Reaching more young people with mental health difficulties: An evaluation of delivering a group-based CBT intervention for children and adolescents in an intensive format

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Original Work Statement

The research reported in this thesis was conducted at Pathways Health & Research Centre in Brisbane, Australia. The study design was partly established by previous studies in the same setting with the design specific to the hypothesis of this thesis being the work of Marthinus Bekker (The Author) with the assistance of Professor Paula Barrett. Interventions were delivered across 44 different participant groups for both young people and their parents separately (a total of 880 individual group sessions lasting 1.5 hours each) over the course of two years and were delivered by a group of skilled clinicians including Marthinus Bekker (The Author), Marita Cooper, Anthony Teoh, and Tania Lake. All clinicians were involved in some aspect of data gathering, with Marthinus Bekker (The Author) and Marita Cooper having significant roles in managing the dissemination and follow-up of the baseline, post-intervention and 12 month follow-up surveys. All written work contained in this thesis is the work of Marthinus Bekker (The Author) with assistance in development and editing from the supervisors and advisors, Professor Kathleen Griffiths, Associate Professor Philip Batterham, Professor Paula Barrett, Professor Brian Fisak , and Associate Professor Alison Calear.

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Dedication

One person who had a key role in shifting my life path to the one that led me to this PhD is the late Dr Louis Leland, Jr. Louis was one of the first individuals in my life that inspired me to do more in academia. He saw something in me that I had not yet discovered and over the course of many years fostered an interest in research that culminated in master's thesis under his supervision. His frequent encouragement to pursue a PhD was one of the many factors that gave me the confidence to do this PhD. Louis was a kind and supportive man who always had his students' interests as his priority. His values will continue to inspire me throughout my career.

Abstract

Aim. A clear need exists for finding alternative delivery formats of psychological treatments that are more transportable and which break down some of the barriers to engagement (Elkins, McHugh, Santucci, & Barlow, 2011) that are stopping as many as four out of five young people who could benefit from therapy from accessing it (Cobham, 2012). Group delivery and intensive formats have the potential to reduce some of the barriers to engagement. The aim of this study was to compare an Intensive 2-week group delivery of the FRIENDS programs to a Standard 10 week group delivery.

Method. In this open effectiveness trial, 260 children and their families participating in the FRIENDS groups at a private community based psychology clinic situated in Brisbane, Australia, agreed to participate in the research. Families self selected Intensive 2-week delivery or standard 10-week delivery and were routed into Fun FRIENDS for 4-7 year olds, FRIENDS for Life for 8-11 year olds, and My FRIENDS Youth for 12 to 15 year olds. All of the caregivers were invited to attend family sessions and the Adult Resilience group. Surveys delivered online were sent both before and after the group.

Results. Mixed model results showed significant ($p<0.01$) outcomes for all formats from baseline to post for the Spence Anxiety Scales (SAS), the Child Depression Inventory (CDI-P), the Strengths & Difficulties Questionnaire (SDQ), and the Devereux Student Strengths Assessment (DESSA), with non-significant interactions ($p>0.05$) comparing Time to the format in which it was delivered, Standard or Intensive, across all these measures. Effect sizes (Cohen's D) across total symptom

scales on the SAS, CDI-P, and SDQ, for both Standard and Intensive all showed small decreases at Post intervention (d = -0.21 – -0.49). Then at 12 month Follow up, further improvements were observed across both formats with Standard still showing small reductions from baseline (d = -0.34 – -0.47), and Intensive showing medium to large reductions (d = -0.57 – -0.90) from baseline across all measures. As well as the decreases noted in symptom scales, strengths measured by the DESSA increased for both formats from baseline to post (d = 0.38 – 0.40), with this rising to large increases in total strengths score at 12 month Follow up (d = 2.25 – 2.52).

Conclusions. Results indicate that both Standard and Intensive delivery of the FRIENDS programs were effective at reducing symptoms of anxiety and depression, as well as conduct, hyperactivity, and peer problems. Whilst also increasing strengths in self-management and awareness, social awareness and relationship skills, personal responsibility, decision making, and optimistic thinking. These changes in measures especially at follow up, with no statistical difference between formats, suggests that Intensive delivery is potentially as effective as Standard delivery and may provide another way of increasing the reach of CBT based interventions. Conclusions are limited by non-randomisation, dropout, and not having a measure of reach.

Publications and Presentations arising from this thesis

Bekker, M. J., Griffiths, K. M. & Barrett, P. M. (2017). Improving accessibility of cognitive behavioural therapy for children and adolescents: Review of evidence and future directions. *Clinical Psychologist, 21(3),* 157-164.

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Chapter1. Introduction. Reaching more young people with mental health difficulties: An evaluation of delivering a group based CBT intervention and prevention program for children and adolescents in an intensive format.

The prevalence of mental disorders in children world wide was estimated at 13.9% by Polanczyk, Salum, Sugaya, Caye, and Rohde (2015) in large scale meta-analysis spanning 27 countries, with some estimates as high as 20% of young people globally (Kieling et al., 2011; Patel, Flisher, Hetrick, & McGorry, 2007). Polanczyk et al. (2015) found that in Oceania estimates were somewhat higher than global averages at 16.3% although not as high as North American estimates at 19.9%. Sawyer, Reece, Sawyer, Johnson, and Lawrence (2018) found that the incidence of mental disorders has not significantly changed for Australian children and adolescents, from 1998, when estimates were 12.5%, to 2014, when estimates were 11.1%. Sawyer et al (2018) did observe some small declines in externalising disorders like Attention Deficit Hyperactivity Disorder (ADHD) and Conduct Disorder, and a small increase in the prevalence of Depression from 2.1% to 3.2%.

A recent large-scale survey of mental health and wellbeing amongst Australia children and adolescents by Lawrence et al. (2016) estimated that the 12-month incidence of mental disorders was 13.9%, noting significant impacts particularly on days missed from school for those meeting criteria for a disorder. Lawrence et al. (2016) also noted that those in step, blended, and single parent households, as well as those in rental accommodation, or with parents not in employment, were more likely to suffer from mental health

difficulties. ADHD was still the most prevalent at 7.4% followed by anxiety disorders at 6,9% and Depression at 2.8% (Lawrence et al., 2016).

The burden of these disorders is immense, with Erskine et al. (2015) describing the global impact of mental and substance use disorders as "the leading cause of disability in children and youth". These impacts correspond to a lifetime cost of $2.1 trillion for children experiencing mental illness in the United States alone (Smith & Smith, 2010) and comes at a huge individual and societal cost in terms of productivity, healthcare, justice interventions, and wider community effects (Belfer, 2008).

Services are struggling to meet demand and many young people are not accessing professional care (Collins, Westra, Dozois, & Burns, 2004). It is estimated that as many as 80% of young people with internalizing disorders worldwide are not receiving appropriate treatment (Cobham, 2012; Essau, 2005). In Australia a recent survey by Johnson et al. (2016) found substantially higher service use of 56% among children and adolescents with a diagnosis in Australia, with them suggesting that service utilisation has been improved through school-based mental health care and the Better Access program (a publicly funded initiative to increase access to private mental health services).

When looking at treatment for internalizing disorders such as depression and anxiety over the last two decades, child- and family focused Cognitive Behavioural Therapies (CBT) have progressed to the point where they are currently the treatment of choice for most childhood internalizing disorders (James, James, Cowdrey, Soler, & Choke, 2013; Reynolds, Wilson, Austin, & Hooper, 2012). CBT is a structured and time-limited therapy that strives to help identify maladaptive

thoughts, behaviours, and emotions, that underlie the problems an individual is experiencing, in order to build an understanding of how they interact and inform the experiences the individual has, and to then develop targeted skills to change maladaptive components of that model (Beck, 2011). CBT approaches for children, as for adults, have typically been administered over 10-12 weekly or bi-weekly sessions by qualified clinicians in a one-on-one clinic setting with varying amounts of parent input (James et al., 2013). In these formats, CBT has produced moderate to large treatment effects (James et al., 2013).

Effective treatments like CBT are available for anxiety and depression in children and adolescents, yet there are a number of individual, provider and system-level barriers to accessing this care. According to Collins et al. (2004), individual level barriers include peoples' willingness to disclose their symptoms and the time needed to do so; stigma or the fear of negative judgement from communities they are part of; negative stereotypes of treatment; cultural factors that minimise mental illness or encourage coping with them in ineffective ways; demographic factors such as the age, stage, and gender of individuals; geographic challenges such as being more remote from available treatments; a desire to handle difficulties in their own way; lack of awareness of what treatments are available; minimizing their symptoms or the impacts they are having; and not being ready to engage in change.

Barriers at the provider level include under-detection by primary care health services; a lack of skill and knowledge, related to mental health and its effects, of people in positions to screen, identify and address difficulties; attribution of difficulties to an organic cause and willingness to diagnose mental health difficulties;

time constraints of primary care clinicians; stigma of providers about mental health; and judgements of presenting difficulties and level of distress (Collins et al. 2004). Lastly, barriers at a system level include the availability of clinicians trained in effective treatments, especially within primary care settings; limited availability of clinicians and services in primary care and in specialist services; limited response to available treatments; and low rates of provision of evidence-based interventions due to training and other factors (Collins et al., 2004).

Owens et al. (2002) assessed barriers to accessing services for a group of 116 families who had children in the first grade and found that 35% of families reported barriers to accessing Children's Mental Health Services, including 'structural barriers' such as the cost, inconvenience, and distance to treatment, and 'perception barriers' such as not believing it was serious enough, fear of stigma, and previous negative experiences.

Results such as those found by Owens et al. (2002) are not uncommon, as discussed in a systematic review of barriers to help seeking by Gulliver, Griffiths, and Christensen (2010). Gulliver et al (2010) identified fear of stigma, not being able to identify symptoms, and a preference for self-reliance (helping oneself) were the key barriers to help seeking identified in the literature. Additionally, Gulliver et al. (2010) identified possible facilitators to accessing mental health services, which included positive past experiences, as well as social support and encouragement to access services. Due to the many barriers to engagement with current services and interventions, including standard CBT interventions (Collins et al., 2004; Gulliver et al., 2010; Owens et al., 2002), there is a clear need to find alternative delivery

formats that break down some of the barriers to engagement and make interventions more accessible (Bekker, Griffiths, & Barrett, 2016; Elkins et al., 2011).

Alternative formats for the delivery of CBT interventions for young people include group delivery, intensive and brief formats, as well as electronic and remote formats. There is research evidence that these approaches can be effective and reduce the barriers to accessing care identified previously (Bekker et al., 2016). Additionally, preventive approaches also offer an alternative use of CBT interventions that may reduce the burden of mental health difficulties for children and adolescents (Bekker et al., 2016). One area with a developing evidence base is intensive and brief formats of CBT based interventions, which have the potential to reduce barriers to engagement on individual, provider, and systemic levels by increasing access to evidence-based treatments through offering CBT interventions in a more time-efficient manner and thereby reducing the resources necessary to access them (Bekker et al., 2016).

Research on intensive and brief formats of delivery for CBT based therapies for young people has to date focused on phobias (Davis III, Ollendick, & Öst, 2009; Ollendick et al., 2009; Öst, Svensson, Hellström, & Lindwall, 2001), post traumatic stress disorder (PTSD) (Ehlers et al., 2010; Ehlers et al., 2014), panic disorder and agoraphobia (Gallo, Chan, Buzzella, Whitton, & Pincus, 2012) and obsessive compulsive disorder (OCD) (Abramowitz, Foa, & Franklin, 2003; Bolton et al., 2011; Storch et al., 2007; Whiteside, Brown, & Abramowitz, 2008). In each of these studies the intervention delivery time was shortened by either offering less content (brief format), for example by offering one session interventions (Davis III et al., 2009; Ollendick et al., 2009; Öst et al., 2001)or by delivering the same amount of content as traditional CBT programs but in

quick intensive succession (intensive format), as illustrated by the 14 session intervention for OCD described by Storch et al. (2007) which was delivered over three weeks. Both approaches have the potential to replace weekly sessions delivered over several months. Sessions implemented over shorter periods of a few days or just a few weeks, potentially creating greater accessibility by reducing the time commitment required to complete the intervention. For example, these alternative formats enable interventions to be delivered during the school holidays, when demands from schooling and other activities are reduced. They also allow families and young people who are geographically distal from intervention sites to spend short periods of time close to the site of intervention rather than travelling long distances on a weekly basis. However, these potential advantages are only beneficial if the interventions continue to deliver meaningful improvements in the mental health and resilience of young people.

Intensive and brief delivery formats have demonstrated effectiveness equivalent to standard delivery formats across several different diagnostic, age, and geographic groups whilst reducing either the duration or time period that is usually required in standard formats, potentially reducing barriers to engagement (Abramowitz et al., 2003; Bolton et al., 2011; Davis III et al., 2009; Ehlers et al., 2010; Ehlers et al., 2014; Gallo et al., 2012; Ollendick et al., 2009; Öst et al., 2001; Storch et al., 2007; Whiteside et al., 2008). The literature in this area is still developing though and gaps exist for the evaluation of more broadly targeted interventions, group interventions, and interventions with a preventative focus. Few of the studies above were delivered intensively, with more being in the brief category, and were mostly focussed on specific anxiety diagnoses like OCD. The FRIENDS programs are one example of

more broadly targeted CBT based group program that currently uses a standard delivery format and has not yet been evaluated in an intensive format.

The FRIENDS programs (Barrett, 2012a, 2012b, 2012c, 2012d, 2012e, 2012f) are a set of developmentally targeted CBT-based treatment and prevention programs for internalizing disorders. The FRIENDS programs have been found to be effective when delivered as both a preventative intervention for anxiety and depression (Barrett, Farrell, Ollendick, & Dadds, 2006; Fisak, Richard, & Mann, 2011) and as a treatment for anxiety in particular (Barrett, Dadds, & Rapee, 1996; Fisak et al., 2011; Shortt, Barrett, & Fox, 2001). They have demonstrated significantly larger effects than many other school-based intervention/prevention programs (Anticich, Barrett, Silverman, Lacherez, & Gillies, 2013; Fisak et al., 2011). Children who have completed FRIENDS in a school based setting have shown both reductions in anxious symptomology, behavioural difficulties, and behavioural inhibition, as well as increases in protective factors such as social and emotional competence (Anticich et al., 2013). Studies have also shown that outcomes have been maintained for 3 years in a preventative format (Barrett et al., 2006) and up to 6 years in a treatment format following program completion (Barrett, Duffy, Dadds, & Rapee, 2001). The FRIENDS programs will be discussed in more detail in chapter 3.

Despite the demonstrated effectiveness of the standard FRIENDS program, there is no evidence of the relative effectiveness of the program in different formats. Given its widespread uptake around the world, there is value in determining if the program might be feasibly and effectively delivered in an intensive format that might increase its accessibility. Accessibility could be increased by reducing long term time demands, the commitment necessary for completion, and allowing interventions to be delivered

during holiday periods or as parts of short programs delivered in health and education settings such as short term inpatient services and camps.

Accordingly, the current study sought to compare the effectiveness of the FRIENDS programs in treating anxiety and depressive symptoms in children and adolescents who either received the standard delivery of the program (10 weekly sessions) or an intensive format (10 daily sessions) in a private community clinic. We hypothesized that the delivery of the FRIENDS program in an intensive format of daily sessions over two weeks would produce similar effects on anxiety and depressive symptoms as the standard delivery over ten weeks. The study only aims to observe whether similar effects on anxiety and depressive symptoms occur in both formats rather than establishing non-inferiority. The current study will provide the first comparison of intensive vs standard delivery of a trans-diagnostic treatment in children and adolescents and will ascertain the benefit of different delivery intensities for this population. Although there is evidence that transdiagnostic CBT interventions are effective for a range of anxiety disorders in children and adolescents, there may be differential effects depending on the type of anxiety disorder experienced (Hudson et al., 2015) .Therefore, the current study examined both overall anxiety symptoms and symptoms of specific manifestations of anxiety disorders (Generalised Anxiety, Social Anxiety, Obsessive Compulsive, Physical Anxiety, and Separation Anxiety and Panic).

This thesis provides a narrative review literature on alternative delivery formats for CBT interventions for children and adolescents in Chapter 2. A more thorough description of the origins, development and current evidence for the FRIENDS programs is then undertaken in Chapter 3. The thesis then goes on to describe the

method of the study including the design, procedure, participants, conditions and measures in Chapter 4. Chapter 5 then explores baseline comparisons between conditions and comparisons of those who dropped out at different time points to consider any biases that may exist due to attrition or imbalances at baseline. The relative effectiveness of the intervention as delivered in traditional versus intensive format is compared, with the results for the main symptom scales of anxiety and depression, as well as secondary symptom and strength scales described in Chapter 6. Potential moderators of observed outcomes are then explored in Chapter 7, to evaluate if there were factors that differentially predicted outcomes across the different formats, including the effects of drop out from the study. The thesis is then concluded with a discussion of the findings, how they compare to previous research, the impact they could have on how CBT is disseminated and directions for future research in Chapter 8.

Chapter 2. Improving accessibility of cognitive behavioural therapy for children and adolescents: Review of evidence and future directions

There are many barriers that contribute to the under-treatment of mental health conditions in young people including but not limited to the demand on available services, the stigma of mental illness, costs and time demands of treatment, and geographic isolation (Collins et al., 2004). Therefore, Elkins et al. (2011) have argued for the increased transportability of effective CBT approaches through creative modifications that allow existing effective treatments to be delivered to young people who are not able to access traditional delivery formats. Turner and Krebs (2013) propose that increased access to CBT-based treatment can be achieved by reducing the cost of treatment through reducing therapist input per patient or employing staff only trained in the protocol being delivered, or by reducing the burden to the individual through briefer interventions and the integration of communication technologies. The term 'Low Intensity CBT' has been more thoroughly defined by Bennett-Levy et al. (2010) who described its purpose as "… to increase access to evidence-based psychological therapies in order to enhance mental health and wellbeing on a community-wide basis, using the minimum level of intervention necessary to create the maximum gain" (p.8). However, to date the effect of many of the different formats that increase transportability of child-focussed CBT on uptake and outcomes has been the subject of relatively less empirical investigation than standard formats (James et al., 2013).

Literature Review Method

A non-structured narrative review of the literature was conducted to identify studies that had evaluated alternate format CBT-based interventions (i.e., not a standard 10-12 week CBT intervention) with children and/ or adolescents. OVID (PsycInfo/ Medline/ PubMed) and Google Scholar searches were conducted in August 2015 and again in May 2018 with a date range from 1970 until May 2018, focussing on titles and key words during the searches. Key words were applied in three categories, intervention type (CBT OR Cognitive Behavioural Therapy), format (intensive OR brief OR rapid OR transportable OR "low intensity" OR group OR telephone OR video OR internet OR bibliotherapy), and age range (child OR adolescent OR paediatric). This search was used to identify articles relevant to this narrative review in group, brief and intensive adaptations, electronic adaptations, and additionally preventative adaptations. The reference sections of identified papers were also searched for further studies. Studies or reviews were retained in the current review if they (a) evaluated or reviewed CBT based interventions, (b) participants were children and/or adolescents (less than 19 years old), and (c) the evaluated intervention(s) were delivered in an alternative format, meaning it differed from a standard 10-12 week individual clinician-led intervention. When significant and comprehensive reviews were available in a particular area, the review focussed on those rather than looking at just individual studies. No active effort was made to limit this review to internalising disorders, however most studies identified focussed on the treatment or prevention of anxiety and depression.

Outcome of review of alternative delivery formats

Many avenues for increased transportability (use of standard treatments in more accessible ways) of child-focussed CBT have been proposed. The extent to which these alternative formats have been investigated has varied. The approaches to increase transportability fall into three broad areas: group therapy, increased intensity or brevity, and distal (primarily online) delivery.

These three areas are individually summarised below, along with the relevant research studies identified from the review of the literature. Following the discussion of the alternative treatment delivery formats, universal preventative approaches are also discussed as an adaptation area of interest that has the potential to reduce the burden of mental health difficulties.

The use of *group* rather than individual therapy to reach larger numbers of children is one of the most researched areas in the transportability of child-focussed CBT, with evidence of effectiveness as well as unique benefits such as normalization and peer learning (Bieling, McCabe, & Antony, 2013). Delivering treatment protocols with *greater intensity over shorter periods* of time is also an area of emerging research on increasing transportability, with some authors reporting equivalent outcomes for intensive (short) formats compared to standard formats (Storch et al., 2007). Another format that is the subject of active investigation is bibliotherapy which to date has demonstrated is little evidence to support its use when therapy is delivered purely through a self-guided workbook (Rapee, Abbott, & Lyneham, 2006). *Online, remote, and electronic delivery*, is quickly emerging as an effective and engaging way of reaching some young people who are not otherwise able to access services (Spence et al., 2011). These formats allow for remote delivery through

internet-based, video conferencing and phone contact, with favourable results (Bieling et al., 2013; Calear & Christensen, 2010; Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; Donovan, Spence, & March, 2013; Ebert et al., 2015; Richardson, Stallard, & Velleman, 2010; Rooksby, Elouafkaoui, Humphris, Clarkson, & Freeman, 2014; Vigerland et al., 2016). Most of these alternative formats and modifications offer promising ways of reaching more of the young people who are experiencing emotional difficulties but are not accessing the needed help. The emerging area of universal preventive, child-focussed, CBT approaches offer another alternative which can reduce the number of young people who are experiencing mental health difficulties. These interventions are showing promise in reducing the future incidence of internalising disorders in young people reaching them before they develop mental illness (Fisak et al., 2011).

Group formats

As noted above, group formats are an evidence-based format that makes effective CBT based treatments more accessible through disseminating treatment in a more efficient manner. The body of research evidence supporting group-based treatments for children and young people has grown substantially over the last decade, with group CBT formats producing medium treatment effect sizes for anxiety and other mental health difficulties in children and adolescents across two major meta-analyses including several randomized controlled trials (James et al., 2013; Reynolds et al., 2012).

The first of these, a recent Cochrane review which included 41 studies with 1806 participants (James et al., 2013) found moderate effects for CBT based treatments for child and adolescent anxiety, showing that only 369 per 1000 participants who

completed CBT based interventions across group, individual, and family formats still met diagnostic criteria after completing the included trials, compared to 818 per 1000 in wait-list control conditions (OR = 0.13). When they compared delivery formats they noted that "CBT appears equally effective in various formats family, individual and group which poses the question whether group CBT is possibly more cost-effective…. Health economic studies are needed to answer this question. (p. 29)." This finding supports group CBT formats as an equivalent to traditional individual CBT whilst reducing therapist time and potentially costs by delivering the intervention to several young people at once, therefore making the treatment more accessible. This analysis did however reveal some gaps in the literature with comparisons to 'treatment as usual' and non-CBT controls being limited and inconclusive.

The other major meta-analysis, undertaken by Reynolds et al. (2012), incorporated an even larger range of studies, with 55 studies focused on children and young people who met a diagnosis for any anxiety disorder in treatment groups. This study also reported moderate effects sizes overall in reduction of anxiety symptoms compared to control groups. However, whereas group based CBT interventions were reported to be associated with moderate effect sizes (d=0.58) in reducing anxiety, individual therapy produced large effect sizes on average (d=0.85), a finding which differed from that of James et al. (2013) who found no difference. One possible explanation for this could be that James et al. (2013) excluded phobias, obsessive compulsive disorder, posttraumatic stress disorder, and selective mutism, whilst Reynolds et al. (2012) included all anxiety disorders. Reynolds et al. (2012) point to the need for individual formulation and treatment planning as an explanation of why individual formats may be more effective. Some of the disorders excluded by

James et al. (2013) can be more complex and as such may fit with the Reynolds et al. (2012) account of a need for individual formulation and treatment planning.

These two large meta-analyses outline the evidence for group-based CBT for childhood emotional challenges, and specifically anxiety, as an effective and efficient treatment modality with lasting effects. Studies investigating the effects of group-based CBT for children and adolescents for conditions other than anxiety, in areas such as depression, are less abundant. A small meta-analysis of 10 studies, of which 8 were group-based CBT interventions for depression in children, did show moderate effect sizes (d=0.66) in reducing depressive symptoms; however, no direct comparison was made between group and individual treatment and the review identified challenges such as a lack of follow-up and methodological issues in the studies (Arnberg & Öst, 2014).

Intensive, brief and rapid delivery formats

Various brief formats of CBT have also emerged ranging from one-session interventions for phobias (Davis III et al., 2009; Ollendick et al., 2009; Öst et al., 2001), to multi-session formats delivered in quick succession for post traumatic stress disorder (PTSD) (Ehlers et al., 2010; Ehlers et al., 2014), panic disorder and agoraphobia (Gallo et al., 2012) and obsessive compulsive disorder (OCD) (Abramowitz et al., 2003; Bolton et al., 2011; Storch et al., 2007; Whiteside et al., 2008). Although many of these studies aimed to increase the transportability of CBT interventions for children and adolescents, many did not fit within the Bennett-Levy et al. (2010) definition for Low-Intensity CBT, since the actual intensity of the delivery in some instances would arguably be greater than traditional formats, with multiple sessions delivered in short succession rather than across many weeks

(Storch et al., 2007; Whiteside et al., 2008). Such formats remove the need to maintain long-term attendance at weekly sessions and involve less travel, thereby making the interventions more accessible for some. For the purpose of this review intervention that reduce the amount of sessions will be referred to as brief whilst interventions that maintain the same content but reduce the period of time over which it is delivered will be referred to as "intensive".

