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“Stupid Little Pointy Needle!”

Dismantling a Cognitive-Behavioural Treatment for Chronically Ill Children with Needle-Related Distress

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Abstract

For some chronically ill children, having an injection is a regular occurrence and can result in distress and avoidance behaviour for the child and their family. There can also be negative health implications of these children not having their injections. Research supports the effectiveness of various cognitive-behavioural therapy (CBT) packages for childhood needle-related distress (NRD), although which components are most effective has yet to be identified. The aim of the present study was to replicate previous research findings from Mclvor (2011), by dismantling an existing manualised CBT package to determine whether cognitive and/or behavioural components were necessary for a reduction in NRD. Three treatment manuals were used to conduct this research, namely (1) a CBT manual (6 sessions), (2) a cognitive therapy (CT, 4 sessions) manual, and (3) a behavioural therapy (BT, 4 sessions) manual. Treatments were evaluated using a multiple-baseline across participants single-case design. Twelve children aged 7-13 of New Zealand European/Pākehā and Māori descent were randomly allocated to one of the three treatment conditions, with four children and their carers assigned to each condition. Case study and group analysis indicated that six sessions of CBT was more effective than four sessions of CT or four sessions of BT based on the magnitude of change displayed in relation to NRD symptoms and the number of promising single-case replications. However, when assessing individual case results in certain areas (e.g., coping and cognitions related to injections), CT and BT were just as effective as CBT for some children. Both children and carers expressed high levels of satisfaction with the three treatments and all children successfully received an injection. Treatment was also characterised by particularly low dropout rates with all 12 participants attending the required assessments and therapy sessions. Finally implications of this study are discussed including the outcome that exposure tasks tend to produce the most change. However, techniques essential for the development of common factors (e.g., therapeutic rapport) should not be eliminated without further research, as these processes may need to be established in order for the client to attempt exposure tasks in the first place.

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– Plus one outlier.**

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Chapter 1: INTRODUCTION

A Child's Description Of Needle-Related Distress Pre-Treatment

- *Therapist: "On the day of your injection, describe for me what happens?"*
- *Child: "Seeing the red blood eww. It even makes me feel like I'm going to die because they are going to drain all of my blood out of me, so I have to be relaxed when I'm dying! I might cry a bit...and try count all the hairs on dad's hand. There's a million and ninety three hairs".*

Lyla – 7½ years old, December 2012

SECTION ONE: So, What's The Problem? A Profile of Needle-Related Distress among Children in New Zealand and Overseas

Chronic Medical Conditions and Injections

Chronic medical conditions affect a large number of children, and tend to be defined as "lasting a year or longer, require specialised treatments or technologies and cause limitations in function, activities, or social roles compared with physically healthy peers" (Drotar, Witherspoon, Zebracki, & Peterson, 2006, p. 9). According to the 2006/7 New Zealand Health Survey, one out of every three children and adolescents (36.5%) had been diagnosed with a chronic physical or mental health condition that had lasted, or was expected to last, for more than six months (Ministry of Health, 2008). The six month or more prevalence¹ of chronic *physical* conditions only, estimates varied between 0.2% for diabetes and 14.8% for asthma (see Table 1).

Injections play a central role in the medical care of chronically ill and non-chronically ill children. The World Health Organisation states that, of all the medical procedures, injections are one of the most common with an estimated 8 - 12 billion given worldwide annually (World Health Organization, 2000, Dec 5). Despite this, in some areas of medical practice the use of needle injections may be decreasing due to the advancement in technology (see for example, Taberner, Hogan, & Hunter, 2012). In particular, the treatment and care of people with diabetes is evolving with the introduction of needle-free insulin injectors, implantable insulin pumps, insulin inhalers and insulin pills (Hanas, de Beaufort, Hoey, & Anderson, 1997; Sentry Health Monitors Inc, 2011). Other methods being explored include administering medication or

¹ Prevalence, as defined in epidemiology, is the total number of *existing cases* of a disorder as a proportion of a population (usually given as a percentage or per 100,000 people) at a specific time (Colman, 2009).

vaccinations to the outer layer of the skin which penetrate cells that reside in the skin (transcutaneous), or through routes such as the nose or mouth (mucosal) (Giudice & Campbell, 2006). Powder-Ject has also been developed, whereby medication is administered to the epidermis via a dry powder injection (Giudice & Campbell, 2006). Lastly, there are now a number of blood sampling options that involve a simple finger prick, although these methods tend to be reserved for people that require small amounts of blood to be drawn.

Table 1

Six-Month Prevalence of Chronic Medical Conditions among Children and Adolescents in New Zealand

Health conditions	Prevalence (95% CI)	Number of children
Eczema	14.1 (12.8–15.5)	120,600
Asthma	14.8 (13.5–16.2)	109,900
Oral conditions*	11.3 (10.1–12.5)	84,000
Allergies**	6.2 (5.3–7.1)	52,700
Birth conditions***	3.9 (3.0–4.8)	33,600
Rheumatic fever	< 0.3%	< 3,000
Cancer	< 0.3%	< 3,000
Diabetes	0.2 (0.1–0.4)	1,700

Note. Data taken from the 2006/7 New Zealand Health Survey (Ministry of Health, 2008). *Oral conditions include tooth decay, abscesses and infections of the mouth and gum disease. ** All allergies except eczema. *** Birth conditions include congenital heart defect, spina bifida, intellectual impairment from birth and Down syndrome.

