intervention works, determining the child's sensory preferences, creating a sensory diet, and embedding it in the child's daily life. A similar structure of education, identification of sensory strategies and embedding these in daily life has been successfully used in adult-focused studies (Champagne, 2011b; Champagne et al., 2010; Pfeiffer, 2012).

Justification for the Present Study

Despite the need for early intervention, treatment of anxiety in younger children has received little scientific inquiry, with gaps in age-appropriate interventions for this population (Barrett et al., 2015; Minde et al., 2010; Rapee & Sanderson, 1998). Several outcome studies have specifically evaluated the efficacy of CBT interventions for children 7-years and younger living with anxiety (Barrett et al., 2015; Creswell et al, 2014; Donovan & March 2014; Hirshfeld-Becker et al., 2008; Hirshfeld-Becker et al., 2010; Hirshfield-Becker., et al., 2011;

Monga et al., 2009; Monga et al., 2015; Minde et al., 2010; Waters et al., 2009). However, because of the limitations of using CBT with young children, highlighted earlier, it is sensible to develop other approaches that will be developmentally appropriate for young children with anxiety. In that regard, children may better engage with sensory-based strategies that do not have huge cognitive requirements. Considering the prevalence of childhood anxiety and the seriousness of its consequences if untreated, more studies that specifically focus on the effectiveness of psychological interventions with children younger than 7-years are needed.

Existing mental healthcare delivery paradigms seek to substantially reduce symptoms, decrease relapses, promote recovery, and improve quality of life (Saraceno, 2004). The focus is on teaching service users' skills or providing care that will allow them to function independently in all aspects of life (Saraceno, 2004). This is achieved by providing a range of interventions such as medications, CBT, behaviour modification, ACT, and DBT. Sensory modulation fits well within this paradigm as it provides skills for enhancing control and modulation of emotions, improving engagement and resilience, and coping skills, which greatly benefit people living with mental health conditions (Champagne, 2008; Sutton & Nicholson, 2011; Te Pou, 2011).

In addition to developing individual self-management and coping skills, the intervention piloted in the present study will seek to develop social support and family involvement. Focusing on involving families and working within the social context of service users aligns with current mental healthcare policy (Mental Health Commission, 2012). Meta-analytic studies have demonstrated that the involvement of parents in the treatment of their children enhanced child health outcomes (Dowell & Ogles, 2010; Karver et al., 2006). Parents have a critical role in the child's development, and their involvement in treatment allows them to support their child's changed behaviour (e.g., parents managing the child's anxiety) and further act as effective role models for their children (Aydin, 2014; Brendel & Maynard, 2013; Haine-Schlagel & Walsh, 2015; Wood et al., 2006). Literature also indicates that parental involvement facilitates increased treatment attendance (Reimers & Wacker, 1988; Sekhon et al., 2017; Tarnowski & Simonian, 1992). If the child and parents find an intervention acceptable, they are more likely to adhere to it (Sekhon et al., 2017). Intervention acceptability refers to whether the family or clients perceive the intervention as effective (Sekhon et al., 2017). Parental acceptance of a proposed intervention may significantly impact usage health outcomes, including compliance, early treatment termination, and rates of improvement (Sekhon et al., 2017). Therefore, this study will focus on evaluating the effectiveness of the modified CBT and sensory-modulation intervention, the acceptability and practicality of the sessions, specific strategies, and the overall intervention.

Conclusion

The literature highlights several issues regarding childhood anxiety assessment and management that need attention to improve the health outcomes of young children presenting with anxiety. First is the lack of evidence-based interventions for children under 7-years presenting with anxiety; second, is difficulty accessing psychological services for children; and third, is the lack of skilled professionals available to deliver such therapy. The literature has also revealed the importance of early intervention for children living with anxiety by involving parents and the benefits of abbreviated CBT sessions. To address these issues a modified CBT-sensory modulation intervention was designed specifically for younger children experiencing anxiety with the inclusion of their families. The following chapter outlines the process involved in developing the intervention manual.

Chapter 3:
Intervention Manual Development

Introduction

This chapter describes the development of the 6-session manualised intervention for anxiety (see Appendix A) that was evaluated in the present study. The discussion includes information on how the idea came into being and theories of intervention development that guided the process. The Coping Kiwi manual developed by Girling-Butcher and Ronan (2002) was chosen as the base manual that guided the development of the first three sessions of the new intervention manual. The other two sessions were guided by sensory modulation theory. This chapter provides detailed descriptions of the processes involved, from beginning to end, to ensure that the process is replicable. It also describes how the decision was reached to choose the Coping Kiwi manual as the base manual.

Rationale for Developing the Manual Tested in This Study

The intervention manual developed and tested in this study was inspired by the researcher's experience as an occupational therapist and mental health clinician working with younger children experiencing mental health challenges. While working with these children, the researcher identified a therapeutic gap that needed filling. Drawing on the researcher's clinical experience and knowledge, there was an urgent need to develop an intervention for anxiety specific to younger children that included them as active participants.

While there are several manualised CBT interventions for anxiety for children over 8 years of age, teenagers, and adults, there are few manualised interventions that are developmentally appropriate for children under the age of 7-years. This limitation in the available interventions has been noted by Minde et al (2010) and Barrett et al (2015). Presently, children need to wait until they are 8 years of age before they can receive evidence-based treatment, in which they can actively participate and learn how to manage or reduce their anxiety. At 8 years of age, the cumulative effect of not receiving early treatment may have lasting consequences on the child's quality of life and functioning.

Due to the overwhelming evidence that supports the effectiveness of manualised treatments (e.g. Barrett et al., 2015; Bayer et al., 2011; Girling-Butcher & Ronan, 2002; Kendall & Hedtke, 2006a; Kendall & Hedtke, 2006b; Khanna & Kendall, 2008; Rapee, 2013; Minde et al., 2010) the researcher decided to test a novel intervention manual that combined CBT and sensory modulation. The reason for combining these two approaches in one module was to

provide more than one strategy. Interventions that provide multiple strategies are more likely to produce change (Webb et al., 2010a). The same approach is the basis of mindfulness-based cognitive therapy and cognitive behaviour play therapy (Knell, 2022) manuals. Furthermore, the researcher wanted the programme to be developmentally appropriate by including sensory modulation, which requires minimal verbal and cognitive requirements. Since sensory modulation uses senses and toys, the researcher was confident it would be offered in a developmentally appropriate and enjoyable way for children.

Theoretical Foundations of Existing CBT and Sensory Modulation Manuals

Overview of Evidence Supporting Manualised Interventions

Compared to non-manualised interventions, manualised interventions improve patient outcomes and promote replicability (Blanche et al., 2011; Goldstein & Kemp, 2012). The development of manualised interventions has become a central component of clinical research (Addis, 1997; Goldstein & Kemp, 2012). Manualised interventions have gained popularity in clinical practice for treating conditions such as anxiety, obsessive-compulsive disorder (OCD), depression, and self-harming (Forbat et al., 2015). Manualised interventions dictate the treatment, systemise interventions, improve treatment fidelity, and facilitate/improve well-designed treatment and clinical outcomes (Kazdin, 2001; Nezu & Nezu, 2008; Rounsaville et al., 2001). Consequently, intervention manuals are considered the most efficacious tools for delivering empirically supported prevention and treatment programmes (Addis, 1997; Chambless & Hollom, 1998; Fraser & Galinsky, 2010; Goldstein & Kemp, 2012).

While intervention manuals are widely supported, they have also been criticised for lack of flexibility in addressing nuances of clinical practice with diverse clients and a lack of opportunity for clinicians to incorporate their clinical expertise (Addis & Krasnow, 2000; Carroll & Nuro, 2002; Kazdin & Kendall, 1998; Rounsaville et al., 2001). Despite these limitations, manualised interventions are still advantageous for delivering behavioural treatments because they provide standard guidance on delivering certain interventions to ensure they are delivered with high fidelity and provide a platform to track, refine, and advance research of empirically supported treatments (Carroll & Nuro, 2002). In mental health, manualised interventions help therapists plan treatments, guide and aid clinical work, and improve their therapeutic skills (Blanche et al., 2011; Carroll & Nuro, 2002; Nezu & Nezu, 2008; Pyatak et al., 2015; Rounsaville et al., 2001; Stern et al., 2021).

CBT Manuals

Several treatment manuals primarily based on CBT have been developed for the treatment of anxiety (Kendall & Hedtke, 2006a; Kendall & Hedtke, 2006b; Khanna & Kendall, 2008;

Rapee et al., 2006), depression (Curry et al., 2000; Muñoz et al., 2000; Rosselló & Bernal, 2007), personality disorders (Davidson, 2007; Wood, 2010), ADHD (Safren et al., 2004), and many others. CBT-based treatment manuals have also been developed for physical conditions such as pain (Carlson, 2014; Palermo et al., 2016), chronic illnesses (e.g., Human Immunodeficiency Virus-HIV, hypertension, cancer, diabetes type 1 and 2) (Kennard et al., 2014; Safren et al., 2007; Safren et al., 2015; Safren et al., 2021), and for children and adults with intellectual disabilities (Malovic et al., 2018). These treatment manuals aim to reduce negative symptoms and promote good mental health and quality of life for children and adults. The main areas covered by the manuals include cognitive restructuring; linking thoughts, feelings, and behaviours; decreasing negative automatic thoughts; skills building; coping strategies; and adherence. As discussed in Chapter 2, manualised interventions have been shown to be effective in helping children manage their anxiety (Arendt et al., 2015; Barrett et al., 1996; Djurhuus & Bikic, 2019; Girling-Butcher & Ronan, 2002; Hudson et al., 2009; Hudson et al., 2015; Kendall & Hedtke, 2006a). However, despite these programmes being effective, only one manual was found that was not delivered in a group setting and exclusively included children under the age of 7-years, and their parent(s)/guardian(s) (Minde et al., 2010).

Sensory Modulation Manuals

Sensory modulation evolved from the original work by Jean Ayres (1968, 1972, 1979) on sensory integration. To ensure that sensory integration was delivered with fidelity, Hunt et al. (2017) developed a manual on how to deliver sensory integration to children with Autism. Champagne (2008) developed sensory modulation intervention programmes that guided the employment of sensory modulation concepts and strategies in different mental health settings. These guidelines provide valuable information on how to deliver sensory modulation interventions to various populations presenting with different mental health conditions, particularly within inpatient settings. There is a dearth of literature on the effectiveness of these programmes that demonstrates sensory modulation is an effective intervention in mental health (Sutton et al., 2013). As the pressure to develop evidence-based interventions increases, occupational therapists must develop sensory modulation intervention manuals that can stand scientific scrutiny (Blanche et al., 2011). In the same vein, no published sensory modulation intervention manuals have been developed for use in mental health or specifically for the management of childhood anxiety; only treatment programmes that offer general information for adults have been developed; for example, the Sensory Connection Program by Moore (2006).

Theoretical Foundation of CBT for the Treatment of Anxiety

As discussed extensively in previous chapters, CBT aims to target maladaptive thinking patterns and unwanted behaviours and replace them with desirable behaviours and adaptive ways of thinking (Brewin, 1996; Fenn & Byrne, 2013; Knapp & Beck, 2008). The goal of therapy is to help people develop new sets of beliefs that counteract old negative thoughts (Brewin, 1996; Fenn & Byrne, 2013; Knapp & Beck, 2008). Thus, the theoretical foundations of CBT formed the basis of the first three sessions of the intervention that was developed and tested in this study.

Theoretical Foundations of Sensory Modulation for the Treatment of Anxiety

In occupational therapy, the term sensory modulation also refers to the 'intervention', which is the use of sensory-based strategies for regulating sensory input. As reviewed in Chapter 2, sensory modulation approaches intentionally use sensory tools and strategies to alter an individual's physiological arousal levels, resulting in behavioural and emotional responses corresponding to environmental demands (Champagne, 2008). Hence, sensory modulation guided the development of sessions three to five of the intervention manual tested in the current study. The literature aided the selection of appropriate sensory strategies for reducing anxiety by providing a calming response.

Considerations in Developing Interventions for Children

Guidance on considerations when developing interventions for children were sought from work by The Social Research Group at Darlington (2013). Using this guidance, the following considerations were made.

a) Intervention specificity: This area focused on answering four questions.

1. *Who is this intervention trying to help (target population)?*

The intervention was developed explicitly for children 4 to 7-years-old presenting with anxiety and their parent(s)/guardians(s).

2. *What is to be achieved?*

The purpose of the intervention was to provide early and age-appropriate treatment for the target group. The intervention focussed on providing the parent(s)/guardian(s) and the child with skills to manage childhood anxiety. A description of the intervention is presented at the end of this chapter.

3. *What evidence underpins the intervention?*

CBT and sensory modulation research underpin the intervention tested in this study. This is described in detail in Chapter 2 and is presented briefly under the theoretical foundation of CBT intervention for anxiety and the theoretical foundation of sensory modulation intervention for the treatment of anxiety in this chapter.

4. *Is the intervention logical and practical?*

The language, concepts and approach of the intervention tested in this study were adjusted to be developmentally appropriate for the target population. The intervention was logical and practical concerning the number of sessions, duration, the material covered, and the sequencing of sessions.

b) System readiness: focuses on the resources required for the intervention to be delivered, including therapists, therapist's training, and the manual. Therapists who delivered the intervention were trained in how to deliver the intervention as outlined in the manual.

Methodology Guiding the Manual Development

While most guidance for manual development focuses on a step-by-step process for creating new intervention manuals from scratch (e.g. Carroll & Nuno, 2002), the manual used in the current study was developed from a base manual. Therefore, Goldstein et al.'s (2012) guidelines for adapting existing manualised interventions was the most suitable framework to guide the process. Goldstein et al.'s (2012) framework was enriched by the work of several other authors (Campbell et al., 2007; Carroll & Nuno, 2002; Fraser et al., 2009; Fraser & Galinsky, 2010; Galinsky et al., 2012; Heath et al., 2015; O'Cathain, 2019; Onken et al., 2014; Pyatak et al., 2015; Wight et al., 2014). This included guidelines produced by the Medical Research Council (2019) on developing complex manualised interventions for health promotion. The approach to manual development taken is supported by O'Cathain et al. (2019) and Taylor et al. (2013) who emphasise intervention manuals should be based on sound theoretical knowledge.

Methods – Steps Completed for Developing the Manual Tested in This Study

Step 1 – Choosing a Relevant Base Manual to Adapt

(a) Identify an empirically supported intervention

Evidence-based interventions that promote children's mental health and wellbeing were reviewed, as Arbesman et al. (2013) recommended. The literature strongly indicated that CBT is the intervention of choice for treating childhood anxiety (Pegg et al., 2022), which was the

study's primary focus condition. The evidence also showed that manualised interventions are efficacious in treating children's anxiety (e.g. Davis et al., 2011; Silverman et al. 2008).

A review of relevant manuals that could be considered for adaptation was completed. The 'Cool Kids' (Rapee et al., 2006) and the 'Cool Little Kids' (Rapee, 2013) manuals were excluded from consideration because adaptations, modified versions, or reproductions of any part of it these programmes is not permitted. The CBT manual by Minde et al. (2010) was excluded because it was not extensively tested. Since the study would be conducted in NZ, the 'Coping Kiwi' intervention manual (Girling-Butcher & Ronan, 2002) was selected as the base manual because it was local and had promising results. In line with Goldstein et al.'s (2012) guidance, the Coping Kiwi manual was further reviewed to identify its benefits, deficits, theoretical foundations, and adaptability, as outlined below.

(b) Review the intervention's theory and mechanisms of action

Kazdin's (2002) three questions for evaluating therapy research were used to evaluate the Coping Kiwi manual and assess the basis of the new intervention manual to be developed. The questions asked were:

1. What is the theoretical foundation of the Coping Kiwi intervention manual?

The Coping Kiwi intervention manual is strongly grounded in CBT theory, and this guided the development of the first three sessions of the new manual.

2. What are the components of the Coping Kiwi intervention that contribute to therapeutic change?

The key components of the Coping Kiwi intervention include psychoeducation, focus on current worries (anxieties), targeting maladaptive thoughts, structuring the intervention sessions, management of parental anxiety, positive parenting, strategies for anxiety, providing an opportunity for practice through homework, emotion regulation, calm down strategies, relaxation, and parental involvement within the therapy process. These components were incorporated in the new manual, forming the main components of sessions one to three.

3. What therapeutic processes are thought to mediate intervention outcomes?

Literature shows that psychological therapies can improve psychological symptoms and increase daily functioning (Smith-Hansen & Probert, 2014). The strength of the therapist-patient alliance (Godfrey et al., 2007; Newman & Stiles, 2006); therapist technique and skills (Newman & Stiles, 2006; Podell et al., 2013); participant factors (i.e., severity, chronicity, co-morbidity, patient attitude, age, sex) (Bohart & Wade, 2013; Firth et al., 2019; Newman & Stiles, 2006); and therapist countertransference (Smith-Hansen & Probert, 2014) have been

identified as mediators that predict health outcomes. Ardito and Rabellino (2011) state that a stronger therapist-patient relationship is associated with better treatment outcomes. The idea of facilitating better relationships between the therapist and the patient was included in the intervention by including feedback informed treatment principles and tools (Prescott et al. 2017). For example, feedback from parent(s)/guardian(s) and children could be discussed to resolve any issues identified in therapy, promoting good therapeutic relationships between the therapist, child, and parent(s)/guardian(s). Specific CBT techniques such as cognitive restructuring, exposure, and behaviour modification reduce symptoms and maximise positive outcomes (Woody & Ollendick, 2006). These three techniques were included in the manual and were taught to parent(s)/guardian(s) so they could be more aware of any inaccurate perceptions regarding their child's anxiety. For example, people with anxiety catastrophise their fears, but these inaccurate perceptions can be objectively disconfirmed through cognitive restructuring and the fears reduced (Woody & Ollendick, 2006). These techniques were included in the new intervention manual, which were used to help children think differently about their anxieties, worries, and fears.

Another key therapeutic process that mediates treatment outcomes is teaching children emotion regulation strategies (Sloan et al., 2017). This concept is used in CBT (Asnaani et al., 2020; Muñoz-Navarro et al., 2022) as well as sensory modulation (Rodríguez & Kross, 2023). Sensory modulation interventions are based on the interconnectedness of the sensory, autonomic and endocrine systems, and how people can regulate their emotions using different sensory modalities (Buckle, 2007; Canbeyli, 2013; Champagne & Koomar, 2012; Garner et al., 2008; Heard et al., 2012; Lepage et al., 2001; Maddocks-Jennings & Wilkinson, 2004; Mollo et al., 2008; Mullen et al., 2008, Streeter et al., 2010; Watson et al., 1998). The most common example of a self-regulation strategy, used in both CBT and sensory modulation, is the use of diaphragmatic breathing. This form of deep, slow breathing can counteract the rapid shallow breathing and increased heart rate associated with anxiety and fear. Mastering emotion regulation reduces maladaptive behaviour (e.g., avoidance) and improves health outcomes (Asnaani et al., 2020; Muñoz-Navarro et al., 2022; Sloan et al., 2017). This therapeutic process is essential in managing phobias and other types of anxiety, such as generalised anxiety (Zsidó et al., 2023) and is most effective when used to cope in anxiety-provoking situations (McCurry, 2015). In the current study, children were taught developmentally appropriate emotion regulation strategies in sessions four and five to help them cope with stressful situations. For example, children learnt to use sensory strategies, such as auditory input (e.g. listening to relaxing music) and deep pressure touch (e.g. using weighted toys), to calm down when anxious.

Several client factors have been identified as determining treatment outcomes (Bohart & Wade, 2013; Firth et al., 2019; Newman & Stiles, 2006). If clients do not believe in or are not satisfied with therapy, the psychotherapy intervention is less likely to be effective due to early dropout or poor adherence (Kullgard et al., 2022; Lindhiem et al., 2014). With this in mind, it is important that children and their parents are given clear explanations as to how the intervention works to produce positive change. In the new intervention manual, psychoeducation was included as a strong intervention component to ensure the child and their parent(s) understand anxiety and how the intervention works.

Good parental support and engagement in therapy has also been attributed to better treatment outcomes for children with psychological disorders (Siddaway et al., 2013; Aydin, 2014; Brendel & Maynard, 2013; Haine-Schlagel & Walsh, 2015; Walczak et al., 2016). Accordingly, the intervention manual in the current study emphasises the importance of the role of parent(s)/guardian(s) in the treatment process. This is supported by Comer et al. (2019) who found that parental/guardian involvement is linked to better treatment outcomes for children with anxiety. Therefore, family-based treatments, including the child, are effective in the management of anxiety in children. For that reason, this new intervention includes the child and their parent(s)/guardian(s).

(c) Determining the Adaptability of the Coping Kiwi to the New Target Population

The Coping Kiwi manual was evaluated for adaptability, and it was determined that it could be modified to suit the intended population. This decision was based on theoretical compatibility with the target group, positive outcomes recorded on the target behaviour, and implementation feasibility (Goldstein et al., 2012). The decision for the manual to have six sessions was based on several factors, including the need for a shorter intervention to maintain interest, reduce the time commitment for parents and avoid dropouts. Studies of similar programmes have reported good outcomes with between 6 and 10 sessions (Barrett et al., 1996; Kendall & Southam-Gerow, 1996; Rapee et al., 2006).

Step 2: Conduct a Focus Group for the New Target Population

The consultation process with experts and cultural advisors was an ongoing process until the completion of the final draft of the intervention manual. This was completed before the treatments began. Parents of young children were not consulted due to the time constraints of the doctoral programme.

Expert Consultation

The researcher consulted several professionals and gained feedback during the development process of the intervention manual tested. Feedback guided the manual development,

implementation, training of therapists, and refining (Carroll & Nuro, 2002; Onken & Blaine, 1997). Two clinical psychologists with mental health practice experience were consulted to give feedback on the intervention manual. One psychologist had experience working with children, and the other had experience working with adults. Additionally, the supervisory team had experience and expertise in sensory modulation and CBT interventions for children and were consulted throughout the study. The supervisory team included a clinical psychologist with many years of experience working with children and families, an occupational therapist with extensive experience in research and sensory modulation, and a nurse with extensive experience in undertaking research with children. Fortnightly meetings with the clinical psychologists and monthly meetings with the supervisors were held throughout the development of the final draft of the intervention manual.

Māori Cultural Consultation

Considering the population of the region in which the study was conducted, there was a possibility that Māori participants would be identified and keen to participate in the study. Hence, cultural advice was sought during the development of the intervention manual through cultural consultation with the local DHB. More information on cultural consultation is discussed in Chapter 4.

During the manual development process, the draft intervention manual was shared with the designated cultural advisor from Māori Health Services. The advisor discussed the manual with two other senior cultural advisors before meeting with the researcher in person. During the first meeting, the intervention and the key drivers for the research were discussed. Since the advisors were not clinicians, detailed descriptions of CBT and sensory modulation were provided to the advisors, as well as how the study would be conducted. Furthermore, there was a discussion about naming the manual. The researcher initially named the manual and programme 'Being Brave' following the work of Hirshfield -Becker et al (2019) but was keen for the manual to have a Māori name. The English name of the manual was translated to the Māori name 'Ngā Timatanga Toa' which became the official name of the intervention manual and programme. 'Being Brave' emphasised the need to teach children with anxiety to be brave and face their fears. For parents, the name would provide them with the strength to praise brave behaviour when their children faced fear.

Weekly meetings with the designated Māori cultural advisor were scheduled until the manual was finalised. During the regular meetings, the advisor shared how sensory modulation principles resonate with traditional Māori health and treatment views. For example, the advisor said from a Māori people's perspective, music vibrates the brain, which results in a calming effect; that is why nga wāiata is an important part of Māori people. The advisors confirmed

the appropriateness of using sensory modulation strategies with Māori participants. The advisor also used the Te Whāriki metaphor to describe the link between intervention components. The metaphor symbolises woven strands, each strand representing a key principle. The Ministry of Education (1996) developed the Te Whāriki principles, which were incorporated into the development of the manual, as shown in Table 3.

Table 3

The Incorporation of the Te Whāriki Principles in the Manual Development Process

Principle	Description
Mana Atua (well-being)	All sectors should promote good mental health, physical health, and wellbeing of children that should start early. In the same vein, the intervention manual developed supports good mental health and well-being of children and their families.
Mana Tangata (contribution)	The findings of this study will contribute to the body of knowledge on treatment for children with anxiety.
Mana Reo (communication)	The intervention teaches children to communicate their emotions and feelings better to their parent(s)/guardian(s). For parent(s)/guardian(s), the intervention teaches them to communicate clearly with their children, particularly concerning what and how to communicate to their anxious children.
Mana Aotūroa (exploration)	The intervention manual encourages children to explore their emotions to understand better how they feel in different situations. The manual teaches parents to be their children's detectives and explore their children's emotional profiles, including things that worry them and things that provide comfort. This principle of exploration resonates with CBT and sensory modulation, where one explores one's thoughts, emotions, feelings, behaviours, and calm-down strategies.

Step 3: Making Initial Manual Revisions – Development of a New Manual from the 'Coping Kiwi' Manual and Sensory Modulation Material

The intervention has six sessions: three sessions based on CBT, two sessions based on sensory modulation, and a final concluding and celebration session. Based on the intended final product, the Coping Kiwi manual was modified to develop the first three sessions of the manualised intervention tested in this study. Adaptations were made for the language to be developmentally appropriate for younger children, and changes were made to the structure and length of the sessions. The new manual used a structured approach based on the KICK plan from the work of Wood and McLeod (2008). The KICK plan was used to structure treatment sessions for anxiety. K stands for Knowing when you are nervous, I stands for Identifying icky thoughts and encouraging independence, C stands for Calm your thoughts, and K stands for Keep practising. With the authors' permission, an extra I was added to the KICK plan to make

it the IKICK plan. The added I stands for interests. The interests component was added to help the therapist explore the child's interests at the beginning of therapy. The interests were used to develop appropriate therapeutic activities for, and in collaboration with, the child. These activities were also used in sessions four and five to develop sensory-based calm-down strategies for children. Including the child's unique interests allowed the therapy and sensory strategies to be tailored to each child. This is because sensory-based strategies are not a 'one size fits all'; they are unique to each individual child based on their needs and sensory preferences.

Procedural changes to the manual included adding feedback-informed treatment measures. The administration of feedback-informed treatment tools (i.e., Outcome Ratings Scale [ORS] and Session Rating Scale [SRS]) were added at the beginning and end of sessions two to six. These tools are based on the work of Miller et al. (2003) and Bringhurst et al. (2006), which improve therapeutic alliance and lead to better treatment outcomes. The therapists used these tools to gain meaningful feedback from children and parent(s)/guardian(s) about therapeutic progress and change.

Structuring the sessions provides a consistent format for how the therapy sessions progress. The structure of the sessions from the Coping Kiwi intervention manual was slightly modified in the new manualised intervention. To ensure the sessions were appealing and interesting for children, at the beginning of every session, each child participant was asked to choose an activity or game they wanted to play at the end of each session as a reward for participating. This would maintain their engagement and motivation.

The sessions have several activities. At the beginning of sessions two to six, the therapist reviews homework from the previous session with the parent(s)/guardian(s) and child. During the homework discussion, the therapist reinforces the importance of homework and practice to the parent(s)/guardian(s) and child. The therapist also allows time for the parent(s)/guardian(s) and child to ask questions. This approach supports the development of good therapist-patient relationships, collaboration, and partnership for improved health outcomes. Since the intervention tested in this study are for younger children, parent(s)/guardian(s) form essential partners of the treatment team since they work as co-therapists, coaches, and mentors for their children. Additionally, parent(s)/guardian(s) are taught strategies to support their children and help them through anxious situations. Parent(s)/guardian(s) also receive support for themselves to overcome anxiety, and their beliefs and perceptions about their child's anxiety are modified to find better ways to support their children.

Results: Intervention Manual (Ngā Timatanga Toa)

The result of the steps described earlier was the intervention manual tested in this study (see Appendix A). The manual comprises a 6-session intervention that combines CBT principles and sensory modulation. Each session is delivered in between 60 and 90-minutes. The detailed intervention manual is attached in Appendix A. The six sessions are briefly described in Table 4 below.

Table 4

The Intervention

Session	Content covered
1	The child and their parent(s)/guardian(s) are introduced to the intervention. The session aims to improve their understanding of anxiety, how it affects their child's function and family life, and strategies that help manage anxiety.
2	The child is taught to identify signs of anxiety. It also teaches the parent(s)/guardian(s) how to notice their child's physical signs and behaviours of anxiety.
3	This is a continuation of session two and focuses on making the connections between anxious (unhelpful) thoughts and what the child feels in their body. Sessions one to three are based on CBT.
4	Teaches the child relaxation techniques using sensory-based strategies (e.g., listening to music, getting a hand massage, doing physical activity, deep breathing exercises, using different smells for relaxation, etc.). The children would make a sensory box with sensory based toys to assist them with calming. The parent(s)/guardian(s) will be encouraged to identify activities that calm their child when worried. The parent(s)/guardian(s) and their child are also taught how to use these activities in times of distress to help the child calm down and relax.
5	Teaches the parent(s)/guardian(s) and their child ways of ensuring that calming activities are practised daily and become part of the child's daily routine.
6	A consolidation and celebration session. Summarises all the materials covered from sessions one to five and encourages the parent(s)/guardian(s) and their child to continue using the skills taught.

* A sensory box is a personalised resource that contains sensory items (e.g. fluffy toy, magazine, tactile toy, headphones, music player, etc) that an individual uses to regulate their sensory experiences or arousal.

Step 4: Pilot Initial Revisions of the Manualised Intervention

The new intervention manual was pilot-tested (current study), and feedback received from the participants are presented in the results chapter. Feedback covered the duration, content, process, activity, feasibility, and benefits of the intervention as a whole.

Steps 5-9:

These steps will be conducted during a second phase of manual refinement, using feedback from the present study. Step five involves conducting a facilitator focus group and making adaptions and creating the second draft. Step six involves acquiring expert feedback of the second draft and step seven involves incorporating feedback from facilitators and expert and updating the manual. Step eight involves the initial open trial of the revised manual and step nine is conducting a randomised clinical trial of the final revised manual.

Conclusion

This chapter has described the development of the Ngā Timatanga Toa: Anxiety Intervention Manual for children aged 4 to 7-years with anxiety. The intervention was designed to be delivered with children and their parent(s)/guardian(s) and uses developmentally appropriate language and activities. The content teaches children basic strategies to manage their worries and provides parent(s)/guardian(s) with ways to support their children in developing resilience and coping tools. The intervention manual is based on multiple theories and sound theoretical knowledge. It provides flexible guidance on delivering CBT combined with sensory modulation, allowing therapists to incorporate their clinical skills, knowledge, and experience depending on the situation, clinical demands, and the child's needs and interests.

Chapter 4:

Methodology and Methods

Introduction

The research described in this thesis involved the development and evaluation of a 6-session manualised intervention for young children presenting with clinical anxiety. The study was conducted at two sites: a primary health Non-Governmental Organisation (NGO) and a CAMHS organisation, both of which provide mental health services for children and their families. These two organisations are described further under the setting. The intervention was designed to benefit children aged 4 to 7-years-old with clinically significant (moderate to severe) anxiety with parent(s)/guardian(s) seeking treatment. The manualised intervention is a relatively novel idea that combines CBT and sensory modulation principles and strategies. The development of this intervention aimed to provide an effective intervention that would be developmentally appropriate for younger children with anxiety. The intervention was delivered to six children and their parent(s) by four therapists.

This doctoral study aimed to determine whether the 6-session CBT-sensory modulation intervention was effective in reducing anxiety for children aged 4 to 7-years who experience clinically significant anxiety. The study also sought to understand if this intervention was acceptable to parent(s), the children, and therapists; and if it was practicable to deliver at two NZ healthcare settings. A single-case experimental design with additional secondary measures and qualitative feedback were used to achieve these objectives. This chapter describes relevant methodological considerations, including underlying philosophical assumptions and the rationale for the chosen methodology. It outlines how the study was completed; and describes the aims, hypotheses, research design, procedures, measures, recruitment, and participants involved in the study. Additionally, the ethical and cultural considerations, and data collection, management and analysis methods employed are discussed.

Part A: Study Methodology and Design

This section presents the study aims, underlying assumptions, and design. A detailed explanation is provided on how the multiple baseline single-case experimental design along with qualitative feedback were used to meet the study aims.

Study Aims

The primary aim of this study was to examine the effectiveness of a CBT-sensory modulation intervention for children 4 to 7-years-old presenting with anxiety. A secondary aim was to

explore the acceptability and practicality of the intervention from the perspective of the children, parent(s), and therapists delivering the intervention.

There were two hypotheses related to the study aims:

1. A modified CBT-sensory modulation intervention will be effective in reducing anxiety in children 4 to 7-years-old who are diagnosed with clinical anxiety.
2. A modified CBT-sensory modulation intervention will improve functioning for children aged 4 to 7-years diagnosed with clinical anxiety.

The secondary objectives of the study involved examining whether:

(a) the modified CBT-sensory modulation intervention is acceptable and practical for children and families.
(b) the delivery of the intervention is acceptable and practical for clinicians within a current NZ CAMHS setting.

Underlying Philosophical Assumptions

All research has an underlying philosophical paradigm that guides inquiry to answer the research question (Polit, 2001). A paradigm describes a set of beliefs and assumptions about the research's ontological, epistemological, and methodological aspects, and provides a theoretical framework that guides the inquiry (Kuhn, 1970). Several paradigms, including positivism, post-positivism, interpretivism, and mixed methods, were considered during the planning stages of the current study. After considering these various paradigms, post-positivism was determined to be the best fit with the study aims to examine the effectiveness, acceptability and practicality of using the combined CBT and sensory intervention manual in practice. The tenets and rationale for drawing on post-positivism are outlined below.

The post-positivist paradigm was selected because it holds that there are multiple truths and that researchers select paradigms that closely relate to their perceptions of reality and personal view of the world (Glense, 1999; Schwandt, 1998). The researcher's experience and beliefs shaped the selection of post-positivism for this research, the nature of the issue being targeted (anxiety), the research questions to be answered, and the ontological and epistemological positions chosen (Giddings, 2006; Slevitch, 2011).

Ontology and epistemology are central to any research inquiry. When generating knowledge through research, ontology and epistemology guide the methodology, which, in turn, guides the research methods to generate new knowledge (Marsh & Furlong, 2002). Ontology is concerned with the nature of reality and what constitutes reality, determining what methods

are used to study that reality (Berryman, 2019; Rehman & Alharthi, 2016). The nature of anxiety, its causes, and factors that affect its presentation and treatment, are complex and, hence, require various approaches to understand them fully. The ontological belief about these multiple factors and the interplay between them is that they are neither solely subjective nor objective, which aligns with post-positivism. Hence, the proposed study was based on the hypothesis that there would be a cause-and-effect relationship (Creswell, 2007) between the intervention and reducing anxiety and improving function in younger children, with secondary aims of exploring the acceptability of the intervention for children, families, and clinicians, and the practicality of delivering the intervention in NZ settings.

The post-positivist paradigm emerged from criticism of positivism. Post-positivism is not the revision of positivism but the rejection of the central tenets of positivism (Trochim, 2006). Positivists believe there is a single reality that can be determined through objective observation and testing of hypotheses (Mackenzie, 2011; Schwandt, 2007). In comparison, post-positivists argue that research is influenced by many theories, background knowledge, hypotheses, and the values of the researcher (Mackenzie & Knipe, 2006). Therefore, there are multiple and competing views of science as well as multiple truths in the empirical world (Guba & Lincoln, 1994). Post-positivists pursue objectivity while recognising the possible effects of bias, and accept that knowledge gained is provisional and open to review. Hence, the truth can only be approximated and can never be explained perfectly or completely (Guba & Lincoln, 1994; Onwuegbuzie et al., 2009).

Epistemology is the generation of knowledge and encompasses the rules that must be followed to generate knowledge (Berryman, 2019; Tennis, 2008). When deciding what methodology to use in a study to understand certain phenomena, researchers are drawn to particular philosophical constructs, ideas, approaches, and a way of doing things (Berryman, 2019). These constructs define the nature of reality as it relates to that construct and also present certain assumptions that go along with that particular philosophical construct (Berryman, 2019). Post-positivists argue that there is no single method that is adequate to study a phenomenon, but the research question and the nature of the information required to answer the question guide which methods to use (Giddings, 2006).

In the present study, a post-positivist approach enabled the use of both quantitative and qualitative methods to answer the research questions in relation to the effectiveness as well as acceptability and practicality of the intervention (Giddings, 2006; Mackenzie, 2011). The effectiveness of different anxiety treatments have largely been studied using quantitative methods, which control for variables that might influence changes in anxiety beyond the intervention (Carl et al., 2020; Infantino et al., 2016; James et al., 2020; Morgan et al., 2017).