In an evaluation comparing a standard weekly family-based CBT intervention for young people with a diagnosis of Obsessive Compulsive Disorder (OCD) to an intensive, daily, format of the same intervention, Storch et al. (2007) found meaningful improvements in both the intensive and standard weekly formats. Their study included 42 young people aged between 7 and 17 years who presented to a University Clinic meeting diagnostic criteria for OCD. Treatment was provided by Clinical Psychology Post-Doctoral Fellows and Doctoral Candidates. Parents were included in all sessions and the intensive format consisted of 14 daily (week days) sessions over 3 weeks, whilst the weekly format consisted of the same 14 sessions delivered in weekly sessions. Outcome measures included the Anxiety Disorders Interview Schedule (ADIS), a clinician rated symptom severity scale called the Clinical Global Impressions Scale (CGI), the Children's Yale Brown Obsessive Compulsive Scale (C-YBOCS), as well as measures of anxiety, depression, and the impact of difficulties on their lives, were administered at baseline, post treatment, and at 3-month follow-up. There was no significant difference in OCD symptoms between the two groups and 75% of the intensive participants met remission criteria at post-treatment compared to 50% in the weekly groups which was not significant. Furthermore 90% of intensive participants were considered treatment responders on the CGI compared to 65% of weekly group participants which was not significant.

Without significant differences between weekly and intensive delivery, these results suggest that intensive delivery formats may be as viable as standard delivery. However, the results of this study are limited by its small sample size and short follow-up times.

The use of intensive delivery strategies was also discussed in a paper reporting three case studies by Whiteside et al. (2008), in which a 10 session CBT-based family treatment was administered over five consecutive days in a multi-disciplinary clinic by a Clinical Psychologist. Both the C-YBOCS and ADIS were used in this study alongside the Spence Child Anxiety Scale (SCAS), Sheehan Disability Scale and intelligence screening. Assessment occurred at baseline, post treatment, and at 3-4 months after treatment. Two participants showed a reduction in their C-YBOCS score from the severe to mild range at post-test an effect which was maintained at follow-up, whilst the third participant also reduced to the mild range by the follow-up assessment. Similarly, parent report of OCD symptoms on the SCAS were reduced for all three participants in the same pattern as the child measures. These results are consistent with those of Storch et al. (2007)

In a higher quality study employing a larger sample size and a non-active control group, Bolton et al. (2011) conducted a randomised controlled trial (RCT) with 96 children and adolescents who suffered from OCD. The study was conducted in two specialist Paediatric OCD clinics and compared a 5 daily session brief intervention to a standard CBT format of 12 weekly sessions, as well as a waitlist control. Their brief intervention was also supplemented by workbooks. A structured interview, the CGI, and measures of OCD, anxiety, depression, and the impact of difficulties on their lives, were administered at baseline, post treatment, and three-month follow-up. Relative to control, both treatment formats were associated with a significant

reduction in OCD symptoms, suggesting that both were effective. Of the brief intervention participants, 49% met remission criteria at post-treatment compared to 61% in the standard treatment and 8% in the waitlist control, with very large effect sizes of 2.2 for the full intervention and 1.6 for the brief format.

Although many studies of the effectiveness of brief and intensive deliveries of CBT-based intervention have focused on OCD, some have investigated panic disorder and agoraphobia (Gallo et al., 2012). To investigate the effects of narrowly targeted interventions on co-morbid diagnoses, Gallo et al. (2012) delivered an 8-day intensive CBT- based treatment for panic disorder and agoraphobia in adolescents and reported on the outcome for non-targeted comorbid diagnoses. Following this intensive intervention, there was a substantial reduction in the percentage of adolescents who met comorbid diagnosis (from 78.2% before treatment to 43.6% after), with the highest rates of remission occurring in the young people who met criteria for social phobia, specific phobia and generalized anxiety disorder before treatment. The findings are not definitive given the lack of a control group and the small sample size. However, they suggest that targeted intensive interventions may yield generalizable effects despite the shorter time bracket.

Öst and Ollendick (2017) reviewed the literature in the area of brief, intensive, and concentrated cognitive behavioural treatments for anxiety in children. They included 23 RCTs in their review and concluded that these interventions had lower attrition rates compared to standard CBT on average, had comparable outcomes to standard delivery with superior outcomes to waitlist control and placebo conditions. They found similar remission rates in both standard and brief, intensive or concentrated conditions with average within effect sizes at follow-up being

between 1.5 and 1.53, compared to standard formats which had effect sizes between 0.98 and 1.05.

The adult literature has also yielded promising findings for intensive CBT interventions. For example, in a recent study Ehlers et al. (2014) investigated the use and effectiveness of a seven-day intensive cognitive therapy program for adults with chronic PTSD using 5-7 daily sessions of up to two hours compared to standard cognitive therapy of 12 weekly one hour sessions over three months, 12 weekly one hour sessions of emotion focused supportive therapy over three months, or a wait-list control. Of the 121 participants who were randomized into the treatment conditions both standard and intensive cognitive therapy were superior to control, with 77% of standard cognitive therapy group and 73% of intensive cognitive therapy participants having recovered after treatment, compared to 43% of the supportive therapy group and only 7% of the waitlist control.

Electronic and Remote Delivery Formats

Research on electronic and remote delivery formats is a rapidly expanding area as communication technologies become increasingly more prominent and accessible (Donovan et al., 2013). Telephone, Internet, and video-conferencing delivery formats of CBT based interventions have been trialled with young people.

Turner, Heyman, Futh, and Lovell (2009) conducted a very small telephone-based CBT study involving 10 adolescents with Obsessive Compulsive Disorder (OCD). At post treatment 7 out of the 10 participants were in remission, which was maintained at 12-month follow-up. However, this pilot study included no controls and employed only a very small sample. Telephone calls seem to be common as a

support medium for CBT based interventions (Lovell, 2010); but as a primary CBT intervention for children and adolescents the literature remains sparse (Slone, Reese, & McClellan, 2012). Another format closely related to telephone based intervention is the use of Short Messaging Services (SMS) on mobile phones; however, the evidence for its use in delivering CBT interventions for children and adolescents remain focused on its role as an adjunct strategy to increase adherence, reduce drop out and relapse, and promote self monitoring (Shapiro & Bauer, 2010).

In a similar approach but with the addition of video, Storch et al. (2011) delivered web–camera-based CBT to a group of adolescents with OCD. Thirty-one young people were randomly assigned to either a treatment or waitlist control group. Of the 16 intervention participants, 13 (81%) responded to treatment with nine meeting remission criteria, compared to only two (13%) out of the 15 participants in the waitlist control. Again, the use of video conferencing for the delivery of CBT is better established in the adult literature compared to studies with children and adolescents (Slone et al., 2012).

Spence, Holmes, March, and Lipp (2006) also conducted a study utilising technology in delivering CBT to children with anxiety. This was a blended intervention in combination with a clinic-based intervention, with half of the sessions being delivered through web-based links and half involving individual therapy. The study included 72 children between the ages of seven and 14, who were randomly allocated to a clinic, clinic plus web, or waitlist-control condition. Both of the intervention groups showed significant treatment responses compared to the waitlist condition with 13 out of 20 children in the clinic based intervention and 14 out of 25 children in the combined clinic plus web based intervention no longer

meeting diagnostic criteria after treatment. By contrast, only 3 out of 23 children in the waitlist control no longer met diagnostic criteria for an anxiety disorder. The effects for both intervention groups were also maintained at 12 month follow up.

The use of online or internet based CBT interventions is rapidly expanding in the child and adolescent literature. Children and adolescents have been labelled "digital natives", showing a strong affinity for technology, making internet-based programs well suited to their communication needs with many reporting that they actively seek mental health support online (Havas, de Nooijer, Crutzen, & Feron, 2011). These interventions may take the form of psycho-educational materials such as videos, interactive games, and self-guided programs (Ebert et al., 2015; Slone et al., 2012; Vigerland et al., 2016). Slone et al. (2012) identified and reviewed four areas in which most of the research within this area is focused including smoking cessation, alcohol/drug use, eating disorders and emotional distress, although not all of the interventions identified were strictly CBT-based. They concluded that internet-based interventions for children and adolescents had a strong emerging evidence base with positive results across all areas reviewed from several RCT's, with large sample sizes, and relatively good study designs.

Since the Slone et al. (2012) review, the research in internet delivered interventions has rapidly expanded and two meta-analyses reviewing CBT for children and adolescents have recently been conducted (Ebert et al., 2015; Vigerland et al., 2016). Vigerland et al. (2016) narrowed their analysis to 24 studies targeting children and adolescents who presented with a variety of psychiatric disorders or somatic conditions. Between-group comparisons between the internet delivered CBT interventions and control conditions showed moderate effect sizes (Pooled g =

0.62). Within group comparisons from baseline to post showed a large effect across the studies included (Pooled g = 0.85), with outcomes for studies focussed on psychiatric conditions like anxiety and depression producing even larger effects (Pooled g = 1.27) as opposed to moderate effects observed for studies targeting somatic conditions such as chronic pain (Pooled g = 0.49). Vigerland et al. (2016) therefore, concluded that CBT for children and adolescents has been successfully adapted to be internet delivered. They note though that measures of cost and time efficiency are rarely included and that any assumptions about increasing access or reducing costs or time are often assumed and need to be investigated further in future.

The Ebert et al. (2015) meta-analyses employed slightly different criteria including computer based interventions as well as internet delivered CBT based interventions for children and adolescents with anxiety or depressive disorders or both. Between group comparison with control groups produced moderate to large effects for those targeting anxiety disorders (Pooled g = 0.68), depressive disorders (Pooled g = 0.76), and those trans-diagnostic interventions treating anxiety and depression (Pooled g = 0.94). Within-group comparisons from pre to post had moderate effect (Pooled g = 0.72). They also concluded that internet and computer delivered CBT based interventions for children and adolescents were effective.

Overall there is increasing focus on the remote electronic formats for the delivery of CBT-based interventions to children and adolescents in particular internet based delivery, and the findings to date suggest that these approaches offer effective CBT interventions for children and adolescents (Ebert et al., 2015; Vigerland et al., 2016)

CBT Based Preventative Programs

Although there is a need to improve the availability of treatments for children and adolescents with emotional difficulties it is also vital to consider the role of preventive programs which aim to provide skills to young people before they experience a mental illness (Fisak et al., 2011). Large scale reviews such as that by Kieling et al. (2011) emphasise the need for early intervention and prevention.

Many large scale reviews and meta-analyses show clear preventive effects (Bennett et al., 2015; Fisak et al., 2011; Merry et al., 2012; Stockings et al., 2016; Werner-Seidler, Perry, Calear, Newby, & Christensen, 2017) as well as unique benefits of reduced stigma and in some cases improved academic performance (Durlak, Weissberg, Dymnicki, Taylor, & Schellinger, 2011). Merry et al. (2012) conducted an extensive Cochrane review spanning 15 studies and 3115 participants, for the efficacy of a range of educational and health programs in preventing the onset of depression in children and adolescents and concluded that there is evidence that prevention programs were effective as compared to no intervention. Merry et al. (2012) did however note some methodological issues inherent in much of the research in the area, pointing to allocation concealment and heterogeneity of findings as some of the major issues.

Stockings et al. (2016) reviewed 146 randomised control trials with a combined 46,072 children and adolescents, evaluating the efficacy of selective, universal, and indicated prevention trials aimed at reducing the incidence of depression and anxiety in young people. Their analyses showed that selective, universal, and indicated prevention trials all showed reductions in both onset and symptoms of internalising disorders for up to 12 months respectively. The interventions

predominantly consisted of "psychological strategies" mostly fitting within a broad definition of Cognitive Behavioural Therapies (CBT). They noted a lack of long term follow-up meaning that effects beyond 12 months were hard to establish and that repeated interventions throughout childhood may be indicated.

Focussing specifically on school based prevention of anxiety and depression programs, Werner-Seidler et al. (2017) evaluated 81 randomised control trials with a total of 31,794 participants. Similar to other reviews they found small effects for both anxiety and depression after the intervention, with small effects still present after 12 months for both anxiety and depression. They noted that targeted interventions produced bigger effects than universal interventions for depression, although no such difference for anxiety. Like Merry et al. (2012) above, Werner-Seidler et al. (2017) note heterogeneity as a challenge with the current evidence potentially due to prevention type and what personnel delivers it. They also noted that the quality of the Randomised Control Trials was generally low.

Deady et al. (2017) looked at the combination of electronic and online platform with prevention in their review of 10 studies covering a total of 4522 participants. The studies predominantly utilised Internet delivered Cognitive Behavioural Therapy, showing small effects for both anxiety and depression. Like Stockings et al. (2016) above, they noted a lack of long term follow-up, which means that the long term efficacy of reducing incidence of internalising disorders cannot be robustly established.

Another large meta-analytic review by Fisak et al. (2011) found significant improvements in measures of resilience post intervention with mixed results at

follow-up across 27 studies. On further analysis of moderating factors, Fisak et al. (2011) reported that although factors such as universal vs. targeted intervention type, gender, and age were not significant predictors of outcome, the FRIENDS program was associated with superior outcomes with an average effect size of *d=0.25* compared to a *d=0.11* for non-FRIENDS interventions.

Studies using the FRIENDS program have consistently demonstrated preventive effects. For example, in a universal sample of Australian school students in Grade 6 and 9, Barrett et al. (2006), showed that at three annual follow-up time periods those who had completed the FRIENDS program were significantly less likely to be in a high-risk group (operationalized as high Children's Depression Inventory total scores or Spence Children's Anxiety Scale scores) than children in the control group. At 36 months only 12% of the intervention group were in the high-risk group compared to 31% of the control group. A recent large scale RCT of a universal prevention program in a school setting using a younger developmental version of the FRIENDS program for children aged 4-7 years old (Fun FRIENDS) as well as an active control demonstrated similar effects (Anticich et al., 2013). Anticich et al. (2013) showed significant improvements on clinical and resilience measures at completion for both Fun FRIENDS and "You Can Do It", the active control, as compared to the waitlist control, with Fun FRIENDS producing superior outcomes to both the "You Can Do It" intervention and control conditions at completion. These improvements were maintained at 12-month follow-up, with Fun FRIENDS still showing significantly better outcomes compared to the active control. Another very large scale implementation by Stallard et al. (2014) also showed significant reductions in anxiety relative to control but only when delivered by health professionals as opposed to teachers.

Conclusion

Recent research demonstrates that effective treatment and prevention protocols in more transportable and accessible formats are quickly being established. These approaches provide more ways of reaching young people who are experiencing emotional difficulties yet fall in the estimated 50-80% not receiving the psychological help they need. Reaching these young people could potentially lessen the life time burden of mental illness. The research also strongly supports group delivery as an effective way of disseminating CBT based interventions to children and adolescents, with reviews showing effects that are comparable to standard formats, potentially reaching more young people with less clinicians, and possibly in a more cost effective manner. Other adaptations are also showing promise, including intensive and brief delivery formats, with several studies demonstrating effectiveness equivalent to standard delivery formats whilst reducing either the duration or time period that is usually required in standard formats. Remote and electronic formats are also showing significant promise with an ever increasing research base; especially Internet based interventions where the majority of the research is now focussed. Many studies in this area are still utilising these interventions as adjunct therapies rather than the primary format. There is however, a paucity of large-scale and controlled studies in areas such as intensive and brief delivery, and a bigger gap for studies with long term follow-up across other areas such as group and electronic delivery formats. Although this review set out to explore alternative formats that have the potential to increase access to CBT based interventions, the results found only report on the effect of the intervention on treating or preventing difficulties, with no data evaluating whether these alternative formats actually increase the accessibility and reach of these interventions.

This review does outline several alternative formats, which are often compared to a standard CBT format, however a direct comparison of how these alternative formats compare to each other has not been conducted. CBT based interventions have been used in a vast range of presenting difficulties and populations and as such, studies that investigate alternative CBT formats have often focussed on particular populations or difficulties. Furthermore, the term "CBT" is also used to describe a range of interventions that share conceptual underpinnings but often differ a lot in their content. Drawing comparisons of how effective each of the alternative formats are compared to each other from the current literature is likely to produce limited useful information, as the different formats likely differ in their content and have largely focused on different populations and presenting difficulties. It could be that aspects of the modifications to the format of delivery lend themselves better to different presenting difficulties or ages, however no data was found to support such claims. This narrative review was not conducted in a structured, systematic manner and could potentially have missed relevant literature that could be within the scope of this topic, as well as leading to potential biases. Furthermore, the current review provides only a broad overview of alternative delivery formats, lacking the more in-depth distinctions that are examined in research on many of these formats.

Since the need for providing accessible treatment and preventive interventions to more young people is very real, research validating alternative formats to enable this is essential. Elkins et al. (2011) provided an important start in reviewing this area, although focussed on delivery settings rather than formats, without any focus intensive and brief formats. A lot of research, especially in electronic and internet delivered intervention has been done since Elkins et al. (2011) completed their review. Therefore,

the current review provides a unique and updated overview of the research on alternative formats of CBT based interventions. Future research could explore whether a range of alternative formats with similar CBT based content has different effects for different ages, presenting difficulties, or cultures. Furthermore, there is a critical need to investigate how alternative formats are impacting on availability and reach of these interventions and how effective modifications in format are at addressing barriers to engagement. The FRIENDS programs discussed above as effective CBT based treatment and prevention programs, are utilised in the main study of this thesis, and further discussed in Chapter 3 below.

Chapter 3. The FRIENDS programs.

This thesis evaluates different delivery methods of a CBT based group intervention, utilising the 2012 version of the FRIENDS programs (Barrett, 2012a, 2012b, 2012c, 2012d, 2012e, 2012f). This chapter will explore the origins and evolution of these programs, developmental iterations and adaptations, and evidence of their use as both a treatment and resilience protocol.

Origins & Evolution

The FRIENDS programs have their early roots in manualised Cognitive Behavioural Therapy programs such as Kendall (1990) "Coping Cat" intervention, a manualised, individually administered, Cognitive Behavioural Therapy program for young people aged 7-13 years old with various anxiety disorders. Coping Cat has a demonstrated ability to make clinically significant reductions in anxiety symptoms that were maintained at 1 year follow up (Kendall, 1994). The Coping Cat program was adapted to an Australian context and to be delivered in a group format by Barrett (1995) and called the "Coping Koala" program. This program went on to be evaluated in several major trials that found that it also made clinically significant reductions in anxiety symptoms that were maintained at 6 and 12 month follow up, which was even more pronounced with a family component added (Barrett et al., 1996). Then to incorporate the family component, expand on the core skills from the 'Coping Koala' program, and to continue with the group format the first FRIENDS program came to be (Barrett, Lowry-Webster, & Turner, 2000a, 2000b, 2000c, 2000d, 2000e, 2000f)

The program has continued to evolve since then, incorporating more third wave strategies such as mindfulness, honing a focus on developing resilience, targeting at

a wider trans-diagnostic level (anxiety and depression), and major updates to artwork and presentation of the programs. The FRIENDS programs have maintained their core skills and structure, but updates have continued to incorporate new and emerging concepts, such as mindfulness and positive attention training. In the current study the 2012 versions of the programs was implemented (Barrett, 2012a, 2012b, 2012c, 2012d, 2012e, 2012f)

Developmental iterations and content

Four developmental iterations of the FRIENDS programs now exist: Fun FRIENDS for those aged 4 to 7 years (Barrett, 2012c, 2012f), FRIENDS for Life for those aged 8 to 11 years (Barrett, 2012a, 2012b; Gallegos, Rodríguez, Gómez, Rabelo, & Gutiérrez, 2012), My FRIENDS Youth for those aged 12 to 15 years (Barrett, 2012d, 2012e), and the STRONG NOT TOUGH Adult Resilience program for those aged 16 years or over (Barrett, 2012g, 2012h). These developmental iterations share all of the core components of the program but alter the delivery format and strategies to suit the developmental stage of the user, such as adding age specific skills such as friendship making skills in the Fun FRIENDS program or managing conflict in the adolescent and adult versions.

Core components of the FRIENDS program are listed in Figure 1 and start with understanding emotions in self and others, as well as the physiological reactions that go along with them; a foundation that other skills build upon. Relaxation skills are then explored, largely based on diaphragmatic breathing and progressive muscle relaxation, whilst also incorporating visualisation techniques. Cognitive awareness and restructuring is then taught (RED/GREEN Thinking) to help participants identify unhelpful thinking styles and challenge them. Exposure

hierarchies and rewarding yourself is then introduced, utilising all the skills already taught, to help participants take on challenges. Further factors to decrease vulnerabilities and increase resilience are then discussed, including support systems, health factors like sleep and diet, and building empathy. Finally building a plan to continue skill utilisation into the future. Although these skills are taught across all programs the manner in which they are taught differs substantially, for instance cognitive restructuring is taught as a game whilst racing around a room pretending to be vehicles started by "green" helpful thoughts and stopped by "red" unhelpful thoughts in the younger programs, whilst with adolescents and adults it is taught in a discussion format.

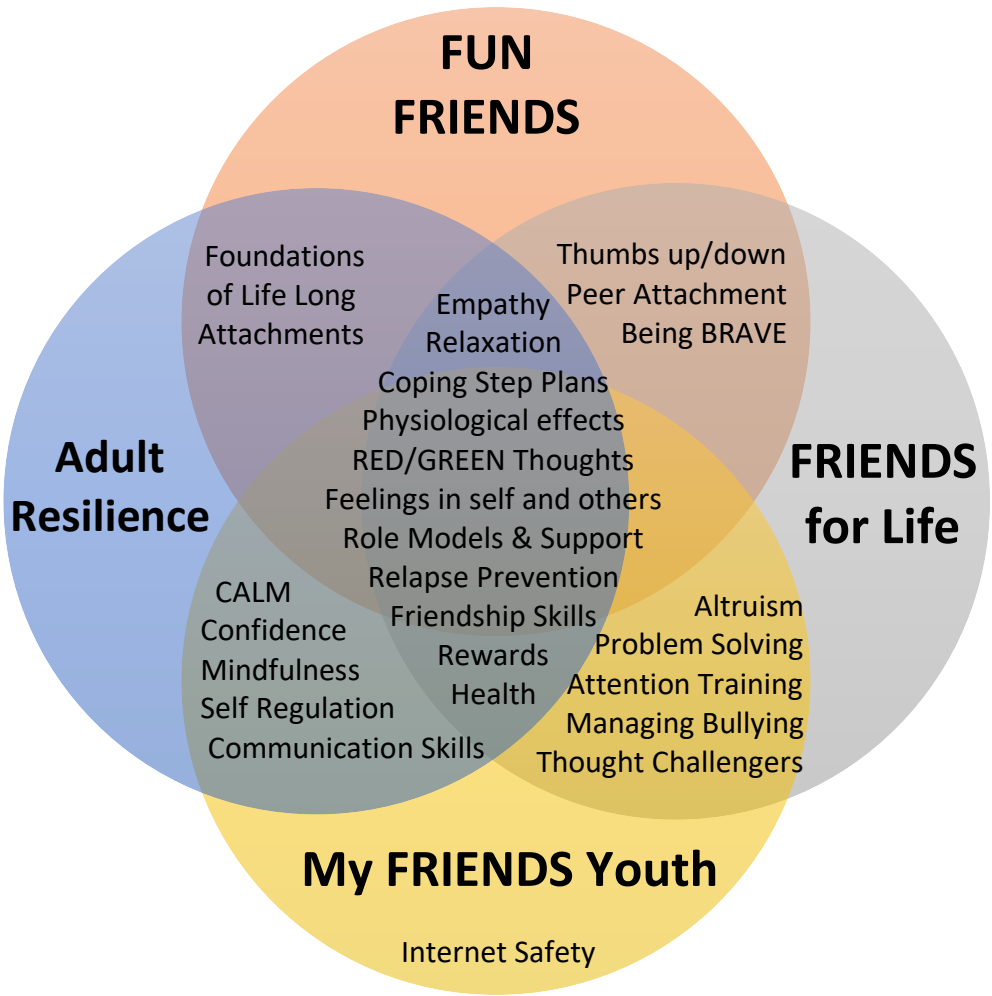

Figure 1. Skills shared across developmental iterations of the FRIENDS programs.

Different developmental iterations then share age specific skills, with the idea of having choice to act in a manner that helps us and others (thumbs up) as opposed to acting in an unhelpful way (thumbs down) being a focus for those aged 4-11 years old in both the Fun FRIENDS and FRIENDS for Life programs. Forming effective friendships and being brave by taking on challenges rather than avoiding them is also emphasised across these two age groups. Strategies shared between those aged 8-15 years old (FRIENDS for Life and My FRIENDS Youth) and the late adolescent to adult program, include problem solving and more directly challenging thoughts using questions. Utilising positive attention to increase confidence and being altruistic to increase happiness is also introduced. Bullying is also addressed with Internet safety being specifically discussed in the My FRIENDS Youth program. Effective and assertive communication, building confidence, and the difference between emotion soothing and regulation is then introduced for those aged 12 and above. Mindfulness is also more formally introduced beyond the positive attention training in younger versions.