Another alternative to traditional injections are jet injectors, which are one of the most commonly used methods having been developed in the 1940s. However, a number of contamination problems during mass vaccinations in the United States led the World Health Organisation to discontinue their use in common practice (Giudice & Campbell, 2006; Levine & Campbell, 2004). Furthermore, due to the jet injector mimicking the use of a needle by delivering medication through a high pressure, high speed nozzle that penetrates the skin, occasional pain and bruising may occur (Giudice & Campbell, 2006). For diabetes, daily insulin injections may still be required when using the jet injector and as yet there is no alternative to oral injections (i.e., injections into the mouth), thus eliminating some advantages of this approach (Meechan, 2000; Sentry Health Monitors Inc, 2011). Regarding oral injections, a method known as the “Wand” has been invented and has resulted in more favourable outcomes (e.g., more comfortable, less tissue damage, and less pain) (Palm, Kirkegaard, & Poulsen,

2004; Versloot, Veerkamp, & Hoogstraten, 2005). Nonetheless, it may be just a matter of time before jet injectors become common practice considering clinical trials are currently underway (see for example Ferayorni, Yniguez, Bryson, & Bulloch, 2012).

Despite these advancements in technology, needle injections continue to be an integral part of modern medicine due to their efficiency and effectiveness in terms of medical testing and/or drug therapies (Sokolowski, 2010). It is also unlikely that needle injections will become obsolete considering they are an important part of acute and chronic medication and surgical care, and medical imaging remains reliant on intravenous access. Therefore, while the range of procedures requiring access to veins could reduce, needles are likely to continue to be an important part of medical care for chronically ill children. The different types of injection procedures that chronically ill children receive all vary according to the type, frequency and location of insertion, which is usually determined by the specific chronic condition.

Many chronic medical conditions require needle injections as a part of diagnosis and on-going treatment including arthritis, cancer, bowel syndromes, rheumatic fever, multiple sclerosis, cystic fibrosis, diabetes, allergies, heart conditions, chronic infections and many more (Mohr, Cox, Epstein, & Boudewy, 2002; Patel, Baker, & Nosarti, 2005). The frequency and intensity of medical care and needle injections varies depending on the time of diagnosis and stage of medical condition. At the less extreme end of the spectrum, some chronically ill children require an injection once per year (hormone deficiency), while other children require them weekly (arthritis), or every two months (cystic fibrosis), and in some extreme cases up to five times per day (diabetes) (Ayers, 2011; Drotar et al., 2006; Hayman & Mahon, 2002). However, illness progression may change for some chronically ill children, particularly those diagnosed with cystic fibrosis, where hospitalisation may be required every six months and involves a two-week course of intravenous antibiotics (Ayers, 2011).

Medical terms used to describe where needle insertion points are made include intradermal (into the skin), subcutaneous (below the skin), intramuscular (into a muscle for slow absorption), intravenous (into a vein for rapid absorption) and intrathecal (into the fluid surrounding the spinal cord) (Martin, 2010). In practice, these areas commonly include the arm, hand, mouth, spinal cord and buttock. In some cases an intravenous catheter may also be inserted, although the location of insertion may vary including the neck or groin (Martin, 2010).

Bone marrow aspirations (BMAs) and lumbar punctures (LPs) are considered the most painful and potentially traumatic injection procedures for chronically ill children (Jay, Elliott, Ozolins, Olson, & Pruitt, 1985). BMAs are routinely given to children with cancer every two to four months, and involve the insertion of a large needle into the child's hip bone, followed by the suctioning out of marrow with a syringe that is then examined for the presence of cancer cells (Jay et al., 1985). LPs are similar, however the needle is inserted into the spinal column.

Alongside BMAs and LPs, there are more general injection procedures that chronically ill children may be required to have. Depending on the health condition, a venepuncture may be necessary, which is the process of obtaining direct access to the vein for the purpose of intravenous therapy or a blood sample (Martin, 2010). The usual site for venepuncture is the

median cubital vein in the forearm, but it can also be administered in other areas of the body (Harvey, 2010). In cases where only a few drops are needed, a simple finger prick can be used instead. Insulin injections are another type of procedure typically used to control blood sugar levels in people with diabetes. Insertions are made subcutaneously usually in the abdomen or thigh at least several times a day as more than one type of insulin may be required (United States National Library of Medicine, 2012). Lastly, some needle injections are required as part of a world-wide public healthcare initiative to prevent the onset of certain diseases, including vaccinations which are one of the most common injection procedures in New Zealand (Grant, Turner, York, Goodyear-Smith, & Petousis-Harris, 2010). There are a number of different sites used for vaccine administration such as those mentioned earlier (Centers for Disease Control and Prevention, 2012; Hickling et al., 2011).

In contrast, an intravenous catheter differs from other injection procedures. This is when a tube is inserted into the body for the administration of drugs and fluids, or when intravenous pressures need to be measured during operations or in intensive care (Martin, 2010). There are different types of central venous catheters, although perhaps one of the more common is a peripherally inserted central catheter (PICC). This is when a long, small, flexible tube is inserted into a peripheral vein, typically in the upper arm, and advanced until the catheter tip terminates into the superior vena cava to obtain intravenous access. PICC lines may stay in place for several days to several months, and in some cases for up to a year. The common use of a PICC is for giving antibiotics, chemotherapy, intravenous medication or fluids.

Though it is important to distinguish between different types of needle injections for medical purposes, it is also important to be aware that they may have different physiological and psychological effects on the child (Jay et al., 1985; Mohr et al., 2002). For example, the Centers for Disease Control and Prevention (2012) reported that certain vaccines can be more painful than others depending on the route taken. Intramuscular injections are considered one of the more painful procedures compared to dermal or subcutaneous routes, possibly due to the fact that the needle needs to be long enough to be inserted below the dermis and subcutaneous tissue to reach the muscle mass (Centers for Disease Control and Prevention, 2012; Mohr et al., 2002). Furthermore, if these injections are not inserted properly they can affect underlying nerves, blood vessels, or bone, resulting in a significant amount of pain. Research also suggests that children who receive venepuncture into peripheral veins and internal ports (e.g., antecubital region of the arm or dorsal side of the hand) report more mild pain, compared to no pain or distress for children who have external central venous lines accessed (Spagrud et al., 2008).