In keeping with previous intervention studies, this research used quantitative methods and an experimental design. However, the literature also provides varied descriptions on how we understand anxiety and people's experiences of receiving various interventions. This is achieved through the collection of subjective information from the families and participants (Allard et al., 2021; Chavira et al., 2014; (Kandasamy et al., 2019; Smart et al., 2021). Therefore, the study will also collect parent(s)'/guardian(s)' subjective feedback related to how they understand their child's anxiety before and after treatment. Feedback from participants (parents/guardians, children, and therapists) will be collected to evaluate the perceived impact effectiveness, acceptability, and practicality of the proposed intervention (Bowen et al., 2009).

Study Design

The methodology that was deemed most appropriate to meet the study aims within the scope of a time-limited applied doctoral study was a multiple-base, single-case experimental design (SCED), with the addition of subjective feedback from the clinicians and families involved. SCED is a methodology that is powerful in establishing causal relationships of a clinical phenomenon in situations where there are few participants (Epstein & Dallery, 2022; Ferron et al., 2023; Smith, 2012). It can be done with one or a small group of participants where each is their own control (Lobo et al., 2017; Nock et al., 2007). Multiple baseline designs are appropriate for answering research questions regarding the effects of a single intervention across three or more individuals, stimuli, or settings (Byiers et al., 2012; Dugard et al., 2012; Kazdin, 2011). Inferences about the causal effect in SCEDs are drawn by analysing changes in the dependent variable during the experimental (intervention) and control (baseline) conditions. Additionally, subjective data collected from significant family members provide further information regarding the effect of the intervention based on changes observed by family members (Kazdin, 2011).

SCED involves providing intervention to multiple participants or 'cases'; these can either be concurrent or non-concurrent (Byiers, 2019; Byiers et al., 2012; Dugard et al., 2012; Kazdin, 2011; Kennedy, 2022; Slocum et al., 2022). The concurrent design allows simultaneous delivery of the intervention to all participants (Kazdin, 2011). The non-concurrent design delivers the intervention with intervals between participants (Kazdin, 2011). In this study, the non-concurrent method was used because it was difficult to recruit all the participants at the same time. More detail on how the single-case experimental design was used is described in the methods section (Part B).

The study involved various stages from the manual development to data analysis and report writing. It also involved four data collection phases, as outlined in Figure 1.

Figure 1

Flowchart of the Study

Manual Development & Therapist training	Participant Recruitment	Baseline Phase (3-5wks)	Intervention Phase (6 weeks)	Post-Intervention Phase (1 week)	Follow-up Phase (4 weeks)	Analysis and Report Writing

Study Process

The data collection began with the confirmation of diagnosis and then the collection of baseline measures to establish the level of anxiety before delivering the intervention. Baseline data were collected across all participants, and the intervention was introduced systematically at the end of each participant's baseline period. The intervention was introduced in a staggered fashion, demonstrating experimental control (Byiers et al., 2012; Dugard et al., 2012; Kazdin, 2011). Baseline measures were completed to establish the stability of the dependent variable (anxiety), as Kazdin (2011) recommended. In this study, baseline periods ranged between 3 to 5-weeks, and participants were randomly assigned to one of these baseline periods. During the allocation of baseline periods, participants one and two were assigned to a three-week baseline period to serve as a pilot, and the randomisation was done for participants three to eight. However, only six participants ended up being recruited for the study. Further details of the randomisation and phases are outlined under the methods section in Part B.

Establishing the Effectiveness of the Intervention

In SCEDs, the effectiveness of an intervention is established by evaluating the presence and degree of change in the dependent variable following a period of baseline measurement and the introduction of the intervention (Byiers et al., 2012; Dugard et al., 2012; Kazdin, 2011). In multiple baseline designs, pre-intervention measurements are taken on at least three points to establish a stable level of the dependent variable which, in this study, is anxiety-related behaviours (Kazdin, 2011). Baseline data should remain stable since no intervention was applied to alter this behaviour (Kazdin, 2011). These multiple baseline measures act as the control for each participant (Kazdin, 2011). A subjective evaluation of the participant's behaviour was collected before and after the intervention from the parent(s)/guardian(s) to

evaluate if any distinct improvements in anxiety and functioning had been seen after the intervention. This subjective information was used to validate if the intervention had been effective (Kazdin, 2011).

In this study, the length of the baseline period varied across participants (either 3, 4, or 5-weeks). The commencement of the intervention was staggered, with the aim being to show that changes only occurred when the intervention was applied and not due to other extraneous events. If the participant's behaviour changed after the baseline period, inferences would suggest that the intervention caused the change. Since this study used the non-concurrent method, this process was repeated for each participant when they were recruited into the study. The repeated demonstration (replication) that behaviour changes in response to the staggering application of the intervention rules out the effect of extraneous factors (Kazdin, 2011). Additionally, it minimises the historical and maturation effects threats to internal validity.

Internal and External Validity

To control extraneous variables that may affect the outcome, several strategies were used to strengthen the internal validity of the study. First, participants were randomly allocated to different lengths of baseline periods (either 3, 4, or 5-weeks). The second strategy was replication which happened in two ways: between subjects and between therapists. First, staggering the intervention across participants replicated the process. Staggering the intervention involved introducing the intervention to participants at different times depending on the length of their baseline period. The second replication was produced by delivering the intervention with a new set of therapists and participants. This provides some evidence to support external validity (Walker & Carr, 2021). Replication is an integral part of experimental research as it allows the causal relationship between the independent and the dependent variables to be demonstrated (Kazdin, 2011; Kazdin & Nock, 2003). Replication across participants requires three or more participants to have their baselines measured to confidently establish a causal effect (Kazdin, 2011; Kazdin & Nock, 2003). Three participants are the recommended minimum, although two participants can still demonstrate the effect of an intervention (Kazdin & Nock, 2003).

Advantages of Multiple Baseline/SCED

The multiple baseline design was chosen over the single case design, such as a reverse design, because it is flexible, efficient, has no ethical concerns around withdrawal of treatment, and does not allow the unethical removal of an effective intervention (Kazdin, 2011). Another reason for using the SCED is that it is not resource-heavy (financial and staff) and can be implemented with modest financial support (Dugard et al., 2012; Kazdin, 2011). SCEDs are

flexible and offer opportunities to make adjustments to treatment to suit each client (Byiers et al., 2012; Kazdin, 2011; Krasny-Pacini & Evans., 2018). This offers an opportunity for innovation and greater clinical options for treatment development (Byiers et al., 2012; Kazdin, 2011). It also allows clinicians delivering the intervention to master the intervention as they deliver it and opportunities to examine the change patterns when an intervention is introduced (Byiers et al., 2012; Kazdin, 2011).

Limitations of Multiple Base/SCED

Limitations of a SCED are the lack of strong evidence for generalisability (Lobo et al., 2017) and the difficulty of adequately controlling for threats (Kazdin, 2011). In this study, the threat of limited generalisability of the intervention to a wider population was addressed by having four therapists deliver the intervention independently. Replication of results between four independent therapists demonstrates the generalisability of the intervention across individuals on a small scale (Kazdin, 2011; Walker & Carr, 2021).

Another threat of multiple baseline designs is the prolonged baseline assessment period for some participants (Kazdin, 2011). Multiple baseline design requires multiple baseline measures, which means that one or more participants may wait a long time before receiving a potentially beneficial intervention. Delaying or withholding a potentially beneficial intervention is unethical, but it is not a problem unique to multiple baseline experimental designs (Kazdin, 2011); for example, waitlist control designs also use this strategy to establish control (Kazdin, 2011). In this study, this issue was addressed by excluding participants with serious anxiety so these children would not wait for up to 8-weeks before receiving the intervention.

Inconsistent effects of the intervention are another limitation of multiple baseline designs (Kazdin, 2011). Inconsistent effects mean that the intervention altered the behaviour of one participant but did not alter the behaviour of another (Kazdin, 2011). It raises serious concern in cases where there are only two baseline measures from two participants. This problem was solved by having three or more participant baselines and three or more participants at a time, as Kazdin (2011) recommended. In this study, six participants were included to mitigate this threat.

Cultural and Ethical Considerations

Cultural Consultation

As discussed in Chapter 3, Māori cultural consultation was completed as recommended by the Health and Research Council of NZ (2010). The Māori Health Services were consulted for

advice and support regarding the appropriateness of the intervention. The consultation ensured that the therapy process, including the forms, questionnaires, and treatment, was acceptable and culturally appropriate (Engel & Schutt, 2017). Feedback was sought on the appropriateness of the intervention, particularly the sensory intervention strategies, and how they fit with Māori culture. Regular meetings were held with the advisor from the Māori Health Services during the manual development phase.

The three principles of the Treaty of Waitangi were the foundation for the cultural consultation process. These principles are Partnership, Participation, and Protection (Hudson & Russell, 2009).

i. Partnership – focused on working together with the Māori Services Unit at the DHB regarding the appropriateness of the study design and intervention, particularly the sensory intervention strategies and how they fit with Māori culture.
ii. Participation – focused on working with the cultural advisor from the Māori Health Services at the DHB to refine the intervention, analyse research data, and report results.
iii. Protection – focused on working with the Māori Health Services to ensure Māori participants were protected concerning their rights, values, culture, and norms. For example, if Māori whānau were recruited into the study, the cultural advisor would have assisted in engaging and creating a culturally safe space through karakia and other practices (Health Research Council of NZ, 2010).

Ethical Considerations

When undertaking research with children and vulnerable populations, it is essential to meet ethical standards to ensure the interests and safety of these people are not compromised (Broome, 1999; Government Printing Office, 1949; National Ethics Advisory Committee, 2018). In the current study, it was ensured that participants had full disclosure, the right to privacy and confidentiality, and there was limited harm. It was also ensured that children were protected by providing age-appropriate, child-friendly information in gaining voluntary informed assent to participate in the study (Broome, 1999, Broome et al., 2003). Every effort was made to ensure that the researcher fully disclosed the pertinent information relating to the study. All study aspects were discussed at length with the participants and their families including the research purpose, assent/consent, assessments, baseline periods, confidentiality, data collection, the right to withdraw, privacy, and dissemination pathways. Participants were informed that depending on what conditions they were randomised to, there could be a delay in receiving the intervention. Efforts were made to ensure that they understood the length of the baseline condition assigned to them when treatment was withheld.

The current research was grounded on three key principles of respect, beneficence, and justice (Graham et al., 2013). Since children can provide informed voluntary assent to participate, by law parent(s) need to give voluntary informed signed consent for their child to participate in the study. Every effort was made to explain to children in an age-appropriate, child-friendly manner the purpose, aim, benefits, and their involvement in the study (i.e. attend six sessions of therapy and give feedback) (Broome, 1999). It was ensured that children had a basic understanding of what was expected of them, what would occur in the sessions, and the benefits and risks of participation. The researcher informed the children that they had a right to refuse participation or withdraw at any time. Informed consent and assent (see Appendices B and C) written in simple language were used to describe the purpose of the study, associated risks, alternative interventions, right to withdraw consent, and time frame (Health Research Council of New Zealand, 2017; National Association of Social Workers, 1999; Spriggs, 2010).

The Health and Disability Ethical Committees (HDECs) granted ethical approval on December 15, 2020 (study number 20NTA165; see Appendix D). Auckland University of Technology Ethics Committee (AUTEC) approval was granted in March 2021 (see Appendix E). Local ethics approval was granted by the Hawkes Bay Hospital Clinical Trials Committee on April 4, 2022, by an endorsement letter (see Appendix F).

Privacy and Confidentiality

Participant information was de-identified, and each participant was assigned an identification number to ensure anonymity, confidentiality, and privacy (Arnett et al., 2019). Only research staff involved in the study could access the research data, to ensure confidentiality. The data collected were stored on the Auckland University of Technology cloud storage system with password-protected access.

Part B: Methods

This section presents the study methods, setting, and therapists, including how participants were carefully selected and how the baseline phase was implemented before introducing the intervention. The assessment tools used are described, including the time points when these tools were used.

Study Context: Setting, Therapists, and Intervention

Setting

The current study was completed at two sites in a semi-rural NZ region. One site was a primary care non-governmental organisation (NGO) that provides services for children, young persons,

and their families. The site mainly employs social workers and provides services such as counselling and social work in schools, as well as parenting and parenting through separation programmes. These services are designed for children presenting with different emotional, social, and behavioural problems and their families. The second site was a regional secondary care CAMHS service for infants, children, and youths aged 0 to 19-years. The service employs a multidisciplinary team comprised of social workers, psychologists, psychiatrists, nurses, occupational therapists, dietitians, and counsellors. It offers assessment and treatment of mental health disorders common in infants, children, and young people, such as anxiety, ADHD, and depression. The interventions offered include medications, talking therapies, and group interventions (Baldwin, 2018).

Therapists

The four therapist participants who delivered the intervention were three social workers and a nurse. The first social worker had over 10 years of experience working with children, young people, and their families. This therapist had experience in delivering counselling and was familiar with CBT but had no formal training in CBT or sensory modulation. The second therapist was a new graduate social worker with an overseas master's degree in social work. This therapist had no experience in child and adolescent mental health, mental health, or CBT and did not know sensory modulation. The third therapist was a new graduate social worker with less than 1-year of practice experience and little experience in working with children. The fourth therapist was a nurse with over 20 years of experience working in adult mental health settings and had no experience working with children. He had just been employed and had no previous experience or training in CAMHS, no formal training in talking therapies, including CBT, and was unfamiliar with sensory modulation.

Therapist Intervention Training and Adherence

Therapists received 8-hours (or more) of training in how to use the intervention manual. The training was delivered 2-hours per week (8-hours in total) and completed in 4 consecutive weeks. The researcher was available for consultation at any time to support the therapists, and they could contact the researcher via e-mail or telephone if they had any questions. The consistent training and support the therapists received for delivering the programme supported the intervention fidelity. All intervention sessions were digitally audio-recorded for fidelity and adherence testing.

Intervention

The Ngā Timatanga Toa intervention (see Appendix A) is a manualised 6-session programme combining CBT and sensory modulation strategies for childhood anxiety, as described in

Chapter 3. Each child, with their mother, received the intervention over 6-weeks, receiving one session per week. COVID-19 restrictions interrupted some of the sessions, and the impact of the pandemic on the study is discussed further at the end of this chapter.

Study Measures

Several measures were used in this study to capture anxiety symptoms, anxiety interference or functional impact and acceptability of the intervention to parents and therapists. These measures are listed in Table 5 and then described below.

The School Anxiety Scale Teacher Report Form (SAS-TR)

The SAS-TR (see Appendix G) was used to measure the child's anxiety at school from the teacher's perspective. The teachers of children involved in this study completed this form during the study. The SAS-TR was designed to assess anxiety in children aged 5 to 12-years-old who are in school (Hajiamini et al., 2012; Lyneham et al., 2008). The SAS-TR was demonstrated to have good clinical utility, acceptable internal consistency, and sensitivity to changes in anxiety with treatment (Lyneham et al., 2013). The SAS-TR has been translated into other languages, demonstrating that it can be used in different settings (Hajiamini et al., 2012; Orgilés et al., 2016).

The Child Behaviour Checklist (CBCL) – pre-school and school aged versions

The CBCL (see Appendix H) is a parent questionnaire developed to screen children's behavioural, social, and emotional problems (Achenbach, 1991). The CBCL has two forms, one for pre-school children aged 1 and a half years to 5-years and the other for children from 6 to 18-years. In this study, the CBCL forms were completed by the child's parent(s). The CBCL syndromes scale scores are associated with disorders in the DSM 5 (American Psychiatric Association, 2013). The CBCL has high interrater reliability, convergent validity, and discriminative validity (Achenbach & Rescorla, 2001; Nakamura et al., 2008).

Table 5

Study Measures

Anxiety symptoms (Diagnostic)	**Focus of measure**
The School Anxiety Scale Teacher Report Form *(SAS-TR)*	Child's anxiety at school (teacher report)
The Child Behaviour Checklist *(CBCL)*	Child's behavioural, social, and emotional issues (parent report)
The Teacher Report Form *(TRF)*	Child's behavioural, social, and emotional issues (teacher report)
Anxiety interference (Functional impact)	**Focus of measure**
The Child Anxiety Life Interference Scale (*CALIS-P, Parent form*) for 6 to 17-year-olds.	Impact of anxiety on school-aged child's everyday life (parent report)
The Child Anxiety Life Interference Scale (*CALIS-C, Child form*) for 6 to 17-year-olds.	Impact of anxiety on school-aged child's everyday life (child report)
The Child Anxiety Life Interference Scale (*CALIS-PV, Pre-School-Version*) for 3 to 5-year-olds.	Impact of anxiety pre-school-aged child's everyday life (parent report)
Behaviour Tracking Diary *(BTD)*	Tracks change in anxiety related behaviours of concern (parent report)
Acceptability and Practicality of Intervention	**Focus of measure**
Outcomes Rating Scale - Child *(C-ORS)*, and Young Child *(YC-ORS)* versions	Perceived progress while participating in therapy (parent and child report)
Session Rating Scale, Child *(C-SRS)*, and Young Child *(YC-SRS)* versions	Therapeutic alliance with mental health clinician (parent and child report)
Participant Satisfaction Questionnaire *(PSQ)*	Overall satisfaction with intervention (parent report)
Therapist Satisfaction Questionnaire *(TSQ)*	Overall satisfaction with intervention (therapist report)

The Teacher Report Form (TRF)

The Teacher Report Form (TRF) (Appendix I) is a parallel form to the CBCL that is completed by the teacher to assess problem behaviour. It was developed by developed by Achenbach, & Rescorla, (2001).

The Child Anxiety Life Interference Scale (CALIS- Parent & Child forms)

The CALIS was used to assess and measure the interference and impairment experienced by the child participant. The CALIS (CALIS-Parent and Child scales; see Appendices J and K) is an assessment tool designed to assess the life interference of fears and worries from the child and parents' perspectives. It is suitable for children aged 6 to 17-years-old. CALIS has good

internal consistency, moderate-to-high test re-test reliability, significant inter-rater reliability, good convergent and divergent validity, and is sensitive to treatment change. The CALIS is a reliable and valid tool for assessing life interference and impairment associated with anxiety disorders in childhood (Lyneham et al., 2013). In this study, CALIS-P was completed by the parent(s), and the child completed the CALIS-C.

The Child Anxiety Life Interference Scale - Preschool Version (CALIS-PV)

The CALIS-PV (see Appendix L) is a parent-report measure of the impact of anxiety on the life of preschool-aged children. This study used the CALIS Preschool Version for children 4 to 5-years-old. CALIS Preschool Version has good internal consistency and good convergent and divergent validity. The CALIS-PV has successfully differentiated children with and without an anxiety diagnosis and is sensitive to treatment effects. The CALIS-PV is a reliable and valid measure of the daily life impacts of childhood anxiety for preschool-aged children and their parents (Gilbertson et al., 2017).

Behaviour Tracking Diary (BTD)

Parents were asked to identify up to three primary child behaviours they were concerned about that they tracked throughout the study using the BTD (see Appendix M). For example, if a child hides in the cupboards, parents were asked to keep a diary of how often (frequency) it happened, for how long (duration), the severity of the behaviour, and how the behaviour affected the child's functioning. Depending on the target behaviour, counting, Likert scale, or subjective units of distress (SUDS) were used to track changes as recommended by Martin and Pear (2016). Parents were asked to provide subjective information about these behaviours and the child's functioning.

Outcomes Rating Scale, Children (C)ORS, and Young Children (YC)ORS

These tools were used to measure and monitor the children's and their parents' feedback on therapeutic progress while participating in therapy. In this study, these tools were administered at the beginning of every session (starting from session two). The ORS (see Appendix N) was administered with the parent(s), the C-ORS (see Appendix O) was administered with children 6 years and older, and the YC-ORS (see Appendix P) was administered with children 5 years and under. These tools have demonstrated to have moderate to high reliability, moderate test-retest reliability and moderate concurrent solid validity (Bringhurst et al., 2006; Low et al., 2019; Miller et al., 2003).

Session Rating Scale, Child (C-SRS), and Young Child (YC-SRS) versions

These tools are designed to solicit real-time feedback from therapy recipients to identify and solve therapeutic alliance problems (Miller et al., 2000, 2003). In this study, the SRS tools (Appendices Q, R & S) were administered at the end of each session to get feedback from the child and their parent(s)/guardian(s) about their relationship with the therapist, so that alliance issues could be identified and addressed (Miller et al., 2003). These tools have good reliability, test-retest reliability, and concurrent validity (Campbell & Hemsley, 2009; Low et al., 2012; Miller et al., 2003).

Parent Satisfaction Questionnaire (PSQ)

Overall feedback about the treatment programme was gathered at the end of the six sessions by asking the parents to complete the PSQ (see Appendix T). This questionnaire was developed specifically for the study. The questionnaire has a Likert scale and open-ended questions to which parents respond using free text. The open-ended questions gather subjective data about the parent(s)'/guardian(s)' opinions regarding their overall satisfaction with the intervention, noted improvement of their child's condition, the effectiveness of the treatment, and the acceptability and practicality of the intervention. The researcher administered the questionnaire to the parents and asked for more information regarding their responses (subjective data) to the open-ended questions to gain further in-depth data, as recommended by Kazdin (2011).

Therapist Satisfaction Questionnaire (TSQ)

The clinician's overall satisfaction with the treatment programme was gathered after the therapist provided treatment to children by administering the TSQ (see Appendix U). This questionnaire was specifically developed for the study and was administered to the therapists by the researcher. The questionnaire has a Likert scale and open-ended questions where therapists provide free text responses regarding the intervention's effectiveness, acceptability, and practicality.

Participant Recruitment and Admission

Purposive sampling was used to identify and select participants for the study. A total of six children (male and female) aged 4 to 7-years and their parent(s) were enrolled in the study. Additionally, four therapists were recruited to deliver and provide feedback on the intervention. The children were new or current clients from the NGO and CAMHS sites where the therapists worked.

Recruitment of therapists began when the researcher approached the management of both sites, presented the proposed study, and requested permission to complete the research within their services. The managers of both services agreed to conduct the study on their sites and informed their staff about the study. Two staff members (social workers) were selected by the NGO service manager, and two staff members (nurse and social worker) from CAMHS volunteered to participate in the study. These four clinicians met the criteria for admission into the study as therapist participants and were keen to participate in the study. They were given the therapist participant information sheet and consent form (see Appendix V). Their profiles have been earlier described in the therapists' section.

Two different methods were used to recruit child participants for the study. The first method involved the clinical managers at both sites checking if any existing clients were suitable candidates for the study. The clinical managers and staff (clinicians) reviewed clients to identify potential participants on individual clinicians' caseloads. One participant was identified through this process.

The second method involved the clinical managers reviewing new referrals to identify potential participants. As new referrals came in, the clinical managers reviewed all referrals, reading through referral reasons, ages, and co-morbid diagnoses. Potential candidates' names were identified and discussed after the initial assessment to determine their suitability. Potential participants' files were handled and allocated to clinicians per the services' allocation process. This was done to ensure that potential participants were not given an unfair advantage concerning waiting time (waitlists) over those not eligible for the study. Five participants were identified through this process. Potential candidates were informed about the study and given the flyer (see Appendix W) containing all the information. The families who were keen to participate in the study contacted the researcher using the contact details on the flyer or through the therapists at the sites. Potential participants were approached until the end of the study.

The following inclusion and exclusion criteria were applied to admit participants into the study.

Inclusion criteria

- Children who met the criteria for at least one anxiety disorder (e.g. GAD, SAD), as confirmed during a clinical interview with the clinical psychologist and supported by clinical documentation from their psychiatrist, paediatrician, clinical psychologist, or general practitioner if available.
- Children with at least one parent/guardian willing to participate in the intervention programme.

- Children aged 4 to 7-years, both boys and girls.
- Children with parent(s)/guardian(s) who were not travelling within 18-weeks of commencing the study so as not to affect their therapy attendance.
- Parent(s)/guardian(s) and child who could speak conversational English.

Exclusion criteria

- Children with co-morbid diagnoses of ASD, ODD, and psychosis.
- Children diagnosed with intellectual disability.
- Children with a history of significant trauma; PTSD or sexual abuse.
- Children who were on anti-anxiety medication or other (anti-psychotic) psychiatric medications.
- Children who were extremely unwell/anxious such that they could not wait for up to 8-weeks to be seen.
- Children who were currently receiving psychotherapy or other psychological treatment for their anxiety.
- Children with attachment disorders.

Once the researcher was informed that a family were keen to participate, a meeting with the family was arranged. During the meeting, an introduction to the research was provided, including the purpose of the study, the inclusion and exclusion criteria, the intervention, the baseline period, what their participation meant, what would happen to their data, privacy, and access to information. The child and families were given opportunities to ask questions regarding the study to which the researcher responded as best as possible.

For suitable candidates who indicated they were keen to participate in the study, the researcher requested their child's clinical information about their anxiety, if any. The researcher then arranged a clinical interview with a clinical psychologist for further evaluation to confirm the diagnosis of anxiety. The children's anxiety diagnosis was confirmed by a clinical psychologist on entry into the study using the DSM-5 diagnostic criteria through a clinical interview with the participant and their parent(s). Before the clinical interview, and as part of the clinical psychologist's assessment on entry, the researcher administered additional assessments to determine the severity and impact of anxiety on admission to the study. The parent(s) completed the CBCL and the CALIS-P or CALIS-PV. Permission was requested from the parents to contact their child's teacher to be part of the study, and the study information including the teacher participation information sheet and consent form (see Appendix X) were sent to the respective teachers as children were recruited. The child completed the CALIS-C; the child's teacher was invited to complete the SAS-TR and the TRF. After the clinical psychologist confirmed the diagnosis, the researcher contacted the parent(s)

to inform them of the outcome. Potential participants diagnosed with anxiety by a clinical psychologist who met the study inclusion criteria were accepted into the study. Six child participants, four boys and two girls, met the criteria for the study and wished to engage in the intervention with their parents. Their profiles are presented in the results chapter.

Families who agreed to participate were fully informed of the study process. This included information about the baseline measures and randomisation to different conditions (3, 4 or 5-weeks of baseline measures), that treatment would start after the baseline measures had been completed, and measures would be taken at four other points in addition to giving subjective feedback following the intervention. They were also reminded that they would not be allowed to receive or start any other forms of intervention or support for anxiety in addition to the study intervention during the study. Information contained in the participant information sheet and the consent form (PISCF) was explained in detail. The assent form was discussed with the child. Developmentally age-appropriate language was used with children to ensure they understood what the study was about and what their participation would involve. The child and the parent(s) were given hard copies of the PISCF. The parents and the child were asked to sign these forms and return them when they decided they wanted to participate in the study. The parent(s) and the child kept a copy of the PISCF. Parents(s) were asked to confirm if they wished to participate or not by emailing the researcher within 14-days.

Data Collection

Participant information was collected at multiple baseline points and then at mid-intervention (MI), post-intervention (PI), and 1-month follow-up (FU), using the measures described earlier.

Randomisation to Baseline Periods

Successfully recruited participants were allocated to a pre-assigned treatment condition using the Microsoft Excel randomisation function. The three conditions included short, medium, or long baseline (3, 4, or 5 baseline data points).

Participants one and two were both assigned to a 3-week baseline period as this was meant to serve as a pilot. Then, using the Microsoft Excel function, participants three to eight were randomly assigned to one of three baseline conditions (3, 4, or 5-weeks). Randomly allocating participants to different treatment conditions is central to having good internal validity and helps to eliminate alternative explanations in studies (Dugard, 2012). The randomisation calculation was completed for six participants, and it was intended to have eight participants

in total recruited in the study. However, due to COVID-19 recruitment challenges, only six participants were recruited.

To randomly assign the participants to one of the three baseline periods, two columns were set up in Excel, one for participants and the other for the baseline period. The following Excel random numbers formula was used to randomly assign participants to one of the three baseline periods:

=CHOOSE (ROUNDUP(RANK(C2,$C$2:$C$7)/3,0),"3WKS", "4WKS", "5WKS")

As participants were recruited into the study, they were assigned to a baseline period corresponding to their recruitment position. That is, the participant who was recruited as participant number three had a baseline period that was already pre-determined and assigned. The result of the execution of the formula is shown below.

Name	**Baseline period**
Participant 1-Pilot participant =3 weeks baseline period	
Participant 2-Pilot participant =3 weeks baseline period	
Participant 3	3WKS
Participant 4	4WKS
Participant 5	3WKS
Participant 6	5WKS
Participant 7	5WKS
Participant 8	4WKS

Baseline Phase

The study began with collecting baseline measures to establish the level of anxiety before intervention. Baseline data were collected for all participants, and the intervention was introduced systematically at the end of each participant's baseline period. The introduction of the intervention in a staggered fashion demonstrated experimental control (Byiers et al., 2012; Dugard et al., 2012; Kazdin, 2011). In multiple baseline designs, at least five baseline measures must be completed during the baseline phase to establish the stability of the dependent variable (anxiety). This is not always possible in clinical settings; therefore, a minimum of three baseline measures has been agreed by convention to be sufficient to establish a stable baseline measure (Kazdin, 2011). In this study, baseline periods ranged between 3 and 5-weeks, and participants were randomly assigned to one of these baseline periods.

When the child met the criteria for the study, weekly baseline measures of the child's anxiety interference levels were collected from the parent(s) and the child using the appropriate form

(i.e. CALIS-P, CALIS-PV or CALIS-C) for a baseline period of either 3, 4, or 5-weeks. Parents were also asked to record the frequency of three anxiety-related behaviours of concern during this period using a BTD.

Intervention Phase

During the 6-week intervention, an ORS, CORS, or YCORS was administered by the therapist with the mother and child at the beginning of each session (starting from session two). This was to measure any change in the level of distress and functioning based on the intervention received the week prior. The mothers completed the ORS, and the children completed the CORS and YCORS. Additionally, the SRS, CSRS, or YCSRS was administered by the therapist to the mother and child at the end of each session to assess how helpful the session was and what could have been improved. The mothers completed the SRS, and the children completed the CSRS and the YCSRS.

Mid-intervention point

At MI, all the mothers and their children completed the relevant CALIS forms to track any change in anxiety interference during the first half of the intervention. This was administered by the researcher.

Post Intervention and Follow Up Phases

One week after completion of therapy, the clinical psychologist conducted a post-intervention interview to determine if the child still met the criteria for a diagnosis of anxiety. The PI meeting comprised a clinical interview and administration of psychometrics (DSM-5 diagnostic anxiety criteria, CALIS, CBCL, SAS-TR, and TRF). Parents were asked to provide feedback regarding three behaviours they were concerned about that they tracked throughout the study using the BTD. Changes were captured through Likert scales, the Subjective units of Distress Scale, and subjective report of frequency and severity. At 1-month follow-up the clinical psychologist reviewed the children's progress, and all the assessments were re-administered, scored, and interpreted to assess whether gains were maintained.

Data Analysis

In alignment with a single-subject design, the evaluation of the effectiveness of the intervention used various methods, including visual and quantitative analyses (Manalov et al., 2016; Satake et al., 2008; Tate & Perdices, 2019), complemented by subjective evidence of behaviour change reported by the patient or family (Kazdin, 2011; Manalov et al., 2016; Martin et al, 2016). Feedback and perspectives of the patient and significant others are

important in establishing intervention effectiveness as well as acceptability and practicality (Kratochwill & Levin, 2010). In this study, data analysis began by analysing the baseline information, including age, gender, race, type of anxiety, and severity. The second step was analysing the assessment scores again at PI and FU.

Visual Analysis

Visual analysis of the results was used to establish the effectiveness of the intervention by analysing changes in scores on measures administered during the baseline and intervention phases. The data collected during the baseline and when the intervention was introduced were graphed. A comparison was made to describe differences in the two phases, as depicted within the patterns or trends in the graphs, to determine changes caused by the intervention. The intervention effects were judged based on the data pattern and its consistency. Analyses emphasised the magnitude and rate of change across the baseline and intervention phases (Kazdin, 2011; Satake et al., 2008).

Statistical Analysis

Statistical methods were used to analyse the Effect Size (ES) of the intervention. ES calculations are used to detect small and weak effects. New interventions are likely to produce weak effects, and statistical methods provide an analytical tool that reduces the ambiguity of the results even when the effects are small (Kazdin, 2011). ES was calculated using Busk and Serlin's (1992) variation of Cohen's *d* formula as below:

$$d_1 = \frac{\bar{x}_{A_2} - \bar{x}_{A_1}}{S_{A_1}}$$

Key: -d_1 is the ES; the numerator is the difference between the post-intervention phase scores mean and the baseline phase scores mean/average; the denominator is the standard deviation of the baseline phase scores.

The ES was interpreted using the benchmark proposed by Robey and Beeson (2005) for single-case designs: 4.0, 7.0, and 10.1 for small, medium, and large, respectively.

$d_1 < 4.0$ is very small

$4.0 <= d_1 < 7.0$ is small

$7.0 <= d_1 < 10.1$ is medium

$d_1 >= 10.1$ is large

Tracking Specific Behaviours

Data collected by the parent(s) regarding three specific behaviours using the BTD were analysed by focusing on changes in the frequency of behaviours, severity, and duration of behaviours pre- and PI, as recommended by Martin and Pear (2016). Additionally, the focus was on how the behaviours impacted the child’s functioning and how this changed during and after the intervention.

Parents’ Evaluation of the CBT-Sensory Modulation Intervention

Feedback regarding the intervention's effectiveness, acceptability, and practicality were collected from the parent(s) using the PSQ after the completion of the intervention and analysed. The subjective data analysis assessed the intervention’s perceived effectiveness, acceptability of the intervention for families, and the practicality of attending the sessions and applying the intervention. The subjective data were analysed by exploring general themes generated from the open-ended responses and searching for patterns in the Likert scores using content analysis (Bengsston, 2016). This information was reported alongside the visual analysis data to determine the child’s improvement, the effectiveness of the intervention, the acceptability of the intervention for families, and the practicality of attending and applying the intervention.

Therapists’ Evaluation of the CBT-Sensory Modulation Intervention

Therapists provided feedback about the intervention, including its perceived effectiveness, acceptability, and practicality of delivering it. The feedback was collected from the therapists using the TSQ and was analysed by looking at general themes (Bengsston, 2016) generated from the open-ended responses and searching for patterns in the Likert scores.

Therapist Treatment Fidelity and Adherence

Intervention fidelity is the degree to which an intervention is delivered, particularly manualised treatments (An et al., 2020; Husabo et al., 2020; Wilczynski, 2017). Intervention fidelity ensures the accurate delivery of a treatment and allows the researcher to make reasonable conclusions about the treatment effects of a particular intervention being tested. In this current study, all sessions (1-6) for all participants were recorded, and six were randomly selected using a Microsoft Excel formula for therapist fidelity and adherence testing. These sessions were representative of all the sessions. The researcher and an independent rater (a registered psychologist) listened to the six sessions and scored the sessions independently using the Therapist Fidelity and Adherence Form (see Appendix Y).

The scores were tested for agreement using the percentage of agreement and Cohen's kappa statistic method (Burns, 2014; McHugh, 2012; Watson & Petrie, 2010). The SPSS software was used to calculate Cohen's Kappa statistic. The kappa statistic was interpreted as follows:

0-0.20 = no agreement

0.21-0.39 = minimal agreement

0.40-0.59 = weak agreement

0.60-0.79 = moderate agreement

0.80-0.90 = strong agreement

0.91-0.99 = almost perfect agreement

1 = perfect agreement

Participant Attrition

Attrition in the study was managed by maintaining open communication between the participants' families and therapists. Communication was maintained with participants and therapists via e-mails, telephone calls, and text messages. There were weekly check-ins with the therapists when they were providing therapy to offer support and troubleshoot any issues that arose during the intervention delivery.

Impact of COVID-19

The current study was impacted by the COVID-19 pandemic, which substantially affected various processes of the study. Chapter 5 presents the specific ways in which COVID-19 impacted participant engagement, data collection, and overall progression of the study. Participant recruitment and treatment delivery encountered challenges due to limitations imposed by social distancing measures, inability to meet face-to-face, and lockdowns. The closure of services, except critical ones, further complicated the research process and delivery of the intervention. The heightened anxiety experienced by individuals (i.e., the researcher, staff, participants, teachers, parents, and children) during the pandemic introduced an additional layer of complexity. The uncertainties surrounding the pandemic required constant adaptation of the research process to minimise the impact caused by the COVID-19-related disruptions. Despite these challenges, the study persevered through using innovative technologies such as telehealth and videoconferencing.

Chapter Summary

The current study used a multiple baseline SCED to answer the research question. The study was grounded in post-positivist theory, which guided the study design. Six child participants and their mothers were recruited and received a 6-session manualised intervention for anxiety.