Language and special population adaptations

The effectiveness of the FRIENDS programs has been supported by many studies across the world and has been adapted for special populations. These populations have included young people with developmental disorders like Autism (Slack, 2013), as well as adaptions and translations for non-English speaking backgrounds (Barrett, Sonderegger, & Sonderegger, 2001) and languages such as Japanese (Matsumoto & Shimizu, 2016), German (Essau, Conradt, Sasagawa, & Ollendick, 2012), Dutch (Kösters et al., 2017; Zwaanswijk & Kösters, 2015a), Norwegian (Wergeland et al., 2014), Portuguese (DeSousa et al., 2016) and Spanish (Gallegos et al., 2012).

Use as a both a treatment and prevention protocol.

Initially the FRIENDS programs were predominantly evaluated as treatment programs for anxiety (Shortt et al., 2001) and evolved to be used and evaluated as a preventative protocol across anxiety and depression (Barrett et al., 2006) with both showing long term follow up efficacy (Barrett, Duffy, et al., 2001; Barrett et al., 2006).

As a treatment protocol the FRIENDS programs has been evaluated a number of times, beginning with one of the earliest studies by Shortt et al. (2001). Shortt et al. (2001) conducted the first Randomised Control Trial of the FRIENDS programs with 71 young people aged 6 to 10 years old. Using the Revised Children's Manifest Anxiety Scale and the Child Behavior Checklist, this study demonstrated efficacy with 69% of young people being diagnosis free directly after the intervention as compared to only 6% in the Waitlist control, a number that was maintained at 12 month follow-up with 68% of young people still being diagnosis free at this time-point.

Subsequent studies, like the one reported by Liber et al. (2008), investigated the FRIENDS program as both a group and individual intervention, with 127 young people aged 8 to 12 years old randomly assigned to either format. The outcomes as measured on the Anxiety Diagnostic Interview Schedule indicated significant improvements with 62% of young people in the individual format and 54% in the group format being free of their primary diagnosis after the intervention and 48% in the individual and 41% in the group treatment being free of any anxiety diagnosis.

More recently a study by Wergeland et al. (2014) replicated this finding with the addition of a waitlist control condition. As measured by the Spence Children's Anxiety Scale, this study demonstrated effective outcomes for all those in treatment as compared to the waitlist control with an effect sizes of d=0.65 at post treatment. Once

Waitlist controls were also treated, effect sizes for both individual (*d*=0.52) and group (*d*=0.72) showed positive outcomes post treatment with little notable difference between them (*d*=0.05). These effects translated into 61.3% being free of at least one diagnosis in the individual treatment and 30.7% being free of all anxiety diagnoses compared to the group intervention, which yielded 69.6% free of at least once diagnosis and 28% being free of all diagnoses. At 12 month follow-up, these results became even more prominent with effect sizes rising to 0.81 and 0.96 respectively, leaving 70.4% in the individual condition without at least one diagnosis, and 42.3% free of all anxiety disorders, whilst 75.7% of those in the group intervention were free of at least one diagnosis and 48.9% free of all anxiety disorders.

Rodgers and Dunsmuir (2015) conducted a targeted treatment randomised controlled trial in a school based setting in Ireland. They assessed both the outcome on anxiety and school adjustment for 62 12-13 year olds. Their results indicated a significant negative association between school adjustment and anxiety. Despite this association the significant reduction in anxiety achieved for those who completed the FRIENDS programs as compared to the control group, did not result in improved school adjustment at post or 4 month follow-up. Eiraldi et al. (2016) compared three group based CBT interventions including the FRIEDNS program at pre and post outcome and although not statistically compared to each other the FRIENDS programs produced a significant reduction in diagnostic severity across internalising and externalising disorders for 70% of participants at three month follow-up as opposed to 60 and 55% for the other interventions. Together these results demonstrate that the FRIENDS programs are effective at treating anxiety disorders in both individual and group formats across several different cultures and languages.

As a preventative protocol, the FRIENDS programs have been evaluated as both a universal and targeted prevention delivered by health professionals and teachers in schools and clinics to children (Barrett et al., 2006; Barrett, Sonderegger, et al., 2001; Fisak, Gallegos-Guajardo, Verreynne, & Barrett, 2018; Higgins & O'Sullivan, 2015; Skryabina, Taylor, & Stallard, 2016; Stallard et al., 2014; Zwaanswijk & Kösters, 2015b). Fisak et al. (2011) identified 10 studies using the FRIENDS programs as a preventative protocol and concluded that studies of the FRIENDS programs had higher effect sizes than studies not using the FRIENDS programs. Studies using the FRIENDS program showed Cohen's d effect sizes of 0.25 as compared to 0.11 for those using other interventions. Since then Kozina (2018) looked not only at the effect on preventing internalising disorders but also demonstrated a reduction in aggressive and conduct related behaviours as compared to a control group at 6 months follow-up.

Conclusions

The FRIENDS programs utilised in the current study come from comprehensive Cognitive Behavioural Therapy roots with close to two decades of development and refinement in the current versions. They have been shown to be effective as intervention and prevention protocols and have been adapted to suit many populations, cultures, and languages. The multiple developmental iterations allow for the same set of core skills to be effectively delivered to different age groups. As such they provide an excellent starting point to evaluate the effects of changing the delivery format of an already effective intervention. Chapter 4 describes the methods for the main study detailed in this thesis utilising the FRIENDS programs to add to the relative paucity of studies investigating intensive formats for delivering CBT to young people.

Chapter 4. Method: Delivering the FRIENDS programs in a private practise clinic setting: Standard vs. Intensive delivery.

Study Design

The study was an open effectiveness trial with no randomization, inclusion, or exclusion criteria. This design was chosen as it was the only practical choice in a real world pay-for-service private community clinic that would not ethically or logistically allow for randomisation or allocation to an inactive control condition. Conducting a study in this manner obviously opens the trial to several confounding factors, such as clients possibly choosing a condition based on a variable that could impact outcome such as initial severity or socio-economic status. These factors may weaken conclusions that may be drawn from the study. However, it also allows for a pragmatic example of the interventions in a real world setting which allows for interpretations of the data in health care settings that are inherently uncontrolled.

Ethics

Ethical approval was obtained for gathering data as part of care at the clinic as part of the wider project including other research topics based in the same setting, from the University of Queensland, School of Education, Research Ethics Committee. The use of the data for this project to specifically compare standard to intensive delivery was submitted as an amendment to the University of Queensland as well as a separate application to the Australian National University Human Research Ethics Committee where this research was hosted (Appendix 3).

Recruitment

All participants were clients of a private community-based psychology clinic situated in Brisbane, Australia, that was run by Paula Barrett, the author of the FRIENDS programs

and were either self-referred or referred through other medical, educational, or psychological services specifically to complete the FRIENDS group interventions. The clinic offers the full suite of FRIENDS programs as well as individual psychological services. All clients who participated in the groups between 1 January 2013 and 31 January 2015, totalling 428 young people and their families were invited to participate in the research when signing up to the groups and completed consent forms as part of their induction forms (Appendix 1 & 2). Those who consented to participating in research based at the clinic (including but not specifically identifying several concurrent projects) were sent links to a set of online surveys via supplied email addresses. The online surveys were administered in LimeSurvey. Participants were able to further discuss the research at the clinic with clinic staff and clinicians during the initial group sessions. Participants were not aware of the particular question, comparing standard to intensive delivery, being investigated in this thesis. Participants were offered the opportunity to receive a research summary via email at the completion of the study, that was sent out after follow-up data collection was completed. Participants were offered an additional 1-2 session individual follow up sessions upon completion of the study as an incentive. This was chosen as it did require any additional funding. The population therefore consisted of parents and children receiving treatment or prevention services in a private community clinic setting.

Participants

Participants were 260 children and their families or carers. The children ranged in age from 4 to 15 years old and were divided into three developmental groups, age 4 to 7 years (N=127), 8 to 11 years (N=107), and 12 to 15 years (N=26). Self-reported annual household income ranged from $40,000 to $5,000,000 with an average of $164,000 a year. The families or carers were either the child's biological or adoptive parent(s), grandparents, or their foster carers. As the FRIENDS interventions were delivered in a

private community setting, participants self-selected their treatment condition based on the timing. As shown in Table 1, 174 children and their families or carers participated in the 'Standard' delivery and 86 children and their families or carers opted for 'Intensive' delivery. At entry 55% of participants had elevated anxiety symptoms (>1 SD above mean of Spence Anxiety Scales Total), 31% elevated depressive symptoms (>1 SD above mean of Children's Depression Inventory Total), with 25% being elevated on both, and the rest (39%) not having elevated anxiety or depression scores.

Table 1. Number of young people for whom data was included at each stage.

		Baseline	Post	Follow-Up
Standard	Fun FRIENDS	93	47	18
	FRIENDS for Life	63	39	17
	My FRIENDS Youth	18	6	0
	Total	**174**	**92**	**35**
Intensive	Fun FRIENDS	34	22	7
	FRIENDS for Life	44	23	7
	My FRIENDS Youth	8	6	1
	Total	**86**	**51**	**15**
Total	Fun FRIENDS	127	69	25
	FRIENDS for Life	107	62	24
	My FRIENDS Youth	26	12	1
	Total	**260**	**143**	**50**

A statistical power analysis was performed for sample size estimation, based on data from the meta-analysis by Fisak et al. (2011), comparing studies utilising the FRIENDS programs to those who don't on preventative effects for anxiety. Given the preventative scope of this analysis the effect size (ES was a very conservative 0.25, considered to be small using Cohen (1988) criteria. With an alpha = .05 and power = 0.80, the projected sample size needed with this effect size (GPower 3.1) was

approximately N = 128 for this simplest between group comparison. Thus, the initial total sample size of N=260 was deemed adequate for the main objective of this study and should also allow for expected attrition and our additional objectives of controlling for possible mediating/moderating factors/subgroup analysis, etc.

Treatment Conditions

Standard 10 weekly sessions FRIENDS programs.

In this condition, Fun FRIENDS 3rd Edition was provided to those aged 4 to 7 years (Barrett, 2012c, 2012f), FRIENDS for Life 6th Edition to those aged 8 to 11 years (Barrett, 2012a, 2012b), and My FRIENDS Youth 6th Edition to those aged 12 to 15 years (Barrett, 2012d, 2012e). Additionally, all parents and carers were invited to complete the Adult Resilience program, an adult iteration of the FRIENDS programs. All programs were delivered in the standardised format prescribed in their manuals and all shared the same core components with modifications in delivery format, examples, and age specific skills for each age group. Sessions lasted 1.5 hours each, with the final 15 minutes shared between the parent and child groups. Groups were run in a large room with a group table and chairs at one end and an open activities area at the other, based at a private community-based psychology clinic situated in Brisbane, Australia.

Intensive 10 daily sessions over 2 weeks FRIENDS programs.

This condition was identical to the standard program described above except that sessions were delivered across a 2-week period instead of in 10 weekly sessions. Sessions were generally offered Monday to Friday on two successive weeks, although some sessions were delivered during weekends to compensate for missed sessions on public holidays. This format was chosen to fit within a typical two week school holiday period. Sessions again lasted 1.5 hours each, with the final 15 minutes shared between the parent and child groups.

Therapists

All therapists were registered Psychologists and Clinical Psychologists with the Australian Health Practitioner Regulation Authority and were trained in the FRIENDS programs. The author of this thesis, Marthinus Bekker, an early career Clinical Psychologist, facilitated approximately half of the children's groups, evenly across conditions, predominantly alongside one other clinically trained Psychologist who was completing their clinical scope registration years (a few sessions were filled in by temporary staff due to illness or scheduling). Therapists were not blinded, although data was de-identified before handling. All therapists received approximately fortnightly supervision from the program's author, Paula Barrett, consisting of group discussions about teaching aspects of the programs, managing challenging behaviour in group settings, and adapting teaching to individual needs of clients in each group. No formal protocol adherence measures were completed across therapists.

Measures

All measures were completed by parents or caregivers of the young people who participated in the groups. Demographic and clinical information was collected on gender, age, the relationship of the respondent to the child, occupation of parents, presence of siblings, family income, custody and residence, school, medical history, utilization of therapy, and family mental health history (Appendix 4). Additionally, information about the child's diet, sleep per week, and activity habits was collected including typical nutritional content, amount and quality of sleep per week, amount of time spent on electronic entertainment devices such as tablets and televisions, outdoor and sports activity, as well as social activity (Appendix 4).

Spence Child Anxiety Scale (SCAS) parent version and the Pre-School Anxiety Scale (PSAS).

Developed by Spence and her colleagues (Nauta et al., 2004; Spence, 1998; Spence, Rapee, McDonald, & Ingram, 2001) both the SCAS and PSAS assess anxiety symptoms in line with the DSM-IV-TR diagnostic system. The scales assess six domains of anxiety including generalized anxiety, panic/agoraphobia, social phobia, separation anxiety, obsessive compulsive disorder and physical injury fears. Both the SCAS and PSAS demonstrate good psychometric properties with strong factor structures and both had high internal consistency for total scores in the current study with Cronbach's Alpha values of 0.90 and mostly adequate scores for individual domains with Cronbach's Alpha values ranging from 0.44 to 0.88 (Nauta et al., 2004; Spence, 1998; Spence et al., 2001). Only the Preschool OCD scale and the Child Physical symptom scales fell under 0.6.

Children's Depression Inventory: Parent Version (CDI:P).

The CDI:P is a 17-item scale that assesses overall levels of depressive symptoms in young people aged 7–17 years as rated by their parents or caregivers (Kovacs, 2004). The CDI assesses depressive symptoms such as sadness, relationship changes, school functioning, and changes in appetite. The CDI is a well validated measure and the parent version has previously also shown good psychometric properties (Moretti, Fine, Haley, & Marriage, 1985; Wierzbicki, 1987). The CDI:P demonstrated high internal consistency, with a Cronbach's Alpha of 0.82 (Kovacs, 2004).

Strengths and Difficulties Questionnaire (SDQ).

The SDQ is a brief behavioural screening questionnaire for young people aged 3-16 year olds (Goodman, 1997). It assesses strengths and difficulties across five domains: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behaviour. The SDQ has demonstrated acceptable psychometric properties in the existing literature (Goodman, 2001). It has demonstrated adequate

internal consistency with a Cronbach Alpha of 0.79 for the total difficulties scale and values ranging between 0.67 and 0.82 across the other domains (Goodman, 2001).

Devereux Student Strengths Assessment (DESSA).

The DESSA is a 72-item, behaviour rating scale that assesses the social-emotional competencies that serve as protective factors for children and young people (LeBuffe, Shapiro, & Naglieri, 2009). These are measured across a variety of domains including optimistic thinking, relationship skills, self-awareness, personal responsibility, self-management, goal-directed behaviour, social-awareness, and decision making. The DESSA has excellent psychometric properties (Nickerson & Fishman, 2009). It showed high internal consistency with the Cronbach Alpha for the total score being 0.97 with individual domains ranging from 0.78 to 0.90.

Procedure

Participants were clients of the clinic as detailed above and were assigned to their families' choice of intervention - either intensive or standard delivery. Participants completed the programs described above alongside clients who chose not to participate in the research study, with 3:2 ratio in favour of study participants. In total 44 groups of young people and their parents started the intervention between 1 January 2013 and 31 January 2015. The programs were delivered in the manner prescribed by each program's respective manual. A maximum of one month prior to the group starting and prior to starting, the parents or caregivers of all group participants were sent an email with a link to relevant surveys, as outlined above, on LimeSurvey. Responses were accepted up until the start of the second session. Parents/caregivers who consented to participate in the research were subsequently sent up to three e-mail reminders at least one week apart to encourage them to complete the baseline survey. In addition, if necessary up to five attempts were

made to contact the parent/caregiver by telephone to encourage survey completion. However, no further contact was attempted once two actual contacts were made. Participants who completed baseline assessments and had not opted out were sent the same set of surveys again on the day of completion (and given up to a month to complete the survey, although most completed it within the days after completing the intervention) and again at one year after completion of the group with the same follow up procedure as above (responses were more spread out at this time point). Participants and their families were offered up to two individual follow-up sessions at the completion of post- and 12- month surveys. Individual sessions could be used in any manner the family wanted and were mostly used to individualise program skills to the specific challenges the family was experiencing.

Analysis

Results from all measures were prepared for analyses with total and domain scores for each measure being calculated according to their respective manuals or published instructions. SCAS and PSAS scores were converted to standardised scores from their respective normative samples (Nauta et al., 2004; Spence et al., 2001). These normative scores were then pooled together into their respective shared domains except for Panic which was only included in the SCAS. Means and standard deviations were calculated for each domain score at baseline, post, and follow-up for completers. Within-group standardized mean difference (Cohen's d) effect sizes were calculated separately for Intensive and Standard delivery formats. Furthermore, the change from baseline to post and from baseline to follow up was calculated for each domain and from the means and standard deviations of these between-group standardized mean difference (Cohen's d) effect sizes were calculated between Intensive and Standard delivery formats.

For the main analysis, a series of Mixed Model Repeated Measures (MMRM) analyses were completed (Molenberghs & Verbeke, 2001). These analyses were undertaken on an Intent-to-Treat basis and allowed for fixed effects of time, format and their interaction (the critical test of whether there were differences between formats), along with a repeated (within-subject) effect of time. Intent-to-treat analysis included all participants (N=260) even if they only completed baseline measures, which was 174 participants in the Standard format and 86 in the Intensive. This analysis assumes that data were missing at random, which is accounted for by only dropping a single time point rather than a whole participant if it was missing (Maxwell & Delaney, 2004), meaning that all available data were incorporated. This approach was well suited to the current context due to the attrition of participants over time, and is more robust to missingness than casewise deletion or last observation carried forward (Molenberghs & Verbeke, 2001). The analyses assumed an unstructured variance-covariance matrix. No transformations were made as any violations of assumptions were likely to be minimal and analysis without transformation allowed for direct interpretation of the outputs. The measures and their domains above (SCAS, PSAS, CDI, SDQ, & DESSA) were the dependent variables. Statistical analyses were conducted in SPSS v23 (IBM Corp, IL, USA).

Chapter 5: Baseline comparisons and drop out

As discussed in Chapter 4, this study is an open effectiveness trial and although intervention dropout was minimal (one family did not complete), attrition of those completing surveys and essentially dropping out of the study component was substantial (Table 1). Gustavson, von Soest, Karevold, and Røysamb (2012) note that differences between participants who stay in a study and those who dropout can limit the generalizability of the findings from the study. As such, comparison of those who stay in a study longer to those who drop out earlier can assist in identifying areas of potential biases that may be associated with dropout. Open effectiveness trials without randomization are also prone to selection biases as participants may have an underlying common bias for selecting one intervention over another. Therefore, comparing attributes and baseline scores between formats is important to establish the comparability of the two self-selected samples and potential for biases.

Comparison of baseline characteristics across dropout points

To compare baseline characteristics across different points of drop out a Multinomial Regression Analysis was conducted in SPSS v23 (IBM Corp, IL, USA). The dependent variable was created by coding for having completed only the baseline measures, the baseline and post measures, and finally all three time points at baseline, post, and 12 month follow up. Independent variables included main demographic variables, age, gender, and household income; as well as, which condition they were in and the total scores from the main outcome measures, the CDI-P, SAS, SDQ, and DESSA.

Addition of predictors to a model that only contained the intercept did not significantly improve the fit between the model and the data, $\chi^2(14, N=266) = 15.39$, Nagelkerke $R^2 = 0.079$, $p = 0.35$. This statistic suggests that baseline values across both demographic and outcome variables did not significantly differ between those who completed only baseline measures, those who completed baseline and post measures, and those who completed baseline, post, and follow-up measures.

Baseline Comparisons

Comparing attributes and baseline scores between intervention formats using ANOVA analysis showed no significant difference in gender, age, household income. There were slightly more males than females in both the Standard and Intensive formats but no significant difference (t (251) = 0.79, p = 0.43) between the gender ratios of formats. Similarly, age showed only 0.47 years difference between the averages for the formats, which was not significant (t (251) = 1.35, p = 0.18). The difference in average household income was less than AU$2000 between formats which was also not significant (t (219) = 0.014, p = 0.89).

All of the measures, SAS, CDI-P, SDQ, and DESSA, and their respective subscales showed no significant differences in their means at baseline between the standard and intensive delivery formats (Table 2, p >0.05). This indicates that although the samples were self-selected they are generally comparable and relatively free from obvious biases at baseline on the basis of the included measures.

Table 2. Baseline characteristics on demographic and main measures across formats.

		Standard Format			Intensive Format					
		N	Mean	SD	N	Mean	SD	*t*	*p*	df
	Gender	168	1.45	0.50	85	1.40	0.49	0.79	0.43	251
	Age	168	7.39	2.66	85	7.86	2.54	1.35	0.18	251
	Household income	150	159566	76200	71	161380	123491	0.13	0.89	219
SAS	Generalised Anxiety	168	2.15	2.48	85	1.96	2.88	0.55	0.59	251
	Social Anxiety	168	1.64	2.37	85	1.44	2.13	0.68	0.49	251
	Obsessive Compulsive	168	0.84	1.67	85	0.49	1.87	1.50	0.13	251
	Physical Anxiety	168	0.28	1.57	85	0.02	1.71	1.20	0.23	251
	Separation Anxiety	168	0.92	2.04	85	0.83	2.41	0.31	0.75	251
	Panic Symptoms	120	0.76	2.68	66	0.54	1.81	0.61	0.54	184
	Total	168	1.51	2.13	85	1.22	2.33	0.99	0.33	251
CDI-P	Emotional Problems	167	7.03	4.05	85	6.19	4.05	1.63	0.11	250
	Functional Problems	167	5.80	3.22	85	5.58	3.22	0.51	0.61	250
	Total	167	14.9	6.94	85	13.8	6.14	1.23	0.22	250
SDQ	Emotional Problems	168	3.76	2.55	85	3.35	2.29	1.23	0.22	251
	Conduct Problems	168	2.59	2.08	85	2.72	2.134	0.46	0.65	251
	Hyperactivity	168	4.40	2.91	85	4.68	3.15	0.70	0.49	251
	Peer Problems	168	2.77	2.27	85	2.66	2.15	0.37	0.71	251
	Impact Score	168	3.10	2.51	85	3.07	2.57	0.09	0.93	251
	Prosocial	168	7.00	2.12	85	7.40	2.19	1.40	0.16	251
	Total Difficulties	168	13.52	6.50	85	13.41	6.04	0.13	0.90	251
DESSA	Self Awareness	167	16.25	4.61	85	16.33	3.68	0.13	0.89	250
	Social Awareness	167	20.79	5.10	85	20.64	4.66	0.23	0.82	250
	Self Management	167	24.11	6.53	85	24.73	5.92	0.74	0.46	250
	Goal Directed Beh.	167	23.87	7.19	85	23.99	7.01	0.13	0.90	250
	Relationship Skills	167	25.57	6.20	85	26.32	5.86	0.92	0.36	250
	Personal Respons.	167	22.95	6.12	85	23.56	5.99	0.76	0.45	250
	Decision Making	167	20.20	4.93	85	20.31	4.81	0.17	0.87	250
	Optimistic Thinking	167	17.13	4.53	85	17.04	4.48	0.15	0.88	250
	Total Score	167	170.86	38.20	85	172.91	34.94	0.41	0.68	250

Note: SAS: Spence Anxiety Scales (combined SCAS AND PAS); CDI-P: Children's Depression Inventory - Parent Version; SDQ: Strengths and Difficulties Questionnaire; DESSA: Devereux Student Strengths Assessment; 'Standard': 10 weekly sessions; 'Intensive': 10 daily sessions.

Chapter 6: Results

Primary Outcomes

The primary outcomes of the study were anxiety and depression symptoms.

Effects on Anxiety Symptoms

To explore the effects on anxiety of the Standard 10-week intervention relative to the Intensive 2-week intervention the combined SCAS-P and PSAS T-scores were compared at baseline, post, and 12-month follow-up. Data and results of the MMRM analyses for the Total scores and each of the subscales for the combined Spence Anxiety Scales are shown in Figure 2 and Table 3.

Total scores: As shown in Table 3, there was a significant main effect for format (F (1,182) = 4.12, p = 0.04), a significant main effect of time (F (2,80) = 25.18, p < 0.01), but no significant interaction between time and format (F (2,80) = 2.04, p = 0.14), indicating that anxiety scores improved significantly over time for both intervention formats but that the magnitude of this change did not differ significantly across formats. Cohen's d within-group effect sizes (Table 4) indicated that the decreases in the Total Anxiety score were small at post-test for both conditions (Standard, d = -0.21; Intensive, d = -0.25) which was slightly higher at follow-up but still with a small effect for the Standard condition (d = -0.34) and a large effect for the Intensive (d = -0.90) condition. A very small effect between Standard and Intensive from baseline to post (d = 0.10) was observed, with a small between-group effect (d = -0.36) from baseline to follow up in favour of the Intensive format. This effect indicated a trend for the Intensive format being more effective at follow-up although it was not significant in the MMRM analysis.