Some degree of apprehension about intrusive and painful medical procedures such as needle injections is considered normal (Blount et al., 2009; Ollendick, Davis, & Muris, 2004). For most children, the process of having an injection does not invoke any significant trauma, and they have adequate coping strategies to deal with these types of procedures (Drotar et al., 2006). Paediatricians also reportedly regard psychological intervention as unnecessary, claiming injections are only “minor procedures” and many children deal with them sufficiently

(Humphrey, Boon, Van den Heuvel, & Van de Wiel, 1992, p. 90). Therefore, for many children, having a needle injection is not a traumatic event and they have effective coping strategies. However, for some chronically ill children, injections can be a great source of distress. One of the most frequently asked question by children about to enter hospital is “Am I going to get a shot?” (Schechter, 2007, p. 1185). This could be because over half (56%) of children admitted to hospital consider their injection to be the most traumatic and painful aspect of their treatment (Eland & Anderson, 1977). This finding was later supported by Princeton Survey Associates (1996) who found that chronically ill children consider repeated injections the worst part of having an illness. Immunisation coverage in New Zealand is also considered to be marginally adequate for public health with a fear of needles and a previous negative experience with vaccinations being a key indicator of immunisation incompleteness among both healthy and chronically ill children (Bland, Clear, Grogan, Hoare, & Waldock, 2009; Grant et al., 2010).

Reasons for some children experiencing distress in connection with intrusive medical procedures may be related to the actual injection process (Kuensting et al., 2009). Based on clinical experience, Mohr et al. (2002) suggests that type, site and frequency of injection regime, as well as adverse injection consequences, are important moderators of injection anxiety. Adverse consequences that may occur include difficulty accessing the vein, incorrectly injecting the vein and piercing surrounding areas or venous collapse (Harrison, 2005). Venous collapse is a common occurrence among chronically ill children as they tend to have long-term repeated injections in the same location leading to scarred or damaged veins (Emanuelson, 2013; Kuensting et al., 2009). Some people also have smaller or deeper veins than normal resulting in poor vein visibility and palpability, while others have fragile veins that can break during needle procedures (Emanuelson, 2013; Kuensting et al., 2009). In the case of a blood test, the vein can also excrete the blood very slowly or stop providing blood altogether, leading to multiple injections (Kuensting et al., 2009). Unexpected pain and the sight of blood can also be adverse consequences for some people (Mohr et al., 2002). In most cases, these complications can result in health professionals performing multiple injections (e.g., in difficult cases up to 10 times) (Kuensting et al., 2009), while for some children it can take up to six hours before they agree to the injection due to a fear of further complications (Harrison, 2005). In extreme cases it was reported that one child was “pinned down on the floor by his father while a doctor attempted to inject him” (Harrison, 2005, p. 12).

In summary, chronic medical conditions among children are increasingly diagnosed and treated using injection procedures, despite advancements in technology and the threat that they are obsolete in medical care. In some circumstances, these procedures can be a great source of distress to the child and their carer due to some of adverse consequences that may occur (Pao & Bosk, 2011). Needle injections may elicit responses from children including phobia in some extreme cases, and more generally fear, anxiety and distress.

Needle-Related Distress: Definition

Several terms are used to describe the anxiety-based reaction children can have towards injections, making it difficult to identify a dominant term (Thurgate & Heppell, 2005). Typically definitions of specific terms such as phobia, anxiety and fear are fairly well distinguished, although not separated that well in psychological literature. Reasons for the diversity of terms used may be directly related to the variety of chronic medical conditions that children are diagnosed with and the different types of injection procedures associated with these conditions. For example, children with diabetes are usually described as having anxiety (Rzeszut, 2011), whereas children with cystic fibrosis tend to be described as having distress (Ayers, 2011). A lack of consensus on what term to adopt could also relate to disagreements with the use of certain terms in relation to children as explained in the previous section. Nonetheless, the most common needle-related terms used in the literature in relation to 'general' injections include *needle and injection phobia*, *needle and injection fear*, *needle-related anxiety* and *needle-related distress*. A more specific term pertaining to the type of chronic medical condition and location of needle insertion includes *dental anxiety* (see Table 2 for a summary).

Table 2

Definitions of Needle-Related Terms

Term	Definition
Needle and Injection Phobia	Full DSM-5 criteria met for specific phobia. Excessive fear in relation to needle insertion, which is unreasonable and causes significant functional impairment (American Psychiatric Association, 2013)
Needle and Injection Fear	An immediate alarm reaction, whereby the individual is afraid of needle insertion (Kendall et al., 1992; Sadock, Kaplan, & Sadock, 2007).
Needle Anxiety	A physiological, behavioural and/or emotional response, in relation to the apprehension of needle insertion (Kendall et al., 1992; Rzeszut, 2011; Sadock et al., 2007).
Needle Distress	Full DSM-5 criteria for specific phobia not met, but significant fear and anxiety regarding needle insertion (Duff, 2003; Taddio et al., 2009; Uman, Chambers, McGrath, & Kisely, 2008).
Dental Anxiety	A physiological, behavioural and/or emotional response, in relation to the apprehension of dental situations (Ng, Stouthard, & Leung, 2005; Williams, 2010).

Phobia

The term *phobia* derives from the Greek language meaning 'fear' or 'dread' (Stewart, 1994). Phobia is defined by many researchers as an excessive fear of a benign situation or object that is not in keeping with the actual danger it can or might present (Butler, 2001; Smalley, 1999; Stewart, 1994). *Needle phobia* and *injection phobia* tend to be similarly defined, and used when diagnosing specific phobia, blood-injection-injury (BII), which is a cluster of phobias that includes an exaggerated fear of blood, injury, injections, or any invasive medical procedure (American Psychiatric Association, 2013). The reaction of a person with needle/injection phobia is extreme and can include a vasovagal response with symptoms of reduced blood pressure and fainting during injections (Howe, Ratcliffe, Tuttle, Dougherty, & Lipman, 2011). Some suggest an avoidance of situations that might involve injections is also an important part of needle phobia (Smalley, 1999).