Six teachers were approached to participate in the study and one teacher agreed to participate. Four therapists delivered the intervention across two sites. Measures of anxiety diagnosis, symptoms and life interference were collected across four phases, from psychologist, children and parents' perspectives. The following chapter presents the primary results.

Chapter 5:

Participant Results

This chapter presents the individual participants' results in relation to the primary aim of the study, which is to evaluate the effectiveness, of the Ngā Timatanga Toa programme for treating anxiety in children aged 4 to 7-years-old. As described in Chapter 4, this study used a non-concurrent multiple baseline SCED to test the following hypotheses:

1. A modified CBT-sensory modulation intervention will be effective in reducing anxiety in children 4 to 7-years-old diagnosed with clinically significant anxiety.
2. A modified CBT-sensory modulation intervention will improve functioning for children aged 4 to 7-years-old diagnosed with clinically significant anxiety.

The results for the individual participants are presented with a focus on outcomes relevant to the above hypotheses. Each single 'case' is outlined to provide context for the child's presenting issues and track any change in the primary outcome (anxiety). The results pertaining to the secondary aims of exploring the intervention's acceptability for parents and therapists are presented in Chapter Six.

The intervention was delivered, and data was collected, during the height of the COVID-19 pandemic which caused several interruptions. Due to nationwide lockdowns, people, including participants, were generally on edge, trying to find ways to cope with the distress associated with the pandemic. Only one teacher agreed to participate, and it is hypothesised that teachers were struggling to adjust to online learning at the time and may not have had the capacity to participate in the study. Equally, parental stress was high as the participating families adjusted to a new way of life (i.e., extended 'lockdowns', lifestyle restrictions, loss of work, vaccinations, and/or no income). This appeared to affect their ability to fully engage with the qualitative component of the study, as the burden of dealing with the pandemic and their child's anxiety, as well as the study, was too much. Despite these challenges and some missing data, enough quantitative data were collected to show general trends for each of the participants.

Participants

Six participants between the ages of 4 and 7-years were recruited from the two sites. The participants were randomised into three different baseline conditions (i.e., 3-, 4-, or 5-week baseline period) before receiving the 6-week Ngā Timatanga Toa programme for anxiety. Table 6 presents the child participants' characteristics. Their biological mothers completed all

parental reports and attended all therapy sessions with them. Fictitious names were used to ensure confidentiality and anonymity.

Table 6

Child Participant Characteristics

Characteristic	Sample
Sex	
Male	4
Female	2
Non-binary	0
Participants	**Ages**
Esther	4 years 7 months
Andy	5 years 10 months
Collin	6 years 4 months
Ben	6 years 10 months
Dorothy	7 years 5 months
Fred	7 years 7 months
Average age	6 years 4 months
Ethnicity	
NZ European	6

Assessment Measures and Primary Outcome

The main objective of the Ngā Timatanga Toa programme was to reduce the children's anxiety and anxiety interference; hence, the primary outcome measures focused on relevant symptoms and associated functional issues (see assessment tools, Table 7). The children's anxiety symptoms were monitored during the study by a clinical psychologist who assessed whether or not the child met the DSM 5 criteria for a diagnosis of anxiety disorder. Monitoring was undertaken on entry into the study, at post-intervention (PI) and at follow-up (FU). Additionally, the Child Behaviour Checklist (CBCL) and The Teacher Report Form (TRF) were administered at the same time points to determine if the children's anxiety levels were within the clinically significant range pre- and post-intervention. A shift in the CBCL and TRF scores from clinical to non-clinical levels indicates a significant reduction in anxiety. It is critical to highlight that when reading the results, please note that a diagnosis of anxiety is not solely based on the scores of psychometric measures such as the CBCL although they are valuable. Diagnosing anxiety typically involves a comprehensive assessment (clinical interview), symptom observation, meeting diagnostic criteria, colleting collateral information and clinical judgment.

The Child Anxiety Life Interference Scale (CALIS) tools measured the level of interference, or functional impact, on the child's everyday life caused by their anxiety. This was administered on entry into the study, during the baseline period, mid-intervention (MI), PI and at FU (i.e., 4-weeks PI). It was anticipated that anxiety interference would reduce by the end

of the intervention (PI), and these gains would be maintained for 4-weeks at FU. While the intervention targeted anxiety reduction, it is critical to note that anxiety interventions, including the programme tested in this study, do not entirely remove anxiety because anxiety is an inherent human condition. Thus, the intervention aims to provide children with strategies to manage their anxiety and reduce its impact, enabling improved functioning and greater enjoyment in life.

Table 7

Anxiety Measures

Anxiety symptoms measures (Diagnostic)
The School Anxiety Scale Teacher Report Form (SAS-TR)
The Child Behaviour Checklist (CBCL)
The Teacher Report Form (TRF)
Anxiety interference measures (Functional impact)
The Child Anxiety Life Interference Scale (*CALIS-P, Parent form*) for 6 to 17-year-olds.
The Child Anxiety Life Interference Scale (*CALIS-C, Child form*) for 6 to 17-year-olds.
The Child Anxiety Life Interference Scale (*CALIS-PV, Pre-School-Version*) for 3 to 5-year-olds.

Individual Participant Results

This section presents the six child participants' individual scores, and the effect size (ES) for each, to demonstrate the effectiveness of the intervention. Visual analysis was also used to describe the trajectory of change, trend, level of stability, and direction of change. The results of the two young participants (Esther and Andy) aged between 3 and 5-years are presented first, and then the older participants (Collin, Ben, Dorothy, and Fred) aged between 6 and 7-years, because each group had different versions of the forms. The parents of the younger participants (Esther and Andy) completed the CALIS-PV. Parents of the older participants completed the CALIS-P, and the older child participants (Collin, Ben, Dorothy and Fred) completed the CALIS-C.

Esther

Esther was a 4-year, 7-month-old girl who lived with her mother and stepfather, and two siblings. She had an older sister and a younger half-brother. Her stepfather was a full-time employee, and her mother was a part-time worker. Esther's older sister presented with challenging behaviours, outbursts, and heightened emotions, affecting the family, including Esther. According to Esther's mother, Esther's anxiety was observed to increase when her sister had outbursts. She was also observed to be distressed by her mother's actions when

dealing with her sister's difficult behaviours. Esther's sister's behavioural outbursts appeared to influence and shape Esther's anxiety and interactions with other children.

Esther presented with clingy behaviour, particularly in novel environments. Her mother reported that Esther struggled to find the right words to express her emotions and worried about 'random' things. She often complained of stomach aches in anxiety-provoking situations and constantly checked if her mother was monitoring her.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

The psychologist's assessment of Esther on entry into the study stated that she presented with an anxious temperament (i.e., being withdrawn in novel situations and social situations), specific fears (e.g., of wind), sensory sensitivities (i.e., loud noises), and separation anxiety (i.e., distress at the transition to kindergarten, or if her mother leaves home). Esther constantly sought proximity and reassurance from her mother. Esther was diagnosed with Separation Anxiety Disorder (SAD) in the context of several family stressors.

At PI, Esther's mother reported that Esther was managing drop-off at kindergarten well and was less distressed during separation from her. Esther was coping better with new people, as observed in her relationship with new relief teachers. Esther could also use different strategies she had learned to manage her emotions in stressful situations. The psychologist's opinion was that Esther's anxiety was in remission.

At FU, Esther had made sustained progress and continued to manage kindergarten drop-offs well. She began school visits, which progressed well, and positively engaged with other children. She was observed to seek greater social contact, including time away from her mother; for example, asking to visit the homes of friends, which she never did previously. She was observed to use her sensory box often, especially when overwhelmed, and continued to use other calming strategies learnt during stressful situations. The psychologist's impression was that Esther's separation anxiety remained in remission.

Table 8 presents Esther's anxiety diagnostic measures, which align with the psychologist's assessment and show a significant decrease in her anxiety symptoms from screening to PI. The CBCL t score (87) was in the clinical range on entry into the study. At PI, the CBCL t score was 59 being in the non-clinical range. The family did not complete the follow-up form. The CBCL forms completed by Esther's mother were scored electronically using the Achenbach System of Empirically Based Assessment (ASEBA) Web (2023) system, which automatically generated percentile and t scores.

Table 8

Anxiety Symptoms Measures Scores for Esther (Diagnostic)

	CBCL	TRF	SAS-TR	Diagnosis
On entry (Screening)	87	*	*	SAD
PI	59	*	*	Did not meet criteria
FU	Not done	*	*	Did not meet criteria

Key: * represents where the class teacher did not consent to participate in the study; Not done represents missing data where the assessment form was sent to the family but was not completed or returned; CBCL Child Behaviour Checklist; FU Follow-Up; PI Post Intervention; SAD Separation Anxiety Disorder; SAS-TR School Anxiety Scale Teacher Report; TRF Teacher Report Form.

Anxiety Interference: Parent Measure

Esther's mother completed the CALIS-PV because Esther was under 6-years-old. This tool measured the anxiety interference in Esther's daily functioning as reported by her mother. Figure 2 shows the trajectory of the CALIS-PV from entry into the study, during the baseline period, at MI, PI, and FU.

The CALIS-PV score had an upward trend from entry into the study to week three of the baseline period. The score started trending downward from when the intervention was introduced and changed by considerable magnitude. At FU, the CALIS-PV score was below the cut-off score (27.5).

The CALIS-PV baseline average (BLA) (57.7) was above the CALIS-PV cut-off score (27.5). The difference between the CALIS-PV BLA and PI scores was +42.7 indicating a large reduction in anxiety interference in Esther's life. The difference between the CALIS-PV PI and FU scores was +8, indicating maintenance of these gains at FU.

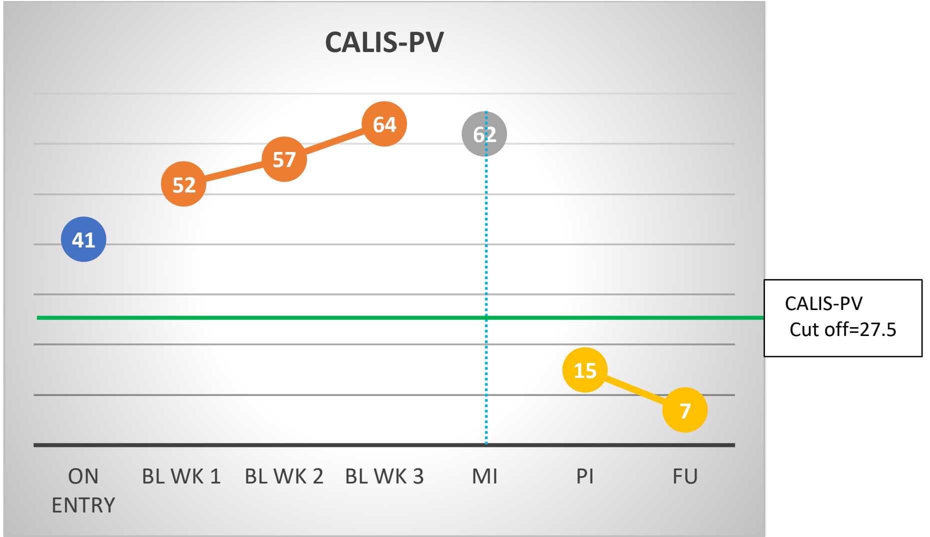
Effectiveness of the Intervention

The effectiveness of the intervention was evaluated by computing the effect size (ES) score. ES is a quantitative measure of the magnitude of the experimental effects and establishes the strength of the relationship between the intervention and effect. A large ES signifies the intervention had a significant impact on the participant and the outcome of the research has practical significance. A small ES indicates a minimal impact on the participant or variable being tested. The ES was interpreted using the benchmark proposed by Robey and Beeson (2005) for single-case designs: 4.0, 7.0, and 10.1; for small, medium, and large respectively. Very small represents an ES under 4.0, small represents an ES from 4.0 to under 7.0, medium represents an ES from 7.0 to under 10.1, and large represents an ES of 10.1 or greater.

The CALIS-PV ES was medium for Esther showing that the intervention had an impact on reducing the level of anxiety interference in her life. Table 9 presents the ES for Esther indicating the intervention effectiveness.

Figure 2

CALIS-PV Scores for Esther



Key: BL Wk Baseline Weeks 1, 2, & 3; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention.

Table 9

ES Scores for Esther's CALIS-PV Scores

Form	**Effect Size**
CALIS-PV	9.5
BL v PI & FU	**CALIS-PV**
BLA & Standard Deviation	57.7 *(4.9)*
PI	15
FU	7

Key: BLA Baseline Average; BL Baseline; CALIS-PV Child Anxiety Life Interference Scale (Pre-school Version); FU Follow-Up; PI Post-Intervention.

Summary of Esther's Results

The CALIS-PV trajectory, CBCL, and ES score indicate that the intervention impacted Esther's anxiety presentation by reducing her anxiety symptoms, anxiety interference, and improving her functioning. This is supported by parental feedback and the psychologist's assessments, providing evidence supporting hypotheses one and two.

Andy

Andy was a 5-year, 10-month-old boy who presented with separation anxiety and constipation. He struggled to separate from his mother, who described him as "*clingy*" with a phobia of water.

Andy was the only child in his family; his mother was a single parent and his primary caregiver. He had limited contact with his father and paternal relatives. Andy spent most of his time with his mother and had regular contact with his maternal grandmother. Being the only child, Andy had a strong relationship with his mother and only separated from her when she went to work, or when he went to school. Andy's mother noted that separating from him during drop-offs to kindergarten and school was challenging, but he would settle a few minutes after she left. Andy's mother thought this was because he was the only child and had never really separated from her, but the distress experienced by Andy during drop-offs to kindergarten or school never improved. Over time, she became accustomed to these challenging drop-offs, but her maternal instinct was she felt Andy was suffering from anxiety.

Andy presented with constipation, yet medical investigations did not find any physical causes for his constipation. Andy's doctors hypothesised that his constipation was due to anxiety as he voiced anxious thoughts about using the toilet to empty his bowel. Andy's mother said he would not use the school toilet to empty his bowel and would wait until he got home. While he was more comfortable using the toilet at home, he did not use it often. In addition to his anxiety-driven constipation, Andy also presented with sensory challenges and anxieties around water. He preferred to bathe than shower and avoided water-based activities.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

At the screening assessment to enter the study, Andy met the criteria for SAD, presenting with worries about toileting, separation from his mother, sensory challenges, and avoiding water-based activities. During the intervention, Andy's mother reported to the psychologist that he was able to enjoy water activities and was better at facing anxiety-provoking situations that he had previously avoided before the intervention. Additionally, she stated that "*the sensory component of the intervention helped address some of Andy's sensory issues*".

At the completion of the intervention, Andy still met the criteria for SAD; however, his anxiety symptoms showed a notable decrease, and he had improved participation in several daily activities, which he avoided before the intervention. The FU psychological assessment to assess whether gains achieved during the intervention were maintained was not completed because Andy was lost to FU.

Table 10 shows Andy's diagnostic measures of anxiety symptoms, which shifted from the clinical range (70 or greater) on entry to borderline range (65 to 69) at PI. Andy's CBCL and TRF scores were scored with the Web ASEBA. The FU data for the CBCL and TRF were not received from the parents or teacher, restricting the measurement of any ongoing effect. The TRF t scores were 53 on entry and 52 at PI, indicating little to no change in Andy's anxiety from the teacher's perspective. However, the teacher's SAS-TR showed some improvement in Andy's anxiety symptoms.

Table 10

Anxiety Symptom Measures for Andy (Diagnostic)

	CBCL	**TRF**	**SAS-TR**	**Diagnosis**
On entry (screening)	70	53	15	SAD
PI	67	52	5	SAD
FU	Not done	Not done	10	Not done

Key: CBCL Child Behaviour Checklist; Not done (missing data where the assessment form was sent to the family but was not completed or returned); SAD Separation Anxiety Disorder; SAS-TR School Anxiety Scale Teacher Report; TR Teacher Report Form.

Anxiety Interference: Parent Measure

Andy's mother completed the CALIS-PV, as Andy fell in the younger age range (3-5 years). Figure 3 shows the trajectory of the CALIS-PV from entry into the study, during the baseline period, at MI, PI, and FU.

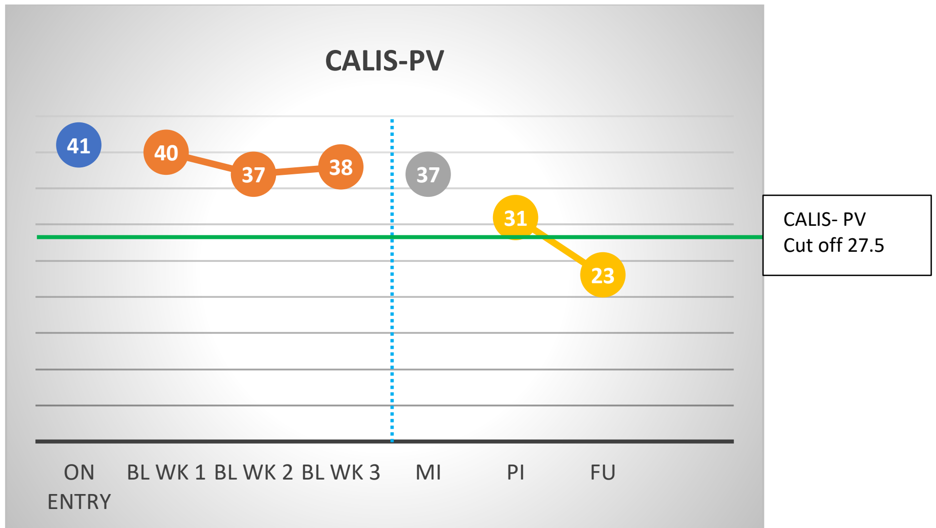
The baseline scores were relatively stable and showed a downward trend when the intervention was introduced. The CALIS-PV score improved significantly at the end of the intervention, measuring 31 at PI. Although this score was still above the cut-off point (27.5), it was a significant improvement from the on-entry and baseline scores, which showed a difference of +7.33 between the CALIS-PV BLA (38.33) and the PI scores. The CALIS-PV scores continued to improve, measuring 23 at FU, which is below the cut-off signalling a clinically significant change. The trajectory of change indicates an improvement in Andy's anxiety interference levels.

Effectiveness of the Intervention

The effectiveness of the intervention was evaluated by computing the CALIS-PV ES score, the calculation of which was discussed earlier. Table 11 presents the ES calculations for Andy's scores. Andy's CALIS-PV had a medium ES, indicating that the intervention had an impact by reducing the interference of anxiety on his daily functioning.

Figure 3

CALIS-PV Scores for Andy



Key: BL Wk Baseline Weeks 1, 2, & 3; FU Follow-Up; MI Mid-Intervention; PI Post-Intervention.

Table 11

ES Score for Andy's CALIS-PV Scores

Form	**Effect Size**
CALIS-PV	9.4
BL v PI & FU	**CALIS-PV**
BLA & Standard Deviation	38.3 *(1.2)*
PI	31
FU	23

Key: BLA Baseline Average; BL Baseline; CALIS-PV Child Anxiety Life Interference Scale (Pre-School Version); FU Follow-Up; PI Post-Intervention.

Summary of Andy's Results

Overall, Andy's results indicate that the intervention reduced his anxiety interference and improved his function. This is supported by his mother's report, the visual analysis of the CALIS-PV, and the ES score. The CALIS-PV score at FU suggests that Andy may not have met the criteria for SAD at FU if the psychological assessment had taken place at this point.

Collin

Collin was a 6-year, 3-month-old boy who presented with separation anxiety. He struggled with separating from his mother during drop-off at school. Leading up to school in the morning he would complain of a headache and a sore tummy and cried repeatedly, begging his mother

to let him stay home. Sometimes his mother kept him home because he was so distressed, and she did not want to force him to go to school in such a distressed state.

Collin's separation anxiety was evident outside of school in social situations; he refused to go for playdates, sleepovers, or play with other children at the playground. He exhibited severe distress and anxiety symptoms such as excessive worry and tearfulness when separated from his mother. During the study, Collin and his family tested positive for COVID-19 and also had to move houses. These events were stressful for Collin and his family and may have influenced Collin's high PI score.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

Upon entry into the study, Collin was diagnosed by the clinical psychologist as having SAD in the context of increased family stressors. He presented with separation anxiety, school avoidance, and avoidance of leaving home to have contact with his father or to spend time with friends. Before leaving for school, Collin complained of stomach aches and expressed distress on separation from his mother. Once at school, he would settle well. The separation anxiety developed 6-months before the referral and worsened over time, although he was still attending school.

At PI, Collin's mother reported that Collin managed separation from her during school drop-off. It was reported that the sensory box benefited him as he used some sensory toys when upset and he also no longer complained of a sore stomach before going to school. His mother described Collin as calmer and said he could manage his emotions better when upset. She also noted that he was more able to express his feelings. Additionally, Collin's mother shared that she found the intervention helpful in improving her communication with Colin and in providing strategies to manage Collin's anxiety. The gains in improvement in functioning and reduction in anxiety were maintained at FU. According to the psychologist's assessment, Collin did not meet the criteria for SAD at PI and FU.

Table 12 presents the CBCL t scores on entry, at PI, and FU. As discussed earlier, a diagnosis of anxiety is not solely based on the scores of psychometric measures which explains why Collin did not meet the anxiety diagnosis at follow-up although his FU CBCL score of 62, was the same as on entry.

Table 12

Anxiety Symptoms Measures Scores for Collin (Diagnostic)

	CBCL	TRF	SAS-TR	Diagnosis
On entry (Screening)	62	*	*	SAD
PI	59	*	*	Did not meet criteria
FU	62	*	*	Did not meet criteria

Key: * represents where the class teacher did not consent to participate in the study; CBCL Child Behaviour Checklist; TRF Teacher Report Form; SAD Separation Anxiety Disorder; SAS-TR School Anxiety Scale Teacher Report.

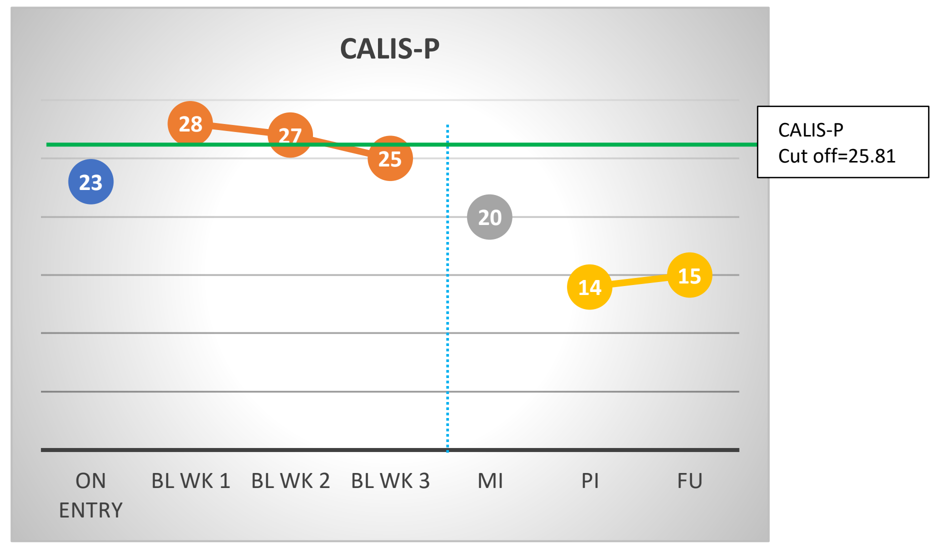
Anxiety Interference: Parent and Collin's Measures

Collin's mother completed the CALIS-P, and because Collin was over 5-years-old, he was able to complete the CALIS-C to measure impact of anxiety on his everyday life. Figures 4 and 5 below shows the trajectory of the CALIS (P & C) from entry into the study, during the baseline (BL) period, at MI, PI, and FU. The CALIS-P score (23) on entry was lower than the CALIS-P (25.81) cut-off. It was higher during the first 2-weeks of the BL period measuring 28 and 27, respectively, and slightly lower during the third week of the BL period measuring 25. The CALIS-P BL average (26.67) was above the CALIS-P cut-off (25.81). The CALIS-P scores changed moderately from when the intervention was introduced. A significant improvement is noted between the baseline period and PI scores. The CALIS-P score was 14 at PI, which is well below the cut-off. The difference between the CALIS-P BL average and PI of +12.67 and the trajectory of change indicate that the intervention positively impacted Collin's anxiety presentation and improved his functioning, as reported by his mother. The CALIS-P PI (14) and FU (15) scores were very close, indicating gains were maintained at FU.

The CALIS-C scores were stable during the baseline period with the average (11.33) being above the CALIS-C cut-off (10.66). While there was a downward trend at MI, there was a sharp increase in the PI score (17), with the score then dropping significantly at FU (5). It was reported that Collin was sick (i.e., had COVID-19) during the PI period and the family moved house, which may have increased his anxiety and affected his score. Overall, the CALIS-C scores suggest that despite a spike at PI, the intervention positively affected Collin's anxiety presentation at FU.

Figure 4

CALIS-P Scores for Collin



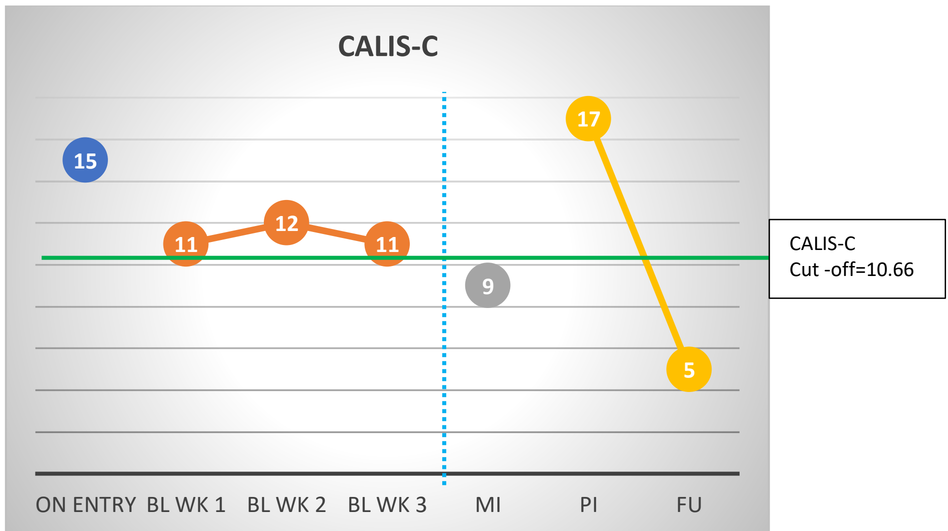
Key: BL Wk Baseline Week 1, 2, & 3; FU4 Week Follow-Up; MI Mid-Intervention; PI Post Intervention.

Effectiveness of the Intervention

The effectiveness of the intervention was evaluated by computing the CALIS (P & C) ES scores. Table 13 presents Collin's ES scores. Collin's CALIS-P ES is large indicating the intervention was effective in reducing his anxiety interreference and improving his daily functioning. The CALIS-C ES is negative indicating that he deteriorated at PI, although he improved at FU.

Figure 5

CALIS-C scores for Collin



Key: BL Wk Baseline Weeks 1, 2, & 3; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention.

Table 13

ES Scores for Collin's CALIS (P & C) Scores

Form		**Effect Size**
CALIS-P		10.2
CALIS-C		-0.6
BL v PI & FU	**CALIS-P**	**CALIP-C**
BLA & Standard Deviation	26.7 *(1.2)*	11.3 *(0.5)*
PI	14	17
FU	15	5

Key: BLA Baseline Average; BL Baseline; CALIS-P-Child Anxiety Life Interference Scale (Parent Version); CALIS-C- Child Anxiety Life Interference Scale (Child Version); FU Follow-Up; PI Post-Intervention.

Summary of Results for Collin

Overall, Collin's CALIS scores indicate that the intervention was effective in reducing his anxiety interference and improving his function. Although the CALIS-C had a sharp increase at PI and a negative ES, the score improved significantly at FU. The trend of an overall improvement is supported by feedback from Collin's mother, CALIS-P ES score, and the psychologist's assessment, providing evidence supporting hypotheses one and two.

Ben

Ben was a 6-year 10-month-old boy and the only child in his family; his mother was a single parent and his primary caregiver. His parents separated when he was young, and he had regular contact with his father. His father had another partner and children. Being the only child, Ben had a strong relationship with his mother and only separated from her when she went to work, and when he went to school. His mother ran her own business and was responsible for all the chores in the house.

Ben's mother was concerned about several aspects of his presentation. She said Ben had trouble socialising with other children without adult supervision. He constantly worried about several things, including past events, plans changing, being placed under pressure (especially when they had to get ready to go somewhere), separation from his mother during school drop-off and going to see his father. His mother described his distress as "*complete meltdowns*" when he had to separate from her. He was described as having difficulty attending school, seeing his father, and making new friends.

During the intervention, Ben's mother discovered that she was pregnant, and she and her new partner planned to move in together. Ben was beginning to see his mother's partner more often and was having to adjust to new settings and developing a relationship with him while maintaining a relationship with his father. At the same time, their dog had puppies, and his mother was trying to restart her business after COVID-19 lockdown restrictions were eased. Ben's mother had financial stress and an extra load of dealing with Ben's anxiety. There was limited finances in the family as his mother was not working, and she needed money to take care of the puppies and prepare for the new baby. Having to separate from his mother after several weeks of staying with her at home during the lockdown was stressful for Ben. These multiple stressors at home, changing circumstances, and COVID-19-related restrictions provide the context in which Ben presented with anxiety. They are important to note as they may have affected his anxiety presentation and scores, particularly the PI score. Equally, his mother may not have had the time and capacity to engage fully with the psychometric and qualitative forms that were elements of the study.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

Ben met the diagnostic criteria for GAD and SAD upon entering the study. Ben presented with anxiety-associated physical symptoms, including complaints of a sore stomach when he was about to separate from his mother, such as before going to school or to his father's place and difficulties building social relationships with peers.

After the intervention, Ben showed improvements in how he managed his anxiety and was able to use sensory-based strategies to shift his focus from anxiety-provoking situations. His mother described him as a lot calmer, and his anxiety related behavioural difficulties settled down and he was more able to manage stress. At PI and FU Ben was free from the anxiety disorders he was diagnosed with on entry into the study, indicating that the intervention significantly impacted his anxiety presentation from a clinical perspective. Additionally, he could separate from his mother with less distress and anxiety through the use of the sensory tools. At FU, Ben was reported to have maintained his gains in other previously anxiety-provoking areas, except for anxiety about going to school, which was starting to increase again. As shown in Table 14, the diagnostic measures of anxiety symptoms were not completed at PI and FU by the parents.

Table 14

Anxiety Symptoms Measures Scores for Ben (Diagnostic)

	CBCL	TRF	SAS-TR	Diagnosis
On entry (Screening)	85	*	*	GAD & SAD
PI	Not done	*	*	Did not meet criteria
FU	Not done	*	*	Did not meet criteria

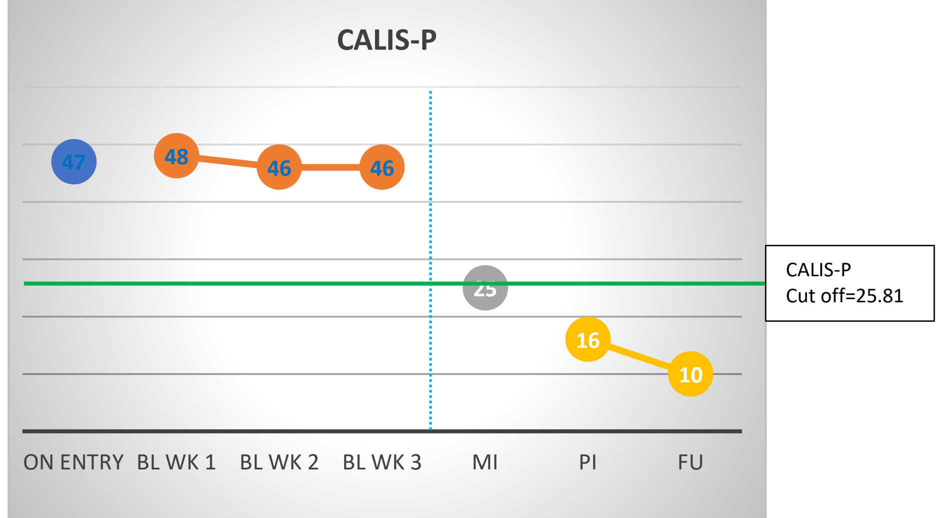
Key: * represents where the class teacher did not consent to participate in the study; Not done represents missing data where the assessment form was sent to the family but was not completed or returned; CBCL Child Behaviour Checklist; GAD Generalised Anxiety Disorder; SAD Separation Anxiety Disorder; SAS-TR School Anxiety Scale Teacher Report; TRF Teacher Report Form.

Anxiety Interference and Symptoms: Parent and Ben's Measures

Ben and his mother completed the CALIS-C and CALIS-P forms respectively which measured the impact of anxiety on his life from his and his mother's perspectives. Figures 6 and 7 shows the trajectory of the CALIS (P & C) from entry into the study, during the baseline period, at MI, PI, and FU.

Figure 6

CALIS-P Scores for Ben



Key: BL Wk Baseline Weeks 1, 2, & 3; FU Follow-Up; MI Mid-Intervention; PI Post-Intervention.

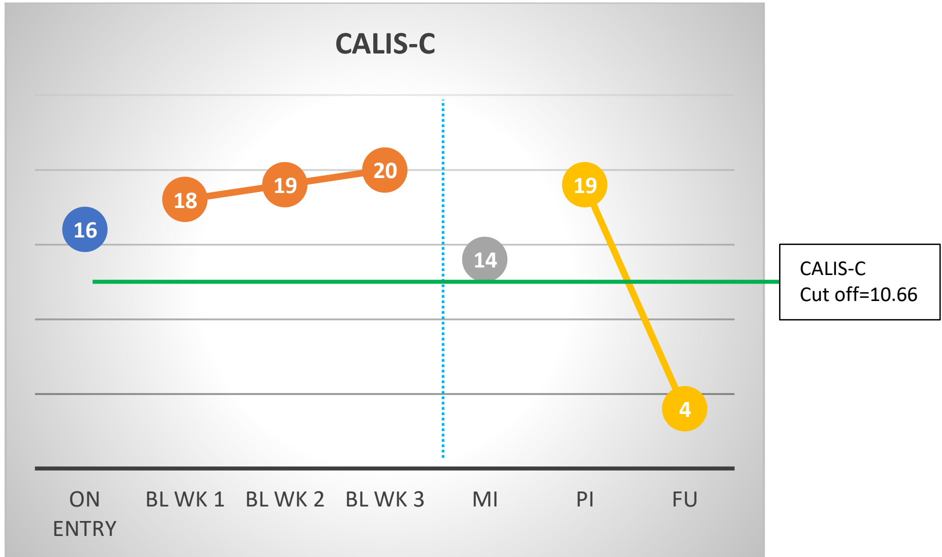
The CALIS-P scores were relatively stable during the baseline period and change when the intervention was introduced. The trend of the scores slope downwards, indicating an improvement in expression of anxiety symptoms and a reduction in anxiety life interference. The CALIS-P shows sudden and significant improvement at MI, indicating that Ben responded quickly to the intervention.

The pre-intervention CALIS-P BLA (46.7) was significantly above the CALIS-P cut-off (25.81). The difference between the CALIS-P BLA and the PI scores was +30.7, indicating a significant intervention impact. Ben continued to make progress at FU.

The CALIS-C showed no improvement from entry to PI, with CALIS-C BLA and PI scores both measuring 19 which was above the CALIS-C cut-off (10.66). However, Ben made improvement at MI after the intervention was introduced. A significant improvement was noted at FU with the score dropping to 4 with a difference of +15 between the CALIS-C PI and FU scores, indicating that Ben continued to experience intervention effects PI.

Figure 7

CALIS-C Scores for Ben



Key: BL Wk Baseline Weeks 1, 2, & 3; FU Follow-Up; MI Mid-Intervention; PI Post-Intervention.

Effectiveness of the Intervention

Tables 15 presents the ES scores for Ben. The CALIS-P ES score was large, and the CALIS-C ES was moderate, both indicating a positive impact of the intervention on Ben's anxiety and reduced functional impact.

Table 15

ES Scores Ben's CALIS (P & C) Scores

Form		**Effect Size**
CALIS-P		37.4
CALIS-C		9.4
FU	**CALIS-P**	**CALIS-C**
BLA & Standard Deviation	46.7 *(0.9)*	19 *(0.8)*
PI	16	19
FU	10	4

Key: BLA Baseline Average; CALIS-P Child Anxiety Life Interference Scale (Parent Version); CALIS-C Child Anxiety Life Interference Scale (Child Version); FU Follow-Up; PI Post-Intervention.