Sub-scale scores: As illustrated in Figure 2 and Table 3, a similar pattern to that of the total score was evident across all five shared sub-scales of the Spence scales (Generalised Anxiety, Social Anxiety, Obsessive Compulsive, Physical Anxiety, and Separation Anxiety) as well as for the Panic scale from the SCAS-P only. Specifically, mixed main effects were found for format, significant main effects were found for time across all subscales, and non-significant interactions between time and format were observed. Again, the findings of these analyses suggest that each of these subscales improved significantly across the time points for both Intensive and Standard delivery but that the formats did not differ from each other.

Within group effects (Table 4) also showed a similar trend to that observed for the total score with small or very small decreases in the anxiety subscales (d = -0.06 – -0.35) at post-test for both formats. This decrease increased somewhat at 12-month follow-up with small decreases for all domains (d = -0.24 – -0.45) except Social Anxiety (d = -0.15) on the Standard format and medium and large decreases across all subscales (d = -0.57 – -0.81) for the Intensive format. When effects were compared between formats there were mostly very small effects between the Standard and Intensive formats from baseline to post (d = -0.07 – 0.21) which increased to small and medium between-group effects from baseline to follow up in both directions. Most were in favour of the Intensive format (d = -0.38 – -0.61) including Generalised Anxiety, Social Anxiety, Physical Anxiety, and the Panic scale from the SCAS-P. The remaining two domains, Separation Anxiety and Obsessive Compulsive Disorder, were in favour of the Standard format with small effects (d = 0.23 – 0.29). It is important to note that these trends in effect sizes are not significant in the MMRM analysis.

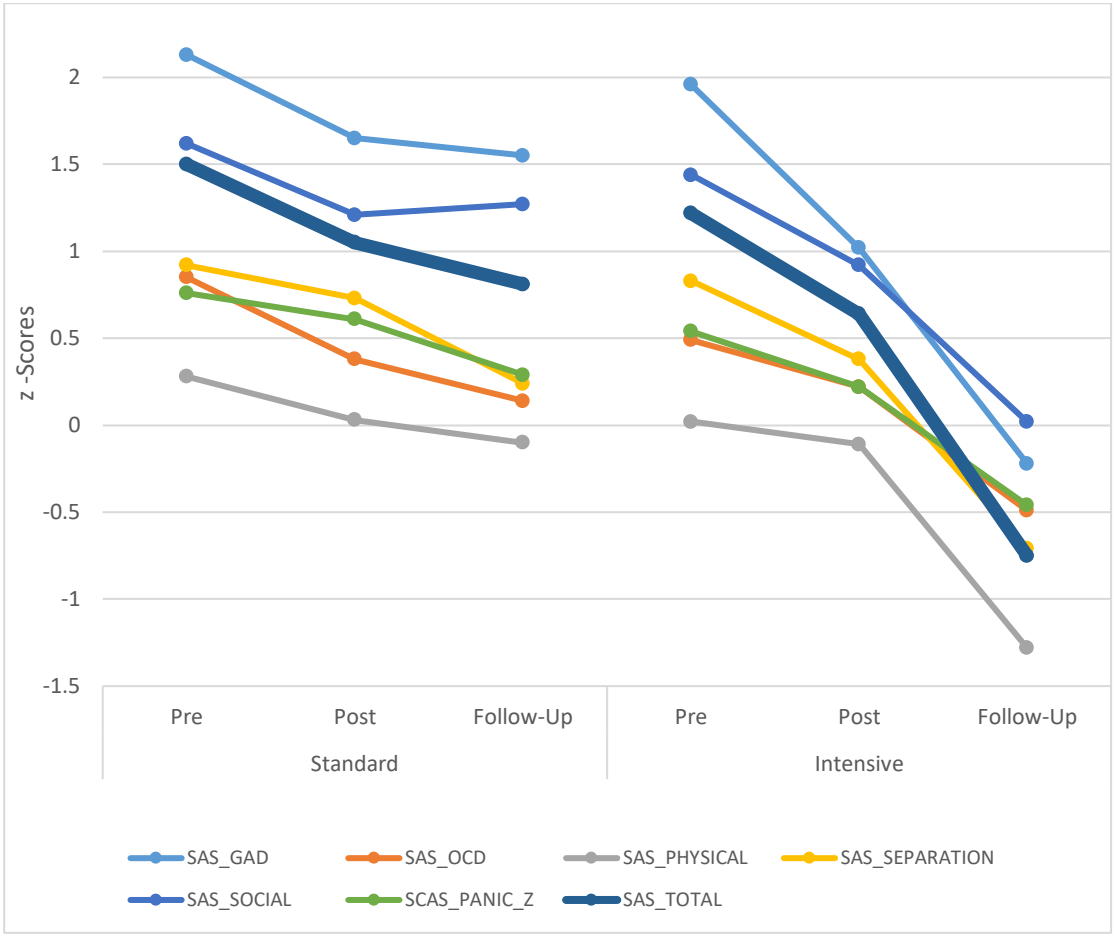

Figure 2. Observed means for Spence Anxiety Scales at baseline, post, and 12 month follow up across formats

Figure: Figure 2 shows a reduction from time point to time point across the observed mean total scores and all subscales for both conditions except for Social Anxiety which reduced from baseline to post but very slightly increased at follow-up in the Standard delivery but not in the Intensive. There also appears to be a more marked decrease in Generalised Anxiety in the Intensive Condition as compared to Standard at both post and follow-up. A general trend across all of the scales showed larger post to follow-up reductions in the Intensive condition as compared to the Standard condition, which is consistent with the effect sizes observed.

Effects on Depressive Symptoms

The effect of the two interventions on depressive symptoms was examined using the CDI-P scores at baseline, post, and 12-month follow-up (see Table 4, Figure 3).

Total scores: MMRM analyses of the Total Depression score showed no significant effect for format (F (1,118) = 3.26, p = 0.07), a significant main effect of time across both formats (F (2,82) = 28.28, p < 0.01), and no significant interaction of format and time (F (2,82) = 0.67, p = 0.51). The results of these analyses indicate that total depressive symptoms significantly reduced across time but that the magnitude if this change did not differ across formats. Effect sizes (Table 5) showed small decreases in depressive symptoms for both the Standard (d = -0.49) and Intensive (d = -0.39) formats from baseline to post-test with a similar effect at 12 month follow-up for the Standard format condition (d = -0.47) and large decrease in total depressive symptoms for the Intensive format (d = -0.90) at follow-up. Between format effects from baseline to post were very small (d = 0.07) which increased to a small between effect (d = -0.20) from baseline to follow up in favour of the Intensive format. The findings of these analyses indicate a trend towards the Intensive format being more effective at follow up which is not significant in the MMRM analysis.

Sub-scale scores: As illustrated in Figure 3 and Table 4, a similar pattern to that of the total score was evident across both sub-scales of the Children's Depression Inventory, Parent Version, with no significant main effects of format for the Emotional Problems Scale (F (1,125) = 2.36, p = 0.13) or the Functional Problem Scale (F (1,124) = 0.93, p = 0.34), significant main effects of time for the Emotional Problems Scale (F (2,74) = 14.57, p < 0.01) and the Functional Problem Scale (F (2,88) = 25.61, p < 0.01), and non-significant interactions between time and format

for the Emotional Problems Scale (F (2,74) = 0.51, p = 0.61) or the Functional Problem Scale (F (2,88) = 0.12, p = 0.88). This again indicates that both intervention formats decreased both emotional and functional symptoms of depression, but the magnitude of this change did not differ between formats. Within group effects (Table 5) also showed a similar trend to that observed for the total score with mostly small effects (d = -0.33 – -0.44) at post-test for both formats which remain small (d = -0.25 – -0.40) for the Standard format and become medium in size (d = -0.52 – -0.67) for the Intensive format at 12-month follow-up. Between-group effect sizes comparing Standard and Intensive formats from baseline to post indicated very small effects (d = -0.04 – 0.15). These increased to a small effect (d = -0.27) for the Functional problems from baseline to follow-up, favouring the Intensive format and remains a very small effect (d = -0.03) on the Emotional problems subscale. These trends in effect sizes were not significant in the MMRM analysis.

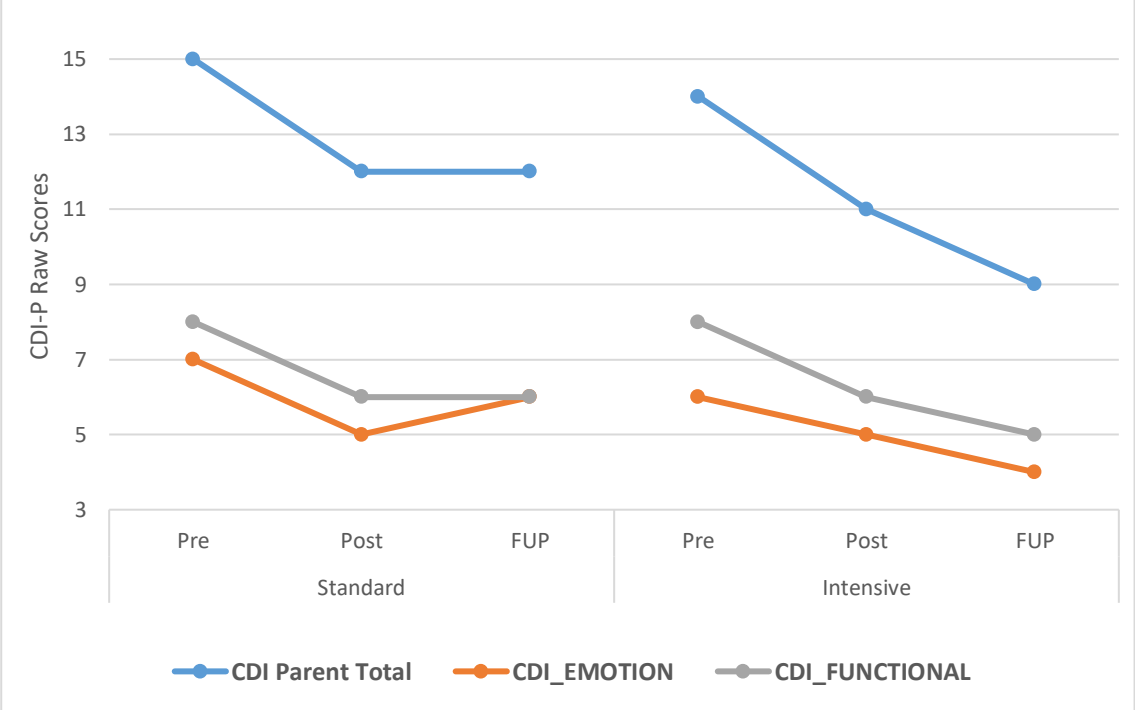

Figure 3. Observed means for Child Depression Inventory –Parent version at baseline, post, and 12 month follow up across formats with subscales on left axis and total on the right axis.

Figure: Figure 3 shows a slightly lower start point of the observed means for the Intensive delivery as compared to the Standard delivery for the Total Depression score, although this was not significant in baseline comparisons (Table 4) with a similar decrease for both formats from baseline to post. Standard delivery stayed very similar from post to follow-up with only a slight non-significant increase. The Intensive delivery continued to improve with a substantial decrease in the Total Depression Score from post to follow up. These visual trends fit with effect sizes observed.

Table 3. MMRM result for Standard and Intensive formats across baseline, post, and follow-up time points.

		Main Effect: Format			**Main Effect: Time**			**Interaction between format and time**		
		df	F	*p*	df	F	*p*	df	F	*p*
SAS	GAD	1, 174	4.34	0.04	2, 81	20.72	<0.01	2, 81	2.38	0.10
	Social Anxiety	1, 184	2.41	0.12	2, 79	16.61	<0.01	2, 79	0.95	0.39
	OCD	1, 195	2.24	0.14	2, 96	14.28	<0.01	2, 96	0.46	0.63
	Physical Injury Fears	1, 189	5.18	0.02	2, 80	8.38	<0.01	2, 80	2.97	0.06
	Separation Anxiety	1, 178	0.24	0.62	2, 78	14.33	<0.01	2, 78	0.19	0.83
	SCAS Panic	1, 157	2.83	0.09	2, 80	5.89	<0.01	2, 80	1.20	0.31
	Total	1, 182	4.12	0.04	2, 80	25.18	<0.01	2, 80	2.04	0.14
CDI-P	Emotional Problems	1, 125	2.36	0.13	2, 74	14.57	<0.01	2, 74	0.51	0.61
	Functional Problems	1, 124	0.94	0.34	2, 88	25.61	<0.01	2, 88	0.12	0.88
	Total	1, 118	3.26	0.07	2, 82	28.28	<0.01	2, 82	0.67	0.51
SDQ	Emotional Problems Scale	1, 165	6.48	0.01	2, 83	20.19	<0.01	2, 83	1.79	0.17
	Conduct Problems Scale	1, 161	0.39	0.53	2, 83	10.15	<0.01	2, 83	0.02	0.98
	Hyperactivity Scale	1, 174	1.69	0.19	2, 73	2.03	0.14	2, 73	0.60	0.55
	Peer Problems Scale	1, 181	0.01	0.94	2, 74	3.89	0.02	2, 74	0.29	0.75
	Impact Score	1, 143	0.19	0.66	2, 96	33.76	<0.01	2, 96	2.83	0.06
	Prosocial Scale (Reverse scored)	1, 185	0.82	0.37	2, 72	1.81	0.17	2, 72	0.71	0.49
	Total Difficulties	1, 171	0.01	0.94	2, 74	17.24	<0.01	2, 74	0.07	0.93
DESSA	Self-Awareness	1, 146	0.38	0.54	2, 70	89.93	<0.01	2, 70	0.36	0.70
	Self-Management	1, 150	0.05	0.83	2, 70	120.02	<0.01	2, 70	0.30	0.74
	Social Awareness	1, 138	0.04	0.85	2, 71	107.97	<0.01	2, 71	0.41	0.67
	Goal Directed Behaviour	1, 157	<0.01	0.98	2, 71	86.72	<0.01	2, 71	0.05	0.95
	Relationship Skills	1, 181	0.30	0.59	2, 70	104.90	<0.01	2, 70	0.13	0.88
	Personal Responsibility	1, 154	0.24	0.62	2, 71	117.74	<0.01	2, 71	0.07	0.93
	Decision Making	1, 158	0.40	0.53	2, 71	98.72	<0.01	2, 71	0.18	0.83
	Optimistic Thinking	1, 151	0.06	0.80	2, 71	104.56	<0.01	2, 71	1.90	0.16
	Total	1, 157	0.08	0.78	2, 70	136.25	<0.01	2, 70	0.27	0.76

Note: SAS: Spence Anxiety Scales (combined SCAS AND PAS); SDQ: Strengths and Difficulties Questionnaire; CDI-P: Children's Depression Inventory, Parent Version; DESSA: Devereux Student Strengths Assessment; 'Standard': 10 weekly sessions; 'Intensive': 10 daily sessions; 'Main Effect: Time': MMRM analysis across baseline, post and 12-month follow-up time points; 'Interaction between format and time': MMRM analysis of the interaction between time points and intervention group.

Table 4. Effect Sizes for Standard and Intensive formats as well as Between format effects across baseline to post and baseline to follow-up time points.

		Baseline Post						Baseline Follow Up					
		Standard		Intensive		Between		Standard		Intensive		Between	
		Cohen's d	Descriptor	Cohen's d	Descriptor	Cohen's d	Descriptor	Cohen's d	Descriptor	Cohen's d	Descriptor	Cohen's d	Descriptor
SAS	GAD	-0.20	Small	-0.35	Small	0.10	Very Small	-0.24	Small	-0.81	Large	-0.48	Small
	Social Anxiety	-0.18	Very Small	-0.25	Small	-0.07	Very Small	-0.15	Very Small	-0.69	Medium	-0.38	Small
	OCD	-0.29	Small	-0.14	Very Small	0.15	Very Small	-0.45	Small	-0.57	Medium	0.23	Small
	Physical Injury Fears	-0.15	Very Small	-0.07	Very Small	0.05	Very Small	-0.25	Small	-0.81	Large	-0.51	Medium
	Separation Anxiety	-0.09	Very Small	-0.20	Small	0.21	Small	-0.35	Small	-0.69	Medium	0.29	Small
	SCAS Panic	-0.06	Very Small	-0.17	Very Small	0.03	Very Small	-0.20	Small	-0.61	Medium	-0.61	Medium
	Total	-0.21	Small	-0.25	Small	0.10	Very Small	-0.34	Small	-0.90	Large	-0.36	Small
CDI-P	Emotional Problems	-0.39	Small	-0.25	Small	0.15	Very Small	-0.33	Small	-0.67	Medium	-0.03	Very Small
	Functional Problems	-0.43	Small	-0.40	Small	-0.04	Very Small	-0.44	Small	-0.52	Medium	-0.27	Small
	Total	-0.49	Small	-0.39	Small	0.07	Very Small	-0.47	Small	-0.90	Large	-0.20	Small
SDQ	Emotional Problems Scale	-0.23	Small	-0.34	Small	0.04	Very Small	-0.27	Small	-0.85	Large	-0.39	Small
	Conduct Problems Scale	-0.36	Small	-0.16	Very Small	-0.06	Very Small	-0.38	Small	-0.21	Small	-0.29	Small
	Hyperactivity Scale	-0.22	Small	-0.11	Very Small	0.02	Very Small	-0.24	Small	-0.17	Very Small	-0.03	Very Small
	Peer Problems Scale	-0.22	Small	-0.14	Very Small	0.03	Very Small	-0.37	Small	-0.25	Small	-0.32	Small
	Impact Score	-0.48	Small	-0.06	Very Small	0.39	Small	-0.78	Medium	-0.98	Large	0.02	Very Small
	Prosocial Scale (Reversed)	0.22	Small	-0.04	Very Small	-0.13	Very Small	0.25	Small	0.18	Very Small	0.14	Very Small
	Total Difficulties	-0.38	Small	-0.29	Small	0.01	Very Small	-0.46	Small	-0.57	Medium	-0.39	Small
DESSA	Self-Awareness	0.33	Small	0.43	Small	0.21	Small	1.73	Large	2.26	Large	0.19	Very Small
	Self-Management	0.37	Small	0.30	Small	0.04	Very Small	2.12	Large	2.33	Large	0.03	Very Small
	Social Awareness	0.27	Small	0.35	Small	0.13	Very Small	2.19	Large	2.26	Large	0.07	Very Small
	Goal Directed Behaviour	0.39	Small	0.32	Small	-0.02	Very Small	1.66	Large	2.11	Large	0.00	Very Small
	Relationship Skills	0.26	Small	0.12	Very Small	0.09	Very Small	1.78	Large	1.66	Large	-0.02	Very Small
	Personal Responsibility	0.49	Small	0.37	Small	-0.02	Very Small	2.10	Large	2.27	Large	0.06	Very Small
	Decision Making	0.25	Small	0.20	Small	0.15	Very Small	1.79	Large	2.22	Large	0.23	Small
	Optimistic Thinking	0.35	Small	0.51	Medium	0.27	Small	2.01	Large	1.87	Large	-0.26	Small
	Total	0.40	Small	0.38	Small	0.13	Very Small	2.25	Large	2.52	Large	0.05	Very Small

Secondary Outcomes

Other Behavioural and pro-social outcomes

Strengths and Difficulties Questionnaire (SDQ) Total score: MMRM analyses of the Total Difficulties score showed no significant effect for format (F (1,171) = 0.01, p = 0.94), a significant main effect of time across both formats (F (2,74) = 17.24, p < 0.01), but no significant interaction between time and format (F (2,74) = 0.07, p = 0.93). These effects indicate that the total social and behavioural problem score significantly decreased across time but that the magnitude of this change did not differ across formats. Effect sizes (Table 5) indicated small decreases across time for both Standard (d = -0.38) and Intensive (d = -0.29) formats from baseline to post and small (d = -0.46) and medium (d = -0.57) decreases respectively at 12-month follow-up. Between format effects from baseline to post were very small (d = 0.01) which shifted to a small between effect (d = -0.39) from baseline to follow up in favour of the Intensive format. This trend toward the Intensive format having a bigger decrease in the total social and behavioural problem score on the SDQ was not significant in the MMRM analysis.

SDQ Social and Behavioural Sub-scale scores: A similar pattern in the MMRM analysis was evident across four of the five emotional, social and behavioural subscales of the SDQ (Emotional problems, Conduct problems, Peer problems, and the Impact score of these) with mixed main effects of format, significant main effects of time and non-significant interactions between time and format across all scales. The one subscale that did not follow this pattern was the hyperactivity scale which showed no significant effects for format, time or the interaction of those. Decreases in social and behavioural problem scales (Table 5) were all small for the standard intervention (d = -0.22 – -0.48) and mostly very small for the intensive intervention (d = -0.06 – -0.34). At 12 month follow up, decreases across the problem scales of the SDQ were mostly small (d = -0.24

- -0.78) for the Standard format with mixed effects ranging from very small (*d* = -0.17) through to large effects (*d* = -0.98) for the intensive format. The emotional problems subscale and the Impact subscale, which measures the impact of all the other difficulties on functioning, had large decreases (*d* = -0.85 – -0.98) at follow-up for the Intensive format. Between format effects from baseline to post showed mostly very small effects (d= -0.06 –0.04) except for the Impact score which had a small effect (*d* = 0.39) in favour of the Standard format. At follow-up, the between effects increases for the Emotional problems, Conduct problems, and Peer problems scales slightly to small effects (d = -0.29 – -0.39) in favour of the Intensive format. The between-format effect for Impact reduced to a very small effect (*d* = 0.02) and the hyperactivity remained very small (*d* = -0.03). The trends for larger decreases for the Intensive delivery at follow-up were not significant in the MMRM analysis.

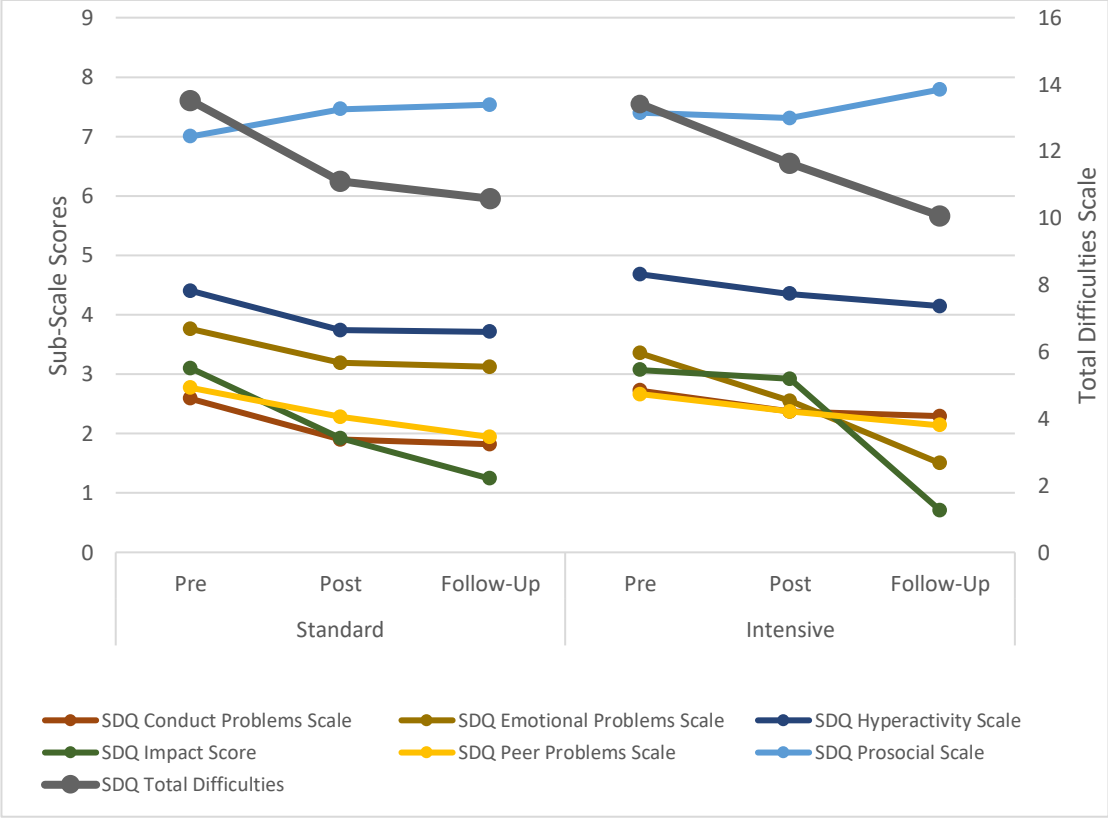

Figure 4. Observed means for Strengths & Difficulties Questionnaire at baseline, post, and 12 month follow *up across formats with subscales on left axis and total on the right axis.*

SDQ Prosocial Sub-scale score: The SDQ also has a prosocial scale which showed no significant main effect for format, no significant effect of time and no significant interaction between time and format indicating no changes across time or formats. Increases in this scale (Table 5) were small for standard delivery at post (d = 0.22) and follow up (d = 0.25). The Intensive format effect at post was very small in the opposite direction (d = -0.04) at post and remained very small at 12 month follow up (d = 0.18). Between format effects were very small from baseline to post (d = -0.13) and baseline to follow up (d = 0.14).