In the general psychological literature, needle phobia and injection phobia are used as both lay and professional terms (Thurgate & Heppell, 2005). They are both seen to cause significant distress and functional impairment particularly when the reaction is out of control and exaggerated (Antony, 1997), although they can also be seen as a natural reaction warning the individual of potential dangers (Mumford, 2004). Needle phobia tends to be defined as a "fear of medical procedures involving the insertion of needles into the body" (Thurgate & Heppell, 2005, p. 15). Others have more broadly defined needle phobia as ranging from "I am not at all scared of needles" (0) to "I am extremely scared of needles" (10) using a visual analogue scale (VAS) (Hanas & Ludvigsson, 1997). Similarly, injection phobia has been defined as a "Fear of receiving various types of injections and having a blood sample drawn from venepuncture or pricking a finger" (Öst, 1992, p. 68).

Overall, researchers have used the term injection/needle phobia relatively broadly, which may be partly due to there being no general agreement on the definition of this term (Hanas & Ludvigsson, 1997). Some researchers also use the term needle or injection phobia regardless of whether it is consistent with Diagnostic and Statistical Manual (DSM-5) criteria (American Psychiatric Association, 2013). There appears to be little difference between the use of needle versus injection phobia, although researchers tend to choose either one or the other (e.g., Öst, 2001; Thurgate & Heppell, 2005).

Fear and Anxiety

In comparison to phobia, *fear* and *anxiety* can be appropriate and adaptive responses to threatening stimuli (Kendall et al., 1992; Szmuk, 2005) and are often used interchangeably in psychological literature. Costello (1982) supports this view and states there is little empirical evidence demonstrating fear and anxiety differ from one another. Instead, both are seen as alerting signals that warn of impending danger (either an internal or external threat) and signal the person to take action (Kendall et al., 1992). On the other hand, others suggest that anxiety can be distinguished from fear in several ways.

In the past, fear has been defined as an immediate alarm reaction to a threatening stimulus (Sadock et al., 2007), whereas anxiety is an apprehension, tension, or uneasiness related to the expectation of danger which includes physiological, behavioural and emotional responses (Kendall et al., 1992). Some suggest fear is also usually directed toward some concrete external object or situation, but the focus of anxiety is more general and tends to be a response to a vague, distant or even unrecognisable danger (Bourne, 2010). Therefore, the person may be anxious about “losing control” of themselves or some situation, or they might feel a vague anxiety about “something bad happening”. Anxiety can also appear in different forms and levels of intensity. In relation to injections, the anxiety that some chronically ill children experience may be categorised as *situational anxiety*, where the anxiety is out of proportion to the actual threat and arises only in response to a specific situation, or it could be categorised as *anticipatory anxiety* in that it tends to build up more gradually over time as the situation draws closer (Bourne, 2010).

Fear and anxiety are not defined so specifically in relation to injections. Instead, they are described quite similarly, and some researchers choose to use both terms interchangeably (e.g., Rzeszut, 2011; Simmons et al., 2007). Most recently, needle fear has been described in an Australian study as a positive response to the question “Are you afraid of needles?” (Wright, Yelland, Heathcote, & Ng, 2009), a process also used by Simmons et al. (2007). Needle fear has been similarly used in a number of other studies (e.g., Agras, Sylvester, & Oliveau, 1969; Antony, 1997; Howe et al., 2011; Rzeszut, 2011). In addition to needle fear, anxiety-related terms are commonly used in the literature to describe the reaction children have toward injections, such as ‘needle anxiety’ (e.g., Howe et al., 2011; Rzeszut, 2011; Simmons et al., 2007), ‘anticipatory anxiety’ (e.g., Ayers, 2011; Duff, 2003), and more broadly ‘injection-related anxiety’ (e.g., Zambanini, Newson, Maisey, & Feher, 1999). Needle anxiety is perhaps the most common term used in relation to children with Type 1 or Type 2 Diabetes Mellitus having insulin injections (Rzeszut, 2011). All of the anxiety-related terms mentioned are typically defined according to the construct ‘anxiety’ as outlined in Table 2.

Another anxiety-related term commonly used in the literature in relation to injections is *dental anxiety*. This differs slightly to the previous constructs mentioned as it is specific to oral injections, although it is just as important considering oral injections are frequently used in dental care. Dental anxiety has typically been defined as “the degree to which a person is apprehensive about the dental treatment, and the duration of and reactions to these feelings” (Stouthard & Hoogstraten, 1990, p. 140). However, this definition may be criticised for being too ambiguous and excluding anxiety in relation to dental assessments (e.g., check-ups) (Williams, 2010). More recent definitions of dental anxiety suggest that it is a situation-specific trait anxiety, in which the person has a disposition to experience anxiety in dental situations (Ng et al., 2005). Overall, fear and anxiety in relation to injections have been broadly defined in the literature, although not quite so much as the term distress.

Distress

Compared to other terms, *distress* is defined as “any type of negative affect including anxiety, fear and stress” (Uman et al., 2008, p. 844). There is also a tendency to include the term *pain* in a definition of distress, despite a lack of empirical evidence supporting the inclusion of this construct (Duff, 2003; Uman et al., 2008). Even so, acute pain is often an inevitable component of medical care and frequently occurs in conjunction with injections. According to the International Association for the Study of Pain definition, “Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (IASP Subcommittee on Taxonomy, 1979). Psychological research tends to incorporate pain when investigating distress as they typically co-occur with regards to injections, although as exemplified below they are quite different concepts.

It has been suggested that *needle-related distress* should be reserved for individuals who do not meet full DSM-5 criteria for specific phobia, blood-injury-injection type (American Psychiatric Association, 2013), but present with significant fear and anxiety regarding injections (Taddio et al., 2009). Essentially, all of the terms used in the literature reflect some form of distress before or upon exposure to needle insertion (Duff, 2003; Thurgate & Heppell, 2005). Most researchers also tend to use either distress (e.g., Jay, Elliott, Katz, & Siegel, 1987; Jay et al., 1985) or phobia (e.g., Öst & Hellstrom, 1997; Öst, Hellstrom, & Kavera, 1992) to represent the reaction people have towards injections.