Summary of Results for Ben

Overall, Ben's CALIS results indicate the intervention effectively reduced his anxiety and improved his function. Visual analysis of the scores from both CALIS (P & C) measures tell a similar story at FU, which indicates the intervention was effective. This is supported by the

psychologist's assessment, parental feedback, and the ES scores, providing evidence supporting hypotheses one and two.

Dorothy

Dorothy was a 7-year, 5-month-old girl, and the only child in her family. Her mother ran her own business, and her father was employed full-time. She presented with longstanding anxiety, which her mother reported as worsening. Her anxiety was associated with behavioural difficulties, including avoiding school and vomiting before or at school. She struggled to interact with other children, particularly in groups and had one close friend. Her mother described her as socially anxious. She did not participate in activities outside of what she was used to and needed constant parental reassurance. Her history of separation anxiety was first observed when she was around 2-years-old when her mother had to return to work after looking after her since birth. Dorothy's mother initially thought the separation anxiety was due to them being together for an extended period, leading Dorothy to struggling to deal with new settings to separate. Her mother thought this would improve, but it never did. Dorothy's mother noticed that Dorothy was also getting anxious around people she knew and struggled to settle at kindergarten. Separation at kindergarten was challenging, as Dorothy would vomit when distressed and her mother would take her home. She would not vomit when she was home with her mother. Once she attended a party and never left her father's side, and vomited the food she ate at the party. When they got home, she was fine and did not vomit her dinner.

Dorothy had sensory sensitivities, as she did not like loud noises or busy environments, was bothered by certain types of fabrics, bright lights, and smells which were emotionally distressing, causing her to experience significant physical symptoms such as stomach aches and vomiting. At school, she only played with one person at a time, or she did not play with anyone at all, as the interaction would be too overwhelming.

Dorothy was distressed by changes in routine and surprises. She started school during a COVID-19 lockdown, requiring her to learn from home, which caused emotional and behavioural disruptions. Her parents observed that she was very anxious and always on edge during this period. She had significant anxiety about school and had trouble sleeping, which improved after she was given sleep medication. The night before school, she would experience a sore stomach. She had extreme anxiety about swimming at school as she had experienced a negative event when younger during swimming lessons. Since then, swimming has caused her high anxiety. During drop-off, the teacher had to physically separate her from her mother. It was observed that her anxiety depended on what was happening at school, breaks in routine (e.g., different teacher), and whether Dorothy had slept the previous night. During the study,

Dorothy did not vomit in school but was often unwell before school and regularly complained of a sore stomach. Dorothy experienced anxiety in other situations when she was separated from her mother, as well as in social situations when she had to interact with multiple people (e.g., birthday parties, family friends visiting). Dorothy would complain that the situation was too loud and became uncomfortable if people were too close to her.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

On entry into the study, Dorothy presented with longstanding anxiety symptoms, including avoidance of novel situations, especially involving many people; distress at the school drop-off; a sore stomach and vomiting in anxiety-provoking situations; and needing a high degree of reassurance regarding activities and routines. Dorothy was diagnosed with SAD upon entry into the study.

At the completion of the intervention, Dorothy's mother reported no improvement in Dorothy's anxiety presentation to the psychologist (although the CALIS-P scores showed improvements). Dorothy continued to meet the criteria for SAD at the completion of the intervention. Despite Dorothy still meeting the criteria for an anxiety diagnosis, her mother reported to the researcher that she did notice some small improvements in Dorothy's functioning, although overall she did not see any improvement in her anxiety level as she reported to the psychologist. She described two situations where Dorothy would go away on her own and participate in different activities during a vacation without needing parental reassurance, something she had never done before. The mother also shared another example where she noted that Dorothy was more settled and calmer when using headphones (i.e., a sensory strategy of listening to music) while travelling. In the past, travelling was stressful for Dorothy and they had never travelled a long journey with her, but she was able to manage this activity after receiving the intervention. These specific improvements are consistent with Dorothy's mother's CALIS-P scores.

As shown in Table 16, the diagnostic measures did not show a significant change in anxiety symptoms from screening to PI. The CBCL t scores for Dorothy increased from entry to PI and FU. Her scores were 68, 72, and 72, respectively. These scores shifted from borderline into the clinically significant range.

Table 16

Anxiety Symptoms Assessment Measures Scores for Dorothy (Diagnostic)

	CBCL	TRF	SAS-TR	Diagnosis
On entry (Screening)	68	*	*	SAD
PI	72	*	*	SAD
FU	72	*	*	SAD

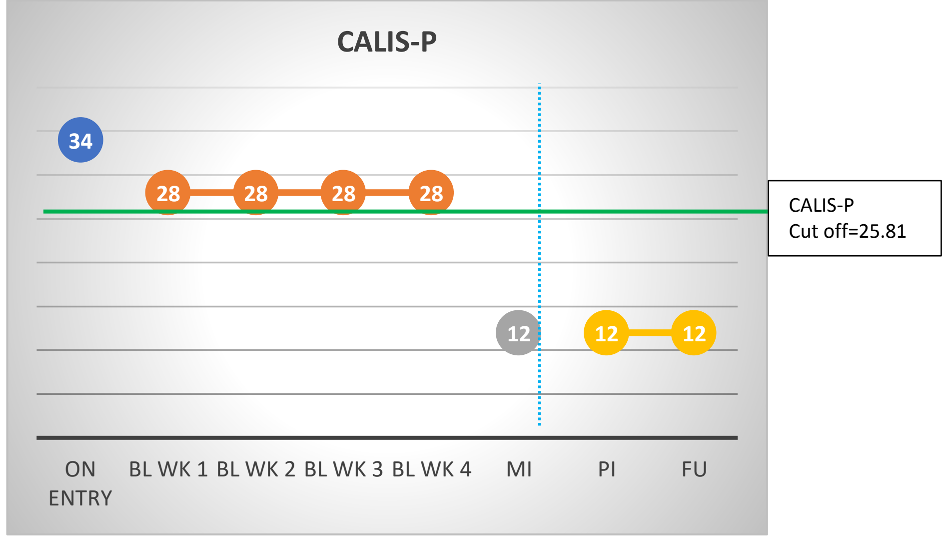
Key: * represents where the class teacher did not consent to participate in the study; CBCL Child Behaviour Checklist; SAD Social Anxiety Disorder; SAS-TR School Anxiety Scale-Teacher Report; TRF Teacher Report Form.

Anxiety Interference and Symptoms: Parent and Dorothy's Measures

Dorothy and her mother completed the CALIS-C and the CALIS-P forms, respectively. Figures 8 and 9 show the trajectory of the CALIS (P & C) from entry into the study, during the baseline period, at MI, PI, and FU. The CALIS-P scores were stable during the baseline period yet changed when the intervention was introduced and were stable throughout the intervention to FU, indicating that the intervention had some impact on Dorothy's anxiety life interference, and presentation. Dorothy's mother's scores were higher on entry and during the baseline period yet were lower after the intervention was introduced. The CALIS-P BL average score (28) was above the CALIS-P cut-off (25.81). The PI score (12) was significantly lower than the CALIS-P BL average, with the difference between the scores (+16), indicating that the intervention impacted Dorothy's anxiety, life interference, and presentation. The CALIS-P score at PI and FU was 12 indicating maintenance of gains at follow-up.

Figure 8

CALIS-Parent Scores for Dorothy

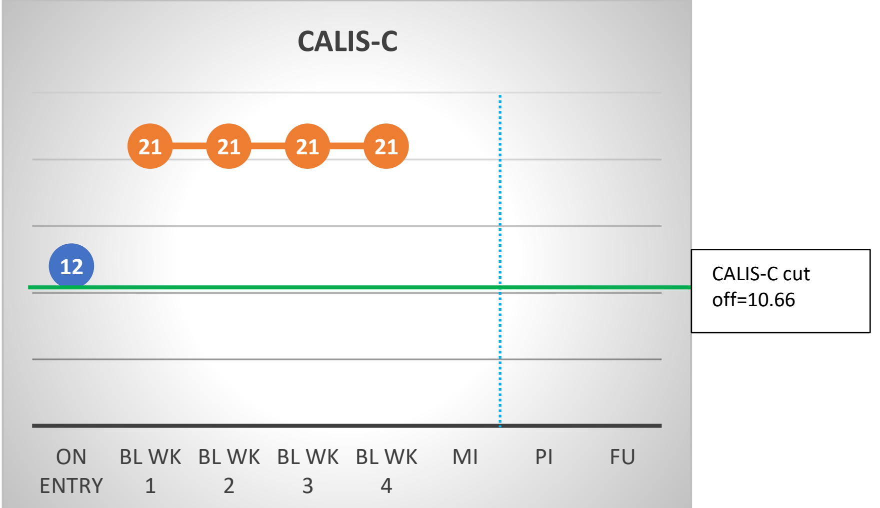


Key: BL Wk Baseline Weeks 1, 2, 3, & 4; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention.

The CALIS-C was stable during the baseline and the BL average score (21) was above the cut-off (10.66). The MI, PI, and FU scores were missing. The mother said Dorothy refused to complete the forms.

Figure 9

CALIS-Child Scores for Dorothy



Key: BL Wk Baseline Weeks 1, 2, 3, & 4; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention. Dorothy did not complete the MI, PI, and FU forms.

Effectiveness of the Intervention

The CALIS-P ES was not calculated for Dorothy because there was no variance in the baseline phase scores, and there was no variance in the post intervention phase scores. This meant that a standard deviation score could not be calculated for the baseline scores as it would result in a zero (Robey & Beeson, 2005). The CALIS-C ES was not calculated due to missing data.

Summary of Results for Dorothy

While Dorothy still met the diagnostic criteria for an anxiety disorder at PI, her CALIS-P scores indicate that the intervention was effective in reducing her anxiety life interference and improved her function in specific situations. While the intervention appeared to be effective in relation to the visual analysis of CALIS-P scores, the verbal reports from Dorothy's mother were mixed. She noted some improvements in specific anxiety-related behaviours but did not find the intervention to be effective in reducing the overall anxiety symptoms.

Fred

Fred was a 7-year, 7-month-old boy who presented with behavioural difficulties at school and was on the verge of being excluded from school. Prior to participating in the study, Fred was diagnosed with ADHD years earlier, which was well managed with stimulant medication. Before being diagnosed with ADHD, Fred was also assessed by an occupational therapist who identified he had challenges with sensory processing in several sensory systems. Fred had separation anxiety when he was a toddler and at kindergarten, teachers noticed that Fred was anxious within the kindergarten setting. As he grew older, he was reportedly aggressive towards other children when anxious.

Fred's challenging behaviours and anxiety were in the context of multiple family stressors (parental separation). His mother reported that Fred's behavioural problems were settling down, and anxiety was the primary presenting problem. Two years earlier, Fred was referred to children's mental health services presenting with anxious behaviours noticed at kindergarten and home. At that time, Fred was referred to a primary care organisation to get help for his anxiety but did not receive the intervention as his anxiety presentation improved before the intervention began.

Anxiety Symptoms: Clinical Psychologist Assessment and Diagnostic Measures

On entry into the study, Fred was seen by a clinical psychologist for a mental health assessment and presented with anxiety and attachment difficulties. Fred presented with generalised anxiety and was worried about COVID-19, religion, and death. His anxiety was noticed at kindergarten, as discussed earlier. He met the criteria for GAD and SAD.

At PI, Fred's presentation had improved as reported in the below quote from the psychologist after the PI completion assessment.

> *Fred was so different to me today compared to when I first met him. He would not look at me or engage with me the first time we met, and today he made good eye contact, engaged with me, answered questions and asked for more information when I told half a story. He seemed much less self-conscious and more confident.*

During the PI assessment, Fred's mother reported that Fred's anxiety had reduced overall. The mother reported that they had a shared language to talk about his anxiety and used the tools from the intervention to manage his anxiety. The mother also reported that Fred was comfortable approaching other children and engaged with them spontaneously, which he did

not do in the past. He still worried about how other children perceived him, but he no longer avoided engaging with others.

The psychologist's impression was that Fred's anxiety was in remission; he still had some anxiety, but not to the degree it was when he first came to the attention of children's mental health services. Fred was doing well at school (i.e., behaviourally, academically, and socially) and had made many friends. His presentation and functioning were significantly better, and gains were maintained at FU.

As shown in Table 17, the CBCL forms were not completed or returned by the parents at the PI and FU points. However, through clinical interviews, the psychologist determined that at the end of the intervention and at FU, Fred did not meet the criteria for diagnosis of an anxiety disorder.

Table 17

Anxiety Symptoms Measures Scores for Fred (Diagnostic)

	CBCL	TRF	SAS-TR	Diagnosis
On entry (Screening)	69	*	*	GAD & SAD
PI	Not done	*	*	Did not meet criteria
FU	Not done	*	*	Did not meet criteria

Key: * represents where the class teacher did not consent to participate in the study; Not done represents missing data where the assessment form was sent to the family but was not completed or returned; CBCL Child Behaviour Checklist; GAD Generalised Anxiety Disorder; SAD Social Anxiety Disorder; SAS-TR School Anxiety Scale Teacher Report; TRF Teacher Report Form.

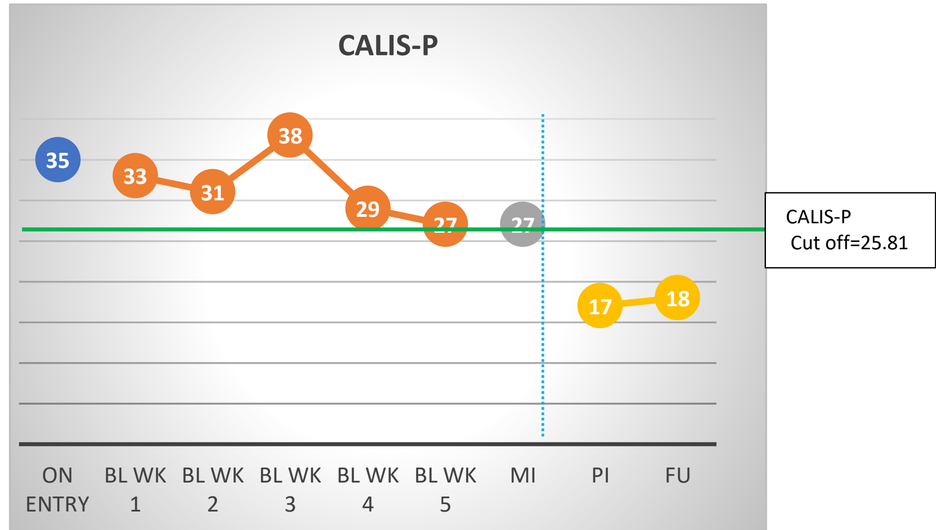
Anxiety Interference: Parent and Fred's Measures

Fred and his mother completed the CALIS-C and CALIS-P assessment forms respectively. Figures 10 and 11 below show the CALIS (P & C) scores on entry into the study during the baseline period, MI, PI, and FU.

The CALIS-P scores were unstable during the baseline period. Between weeks one and three, the scores went down and then up, reaching a peak during week three. The score took a downward trend from weeks four and five. The scores were fairly stable between week four and MI. All the CALIS-P scores from entry to MI were above the cut-off (25.81). The CALIS-P BL average score was 31.6. The CALIS-P scores shifted downwards and were below the cut-off at PI indicating the intervention positively impacted Fred's anxiety and life interference. The difference between the CALIS-P BLA and the PI scores was +14.6, indicating significant improvement. The difference between the PI and FU scores was -1, indicating maintenance of gains at follow-up.

Figure 10

CALIS-P Scores for Fred

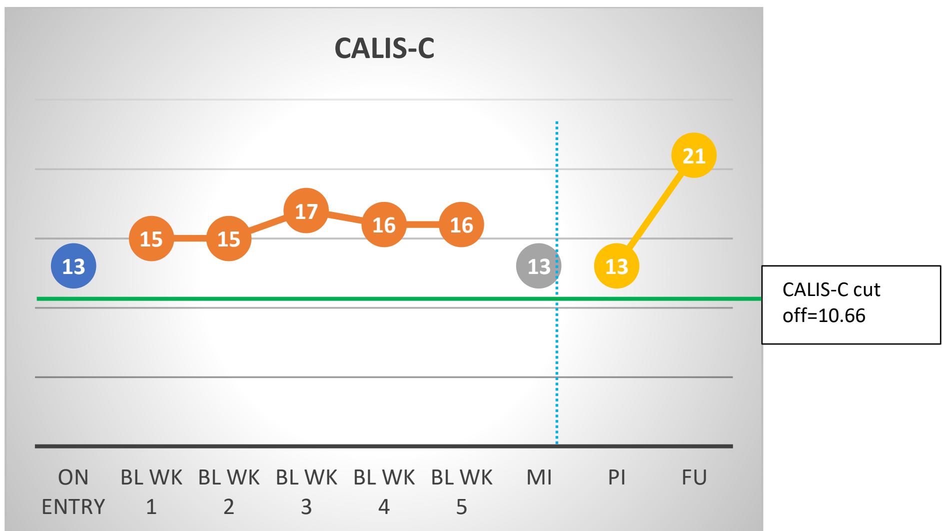


Key: BL Wk Baseline Weeks 1, 2, 3, 4, & 5; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention.

The CALIS-C scores were very stable during the baseline period and showed a slight downward trend at MI signalling a small improvement. The CALIS-C BLA was 15.8 and the difference between the CALIS-C BLA and the PI score was +2.8, indicating an improvement. The difference between the CALIS-C scores at PI and FU was -8, indicating a significant loss of gains at FU. This is in contrast to the reports from the mother, psychologist, and therapist who delivered the intervention, who all reported improvements in Fred's anxiety presentation. After completion of the therapy, Fred was reported to struggle with leaving his grandmother after visiting for an extended period, and he was worried about transitioning to a new class in the following academic year. These two events seem to explain why his scores were high at FU.

Figure 11

CALIS-C Scores for Fred



Key: BL Wk Baseline Weeks 1, 2, 3, 4, & 5; FU 4 Weeks Post-Intervention Follow-Up; MI Mid-Intervention; PI Post-Intervention.

Effectiveness of the Intervention

The effectiveness of the intervention was evaluated by computing the CALIS (P & C) ES and Table 18 presents the ES scores for Fred. The CALIS-P ES was very small and the CALIS-C was negative, indicating no improvement.

Table 18

ES Scores for Fred's CALIS (P & C) Scores

Form		**Effect Size**
CALIS-P		3.7
CALIS-C		-1.7
FU	**CALIS-P**	**CALIS-C**
BLA & Standard Deviation	31.6 *(3.8)*	17*(4)*
PI	17	13
FU	18	21

Key: BLA Baseline Average; CALIS-P Child Anxiety Life Interference Scale (Parent Version); CALIS-C Child Anxiety Life Interference Scale (Child Version); FU Follow Up; PI Post-Intervention.

Summary of Results for Fred

Fred's results indicate that the intervention had a positive impact on his anxiety symptoms and presentation, with some reduction of his anxiety symptoms and improvement in functioning at PI. However, there was a mixed picture as to whether the improvements were maintained at FU, with Fred's CALIS-C score not aligning with reports from his mother, the psychologist and the therapist who delivered the intervention.

Summary of Participant Results

Table 19 presents the summary of the scores and diagnostic status of all the children pre- and post- intervention. Four children (67%) did not meet the criteria for an anxiety disorder following the intervention, after being diagnosed with one at entry to the study. "*Met diagnosis*" is based on the clinical psychologist's assessment using clinical interviews and CBCL forms (where completed) to make a diagnosis. Although Andy was one of two children who still met the diagnostic criteria at PI, he did show some improvement in anxiety symptoms and moved out of the clinically significant level to the borderline level of symptoms in the CBCL measure. While Dorothy had no improvement in her anxiety symptoms, she did appear to reduce the impact of the symptoms through using some of the strategies learnt in the intervention. While the results related to reducing anxiety symptoms were mixed, they do provide some preliminary support for hypothesis one, in that the majority of the children had reduced anxiety after the intervention and at follow-up.

Anxiety interference (CALIS-P) scores at PI and FU were below the cut-off for all four older participants, signalling an improvement noted by their parents. A below cut-off score signals improvement and reduction in anxiety interference; hence, an improvement in functioning. As for the CALIS-PV scores for the two younger participants, the scores were below the cut-off at PI and FU for Esther and below the cut-off at FU for Andy. These scores also signal a reduction in anxiety interference and an improvement in functioning. For the CALIS-C, no score was below the cut-off at PI, while, two scores were below the cut-off at FU, and one was not done. The trajectory of change of the CALIS forms for child participants, except for Dorothy's CALIS-C, which was not done, indicates an improvement in anxiety interference levels from entry to follow-up. The CALIS ES scores, the trajectory of change, diagnostic results and parent reports all suggest that the intervention was effective in reducing anxiety interference in daily functioning, providing evidence supporting hypotheses two.

Table 19

Summary of All the Participants' Results

Participant	Period	Met diagnosis	CALIS-PV below cut-off	CALIS-P below cut-off	CALIS-C below cut-off	Hypothesis 1 & 2 supported
Esther	On Entry	Yes	No	N/A	N/A	Yes
	Baseline	Yes	No	N/A	N/A	
	PI	No	Yes	N/A	N/A	
	FU	No	Yes	N/A	N/A	
Andy	On Entry	Yes	No	N/A	N/A	Yes
	Baseline	Yes	No	N/A	N/A	
	PI	Yes	No	N/A	N/A	
	FU	Not done	Yes	N/A	N/A	
Collin	On Entry	Yes	N/A	No	No	Yes
	Baseline	Yes	N/A	No	No	
	PI	No	N/A	Yes	No	
	FU	No	N/A	Yes	Yes	
Ben	On Entry	Yes	N/A	No	No	Yes
	Baseline	Yes	N/A	No	No	
	PI	No	N/A	Yes	No	
	FU	No	N/A	Yes	Yes	
Dorothy	On Entry	Yes	N/A	No	No	Partially
	Baseline	Yes	N/A	No	No	
	PI	Yes	N/A	Yes	Not done	
	FU	Yes	N/A	Yes	Not done	
Fred	On Entry	Yes	N/A	No	No	Yes
	Baseline	Yes	N/A	No	No	
	PI	No	N/A	Yes	No	
	FU	No	N/A	Yes	No	

Key: CALIS-P Child Anxiety Life Interference Scale (Parent Version); CALIS-C Child Anxiety Life Interference Scale (Child Version); FU Follow Up; PI Post-Intervention; Not done represents missing data where the assessment form was sent to the family but was not completed or returned; N/A where the phone was not applicable to the child because of their age (refer to description at the beginning of the chapter).

Chapter Summary

The individual results obtained in this study support a functional relationship between the intervention (i.e., the Ngā Timatanga Toa programme) and anxiety, and the ability of the intervention to reduce anxiety interference in children aged 4 to 7-years, presenting with clinical anxiety. The psychologist reports and parent feedback indicated that the intervention was effective in reducing anxiety symptoms, behaviours of concern, and improving the child's

functioning by reducing anxiety interference in the children's lives. The data showed that the intervention may help improve children's functioning across settings as their anxiety decreased due to the therapeutic intervention. The intervention effects were replicated across six participants, where all baseline scores changed when the intervention was introduced. The magnitude of the changes ranged from small to significant, and the gains were maintained at FU for most participants. Four of the six children no longer meet the criteria for a diagnosis of an anxiety disorder at PI. The overall results provide preliminary evidence to support study hypotheses one and two. A reasonable conclusion can be drawn that the Ngā Timatanga programme may be effective in facilitating the management of anxiety in 4 to 7-year-old children presenting with clinical anxiety; however, this outcome cannot be generalised with certainty to a wider population.

Chapter 6:

Acceptability and Practicality of the Intervention

Introduction

This chapter is a continuation of the results, in which the data related to the acceptability and practicality of the intervention is presented. Specifically, the chapter addresses the secondary objectives of the study related to examining whether:

(a) the modified CBT-sensory modulation intervention is acceptable and practical for children and families.
(b) the delivery of the intervention is acceptable and practical for clinicians within a current NZ CAMHS setting.

The parents and therapists provided feedback regarding the intervention's acceptability and practicality by completing the parent and therapist satisfaction questionnaires (PSQ & TSQ). Additionally, the relevant Session Rating Scales (SRSs) completed by the parents and children were used as a proxy measure for the acceptability of the intervention. The chapter also presents feedback on the impact and outcomes of the intervention, as reported by children using the Outcome Rating Scales (ORSs), along with parental feedback collected in clinical interviews with the psychologist post-intervention and follow-up.

Feedback on Programme Process and Delivery

All participants (100%) attended all six intervention sessions; hence, there were no dropouts. Parents reported that having six sessions to attend was a practical and achievable commitment. At the end of each session, parents completed the standard Session Rating Scale while the children completed the Child (C-SRS) and Young Child (YC-SRS) versions as proxy measures of the acceptability of the intervention. These tools measure four areas of effective therapeutic relationships: respect and understanding, the relevance of the goals and topics, client-practitioner fit, and overall alliance. All parent SRS scores were above the cut-off point, indicating that parents developed a good therapeutic relationship with the therapists and found the process and delivery of the sessions acceptable and helpful (see Table 20). The child participants completed the C-SRS and YC-SRS versions, which mostly indicated that they enjoyed the sessions, and found the intervention helpful. One parent reported that their therapist struggled to deliver the intervention and recommended more training for therapists. Overall, the SRS scores reflected high therapeutic alliance, and acceptability of the intervention for both parents and children as presented in Table 20.

Table 20

SRS Scores for All Participants

SRS scores							
Participant	Measure	Measuring points					Cut-off
		Session 2	Session 3	Session 4	Session 5	Session 6	
Esther	SRS	39.5	39.7	35.7	40	39.8	36
	YC-SRS	☺	☺	☺	☺	☺	-
Andy	SRS	40	40	40	40	40	36
	YC-SRS	☺	☺	☺	☺	☺	-
Ben	SRS	40	38.4	38.6	38.6	36.8	36
	C-SRS	18.2	30	-	20	-	36
Collin	SRS	40	36	40	40	40	36
	C-SRS	40	40	40	40	40	36
Dorothy	SRS	40	40	40	40	40	36
	C-SRS	40	32	-	40	31	36
Fred	SRS	40	40	40	40	39	36
	C-SRS	32	34	38	27	37	36

Key: CSRS Child Session Rating Scale; SRS Session Rating Scale; YCSRS Young Child Session Rating Scale.

Feedback from the mothers was also collected after completion of the intervention using a PSQ, which contained questions about the programme's overall acceptability and practicality as well as the individual sessions. Four mothers rated the programme from very good to excellent, one mother rated it good, and one parent rated it very poor. Five mothers found the programme helpful, valuable, and informative; and would recommend it to other parents of children with anxiety. One parent who did not find the programme helpful felt that the language was too advanced for young children and that 60 minutes was too long for a therapy session. She said she would not recommend the programme to young children but would for older children.

Feedback on Programme Content

The parents' feedback was positive regarding the usefulness of the intervention in helping their children with their anxiety. Parents reported that they found the CBT sessions helpful as they provided education about anxiety, which increased their knowledge about how to support their children. In addition to the psychoeducation giving them a better understanding of anxiety, parents also said it also provided a common language when communicating with their children. Parents found that when they had the same understanding about anxiety as their children it was easier for them to support their children or suggest anxiety management strategies for them to use. Parents found the amount of CBT content appropriate and adequate.

Parents shared that the sensory component of the intervention was helpful for their children and allowed them to identify how the sensory toys could help them when they were distressed.

Parents found that their children enjoyed learning about using sensory tools to manage their distress and anxiety. They appreciated how it allowed the children to experiment with different sensory-based materials to identify sensory input that was calming specifically for them. Several expressed that they particularly liked the development and use of the sensory box. For example, Andy's mother reported that Andy enjoyed the sensory box activities and was excited when told he would keep the sensory box and could add more resources. Parents found that the sensory box increased the children's sense of autonomy to manage their anxiety, was simple to use and parents could support their child to identify calming toys.

Overall, parents reported that the intervention "*had a nice balance between the CBT and the sensory modulation components*". During the post-intervention assessment with the clinical psychologist, most parents used terms such as "*acceptable*", "*helpful*", and "*effective at reducing anxiety symptoms*" to describe the intervention. Parents also indicated that they would be "*comfortable recommending the intervention to parents*" of children presenting with anxiety.

Feedback on Programme Impact and Outcomes

While outcomes related to anxiety symptoms, diagnosis and life interference were presented in the preceding chapter, further feedback was sought from the parents and children about their perceptions of the impact of the intervention. Regarding the achievement of outcomes through attending the programme, five parents rated this between 6 and 10, out of 10 in the PSQ (with a rating of 10 indicating they achieved their expected outcomes and zero indicating they did not achieve their expected outcomes). One parent rated it as zero out of 10, indicating that she did not achieve her expected outcomes.

The C-ORS and YC-ORS forms were used to assess whether there was any change in the children's life, family, school, and, overall, how things were going for them as a result of the intervention. These measures were completed by all the children at the start of each session (see Table 21). The scores of most participants were above the cut-off point, indicating that they noticed some improvement in their lives as a result of the intervention in the preceding week. Andy and Esther completed the Y-CORS because they were under 6-years old. Both participants chose 'smiley faces', indicating that they noticed improvements in different areas of their lives because of the intervention.

Table 21

Outcome Rating Scales for All Participants

CORS scores							
Participant	Measure	Measuring points					Cut -off
		Session 2	Session 3	Session 4	Session 5	Session 6	
Esther	YCORS	😊	😊	😊	😊	😊	-
Andy	YCORS	😊	😊	😊	😊	😊	-
Ben	CORS	18.2	9.1	24.8	40	40	32
Collin	CORS	40	40	40	40	37	32
Dorothy	CORS	40	35	40	-	40	32
Fred	CORS	24	21	33	28	33	32

Key: CORS Child Outcome Rating Scale; YCORS Young Child Outcome Ratings scale.

A further source of feedback about the impact of the intervention was the parent clinical interviews with the psychologist at post-intervention and follow-up points. Each of the mothers shared their perceptions of how the programme affected their child, as summarised below.

Esther's Mother's Feedback

Esther's mother noted that Esther had begun to be more independent, was keen to interact with other children, and did not need parental reassurance. Esther was more able to use strategies taught to manage her emotions and was more able to decide on what coping strategies to use when feeling anxious. As treatment progressed, she started sleeping independently, engaged in outside play without her mother's supervision, was less clingy towards her mother, and displayed fewer tantrums. Esther's mother's comments were consistent with the report from the therapist, who delivered the intervention, who shared that at the beginning of the intervention, Esther was timid and shy, although she interacted well with the therapist. As treatment progressed, she became more confident and gradually responded and engaged more. She became more conversational, would share information voluntarily, and ask questions to clarify information shared by the therapist. She started to feel comfortable being left with the therapist in the room during breaks, something she could not do during the early sessions.

Andy's Mother's Feedback

Andy's mother stated that she found the CBT-sensory modulation intervention helpful for her and Andy as it provided a common language to use when discussing Andy's worries and anxious feelings. She said her knowledge of anxiety increased, and she was equipped with strategies to better support her son. She also said she found information about how her anxiety

and behaviour affected Andy's presentation of anxiety helpful. As the intervention progressed, she noted the school drop-offs became easier, and Andy handled separating from her better. Using the toilet to empty his bowels became easier and more frequent, and it was reported that he used the bathroom at school once to empty his bowels, which he had never done before. Andy was reported to enjoy water-based activities that he used to avoid before the intervention and even went swimming in a pool, which he had previously avoided. Andy's mother believed that the sensory strategies offered in sessions four and five were critical in helping Andy with his sensory sensitivities. Overall, Andy's mother reported that she found the intervention helpful in reducing Andy's anxiety, as he learnt strategies to face his fears and anxiety-provoking situations, improving his function. Andy's mother said she was disappointed that the programme ended quickly as he enjoyed it.

Ben's Mother's Feedback

Ben's mother reported that she found the intervention helpful for both Ben and herself. She said the intervention provided Ben with several strategies to manage his anxiety, and he particularly liked the sensory modulation sessions. Ben was excited to add more toys to his sensory box and was observed several times using his sensory toys to manage his distress when in anxiety-provoking situations. Separation from his mother to go to his father's home and school was much easier, and his 'meltdowns' were less severe. His mother also reported that Ben was easier to manage and redirect his emotions and behaviour instead of being emotionally explosive. He was better at socialising with other children and made progress at making new friends. As therapy progressed, he became more aware of his anxiety and how to manage his emotions. His mother found the strategies helpful and even used them to manage her anxiety. The strategies taught in the sessions helped her to be a better coach for Ben when supporting him in dealing with his fears.

Collin's Mother's Feedback

Collin's mother stated that strategies offered in the intervention programme, such as supporting Collin's brave behaviour towards anxiety-provoking situations; offering reassurance; managing her anxiety; and embedding the sensory strategies in a daily routine, were helpful. Collin's mother also found the learning around how her actions of keeping him at home when he cried and when he refused to separate to go to school reinforced Collin's anxiety. She also learned how this made it harder for her to manage Collin's anxiety. Collin's mother reported that being part of the programme contributed to Collin's continued progress. At the end of the intervention, Collin's anxiety had reduced, and he was more independent and easier to separate.

Dorothy's Mother's Feedback

Dorothy's mother felt the intervention was inappropriate and too advanced for Dorothy. She said the intervention was appropriate for older children. She indicated that Dorothy had complex anxiety and sensory challenges and required more specialist interventions. Dorothy's mother said she did not find the intervention helpful at all. Still, she described how Dorothy's function improved during the intervention, particularly when using sensory modulation strategies. She described how Dorothy's noise-cancellation headphones from her sensory box helped manage her sensitivity to noises and anxiety. During the intervention, the family managed to go on a trip without issues, something they had never done before, and Dorothy used sensory modulation strategies (i.e., headphones) to manage her anxiety.

Fred's Mother's Feedback

Fred's mother reported that she found the therapy sessions helpful and valuable and was surprised at how Fred engaged; she said '*he engaged in ways I never expected'.* Fred's mother reported that she found that Fred was becoming better at vocalising his feelings and emotions and was becoming more confident in sharing things that were worrying him. Fred's mother reported that it was helpful to walk alongside Fred, supporting him with his therapy and being his coach at home. Fred was noted to use his sensory box most nights before bed and would go straight to sleep. When he did not use his sensory box, he was noted to have trouble falling asleep. Fred reported that his thoughts wandered when he did not have the sensory box, and he had trouble winding down. Fred's mom told the psychologist that the anxiety intervention was "*awesome*" and thanked her for referring her to attend it. During session six, Fred reported to the therapist that he did not like a particular room they used for therapy, and he felt sick after being in that room. This may explain his SRS and ORS scores. After completion of the therapy, Fred was reported to struggle leaving his grandmothers after an extended visit, and he was worried about transitioning to a new class in the following academic year. These two events seem to explain why his scores were high at FU.

Overall, all the parents feedback suggests that the intervention impacted their children's ability to manage their anxiety, which made a meaningful impact on their functioning in specific situations such as separating from their parents or socialising with other children. The children became more aware of their anxiety, triggers, early warning symptoms and helping strategies, hence they were more in control of their anxiety positively impacting their general wellbeing.

Therapist Feedback on Acceptability and Practicality of the Programme

Feedback from the therapists who delivered the intervention was collected using the Therapist Satisfaction Questionnaire (TSQ). The questionnaire asked the therapists how they felt about

the overall programme, acceptability, and practicality. Overall, all the therapists were satisfied with the programme and would recommend it to other therapists. Most therapists were new to working with children and reported that they found the intervention very helpful in assisting them in knowing what to do when delivering anxiety interventions to children. While they needed more training in CBT and sensory modulation, the therapists reported that the training on how to deliver the Ngā Timatanga Toa intervention programme gave them good background knowledge on the basics of CBT and sensory modulation, which helped them develop effective treatment plans.

The therapists described the intervention as a utility intervention that could be modified and delivered to older children with anxiety. All the therapists said they used the manual to deliver the intervention to older children on their caseloads by adjusting the language and activities indicating the utility of the intervention. Therapists identified the value of the sensory components, how it made it easy for children to understand the concepts of sensory modulation, and how the toys (i.e., sensory tools) helped them when distressed. Therapists found the CBT components helpful in exploring the cognitive contributors to the children's anxiety, which helped target the root of the problem in some children.

Therapists reported that the children engaged well during the therapy sessions and enjoyed the content, particularly the sensory modulation part. Children liked the sensory box and enjoyed adding more resources to it that they found helpful. The sensory discussion and personalising of the sensory box improved engagement with children because it involved toys that appealed to them. This part also made the intervention appropriate for children. Therapists also reported that parents engaged well during therapy sessions and that parents liked both intervention components. Parents reported to therapists that they found the CBT component helpful in helping them understand their anxiety and their child's anxiety. The sensory modulation part helped them identify basic strategies and sensory things they could use to help their child when distressed.