Figure: Figure 4 shows that the observed means for the total difficulty scores reduced in both conditions with similar decreases from baseline to post and Intensive having a steeper decrease from post to follow up, although the between-group effect was not significant. The prosocial scale increased slightly from baseline to post in the standard delivery with no marked change in the intensive, whilst at follow up the Standard delivery did not change much whilst the Intensive format did increase. The subscales mostly showed decreases between time points from baseline to post with more marked decreases for the standard delivery in the Impact, Conduct Problems, and Hyperactivity subscales. From post to follow up subscales generally showed a steeper decrease for the Intensive format. These trends fit well with the effect sizes described above but differences between formats are were not significant in the MMRM analysis.

Positive Outcomes

The effects of the two interventions on social-emotional competencies were assessed using the Devereux Student Strengths Assessment (DESSA) at baseline, post, and 12-

month follow-up (see Table 4, Figure 5). Note that since this assessment measures strengths, the effects are in a positive direction.

DESSA Total score: MMRM analyses of the Total score across the DESSA showed no significant effect for format (F (1,157) = 0.08, p = 0.78), a significant main effect of time across both formats (F (2,70) = 136.25, p < 0.01), but no significant interaction between format and time (F (2,70) = 0.27, p = 0.76). These results suggest that social-emotional competencies significantly increased across time but that the magnitude of this change did not differ across formats. Effect sizes indicated small increases for both Standard (d = 0.40) and Intensive (d = 0.38) formats from baseline to post and large effects for both Standard (d = 2.25) and Intensive (d = 2.52) formats at 12-month follow-up. Between format effects were very small (d = 0.05 – 0.13) from baseline to post and baseline to follow up.

DESSA Subscale scores: The same pattern as with the total score was evident across all eight sub-scales of the DESSA (Self Awareness, Self Management, Social Awareness, Goal Directed Behaviour, Relationship Skills, Personal Responsibility, Decision Making, and Optimistic Thinking) with no significant main effects of format, significant main effects of time, and non-significant interactions between time and format. Effects were mostly small (d = 0.25 – 0.51) at post across both formats, with the exception of Relationship skills which only had a very small increase (d = 0.12) in the Intensive format and Optimistic Thinking which had a medium increase (d = 0.51) in the Intensive format. At 12-month follow-up there were universally large effects (d = 1.66 – 2.33) for both formats. Between format effects were mainly very small (d = -0.02 – 0.27) from baseline to post and baseline to follow up.

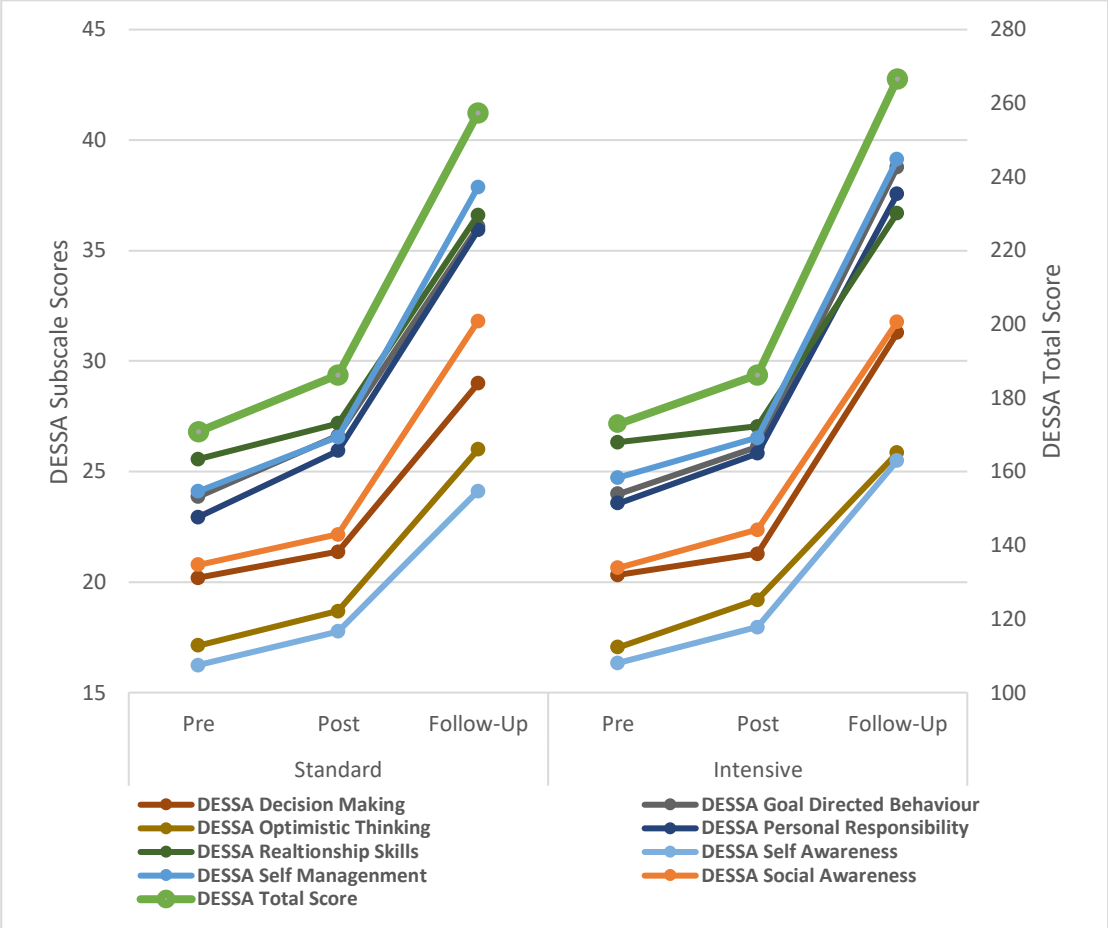

Figure 5. Observed means for Devereux Student Strengths Assessment (DESSA) at baseline, post, and 12 month follow up across formats with subscales on left axis and total on the right axis.

Figure: Figure 5 shows almost identical patterns across observed means for the total and subscales for both the Intensive and Standard formats. Increases were noted across all subscales for baseline to post, with substantial increases from post to follow up. These trends are consistent with the effect size estimates.

Chapter 7: Moderator and Predictor analysis

Introduction

Although the assumption is that changes in treatment targets are due to the treatment, there are many other factors that can influence the outcomes of CBT interventions for young people (Brent et al., 1998; Compton et al., 2014; Curry et al., 2006; Nilsen, Eisemann, & Kvernmo, 2013). Many studies indicate the effectiveness of CBT based interventions (Bennett et al., 2015; Hetrick, Cox, Witt, Bir, & Merry, 2016; James et al., 2013), yet as many as 40-50% do not respond adequately to treatment (Compton et al., 2014). A range of factors may attenuate treatment response, such as the level and type of anxiety at baseline (Compton et al., 2014).

Compton et al. (2014) examined the effect of 22 potential mediators or predictors of outcome including demographic characteristics, symptom severity, diagnosis, family psychopathology, other psycho-social factors, and treatment expectancy, on the Paediatric Anxiety Ratings Scale (PARS) at 12 months follow up. Their sample included 488 young people aged 7 -17 years old, undergoing treatment with CBT, Sertraline (SSRI Medication), their combination, or a placebo. Their findings showed that three baseline factors predicted better outcomes on a measure of Anxiety (PARS) at 12 weeks: lower baseline anxiety, lower caregiver strain, and having a primary diagnosis that was not social anxiety.

In another study investigating outcomes for adolescents with depression (n= 439) undergoing CBT, pharmacotherapy or a combination, Curry et al. (2006) demonstrated that younger age, lower severity, and less comorbidity predicted better outcomes. Other findings showed that higher family income predicted that CBT worked as well as combined treatment.

Nilsen et al. (2013) also completed a large review examining the predictors and moderators of outcomes in treatment studies for young people with anxiety or depression. Their findings suggest that demographic factors had little effect, and that in anxiety interventions few factors showed consistent effects. However, in depression studies higher symptom severity and comorbid anxiety appeared to lessen the effects of interventions.

Brent et al. (1998) looked at the effect on treatment for adolescents with depression with a range of potential moderators including demographic variables, clinical variables such as duration, onset and severity, cognitive variables, and family variables. They used three different interventions including Cognitive Behavioural Therapy (CBT), systemic-behavioural family therapy, and nondirective supportive therapy. They found that a co-morbid anxiety disorder at baseline predicted a higher likelihood ($p = 0.01$) of still having depression by the end of the study. This effect was only found for systemic-behavioural family therapy and nondirective supportive therapy, with those in the CBT group fairing similarly regardless of comorbidity. Greater cognitive distortions and hopelessness also predicted worse outcomes at post-test ($p < 0.01$). They also found that when comparing referral source between being professionally referred or answering an advertisement made a difference, with those answering an advertisement being more likely ($p < 0.01$) to be depression-free at the end of the intervention.

Other factors have not been actively investigated as moderators of treatment effects but have shown associations with anxiety and depression. For instance, Biddle and Asare (2011) report a negative association between physical activity and depression and anxiety across several reviews, with some associations between sedentary screen-time and poorer mental health. Maras et al. (2015) investigated

the relationship between screen time, especially video gaming and computer use and found a strong association with the severity of depressive and anxiety symptoms even when controlling for other factors such as age, BMI and activity level. Others like Spagnola and Fiese (2007) discuss the relationship of family routines such as meal times on the social and emotional wellbeing of children. Chaput et al. (2016) also highlights the relationships between sleep and mental health in young people. Yet the relationship and directionality of sleep and anxiety in particular is still very unclear with Leahy and Gradisar (2012) noting that sleep problems can predict anxiety, yet the connection from anxiety leading to sleep problems in young people is less clear. Just as these factors have the potential to affect mental health in young people, they also have the potential to moderate the effects of interventions aimed at treating or preventing mental health difficulties.

Method

The data set described above in the results section was further evaluated to look for moderating effects from other variables on treatment outcomes. The potential moderators of interest were: anxiety severity, depression severity, developmental iteration of the program, medication use, age, gender, outdoor and sports activity, screen time, sleep, socialising, family income, family meal times, medical problems, family psychological histories, and previous treatment. Moderator variables included variables gathered in the demographic questionnaire and outcome factors that matched commonly investigated variables such as those explored in previous research as detailed above. Other variables that have been associated with the mental health of young people like physical activity, screen time, and family routines were also included as potential moderators. The two main outcome variables, anxiety severity and depression severity, were calculated in the same manner as in

the main outcome analyses. To compare the main outcome measures across different points of dropout, a variable was created to code for having completed only the baseline measures, the baseline and post measures, and finally all three time points at baseline, post and 12 month follow up. To investigate the effects of initial symptom levels on treatment outcomes, median splits were calculated for the Spence Anxiety Scales Total score and the Children' Depression Inventory total score, and new variables were calculated to dichotomously split above and below the median for each of these. Nominal variables such as medications taken by the child were coded into meaningful categories (None, Physical Health, ADHD, or Mental Health).

For the moderator analysis, a series of Mixed Model Repeated Measures (MMRM) analyses were completed as for the main outcome data but with each of the moderators individually added to the model. These analyses were again undertaken on an Intent-to-Treat basis and allowed for fixed effects of time, format, each moderator, and their interactions with each other, along with a repeated (within-subject) effect of time. The effect on either anxiety severity or depression severity as measured by the SAS and CDI-P across time points, was compared across the levels of potential moderator variables, accounting also for the main effects of treatment format and time; the two-way interactions of moderator with time and moderator with format; and the three-way interaction of moderator with time and format. As before, these analyses assumed that data were missing at random, which was accounted for by only dropping a single time point if it was missing rather than a whole participant, meaning that all available data were incorporated. Multiple comparisons were not adjusted for, as this was an exploratory analysis which may temper any conclusions that can be drawn from these results. If a significant interaction between a moderator variable and either time, format, or time with

format was noted, the means and standard deviations were calculated for each domain score at baseline, post, and follow-up. Within-group standardized mean difference (Cohen's d) effect sizes were then calculated for the different groups in the interaction to further explore the interaction.

Comparison of main outcomes across points of dropout

An MMRM analysis to assess the interactions of the dropout variable (only baseline completed vs. baseline and post vs. all three assessments completed) with format (Intensive vs. Standard delivery) and time (baseline, post, and 12-month follow up) was conducted. Essentially this analysis examined whether dropout moderated any of the observed effects described in Chapter 6.

As shown in Table 5 no significant interaction effects were observed across total score indices for the CDI-P, SAS, SDQ, or DESSA. The lack of significant interactions suggests that the magnitude of changes across these measures did not shift significantly due to dropout for either format across all three time points. This finding provides more confidence to interpreting the observed effects, suggesting that factors associated with dropout did not systematically impact on outcomes.

Table 5. MMRM analyses for effect of dropout on main outcomes.

	Format * Dropout		Time * Dropout		Format * Time * Dropout	
	F	Sig.	F	Sig.	F	Sig.
CDI Parent Total.	0.934	0.394	0.455	0.636	0.175	0.676
SAS_TOTAL.	1.743	0.177	0.662	0.579	0.052	0.819
SDQ Total Difficulties.	0.32	0.727	2.856	0.064	3.534	0.062
DESSA Total Score.	2.005	0.137	2.453	0.094	2.423	0.122

Moderators of the Total Spence Anxiety Scales (SAS) score.

As can be seen in Table 6, both the median splits of the SAS and CDI-P at baseline, produced significant interactions with time in moderating the outcome of the total score on the Spence Anxiety Scales across both formats, with no interactions with format or format with time noted. The significant interaction with the SAS median split and time (F (2, 68.1) = 14.65, p <0.01) suggests that depending on whether participants fell above (n =150) or below (n= 106) the median 'total anxiety score' on the SAS at baseline, effects differed on anxious symptoms across the time points from baseline to post and 12 month follow up. As can be seen in Figure 6, this appears to come from a small difference for those below the SAS median at post (n=82, d = 0.05) and follow-up (n=35, d = -0.03), whilst the SAS total score for those above the median had little change at post (n=57, d = 0.07) and a small decrease at follow-up (n=15, d = -0.20). This finding seems to suggest that those with more severe initial anxiety (total SAS scores above the median) had larger reductions in total anxiety symptoms at 12 month follow-up.

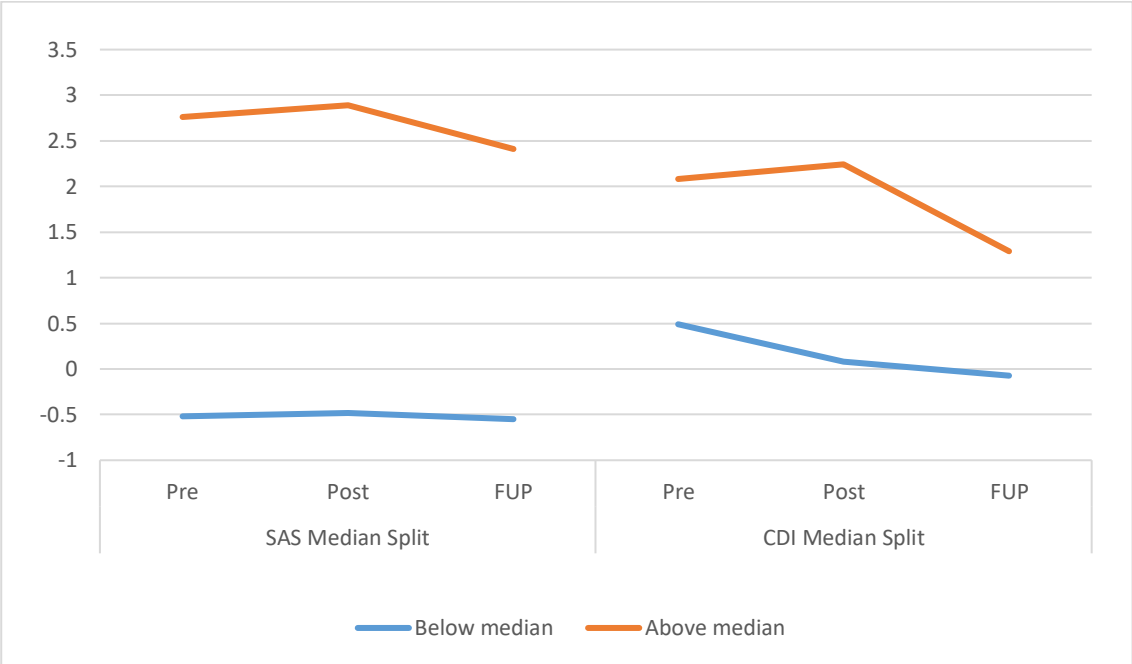

Figure 6. Total observed means Z Scores for Spence Anxiety Scales for those above or below the median for the CDI and SAS.

Table 6. MMRM Moderator analysis for demographic and main outcome variables moderation of the Total CDI-P and SAS Scores.

	Spence Anxiety Scales Total									**Children's Depression Inventory (Parent) Total**								
	Interaction with Format			Interaction with time			Interaction with Format and Time			Interaction with Format			Interaction with time			Interaction with Format and Time		
	df	*F*	*p*	df	*F*	*p*	df	*F*	*p*	df	*F*	*p*	df	*F*	*p*	df	*F*	*p*
SAS Median Split	1, 136.3	0.01	0.94	2, 68.1	14.65	**<0.01**	2, 68.1	0.73	0.48	1, 105.8	0.01	0.92	2, 70.1	10.13	**<0.01**	2, 70.1	0.12	0.88
CDI-Parent Median Split	1, 175.7	0.27	0.60	2, 70.4	8.02	**<0.01**	2, 70.4	1.89	0.16	1, 81.2	0.53	0.47	2, 67.0	18.64	**<0.01**	2, 67.0	0.36	0.70
Developmental Iteration of Group	2, 206.3	0.54	0.59	4, 75.0	1.73	0.15	3, 148.5	1.02	0.39	2, 154.0	0.46	0.63	4, 76.3	1.76	0.15	3, 153.2	0.97	0.41
Gender	1, 177.5	5.60	**0.02**	2, 77.2	0.51	0.60	2, 77.2	1.59	0.21	1, 115.9	5.33	**0.02**	2, 79.0	0.50	0.61	2, 79.0	2.73	0.07
Age	1, 190.2	0.25	0.62	2, 77.2	2.98	0.06	2, 77.2	0.24	0.79	1, 118.5	0.02	0.88	2, 79.1	2.52	0.09	2, 79.1	1.18	0.31
Annual Family Income	1, 164.8	2.62	0.11	1, 68.9	2.06	0.14	1, 68.9	5.03	**<0.01**	1, 92.6	1.45	0.23	2, 73.2	0.48	0.95	2, 73.2	0.24	0.78
Hours Outdoors	2, 157.9	1.28	0.28	6, 68.2	1.09	0.38	4, 68.3	0.30	0.88	2, 109.6	2.57	0.08	6, 65.0	1.44	0.21	4, 65.3	0.81	0.52
Hours Screen Time	3, 222.9	0.94	0.42	6, 66.4	2.88	**0.01**	4, 87.3	2.94	**0.02**	3, 170.2	1.68	0.17	6, 67.3	1.02	0.42	4, 89.7	1.56	0.19
Hours' Sleep per night	2, 214.7	0.05	0.95	4, 68.5	3.38	**0.01**	3, 82.7	0.25	0.86	2, 161.4	1.42	0.25	4, 68.8	4.69	**<0.01**	3, 83.0	0.74	0.53
Hours Social	3, 218.0	2.56	0.06	6, 67.2	0.62	0.72	5, 73.6	0.90	0.48	3, 145.6	0.48	0.69	6, 70.5	2.52	**0.03**	5, 78.5	1.41	0.23
Hours Sports	3, 195.4	2.99	**0.03**	6, 73.4	3.09	**0.01**	5, 80.9	0.69	0.63	3, 150.0	0.37	0.78	6, 68.9	1.02	0.42	5, 73.3	0.64	0.67
Times spent sharing meal with family	2, 161.2	0.50	0.61	6, 67.3	0.42	0.86	4, 67.0	0.48	0.75	2, 146.5	0.11	0.90	6, 67.9	0.65	0.69	3, 82.8	0.14	0.94
Medical problems	1, 145.5	0.86	0.36	2, 64.1	0.37	0.69	2, 64.1	1.05	0.36	1, 104.0	2.69	0.10	2, 69.7	0.25	0.78	2, 69.7	0.82	0.45
Medication	2, 181.7	0.78	0.46	4, 125.0	0.21	0.93	2, 64.3	0.95	0.39	2, 138.8	3.49	**0.03**	4, 129.1	0.45	0.78	2, 64.3	0.10	0.90
Maternal psychiatric history	2, 159.4	0.30	0.74	4, 67.2	0.61	0.66	4, 67.2	2.68	**0.04**	2, 113.2	0.48	0.62	4, 67.9	1.21	0.31	4, 67.9	0.67	0.62
Other therapies (non psychological)	1, 153.9	0.10	0.75	3, 81.9	0.61	0.61	2, 65.0	1.82	0.17	1, 105.5	0.52	0.47	3, 82.9	0.38	0.77	2, 65.9	1.25	0.29
Previous psychological therapy	1, 143.6	0.01	0.90	2, 60.0	5.73	**0.01**	2, 60.0	1.40	0.25	1, 92.5	0.01	0.93	2, 60.7	1.05	0.35	2, 60.7	1.10	0.34
Sibling psychological history	1, 158.9	1.23	0.27	2, 68.7	0.33	0.72	2, 68.7	1.03	0.36	1, 102.2	0.09	0.76	2, 66.0	0.97	0.38	2, 66.0	0.83	0.44

Note. SAS: Spence Anxiety Scales (combined SCAS AND PAS); CDI-P: Children's Depression Inventory, Parent Version; Format refers to: 'Standard': 10 weekly sessions; 'Intensive': 10 daily sessions; 'Interaction with Format/Time': MMRM analysis across either baseline, post and 12-month follow-up time points or different formats with the respective moderator variable; 'Interaction between format and time': MMRM analysis of the interaction between time points and intervention group as well as the respective moderator variable. Gender is dichotomous as all participants identified as either Male or Female, Age and Annual Family Income (Australian $) was treated as continuous scale variables. Hours of outdoor activity, screen time, sleep per week, social, or sports, as well as time spent with family at meal times were categorical with four categories each. Medical problems, Medication, Maternal Psychiatric History, Other therapies, and Previous Psychological Therapy or Testing, and Sibling Psychiatric history were string variables code into meaningful categories

The significant interaction with the CDI median split and time (F (2, 70.4) = 8.02, p <0.01) similarly suggests that that depending on whether participants fell above (n=147) or below (n=105) the median total depression score on the CDI-P at baseline they had different effects on anxious symptoms across the time points from baseline to post and 12 month follow up. Figure 6 shows small decreases in anxiety symptoms for those below the CDI median at post (n=86, d = -0.27) and follow-up (n=32, d = -0.36), whilst the SAS total score for those above the CDI median had little change at post (n=53, d = 0.07) and decreased more at follow-up (n=16, d = -0.35). This seems to suggest that those with less severe initial depression (total CDI scores below the median) had larger reductions in anxiety at post, which were maintained at follow up, whilst those with more severe initial depression (total CDI scores above the median) had larger reductions in anxiety at 12-month follow-up. Both of the moderating effects with the CDI and SAS median splits had no interactions with format suggesting that the magnitude of the changes did not differ between the intensive and standard formats.

A significant interaction (F (1,177.5) = 5.60, p = 0.02) can be seen between gender and format with the SAS total score, however this is not particularly meaningful, and no significant interactions were observed for time or for time with format.

A significant interaction was also seen between annual family Income with time and Format (F (1,68.9) = 5.03, p < 0.01), suggesting that the magnitude of change on the total score for the Spence Anxiety Scales was different between formats across time points depending on a family's annual income. As income was a scale variable it is not easily explored further, a dichotomous variable distinguishing those below and above the median was created. Although the effect was no longer significant (F (2, 72.4) = 2.63, p = 0.08) using the dichotomous variable, it allowed for visual analysis and the calculation of effect sizes to explore it further.