There are several disagreements in the literature regarding the use of the term needle phobia in relation to children that are relevant to using the alternative term distress. For example, Humphrey et al. (1992) argue that injections are not benign stimuli for children, but unpleasant sensory and emotional experiences that threaten the child's loss of control. Therefore, the child's response is not necessary phobic, but can instead be a normal fear which involves the distress response (Ellis & Spanos, 1994; Humphrey et al., 1992). Duff (2003) supports this view and argues that what is seen clinically is not needle fear or phobia, but anticipatory or procedural distress and anxiety. Furthermore, Ollendick, King and Muris (2002, p. 99) outline that some fear is considered normal in children provided the “fear is proportionate to the intensity of the perceived threat”. In light of these arguments, the term used in the current study was needle-related distress (NRD), which was defined as distress occurring in relation to the expectation or experience of needle insertion. NRD was considered the most inclusive term, with regards to situational parameters (e.g., medical or dental situations), level (e.g., mild, moderate to severe) and breadth of the reaction to the feared stimuli, thus making the present study relevant for a broader range of children. Injections are also often not benign stimuli for children, but rather are a legitimate threat that may involve the distress response. Given these considerations, distress was the primary phenomenon of interest in the present study, as opposed to the more narrowly defined phobia.

Now the phenomenon of interest has been defined, the second part of this section describes why NRD is an important problem by reviewing the frequency and implications of this problem. Section two then provides a review of the evidence regarding etiology. These three

sections are followed by an examination of the effectiveness of psychological interventions in relation to NRD and the limitations of these interventions. This discussion paves the way for the premise of the current study; namely, to assess whether cognitive and/or behavioural therapies are more effective than no treatment (i.e., the baseline phase) for a reduction in NRD and increase in coping among chronically ill children and their carers.

Frequency of Needle-Related Distress

The exact frequency of NRD among chronically ill children is unknown. Instead, the majority of research has focused on *healthy* children experiencing NRD and, more commonly, injection fear and needle phobia while having routine procedures such as immunisations and blood tests. Some studies report prevalence while others report incidence, therefore the specific term used in a particular study will be reported otherwise the word “frequency” will be applied more generally. Furthermore, of the research that has been conducted, large-scale epidemiological studies using specific diagnostic criteria to define the presence of NRD among children are rare. Most studies have instead estimated frequency by selecting largely arbitrary cut-off criteria on a variety of psychometric scales to define the presence of NRD. For instance, anchors such as “very calm/relaxed” versus “very upset/distressed” have been used (Fradet, McGrath, Kay, Adams, & Luke, 1990), while other studies have used anchors relating to nervousness and pain using the 10cm visual analogue scale (VAS) (Humphrey et al., 1992). Nevertheless, a literature review is necessary to obtain an estimate of the number of children and adolescents affected by reasonably high levels of NRD.

Needle-Related Distress, Needle Fear and Needle Phobia

International studies with child and adolescent samples have generally found fairly high levels of NRD. The first study was conducted in Canada by Fradet et al. (1990), who found in a mixed sample of 171 chronically ill and healthy children aged 3 - 17 that 36 - 64% experienced moderate to high levels of distress during venepuncture. Age accounted for 14% of the variability in the distress scores, with children aged 3 - 6 years exhibiting more distress behaviours than children over 7 years. Distress behaviours displayed before and after the blood test included crying, verbal complaints, torso movements, arm movements and facial grimaces. Consistent with previous research, no gender effect was observed, but parental anxiety and previous trauma experiences were correlated with the actual distress of the child (Jay & Elliott, 1983). This study was closely followed by Humphrey et al. (1992) who investigated the frequency of NRD in the Netherlands among 223 healthy children and found 83% of toddlers (aged 2.5 - 6), 51% of preadolescents (aged 7 - 12) and 28% of adolescents (aged 12 to 18) were distressed while having an injection. Similar to Fradet et al. (1990) age and distress were strongly correlated, with younger children (aged 2.5 - 6) experiencing higher levels of distress. A qualitative study carried out in the UK also estimated quite high rates whereby 13 of 14 (93%) children and adolescents diagnosed with cystic fibrosis (CF, aged 7 - 17) had self-reported NRD

(Ayers, 2011). Participants were a convenience sample recruited from a CF clinic at a paediatric hospital. Semi-structured interviews using thematic analysis and the Revised Child Manifest Anxiety Scale were used to screen for clinical levels of NRD. Overall, there appear to be fairly high rates of NRD among children regardless of whether they are chronically ill or not.

In comparison to research on NRD, there is somewhat more information on injection fear and needle phobia for healthy children. Studies have generally used fairly small samples apart from one large-scale epidemiological study ($N = 10,496$; Meltzer et al., 2008). Research has found that there are generally lower levels of needle phobia (8%; Hanas & Ludvigsson, 1997) compared with fear and anxiety of injections among chronically ill and healthy children (11 - 41%; Howe et al., 2011; Meltzer et al., 2008). However, the nature of these studies differed as some were epidemiological (Meltzer et al., 2008) while others simply reported frequency (Hanas & Ludvigsson, 1997), so it is difficult to compare them. They have also used different approaches to defining needle phobia or fear, such as determining phobia based on a VAS scale (Hanas & Ludvigsson, 1997) or using a measure not yet validated with children (Simmons et al., 2007). In other cases, the carer completed the outcome measure (Agras et al., 1969), despite research suggesting that child self-report is a more valid and reliable measure of psychological functioning (Engel, Rodrigue, & Geffken, 1994; Klein, 1991). Carers may also over- or under-estimate the amount of distress or coping strategies the child displays during medical procedures (Engel et al., 1994; Klein, 1991). As a result of these limitations, only indirect prevalence estimates of needle phobia can be inferred from the literature.