The therapists reported the content was appropriate and adequate for treating anxiety in children. However, some therapists found the therapy session length of between 60 to 90 minutes was too long for young children. In that regard, therapists liked that the intervention allowed them to take breaks in between, and they had the choice to decide the length of the sessions. Thus, the therapists liked the flexibility of the intervention.
Therapists reported that the intervention was practical to deliver in NZ settings for several reasons. First, therapists liked the intervention's flexibility, allowing them to deliver it between 60 and 90 minutes, depending on the child's presentation. Second, therapists liked that the intervention was neither too short nor too long with respect to the number of sessions, allowing

them to deliver a meaningful intervention within a relatively short period. Parents and therapists reported that six sessions were practical and achievable for parents to commit to. Third, since most therapists were new to working with children, they liked the intervention because it gave them a guide and some structure for working with children experiencing anxiety, The therapists also reported that the intervention was easy to deliver, and new clinicians in CAMHS could be trained to use the intervention in a short time. Fourth, therapists liked the utility of the intervention and believed it could be used with little adaptation to treat older children presenting with anxiety, as well as younger ones. Overall, feedback from the therapists and parents about the practicality of the intervention was positive and provided evidence to support the secondary study aims.

Therapists' Intervention Fidelity and Adherence in Delivering the Programme

While not a direct measure of acceptability and practicality, the therapists' adherence to the manualised sessions indicates that it was practicable and able to be applied as intended. The researcher and an independent psychologist assessed the therapist intervention fidelity and adherence by listening to six randomly selected audio-recorded sessions and scoring them using the intervention fidelity and adherence (see Appendix X) form developed explicitly for this study. The six sessions were representative of all the sessions. The intervention fidelity and adherence form assessed the delivery of the session structure, content, and collaboration. Cohen's Kappa inter-rater agreement was 0.55, indicating moderate agreement between the raters. This indicates acceptable fidelity and adherence across all four therapists, and that the intervention was mainly delivered as per the intervention manual. Cohen's kappa is interpreted as: values less than 0 indicate no agreement, values between 0.01 and 0.20 indicate none to slight agreement, values between 0.21 and 0.40 indicate fair agreement, values between 0.41 and 0.60 indicate moderate agreement, values between 0.61 and 0.80 indicate substantial agreement, and values between 0.81 and 1 indicate perfect agreement (McHugh, 2012).

Chapter Summary

The results obtained in this study suggest that the intervention was acceptable to the children, parents, and therapists, and was found helpful as it improved the children's functioning. The parents and therapists found the intervention practical to be delivered in NZ settings. Thus, the feedback supports hypothesis two and meets the two secondary aims of the study. The results related to the acceptability and practicality of the Ngā Timatanga Toa programme are promising but require further study with a wider and more diverse sample of children and parents to validate the findings.

Chapter 7:

Discussion

Introduction

This study set out to investigate the effectiveness, acceptability, and practicality of the Ngā Timatanga Toa intervention programme when delivered to young children presenting with anxiety, as well as their parents. The manualised intervention was delivered by four therapists, who were provided with 8-hours of training in how to deliver the six sessions. The therapists had little or no previous training or experience in delivering similar CBT or sensory modulation-based interventions. The study tracked the children's anxiety-related symptoms, anxiety life interference, and diagnostic status using several pre- and post-psychometric measures completed by the children, their mothers, and a teacher. A clinical psychologist completed assessments to establish the pre- and post-diagnostic status of the children. The results of this study provide preliminary evidence that indicates that the Ngā Timatanga Toa intervention effectively reduced anxiety symptoms, improved function and was acceptable to mothers and therapists in the study. This chapter summarises the study's overall findings and discusses key elements of the findings in relation to the wider literature. Implications for practice and further research are outlined, followed by a discussion of the study's strengths and limitations.

Discussion of Findings

Two hypotheses concerning the effectiveness of the Ngā Timatanga Toa intervention were tested in this study. It was hypothesised that the intervention would 1) reduce anxiety-related symptoms, and 2) improve children's functioning by reducing the life interference caused by anxiety. Additionally, the study had two secondary objectives, which sought to understand if 1) the parents and 2) the therapists would find the intervention acceptable and if it would be practical to deliver in a NZ CAMHS setting. Overall, the study provides some preliminary support for the effectiveness, acceptability, and practicality of this 6-session CBT and sensory modulation intervention for young children experiencing clinically significant anxiety.

Effectiveness of the Intervention

The findings support hypothesis one, as the intervention reduced anxiety symptoms in children with varying anxiety presentations. Four of the six children (67%) did not meet the criteria for an anxiety disorder at the end of the intervention, indicating that the intervention helped to

reduce anxiety-related symptoms of these participants to a sub-clinical level. While two participants (33%) still met the criteria for a diagnosis of anxiety at the end of the intervention and at 1-month follow-up, their CALIS scores showed significant improvement in anxiety-related symptoms and functioning.

These results are comparable to findings in other studies, which investigated the use of CBT-based interventions for the treatment of childhood anxiety (Anticich et al., 2013; Barrett et al., 2015; Bayer et al., 2017; Breinholst et al., 2021; Carlyle, 2014; Cobham, 2012; Creswell et al., 2017; Donovan & March et al., 2014; Esbjørn et al., 2019; Hirshfeld-Becker et al., 2008; Hirshfield-Becker et al., 2010; Hirshfield-Becker et al., 2011; Infantino et al., 2016; Kendall et al., 2008; Khanna & Kendall, 2010; Lawson et al., 2023; Lundkvist-Houndoumadi & Thastum, 2013; March et al., 2009; Monga et al., 2015; Minde et al., 2010; Pahl & Barrett, 2010; Ruocco et al., 2016, Salari et al., 2018; Spence et al., 2006; Thirlwall et al., 2013; Villabø et al., 2018; Waters et al., 2009). In these studies, significant reductions in anxiety symptoms and improvements in functioning were noted post-intervention (PI) and at follow-up (FU). The anxiety reductions ranged from 55% of participants at PI to 95% at FU, making the present study's 67% of participants with reduced anxiety at PI comparable, although the sample size was much smaller than most of the previous studies.

However, it is important to note that there were significant differences across the previous studies in terms of mode of delivery, number of sessions, age of participants, length of FU, and therapist training and support. Gains were maintained over varying durations, from 4-weeks (Khanna & Kendall, 2010) through to 2-years in a Norway-based study with children aged 7-13 years old (Villabø et al., 2018). The current study had a one-month follow-up period which may not have been enough to determine how gains were maintained as compared to other studies. Many of the studies involved more intensive CBT delivered over 6 to 20 sessions (Fenn et al., 2013) and some studies (March et al., 2009; Spence et al., 2006;) had booster sessions at 1- and 3-months PI respectively. Additionally, many of the interventions were delivered by more experienced therapists (Minde et al., 2010, Kendall et al., 2008). In comparison to the results of the current study, this seems to suggest that clinically significant results may be achieved in only six sessions for some children particularly those with mild anxiety presentations and with relatively inexperienced therapists.

The ages of the children in existing studies ranged from 2-years (Hirshfield-Becker et al., 2019) to 14-years (Spence et al., 2009; Villabø et al., 2018). The results from all those studies highlight the effectiveness of CBT in addressing childhood anxiety across different age groups, regardless of the delivery format. These results are comparable to the results found in the current study. Additionally, these studies were conducted in different countries including

Australia, Norway, Denmark, United Kingdom, the USA, Canada and Iran and cultural differences were not reported to impact the effectiveness of the intervention. Most of these countries are comparable to New Zealand making the results of the current study significant in contributing knowledge in the management of childhood anxiety.

It is critical to highlight that other studies tested different formats of CBT (i.e., parents only, child-parent, mixed internet and face-to-face, groups, and audio-based (Donovan & March et al., 2014; Esbjørn et al., 2019; Hirshfield-Becker et al., 2011; Infantino et al., 2016; Kendall et al., 2008;). As discussed in Chapter 2, most of these studies were targeted at older children and those that were targeted at younger children were either group programs or did not involve children as well as parents. None had tested an intervention that combines CBT with sensory modulation strategies. This puts the current study in a suitable position to be considered as a viable option to offer to young children presenting with anxiety. The preliminary evidence suggests there is merit in the inclusion of a sensory-modulation component as it appeals to young children, has fewer cognitive requirements and was reported to be effective in helping the management of anxiety symptoms in specific situations.

The findings also support the second hypothesis, in that the intervention was found to improve the functioning of child participants, as shown by the reduction in anxiety interference and high outcome rating scores. All participants had a reduction in their CALIS scores when the intervention was introduced, signalling a reduction in anxiety life interference, implying the children had better functioning. Parental feedback also indicated children had improved functioning when the intervention was introduced. Improvement in functioning is consistent with the findings of Wood's (2006) study, where a reduction in anxiety after a CBT intervention improved children's (6-13 years) academic and social functioning. Although some follow-up data was missing, the data collected in the current study showed improvements in anxiety-related life interference in most children, and it was established that gains were maintained at 1-month PI. Of note, two of the participants' CALIS-P scores had a downward trend during the baseline period. This may be due to parents' scoring bias after knowing their child was going to receive the intervention, which may be influenced by the expectancy of receiving beneficial treatment (Furukawa et al., 2014; Hawryluk & Bullock, 2015) or potentially due to the 'Hawthorne effect' (Blease, 2019).

Acceptability and Practicality of the Intervention

The findings suggest the intervention was acceptable to five participating mothers, the children, as well as the therapists, providing feedback that it is a helpful intervention which is practicable to be delivered in NZ settings. The mothers and therapists provided feedback on the acceptability and practicality of the Ngā Timatanga Toa intervention programme by

completing respective questionnaires. Five mothers gave strong positive feedback regarding the programme, as shown by their high ratings of satisfaction. The mothers stated they found the intervention helpful and would recommend it to other parents. Studies that tested similar interventions (Van Der Mheen et al., 2019; Monga et al., 2009; Morgan et al., 2016) were similarly accepted by mothers and families.

The therapists also provided positive feedback about the intervention and indicated they would recommend it to other therapists. Acceptance of the intervention by the therapists was corroborated by moderate to high adherence scores in the fidelity review. Sekhon et al. (2017) stated that if therapists perceive an intervention as not helpful to patients, they will not accept it and will not deliver it as intended.

The acceptability of an intervention is affected by how the intervention is delivered, the content of the intervention, and the perceived effectiveness of treatment (Sekhon et al., 2017). These were all rated highly by the mothers. In relation to delivery, the session rating scales were used to measure therapeutic alliance during the treatment sessions. The tools helped mothers and therapists discuss any disagreements in therapy that may have hindered the outcome (Duncan et al., 2003). High session rating scores indicated solid therapeutic alliances were formed, suggesting acceptance of the intervention goals and delivery. If mothers had disagreed on the treatment goals; they may not have accepted the intervention as helpful because the acceptability of an intervention is centred around the appropriateness of the intervention to address the clinical problem and its effectiveness (Sekhon et al., 2017).

Sekhon et al. (2017) also argued that if patients do not accept a health intervention, they are likely to default treatment and will not adhere to it, with dropout rate being a good indicator of acceptability and practicality. In this study, there were no dropouts and mothers adhered to the intervention requirements, which suggests that the Ngā Timatanga Toa programme was practicable and appropriate for delivery in NZ settings. Additionally, if the therapists and mothers had not found the intervention acceptable, they would not be comfortable recommending it to other families or therapists. The children's session rating scales were also high, indicating they enjoyed the sessions. A strength of the present study was the inclusion of young children and their voices in the intervention, which placed them as the focus of treatment alongside their parents.

Child Related Factors: Early Intervention and Developmental Considerations

The notion of early intervention was central to this study, with the aim of teaching young children coping skills as early as possible. The results support the point that young children can indeed learn strategies for managing their anxiety if early identification and intervention

are prioritised. As discussed in Chapter 2, anxiety is prevalent, and if it starts in early childhood and left untreated, it can have long-term consequences (Afshari, 2014; Bennett et al., 2015; Chiu, 2013; Creswell et al., 2010; Galla et al., 2011; Ginsburg et al., 2011; Lalongo, 1995; Langley et al., 2004; Minde et al., 2010; Scainia et al., 2016). Early childhood is an ideal time to provide new understanding and coping skills because of increased neural plasticity (Luby, 2013), which may amplify the benefits of the intervention. The National Centre for Health Statistics (2014) in the United States of America emphasises the importance of early interventions in children presenting with psychological problems to prevent long-term effects, which can be costly to manage later if left untreated. Despite this understanding, treatment for younger children has not been readily available, which puts them at risk of developing chronic maladaptive anxiety and impairments (Cheney et al., 2014). Thus, the Ngā Timatanga intervention has the potential to be delivered early to young children as it can be taught to allied health professionals working in CAMHS with a wider impact on access to services.

The results of the present study suggest that the Ngā Timatanga intervention could provide an alternative treatment that is easily accessible, affordable, and effective for younger children. The studies by Hirschfield-Becker, Henin et al. (2008, 2010), Hirschfield-Becker, Mazursky et al. (2011) and Monga et al. (2016) concluded that early treatment of young children improved outcomes. For example, Minde et al. (2010) evaluated a 17-session modified CBT intervention with 37 young children aged between 37 to 89-months diagnosed with anxiety where significant improvements were noted in anxiety reduction PI. The youngest child enrolled in the study was aged 37-months, indicating that modified treatment can be delivered to young children as early as 3-years. Minde et al. (2010) mainly adjusted the language to suit young children, added concrete ways to overcome fears suitable for children, included psychoeducation for parents, and actively involved parents in the treatment. A critical consideration is for the intervention to be flexible and modifiable enough to be developmentally appropriate for a range of children. The inclusion of sensory-based approaches in the current study adds greater flexibility and an increased number of possible strategies, which are not cognitively based. This aids the ability for therapists to modify sessions to the child's unique developmental needs and interests. In that regard, the number of flexible variables of the Ngā Timatanga intervention makes it a suitable intervention that can be delivered to younger children in clinical practice.

The context of some participants (i.e. raised by a single parent) suggests an association between anxiety and single parenting of young children as reported by Liang et al. (2019). Interestingly, three of the participants had sensory challenges highlighting another important association between, anxiety, attachment and sensory challenges (Carpenter et al., 2019;

Meredith et al., 2016; Sperati et al., 2024). These associations are significant in this study as they underscore the importance of combining sensory strategies with CBT as suggested by Green and Ben-Sasson (2010) in effectively managing childhood anxiety, particularly in children with sensory challenges. The results of this study support this suggestion as evidenced by the popularity of the sensory component of the intervention (e.g. the sensory box) and its impact on reducing the children's anxiety. The sensory strategies empowered the children to learn strategies to manage their anxiety as found in another study by Steele and Kuban (2013).

One mother suggested the language and concepts used in the CBT aspect of the intervention were too advanced for her child. This highlights the need to consider variations in developmental processes including cognitive and language development. Assessment of the children's cognitive abilities on entry into the study would have provided insight into each child's ability to understand the programme content. The present study did not evaluate children's cognitive abilities using standardised cognitive assessments such as the Wechsler Intelligence Scale for Children (Weiss et al., 2015) because the cost of these assessments was prohibitive. There was also a long waiting time for children to get cognitive assessments through the study site due to a shortage of psychologists; therefore, this assessment was only done if clinically indicated. However, no child in this study was identified as having an intellectual disability, according to parental reports. Thus, knowing the children's level of cognitive ability and language development in more detail may have helped the therapist to adapt the material for the child and provided insights into which children would benefit most from the intervention. Lickel et al. (2011) investigated levels of cognitive ability in 40 children aged between 7 to 12-years with ASD and typically developing children. The children with ASD demonstrated functioning comparable to typically developing children, except for emotion recognition tasks. The current intervention has portions where the child was required to recognise emotions, which could have been difficult for some children if they had cognitive challenges. Understanding the cognitive profiles of children would assist in overcoming any related challenges and allow developmentally appropriate modifications to the Ngā Timatanga intervention. Therefore, cognitive assessment to estimate the intellectual functioning of children is recommended in future studies as it may assist when making adaptations.

One participant's follow-up scores showed a continued improvement from the intervention completion to FU, suggesting that they continued to benefit from the treatment. Similar findings can be extrapolated in studies by Spence et al. (2006) and March et al. (2009) at 6-months FU; however, continued benefits in these studies appeared to have been exaggerated by two booster sessions offered a post-intervention, which were not offered in the current study. Thus, the continued effects experienced by this participant put the Ngā Timatanga

intervention in a suitable position to be further tested as it appears to have lasting effects without the need for booster sessions. Hence, it will not be resource-heavy and less costly to deliver in NZ settings where there is a shortage of mental health professionals.

In contrast, some participant's CALIS-P scores were starting to slowly rise at FU, indicating two possibilities: 1) that a longer FU period could have presented a better picture of maintenance of gains, and 2) that they may have needed a booster session after 6-weeks to ensure that they received adequate therapy dosage. One participant's score CALIS-C scores were elevated at followed and did not show significant improvement throughout the study; however, he appeared to make slow, stable progress. This is common in some conditions where some behaviours may take time to respond to interventions (Wiles et al., 2014). It potentially suggests that the intervention may be inadequate for children with high anxiety levels and co-morbidities, while it is effective for children with mild to moderate anxiety. This participant had co-morbidities which have been reported to affect treatment responsiveness and outcomes (Nilsen et al., 2013; Ollendrick et al., 2008). Hence, the intervention may need to be modified for children with high anxiety; for example, by increasing the dosage (i.e., increasing the number of sessions or having booster sessions), and co-morbidities need to be managed appropriately. It is worth noting that although the intervention tested in this study included six sessions, the results were similar to those found in interventions that offered more than six sessions (Malindi et al., 2020; Monga et al., 2009; Morgan et al., 2016). Thirlwall et al. (2017) and Wiles et al. (2014) further stated that understanding the moderator factors is clinically useful as it helps clinicians determine which patients will likely benefit from an intervention. This study did not identify treatment moderators to establish how they would affect treatment outcomes.

The CALIS-C scores for two participants increased at PI and significantly decreased at FU. The rise in their scores can be explained by contextual factors at that time. One participant was sick (i.e., had COVID-19) during the PI period and they moved house, both of which may have increased their anxiety and affected their score. The other participant's PI assessment point coincided with the easing of COVID-19 restrictions, returning to school, and their mother returning to work. This may have increased their anxiety after spending extended periods with their mother at home due to the lockdown, as discussed earlier.

Parent Involvement and Perceptions

The study involved mothers in the intervention as coaches and investigators for their children who helped their children identify worries and fears, as well as calming strategies that worked for them. Additionally, parental involvement allowed mothers to help their children and the therapists to develop accurate, personalised sensory modulation interventions for the children.

The mothers also played a significant role in ensuring their child did their home tasks and practised the strategies taught. Additionally, the parent's role was to model non-anxious behaviours and support their children throughout therapy.

Understanding the differences in outcomes between child-parent and parent-only interventions was outside the scope of this study. This has been investigated in several studies, and the results have been inconclusive. Monga et al. (2015) and Waters et al. (2009) found no significant difference between child-parent and parent-only groups. Jewell et al. (2022) found significant treatment effects for parent-only anxiety interventions compared to the waitlist group, but no significant difference versus other active interventions. However, Monga et al. found that children with mothers' involvement in treatment had more significant long-term gains. A study by Van der Bruggen et al. (2008) found a positive association between childhood anxiety and parental control, which strongly indicates better outcomes. Thus, mothers need to be involved in treatment to learn how their behaviour influences the expression of anxiety in their children. In the current study, parents were involved, psychoeducation was provided to the mothers and they were encouraged to model non-anxious behaviours to their children, which may have increased their efficacy and skills to support their children. This alone may have reduced the mother's anxiety, positively influencing their child's anxiety. Overall, it appears that parental involvement was critical in the current study as it may have helped the young children to better understand key concepts and supported to use relevant strategies at home (Haine-Schlagel & Walsh, 2015; Van der Bruggen et al., 2008).

Parental profiles were not collected in this study to understand the parents' levels of education, past medical history, past psychiatric history, housing, relationships, and employment status. Parent mental health and social determinants are associated with poor mental and physical health of children (Allen et al., 2015; Elgar et al., 2015; Gibson et al., 2017; Guy et al., 2016; Phelan et al., 2010; Reiss et al., 2019; Wolicki, 2021). Creating parent profiles would have provided vital information regarding the parent's capabilities to support their child and continue therapy at home. Hence, parental mental health can affect the parent's capability to participate in therapy (Department of Health, 2023; Leinonen et al., 2003) and may influence the overall outcome of the intervention. For example, if a parent cannot do homework with their child, and the child needs help understanding the basic concepts being taught in the programme, the parent may not be able to support their child to gain the greatest benefit from the programme. Furthermore, it is well documented that poverty hugely impacts children's life course (Ministry of Social Development, 2018); hence, understanding parental employment and economic status is vital in developing effective wrap-around services. In that regard, in

future studies, parent(s)/guardian(s) profiles should be collected to determine the association between the child's anxiety outcome and the parents' profile.

While mothers reported this intervention was helpful, it is possible that mothers were biased towards the intervention which may have affected their perception of their child's anxiety, how they reported it, and how they scored the outcome measures (Furukawa et al., 2014; Hawryluk & Bullock, 2015). This is because mothers' perceptions of the intervention were collected through open-ended questions, the mothers knew what intervention they were receiving and may have had preconceived expectations. It may also have been because of expectancy or the Hawthorne effect as noted earlier. In that regard, a blinded study (RCT) could help mitigate parental bias if this intervention were to be tested in the future. The placebo would be a group that involves playing games, reading, discussing friendships, hobbies and having non-clinical conversations, consistent with studies by Gaab et al. (2019) and Blease (2023). However, placebos can be challenging in psychological interventions due to placebo effects resulting from merely interacting, talking, and engaging with a therapist (Peiris et al., 2018).

A Behaviour Tracking Diary (BTD) was used by mothers to track three anxiety-related behaviours of concern throughout the study. The BTD was only partially completed by one mother. One mother said the BTD form was too complicated and challenging to complete. During the study, families were contacted at midway to remind them to complete their forms, including the BTD. In hindsight, the families could have been offered weekly phone calls or texts to remind them to complete the BTD form. The weekly contact could have provided motivation and acted as a reminder. An alternative approach would be for the BTD to be completed in sessions to allow mothers and therapists to track behaviours of concern and progress together.

It is possible that the stress of raising a child struggling with anxiety could have contributed to the issue of not completing the BTD. Increased parental stress because of their child's psychological problems (e.g., increased level of anxiety) has been identified in several studies (Ambikile & Outwater, 2012; Chung et al., 2012; Davidson et al., 2023; Manti et al., 2019; Mazur & Mickle, 2017; Păsărelu et al., 2022; Wang et al., 2012). This was not explored in the present study, but measuring changes in parental stress levels before and after treatment may capture the impact of the child's improvement on parents as a proxy measure of the intervention effectiveness. Findings from Keeton et al (2013) showed successful child treatments can result in improvements in non-targeted parents' symptoms and family functioning.

Teacher Involvement and Perceptions

Only one teacher agreed to participate in the study, and their TRF scores contrasted with the parent's CBCL scores. The TRF showed little or no treatment effect, but the SAS-TR showed a reduction in anxiety symptoms from entry into the study until completion of the intervention. The teacher's TRF did not show high levels of anxiety on entry into the study; however, it is worth noting that the referral was done by the parent, indicating that the teacher was not concerned about the child's behaviours. According to Molis and Clopton (2002, cited in Headley & Campbell, 2013), anxious children do not always present with concerning externalising behavioural problems in school, are well-behaved, and, therefore, do not gain the teacher's focus (Loades & Mastroyannopoulou, 2010; Papandrea & Winefield, 2011). Additionally, it has been found that teachers feel they do not have sufficient training to identify symptoms of anxiety in students (Papandrea & Winefield, 2011), which may have affected their rating. All these factors may provide a plausible explanation for why the teacher's TRF scores were low on anxiety symptoms.

Therapist Perceptions, Training, and Fidelity

The intervention delivery was flexible, allowing the therapist to modify sessions depending on the child's ability to focus. The sessions were delivered between 60 and 90 minutes. Some therapists and one mother reported that the sessions were too long for younger children. However, one therapist said 90 minutes went very quickly with one of her clients because the child was very engaged throughout the sessions. Therapists were allowed to give children breaks in between, which allowed children an opportunity to re-energise. This flexible approach enabled children to refocus and provided them with an opportunity to manage their emotions when overwhelmed. Additionally, the flexibility of the intervention allowed clinicians to incorporate their personal qualities and experience without losing experimental control. It is recommended that this flexibility be kept in clinical practice depending on the child's capabilities.

The therapists who participated in the study had varied experiences in CAMHS and CBT. Sensory modulation was a new concept to all therapists. The 8-hours of training appeared to be insufficient for therapists to be comfortable delivering all the manual components. For example, it was apparent that therapists needed more training in using feedback-informed forms and sensory modulation. Considering the training had three new concepts for therapists to grasp (i.e., CBT, sensory modulation, and feedback-informed approach), more time is required to train therapists before they deliver the intervention. Secondly, training should include demonstration videos and role play to ensure the therapists gain essential clinical skills in the intervention delivery, the trainer should provide proper weekly supervision and

coaching, including learning exercises, demonstration, discussion of clinical cases, role-playing and lectures, as suggested by Amrhein (2004), who reported therapists' skills in delivering motivational interviewing improved after ongoing supervision. In the current study, therapists received a weekly check-in email, phone call, or face-to-face visit to support them.

One parent reported the therapist struggled to deliver the intervention and continuously referred back to the manual, which may have affected the quality of how the intervention was delivered. This is a limitation of the current study because the fidelity and adherence testing tool used did not test therapist's competence in delivering the intervention. Competence tests the quality of delivery of the intervention (McLeod et al., 2018); in future studies, the form should be modified to include competency testing. One mother suggested more in-depth training for therapists in the future. Inadequate training may contribute to poor adherence (Becker et al., 2012). In a study by Husabo et al. (2022), participants were trained for 6-days indicating that the training time in the current study may not have been adequate, considering the study had novice therapists. More internal training and supervision is recommended for future studies, as suggested by Hilderbrand et al. (2012). Having said that, the adherence score in the present study was moderate, indicating the intervention was mostly delivered as per the manual.

In the current study, all 36 therapy sessions were audio-recorded for fidelity and adherence testing. Six randomly selected sessions (16.67%) were then reviewed and coded as a representation of fidelity across all sessions. This is consistent with other studies; for example, Kendall et al. (2008) tested 14% of all sessions, and the adherence score was 0.85 (Cohen Kappa), indicating almost perfect agreement. The fidelity and adherence score in this study was 0.55 (Cohen Kappa), indicating moderate agreement overall. This indicates the intervention was delivered with moderate levels of adherence despite limited time to train the therapists in new concepts. The difference in scores with Kendall et al.'s study may be due to several issues. Kendall et al.'s study was completed in a controlled research setting and was well-resourced with experienced trainers and therapists who delivered the intervention. In comparison, the current study was undertaken with novice clinicians who had varied clinical experience. Noell et al. (2013) asserted that fidelity is more challenging to establish in natural environments than in controlled research settings. This applies to the current study, where other factors, including work and COVID-19-related challenges, may have affected treatment fidelity. A further difference in Kendall et al.'s study, was that only 15-minutes of randomly selected sessions were tested for adherence. In contrast, in the current study, the entire length of the selected sessions, ranging between 60 and 90 minutes, were reviewed.

The adherence score (Cohen Kappa discussed above) of the current study was cross validated with an interrater agreement score which was 82%. According to Borelli's (2011) scoring system, a score of 80% to 100% is acceptable. Wilczynski (2017) stated that treatment fidelity benchmarks vary, and some studies have used 80% as the minimum, but a higher score over 80% tends to produce meaningful changes in the target behaviour. Use of an agreement score has been used in other studies for example, Sprange et al. (2021) used it in an RCT testing the intervention fidelity of a complex psychosocial intervention. In future studies, the researchers should aim for an agreement score of greater than 82% through rigorous therapist training. To achieve a higher fidelity score in future studies, the following could be done. First, allow therapists to listen to their recorded therapy sessions during weekly supervision with the trainer to provide a way of reflecting on their practice and learning. This will offer another opportunity for therapists to be supported by the trainer to improve their skills which will inform practice and provide windows for quality assurance checks. Second, provide adequate training to people who deliver an intervention as recommended by Wilczynski (2017).

The issue of therapist adherence and outcomes is critical to the current study. The findings in studies that investigated the relationship between fidelity and adherence to clinical outcomes are mixed (Collyer et al., 2019; Rapley & Loades, 2018; Southam-Gerow et al., 2021; Webb et al., 2010b). Studies by Hogue et al. (2008) and Podell et al. (2013) predicted a positive relationship between higher adherence and clinical outcomes. Alternatively, several other studies (Hartnett et al., 2015; Heywood & Fergusson, 2016; Overbeek et al., 2013) did not find a significant relationship between adherence and clinical outcomes. However, it is sensible to assume that delivering an intervention with a high degree of accuracy makes it easier to evaluate and make reasonable assumptions about its effectiveness. This is supported by evidence from Caron et al. (2020) and Ginsburg et al. (2011), which showed high adherence to CBT predicted better clinical outcomes and symptom reduction. Additionally, Rapley and Loades (2018) asserted high intervention adherence is critical in establishing experimental validity.

Implications for Practice and Research

The findings of this study have several implications for research in the current treatment of childhood anxiety, particularly for children under the age of 7-years-old presenting with anxiety. The current findings contribute to the growing body of evidence in treating childhood anxiety using variants of manualised CBT interventions. Most importantly, this study supports using modified CBT and sensory modulation with younger children in a developmentally age-appropriate manner. Thus, encouraging therapists to use play and sensory-based techniques that appeal to younger children and support modifications of CBT to align with the cognitive

level and capacity of the children they are working with. This was the first known study to combine CBT and sensory modulation as a treatment for younger children under 7-years-old presenting with anxiety. The results of this study provide preliminary evidence that supports the use of CBT and sensory modulation with young children under 7-years old. Further research using a larger sample size and RCT methodology would be appropriate to further evaluate the effectiveness of the Ngā Timatanga Toa intervention. This will provide more information about the generalisability of results to a wider population. Fresh insights open new avenues to innovative ideas in treating young children with anxiety.

Mothers involved in this study received psychoeducation and learned about their anxiety and how it impacts their children. They also learned about their children's anxiety and were taught basic helpful strategies they can use to support their children. Mothers supported their children with homework and continued with therapy at home, allowing treatment continuity. Hence, this study recommends parental involvement in the treatment of younger children with anxiety.

The discrepancy in anxiety scores between the TRF (Teacher Report Form) completed by teachers and the CBCL (Child Behaviour Checklist) completed by parents highlights the complexity of evaluating a child's anxiety. This difference suggests that the perception of anxiety in children may vary depending on the context and the observer. One possible explanation for this discrepancy is the distinct environments in which the child is observed. Teachers assess the child's behaviour in a school setting, allowing for a comparison to peers and potentially providing a more objective view of the child's social behaviour. However, the school environment may mask some anxiety symptoms if they do not result in overt disruptive behaviour that catches the teacher's attention.

Conversely, mothers observe their child in a home environment where anxiety symptoms may be more noticeable and their familiarity with their child may make them more attuned to subtle signs of distress. The potential for reporting biases should also be considered. Mothers may be more sensitive to their child's anxiety due to their emotional connection, but this may also lead to over-reporting, especially if the mother herself experiences anxiety. Therefore, it is important to examine whether parental anxiety influences their perception of their child's symptoms, potentially amplifying or distorting the presentation of anxiety. In contrast, teachers who have the responsibility of managing an entire classroom may overlook anxiety symptoms in children who do not display challenging or disruptive behaviours, potentially leading to under-reporting.

The assessment tools used, such as the TRF and CBCL, may also contribute to the differing perspectives. The TRF, designed for use in a school setting, may not fully capture the nuances

of a child's anxiety in the classroom. Consequently, the TRF might not be the most appropriate tool for measuring anxiety in this particular context. On the other hand, the CBCL, completed by parents, may reflect a broader range of behaviours observed across different settings, but it could also be influenced by parental perceptions and biases. These considerations emphasise the need for further research to determine the most appropriate methods for evaluating a child's anxiety in various settings, particularly in the classroom. Understanding the impact of the environment, the observer's relationship with the child, and potential reporting biases is crucial for the development of more accurate and comprehensive assessment tools. This is especially important in clinical practice, where teachers are often asked to provide supplementary information during mental health assessments. Ensuring the accuracy and representativeness of this information is essential for effective diagnosis and intervention.

While this 6-session intervention produced results similar to other studies, future studies should consider how to effectively use different intervention formats; for example, groups or individual therapy with limited parental sessions and parent-child sessions. This approach may help understand which format is most effective and which is cost-effective and efficient. Delivering interventions in a group format increases accessibility and maximises the intervention uptake by families. There should also be consideration of delivering the intervention online since most families in NZ have access to the internet and may have at least one device that can be used online. This approach considers how the current intervention was interrupted by COVID-19 several times, and the intervention could have been delivered online as telehealth became the popular platform for delivering interventions during nationwide COVID-19 lockdowns. Delivering the intervention online would require the Ngā Timatanga Toa programme to be adapted to an online format.

Since the intervention manual was developed for non-psychology professionals with limited knowledge of therapy and new to working with children, it would be fascinating to understand if there is any relationship between the outcomes and experience of the clinician who delivers the intervention using quantitative methods. Another area that may need further investigation is the impact of training on staff skills and confidence to work with young children with anxiety. This will inform the best way to train therapists on how to use the intervention. It may include considerations such as the duration of the training, demonstrations by the facilitator, ongoing supervision, and specific training on psychometrics such as feedback-informed treatment measures.

Another study could examine the relationship between training this intervention to more professionals in primary care with access rates and waiting times to receive therapy. Some children may not meet the criteria for admission to secondary services (Ministry of Health,

2018b; Thabrew et al, 2023) which make it difficult for service users to access services (Cumming, 2011) and must therefore seek assistance in primary care. In primary care, they are met with long waiting times and a lack of professionals trained to support these children (Butryn et al., 2017; Kowalewski et al., 2011; Moroz et al., 2020; O'Brien et al., 2016). If more professionals, including school guidance counsellors, are taught how to deliver essential interventions like the Ngā Timatanga Toa, it may remove some barriers to accessing services, improve access to talking therapies, and impact patient flow and wait times in secondary services. This notion is supported by the work of Fazel et al who advocate for the delivery of mental health care in schools (Björklund; 2014; Fazel et al., 2014). This may improve access to mental health services and solve some of the known barriers to accessing mental health services for children (Richter et al., 2022).

This study opened new insights into how CBT and sensory modulation impact anxiety in young children. Although sensory modulation effectively reduces anxiety in adults, it would be beneficial to carry out similar studies with children to understand how sensory approaches alone would alleviate anxiety and distress in young children under 7-years. This presents an opportunity for a dismantling study that may help understand which intervention components are helpful and refine them further. It will be interesting to know which components—CBT, sensory modulation, parent education, or involving the parent in the therapy—had the most significant effect and to what extent. This would provide more information as to whether there is a benefit in combining these two interventions or providing them separately as standalone interventions and establishing effective dosages.

In some participants, the CBCL scores showed the intervention reduced depressive symptoms, which were not targeted by the intervention. This may suggest that some components of the intervention may help alleviate depressive symptoms if the intervention is modified. This phenomenon may also suggest a two-way cause-effect relationship between anxiety and depression, such that improvement in anxiety may improve depressive symptoms. This is another opportunity for future research.

Strengths of Study

As mentioned earlier, this is the first study to test an intervention that combines CBT and sensory modulation for young children presenting with anxiety. The study adds to the body of knowledge on treating young children diagnosed with clinical anxiety and provides a platform for future research in managing childhood anxiety.

The study used several well-researched psychometrics in assessing anxiety and corroborated the data collected from different informants, which strengthened the study results. This has allowed reasonable inferences to be made regarding the cause-effect relationship between the intervention and anxiety. This research provides many opportunities for future research to build on the current programme. In future research, it may be essential to cross-validate the effectiveness of the intervention using different validated measures (e.g., SCARED, Anxiety and Related Disorders Interview Schedule-ADIS, Strengths and Difficulties Questionnaire-SDQ, Global Assessment of Functioning-GAF). The current study also used real-time feedback tools (i.e., feedback-informed treatment tools) to solicit feedback to improve therapeutic alliance, which had a direct effect on patient outcomes; it is recommended to be included in future psychological research.