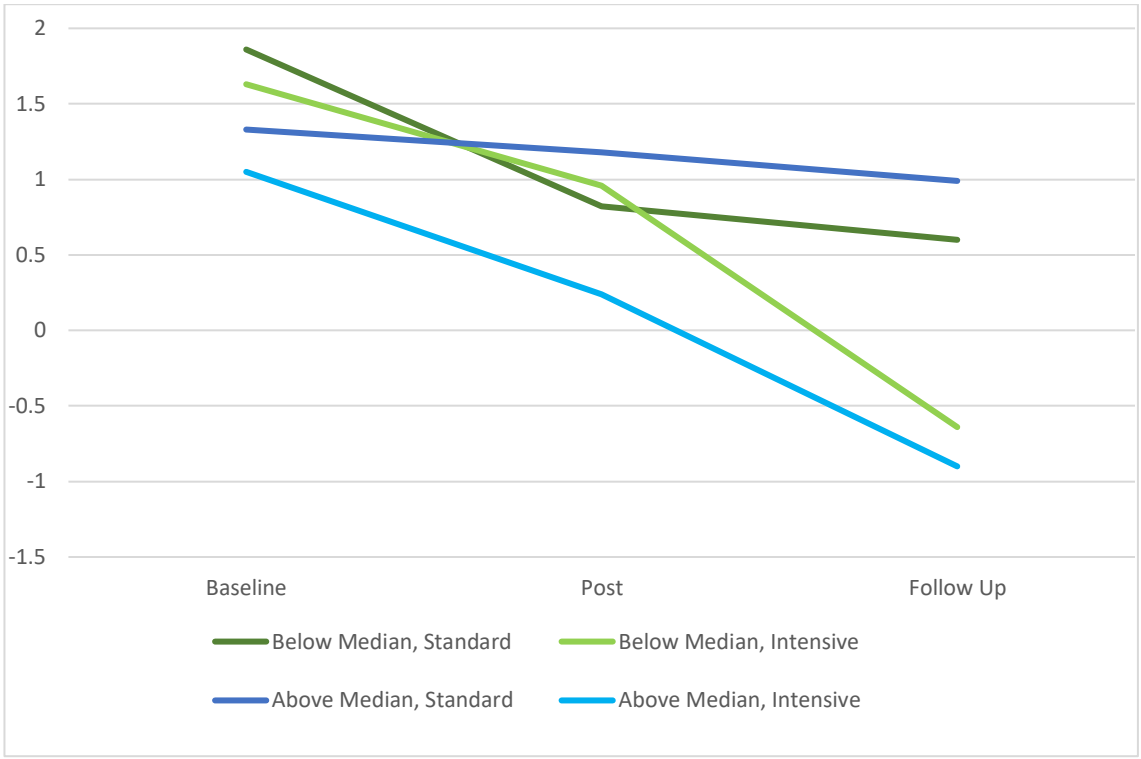

Figure 7. Total observed mean Z Scores for Spence Anxiety Scales for those above or below the median annual income in both the standard and intensive Groups.

Figure 7 shows that for those above the median income in standard delivery format minimal change was achieved at post (n=48, d = -0.07) and 12 month follow up (n=19, d = -0.16). Whilst for those below the median income in standard delivery format, medium decreases were achieved at post (n=37, d = -0.51) and 12 month follow up (n=16, d = -0.64). For the intensive delivery, despite a slightly higher starting anxiety point for those below the median income, an initially similar picture is apparent across incomes. For those below the median a small baseline to post decrease in anxiety can be seen (n=28, d = -0.28) with a large decrease from baseline to follow-up (n=7, d = -1.13). With the same pattern for those above the median income with a small baseline to post decrease in anxiety (n=19, d = -0.37) with a large decrease from baseline to follow-up (n=7, d = -0.85). This suggest that young people from families with higher annual incomes may have fared better in the intensive format especially at 12 month follow up, whilst those

with lower family incomes faired similarly from baseline to post across formats but again those in the intensive format fared better at 12 month follow up. The two-way interaction effects of income with time or format were not significant.

A significants interaction was also observed for the amount of screen time per day with time (F (6,66.4) = 2.88, p = 0.01) and time with format (F (4,87.3) = 2.94, p = 0.02). This appears to arise due to a very large decrease in anxiety symptoms from baseline to post in the standard format for those who had 6 hours or more of screen time at baseline, and a large increase in the intensive format for the same group. However, on closer inspection, the group with 6+ hours of screen time had a very small sample size – one person in standard format and two for intensive. This analysis was done with the four answer options, 0-1 (n=121), 2-3 (n =116), 4-5 (n=12), or 6+ hours (n=3), however as can be seen the number of participants drops off substantially towards the higher end of the scale with most participants sitting between 0-1 or 2-3 hours a day, so the analysis was run again with a split between having under 2 hours of screen time or 2 hours or more of screen time. In this analysis, all of the interactions disappeared, with no interaction with time (F (2,78) = 1.57, p = 0.21) and no interaction with time and format (F (2,78) = 0.57, p = 0.94). Together the findings of these analyses suggest that a small number of outliers may have accounted for the moderation effect observed in the first analysis.

A significant interaction could also be seen with the amount of sleep per night at baseline and time (F (4,68.5) = 3.38, p = 0.01) but not for time with format (F (3,82.7) = 0.25, p = 0.86). This suggests that depending on sleep participants reported at baseline they had different effects on anxious symptoms across the time points from baseline to post and 12 month follow up. This analysis was comparing those who got

less than 5 hours sleep a night (n = 0) those who got 5-8 hours, 8-10 hours, or more than 10 hours across the time points on the SAS total.

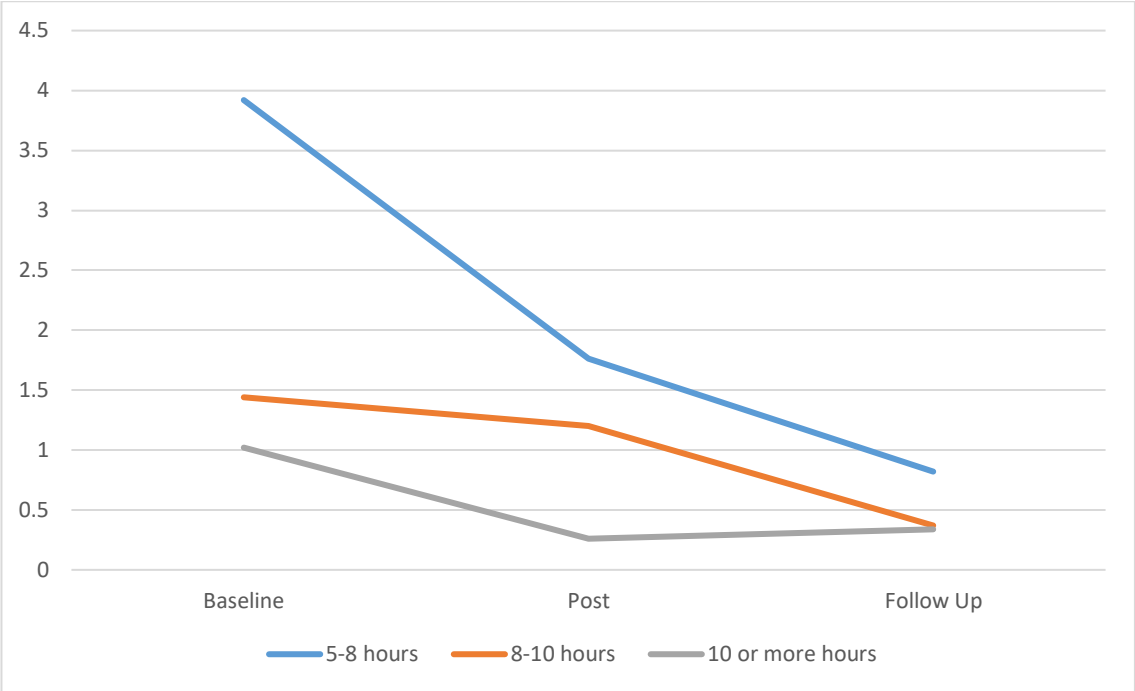

Figure 8. Total observed mean Z Scores for Spence Anxiety Scales across time for different amounts of sleep per week at baseline.

As can be seen in Figure 8, all those above 8 hours of sleep per night at baseline had mostly small decreases in anxiety symptoms from baseline to post and baseline to follow up. Those who got 8-10 hours of sleep per week at baseline initially had almost no effect (n = 84, d = -0.10) which increased to a small effect at follow-up (n = 33, d = -0.48), and those at 10 hours or more initially had a small decrease in total anxiety (n = 48, d = -0.44) which was then maintained at follow-up (n = 14, d = -0.40). However, the small number of participants who got less than 8 hours of sleep a night at baseline had much higher initial anxiety and had large decreases at post (n = 7, d = -1.12) and even larger decreases at follow-up (n = 2, d = -1.62). This does suggest that those with worse sleep per week at baseline benefitted more from the intervention, although the small sample of young people in this group lessens the strength of this assertion.

Moderation effects for the amount of time children exercised per week were found for format (F (3,195.4) = 2.99, p = 0.03) and Time (F (6, 73.4) = 3.09, p= 0.01) with the Total Spence Anxiety Score but not for Format with Time. This indicates effects on anxious symptoms over time were dependent on how much exercise participants reported at baseline.

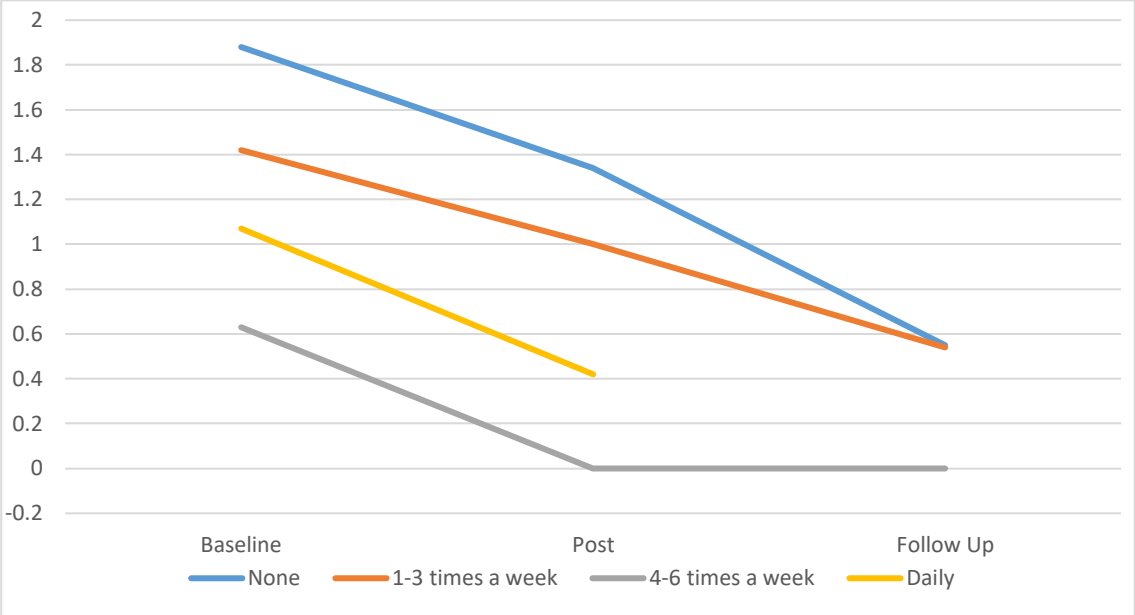

Figure 9. Total observed mean Z Scores for Spence Anxiety Scales across time for different number of times children exercised per week.

As Figure 9 shows, a very similar pattern can be observed from baseline to post across all groups with universally small decreases (d = -0.20 – -0.37) in anxiety symptoms. At 12 month follow up the effects diverge with a medium decrease for those who had no regular exercise at baseline (n = 6, d = -0.58), a small decrease for those who exercised 1-3 times a week (n = 32, d = -0.43), and a smaller decrease for those who exercised 4-6 times a week (n = 10, d = -0.28). No one in the daily exercise group was still in the study by follow up. Similar effects to those noted above for sleep were seen, with those who did less exercise at baseline having larger decreases in anxiety at follow up. No interactions with format and time were observed suggesting that the magnitude of these changes did not differ across formats.

Maternal psychiatric history coded as none, extended family, or mother also had a significant moderating effect with time and format (F (4,67.2) = 2.68, p = 0.04). This effect suggests that the magnitude of change across time and the formats was different depending on family psychiatric history. Figure 10 demonstrates a very small change from baseline to post for those with no reported maternal psychiatric history (n=61, d = -0.13) with a medium decrease at 12 month follow up (n=16, d = -0.67). Those who had extended maternal family with a psychiatric history had a small decrease from baseline to post (n=26, d = -0.43), continuing to decrease at 12 month follow up as compared to baseline (n=10, d = -0.80). Those with a direct maternal psychiatric history showed a similar small decrease from baseline to post (n=48, d = -0.30) which was only maintained with a small decrease at 12 month follow up as compared to baseline (n=19, d = -0.36). This suggests that those with a maternal history of mental illness may have benefitted less from the interventions at 12 month follow up, as compared to those with no history or those with extended maternal family history.

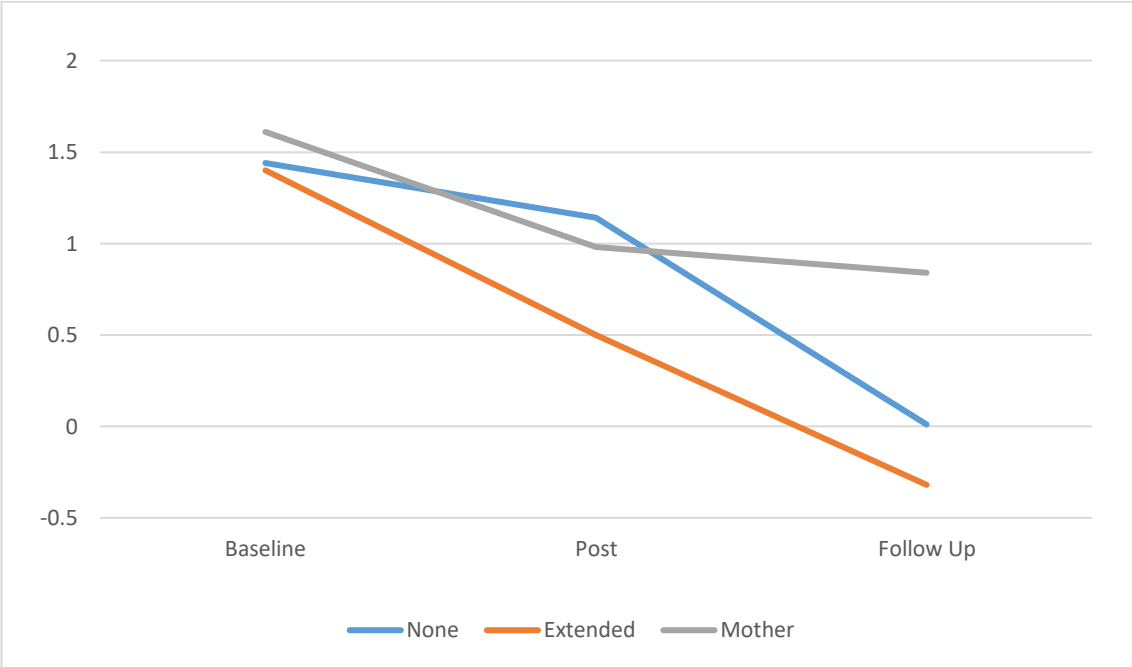

Figure 10. Total observed mean Z Scores for Spence Anxiety Scales across those with no reported maternal psychiatric history, extended family, or direct maternal psychiatric History.

A moderation effect of the Spence Anxiety Scale total score across time was observed for those who had previous psychological therapy or testing (F (2,60.0) = 5.73 p = 0.01). This showed a significant difference in the magnitude of the change achieved over time depending on whether they had engaged in other psychological therapies or testing before the baseline assessment. Figure 11 shows small decreases in the total anxiety score from baseline to post (n=88, d = -0.36) and baseline to follow-up (n=23, d = -0.28) for those who did not have other psychological therapies or testing before. Yet for those who did have other psychological therapies or testing before only a very small change was observed (n=43, d = -0.09) from baseline to post, with a large decrease (n=16, d = -0.96) from baseline to follow-up. There was no significant interaction with format though, which suggests that the magnitude of this difference did not differ between intensive and standard formats. Overall, this suggests that those who accessed other psychological therapies or testing before benefitted more in terms of reduced anxiety at 12 month follow-up, this could be partially due to the higher starting point allowing for the bigger drop or may indicate a possible bias from the effects of previous therapy.

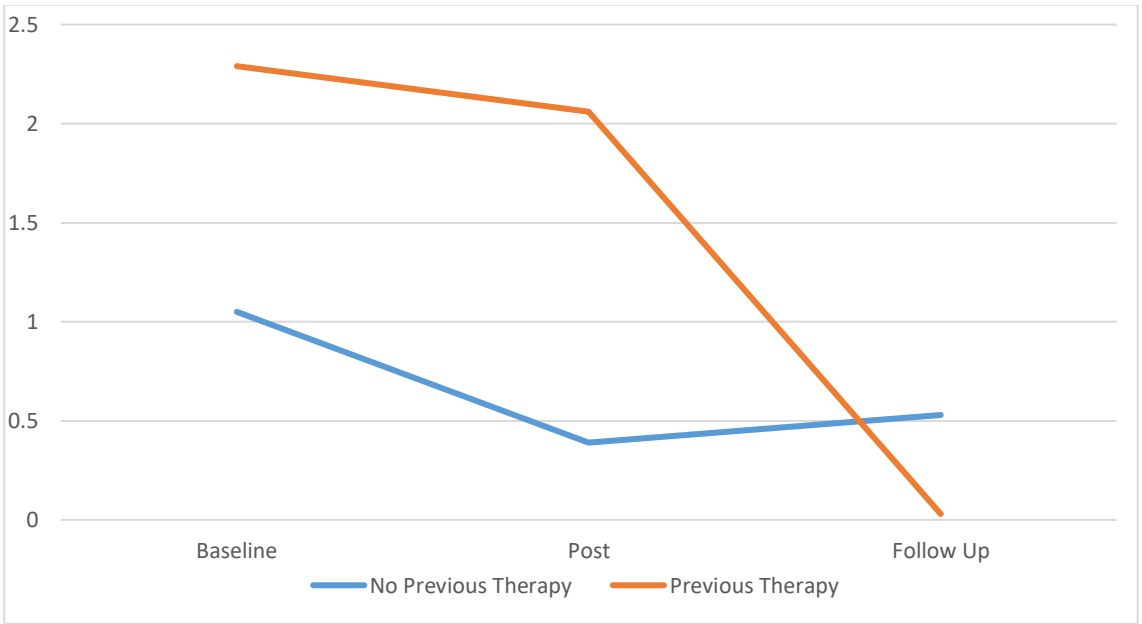

*Figure 11. T*otal observed mean Z Scores for Spence Anxiety Scales across time for those who had accessed previous psychological therapy or not.

A significant interaction (F (1,165.9) = 4.58, p = 0.03) can be seen in the interaction between custody arrangements and format with the SAS total score, however this is not particularly meaningful, and no significant interactions were observed for time or for time with format.

Moderators of the Total Children's Depression Inventory

As can be seen in Table 6, both median splits of the SAS and CDI-P at baseline, produced significant interactions with time in moderating the outcome of the total score on the Children's Depression Inventory, Parent Version, with no interactions with format noted. In Figure 12 the interaction with the CDI median split and time (F (2, 67.0) = 18.64, p <0.01) shows a small decrease for those below the CDI median at post (n=86, d = -0.25) with almost no effect from baseline to 12 month follow-up (n=32, d = -0.09), whilst the CDI-P total score for those above the CDI median also showed a small decrease at post (n=53, d = -0.24) with a medium decrease at follow-up (n=16, d = -0.52). This seems to suggest that those with lower initial depression severity had only small reductions in depressive symptoms at post which were not maintained at follow up, whilst those with total CDI scores above the median had more substantial reductions by 12 month follow-up. The higher starting point for those above the median does allow for greater scope for symptom reduction over time, which may have contributed to the effect observed.

The interaction with the SAS median split and time (F (2, 70.1) = 10.13, p <0.01) shows small decreases in depressive symptoms for those below the SAS median at post (n=82, d = -0.39), maintained at follow-up (n=35, d = -0.34). In contrast, the CDI total score for those above the median also showed a small decrease in

depressive symptoms at post (n=57, d = -0.32) but improved further at follow-up (n=15, d = -0.48). This seems to suggest that those with greater severity of anxiety had slightly larger reductions in depressive symptoms at 12 month follow-up. Both of the moderating effects with the CDI and SAS median splits had no interactions with format suggesting that the magnitude of the changes did not differ between the intensive and standard formats.

As with the SAS total, the interaction between gender and format with the CDI Total score was significant (F (1,177) = 5.33, p = 0.02), however this is not particularly meaningful, and no significant interactions were observed for time or for time with format.

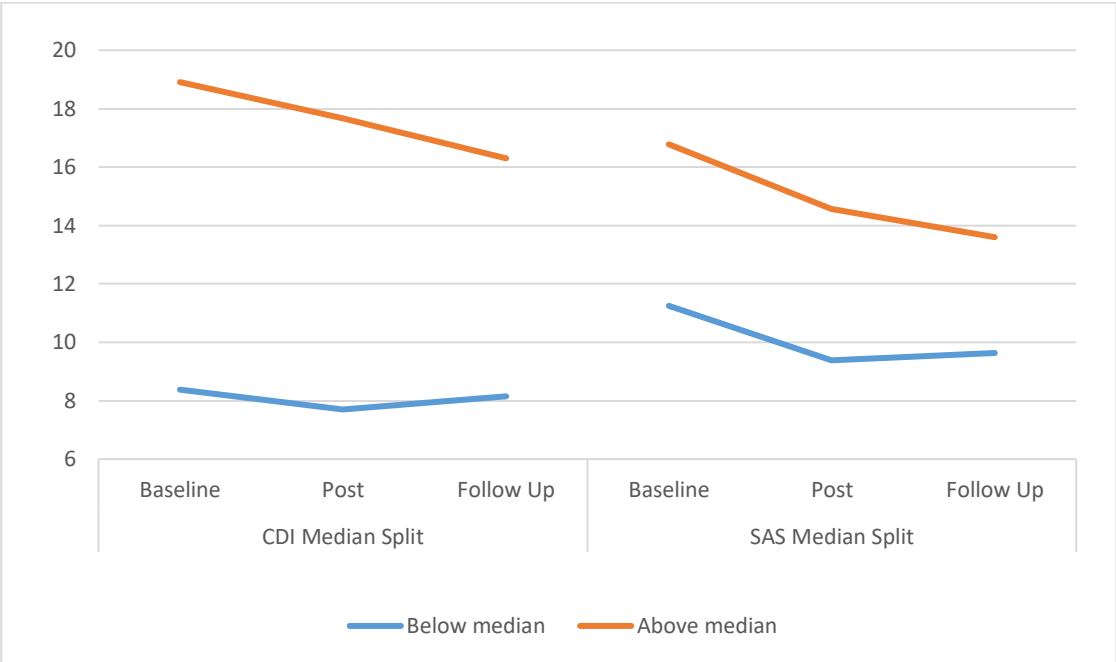

Figure 12. Total observed mean raw scores for Children's Depression Inventory, Parent Version for those above or below the median for the CDI and SAS.

An interaction can also be seen with the amount of sleep per week participants got and time (F (4,68.8) = 4.69, p < 0.01). As above, this analysis compared those who got

less than 5 hours sleep per night (n = 0), those who got 5-8 hours, 8-10 hours, or more than 10 hours at baseline, followed over time on depression scores. As can be seen in Figure 13 those who reported 8 hours of sleep per night got small to medium decreases in depressive symptoms from baseline to post and baseline to follow up. With those who got 8-10 hours of sleep per week at baseline initially had a small decrease (n = 84, d = -0.34) which decreased further at follow-up (n = 33, d = -0.56), and those at 10 hours or more initially had a medium decrease in total anxiety (n = 48, d = -0.58) which was maintained at follow-up (n = 14, d = -0.51). However, the small number of participants who got less than 8 hours of sleep per night a night at baseline had much higher initial depressive symptoms and had large decreases (n = 7, d = -2.06) at post which were maintained at 12 month follow up (n = 2, d = -2.07). This finding suggests that those with worse sleep at baseline benefitted more from the intervention, however the small sample of young people in this group lessens the strength of this assertion.