In summary, various research methods have been used to investigate the frequency at which children have a negative reaction towards injections. This has resulted in varying estimates from 8% (needle phobia) to 93% (NRD) (see Table 3 for a summary). Three main factors may have contributed to this variation.

Table 3
Frequency Estimates for Needle-Related Problems

Author	Construct	N	Age	Frequency	Health Condition
Fradet et al. (1990)	NRD	171	3-6	36-64%	Chronically ill/healthy
Humphrey et al. (1992)	NRD	233	2-18	28-83%	Healthy
Ayers (2011)	NRD	14	7-17	93%	Cystic fibrosis
Agras et al. (1969)	Injection fear	325	8-12	14%	Healthy
Meltzer et al. (2008)	Injection fear	10,496	5-16	11%	Healthy
Howe et al. (2011)	Injection fear	23	4-16	41%	Diabetes
Simmons et al. (2007)	Needle anxiety	54	11-14	27%	Diabetes
Hanas & Ludvigsson. (1997)	Needle phobia	159	10-18	8%	Diabetes

First, numerous terms and definitions have been used to investigate the frequency of this phenomenon, which may be due to the restrictive definition of some terms in which full DSM-5 criteria must be met (i.e., needle phobia), in comparison to the broader definition of other terms whereby DSM-5 criteria are not required (i.e., NRD). For instance, needle phobia may represent a small proportion of children with persistent fear that is excessive and interferes with functional activities, in contrast to NRD that encompasses a wider range of negative affect where everyday functioning is not necessarily impacted. There are also inconsistencies regarding the definition of some terms used, which may have impacted on the design and theoretical framework of some studies. For example, NRD has been defined using one term or a combination of terms including fear, anxiety, stress and/or pain.

Second, the variability in prevalence rates may be related to whether the research sample included chronically ill children, healthy children or both. For example, the study by Ayers (2011) used a sample of children diagnosed with cystic fibrosis and had a prevalence rate of 93% for distress. Age is also a significant predictor of NRD, with younger children experiencing higher levels of distress and pain compared to older children. Therefore, variability in the age range across research samples may have also influenced frequency estimates.

Third, different measures and procedures have been used to investigate the same construct, potentially impacting on research conclusions (Silverman & Rabian, 1994). In this case, previous researchers have assessed the same constructs using different questions, answer formats and even scales (e.g., VAS versus Likert Scale) (see Cassidy et al., 2002; Chen, Zeltzer, Craske, & Katz, 1999; Cohen, Bernard, Greco, & McClellan, 2002; Cohen, Blount, Cohen, Schaen, & Zaff, 1999; Fanurik, Koh, & Schmitz, 2000; Tak & van Bon, 2005; Wint, Eshelman, Steele, & Guzzetta, 2002).

Despite these limitations, some researchers suggest that a prevalence estimate of 10% for childhood needle phobia is credible (Agras et al., 1969; Hamilton, 1995; Hanas & Ludvigsson, 1997; Wright et al., 2009), with up to 50% of children experiencing significant levels of NRD (Fradet et al., 1990; Humphrey et al., 1992). However, a prevalence of 10% for needle phobia should also be interpreted with caution as estimates vary considerably. For example, several other researchers suggest the more inclusive phobia known as blood-injury-injection (BII) to have a prevalence rate of only 2 - 5% in the general population (Kleinknecht, 1987; Marks, 1988; Öst, 1992). Therefore, estimates for primarily needle phobia may be even lower considering BII phobia includes a fear of blood, injury, injections, or any invasive medical procedure. Overall, the frequency of NRD appears to be fairly common among healthy and chronically ill children, which if left untreated can have both short- and long-term implications.

Implications of Needle-Related Distress

NRD has been associated with a number of deleterious short- and long-term physical, medical, psychological and social outcomes during childhood and later in life. Little research is available on the clinical implications of NRD among chronically ill children; instead research has

been conducted more broadly. Most studies have investigated the impact of childhood medical experiences such as injections on future emotion states (e.g., anxiety) and behaviours (e.g., avoidance) (Bijttebier & Vertommen, 1998; Jones, DeMore, Cohen, O'Connell, & Jones, 2008; Kennedy, Luhmann, & Zempsky, 2008; Pate, Blount, Cohen, & Smith, 1996).

Short- and Long-Term Implications during Childhood

Some chronically ill children can experience severe physical (e.g., nausea, sleep and eating difficulties), behavioural (e.g., psychomotor agitation, freezing, clinging and avoidance) and emotional reactions (e.g., anxiety) when undergoing medical procedures (Ayers, 2011; Bush & Holmbeck, 1987; Howe et al., 2011; Jones et al., 2008; Kennedy et al., 2008; Young, 2005). In some cases, these reactions can occur hours, days, weeks or even months leading up to the procedure, whereas for other children they primarily appear when in the waiting room preparing for the injection (Bijttebier & Vertommen, 1998). The vasovagal reflex is a more severe physical reaction that some children may also experience. Affected children will show a transient slight rise in heart rate and blood pressure, that within a few seconds or minutes is followed by marked vasovagal slowing of the heart rate and drop in blood pressure, which can cause dizziness, light-headedness, paleness, sweating, nausea and even loss of consciousness (fainting) (Howe et al., 2011). Children that do not experience the vasovagal response may still exhibit some of these symptoms, which alone may be aversive when experienced, and generate both unconditioned and conditioned fear/anxiety that can combine with NRD to exacerbate distress. In contrast to other specific phobias (e.g., fear of animals and heights), merely the presence of the feared stimuli can elicit the vasovagal response in BII phobia (Öst, 1992). The initial short-term implications of NRD for children can be debilitating, but there are also significant long-term implications.