The study design allowed reasonable inferences to be made regarding the effectiveness of the intervention, reduction of anxiety, and improvement in functioning. Randomly allocating different baseline periods to participants significantly reduced the effect of confounding factors, which strengthened the results of the study. The replication of the study across six participants and getting similar results (i.e., the reduction of anxiety-related symptoms and reduction in anxiety interference) demonstrated the intervention's positive treatment effects and effectiveness. Another strength of the study is that it was offered by different therapists who worked at two different services (i.e., primary and secondary care services) with varying years of experience. This speaks to the generalisability of the intervention across different settings and therapists. However, this should be further confirmed in more extensive studies as indicated above.

The study's inclusion criteria recognised that anxiety exists with other disorders in actual clinical situations. Hence, accepting children with comorbid conditions was a strength of this study. Future studies can focus more on specific conditions armed with preliminary evidence from the present study. Some participants in the study had comorbid conditions alongside their anxiety which was the primary outcome. While the treatment tested in this study successfully reduced anxiety symptoms, it is unknown whether the intervention affected other comorbid conditions as it did on depressive symptoms as discussed earlier.

The intervention was short enough to commit to when compared to other therapies delivered (e.g., intensive CBT that is offered in 10 or more sessions) which may have improved compliance to attend therapy sessions. Although some mothers were not contactable to attend the 1-month PI completion assessment, including completing the psychometric forms, all mothers and their children attended all six therapy sessions.

The study demonstrated an acceptable internal validity and experimental control level. Participants were randomly allocated to a baseline period, there were multiple measurement points in both phases, there was replication (i.e., between child participants and between therapists), and there was an independent assessment of treatment fidelity and adherence. This approach has been used in several studies to establish good internal validity (Tate & Perdices, 2019). Studies should have strong internal validity to ensure that results represent true findings (Andrade, 2018; Patino & Ferreira, 2018; Slack & Draugalis, 2001). The study design had mechanisms that strengthened the study's internal validity, which made it possible to make inferences about the cause-and-effect relationship between the programme and the children's anxiety levels and functioning. The study design met three of the four standards required for a SCED to establish a functional relationship between the dependent and independent variables. The fourth one was partially achieved. Tate and Perdices (2019) summarised the standards as follows:

- *Standard 1: The independent variable should be manipulated in the study.* This was achieved by controlling when each participant received their intervention by randomly allocating participants into different baseline conditions.
- *Standard 2: Data should be measured accurately and dependably and measured by at least two people.* In this study, data were collected by the researcher and the clinical psychologist.
- *Standard 3: The experimental effects should be demonstrated by taking at least three measures in each phase or demonstrating it in three different participants.* This was achieved by replicating it in six participants.
- *Standard 4: At least three measuring points should be in each phase.* This was only partially achieved; at least three measures were included in the baseline phase, two related to the intervention phase (mid-way and end), and only one in the follow-up measure.

Limitations of the Study

It is impossible to conduct a textbook-perfect study using human subjects in real-world conditions, particularly during a pandemic. Therefore, it is important to note the current study had a number of limitations. This study was interrupted several times by COVID-19 lockdowns, COVID-19-related staff sicknesses and staffing issues, such as staff redeployment (see Chapter 4). It is unclear how and to what extent this may have affected the participants and their families. Studies show there was an increase in anxiety presentations in children and an increase in parental stress, anxiety, and depression during the pandemic (Athapathu et al., 2022; Gloster et al., 2020; Grover et al., 2020; Johnson, 2021; Li et al., 2022; Spinelli et al.,

2020; Theberath et al., 2022), which negatively impacted their full participation in life, and potentially in health care and research. Additionally, COVID-19-related misinformation spread on social media by anti-vaccination groups may have created mistrust in research, resulting in parents not wanting to participate in the study.

Needless to say, the recruitment of children with anxiety was challenging and the resulting study sample was small and heterogeneous, making the statistical and theoretical generalisation of findings difficult. Because the research was being conducted as part of a Doctor of Health Science qualification, there were also constraints on the timeframe and, therefore, size of the study. However, Walker and Carr (2021) state that there is a misconception that the generalisation of findings in single-case studies requires large sample sizes; it is achieved through replication.

As a consequence of the time constraints, the follow-up period was short; an additional 3-, 6- or 12-month FU period could have helped clarify how long the gains were maintained. For example, in studies by Spence et al. (2006) and March et al. (2009), the number of children free from anxiety increased at 6 months FU after receiving treatment for anxiety. It is unclear if the same result would have been achieved in the present study if it had a longer FU period. Thus, multiple and longer FU periods (e.g. 1-, 3-, 6-, 12-, 18-, and 24-months) may be required to obtain a clearer picture of how long gains are maintained.

This was an open study and vulnerable to bias. Since mothers knew what treatment, they were receiving, this may have affected their scoring based on their expectations of the intervention, as discussed earlier. Future studies could consider completing an RCT in which mothers are not aware of what interventions their children are receiving.

Another limitation is that the training period for therapists may not have been adequate to cover all the material, although they continued to receive support throughout the intervention period. Considering that most of the therapist participants had limited training in therapy, 8 hours of training may not have been adequate to satisfactorily cover all manual content, including the use of psychometric tools that they were not familiar with. For some of the therapists, CBT and sensory modulation were completely new to them. In that regard, more training hours could adequately cover all these materials (Bearman et a., 2013). Other ideas for improving therapists' training have been discussed in the therapists' training section.

Only one teacher agreed to participate in the study. In SCED, multiple informants help to build a more accurate picture of the child's presenting issues (Tate & Perdices, 2019). Information from the teachers would have helped to understand the accurate picture of the children's

anxiety and the impact of the intervention. The researcher learnt an important lesson regarding the recruitment of teachers for research during the course of the current study. Recruiting teachers for research studies, particularly those conducted within educational settings, poses unique logistical challenges that necessitate meticulous planning and strategic relationship-building. Researchers consistently acknowledge these difficulties. Jago et al. (2011) and Mishna et al. (2012), for instance, underscore the complex process of attaining permission to enter schools and engage teachers. This complexity often stems from the multiple layers of authority that researchers must navigate. To surmount these challenges, researchers must adopt a structured and systematic approach to recruitment.

The initial step in this process involves obtaining permission from the highest appropriate governing authority, which is the Ministry of Education (Bartlett et al., 2017). This ensures that the research endeavour possesses the endorsement and credibility necessary to approach individual schools. Once this endorsement is obtained, the researcher should subsequently endeavour to secure permission from the individual school boards, which govern the operation of schools within a specified district or region where they intend to carry out the study. This hierarchical approach not only facilitates smoother access but also manifests deference to the established administrative structures within the educational system.

In addition to obtaining formal permissions from the Ministry of Education and the school boards, researchers need to invest considerable time and effort in cultivating robust, collaborative relationships with the schools participating in the study. Bartlett et al. (2017) highlight the pivotal significance of fostering healthy, ongoing relationships with school administrators and staff members. Establishing trust and mutual understanding is fundamental to acquiring the necessary cooperation for successful research implementation. Researchers should conceive of these relationships as partnerships, wherein the objectives and needs of both the researcher and the school are acknowledged and addressed.

Once a solid relationship with the school is established, the researcher should identify a designated staff member who can function as the primary point of contact for the study. This individual assumes a critical role, serving as an intermediary between the researcher and the school, adeptly navigating the often intricate educational ecosystem, and ensuring seamless execution of the research project. This designated point of contact can assist with scheduling, communication with other staff members, and managing any logistical challenges that may arise during the study (e.g. completion of study questionnaires, forms, etc).

Involving parents in the research process is another crucial aspect that should not be neglected. Parents play a vital role in their children's education and should be kept informed and consulted about studies concerning their children. Engaging parents early on not only guarantees their support but also addresses any concerns they may have about the study's impact on their child's education and well-being.

Another significant factor to consider is the timing of the research. Teachers often have demanding workloads, and adding research activities to their responsibilities can be challenging. Petosa and Smith (2018) suggest that teachers should be provided with sufficient notice about the research study to allow them to adjust their schedules and plan their work accordingly. Providing ample lead time helps teachers incorporate the study into their routine with minimum disruption to student learning. Furthermore, this advance notice can also encourage teacher commitment to the study as it allows them to adequately prepare and understand the alignment of the research with their educational goals.

To ensure optimal teacher participation and effectively address the logistical challenges mentioned previously, researchers should begin obtaining permissions, building relationships, and planning logistics at least one year before the study commences (Petosa & Smith, 2018). This preparation period facilitates the essential groundwork to inform and garner support from all stakeholders, including authorities, school staff, teachers, and parents. By carefully considering these aspects, researchers can significantly enhance the likelihood of successful teacher recruitment and the overall success of their studies in school settings.

Despite all efforts, some forms were not completed by mothers. Three mothers did not complete the 4-week PI CBCL form, and five did not complete the BTD despite efforts made to follow up with the mothers. These families were contacted to understand their reasons for not completing the forms, and the general theme was that they were busy and did not have time to complete the forms. The CBCL online form takes about 45 minutes to 1 hour to complete, which may have burdened mothers. The other reason for the mothers not completing their CBCL form was the need for appropriate devices (i.e., laptop or desktop computer) to complete the form. Mothers reported that completing the form on a mobile device was challenging. A laptop was offered to some mothers to complete the form, but it was difficult to find a suitable time to meet due to their busy schedules. COVID-19-related stress could also have affected their ability to engage with the forms.

The mothers’ reasons for not completing the forms provide a narrative to explain the missing data, expose the study’s weakness and appear to suggest that the study had too many forms. In that regard, future studies may need to consider using fewer and shorter forms, which are

easier to complete. Kang (2013) and Dziura et al. (2013) asserted that missing data are expected in almost all research and provided suggestions on how to deal with missing data, including imputation, estimation, mean substitution, and deletion. During analysis, missing data were excluded from the analysis, as suggested by Kang (2013). In hindsight, collecting feedback on the programme's acceptability and practicality from the mothers and therapists using a questionnaire may not have been adequate. In future studies, it may be helpful to consider other methods of collecting feedback such as online or in-person focus groups. This would allow for more in-depth discussions of issues that may have arisen during treatment, as well as improvements and suggestions (Roller & Lavrakas, 2015; Tausch & Menold, 2016).

Evaluation of the acceptability of the intervention lacked cultural input as the participant group was not ethnically diverse. With Māori and Pacific people being over-represented in mental health statistics, developing culturally responsive early intervention tools is an important consideration in the New Zealand context. Future studies should include greater input from Māori and Pacific groups to assist with the recruitment and support of children from these ethnic communities.

Conclusion

After considering the strengths and weaknesses, this study provides preliminary evidence that supports the use of modified CBT and sensory modulation together for younger children under 7-years-old presenting with anxiety. It also provides valuable insights into what could be done differently and illuminate opportunities for future research in childhood anxiety treatments. The results indicate that the Ngā Timatanga Toa programme is effective, acceptable, and practicable for children aged between 4 and 7-years-old presenting with anxiety in NZ settings. It is recommended that this study be replicated with improvements to the study design and after consideration of the issues/limitations highlighted. Although this study produced promising results in reducing anxiety symptoms and improving function in children, further studies are required to make firm conclusions about its effectiveness, acceptability, practicality, and generalisability.

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Appendices

Appendix A: The Ngā Timatanga Toa-Intervention Manual

Ngā Tīmatanga Toa

A CBT and Sensory Modulation Intervention for Young Children with Anxiety

Intervention Manual

Developed by Tafadzwa Mavhunga

-for research purposes only-

Appendix B: Parent/Guardian Participant Information Sheet and Consent Form

Parent/Guardian Participant Information Sheet

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.

Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.

Study Site: Birthright Hawkes Bay Child & Family Care Trust.

Contact phone number: 021 756 400.

Ethics committee ref.: 20/NTA/165.

My name is Tafadzwa Mavhunga, I am an Occupational Therapist at Hawkes Bay District Health Board and a Doctor of Health Sciences student at Auckland University of Technology. I would like to invite you and your child to participate in a study to test a new intervention for reducing anxiety in children aged 4-7 years old. There may be no clear benefit to participation.

This Parent/Guardian Participant Information Sheet will help you decide if you and your child would like to take part. It sets out why we are doing the study, what you and your child's participation would involve, what the benefits and risks to you and your child might be, and what would happen after the study ends. We will go through this information with you and your child and answer any questions you and your child may have. You do not have to decide today whether or not you and your child will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, Hawkes Bay DHB or Birthright Hawkes Bay Child & Family Care Trust management. Feel free to do this. If you require Māori cultural support, you will be able to talk to a cultural advisor at the DHB, please talk to the researcher for more information.

We want you to understand this clearly, let us know if you need help to read this or if you want someone to read this aloud and explain the information to you. If you have any questions or require any clarification, please contact me directly on my mobile number 021 756 400 or landline number 06 878 8109 extension 5802.

You will be given up to 14 days to decide whether you and your child want to take part in the study or not. Before you decide, we encourage you to read this carefully and talk to others such as family members, friends and other healthcare providers. Your child can decline to participate in the study even if you consent.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Parent/Guardian Participant Information Sheet and the Consent Form to keep.

The study intervention will be delivered by therapists using a treatment manual. The treatment manual was developed by the lead researcher and has been based on evidence-based practices. The therapists are social workers and will be trained in how to deliver the intervention as recommended in the manual.

The intervention

The intervention uses principles of cognitive behaviour therapy (CBT) and sensory modulation. The intervention will be delivered to you and your child over a 6-week period (one session per week). The 6 sessions are as follows.

The first session introduces the intervention to you and your child. The session aims to improve your understanding of anxiety, how anxiety affects your child's function, how anxiety affects family life and strategies that are helpful to manage anxiety.

The second session teaches your child how to identify signs of anxiety in themselves. It also teaches you how to notice the physical signs and behaviours of anxiety in your child.

The third session is a continuation of session two and focusses on making the connections between anxious (unhelpful) thoughts and what your child feel in their body. Session one to three are based on cognitive behaviour therapy.

Session four teaches your child relaxation techniques using sensory based strategies (for example listening to music, getting a hand massage, doing a physical activity, deep breathing exercises, using different smells for relaxation etc). You will be encouraged to identify activities that calm down your child when they are worried. You and your child will be taught how to use these activities in times of distress to help your child to calm down and relax.

Session five teaches you and your child ways of ensuring that the calming activities are practiced every day and become part of your child's daily routine.

Session six is a consolidation and celebration session. This session summarises all the materials covered from session one to session six and encourages you and your child to continue using the skills taught. Every session comes with a home task that you and your child will have to complete at home. The home task will be reviewed at the beginning of every new session. Each session will be evaluated using outcome scales to make sure that the treatment is progressing as intended.

The intervention sessions will be recorded using audio equipment as part of a fidelity evaluation. An independent person and the lead researcher will listen to random sessions to check if the therapist delivered the intervention as described in the manual.

The study design

There are three phases in the study (see table below) and several methods will be used to collect data including administration of questionnaires and recording of functional improvements, as observed by you and the teacher.

Before the intervention starts there will be a baseline period, when the lead researcher will assess the child's levels of anxiety over time. Your child will be assigned to one of three baseline conditions; 3-week baseline period, 4-week baseline period or 5-week baseline period. Please note that your child will not receive treatment until the baseline period is over. There is a possibility that your child may get worse during this period. If this happens, feel free to contact your GP to ensure that your child gets the help he/she needs. Please also note, we are required to inform your child's GP of their participation in the study and will need your consent to do so.

One month following the intervention there will be a follow-up phase, where assessments will be conducted to see if any changes in anxiety have been maintained.

1. Initial Assessment and Baseline Phase (3-5 weeks)		
You and your child will meet with a clinical psychologist for an initial assessment (to confirm anxiety diagnosis)	Information about your child's anxiety (including year of diagnosis, previous treatments, response to treatment) and related challenges (e.g., other mental health diagnoses) will be collected from your child's GP and teacher. This will help the clinical psychologist to understand your child's level of anxiety and will help in confirming the anxiety diagnosis.	If the child meets the criteria for the study, weekly measures of your child's anxiety levels will be collected from you using a questionnaire called the *Child Anxiety Life Interference Scale.* You may be asked to complete the questionnaire for a baseline period of either 3, 4 or 5 weeks. You will also be asked to record the frequency of anxiety related behaviour during this period using a behaviour tracking diary form.

2. Intervention Phase (6 weeks)
• You and your child will attend weekly intervention sessions at Birthright for 6 weeks • You and your child will be asked to do simple activities at home between each session • You will also be asked to complete short questionnaires in sessions 2-6 • At the end of the 6 sessions, you and your child's teacher will be asked to complete brief questionnaires to capture any changes in anxiety levels or related behaviours.

3. Follow up Phase (4 weeks)

- You and your child will be asked to keep using the strategies learned in the intervention at home
- You and your child's teacher will be asked to complete questionnaires related to your child's anxiety 1 month after the intervention has ended.

Standard treatment

If you decide not to participate in this study, you and your child will be offered standard treatment at Birthright Hawkes Bay Child and Family Care Trust. Standard treatment for children with anxiety involves a number of options, typically involving talking-based therapies. The approach used and number of sessions provided will depend on the needs of your child. If you would like further details about the options offered, you can talk to the staff at Birthright.

WHO CAN TAKE PART IN THE STUDY?

Children aged 4-7 with anxiety are being invited to participate in the study with their parents/guardians. One or more parents/guardians may participate in the study. We are contacting you because your child has been referred to Birthright Hawkes Bay Child & Family Care Trust for assessment and management of anxiety.

What will my participation in the study involve?

Your participation will involve you and your child attending and participating in 6 - sessions of intervention once every week at Birthright Hawkes Bay Child & Family Care Trust. During these sessions, you and your child will learn about anxiety, its causes and strategies to manage anxiety. You and your child will also learn about CBT and sensory modulation and how they can help lower anxiety. You and your child will be given work to complete at home as part of the intervention.

In order for the lead researcher to understand if this intervention is helpful, you will be asked to complete some forms and questionnaires before the intervention, during the intervention, straight after the sixth session and one month after the intervention ends. These questionnaires are brief and should take about 15 minutes to complete.
Over the course of the study, you will also be asked to observe and track three behaviours related to your child's anxiety that you are concerned about. You will be given a behaviour tracking form at the beginning of the study that you will complete throughout the study. It will take about 5 minutes every day to enter the data on the form until the end of the study. At the end of the study, you will report the changes that you have noticed in these behaviours that you can attribute to the intervention.

Finally, in order to understand if this intervention is acceptable to you and your child, you will be asked to complete a parent satisfaction and improvement questionnaire. You will also be asked to give feedback regarding your overall experience of the

intervention and your child's improvement. This form will take about 10 minutes to complete.

We also ask for your consent to approach your child's teacher to complete some questionnaires on entry into study and after the completion of the intervention. This information will help the researcher to understand your child's anxiety from their teacher's view. We need you and your child's permission to contact the teacher.

While in the study, your child will not be allowed to receive any other medication or psychological treatment for anxiety. If further treatments for anxiety are required, your child may have to withdraw from the study.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study has a low level of risk to you and your child. There is a potential risk of your child's anxiety getting worse during the baseline period before the treatment begins. It is also possible that your child may become distressed during the intervention sessions. For example, they may experience anxiety related to an unfamiliar situation or activities. The therapist will be focused on making your child feel safe and comfortable and will not force them to continue in any activity or situation that is distressing for them.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

This intervention may have potential benefits for you and your child and the therapist involved. Your child will learn ways to reduce their anxiety in stressful situations and in everyday life. These skills can continue to be practiced after the study and can improve through regular use. You will be taught skills and strategies on how to support your child to be more resilient. The therapists will learn a new therapy approach to use with younger children presenting with anxiety. The study will also provide evidence related to the impact of the intervention and how acceptable and practical it is for the children, parents/guardians and therapists.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

If you do not want your child to receive the intervention tested in this study, you will be able to access the standard treatment offered at Birthright Hawkes Bay Child and Family Care Trust. Alternatively, if your child's anxiety is severe and requires a clinical psychologist or psychiatrist, a referral to a secondary service can also be completed by the Birthright therapist.

WILL ANY COSTS BE REIMBURSED?

You will be provided with petrol vouchers of 20 liters per week to attend the therapy sessions.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that you or your child were injured in this study, you or your child would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During the study, the therapist and a clinical psychologist will record information about you and your child's participation. This includes the results of any study assessments.

Identifiable Information.

Identifiable information is any data that could identify you or your child (e.g. your name, date of birth, or address). Only researchers have access to you or your child's identifiable information. Randomly selected audio -recorded sessions will be accessed by an independent third party as part of a fidelity test.

De-identified (Coded) Information.

To make sure your personal information is kept confidential, information that identifies you or your child will not be included in any report generated by the researcher. Instead, your child will be identified by a code. The researcher will keep a list linking your child's code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

You and your child's identifiable information including consent forms and post analysis data will be held at a secure archiving site at Auckland University of Technology and stored for at least 10 years after the youngest child in the study turns 16, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect you and your child's privacy, absolute confidentiality of you and your child's information cannot be guaranteed. Even with coded and anonymised information, there is no complete guarantee that you and your child cannot be identified. The risk of people accessing and misusing your information

is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information and correct information.

You and your child have the right to request access to your information held by the research team including the feedback from the teacher. You and your child also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you and your child, you should ask the researcher.

Rights to Withdraw Your Information.

You and your child may withdraw your consent for the collection and use of you and your child's information at any time, by informing the researcher.

If you and your child withdraw your consent, your study participation will end, and the study team will stop collecting information from you and your child.

Information collected up until you and your child's withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you and your child change your mind during the study and no longer wish to participate, you and your child will be free to pull out of the study at any time. The information collected about the intervention up to the point when you withdraw will continue to be processed.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You and your child may request a copy of the study results, which will be available within 1 year from the end of the study. All of your data will be kept private and confidential, and you and your child won't be personally identified in any of the study results.

WHO IS FUNDING THE STUDY?

This study is being completed as part of a doctoral training by the lead researcher. The lead researcher is a student at Auckland University of Technology. The study is funded by a small grant that doctoral students get from the university. Additionally, the researcher has also been awarded some funding from the Hawkes Bay Medical Research Foundation towards the research. Other costs will be met by the lead researcher.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A HDEC has approved this study.

Who do I contact for more information or if I have concerns?

If you have any questions or require any further information, please contact:

Tafadzwa Mavhunga
Phone: 021 756 400
E-mail: tafadzwamavhunga@yahoo.co.uk

If you wish to receive Māori support, please inform the lead researcher and he will arrange Laurie Te Nahu from Maori Health Services at Hawkes Bay DHB to provide this support. You can also contact Maori Health Services directly and ask to speak to Laurie. You can call Maori Health Services on:

Phone 06 878 8109 ext. 5779 or
06 878 1654 or
0800 333 671 or
call Laurie directly on 027 704 9665 or
Email laurie.TeNahu@hbdhb.govt.nz

If you want to contact someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hrc.org.nz

You can also contact the health and ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@health.govt.nz

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.
Study Site: Birthright Hawkes Bay Child & Family Care Trust.
Contact phone number: 021 756 400.
Ethics committee ref.: 20/NTA/165.

Consent Form

If you would like to provide consent verbally instead of in writing and/or have the form read to you aloud, please let us know. You may also have a family/whānau member complete this form on your behalf. For each item below, please tick the box beside the text to indicate you consent to the following. Where there is a choice please tick 'Yes' or 'No'.

I have read (or have had read to me) the Parent/Guardian Participant Information Sheet and I understand the information presented.	☐
I have been given sufficient time to consider whether or not I and my child participate in this study.	☐
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.	☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and parent/guardian participant information sheet.	☐
I understand that taking part in this study is **voluntary** (my choice) and that I and my child may withdraw from the study at any time without this affecting my child's care at Birthright Hawkes Bay Child & Family Care Trust or a future referral to Birthright Hawkes Bay Child & Family Care Trust.	☐
I consent to the research staff collecting and processing my child's information, including information about my child's health.	☐
If I and my child decide to withdraw from the study, I agree that the information collected about my child up to the point when I and my child withdraw may continue to be processed.	☐
I understand that my participation in this study is confidential and that no material, which could identify me personally or my child, will be used in any reports on this study.	☐
I consent to information about my child to be collected from the teacher.	☐

I understand that my child's GP will be informed about my child's participation in this study.	☐	
I give consent for the researchers to contact my child's GP to collect information about my child specific to the study and not all the health records.	☐	
I know who to contact if I have any questions about the study in general.	☐	
I understand my responsibilities as a study participant.	☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I would like to have Māori cultural support during the study.	Yes ☐	No ☐
I give consent for my child to participate in the study.	☐	
I give consent to participate in the study.	☐	

Declaration by participant:

I hereby consent to take part in this study and also give consent for my child to participate in the study. My child will give their own assent to participate.

Participant's name: ____________________

Signature: ________________ Date: ____________

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Lead researcher's name: ____________________

Signature: ________________ Date: ____________

Appendix C: Child Participant Information Sheet and Assent Form

Child Participant Information Sheet and Assent Form

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.
Study Site: Birthright Hawkes Bay Child & Family Care Trust.
Contact phone number: 021 756 400.
Ethics committee ref.: 19/NTA/174.

(The lead researcher will read this aloud to the child and explain in child-friendly language)

My name is Tafadzwa Mavhunga, and I work at Child, Adolescent and Family Service at the Hawkes Bay District Health Board. I am inviting you to participate in a study to test if some activities that we have put together are helpful in reducing worries.

Whether you take part or not is your **choice.** If you do not want to take part in the study that is OK. You don't have to decide today. You will be given 14 sleeps to decide. You can still say no even if your parents/guardians say yes.

WHAT IS THE PURPOSE OF THE STUDY AND ITS BENEFITS?

The purpose of this study is to understand if these new activities help children with their worries. We also want to understand if you and your family find these activities helpful.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will be expected to attend 6 sessions of therapy weekly with one or both of your parents at Birthright Hawkes Bay Child & Family Care Trust. A therapist will work with you and your family and play some fun activities with you. Each session will be 90 minutes long.

With your permission, we will also talk to your teacher to hear how you are doing at school.

WHO CAN I ASK QUESTIONS IF I WANT TO?

You can ask your parent, or you can ask me questions that they may not be able to answer.

Child Assent Form

(Tick the box next to each statement if the child agrees with the statement).

1. I understand what being in this study involves.		
2. I agree for you to talk to my teacher.		
3. **I want to participate in the study**		
4. I understand that even if my parents/ guardians say yes, I can say no.		

Verbal assent given of the child is too young to sign:___________________________

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed assent to participate.

Child's name: ____

Lead Researcher's name: ____

Signature: ______________________________ Date: ______________________________

Appendix D: HDEC Approval Letter

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@health.govt.nz

15 December 2020

Mr Tafadzwa Mavhunga
14 St Hill lane
Havelock North
Hastings
Hastings 4130

Dear Mr Mavhunga,

Re:	**Ethics ref:**	**20/NTA/165**
	Study title:	The effectiveness, acceptability and practicality of a CBT-sensory modulation intervention for 4-7 year old children presenting with anxiety.

I am pleased to advise that this application has been *approved with non-standard conditions* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. Childhood anxiety is associated with long-term consequences including development of mood disorders if not treated early. However, literature shows that young children do not receive timely interventions due to long waiting lists, a shortage of psychologists and inability to complete interventions that are between 9-20 sessions, due to their parents' other commitments.
2. This study proposes to test the effectiveness, acceptability and practicality of a 6-session anxiety intervention developed for children aged 4-7 years old presenting with anxiety. Cognitive Behavioral Therapy (CBT) is the main non-pharmacological intervention used in the treatment of anxiety. CBT is a talking-based therapy, which helps people explore and manage unhelpful thoughts in order to reduce distressing emotions or problematic behaviours. While often recommended, CBT alone may not be effective in treating anxiety and is not developmentally appropriate for younger children.
3. The proposed study will use a developmentally appropriate intervention that combines modified CBT and sensory modulation. Sensory modulation is a clinical intervention that uses sensory-based strategies to help people regulate their emotions.
4. The study will use a multiple baseline single case experimental design. Eight candidates meeting the inclusion criteria will be admitted into the study. Two therapists will each deliver the intervention with four children and their families (N=8).

- This design included a differential start baseline (to ensure the time to intervention is not a factor), in this case the children will be randomised to baseline start time of 3, 4 or 5 weeks.
- Two of the children will receive the intervention during a pilot phase, after which potential modifications to the method may be considered (requiring an amendment).

- Then six children will receive the intervention during the study phase, where the intervention will be delivered in a staggered fashion.

5. Data, including the levels of each child's anxiety and functioning, will be collected before the intervention, during the intervention and one-month post intervention. Subjective feedback will be gathered from participants and therapists to determine the practicality and acceptability of the intervention.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

1. Child's assent form: The Committee requested that the child's assent form be one page long and to include that the researchers want to speak to the child's teacher (points 26 and 27). Whilst the cover letter provided states that this request has been complied with, the assent form is in fact 2 pages long and is still too complex for a 4-7-year-old age group. Please reduce the assent form to one page and the 'signature' page should include the child's name.

2. Teacher Participant Information Sheet and Consent Form (PISCF) 2:

    - Page 1: Do teachers have relationships with the Birthright Hawkes Bay Child & Family Care Trust which might be affected? If there is never any relationship between teachers and the Trust, then the statement is simply confusing. The more likely relationship is the teacher's employment relationship with the school, but it would seem unlikely that a teacher's contract of employment requires completion of the surveys which are stated to be standard TRF and the SAS TR.

    - Page 2 – under the heading "what will my participation in the study involve?" Please state that the parent/guardian has consented, and the child has assented, to the teacher completing the surveys about the child for the purpose of the research.

    - Page 2- under the heading "What are the possible benefits of the study" please amend statements which suggest that there will be

benefits from the study – it cannot be known whether there will definitely be benefits until the study has concluded. Please amend by noting that there **may** be the benefits (requested in point 16 of the PA letter).

- Page 3 under the heading "What are the possible risks of this study" at the top of page 3, please consider rephrasing because the parent and child will know the teacher's identity – they have consented to the teacher completing the survey. It would seem that no other information about the teacher will be given for the research. Isn't the risk for the teacher that a parent will ask to see the answers to the teacher surveys and be upset/disagree/complain about the answers given?

- Under the heading "Identifiable information' it is incorrect to state that only the researchers will have identifiable information for the reasons given above – i.e. the parent and the child knows the identity of the teacher (unless multiple teachers will answer surveys for the one child). Please amend.

- Under the heading "Security and storage of your information", the following statements appear to be incorrect because there is no 'sponsor' for the study. Please amend accordingly.

a) "Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor".
b) "Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely."

- Under the heading 'risks', which appears at the bottom of page 3, please rephrase having regard to the matters mentioned above.

- Page 3 – under the heading "Rights to Access Your Information" – please include the right to correct the information.

- On the last page, please include Maori cultural support numbers (as requested point 22 PA letter).

3. The consent form for the teacher Participant Information Sheet should only include tick boxes for the things which are truly optional (point 24 of the PA letter).

4. Therapist Participant Information Sheet - The Committee have requested the following amendments to be made to this PISCF:

- Page 3: under the heading 'study design', reference is made to a table. However, there is no table.

- Page 3: what are the possible benefits of the study – similar amendments are required as for the teacher PIS.

- Page 4 – Security and storage of your information" – similar amendments as required for the teacher PIS.

- Page 5 - under the heading "Rights to Access Your Information" – please include the right to correct the information.

- Page 6 – include Maori support numbers.

5. Parent/Guardian Participant Information Sheet. The Committee have requested the following amendments be made to this PISCF:

    - Please check the entire PIS for correct references to the parent and the child. For example, on page 2 the statement is made: "*The intervention will be delivered to the child and their parent(s)*". It should be "*The intervention will be delivered to you and your child*". Another example is on page 4 where the following statement is made: "*as observed by the child's parents and teacher*." This PIS is addressed to the parents/guardians, so the correct reference should be as follows: '*As observed by you, as the child's parent/guardian and teacher*'. Similarly, all the interventions on pages 2-3 should refer to your child etc.

    - Please also use the term 'parent/guardian instead' of only 'parent'.

    - Please also thoroughly check the entire PIS to ensure references are to both the parent/guardian and to the child – for example, page 7. (point 18, PA letter).

6. Other amendments:

- Pages 4-5 – please make it clear that the parent/guardian's consent is being sought to approach the child's teacher and request s/he complete the questionnaires for the purpose of the research.

- Pages 6 – 7 – please refer to the child's position and the parent/guardian's position vis-à-vis identifiable and de-identified data

- Page 6 – the data FUR section must also refer to the child's coded data as well as the parent/guardian's coded data. Please also very carefully review this section to ensure that all the statements in it are accurate for this study and have not been included only because they appear in the template. For example: (i) Will the coded data really be sent overseas? (ii) Will it really be combined with data from other data sets? (iii) If this is intended, further statements must be included in the data Future Unspecified Research (FUR) section including the risks associated with sending data overseas – these are referred to in the template but have not been used in this PIS. Furthermore, the data FUR hasn't been mentioned in the teacher's PIS or the therapist's PIS – if the data from the therapists and teachers will be used for data FUR then those two PISCFs must also include data FUR sections.

- Page 6 - Security and storage of your information – similar amendments as required for the teacher PIS.

- The consent form should only include tick boxes for the things which are truly optional (point 24 of the PA letter). Note continued use of data after withdrawal is stated to be mandatory in the PIS but it is made optional in the consent form – please ensure consistency.

- The consent form should also name the child because the consent is also on behalf of the child – the child's assent, on its own, is insufficient for this age group.

The Committee also wish to advise the research team that if any changes are made to the intervention manual after the pilot, it will need to be resubmitted to HDEC with tracked changes for ethics approval.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 15 December 2021.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs. Kate O'Connor
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*
Investigator's Brochure: Study Flyer-updated	1.2	22 November 2020
Survey/questionnaire: Parent satisfaction questionnaire	1.0	04 October 2020
Survey/questionnaire: Therapist satisfaction questionnaire	1.0	04 October 2020
PIS/CF: Teacher PIS & Consent Form updated	1.2	04 October 2020
PIS/CF: Therapist PIS & Consent Form updated	1.2	04 October 2020
PIS/CF: Parent PIS & consent updated	1.2	22 November 2020
PIS/CF: Child PIS & Assent-updated	1.2	22 November 2020
Intervention manual	1.0	07 October 2020
Response to HDEC	1.0	07 October 2020
Protocol: Study protocol	1.0	07 October 2020
Declined letter for previous application in respect of the same (or substantially similar) study: HDEC decline letter	1.0	07 June 2020
CV for CI: CV	1.0	07 June 2020
Evidence of scientific review: Confirmation of candidature - after review of protocol	1.0	07 June 2020
Evidence of scientific review: Evidence of review by external reviewer 1. 1	1.0	07 June 2020
Evidence of scientific review: Evidence of review by external reviewer 2.	1.0	07 June 2020
Application		08 October 2020
Behavior Tracking Diary V1.docx	1.0	
CALIS_ChildReport_2015_copyright_BC0278_Approved_RD.doc		
CALIS_Parent_2016_copyright_BC0278_Approved_RD-converted.docx		
CALIS_Preschool_2017_copyright_BC0278_Approved_RD-converted.docx		
cors-and-csrs.doc		
Intervention fidelity form V1.doc	1.0	
ORS.docx		
PASR__English_copyright_2015 2.doc		
SAS_TR_copyright_2015.doc		
SRS.docx		
YCORS.docx		
YCSRS.docx		
SC36802592 20101915440.pdf		
SC36802592 20101915450.pdf		
SC36802592 20101915451.pdf		
SC36802592 20101915452.pdf		
Covering Letter: Covering letter - response to HDEC	1.2	22 November 2020
PIS/CF: Assent for child with tracked changes	1.3	22 November 2020
PIS/CF: Parent PIS with tracked changes	1.3	22 November 2020
Investigator's Brochure: Study flyer with tracked changes	1.3	22 November 2020
PIS/CF: Teacher PIS with tracked changes	1.3	22 November 2020
PIS/CF: Therapist PIS with tracked changes	1.3	22 November 2020

Appendix E: AUTEC Approval Letter

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

31 March 2021

Daniel Sutton
Faculty of Health and Environmental Sciences

Dear Daniel

Ethics Application: **21/63 The effectiveness, acceptability and practicality of a CBT-sensory modulation intervention for children aged 4-7 years old presenting with anxiety**

Thank you for submitting your application for ethical review. We are pleased to advise that a subcommittee of the Auckland University of Technology Ethics Committee (AUTEC) approved your ethics application, subject to:

1. Post-analysis data and Consent Forms should be stored separately on AUT premises. Provision of an assurance that this will occur and that neither data nor Consent Forms will be stored on the researcher's computer or in their office;
2. Inclusion of the AUT logo on the advertisement for participants;
3. Inclusion of the funder on each of the Information Sheets;
4. Clarification of whether or not observations are included in the research as noted in Section A.5.1. If there are, then please provide an observation protocol;
5. Clarification of the total number of participants. There are eight children; at least eight parents/guardians, two therapists and up to eight teachers. Clarification of whether two parents/guardians may attend with each child;
6. Provision of the Head of School signature;
7. Clarification of whether the withdrawal of a teacher means that the child and their parent/guardian also withdraws;
8. Amendment of the Information Sheet for teachers as follows:
    a. Inclusion of advice that parents and social workers, and perhaps the child's school, will be aware of the teachers' participation;
    b. Clarification of how teachers will be recruited and if they will be approached by email, then provision of the draft text for this communication;
9. Amendment of the Information Sheet for parents/guardians as follows:
    a. State that children on medication are excluded;
    b. State that if parents/guardians are contemplating changes to that medication so the children can participate, they are advised to consult their GP;
    c. Under "How is the study designed", rephrase for clarity that "The therapists *are social workers* and will be trained in how to deliver" ...

d. Include the time required for parents to complete the tracking document and the satisfaction survey;

e. Inclusion in the follow-up phase section of the table on P4 that the teacher will be requested to do the same;

f. Inclusion of advice that the researcher will assess the students' anxiety at weeks 3, 4 and 5, and explain the tool that will be used;

10. Clarification of how many litres of petrol will be supplied per week as there were differing amounts across the application and update the parent/guardian Information Sheet as appropriate;
11. Clarification of who will make the referral to the psychologist or psychiatrist and update the parent/guardian Information Sheet as appropriate;
12. Clarification of what information will be requested from the GP and the rationale for this. Include advice about this in the Information Sheet and provide the letter to the GP, noting that only specific information should be supplied, not the entire health record;
13. Clarification of whether parents will be able to view teachers' documents about their children;
14. Amendment of all the Consent Forms so that tick boxes are included only for the items that are truly optional, such as the choice to receive a research summary;
15. Amendment of the parent/guardian Consent Form as follows:

    a. Inclusion of a bullet point noting that their child can decline to participate even if they consent;

    b. Inclusion of a bullet point with a yes/no tick box allowing the researchers to contact the GP for their child's information (specific to the study, not all health records);

    c. Removal of the bullet point seeking the signature of another family/whānau member;

16. Clarification of whether or not the social workers have an existing therapeutic relationship with the child and/or their parent/guardian; and whether or not the social workers report to the researcher. If the answer to either of these is yes, please reconsider the conflicts of interest and power differences involved; clarify how these will be avoided, minimised, and/or managed through the research process; and provide revised protocols/updated public documents;
17. Amendment of the therapist Information Sheet as follows:

    a. Inclusion of advice about the anxiety tool the researcher will administer at weeks 3, 4 and 5;

18. Amendment of the child Information Sheet as follows:

    a. Inclusion of the time each session will take;

    b. Include advice that even if their parents consent, they can say no;

19. Inclusion of a bullet point in the Consent Form for children that 'even if my parents say yes I can say no';
20. Clarification of the inclusion of the SRS for ages 13 to adult as this study relates to a different age group.