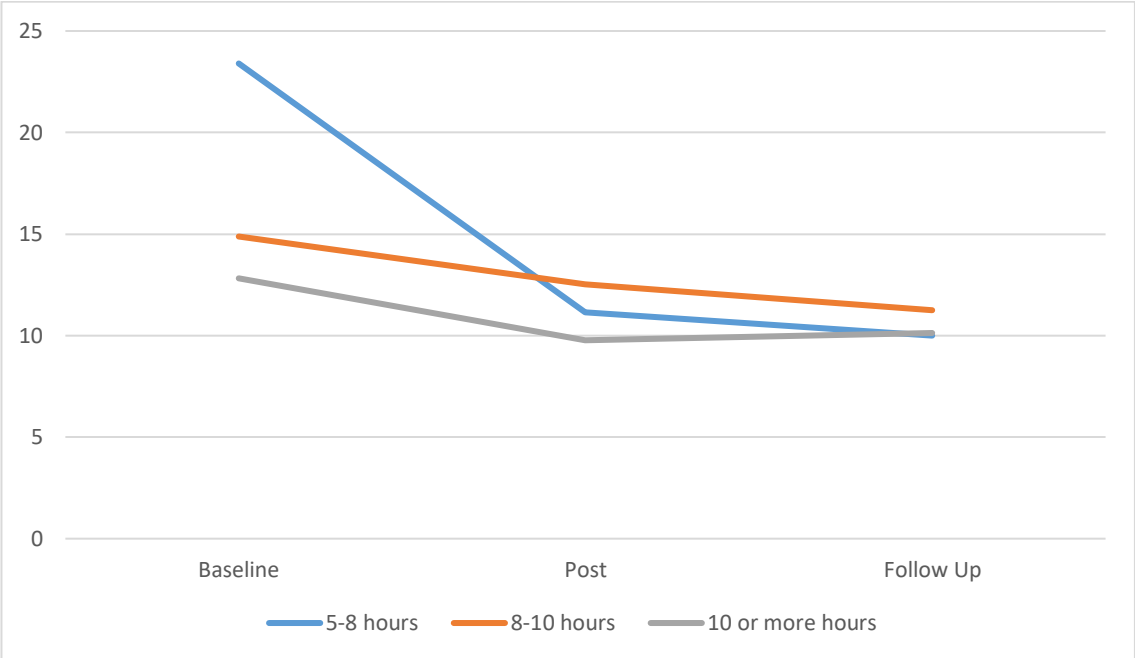

Figure 13. Total observed mean raw scores for Children's Depression Inventory, Parent Version across different amounts of sleep per week at baseline.

An interaction can also be seen between the amount of Social Time per week participants reported and time (F (6,70.5) = 2.52, p = 0.03). As can be seen in Figure 14 those who got between 6 and 8 hours of social time per week had less improvement at follow up (n = 13, d = -0.26) than those with either less or more social time per week (d = -0.50 – -0.94), although these results may be more reflective of a small number of outliers.

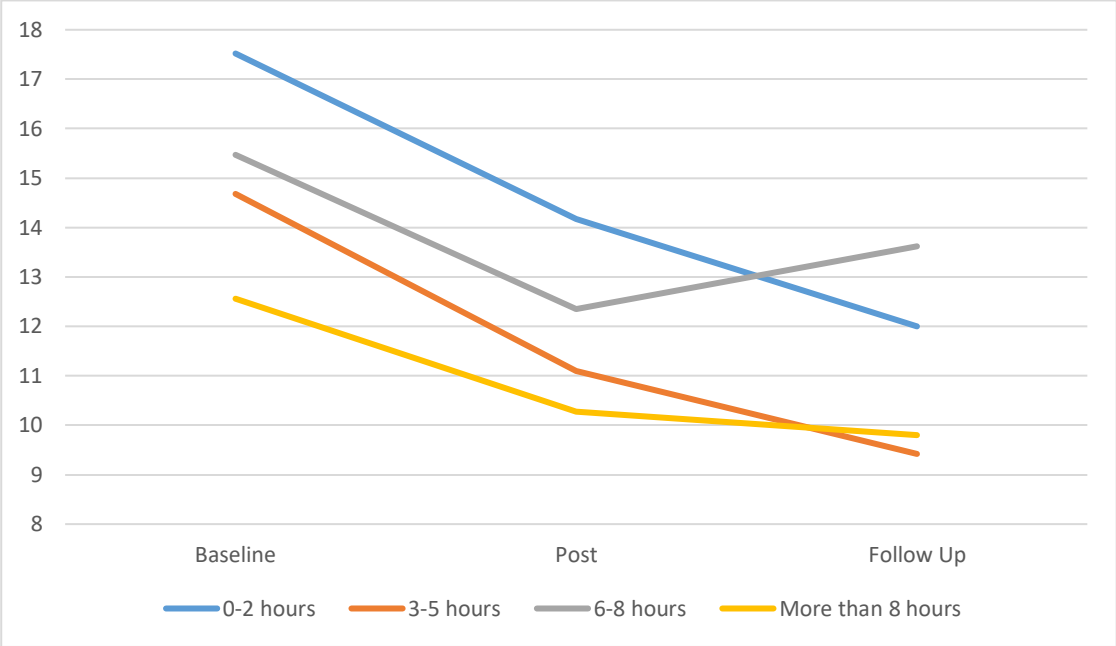

Figure 14. Total observed mean *raw scores for Children's Depression Inventory, Parent Version across different amounts of social time per week at baseline.*

There was an interaction between whether participants were taking no medication, medications for physical health, medication for ADHD, or other psychiatric medications, with format on the CDI total score, (F (2,143) = 3.49, p = 0.03), however this is not particularly meaningful, and no significant interactions were observed for time or for time with format.

Discussion & Conclusion

Several factors were identified that may have had an influence on the outcomes observed. It is important to continue to note that this is purely an exploratory investigation and any factors identified would need to be more thoroughly investigated to determine more reliable relationships.

Factors associated with dropout did not have a systematic impact on outcomes, which provides more confidence to interpreting the observed effects in Chapter 6.

Looking at moderators of anxiety symptoms, as measured on the Spence Anxiety Scales, they showed that those with more severe initial anxiety exhibited larger reductions in total anxiety symptoms at 12 month follow-up. Similarly, those with more severe initial depression also had larger reductions in anxiety at 12-month follow-up. These higher baseline start points may have provided more room for reductions before reaching a floor effect. Both of the analyses investigating moderating effects of the CDI and SAS median splits showed no interactions with format suggesting that although having higher or lower intensity of anxiety or depression symptoms seems to have affected the magnitude of the improvements in anxiety at later time points they did not differ between the intensive and standard formats. These results are somewhat at odds with those of Compton et al. (2014) who found that lower severity of anxiety symptoms predicted better outcomes. This may be in part due to the current study including sub-clinical participants who did not have much room for improvement whilst Compton et al. (2014) used a clinical sample.

Furthermore, families with higher annual incomes had bigger reductions in anxiety symptoms when partaking in the intensive format as compared to the standard format, especially at 12 month follow up. Those with lower family incomes fared

similarly from baseline to post intervention across intensive and standard formats, but again those in the intensive format had larger reductions in anxiety symptoms at 12 month follow up. One possible explanation for this finding could be related to family involvement in the intervention, although data is not available for the level of family involvement. Specifically, the shorter intensive intervention over school holidays may have allowed for more parental participation and encouragement, especially for higher income families who may have been more able to afford time away from work for one or more parents during this period. These findings are similar to those reported by Curry et al. (2006) who found that those with higher incomes were more likely to benefit from CBT as well as those who had a combined treatment with medication. They proposed that parental education may explain at least some of their effects and that higher education in the household may bode well for teaching and reinforcing CBT skills, which may also be true in the current study.

Significant interaction was also observed for the amount of screen time per day with time; however, a closer look at results suggests that a small number of outliers may have accounted for the moderation effect observed. Similarly, a possible effect for those with worse sleep at baseline having larger reductions in anxiety at later time points, however a very small sample of young people in this group lessens the strength of this assertion. The lack of substantial findings here don't support screen time and sleep as moderators of outcome despite their association with mental health highlighted by Chaput et al. (2016); Maras et al. (2015), although further research on sleep as a moderator may be warranted.

When looking at the effect of the amount of exercise participants were reported to be engaging in at baseline, similar effects to those noted above for sleep were seen, with

those who did less exercise at baseline having larger decreases in anxiety at follow up. Again, no interactions with format and time were observed suggesting that the magnitude of these changes did not differ across formats. This effect could potentially be due to lower levels of behavioural activation at baseline providing greater opportunity for behavioural change that can lead to symptom improvement, which would be consistent with conclusions by Biddle and Asare (2011) who found higher amounts of physical activity was associated with lower anxiety and depression.

Evaluation of the effect of reported maternal psychiatric history at baseline on anxiety symptoms, as rated on the Spence Anxiety Scales, indicated that those with a maternal psychiatric history benefited less at follow up as compared to those without or those with only extended maternal family psychiatric histories. Maternal mental health may potentially lead to more maladaptive role-modelling and a less validating environment, or a shared genetic component, which may explain this effect.

Young people who had accessed other psychological therapies or testing before starting the current intervention started at higher anxiety levels compared to those who had not and appeared to benefit more in terms of reduced anxiety at 12 month follow-up. This effect could be related to those starting with more severe symptoms having more scope for symptom reduction, or it could indicate a possible bias from other therapy input.

Moderation of the depressive symptoms, as measured by the CDI-P, was found with more severe baseline depression being associated with larger reductions at 12-month follow-up. Due to the split of higher vs lower baseline scores, higher starting scores may provide more scope for symptom reduction and may explain some of the observed effect. Similar to those for anxiety this finding stands at odds with

those of Curry et al. (2006) who found lower depressive symptoms to be associated with better outcomes. This could again be explained by the full clinical sample in their study as opposed to the inclusion of some subclinical participants in the current study who may not have had much room for improvement from their relatively low baseline.

Similarly, evidence for moderation of depression outcomes by anxiety severity was observed, with more severe initial anxiety symptoms associated with larger decreases in depression symptoms particularly at 12 month follow-up. Again, a higher starting point on symptom intensity may have provided more opportunity for reductions. Both of the moderating effects with the CDI-P and SAS median splits had no interactions with format suggesting that the magnitude of the changes did not differ between the intensive and standard formats.

Those with worse sleep (<8 hours) benefitted more from the intervention in terms of reductions in depressive symptoms, however they also started at a higher reported number of depressive symptoms and comprised only a small sample of young people, which lessens the strength of this finding. Findings from Chaput et al. (2016) showed more sleep was associated with better emotional wellbeing, which may explain the associations seen in the current study, although more research to investigate the role of the moderator is warranted.

Comparing the moderation effects of social contact on depressive symptoms found that most groups continued to improve or at least maintained improvement at follow up, except for those who got between 6 and 8 hours of social time per week, who did worse from baseline to follow up than from baseline to post.

Overall many interesting moderating effects seem to arise, although many are limited by the relatively small numbers that comprise them once they are broken down into smaller categories. This exploratory analysis does provide avenues for future study. It was interesting to note that initial severity of either anxiety or depressive symptoms affected the magnitude of reductions in both anxiety and depressive symptoms, particularly at follow up. This effect occurred regardless of format suggesting no difference between standard and intensive delivery even when baseline severity of anxiety or depressive symptoms are higher. One hypothesis as to why this effect has been observed could be that those above the median had more scope for symptoms to reduce, with those with fewer symptoms reaching a floor effect where further reduction was less likely. More depressive or anxious symptoms also provide more avenues by which the intervention can establish new, more effective, behaviours which may then serve to reduce severity of overall depressive and anxiety symptoms. For instance, higher symptom counts would possibly allow for changes in sleep, diet, thinking styles, relaxation, and other symptoms whilst lower symptom counts may only provide avenues for meaningful improvements in a couple of those domains.

One of the few effects that did seem to differ across different formats was median family income. Those below the median income had a much larger reduction in anxiety symptoms in the intensive format compared to those in the standard format, both directly after intervention and at 12 month follow up. This suggests that the shorter format may lend itself better to young people whose family earn below the median income. Although those above the median income in the standard format appeared to do as well as those in the intensive format, both income brackets had larger reductions in anxiety at follow-up in the intensive format as compared to the

standard format. This finding may be explained by families having more of a chance to focus on developing skills across a short period of time, rather than maintaining engagement over 10 weeks, with skills then slowly strengthening over the year that follows. The effects of sleep on both anxiety and depression outcomes suggest that those who got less than 8 hours of sleep at baseline seemed to have greater reductions in anxiety and depressive symptoms over time. For many young people, sleep disturbance is a key factor in the onset and maintenance of anxiety and depression and these effects may be bi-directional (Chaput et al., 2016). Therefore, worse sleep problems at baseline may have provided a clear intervention avenue that in turn reduced internalising symptoms in response to the treatment. Further investigation of the effects of sleep should examine whether such mediation effects occur over time. Targeting sleep disturbance in treatment may also be worthy of investigation, along with tailoring of treatment to specific internalising symptoms including sleep disturbance (Ashworth et al., 2015; Christensen et al., 2016).

This chapter identified several potential moderators of the effectiveness of the intervention on anxiety and depression symptoms. Limitations include the limited number of characteristics available for exploration, limited power to detect two- and three-way interactions, and other design features of the trial including the lack of randomisation as noted previously. Nevertheless, the findings suggest potential avenues for future research to optimise the outcomes of the intervention. Targeting individuals who are most likely to respond to the intensive intervention may lead to stronger outcomes. Another use of these results may be the exploration of tailoring of intervention materials to specific subgroups, with intensity and delivery personalised based on the characteristics, symptom profiles and preferences of young people and their families.

Chapter 8. Discussion & Conclusion

Main hypotheses

This study is one of the first to compare the intensive delivery with standard delivery of a CBT based group program for children, adolescents, and their families. Studies have established the efficacy of the FRIENDS programs in both treating mental health difficulties and in preventing them. However, the FRIENDS programs have usually been delivered in the standard format consisting of one session a week over 10-12 weeks (Anticich et al., 2013; Rodgers & Dunsmuir, 2015; Shortt et al., 2001; Stallard et al., 2014).

It was hypothesized that delivering the same program in an intensive format of daily sessions over two weeks would produce similar effects to the standard delivery. Overall this hypothesis was supported, a finding which was true after intervention and again at 12-months follow-up. The results demonstrated significant ($p< 0.01$) reductions in anxiety for both formats directly after the group, which reduced even further at follow up. This outcome supports the notion that both formats are effective at reducing symptoms associated with anxiety even when assessed a year later. Similarly, significant ($p< 0.01$) reductions in depressive symptoms were noted across both formats and was maintained at follow up for the standard delivery and reduced even further for the intensive group. In the mixed model repeated measures analysis, no significant ($p>0.05$) interaction effects between Time and Format were found showing that, although statistically significant ($p<0.01$) and meaningful change occurred from before the group to after the group and even at one year follow up, the standard and intensive formats did not significantly differ. This finding also supports the notion that the two formats produce comparable

outcomes. On other measures, significant (p<0.01) reductions were observed in conduct and peer problems across both formats, also maintained at follow up. Significant (p<0.01) increases were observed across strength measures across both formats, increasing further at follow up, again with no significant difference between formats. This finding demonstrates not only the treatment effect of these programs across both formats but also the effectiveness of the program in building strength based outcomes. Many of the strengths measured such as friendship skills, decision making, positive thinking, and awareness of self and others better equip young people to take on future challenges and will likely reduce recurrence of clinical symptoms whilst increasing their quality of life.

Comparison to existing literature in Intensive formats

Similar to Storch et al. (2007), the current study found equivalent results for an intensive delivery of a family based CBT intervention as compared to a standard format. However the Storch et al. (2007) intervention focused on a specific diagnostic and age group whilst the current study had a wider range of individuals and was able to demonstrate effects at a longer follow up period. Current findings are also consistent with those found in Bolton et al. (2011) well-designed randomized controlled trial which found that both a standard and a brief intervention were effective compared to a waitlist control group, although the current study was not able to apply the same scientific rigor of a waitlist control or randomisation. The current study also demonstrated in part the findings of Gallo et al. (2012) who found that an intensive CBT based program could have positive effects on more than one presenting difficulty. This was demonstrated in similar reductions across both formats in various areas of anxiety, depression, and disruptive behaviour, as well as increases in positive measures. The results of the

current study fill a gap in the literature by demonstrating the relative effectiveness of both intensive and standard delivery of a more broadly aimed group based CBT intervention for children and adolescents.

The recent and through review by Öst and Ollendick (2017) reported an overall effect size of 1.75 at post and 1.62 at follow up for what they called concentrated treatments (reduced start to finish duration but not total time or content). In comparison, the current study had more modest effects on the intensive intervention with 0.25 and 0.39 on anxiety and depression respectively at post and 0.9 and 0,9 at follow up for anxiety and depression. The fact that the current study included some subclinical participants whilst the studies reviewed by Öst and Ollendick (2017) were predominantly conducted within clinical samples may explain some of that discrepancy. Their finding of standard format CBT mirrors this with post effect sizes of 0,98 and follow-up of 1.05, whilst for the standard delivery the current study produced effect sizes of 0.21 and 0.49 on anxiety and depression respectively at post and 0.34 and 0,47 at follow-up for anxiety and depression. Their analysis of the brief, intensive and concentrated intervention vs. standard CBT does mirror findings in the current study at post, with between effect sizes of only 0.01 at post in their analysis, comparable to the 0.1 and 0.07 on anxiety and depression respectively at post in the current study. There is somewhat more discrepancy at follow up though between brief, intensive and concentrated intervention vs. standard CBT, where Öst and Ollendick (2017) found a between effect of 0.1 while the current study found effect sizes of 0.36 and 0.2 on anxiety and depression respectively. This greater change in the intensive condition was not significant in the MMRM analysis though and may just reflect biases arising from drop out at the follow up time point.

Predictors and moderators

The exploratory moderator analyses in Chapter 7 further emphasise the results of the current study with few effects showing any interactions with format. The only factor with a notable significant interaction with format is the comparison of those above and below the median family income of this study. These results suggest that although those above the median income in the standard format appear to have done as well as those in the intensive format, both income brackets have larger reductions in anxiety at follow-up in the intensive format as compared to the standard format. This result mirrors the overall effect sizes which show larger reductions at follow-up for those in the intensive format as compared to the standard format. However, the lack of overall statistical significance of this difference emphasises the likely equivalence of the two formats rather than to support a true superior effect from the intensive format at follow-up.

Furthermore, the exploratory moderator analysis provides some potential clues as to what factors may have influenced the outcomes that were observed. In examining the effects of initial anxiety and depression scores on outcomes, those with more severe symptoms appeared to have greater reductions from post to follow up than those with fewer symptoms. This effect occurred regardless of whether the participants received the intensive or a standard format, suggesting no difference between these delivery formats even when baseline severity of anxiety or depressive symptoms was higher. This is not an entirely unique finding with studies like Anticich et al. (2013) showing greater effects on behavioural difficulties at follow-up for those in a high anxiety group. It is however at odds with findings from Nilsen et al. (2013) who found that higher severity of depressive symptoms and comorbidity of anxiety with depressive symptoms predicted worse outcomes. Curry

et al. (2006) also found similar effects, with higher severity and comorbidity being associated with worse outcomes.

Furthermore, Compton et al. (2014) found that higher anxiety at baseline predicted worse outcomes for children and adolescents in their study as well. The findings from Compton et al. (2014) were reported at 12 weeks after baseline. Over a similar time period from baseline to 2 or 10 weeks post, the current study didn't show substantial differences in outcome, only showing the greater outcomes for those with higher severity at 12 month follow-up. It is also plausible that Compton et al.'s (2014) sample from a public mental health service had a higher severity of anxiety symptoms even in their "low anxiety" group, as compared to the current study which was run in a private community clinic for both treatment and preventative interventions. It could also be that the interventions delivered in the Compton et al study had a different intensity to the FRIENDS program delivered in the present study. A lower overall severity may mean that a floor effect occurred where those in the lower anxiety and depression groups had reached a relatively normal level by the end of the intervention with further reductions not plausible or necessarily desirable. This explanation, alongside the lack of long-term follow-up in previous studies, may go some way to explaining the conflicting results from Compton et al. (2014); Curry et al. (2006); Nilsen et al. (2013) and the current study. The similarity with studies like Anticich et al. (2013) may be due to the severity of symptoms observed in the participants, with Anticich et al. (2013) study being a universal preventative intervention as compared to treatment programs used in Compton et al. (2014); Curry et al. (2006); Nilsen et al. (2013).

The amount of sleep per night reported at baseline was another factor that appeared to show some effect on anxiety and depression outcomes, with those who reported less than 8 hours of sleep at baseline having greater reductions in anxiety and depressive symptoms particularly at post-test than those who got more sleep at baseline. Participants with less reported sleep at baseline also had higher severity of anxiety and depression symptoms at baseline compared to those who had more than 8 hours of sleep per night at baseline. The initial higher anxiety and depressive symptoms in the lower sleep group could be due to the well documented relationship between lower sleep duration in children and adolescents and worse mental and physical health outcomes (Chaput et al., 2016). The higher scores in these domains may provide more opportunities to decrease, while those reporting more sleep may have had fewer symptoms and a floor effect which may be consistent with the directional findings from Leahy and Gradisar (2012) that suggest that sleep problems predate anxiety rather than the other way around.

Similar effects to those noted above for sleep were seen, with those who did less exercise at baseline having larger decreases in anxiety at follow up. One explanation for this was that lower levels of activity is associated with poorer mental health as Biddle and Asare (2011) found, and could allow for more improvement given the potential for a floor effect in the current study. None of the other potential or hypothesised moderators seemed to have meaningful or interpretable effects on the outcomes.

Limitations

Although the analyses provide substantial support that the standard and intensive delivery formats produced similar outcomes, they do not necessarily show non-inferiority. A non-inferiority study design is commonly used in medical research when a new pharmaceutical treatment is compared to a very similar treatment that has been shown to be an effective through randomised placebo controlled trials (D'Agostino, Massaro, & Sullivan, 2003). In these situations, it is not ethical to withhold a treatment known to be effective to run a new placebo controlled trial for treatment that will likely have the same efficacy. So, the new treatment variant is compared directly to the existing without another control. However, to establish that the new treatment is not inferior to the established treatment requires much higher statistical power than traditional superiority trials, since factors such as poor study design or low participant numbers, that would usually only serve to weaken effects in superiority trials, may actually serve to increase the likelihood that no difference is found. Conducting the current study as a non-inferiority trial was not possible since a suitable controlled trial of the FRIENDS program run in a similar way, in a similar setting, and using the same measures was not readily available to calculate the necessary non-inferiority margin and despite the relatively large number of participants the power to complete a non-inferiority trial may still not have been sufficient. Therefore, this is a weakness of the current study as the design may serve to increase the likelihood of finding no difference between the two formats. The significant decreases in anxiety and depressive symptoms as well as the increases in positive factors observed across both formats in the current study is however comparable to other studies that have previously evaluated FRIENDS in its standard format. This evidence suggests a true treatment effect that appears

similar across formats was observed, even if non-inferiority cannot be more formally established.

As highlighted in the participant demographics (Table 2.) the average household income of the study sample is over double that of the wider Australian average household income. This clearly demonstrates that on average the participants in the current study had relative privilege which does lessen the generalisability of the findings to average or under-privileged families.

A major strength of this study is that it was conducted in a 'real-world' private community psychology setting without major exclusion or inclusion criteria, however this also gives rise to this study's major challenges. Due to the nature of the setting and using a known effective treatment with paying clients in a private community setting, randomization and a control condition, such as a waitlist, placebo, or TAU, were not used, which does limit the conclusions that can be drawn from this research. This serves as a significant limitation, as issues of development and natural remission of symptoms could not be controlled for when comparing two active interventions. Nevertheless, the present research design was seen as appropriate for answering the current research questions, due to the existence of previous trials that have compared FRIENDS to a non-active control condition (Barrett, Sonderegger, et al., 2001; Rodgers & Dunsmuir, 2013; Shortt et al., 2001). Clients and their families self selected into the study and chose the format of intervention that they would prefer to attend. The very nature of their choice to attend an intensive group over a shorter period of time as opposed to a standard format may give rise to confounding factors, although no such factors were readily identified in comparing the two groups. Dropout did not moderate any of the

observed effects in an analysis which provides reassurance that there was not an inherent bias that affected both outcomes and dropout.

The effect of particular therapists and the lack of formal adherence measures also leave some questions unanswered and weaken the conclusions of this study. A measure of adherence by participants such as completion of homework or even self-reported adherence may have allowed for greater understanding of the factors associated with outcome. Although families were involved in this intervention, additional measures of the depth of engagement may also have provided insights into individual differences in outcomes. Due to the real-world setting of this research and limited scope for administration of lengthy survey instruments, these factors were overlooked. A further challenge was the significant drop in response rate across the phases of this study. While attrition rates were similar to those seen in related research (Taylor & Montgomery, 2007), the possibility remains that families with a particular shared attribute (e.g. good or poor outcomes) may also have been more likely to continue responding to the research surveys. This is an inherent weakness in this kind of study and remains a challenge for assessing the effectiveness of interventions in trials and within clinical service settings. It does however also have the strength of showing improvements in a real world clinic without the biases that are often inherent in highly controlled clinical trials.

Alternative delivery formats such as group and intensive formats could also potentially reduce the costs to families, public health services, and society. However, data to assess the full costs of receiving the service and benefits in health-related quality of life and reduced long-term service use related to the intervention were not gathered as part of this study, which is an area for future economic evaluation.

Group interventions were generally charged at under quarter of the cost of engaging in the equivalent amount of individual therapy, however variations with government and insurance rebates means that this was not constant across families and individual data of these costs was not gathered.

Although intensive treatments could reduce barriers to engagement, there was no measure of client preference in terms of whether the intensive treatment was considered more acceptable to families than the standard treatment, or perhaps more challenging to sustain for two weeks. So, although there were similar outcomes in both conditions (i.e., very few significant between-group differences), it perhaps should not be assumed that intensive is preferable given it may be more taxing albeit over a short duration of time. Without patient acceptability or organisational feasibility data, it is difficult to conclude whether or not there is an advantage to the intensive format over standard care in this setting. To limit response burden, measures of preferences were not included, but may be investigated in future research.