Research has shown that previous traumatic medical experiences in childhood may result in behaviour problems, later psychological disturbances, and avoidance of contact with other associated medical procedures and settings (Bush & Holmbeck, 1987; Pate et al., 1996). For instance, children with NRD have been reported to display increased pain and anxiety during oral injections (Poulton, Thomson, Brown, & Silva, 1998). In part, this may be due to children recalling between 59% (Chen, Zeltzer, Craske, & Katz, 2000) and 63% (Duff & Brownlee, 1999) of negative factual details about injection encounters (e.g., the length of the needle), and over 46% of them rating their subsequent fear and anxiety of injections as "very" or "extremely" high (Duff & Brownlee, 1999, p. 8). These findings have been replicated in more recent research on the influence of pain memory in relation to subsequent pain experiences when undergoing immunisations (Noel, Chambers, McGrath, & Klein, 2012).

Other research suggests that those with a history of more negative injection experiences show higher levels of state anxiety, more distress and less cooperation during subsequent procedures compared to children with previous positive or neutral experiences (Bijttebier & Vertommen, 1998; Fradet et al., 1990). Furthermore, the *quality* of negative experiences rather than the *quantity* appears to influence subsequent reactions during

injections (Bijttebier & Vertommen, 1998; Fradet et al., 1990; Katz, Kellerman, & Siegel, 1980). This is an idea that has been supported by qualitative research with children diagnosed with cystic fibrosis, whereby participants believed that NRD was caused by negative previous needle experiences during which medical staff failed to locate a vein resulting in excessive bleeding or bruising (Ayers, 2011). As a result of previous trauma, more extreme long-term effects of NRD were described in several other studies such as increased fear and pain, anticipatory anxiety, and less cooperation leading to physical restraint (Ayers, 2011; Howe et al., 2011).

Despite the compelling evidence that previous trauma experiences influence subsequent distress levels during injections (Dahlquist et al., 1986; Jones et al., 2008), there is debate in the literature as to whether fear acquisition is caused by an association with traumatic experiences (see Poulton & Menzies, 2002). For example, one study in particular showed that NRD may escalate over time with successive procedures irrespective of a previous traumatic experience (Ellis & Spanos, 1994; Young, 2005). Overall, NRD can be associated with increased anxiety, behavioural avoidance and less cooperation during subsequent procedures, as well as generalise to a number of other medical settings. Furthermore, children's recollections of injections can be vivid, which may or may not result in aversive responses during subsequent procedures.

Long-Term Implications during Adulthood

Anxiety and avoidance associated with injections are fairly stable across time, and may lead to health complications during adulthood (Bush & Holmbeck, 1987; Jones et al., 2008; Pate et al., 1996). This may be due to memories of painful and distressing medical encounters enduring for years, and childhood negative experiences leading to negative attitudes about, and avoidance of, healthcare situations in adulthood (Noel et al., 2012). Pate et al. (1996) and Jones et al. (2008) found similar results whereby those with negative childhood healthcare experiences had the least adaptive healthcare behaviours and behavioural avoidance of similar procedures. This is consistent with other research showing the stability over time of child distress associated with injections (Blount et al., 1992; Dahlquist et al., 1986).

Healthcare situations that may later be avoided in adulthood are numerous, and may include refusal of various injection procedures. For example, 23% of 200 Swedish and 27% of 177 American college students reported needle phobia was the main reason for not donating blood (Arvidsson, Ekroth, Hansby, Lindholm, & William-Olsson, 1984; Oswalt & Napoliello, 1974). Similarly, Yelland et al. (2009) found that, of 46% of adults who had a negative injection experience during childhood, at least 21% of them went on to avoid medical treatment including a flu shot, tetanus shot, blood test, pain relief, and donating blood.

Studies investigating the consequences and correlates of NRD have also not been limited to associations with physical, medical and psychological pathology indices; associations with quality of life and other psychosocial variables during adulthood are also apparent. A Masters thesis by Mathews (2011) described some of the short- and long-term implications of needle phobia among adults in New Zealand. A thematic analysis of interventions with five

adults (18 years and over) found that their fear made medical appointments stressful and resulted in on-going concern as to how they would cope in the event of serious ill health. They also described their behaviour as a source of shame and threat to personal competence. Three nurses were also interviewed in this study to assess the impact that needle phobia patients had on them. Overt signs of emotion and fear were distressing for nurses. Nurses acknowledged limited understanding of needle phobia and found it challenging caring for and carrying out procedures with distressed and fearful patients. A patient's fear also reinforced the novice nurse's self-doubt in their competence. Therefore, in addition to there being several implications for patients themselves, nurses and other medical personnel may be impacted both personally and professionally.

Researchers have also reported anecdotal evidence stating that, "in their clinical experience and that of others treating this type of patient", needle phobia results in numerous social problems (Öst et al., 1992, p. 263). For example, NRD can interfere with or destroy plans for education and/or employment as people can be discouraged from biological, nursing, or medical careers due to a fear of performing injection procedures (Mathews, 2011; Sokolowski, 2010). An aversion to injections can affect plans for travel and/or immigration, as vaccinations are mandatory in some countries (Hamilton, 1995). Other events such as visiting family or friends in hospital and leisure activities with a high risk of injury tend to be avoided (Hamilton, 1995; Marks, 1988; Öst et al., 1992). NRD can also result in extra costs and resources within medical settings due to failed procedures and having to repeat the injection (Jay et al., 1985; Willemsen, Chowdhury, & Briscall, 2002). In some cases women wishing to have children may decide against conceiving because of needle fear (Öst, 1992).