Please provide us 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. You are not required to resubmit the application form again. Any changes to responses in the form required by the committee in their conditions may be included in a supporting memorandum.

Please note that the Committee is always willing to discuss with applicants the points that have been made. There may be information that has not been made available to the Committee, or aspects of the research may not have been fully understood.

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.

We look forward to hearing from you,

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: tafadzwamavhunga@yahoo.co.uk; margaret.sandham@aut.ac.nz

Appendix F: Hawkes Bay DHB Ethics Approval Letter

Corporate Services

4th April 2022

Melissa Spooner
Research Coordinator, HBDHB, Research Committee

Tēnā koe Melissa

Re: The effectiveness, acceptability, and practicality of a CBT-Sensory modulation intervention for children 4-7 years old presenting with anxiety.

Māori Health Service has reviewed the above-mentioned research proposal as per ethical and legislative requirement for research conducted in District Health Boards (DHBs) in Aotearoa / New Zealand. District Health Boards are required to ensure that research carried out within their region protects Māori cultural interests, promotes Māori wellbeing and provides mechanisms for Māori participation (NEAC 2012a, 2012b).

The applicant presents an extensive literature review, gaps and benefits of the study, the aim and objectives of the study, as well as the systematic research methodology for execution of the study. The evidence generated from the proposed study will highly enhance interventions for children presenting with anxiety at the Child Adolescent and Mental Health Services (CAMHS) and primary care organizations at HBDHB and beyond.

We would like the applicant to note that Māori Health Service values patients consent in these types of studies and require that their participation should result from broad understanding of all the issues involved while ensuring their safety and respect of their cultural values and interests. We are happy to note that the applicant has developed information sheets and consent forms not only for the parent/guardian of the children likely to participate in this study, but has done the same for the teachers and therapists who are going to take part in the study.

We endorse the research application and look forward to the research results.

Ngā mihi nui

Justin K. Nguma
Māori Health Improvement Advisor
Health Improvement and Equity Directorate
Email: justin.nguma@hawkesbaydhb.govt.nz

Cc: Charrissa Keenan
Programme Manager, Māori Health
Health Improvement and Equity Directorate
Email: charrissa.keenan@hawkesbaydhb.govt.nz

Cc: Ngaira Harker
Nurse Director Māori Health
Health Improvement and Equity Directorate
Email: ngaira.harker@hawkesbaydhb.govt.nz

Appendix G: The School Anxiety Scale Teacher Report Form (SAS-TR)

School Anxiety Scale – Teacher Report

Teacher's name:	Date:
Child's name:	Grade:

For each item please fill in the circle that best describes how this child has been **over the last three months or this school year**. Please answer all of the items.

	Never	Sometimes	Often	Always
1. This child is afraid of asking questions in class	0	1	2	3
2. This child speaks only when someone asks a question of them	0	1	2	3
3. This child worries what other people think of him/her	0	1	2	3
4. This child does not volunteer answers or comments during class	0	1	2	3
5. This child is afraid of making mistakes	0	1	2	3
6. This child hates being the centre of attention	0	1	2	3
7. This child hesitates in starting tasks or asks whether they understood the task before starting	0	1	2	3
8. This child worries about things	0	1	2	3
9. This child worries that (s)he will do badly at school	0	1	2	3
10. This child worries that something bad will happen to him/her	0	1	2	3
11. This child seems very shy	0	1	2	3
12. This child complains of headaches, stomach aches or feeling sick	0	1	2	3
13. This child feels afraid when (s)he has to talk in front of the class	0	1	2	3
14. This child hesitates to speak when in group situations	0	1	2	3
15. When this child has a problem, (s)he feels shaky	0	1	2	3
16. This child appears nervous when approached by other children or adults	0	1	2	3

© Centre for Emotional Health, Macquarie University, Sydney, Australia
Original Publication: Lyneham, Street, Abbott, Rapee (2008)

The information in this document is not intended as a substitute for professional medical advice, diagnosis or treatment

Appendix H: Child Behaviour Checklist

Please print CHILD BEHAVIOR CHECKLIST FOR AGES 6-18

For office use only
ID #

CHILD'S FULL NAME First Middle Last

CHILD'S GENDER ☐ Boy ☐ Girl

CHILD'S AGE

CHILD'S ETHNIC GROUP OR RACE

TODAY'S DATE Mo.____ Date____ Yr.____

CHILD'S BIRTHDATE Mo.____ Date____ Yr.____

GRADE IN SCHOOL ____

NOT ATTENDING SCHOOL ☐

Please fill out this form to reflect your view of the child's behavior even if other people might not agree. Feel free to print additional comments beside each item and in the space provided on page 2. ***Be sure to answer all items.***

PARENTS' USUAL TYPE OF WORK, even if not working now. *(Please be specific — for example, auto mechanic, high school teacher, homemaker, laborer, lathe operator, shoe salesman, army sergeant.)*

FATHER'S TYPE OF WORK ____

MOTHER'S TYPE OF WORK ____

THIS FORM FILLED OUT BY: (print your full name)

Your gender: ☐ Male ☐ Female

Your relation to the child:

☐ Biological Parent ☐ Step Parent ☐ Grandparent
☐ Adoptive Parent ☐ Foster Parent ☐ Other (specify) ____

I. Please list the sports your child most likes to take part in. For example: swimming, baseball, skating, skate boarding, bike riding, fishing, etc.

☐ None

	Compared to others of the same age, about how much time does he/she spend in each?				Compared to others of the same age, how well does he/she do each one?			
	Less Than Average	Average	More Than Average	Don't Know	Below Average	Average	Above Average	Don't Know
a. ____	☐	☐	☐	☐	☐	☐	☐	☐
b. ____	☐	☐	☐	☐	☐	☐	☐	☐
c. ____	☐	☐	☐	☐	☐	☐	☐	☐

II. Please list your child's favorite hobbies, activities, and games, other than sports. For example: stamps, dolls, books, piano, crafts, cars, computers, singing, etc. (Do *not* include listening to radio or TV.)

☐ None

	Compared to others of the same age, about how much time does he/she spend in each?				Compared to others of the same age, how well does he/she do each one?			
	Less Than Average	Average	More Than Average	Don't Know	Below Average	Average	Above Average	Don't Know
a. ____	☐	☐	☐	☐	☐	☐	☐	☐
b. ____	☐	☐	☐	☐	☐	☐	☐	☐
c. ____	☐	☐	☐	☐	☐	☐	☐	☐

SAMPLE

III. Please list any organizations, clubs, teams, or groups your child belongs to.

☐ None

	Compared to others of the same age, how active is he/she in each?			
	Less Active	Average	More Active	Don't Know
a. ____	☐	☐	☐	☐
b. ____	☐	☐	☐	☐
c. ____	☐	☐	☐	☐

IV. Please list any jobs or chores your child has. For example: paper route, babysitting, making bed, working in store, etc. (Include both paid and unpaid jobs and chores.)

☐ None

	Compared to others of the same age, how well does he/she carry them out?			
	Below Average	Average	Above Average	Don't Know
a. ____	☐	☐	☐	☐
b. ____	☐	☐	☐	☐
c. ____	☐	☐	☐	☐

Be sure you answered all items. Then see other side.

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PAGE 1

Please print. **CHILD BEHAVIOR CHECKLIST FOR AGES 1½-5**

For office use only
ID #

CHILD'S FULL NAME First Middle Last

CHILD'S GENDER ☐ Boy ☐ Girl

CHILD'S AGE

CHILD'S ETHNIC GROUP OR RACE

TODAY'S DATE Mo.____ Day____ Year____

CHILD'S BIRTHDATE Mo.____ Day____ Year____

Please fill out this form to reflect your view of the child's behavior even if other people might not agree. Feel free to write additional comments beside each item and in the space provided on page 2. ***Be sure to answer all items.***

PARENTS' USUAL TYPE OF WORK, even if not working now. *Please be specific — for example, auto mechanic, high school teacher, homemaker, laborer, lathe operator, shoe salesman, army sergeant.*

FATHER'S TYPE OF WORK __________

MOTHER'S TYPE OF WORK __________

THIS FORM FILLED OUT BY: (print your full name)

____

Your relationship to child:

☐ Mother ☐ Father ☐ Other (specify):

Below is a list of items that describe children. For each item that describes the child ***now or within the past 2 months***, please circle the ***2*** if the item is ***very true or often true*** of the child. Circle the ***1*** if the item is ***somewhat or sometimes true*** of the child. If the item is ***not true*** of the child, circle the ***0***. Please answer all items as well as you can, even if some do not seem to apply to the child.

0 = Not True (as far as you know) **1 = Somewhat or Sometimes True** **2 = Very True or Often True**

0 1 2 1. Aches or pains (without medical cause; ***do not*** include stomach or headaches)
0 1 2 2. Acts too young for age
0 1 2 3. Afraid to try new things
0 1 2 4. Avoids looking others in the eye
0 1 2 5. Can't concentrate, can't pay attention for long
0 1 2 6. Can't sit still, restless, or hyperactive
0 1 2 7. Can't stand having things out of place
0 1 2 8. Can't stand waiting; wants everything now
0 1 2 9. Chews on things that aren't edible
0 1 2 10. Clings to adults or too dependent
0 1 2 11. Constantly seeks help
0 1 2 12. Constipated, doesn't move bowels (when not sick)
0 1 2 13. Cries a lot
0 1 2 14. Cruel to animals
0 1 2 15. Defiant
0 1 2 16. Demands must be met immediately
0 1 2 17. Destroys his/her own things
0 1 2 18. Destroys things belonging to his/her family or other children
0 1 2 19. Diarrhea or loose bowels (when not sick)
0 1 2 20. Disobedient
0 1 2 21. Disturbed by any change in routine
0 1 2 22. Doesn't want to sleep alone
0 1 2 23. Doesn't answer when people talk to him/her
0 1 2 24. Doesn't eat well (describe): __________
0 1 2 25. Doesn't get along with other children
0 1 2 26. Doesn't know how to have fun; acts like a little adult
0 1 2 27. Doesn't seem to feel guilty after misbehaving
0 1 2 28. Doesn't want to go out of home
0 1 2 29. Easily frustrated
0 1 2 30. Easily jealous
0 1 2 31. Eats or drinks things that are not food—***don't*** include sweets (describe): __________
0 1 2 32. Fears certain animals, situations, or places (describe): __________
0 1 2 33. Feelings are easily hurt
0 1 2 34. Gets hurt a lot, accident-prone
0 1 2 35. Gets in many fights
0 1 2 36. Gets into everything
0 1 2 37. Gets too upset when separated from parents
0 1 2 38. Has trouble getting to sleep
0 1 2 39. Headaches (without medical cause)
0 1 2 40. Hits others
0 1 2 41. Holds his/her breath
0 1 2 42. Hurts animals or people without meaning to
0 1 2 43. Looks unhappy without good reason
0 1 2 44. Angry moods
0 1 2 45. Nausea, feels sick (without medical cause)
0 1 2 46. Nervous movements or twitching (describe): __________
0 1 2 47. Nervous, highstrung, or tense
0 1 2 48. Nightmares
0 1 2 49. Overeating
0 1 2 50. Overtired
0 1 2 51. Shows panic for no good reason
0 1 2 52. Painful bowel movements (without medical cause)
0 1 2 53. Physically attacks people
0 1 2 54. Picks nose, skin, or other parts of body (describe): __________

Be sure you answered all items. Then see other side.

SAMPLE

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Appendix I: The Teacher Report Form

TEACHER'S REPORT FORM FOR AGES 6-18

For office use only
ID #

Your answers will be used to compare the pupil with other pupils whose teachers have completed similar forms. The information from this form will also be used for comparison with other information about this pupil. Please answer as well as you can, even if you lack full information. Scores on individual items will be combined to identify general patterns of behavior. Feel free to print additional comments beside each item and in the spaces provided on page 2. ***Please print, and answer all items.***

PUPIL'S FULL NAME First Middle Last

PUPIL'S GENDER ☐ Boy ☐ Girl

PUPIL'S AGE

PUPIL'S ETHNIC GROUP OR RACE

TODAY'S DATE Mo.____ Date____ Yr.____

PUPIL'S BIRTHDATE (if known) Mo.____ Date____ Yr.____

GRADE IN SCHOOL ____

NAME AND ADDRESS OF SCHOOL

PARENTS' USUAL TYPE OF WORK, even if not working now (Please be specific — for example, auto mechanic, high school teacher, homemaker, laborer, lathe operator, shoe salesman, army sergeant.)

FATHER'S TYPE OF WORK ____

MOTHER'S TYPE OF WORK ____

THIS FORM FILLED OUT BY: (print your full name)

Your gender: ☐ Male ☐ Female

Your role at the school:

☐ Classroom Teacher ☐ Counselor

☐ Special Educator ☐ Administrator

☐ Teacher's Aide ☐ Other (specify):

I. For how many months have you known this pupil? ________ **months**

II. How well do you know him/her? 1. ☐ Not Well 2. ☐ Moderately Well 3. ☐ Very Well

III. How much time does he/she spend in your class or service per week?

IV. What kind of class or service is it? (Please be specific, e.g., regular 5th grade, 7th grade math, learning disability, counseling, etc.)

V. Has he/she ever been referred for special class placement, services, or tutoring?

☐ Don't Know 0. ☐ No 1. ☐ Yes — what kind and when?

VI. Has he/she repeated any grades? ☐ Don't Know 0. ☐ No 1. ☐ Yes — grades and reasons:

VII. Current academic performance — list academic subjects and check box that indicates pupil's performance for each subject:

Academic subject	1. Far below grade	2. Somewhat below grade	3. At grade level	4. Somewhat above grade	5. Far above grade
1. ____	☐	☐	☐	☐	☐
2. ____	☐	☐	☐	☐	☐
3. ____	☐	☐	☐	☐	☐
4. ____	☐	☐	☐	☐	☐
5. ____	☐	☐	☐	☐	☐
6. ____	☐	☐	☐	☐	☐

Be sure you answered all items. Then see other side.

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SAMPLE

Appendix J: Child Anxiety Life Interference Scale (CALIS Parent Version)

Child Anxiety Life Interference Scale (CALIS Parent Version)

Participant ID:	Child's DOB:
Your relationship to child:	Today's Date:

NOTE: Each rating should be considered in the context of what is appropriate for the age of your child. When completing this form, please think about your child's behaviours in the past 6 months.

1. Do fears and worries upset or distress your child?

Not at all	Only a little	Sometimes	Quite a lot	A great deal
0	1	2	3	4

2.	**How much do fears and worries interfere with your child's everyday life in the following areas?**	**Not at all**	**Only a little**	**Some times**	**Quite a lot**	**A great deal**
a.	Getting on with parents	0	1	2	3	4
b.	Getting on with siblings (Answer 'Not at All' if you have only one child)	0	1	2	3	4
c.	Being with friends outside of school	0	1	2	3	4
d.	Performance in the classroom	0	1	2	3	4
e.	Interacting with peers at recess and lunch	0	1	2	3	4
f.	Playing sport	0	1	2	3	4
g.	Doing enjoyable activities like going to parties, movies or holidays	0	1	2	3	4
h.	Daily activities (eg sleeping, going to school, homework, playing)	0	1	2	3	4
3.	**How much do your child's fears and worries interfere with your everyday life in the following areas**	**Not at all**	**Only a little**	**Some times**	**Quite a lot**	**A great deal**
a.	Your relationship with your partner or a potential partner	0	1	2	3	4
b.	Your relationship with extended family	0	1	2	3	4
c.	Your relationship with friends	0	1	2	3	4
d.	Your career (choice to work, how many hours you do or how often you miss work)	0	1	2	3	4
e.	Your ability to go out to activities/events without your child	0	1	2	3	4
f.	Your ability to go out to activities/events with your child	0	1	2	3	4
g.	Your level of stress	0	1	2	3	4

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Original Publication: Lyneham, Sburlati, Abbott, Rapee, Hudson, Tolin & Carlson (2013)

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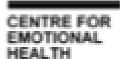
Appendix K: Child Anxiety Life Interference Scale (CALIS Child Version)



Child Anxiety Life Interference Scale (CALIS Child Version)

Child's name:	**Date:**

1. Do fears and worries upset or distress you?

Not at all	Only a little	Sometimes	Quite a lot	A great deal
0	1	2	3	4

2. How much do fears and worries make it difficult for you to do the following things?

		Not at all	**Only a little**	**Some times**	**Quite a lot**	**A great deal**
a.	Getting on with parents	0	1	2	3	4
b.	Getting on with brothers and sisters (Answer 'Not at All' if you are an only child)	0	1	2	3	4
c.	Being with friends outside of school	0	1	2	3	4
d.	Getting your schoolwork done	0	1	2	3	4
e.	Being with class mates at recess and lunch	0	1	2	3	4
f.	Playing sport	0	1	2	3	4
g.	Doing enjoyable activities like going to parties, movies or holidays	0	1	2	3	4
h.	Daily activities such as getting ready for school, homework, playing and going to sleep	0	1	2	3	4

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Appendix L: Child Anxiety Interference Scale Preschool Version (CALIS-PV) Form

Child Anxiety Life Interference Scale - Preschool Version (CALIS-PV)
Scoring

These statistics were determined using a sample of 784 parents of a child aged 3-7 yrs, who were enrolled in an anxiety prevention trial for temperamentally inhibited preschool children. Further details are available in:

> Gilbertson T., Morgan, A. J., Rapee, R. M., Lyneham, H. J., & Bayer, J. K. (2017). Psychometric properties of the Child Anxiety Life Interference Scale – Preschool Version. *Journal of Anxiety Disorders, 52*, 62–71. doi.org/10.1016/j.janxdis.2017.10.002

IMPORTANT NOTE: Psychometric analyses and mean scores are based on parent reports of children with temperamental inhibition. Forty-eight percent of these children were assessed as having an anxiety disorder. Community norms have yet to be established for the CALIS-PV. The scale is not designed for determining if a child meets criteria for a disorder. It's most appropriate use is in tracking treatment change.

Scoring

For all questions the responses are scored as follows:

Not at all	Only a little	Sometimes	Quite a lot	A great deal
0	1	2	3	4

For each subscale add scores for the appropriate items to get subscale scores.

Data summary for preschool children with temperamental inhibition

Subscale	Items	Score Range	No Anxiety Diagnosis Mean (SD)	Anxiety Diagnosis Mean (SD)
Child At Home	1, 2a, 2b, 2i, 2j	0–20	3.2 (2.8)	6.4 (4.0)
Child Outside Home	2c, 2d, 2e, 2f, 2g, 2h	0–24	7.4 (4.1)	12.1 (5.1)
Parent Life	3a, 3b, 3c, 3d, 3e, 3f, 3g	0–28	4.1 (4.5)	9.0 (6.5)
Total Score	All items	0–72	14.7 (9.9)	27.5 (13.4)

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Original Publication: Kennedy, Rapee, Edwards (2009)

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Appendix M: Behaviour Tracking Diary (BTD)

Behaviour Tracking Diary

Child Participant ID:
Completed by: Mother /Father/Guardian
Start date:
Finish date:
Anxiety provoking situation/s (e.g. needing to get ready for school):
Anxiety related behaviour (e.g. refusing to get out of bed)

	How many times did the anxiety provoking situation/s arise?	How many times did the anxiety related behaviour occur?	How severe was the anxiety related behaviour (on a scale of 1-10, with 10 being as worst it's ever been)?	What anxiety reducing strategies were used and how often?
Week 1				
Week 2				
Week 3				
Week 4				
Week 5				
Week 6				
Week 7				
Week 8				

Appendix N: Outcome Rating Scale (ORS)

Outcome Rating Scale (ORS)

Name ________________________ Age (Yrs):____ Gender_____________
Session # _____ Date: ________________________
Who is filling out this form? Please check one: Self_______ Other_______
If other, what is your relationship to this person? ____________________________

Looking back over the last week, including today, help us understand how you have been feeling by rating how well you have been doing in the following areas of your life, where marks to the left represent low levels and marks to the right indicate high levels. *If you are filling out this form for another person, please fill out according to how you think he or she is doing.*

ATTENTION CLINICIAN: TO INSURE SCORING ACCURACY PRINT OUT THE MEASURE TO INSURE THE ITEM LINES ARE 10 CM IN LENGTH. ALTER THE FORM UNTIL THE LINES PRINT THE CORRECT LENGTH. THEN ERASE THIS MESSAGE.

Individually
(Personal well-being)

I--I

Interpersonally
(Family, close relationships)

I--I

Socially
(Work, school, friendships)

I--I

Overall
(General sense of well-being)

I--I

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Appendix O: Child Outcome Rating Scale (CORS)

Child Outcome Rating Scale (CORS)

Name ________________________Age (Yrs):____
Gender:_________
Session # ____ Date: ________________________
Who is filling out this form? Please check one: Child_______ Caretaker_______
If caretaker, what is your relationship to this child? ____________________________

How are you doing? How are things going in your life? Please make a mark on the scale to let us know. The closer to the smiley face, the better things are. The closer to the frowny face, things are not so good. *If you are a caretaker filling out this form, please fill out according to how you think the child is doing*.

Me
(How am I doing?)

I---I

Family
(How are things in my family?)

I---I

School
(How am I doing at school?)

I---I

Everything
(How is everything going?)

I---I

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Appendix P: Child Outcome Rating Scale (YCORS)

Young Child Outcome Rating Scale (YCORS)

Name ______________________Age (Yrs):____
Gender:________________________
Session # ____ Date:______________________

Choose one of the faces that shows how things are going for you. Or, you can draw one below that is just right for you.

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Appendix Q: Session Rating Scale (SRS)

Session Rating Scale (SRS V.3.0)

Name ________________________ Age (Yrs):____
ID# ________________________ Gender:_______
Session # ____ Date: ________________________

Please rate today's session by placing a mark on the line nearest to the description that best fits your experience.

Relationship

I did not feel heard, understood, and respected.	I---I	I felt heard, understood, and respected.

Goals and Topics

We did *not* work on or talk about what I wanted to work on and talk about.	I---I	We worked on and talked about what I wanted to work on and talk about.

Approach or Method

The therapist's approach is not a good fit for me.	I---I	The therapist's approach is a good fit for me.

Overall

There was something missing in the session today.	I---I	Overall, today's session was right for me.

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Appendix R: Child Session Rating Scale (CSRS)

Child Session Rating Scale (CSRS)

Name ______________________Age (Yrs):____
Gender:_______________
Session # ____ Date:______________________

How was our time together today? Please put a mark on the lines below to let us know how you feel.

Listening

did not always listen to me. I---I listened to me.

How Important

What we did and talked about was not really that important to me. I---I What we did and talked about were important to me.

What We Did

I did not like what we did today. I---I I liked what we did today.

Overall

I wish we could do something different. I---I I hope we do the same kind of things next time.

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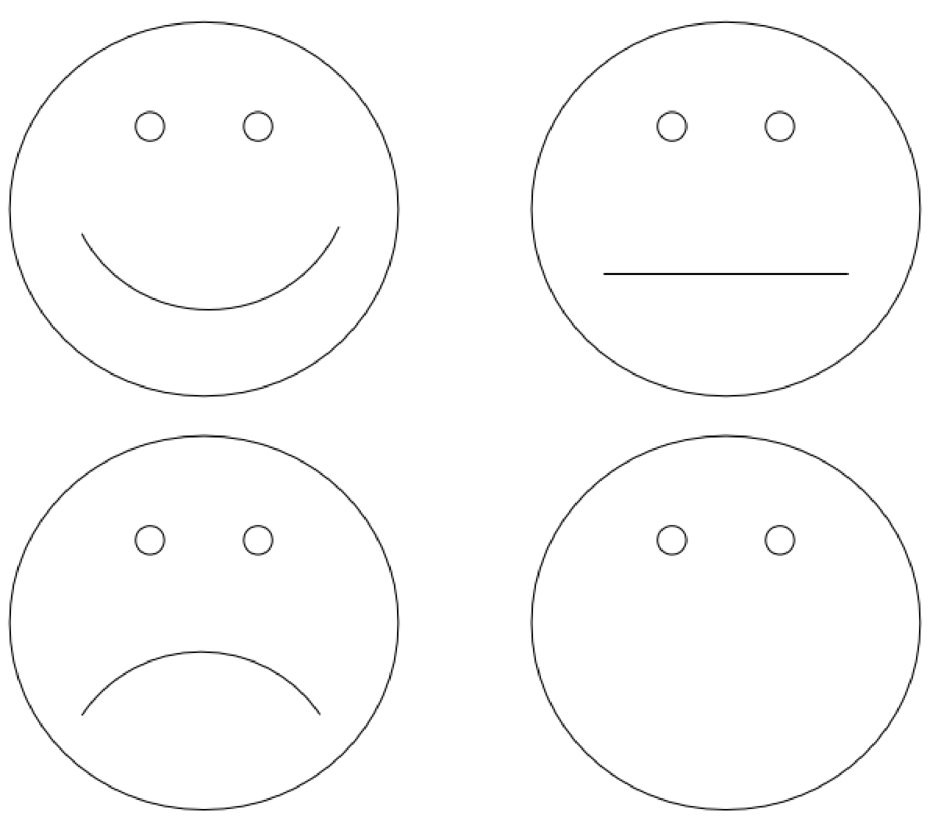
Appendix S: Young Child Session Rating Scale (YCSRS)

Young Child Session Rating Scale (YCSRS)

Name ______________________Age (Yrs):____
Gender:__________________
Session # ____ Date:______________________

Choose one of the faces that shows how it was for you to be here today. Or, you can draw one below that is just right for you.



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Appendix T: Parent Satisfaction Questionnaire (PSQ)

Parent Satisfaction Questionnaire

CBT- sensory modulation intervention for anxiety

What is the evaluation about?

This evaluation is about your overall experience with the 6-week CBT-Sensory modulation programme that you and your child participated in. Your feedback is much appreciated, it is important for us to know how you found the intervention. Your feedback will be used to make adjustments to the programme and improve it.

Completing the questionnaire

You will be asked several questions relating to the 6 therapy sessions that you attended. For each question please respond as required. We are interested in your perspective, so please feel free to answer honestly.

Participant ID: _

Was this your first involvement in an intervention like this? Circle your response.

Yes No

If no, what other interventions have you and/or your child engaged in?:

____

____

____

Overall programme:

How did you find the programme as a whole?

Please tick the box that matches your response.

	Very poor	Poor	Good	Very good	Excellent
The overall programme					
Content					
Presentation					
Knowledge of the therapist					

Please comment on your experience of the programme overall :

To what extent did you achieve the outcomes that you anticipated after attending this programme?

Circle a number that strongly represents your response.

Fully achieved					Moderately achieved					Not achieved at all
10	9	8	7	6	5	4	3	2	1	0

Please comment on the specific impact the programme has had on you and your child:

Acceptability

1. Based on your overall experience, did you find the intervention acceptable for you and your child? (Consider the programme content and therapist's facilitation from a cultural perspective and in relation to the age, gender and interests of your child)

Please circle your response: Yes No

Please explain your response.

2. Would you recommend this intervention for other children with anxiety?

Circle your response. Yes No

Practicality

1. Based on your experience of attending the therapy sessions, please give feedback about the following:

a) What are your thoughts about the length of the sessions (90mins)

b) Were 6 sessions enough to meet your needs?

c) Were there any barriers to getting to and attending the weekly sessions?

d) How did you find the time commitment and practicality of applying the strategies at home and/or school?

Therapy sessions

Please comment on the value of each of the sessions below.

Session 1

Session one helped you to familiarise with the overall programme and also focussed on information about identifying causes of anxiety.

How valuable did you find the first session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Session 2

Session two introduced the concept of appropriate cognitive behavioural therapy techniques for children, including making connections between worries and body feelings.

How valuable did you find the second session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Session 3

Session three continued to emphasise and strengthen learnings from session 2.

How valuable did you find the third session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Session 4

Session four introduced the concept of sensory modulation including some helpful calm down techniques.

How valuable did you find the fourth session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Session 5

Session five covered information on sensory diets and strategies to embed sensory strategies into daily routines.

How valuable did you find the fifth session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Session 6

Session six was a consolidation and celebration session. It discussed all the learnings from session 1 to session 5 and celebrated the successes achieved by you and your child.

How valuable did you find the sixth session?

Please tick the box that represents your response.

Not valuable at all ☐ Somewhat valuable ☐ Valuable ☐ Very valuable ☐

Please comment on what was most useful and any changes you would recommend:

Thank you for your participation.

Appendix U: Therapist Satisfaction Questionnaire (TSQ)

CBT- sensory modulation intervention for anxiety

Therapist satisfaction questionnaire

About the survey.

Thank you for participating in the delivery of the CBT-sensory modulation intervention for anxiety. We would like to get some feedback about the different aspects of the intervention and how you found it overall. Your feedback is important to us and will allow the researcher to make improvements to the intervention, the intervention manual and its delivery.

Overall satisfaction

1. Overall, how satisfied were you with the CBT-sensory modulation intervention for anxiety with children?

Please tick the box that represents your response.

1	2	3	4	5
Strongly dissatisfied	Moderately dissatisfied	Indifferent	Moderately satisfied	Strongly satisfied

2. I will be happy to use the CBT–sensory modulation intervention with my future clients.

Yes ☐ No ☐

Please explain your response.

3. Would you recommend this intervention to other mental health professionals as a helpful intervention?

Yes ☐ No ☐

Please explain your response.

4. If you were given an opportunity to improve this intervention, what would you do differently?

The treatment

1. The structure of the content was logical and was easy to follow.
2. The treatment manual as easy to use and easy to read.
3. It was easy to adhere to the treatment manual in all the sessions.

Number of sessions and duration

1. The number of sessions were adequate to cover all the material in the intervention manual.

1	4	5	6	10
Strongly disagree	Moderately disagree	Indifferent	Moderately agree	Strongly agree

Content

1. The content was appropriate for young children and was easy to understand for the therapist.

1	4	5	6	10
Strongly disagree	Moderately disagree	Indifferent	Moderately agree	Strongly agree

The intervention and the intervention manual

1. The intervention manual was clear and easy to follow.

1	4	5	6	10
Strongly disagree	Moderately disagree	Indifferent	Moderately agree	Strongly agree

2. The intervention was easy to deliver.

1	4	5	6	10
Strongly disagree	Moderately disagree	Indifferent	Moderately agree	Strongly agree

3. What things went well during the delivery of the intervention?

4. What things did not go well during the delivery of the intervention?

Acceptability

Would you consider this intervention as an acceptable intervention for children with anxiety.

Yes ☐ No ☐

Please explain your response.

Practicality

Based on your experience of delivering this intervention, do you think it is practical to deliver this intervention in current New Zealand mental health service settings (in relation to time, resources and clinicians' skills & knowledge)?

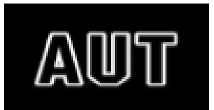
Yes ☐ No ☐

Please explain your response.

Additional comments.

Thank you for taking time to complete this questionnaire.

Appendix V: Therapist Participant Information Sheet and Consent Form



Therapist Participant Information Sheet and Consent Form

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.
Study Site: Birthright Hawkes Bay Child & Family Care Trust.
Contact phone number: 021 756 400.
Ethics committee ref.: 20/NTA/165.

You are invited to take part in a study testing the effectiveness of a CBT-Sensory modulation intervention for reducing anxiety in children. The study is being completed as a project for the attainment of a Doctor of Health Sciences qualification.

This Therapist Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. I will go through this information with you and answer any questions you may have. You do not have to decide today whether or not to participate in the study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or the Hawkes Bay DHB/ Birthright Hawkes Bay Child & Family Care Trust management. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Therapist Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect your employment with Birthright Hawkes Bay Child & Family Care Trust. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

The study is a requirement for the attainment of a Doctor of Health Sciences degree at Auckland University of Technology where the lead researcher is a student.

The purpose of this study is to evaluate a 6-week intervention to reduce anxiety in young children aged 4-7 years old. The intervention combines strategies from Cognitive Behavioural Therapy (or CBT) and sensory modulation. CBT is a talking-based therapy, which helps people explore and manage unhelpful thoughts in order to reduce distressing emotions or problematic behaviours or anxiety. Sensory modulation is a clinical intervention that uses our senses such as touch, movement, smells and sounds to help people regulate their emotions.

The study aims to understand if this intervention:

(a) Can reduce anxiety in young children presenting with anxiety.
(b) Helps improve young children's functioning and quality of life.
(c) Is acceptable and practical for children and their parents.
(d) Is acceptable and practical for the therapists delivering the intervention.

The study will include children with anxiety as the main presenting problem which may present in isolation or with other disorders such as Attention Deficit Hyperactivity Disorder (ADHD).

HOW IS THE STUDY DESIGNED?

We are looking for 8 children and their parent(s)/guardian(s) to participate in 6 sessions of therapy with a trained therapist. Potential candidates will be seen by a clinical psychologist and their medical file will be reviewed to confirm their diagnosis. Children or parents/guardian(s) who decline participation in the study will receive standard treatment for anxiety offered at Birthright Hawkes Bay Child & Family Care Trust.

The study intervention will be delivered by therapists using a treatment manual. The treatment manual was developed by the lead researcher and has been based on evidence-based practices. The therapists will be trained in how to deliver the intervention as recommended in the manual.

The intervention

The intervention uses principles of cognitive behaviour therapy (CBT) and sensory modulation. The intervention will be delivered to the child and their parent(s)/guardians over a 6-week period (one session per week). The 6 sessions are as follows.

The first session introduces the intervention to the child and the parent(s)/guardian(s). The session aims to improve the parents/guardians understanding of anxiety, how anxiety affects children's function, how anxiety affects family life and strategies that are helpful to manage anxiety.

The second session teaches the child how to identify signs of anxiety in themselves. It also teaches the parents/guardians how to notice the physical signs and behaviours of anxiety in their child.

The third session is a continuation of session two and focusses on making the connections between anxious (unhelpful) thoughts and what they feel in their body. Session one to three are based on cognitive behaviour therapy.