Another limitation is that the current study relied on parent or caregiver report only. Parents or caregivers may not have clear insight into how child or adolescent feels as many symptoms of anxiety and depression are internal. This is particularly true with the older age groups who may hide more symptoms from parents or caregivers.

The sleep data were collected using categories rather than continuous indices for hours of sleep, limiting the utility of this measure for comparison to other data. Objective actigraphy data would provide further insight into the relationships

between sleep and treatment response, although such data collection was beyond the scope of the present study.

Future directions

The current study does offer promising support for the intensive delivery of family based CBT programs for children and adolescents, which has the potential to reduce barriers to engagement and therefore reach more young people. Delivering effective treatment and prevention programs in group formats across short periods of time could allow programs to be utilised during school holidays, as part of camps, or even in short stay hospital environments. Intensive formats in these settings could reduce the need for long term commitments from families and services alike. It also raises the possibility of more rural and isolated families being able to access short term treatments in relatively bigger centres. Future research would ideally validate the current finding in randomized controlled trials with non-inferiority designs, to further establish the use of intensive interventions as an effective alternative format.

Furthermore, testing the assertion that reductions in the delivery period reduces barriers to engagement would add substantially to the reasoning for using them as the reduction in barriers is assumed in the current study. Areas with low service utilisation could provide an ideal setting to assess the delivery of an intensive group intervention with comparison to a standard weekly format. Assessing barriers to engagement that may have prevented access to either format such as transport, time off work or school, or stigma would perhaps offer further insights. Furthermore, assessing factors associated with up-take, adherence, treatment completion, and both symptom and strength assessments, may go some way to assessing the impact of intensive and group formats on barriers to engagement, although adherence was

high in the current study. Further evaluations designed to assess predictive and moderating factors may also serve to provide better targeting of delivery format. Differences observed in the current study between outcomes post intervention and then at follow-up, further suggest that follow-up evaluation is essential in future research, especially when looking for predictors and moderators, as long-term outcomes may build upon short-term gains. As mentioned above, the lack of cost-effectiveness data was a limitation of this study that could be explored in future studies. Costs of the treatment to the families, government, and insurance providers would be a start, however other practical costs such as transport, time off work to attend the sessions, and any materials accessed in relation to the program would be necessary. Furthermore, measures of health related quality of life, days out of education and days out of usual roles for parents, may offer some insights as to how intensive and standard delivery formats compare in terms of their costs and potential benefits.

The current study also challenges an assumption often held that many psycho-social interventions including Cognitive Behavioural Therapies for children, as for adults, are ideally administered over 10-12 weekly or bi-weekly sessions (James et al., 2013). This assumption suggests that more time is needed to consolidate the skills gained through therapy. However, the current findings suggest that intensive delivery may lead to more rapid establishment of the skills needed to manage the symptoms of anxiety and depression. Future studies could look at adding more time points, for instance a time point in the standard delivery where the intensive would finish and a time point after the intensive delivery where the standard would finish, to further explore the speed of change. Furthermore, investigating other interventions that may also hold the same

assumption that standard delivery practises are the most effective, and investigating how alternative formats like intensive delivery fares, may allow other therapies to also reduce barriers to their implementation.

Conclusion

This study supports the notion that an intensively delivered CBT based group program for children and adolescents can be as effective in reducing anxiety and depressive symptoms as a traditional weekly format. It also advances research on increasing the transportability of effective CBT approaches through creative modifications that allow existing, effective, treatments to be delivered to young people who are not able to access traditional delivery formats. With the incidence of childhood mental health problems affecting so many young people, many of whom do not access treatment, any attempts to reduce the barriers to engagement is essential. Further investigation of the factors associated with treatment response are warranted, with a particular emphasis on identifying the severity of symptoms that are most appropriate for a program like FRIENDS and examination of the roles of sleep and socioeconomic status on symptom reduction. The study also adds to the increasing literature on the FRIENDS programs being delivered in diverse ways to effectively treat and prevent mental health difficulties in children and adolescents.

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Appendices

Appendix 1: Electronic Information Sheet

Dear [FIRSTNAME],

Thank you for participating in the [Program Name] research by completing the questionnaires as outlined in the information and consent sheets. These questionnaires help us in gathering information about your child's current strengths and challenges. By completing these we are able to track your child's progress during and after the program and contribute to ongoing research.

Each parent/caregiver will be sent two questionnaires each, four in total per family:
Mother/Caregiver 1 (**one** survey for self and **one** with child specific questions)
Father/Caregiver 2 (**one** survey for self and **one** with child specific questions)

Both parents/caregivers need to be filled out **independently** of each other to obtain independent data. Ideally at different times in separate spaces.

a. Your family will receive a link to their child's questionnaire (to be completed by both parents on behalf of your child). Each parent/caregiver will also be sent a link to a questionnaire. Each parent/caregiver must carefully complete the questionnaire independent of the other.
b. If you do not complete the questionnaires at home, you must complete them onsite at FRIENDS International using the iPads provided. You will need a minimum of two hours at FRIENDS International in order to complete the questionnaire onsite.

Please note that these questionnaires will be sent at three intervals: before the intervention, upon completion of the intervention and then 12 month intervals after the intervention has ended. This way, you can track the progress of your child/family.

All information collected through the research questionnaires is strictly confidential and will not be shared with any other agency or professional without your written permission. You can be assured of total privacy and, if interested, can view our privacy policy on our website.

This data is extremely important in evaluating the effectiveness of the FRIENDS Program and ensuring that the gold standard of our group intervention is maintained.

As a token of our appreciation, following completion of all research stages (pre, post, and 12-month follow up, we would like to off you one complimentary session at program completion and two further sessions at 12-months (with a mental health care plan). These sessions can be used for yourself or child, to feedback your child's full assessment results, check in on their progress, and provide you with further individualised strategies.

Additionally, results will contribute to our ongoing research supporting the effectiveness of our programs. Research is key in ensuring our programs continue to be revised to meet the same high standards that received World Health Organisation endorsement.

The link below will take you to one Child Survey- to be completed by one parent independently of the other on behalf of the child. The remaining surveys will follow in subsequent emails.

The survey is titled:
"[SURVEYNAME]"

To participate, please click on the link below.
Thank you for your contribution.
Sincerely,
[ADMINNAME] ([ADMINEMAIL])
Click here to do the survey: [SURVEYURL]

Appendix 2 Information Sheet

Increasing Resiliency in Children and their Families: An evaluation of the FRIENDS program in a Community Clinic Setting

Chief Investigator: Professor Paula Barrett, the University of Queensland

Researchers: Catherine Morris, Doctorate Candidate, University of Queensland. * Marthinus Bekker, Clinical Psychologist, PhD Candidate at ANU, Marita Cooper, Registered Psychologist, PhD Candidate at ANU, Professor Kathy Griffiths, National Institute for Mental Health Research, Australian National University, Professor Robyn Gillies, University of Queensland.

This letter is to provide information to you regarding some research which is currently being carried out at Friends Programs International foundation (formerly known as Pathways Health and Research Centre.)

All parents/caregivers who enrol their children in the FRIENDS program are being offered the opportunity to take part in a research project which aims to evaluate the effectiveness of the FRIENDS program. Participation is entirely voluntary and the decision to not take part will have no impact on the intervention your child receives. Below is some information about the proposed study and its relationship to the FRIENDS program.

Purpose of the Study:

The purpose of this study is to examine the effectiveness of the FRIENDS program within a community clinic setting across different age groups. This will look at developmental differences between these groups in areas of strength and challenges in how they cope with life. It will then look at how these change after involvement in the program.

It also aims to examine how childhood anxiety and parental anxiety interact and can impact on the rest of the family. Parents/Caregivers may choose to take part in additional training, and this will allow us to examine what relationship might exist between their own anxieties and their children's, and how this changes as the result of the program.

What we'll be doing:

Parents/Caregivers may be asked to complete diagnostic interviews and/or questionnaires in the first weeks of the FRIENDS program. This can occur over the phone or face-to-face or via internet survey system, at your convenience and will take up to one hour per participant. Further diagnostic interviews may be carried out at the end of the program and at 12 months follow up

intervals, both will again take up to one hour. This will show the gains your child has made and maintained, and help assess the effectiveness of the program. Parents/Caregivers will also be asked to complete a set of questionnaires before, after, and at 12 month intervals following the intervention; this will take approximately an hour. This is to determine whether the gains made during the program have been maintained, and whether your child requires further intervention. If this is the case your child will be offered treatment at Pathways Health and Research Centre. These pre-assessment questionnaires will be distributed at the beginning of the first FRIENDS session. The questionnaire packages are relatively lengthy and some questions are quite personal. Some of the material in the questionnaires may be confronting and make one feel uncomfortable. It is important to know that all of the information you provide on the questionnaires is confidential. Your data will be entered electronically through a secure survey system that is only accessible by researchers and will be anonymised once extracted from the system. Your name will not be associated with the questionnaire when placed into the database. If you feel discomfort while answering the questionnaires, we encourage you to call one of the registered psychologists working with this project for support. If you have any other difficulties or questions throughout this process, you can call the researchers or chief investigator at any time.

At the 12 month follow-up interval you will be offered a free booster session at Friends Programs International Foundation to go over the skills again and help with any difficulties that have arisen in the 12 months after completion of the FRIENDS program.

Benefits of the Research

The benefits of the research for children, parents/caregivers and the community include the following:

1. Individual families who decide to participate in the research will receive free assessment in the form of a diagnostic interview with feedback prior to taking part in the FRIENDS programs. They will also receive feedback at the end of the treatment after a follow-up interview. Twelve months after the intervention they will receive a free booster session and the chance to meet with a clinician to discuss issues that have arisen in the previous year.

2. Parents/caregivers will also be given the opportunity to attend our new Adults Resilience program free of charge.

3. The research will also benefit future FRIENDS participants. A greater understanding of how anxiety is effected by family dynamics will help us to further tailor our interventions so that they specifically target risk and protective factors which will allow even better results for children and their families who enrol in the FRIENDS program.

4. Parents/caregivers will be provided with the opportunity to attend parent training evenings to support the practice of skills in the home environment.

5. Early intervention enhances a child's social and emotional skills and therefore reduces the likelihood that they will later develop anxiety or other emotional difficulties.

Confidentiality and Informed Consent

Please understand that you can withdraw from this project at any time without penalty or explanation. All of the information you provide to us is confidential and will only be seen by the research team working on this project, which includes; Catherine Morris, Marthinus Bekker, Marita Cooper, Lauren Smyth, and Paula Barrett. All information provided will also be kept strictly confidential and private as far as the law allows in accordance with University Policies. Data will be securely stored on password protected Lime survey system as well as password protected files. These will be kept for a minimum of five years in accordance with University and Ethical obligations.

Upon completion of the project, you will receive a report containing the results of the research if you request it. This will be mailed to your home.

As a token of our appreciation, following completion of all research stages (pre, post, and 12-month follow up, we would like to off you one complimentary session at program completion and two further sessions at 12-months (with a mental health care plan). These sessions can be used for yourself or child, to feedback your child's full assessment results, check in on their progress, and provide you with further individualised strategies.

If you are interested in participating in this study, please sign the consent form attached and return it to at your earliest convenience. Please note a witness is required when giving your consent.

If you have any further questions, please contact the Chief Investigator Dr. Paula Barrett on (07) 3846 4443 or Catherine Morris 0414 767 353, research@friendsprograms.com.au.

This study has been cleared in accordance with the ethical review guidelines and Processes of The University of Queensland and by the ANU Human Research Ethics Committee. These guidelines are endorsed by the University's principal human ethics committee, the Human Experimentation Ethical Review Committee, and registered with the Australian Health Ethics Committee as complying with the National Statement. You are free to discuss your participation in this study with project staff (contactable on 3846 4443).

If you would like to speak to an officer of the University not involved in the study, you may contact: University of Queensland School Ethics Officer on 3365 6502. Or The Australian National University Ethics Manager on+61 2 6125 3427 or Human.Ethics.Officer@anu.edu.au.

Appendix 3 Ethics Approval

From: <aries@anu.edu.au>
Subject: Human Ethics Protocol 2015/112
Date: 19 April 2016 at 12:32:01 PM NZST
To: <u5485519@anu.edu.au>
Cc: <human.ethics.officer@anu.edu.au>, <u5159254@anu.edu.au>, <paula.barrett@friendsprograms.com>

THIS IS A SYSTEM-GENERATED E-MAIL. PLEASE DO NOT REPLY. SEE BELOW FOR E-MAIL CONTACT DETAILS

Dear Mr Marthinus Bekker,

Protocol: 2015/112
Modalities of delivering an anxiety treatment protocol: A clinical trial of the FRIENDS program

On 19/03/2015 the above-noted human ethics protocol was approved. Under the NHMRC National Statement on Ethical Conduct in Human Research (2007), monitoring of approved research is required. We request a brief summary in ARIES on any ethical issues which may have arisen during your research and whether it proceeded according to the plan outlined in the above protocol.

To begin your monitoring report in ARIES, click on the following link.

https://aries.anu.edu.au/content/ASP/ANULogin.asp

Process:

Login > Human Ethics > Current Protocols > Find your protocol > Pencil > Monitoring > "Add" > Answer YES/NO questions > "Next" > Edit all answers with appropriate responses > "Save" > "Submit"

If you require further assistance with the monitoring process, please download the ARIES Monitoring Report Quick Guide (see the link below) and follow the instructions.

https://services.anu.edu.au/files/guidance/Quick%20guide%20MonitoringReport.doc

If you have any technical difficulties with ARIES, please call Gavin on x56782 or email human.ethics.officer@anu.edu.au. Please ensure your response on the Monitoring Tab of your application in ARIES is submitted within 2 weeks of this notice.

Kind regards,

Human Ethics Officer
Research Integrity & Compliance
Research Services Division
Level 2, Birch Building 36
Science Road, ANU
The Australian National University
Acton ACT 2601

T: 6125-3427
E: human.ethics.officer@anu.edu.au
W: https://services.anu.edu.au/research-support/ethics-integrity

Appendix 4 Questionnaires

Demographics		
First name.		
Last name.		
Email address.		
Child's name:		
Gender:	Male	Female
Age:		
Person completing this form:		
Relationship to child:		
Biological Mother's name:		
Mother's occupation:		
Biological Father's name:		
Father's occupation:		
Other children in the family (include name, age, sex):		
Approximate household yearly income (of child's primary residence):		
Who does the child live with:		
Custody arrangements:		
Name of school/kindergarten:		
Any relevant medical problems in child or family:		
Is your child on any medication? If so, what? And in what dose:		
Has your child had any previous Psychological therapy or testing? Please describe:		
Has your child been involved in any other therapies (e.g. Speech therapy, occupational therapy):		
Family Psychological History:		
Has the child's mother or mother's relatives had psychiatric problems? Please describe, including treatment:		
Has the child's father or father's relatives had psychiatric problems? Please describe, including treatment:		
Does the child's brother(s) or sister(s) have any psychiatric problems? Please describe, including treatment:		

Spence Child Anxiety Scale (SCAS)				
Below is a list of items that describe children. For each item please choose the response that best describes your child.				
My child worries about things.	1 (Never)	2	3	4 (Always)
My child is scared of the dark.	1 (Never)	2	3	4 (Always)
When my child has a problem, he/she complains of having a funny feeling in their stomach.	1 (Never)	2	3	4 (Always)
My child complains of feeling afraid.	1 (Never)	2	3	4 (Always)
My child would feel afraid of being on their own at home.	1 (Never)	2	3	4 (Always)

My child is scared when he/she has to take a test.	1 (Never)	2	3	4 (Always)
My child is afraid when he/she has to use the public toilets or bathrooms.	1 (Never)	2	3	4 (Always)
My child worries about being away from us/me.	1 (Never)	2	3	4 (Always)
My child feels afraid that he/she will make a fool of themselves in front of people.	1 (Never)	2	3	4 (Always)
My child worries that he/she will do badly at school.	1 (Never)	2	3	4 (Always)
My child worries that something awful will happen to someone in our family.	1 (Never)	2	3	4 (Always)
My child complains of suddenly feeling as if he/she can't breathe when there is no reason for this.	1 (Never)	2	3	4 (Always)
My child has to keep checking that he/she has done things right (e.g. Turning the lights off, lock the door).	1 (Never)	2	3	4 (Always)
My child is scared if he/she has to sleep on their own.	1 (Never)	2	3	4 (Always)
My child has troubles going to school in the mornings because he/she feels nervous or afraid.	1 (Never)	2	3	4 (Always)
My child is scared of dogs.	1 (Never)	2	3	4 (Always)
My child can't seem to get bad or silly thoughts out of his/he head.	1 (Never)	2	3	4 (Always)
When my child has a problem he/she complains of his/her heart beating really fast.	1 (Never)	2	3	4 (Always)
My child suddenly starts to tremble or shake when there is no reason for this.	1 (Never)	2	3	4 (Always)
My child worries that something bad will happen to him/her.	1 (Never)	2	3	4 (Always)
My child is scared of going to the doctor or dentist.	1 (Never)	2	3	4 (Always)
When my child has a problem, he/she feels shaky.	1 (Never)	2	3	4 (Always)
My child is scared of heights (e.g. Being at the top of cliff)	1 (Never)	2	3	4 (Always)
My child has to think special thoughts (like numbers or words) to stop bad things from happening.	1 (Never)	2	3	4 (Always)
My child feels scared if he/she has to travel in the car, or on a bus or train.	1 (Never)	2	3	4 (Always)
My child worries what other people think of him/her.	1 (Never)	2	3	4 (Always)
My child is afraid of being in crowded places (like shopping centres, the movies, buses, busy play grounds).	1 (Never)	2	3	4 (Always)
All of a sudden my child feels really scared for no reason at all.	1 (Never)	2	3	4 (Always)
My child is scared of insects or spiders.	1 (Never)	2	3	4 (Always)
My child complains of suddenly becoming dizzy or faint when there is no reason for this.	1 (Never)	2	3	4 (Always)
My child feels afraid when he/she has to talk in front of the class.	1 (Never)	2	3	4 (Always)
My child complains of his/her heart suddenly starting to beat to quickly for no reason.	1 (Never)	2	3	4 (Always)

My child worries that he/she will suddenly get a scared feeling when there is nothing to be afraid of.	1 (Never)	2	3	4 (Always)
My child is afraid of being in small closed places (e.g. like tunnels or small rooms).	1 (Never)	2	3	4 (Always)
My child has to do some things over and over again (e.g. Washing their hands, cleaning or putting things in certain order).	1 (Never)	2	3	4 (Always)
scribes your child.	1 (Never)	2	3	4 (Always)
My child gets bothered by bad or silly thoughts or pictures in his/her head.	1 (Never)	2	3	4 (Always)
My child has to do certain things in just the right way to stop bad things from happening.	1 (Never)	2	3	4 (Always)
My child would feel scared if he/she had to stay away from home over night.	1 (Never)	2	3	4 (Always)
Is there anything else your child is really afraid of?	Yes		No	
If Yes, Please write down what it is:				

Spence Pre-School Anxiety Scale (PSAS)					
Below is a list of items that describe children. For each item please select the response that best describes your child. Please select a value between Not True at All and Very Often True.					
Has difficulty stopping him/herself from worrying	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Worries that he/she will do something to look stupid in front of other people.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Keeps checking that he/she has done things right (e.g., that he/she closed a door, turned off a tap).	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is tense, restless or irritable due to worrying	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is scared to ask an adult for help (e.g., a preschool or school teacher).	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is reluctant to go to sleep without you or to sleep away from home.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is scared of heights (high places).	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has trouble sleeping due to worrying	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Washes his/her hands over and over many times each day.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid of crowded or closed-in places.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid of meeting or talking to unfamiliar people	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Worries that something bad will happen to his/her parents.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is scared of thunder storms.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.

Spends a large part of each day worrying about various things.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid of talking in front of the class (preschool group) e.g., show and tell.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Worries that something bad might happen to him/her (e.g., getting lost or kidnapped), so he/she won't be able to see you again.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is nervous of going swimming.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has to have things in exactly the right order or position to stop bad things from happening	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Worries that he/she will do something embarrassing in front of other people	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid of insects and/or spiders	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has bad or silly thoughts or images that keep coming back over and over	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Becomes distressed about your leaving him/her at preschool/school or with a babysitter.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid to go up to group of children and join their activities.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is frightened of dogs	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has nightmares about being apart from you.	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Is afraid of the dark	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has to keep thinking special thoughts (e.g., numbers or words) to stop bad things from happening	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Asks for reassurance when it doesn't seem necessary	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Has your child ever experienced anything really bad or traumatic (e.g., severe accident, death of a family member/friend, assault, robbery, disaster).	Yes		No		
Please briefly describe the event that your child experienced.					
Do the following statements describe your child's behaviour since the event?					
Has bad dreams or nightmares about the event	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Remembers the event and becomes distressed	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Becomes distressed when reminded of the event	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Suddenly behaves as if he/she is reliving the bad experience	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.
Shows bodily signs of fear (e.g., sweating, shaking or racing heart) when reminded of the event	Not True at All	Seldom True	Sometimes True	Quite Often True	Very Often True.

Strengths and Difficulties Questionnaire (SDQ)				
For each item please tick whether the statement about your child is False, Somewhat true or True. It would help us if you could answer all the items as best as you can even if you are not absolutely certain. Please give your answers on the basis of your CHILD'S behaviour over the last 6 months..				
Considerate of other people's feelings.	False	Somewhat True		True
Restless, overactive, cannot stay still for long.	False	Somewhat True		True
Often complains of headaches, stomach-aches or sickness.	False	Somewhat True		True
Shares readily with other children, for example, toys, treats, pencils.	False	Somewhat True		True
Often looses temper.	False	Somewhat True		True
Rather solitary, prefers to play alone.	False	Somewhat True		True
Generally well behaved, usually does what adult request.	False	Somewhat True		True
Many worries, or often seems worried.	False	Somewhat True		True
Helpful if someone is hurt, upset or feeling ill.	False	Somewhat True		True
Constantly fidgeting or squirming.	False	Somewhat True		True
Has at least one good friend.	False	Somewhat True		True
Often fights with other children or bullies them.	False	Somewhat True		True
Often unhappy, depressed or tearful.	False	Somewhat True		True
Generally liked by other children.	False	Somewhat True		True
Easily distracted, concentration wanders.	False	Somewhat True		True
Nervous or clingy in new situations, easily loses confidence.	False	Somewhat True		True
Kind to younger children.	False	Somewhat True		True
Often lies or cheats.	False	Somewhat True		True
Picked on or bullied by other children.	False	Somewhat True		True
Often volunteers to help others (parents, teachers, other children).	False	Somewhat True		True
Thinks things out before acting.	False	Somewhat True		True
Steals from home, school or elsewhere.	False	Somewhat True		True
Gets along better with adults than with other children.	False	Somewhat True		True
Has many fears, easily scared.	False	Somewhat True		True
Good attention span, sees tasks through to the end.	False	Somewhat True		True
Overall do you think your child has difficulties in any of the following areas: Emotions, concentration, behaviour or being able to get along with other people?	No	Minor	Definite	Severe
How long have these difficulties been present?	Less than a month	1-5 months	6-12 months	Over a year
Do the difficulties upset or stress your child?	Not at all	A little	A medium amount	A great deal
Do the difficulties interfere with your child's everyday life in the following areas?				
Home life	No	A little	A medium amount	A great deal
Friendships	No	A little	A medium amount	A great deal
Classroom learning	No	A little	A medium amount	A great deal
Leisure Activities	No	A little	A medium amount	A great deal
Do the difficulties put a burden on you or the family as a whole?	No	A little	A medium amount	A great deal

Health Questions				
Does your child eat wholemeal bread, grains or porridge?	Never	Sometimes	Often	Always
Does your child eat fresh fruit daily?	Never	Sometimes	Often	Always
Does your child eat vegetables daily?	Never	Sometimes	Often	Always
Does your child drink more than 3 cups of water a day?	Never	Sometimes	Often	Always
Does your child eat Organic or free range meat?	Never	Sometimes	Often	Always
Does your child eat Cheese, Yogurt or drink Milk daily?	Never	Sometimes	Often	Always
Does your child eat Eggs, Fish or Beans?	Never	Sometimes	Often	Always
How many hours does your child normally sleep a day?	2-5 hours	5-8 hours	8-10 hours	10 or more hours.
How many hours a day does your child usually spend on screen time?	6 or more hours	4-5 hours	2-3 hours	0-1 hours.
How many times a week does your child normally spend on outdoor activities?	None	1-3 times a week	4-6 times a week	Daily.
How many times a week does your child normally spend playing sports (Team or individual)?	None	1-3 times a week	4-6 times a week	Daily.
How many hours a week does your child spend with friends or animals?	0-2 hours	3-5 hours	6-8 hours	More than 8 hours.
How many times a week does your child share a meal with your family	None	1-3 times a week	4-6 times a week	Daily.

Children's Depression Inventory (CDI)

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Devereux Student Strengths Assessment (DESSA)

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