Session four teaches the child relaxation techniques using sensory based strategies (for example listening to music, getting a hand massage, doing a physical activity, deep breathing exercises, using different smells for relaxation etc). Parents/guardians will be encouraged to identify activities that calm down their child when they are worried. The child and the parent/guardian will be taught how to use these activities in times of distress to help the child to calm down and relax.

Session five teaches the child and the parents'/guardians ways of ensuring that the calming activities are practiced every day and become part of the child's daily routine.

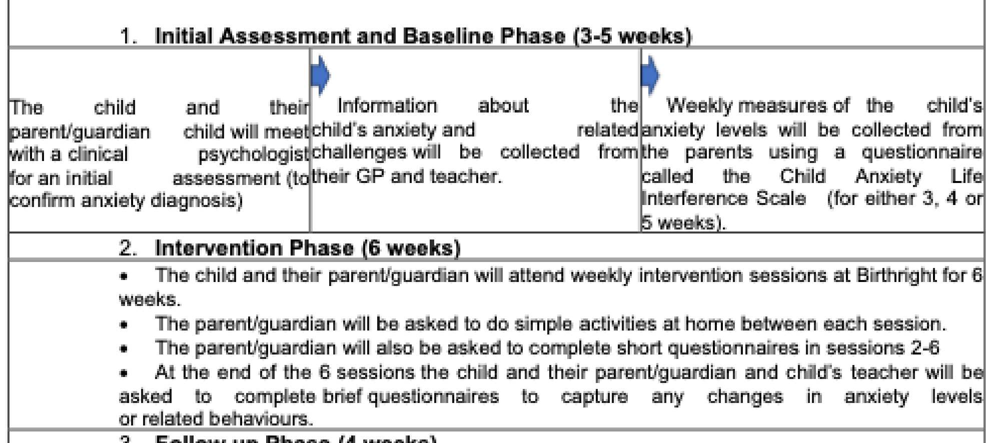
Session six is a consolidation and celebration session. This session summarises all the materials covered from session one to session six and encourages the child and the family to continue using the skills taught. Every session comes with a home task that the child and parent/guardian will have to complete at home. The home task will be reviewed at the beginning of every new session. Each session will be evaluated using outcome scales to make sure that the treatment is progressing as intended.

The intervention sessions will be recorded using audio equipment as part of a fidelity evaluation. An independent person and the lead researcher will listen to random sessions to check if the therapist delivered the intervention as described in the manual.

The study design

There are three phases in the study (see table below) and several methods will be used to collect data including administration of questionnaires and recording of functional improvements, as observed by the child's parents/guardians and teacher.

Before the intervention starts there will be a baseline period, when the lead researcher will assess the child's levels of anxiety over time. The child will be assigned to one of three baseline conditions: 3-week baseline period, 4-week baseline period or 5-week baseline period.



1. **Initial Assessment and Baseline Phase (3-5 weeks)**		
The child and their parent/guardian child will meet with a clinical psychologist for an initial assessment (to confirm anxiety diagnosis)	Information about the child's anxiety and related challenges will be collected from their GP and teacher.	Weekly measures of the child's anxiety levels will be collected from the parents using a questionnaire called the Child Anxiety Life Interference Scale (for either 3, 4 or 5 weeks).
2. **Intervention Phase (6 weeks)**		
• The child and their parent/guardian will attend weekly intervention sessions at Birthright for 6 weeks. • The parent/guardian will be asked to do simple activities at home between each session. • The parent/guardian will also be asked to complete short questionnaires in sessions 2-6 • At the end of the 6 sessions the child and their parent/guardian and child's teacher will be asked to complete brief questionnaires to capture any changes in anxiety levels or related behaviours.		
3. **Follow up Phase (4 weeks)**		
• The parent/guardian will be asked to keep using the strategies learned in the intervention at home. • The parent/guardian will also be asked to complete questionnaires 1 month after the intervention has ended.		

Standard treatment

If parents/guardians decide not to participate in this study, their child will be offered standard treatment at Birthright Hawkes Bay Child and Family Care Trust. Standard treatment for children with anxiety involves a number of options, typically involving talking-based therapies. The approach used and number of sessions provided will depend on the needs of the child.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your participation in the study will involve you delivering the 6-session manualised intervention to four children and their families. The parent/guardian has consented, and the child has assented to participate in the study. You will deliver this intervention individually to each child and their parent(s)/guardian(s). Before the study begins, you will be taught how to deliver the intervention by the lead researcher. The study is expected to run for twelve months.

During the study, you will be expected to deliver a 6-session intervention as per the intervention manual. You will administer several forms during each session as described in the intervention manual. At the end of the study, you will complete a therapist satisfaction survey. The survey is for you to share your thoughts about the interventions' acceptability and practicality. All interventions sessions will be recorded using audio equipment. Random recorded sessions will be selected and analysed by an independent person and the lead researcher to test for fidelity and treatment adherence.

You would see these children as part of your normal caseload that is allocated to you at Birthright Hawkes Bay Child & Family Care Trust. You would be expected to complete all other documentation (clinical notes, outcome measures, Multi-Disciplinary Team discussions) as you normally do and as per your service requirements.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

This intervention may have benefits for the therapist, parent(s)/guardians and the children involved. The children will learn ways to reduce their anxiety in stressful situations and in everyday life. These skills can continue to be practiced after the study and can improve through regular use. Parents/Guardians will be taught skills and strategies on how to support their children to be more resilient. The therapists will learn a new approach to use with younger children presenting with anxiety.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study has a very low level of risk to you. The low risk is that it cannot be guaranteed with complete certainty that someone (excluding the parents/guardians and the child who already know you) may not end up having access to your identifiable information despite all efforts to prevent that from happening, as outlined below. There is also a very small chance that the child may become dysregulated and aggressive towards you during therapy. Like any therapeutic relationship, parents/guardians may also complain about your approach, your comments or how you interact with them which may cause conflict.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

Identifiable Information.

Identifiable information is any data that could identify you (e.g., your name). Only researchers, parents/guardians and the child will know your name your name. Randomly selected audio -recorded sessions will be accessed by an independent third party as part of a fidelity test.

De-identified (Coded) Information.

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

Your coded and identifiable information including consent forms and post-analysis data will be held at a secure archiving site at Auckland University of Technology and stored for at least 10 years after the youngest child in the study turns 16, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy (except from the parents/guardians and the child who already know you), absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information and correct information.

You have the right to request access to your information held by the research team. You also have the right to ask for inaccurate information about you or your feedback to be corrected.

If you have any questions about the collection and use of information from you, you should ask the researcher.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing me.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

What happens after the study or if I change my mind?

If you change your mind during the study and no longer wish to participate, you will be free to pull out of the study at any time. The information collected about the intervention up to the point when you withdraw will continue to be processed.

Can I find out the results of the study?

You may request a copy of the study results, which will be available within 1 year from the end of the study. All of your data will be kept private and confidential, and you won't be personally identified in any of the study results.

Who is Funding the study?

This study is being completed as part of doctoral training by the lead researcher. The lead researcher is a student at Auckland University of Technology. The study is funded by a small grant that doctoral students get from the university. Additionally, the researcher has also been awarded some funding from the Hawkes Bay Medical Research Foundation towards the research. Other costs will be met by the lead researcher.

Who Has Approved the study?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A HDEC has approved this study.

Who do I contact for more information or if I have concerns?

If you have any questions or require any further information, please contact:

Tafadzwa Mavhunga
Phone: 021 756 400
E-mail: tafadzwamavhunga@yahoo.co.uk

If you want to contact someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hrc.org.nz

If you wish to receive Māori support, please inform the lead researcher and he will arrange Laurie Te Nahu from Maori Health Services at Hawkes Bay DHB to provide this support. You can also contact Maori Health Services directly and ask to speak to Laurie. You can call Maori Health Services on:

Phone 06 878 8109 ext. 5779 or
06 878 1654 or
0800 333 671 or
call Laurie directly on 027 704 9665 or
Email laurie.TeNahu@hbdhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@health.govt.nz

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.
Study Site: Birthright Hawkes Bay Child & Family Care Trust.
Contact phone number: 021 756 400.
Ethics committee ref.: 20/NTA/165.

Consent Form

If you would like to provide consent verbally instead of in writing and/or have the form read to you aloud, please let us know.

For each item below, please tick in the "Yes" or "No" box beside the text to indicate you consent to the following. For some statements just tick in the box besides the statement to indicate that you agree with the statement.

I have read (or have had read to me) the Therapist Participant Information Sheet and I understand the information presented.		☐
I have been given sufficient time to consider whether or not to participate in this study.		☐
I have had the opportunity to use a legal representative, whānau/family support, Hawkes Bay DHB/ Birthright Hawkes Bay Child & Family Care Trust management or a friend to help me ask questions and understand the study.		☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this therapist consent form and therapist participant information sheet.		☐
I understand that taking part in this study is **voluntary** (my choice) and that I may withdraw from the study at any time without this affecting my employment with Birthright Hawkes Bay Child & Family Care Trust.		☐
I consent to the research staff processing information that I will gather for the study.		☐
If I decide to withdraw from the study, I agree that the information collected about the intervention up to the point when I withdraw may continue to be processed.		☐
I understand that my participation in this study is confidential and that no material, which could identify me personally will be used in any reports on this study.		☐
I know who to contact if I have any questions about the study in general.		☐
I understand my responsibilities as a study participant.		☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I give consent to participate in the study.		☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by a member of the research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Lead researcher 's name:

Signature: Date:

Appendix W: Study Flyer

RESEARCH PARTICIPANTS WANTED

for a study on CBT, sensory modulation and anxiety

We are looking for 8 children aged between 4 and 7 who experience anxiety to participate in a **free 6-week intervention of Cognitive Behavioural Therapy (CBT) and sensory modulation**. The children will participate in the intervention with at least one parent.

CBT is a talking-based therapy, which helps people explore and manage unhelpful thoughts in order to reduce distressing emotions or problematic behaviours. Sensory modulation is a clinical intervention that uses sensory-based strategies such as touch, movement, smells and sounds to help people regulate their emotions.

You and your child will receive **6 intervention sessions** delivered by a therapist at Birthright. The sessions will be between 60 and 90 minutes long. You and your child will learn strategies to help reduce your child's anxiety and improve their wellbeing.

The intervention is offered as part of a doctoral research project and there may be not clear benefits to participation.

If you are interested in participating or want to learn more, contact Tafadzwa Mavhunga.

CALL OR TEXT or WhatsApp on 021 756 400

Appendix X: Teacher Participation Information Sheet and Consent Form

Teacher Participant Information Sheet

Title of study: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Lead Researcher: Tafadzwa Mavhunga, Senior Occupational Therapist, Child, Adolescent & Family Service, Hawke's Bay District Health Board.
Study Site: Birthright Hawkes Bay Child & Family Care Trust.
Contact phone number: 021 756 400.
Ethics committee ref.: 20/NTA/165.

My name is Tafadzwa Mavhunga, and I the am lead researcher in a study to test the effectiveness of a CBT-Sensory modulation intervention for reducing anxiety in children. The study is being completed as a project for the attainment of a Doctor of Health Sciences qualification. I am sending you this information because you are a teacher of a child that was recently referred to Birthright Hawkes Bay Child & Family Care Trust for assessment and management of anxiety. The child and his or her parents/guardians have agreed to participate in the study.

This Teacher Participant Information Sheet will help you decide if you'd like to take part in the study. It sets out why we are doing the research, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information, and I can answer any questions you may have. You do not have to decide whether or not you will participate today. Before you decide you may want to talk about the study with other people, such as colleagues, your Principal or Birthright Hawkes Bay Child & Family Care Trust management. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Teacher Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate a 6-week intervention to reduce anxiety in young children aged 4-7 years old as a project for a Doctor of Health Sciences training. The intervention combines strategies from Cognitive Behavioural Therapy (or CBT) and sensory modulation. CBT is a talking-based therapy, which helps people explore and manage unhelpful thoughts in order to reduce distressing emotions or problematic behaviours or anxiety. Sensory modulation is a clinical intervention that uses our senses such as touch, movement, smells and sounds to help people regulate their emotions.

The study aims to understand if this intervention.

(a) Can reduce anxiety in young children presenting with anxiety.
(b) Helps improve young children's functioning and quality of life.
(c) Is acceptable and practical for children and their parents/guardians.
(d) Is acceptable and practical for the therapists delivering the intervention.

How is the study designed?

We are recruiting 8 children and their parent(s) to participate in 6 sessions of therapy with a trained therapist. Participants will be selected from children who will have been referred to Birthright Hawkes Bay Child & Family Care Trust for assessment and management of anxiety. Potential candidates will attend 6 sessions of therapy once a week.

Several methods will be used to collect data in this study including completion of questionnaires by parents/guardians, the child and the teacher.

What will my participation in the study involve?

Your participation in the study will involve you completing two assessment forms (the Teacher Report Form (TRF) and the School Anxiety Scale Teacher Report (SAS TR). These will be completed in relation to the child that you teach, who has been referred to Birthright Hawkes Bay Child & Family Care Trust. These two forms are used to assess the child's anxiety levels and how they generally present. Both forms take about 25 minutes to complete in total.

You will complete these two forms three times as follows:

1. When the child enters the study (at the beginning of the study before the intervention begins)
2. After 6 weeks of the child receiving the intervention (at completion of the intervention).
3. 1-month post-intervention

The child and the family have already agreed to participate in the study. The parent/guardian has consented, and the child has assented for you to complete the surveys about the child for the purpose of the research. Collecting collateral information from the school about a child by Birthright Hawkes Bay Child & Family Care Trust is usual practice. Gathering this information helps the service to have another perspective of how the child presents in other settings. You may have been asked to complete similar forms in the past. The child's parents/guardians, the child, the school and the social workers (therapists) will be aware of your participation.

What are the possible benefits of this study?

This intervention may have benefits for the therapist, parent(s) and the children involved. The children will learn ways to reduce their anxiety in stressful situations and in everyday life. These skills can continue to be practiced after the study and can improve through regular use. Parents/guardians will be taught skills and strategies on how to support their children to be more resilient. The therapists will learn a new approach to use with younger children presenting with anxiety.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study has a very low level of risk to you. The low risk is that it cannot be guaranteed with complete certainty that someone (excluding the parents/guardians and the child who already know you) may not end up having access to your identifiable information despite all efforts to prevent that from happening, as outlined below. There is also a risk that the parents/guardians may request to see your responses and may not agree with your responses on the questionnaires about their child which may cause conflict between you and the parent/guardian.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind during the study and no longer wish to participate, you will be free to pull out of the study at any time. The information collected about the intervention up to the point when you withdraw will continue to be processed.

WHAT WILL HAPPEN TO MY INFORMATION?

Identifiable Information.

Identifiable information is any data that could identify you (e.g. your name). Only researchers, parents/guardians and the child have access to your identifiable information particularly your name since they already know you.

De-identified (Coded) Information.

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

Your coded and identifiable information including consent forms and post analysis data will be held at a secure archiving site at Auckland University of Technology and stored for at least 10 years after the youngest child in the study turns 16, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy (except from the parents/guardians and the child who already know you), absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information and correct information.

You have the right to request access to your information held by the research team. You also have the right to ask for inaccurate information about you or your feedback to be corrected.

If you have any questions about the collection and use of information from you, you should ask the researcher.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time by informing me.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You may request a copy of the study results, which will be available within 1 year from the end of the study. All of your data will be kept private and confidential, and you won't be personally identified in any of the study results.

WHO FUNDING THE STUDY?

This study is being completed as part of a doctoral training by the lead researcher. The lead researcher is a student at Auckland University of Technology. The study is funded by a small grant that doctoral students get from the university. Additionally, the researcher has also been awarded some funding from the Hawkes Bay Medical Research Foundation towards the research. Other costs will be met by the lead researcher.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A HDEC has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions or require any further information, please contact:

Tafadzwa Mavhunga
Phone: 021 756 400
E-mail: tafadzwamavhunga@yahoo.co.uk

If you want to contact someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hrc.org.nz

If you wish to receive Māori support, please inform the lead researcher and he will arrange Laurie Te Nahu from Maori Health Services at Hawkes Bay DHB to provide this support. You can also contact Maori Health Services directly and ask to speak to Laurie. You can call Maori Health Services on:

Phone 06 878 8109 ext. 5779 or
06 878 1654 or
0800 333 671 or
call Laurie directly on 027 704 9665 or
Email laurie.TeNahu@hbdhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@health.govt.nz

Study Title: An evaluation of a CBT-sensory modulation intervention for children with anxiety.
Locality: Birthright Hawkes Bay Child & Family Care Trust.
Lead researcher: Tafadzwa Mavhunga
Ethics committee ref. (HDEC): 20/NTA/165
Contact phone number: 021 756 400

Consent Form

If you would like to provide consent verbally instead of in writing and/or have the form read to you aloud, please let us know.

For each item below, please tick in the "Yes" or "No" box beside the text to indicate you consent to the following. For some statements just tick in the box besides the statement to indicate that you agree with the statement.

I have read (or have had read to me) the Teacher Participant Information. Sheet and I understand the information presented.		☐
I have been given sufficient time to consider whether or not to participate in this study.		☐
I have had the opportunity to use a legal representative, whānau/family support, Hawkes Bay DHB/Birthright Hawkes Bay Child & Family Care Trust management, school principal or a friend to help me ask questions and understand the study.		☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and Teacher Participant Information Sheet.		☐
I understand that taking part in this study is **voluntary** (my choice) and that I may withdraw from the study at any time without this affecting my relationship with the Child, Adolescent and Family Service and/or Birthright Hawkes Bay Child & Family Care Trust.		☐
I consent to the research staff processing information that I will provide for the study.		☐
If I decide to withdraw from the study, I agree that the information collected about the intervention up to the point when I withdraw may continue to be processed.		☐
I understand that my participation in this study is confidential and that no material, which could identify me personally will be used in any reports on this study.		☐
I know who to contact if I have any questions about the study in general.		☐
I understand my responsibilities as a study participant.		☐
I give consent to participate in the study.		☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: ____

Signature: _______________________ Date: ____________________

Declaration by a member of the research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Lead researcher's name: ____

Signature: _______________________ Date: ____________________

Appendix Y: Therapist Fidelity and Adherence Form

Intervention Fidelity & Adherence Form for Ngā Tīmatanga Toa intervention programme for anxiety disorders in children aged 4-7 years old.

This form is designed to assess how well the therapist delivers the 6-session intervention as intended in the manual. The form covers specific CBT and sensory modulation components that should be covered by the therapist and assessed by the rater.

SCORING INSTRUCTIONS FOR THE RATER

Before listening to the audio sessions

Please familiarise yourself with the intervention manual. Read it thoroughly and ensure that you understand the session content including the home tasks. Pay particular attention to session goals and key content that need to be covered in each session.

Intervention fidelity and adherence will be assessed by checking whether the therapist has delivered the actual intervention process as described in the manual. This also assesses whether specific components have been covered and to what extent. This will be rated on a scale from 0-3. The scale is described as follows:

0-No adherence at all
1-Little adherence
2-Moderate adherence
3-Strong adherence

During scoring

Please have your Intervention Fidelity & Adherence Form, your intervention manual and audio playing equipment fully charged or plugged into a power supply. Ensure that you are in a quiet environment with no distractions. When listening and scoring, please feel free to pause the recording to take notes. Write your notes on the form. Also, feel free to rewind. Allow about 120 minutes to listen and score a session.

Session 1:

Session structure

This item assesses whether session 1 was delivered according to the session structure in the manual. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	The introduction of the session was covered.				
2.	The child was given an opportunity to choose a concluding activity.				
3.	The child and family were orientated to the programme.				
4.	The material covering the description of anxiety was covered.				
5.	The YouTube video on anxiety was watched with the parent and child.				
6.	The material covering the management of anxiety was covered.				
7.	Parental discussion with the family was completed.				
8.	The home task was given to the child and explained to the child and parent.				
9.	The handout on anxiety was given to the parent.				
10.	A concluding activity was done.				
11.	The session was covered within the allocated time of 60-90 minutes.				

- ⇒ *A score of **3** should be given if the material is delivered according to the manual session structure and the material is covered within the allocated time.*
- ⇒ *A score of **2** should be given if there is continuous adherence to most but not all of the session structure, and the material is covered within the allocated time.*
- ⇒ *A score of **1** should be given if the material is covered inconsistently, the session structure is not followed, and the session is not delivered within the time allocated.*
- ⇒ *A score of 0 should be given if the material was not delivered according to the session structure outlined in the manual.*

Session content

This item assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in was completed adequately and the home task for the parent and child was checked.				
2.	The outcome rating measures were administered with the child and parent adequately.				
3.	The intervention is described adequately and clearly to the parent and child (the vignette is used).				
4.	Cognitive Behaviour Therapy (CBT) principles are explained clearly as described in the manual.				
5.	Sensory modulation is adequately and clearly described to the child and parent using some examples described in the manual.				
6.	The IKICK plan is introduced and explained adequately to the child and the parent.				
7.	Anxiety is described to the child and parent clearly and adequately using developmentally appropriate language.				
8.	Home task is explained clearly and given to the parent and child.				

⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*

⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers six of these areas adequately and it is obvious that they did not explain two areas clearly and adequately.*

⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain CBT or sensory modulation or does not review homework adequately with the family.*

⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of 3 should be given if there is evidence that the therapist facilitated the session clearly and demonstrated* ***excellent*** *collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, and the therapist clarified questions the child and family had.*

⇒ *A score of 2 should be given if there is evidence that the therapist demonstrated* ***good/moderate*** *collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of 1 should be given if there is evidence that the therapist demonstrated* ***poor*** *collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of 0 should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 1 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{60}} \textbf{ X 100 = A\%}$$

Example:

Session structure =20, Content = 20, Collaboration = 3. Session total =43.

$$\frac{\text{Session total (43)}}{60} \text{ X } 100 = 71.6\%$$

Session 2:

Session structure

This item assesses whether session 2 was delivered according to the session structure. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in and recap of material from session 1 were covered.				
2.	The child's home task was reviewed.				
3.	The session rating scale and outcome rating scale were completed with the parent and the child.				
4.	The parent's home task material covering anxiety was reviewed.				
5.	The child was given an opportunity to choose a concluding activity.				
6.	The first "K" of the IKICK plan was introduced and explained.				
7.	The material on "knowing that I am anxious" was delivered.				
8.	The home task was given to the child and explained to the child and parent.				
9.	The handout on anxiety management was given to the parent.				
10.	A concluding activity was done.				
11.	The session was covered within the allocated time of 60-90 minutes.				

⇒ *A score of **3** should be given if the material is delivered according to the manual session structure and the material is covered within the allocated time.*

⇒ *A score of **2** should be given if there is continuous adherence with most but not of the session structure, and the material is covered within the allocated time.*

⇒ *A score of **1** should be given if the material is covered inconsistently, the session structure is not followed, and the session is not delivered within the time allocated.*

⇒ *A score of 0 should be given if the material was not delivered according to the session structure outlined in the manual.*

Session content

This item assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in was completed adequately and the home task for the parent and child was checked.				
2.	The outcome rating measures were administered with the child and parent adequately.				
3.	The anxiety information sheet was reviewed, and the therapist clarified any questions the parents had.				
4.	The first K of the IKICK plan is introduced and explained adequately to the child and parent.				
5.	The material on "knowing that I am anxious" was delivered adequately and clearly.				
6.	Different feelings are introduced and explained adequately to the child and the parent.				
7.	Parental discussion around normalising anxiety is delivered adequately and clearly. Parents are given a handout on the management of anxiety.				
8.	Home task is explained clearly and given to the parent and child.				

- ⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*
- ⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers six of these areas adequately and it is obvious that they did not explain two areas clearly and adequately.*
- ⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain the "K" of knowing that I am anxious or does not review homework adequately with the family.*
- ⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of **3** should be given if there is evidence that the therapist facilitated the session clearly and demonstrated **excellent** collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, the therapist clarified questions the child and family had.*

⇒ *A score of **2** should be given if there is evidence that the therapist demonstrated **good/moderate** collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of **1** should be given if there is evidence that the therapist demonstrated **poor** collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of **0** should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 2 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{60}} \textbf{ X 100 = A\%}$$

Example:

Session structure =23, Content = 23, Collaboration = 3. Session total =49.

$$\frac{\text{Session total (49)}}{60} \text{ X } 100 = 81.7\%$$

Session 3:

Session structure

This item assesses whether session 3 was delivered according to the session structure. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in and recap of material from session 2 were covered.				
2.	The child's home task was reviewed.				
3.	The session rating scale and outcome rating scale were completed with the parent and the child.				
4.	The parent's home task material covering the management of anxiety was reviewed.				
5.	The child was given an opportunity to choose a concluding activity.				
6.	The second "I" of the IKICK plan were introduced and explained.				
7.	The material on "making connections" was delivered.				
8.	The anxiety worksheets are covered.				
9.	The home task was given to the child and explained to the child and parent.				
10.	A concluding activity was done.				
11.	The session was covered within the allocated time of 60-90 minutes.				

⇒ *A score of **3** should be given if the material is delivered according to the manual session structure and the material is covered within the allocated time.*

⇒ *A score of **2** should be given if there is continuous adherence with most but not of the session structure, and the material is covered within the allocated time.*

⇒ *A score of **1** should be given if the material is covered inconsistently, the session structure is not followed, and the session is not delivered within the time allocated.*

⇒ *A score of 0 should be given if the material was not delivered according to the session structure outlined in the manual.*

Session content

This assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in was completed adequately and the home task for the parent and child was reviewed.				
2.	The outcome rating measures were administered with the child and parent adequately.				
3.	The "Feelings exercises worksheets" were administered adequately and the therapist clarified any questions the parents and the child had.				
4.	The second "I" of the IKICK plan is introduced and explained adequately to the child and parent.				
5.	The connections between emotions and body reactions were adequately explained.				
6.	The therapist explained the difference between helpful and unhelpful thoughts using the example given.				
7.	Parental discussion around the role of parents in the intervention is delivered adequately and clearly.				
8.	Home task is explained clearly and given to the parent and child.				

⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*

⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers six of these areas adequately and it is obvious that they did not explain two areas clearly and adequately.*

⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain helpful and unhelpful thoughts or the feeling exercises worksheets or does not review homework adequately with the family.*

⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of **3** should be given if there is evidence that the therapist facilitated the session clearly and demonstrated **excellent** collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, the therapist clarified questions the child and family had.*

⇒ *A score of **2** should be given if there is evidence that the therapist demonstrated **good/moderate** collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of **1** should be given if there is evidence that the therapist demonstrated **poor** collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of **0** should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 3 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{60}} \textbf{ X 100 = A\%}$$

Example:

Session structure =23, Content = 23, Collaboration = 3. Session total =49.

$$\frac{\text{Session total (49)}}{60} \text{ X } 100 = 81.7\%$$

Session 4:

Session structure

This item assesses whether session 4 was delivered according to the session structure. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in and recap material from session 3 was covered.				
2.	The child's home task was reviewed.				
3.	The session rating scale and outcome rating scale were completed with the parent and the child.				
4.	The child was given an opportunity to choose a concluding activity.				
5.	The "C" of the IKICK plan (calming down techniques) was introduced and explained.				
6.	The material on sensory modulation was delivered.				
7.	A sensory modulation plan was developed for a specific problem.				
8.	Breathing techniques are explained/taught and demonstrated to the child and parent.				
9.	The home task was given to the child and explained to the child and parent.				
10.	A concluding activity was done.				
11.	The session was covered within the allocated time of 90 minutes.				

- ⇒ *A score of **3** should be given if the material is delivered according to the manual session structure and the material is covered within the allocated time.*
- ⇒ *A score of **2** should be given if there is continuous adherence with most but not of the session structure, and the material is covered within the allocated time.*
- ⇒ *A score of **1** should be given if the material is covered inconsistently, the session structure is not followed, and the session is not delivered within the time allocated.*
- ⇒ *A score of 0 should be given if the material was not delivered according to the session structure outlined in the manual.*

Session content

This assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	The relationship between anxiety and body sensations is explained adequately (e.g., breathing fast, heart beating fast, shaking).				
2.	Behaviour problems that result from anxiety are explained to the parent.				
3.	Sensory modulation and calm-down techniques are presented clearly and adequately to the child and parent using examples and developmentally appropriate language.				
4.	A specific sensory modulation strategy is clearly developed for a specific problem.				
5.	Breathing techniques are adequately explained and demonstrated to the child and parent.				
6.	The "smell a rose and blow a candle" and "blowing bubbles" techniques to calm down are explained and demonstrated to the child and parent.				
7.	The therapist offers basic cognitive strategies to manage unhelpful thoughts using the example given.				
8.	Home task is explained clearly and given to the parent and child.				

⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*

⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers six of these areas adequately and it is obvious that they did not explain two areas clearly and adequately.*

⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain sensory modulation or does not review the "smell a rose and blow a candle" and "blowing bubbles" techniques adequately with the family.*

⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of **3** should be given if there is evidence that the therapist facilitated the session clearly and demonstrated **excellent** collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, the therapist clarified questions the child and family had.*

⇒ *A score of **2** should be given if there is evidence that the therapist demonstrated **good/moderate** collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of **1** should be given if there is evidence that the therapist demonstrated **poor** collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of **0** should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 4 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{60}} \textbf{ X 100 = A\%}$$

Example:

Session structure =20, Content = 20, Collaboration = 3. Session total =43.

$$\frac{\text{Session total (43)}}{60} \text{ X } 100 = 71.6\%$$

Session 5:

Session structure

This item assesses whether session 5 was delivered according to the session structure. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in and recap of material from session 4 were covered.				
2.	The child's home task was reviewed.				
3.	The session rating scale and outcome rating scale were completed with the parent and the child.				
4.	The child was given an opportunity to choose a concluding activity.				
5.	Material on sensory modulation modalities was presented.				
6.	Embedding sensory modulation in daily life was completed.				
7.	The home task was given to the child and explained to the child and parent.				
8.	A concluding activity was done.				
9.	The session was covered within the allocated time of 90 minutes.				

⇒ *A score of **3** should be given if the material is delivered according to the manual session structure and the material is covered within the allocated time.*

⇒ *A score of **2** should be given if there is continuous adherence with most but not of the session structure, and the material is covered within the allocated time.*

⇒ *A score of **1** should be given if the material is covered inconsistently, the session structure is not followed, and the session is not delivered within the time allocated.*

⇒ *A score of 0 should be given if the material was not delivered according to the session structure outlined in the manual.*

Session content

This assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	The child's home task was reviewed adequately, and the therapist answered any questions the child and parent had.				
2.	Different sensory modalities were explained adequately and clearly by the therapist using examples given.				
3.	The therapist explained how to embed sensory modulation techniques in daily routines using a sensory diet method.				
4.	Home task is explained adequately and clearly and is given to the parent and child.				

⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*

⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers three of these areas adequately and it is obvious that they did not explain one area clearly and adequately.*

⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain sensory modalities or does not review homework adequately with the family.*

⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of **3** should be given if there is evidence that the therapist facilitated the session clearly and demonstrated **excellent** collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, the therapist clarified questions the child and family had.*

⇒ *A score of **2** should be given if there is evidence that the therapist demonstrated **good/moderate** collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of **1** should be given if there is evidence that the therapist demonstrated **poor** collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of **0** should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 5 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{42}} \textbf{ X 100 = A\%}$$

Example:

Session structure =20, Session content = 10, Collaboration = 3. Session total =33.

$$\frac{\text{Session total (33)}}{42} \text{ X } 100 = 78.6\%$$

Session 6:

Session structure

This item assesses whether session 6 was delivered according to the session structure. The rater should compare the delivery of the session to the session outline. Whether the session was delivered within the time allocated and if the therapist used time efficiently is also assessed here. Under this item, the rater is not assessing content, they are only assessing whether the session structure was followed.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	Check-in and recap of material from session 5 were covered.				
2.	The child's home task was reviewed.				
3.	The session rating scale and outcome rating scale were completed with the parent and the child.				
4.	The child was given an opportunity to choose a concluding activity.				
5.	Material on anxiety and body connections was reviewed.				
6.	Material on calm-down strategies was reviewed.				
7.	The role of parents as coaches was covered.				
8.	Material on developing a crisis plan was covered.				
9.	Celebration.				
10.	A concluding activity was done.				
11.	The session was covered within the allocated time of 90 minutes.				

Session content

This assesses whether the therapist covered the key content of the session adequately as described in the manual. This item assesses the extent and depth to which the content was covered.

Adherence rating:

0-No adherence; 1-Little adherence; 2-Moderate adherence, 3-Strong adherence.

Number	Statement	0	1	2	3
1.	The child's home task was reviewed adequately, and the therapist answered any questions the child and parent had.				
2.	The therapist reviewed session 5 adequately and answered any questions the child and family had.				
3.	Key content from session 1 to session 5 is reviewed adequately and clearly. This includes explaining what anxiety is, management of anxiety, knowing that I am anxious, icky thoughts (unhelpful thoughts), the connection between anxiety and body connection, calm-down strategies (sensory modulation), embedding calm-down strategies n daily life and parental role.				
4.	The therapist develops a crisis intervention with the parent and the child and explains it clearly.				
5.	The therapist discussed the role of the parents clearly and answered any questions the parents had.				
6.	The idea of keep practising is explained to the family and the child.				

⇒ *A score of **3** should be given if **all** the key concepts are covered adequately and clearly as described in the manual.*

⇒ *A score of **2** should be given if **most** of the concepts are moderately covered but some of the concepts are not covered adequately or not explained clearly. For example, if the therapist covers four of these areas adequately and it is obvious that they did not explain two areas clearly and adequately.*

⇒ *A score of **1** is given if the therapist vaguely covers the material and not providing clear explanations. For example, the therapist struggles to explain CBT or sensory modulation or does not review homework adequately with the family.*

⇒ *A score of 0 should be given if these concepts are not covered at all.*

3. Collaboration

This item is scored based on whether there is evidence of collaboration and involvement of the child and the parent in the therapy session. Particular attention should be paid to the degree the therapists facilitate collaboration and the degree to which the parents and child are involved.

Rating:

0	1	2	3
No collaboration	Little collaboration	Moderate collaboration	Strong collaboration

⇒ *A score of **3** should be given if there is evidence that the therapist facilitated the session clearly and demonstrated **excellent** collaborative skills. Things to consider here are the therapist presented the material very clearly, the therapist engaged with the child and family positively and allowed them to ask questions, the therapist clarified questions the child and family had.*

⇒ *A score of **2** should be given if there is evidence that the therapist demonstrated **good/moderate** collaborative skills with the child and family. Mostly the therapist was able to engage with the family.*

⇒ *A score of **1** should be given if there is evidence that the therapist demonstrated **poor** collaborative skills with the child and parents. This includes talking to the parents and child, not clarifying any questions they have, not inviting them to be part of the discussion, not allowing them opportunities to ask any questions, and being cold.*

⇒ *A score of **0** should be given if there is no evidence of collaboration with the child and parents at all.*

Adherence score for session 6 is calculated as:

$$\frac{\textbf{Session score}}{\textbf{54}} \textbf{ X 100 = A\%}$$

Example:

Session structure =20, Session content = 20, Collaboration = 3. Session total =43.

$$\frac{\text{Session total (43)}}{54} \text{ X } 100 = 79.6\%$$

Overall evaluation scoring sheet

Rater-ID: ___________	Therapist ID: ___________
Date: ___________	Client ID: ___________
Audio recording -ID: ___________	Session number: ___________

Session structure

Session 1	
Session 2	
Session 3	
Session 4	
Session 5	
Session 6	
Total	

Session Content

Session 1	
Session 2	
Session 3	
Session 4	
Session 5	
Session 6	
Total	

Collaboration

Session 1	
Session 2	
Session 3	
Session 4	
Session 5	
Session 6	
Total	

Total Adherence score: ____________%

* Use method 3 to calculate the total adherence score.

Calculating adherence scores.

Different adherence scores can be calculated. Below are some examples of how to do the calculations.

1. Adherence score for an individual session is shown at the end of each session.

2. Calculating adherence score for the same session across different therapists is calculated as follows:

Example: A rater is calculating adherence from 2 therapists for session 1 only.

Audio tape 1 scores from Therapist A=Session 1 score =43
Audio tape 1 scores from Therapist B=Session 1 score =49

$$\frac{\text{Total of sessions rated (43+49)}}{120} \times 100 = \mathbf{76.6\%}$$

3. Calculating the adherence score for 6 sessions delivered by one therapist is done as follows:

The formula for calculating adherence is:

$$\frac{\text{The total of sessions rated}}{336} \times 100 = \mathbf{H\%}$$

Example- If a rater scored 6 sessions completed by a therapist with one patient.

Session 1 score =43
Session 2 score =49
Session 3 score =47
Session 4 score =56
Session 5 score =40
Session 6 score =50

Total of sessions 1-6 (325)

$$\frac{325}{336} \times 100 = \mathbf{96.7\%}$$