Through the process of generalisation, fear can also develop in relation to objects or situations associated with needles such as the sight of blood, syringes, white coats and even the antiseptic smell of hospitals (Ellinwood & Hamilton, 1991; Torgersen, 1979). Moreover, some patients typically avoid routine medical check-ups, seeing a physician when ill, and taking their children to medical check-ups or to a physician when ill (Hamilton, 1995; Marks, 1988; Öst et al., 1992; Taddio et al., 2009; Willemsen et al., 2002). They may even avoid small operations (Hamilton, 1995; Marks, 1988; Öst et al., 1992). Legal problems can also be unavoidable and in some cases result in death. For example, Marks (1988) reported that people with needle phobia have been charged by the police for refusing to provide blood tests ordered by the court in paternity cases (Marks, 1988). In the past, the same people had also refused local anaesthesia for dental operations and suturing, preferring to bear the pain instead. Lastly, there have been at least 23 reported deaths attributed solely to needle phobia and the vasovagal reflex during procedures such as venepuncture, blood donation, arterial puncture, pleural tap, and intramuscular and subcutaneous injections (Boas, 1942; Dale, 1952; Kulvin, 1966; Lockey, Benedict, Turkeltaub, & Bukantz, 1987; Lockhart, 1939; Morland, 1949; Rutsky, 1971; Sauls, 1966; Turk & Glenn, 1954; Turkeltaub & Gergen, 1989; Zukerman, 1947).

In summary, research shows that childhood NRD and the related consequences can continue into adulthood, resulting in potentially serious implications for health and quality of life

(Pao & Bosk, 2011). The social implications of NRD are also considerable, ranging from limited travel, leisure, legal problems and limited job opportunities. Consequently, the need for effective psychological interventions to alleviate NRD in children is crucial so that health complications later in life can be mitigated. An in-depth understanding of the etiology of NRD is also essential as it provides the foundation for treatment models.

SECTION TWO: Etiology of Needle-Related Distress

The majority of the research on the etiology of NRD has focused specifically on needle phobia, so this will be discussed thoroughly, although given the focus of this study emphasis will also be placed on research relating to NRD (where available). Several theories are influential in explaining the onset and maintenance of phobic anxiety, with clear evidence suggesting that evolutionary processes and a genetic predisposition have some influence (Coelho & Purkis, 2009; Öst, 1991). From an historical perspective, behavioural theories of phobic anxiety have the most empirical evidence, closely followed by cognitive theories. Others suggest that, rather than a single linear model of causation leading to fear learning, it is influenced by multiple competing contingencies that are then modified over time by feedback loops (Mineka & Sutton, 2006; O'Donohue, 1998). In other words, phobias can result from the complex interplay of various factors, as will now be discussed.

Evolution and Genetic Predisposition

Referring to factors also known as biological preparedness and non-associative pathways, the evolutionary perspective suggests that some stimuli are predisposed to evoke fear responses in humans. According to Seligman (1971), ontogenetic and phylogenetic selection creates tendencies to respond with fear to certain threatening stimuli, favouring the survival of those members of the species who developed those tendencies through the course of evolution. This theory may account for the distribution of specific phobias, in that the more commonly feared stimuli are usually evolutionarily old threats (e.g., fear of animals, especially insects and snakes, water and heights) (Coelho & Purkis, 2009). The DSM-5 acknowledges this by outlining that feared objects or situations tend to involve situations that might have presented with threat at some point in human evolution (American Psychiatric Association, 2013). Sokolowski (2010) also surmises that most violent deaths in our evolutionary history have been caused by penetrations from teeth, claws, fangs, tusks, stone axes, knives, spears, swords, and arrows. Therefore, an evolutionarily developed strong fear of skin puncture that in turn induces humans to avoid such injuries may have been selected for. There are however criticisms of the evolutionary perspective, particularly in relation to the identification and discrimination of plausible prepared fears. Some suggest that even though spiders and snakes are considered biologically prepared, only some of the species actually cause harm (Diaz, 2004). On the other hand it can be argued that unless there is an evolutionary need to discriminate between

different species, a more general tendency to fear and avoid all snakes and spiders is more likely to develop.

There is clear evidence that supports the hypothesis of a hereditary component to injection fear considering both the vasovagal reflex and needle phobia tend to run strongly in families (Hamilton, 1995). The heritability of BII phobia is also estimated at 48% in twin studies (Torgersen, 1979). Furthermore, in a more recent study the high percentage of individuals with injection phobia who reported having first-degree relatives with the same fear (29%) could, together with the high proportion of fainting history (56%), mean that a hereditary component is of some importance (Öst, 1992). Overall, it is clear that evolution and an individual's genetic endowment play a role in the development of specific phobias; however it is unlikely that these factors alone account for all of the individual variability in the acquisition of specific phobias. The influence of behavioural and cognitive theories must also be taken into account.

Behavioural Theory

Classical, Vicarious and Informational Conditioning

Traditionally, the acquisition of specific phobias favoured a classical conditioning-based explanation determined by Pavlovian principles (O'Donohue, 1998). This was illustrated by Watson and Rayner (1920) who conditioned a child to respond with fear to a harmless situation by repeatedly linking a harmless conditioned stimulus (CS) with a frightening unconditioned stimulus (US).

The classical conditioning theory of the origin of phobias has been tested exhaustively with adults. A study by Öst (1991) with 56 adults aged 17 to 58 with injection phobia showed that 56% could trace their fear back to negative conditioning from a healthcare experience. The study also showed that 24% could trace their phobias to having seen another child, often a sibling, have a negative experience with injections. In short, 80% of the sample could report either direct or vicarious conditioning experiences leading to the development of their phobia. The mean age of onset was eight years and often correlated with a first-time healthcare-related appointment. These results were replicated by Kleinknecht (1994), whereby 53% of 128 students aged 17 to 76 attributed the onset of their injection fear to traumatic conditioning. Kleinknecht (1994) went further and investigated the specific event that led to the development of fear and classified this according to either "pain-related trauma" or "frightening trauma". Frightening trauma (e.g., being physically restrained) was more frequently reported as being the conditioning event. Onset was less often due to multiple events that occurred gradually over time (22.5%), as opposed to having a single onset event (77.5%). In a more recent study, a sample of 177 adults attending an urban general practice in Australia completed a questionnaire related to needle injection encounters, and 46.2% of participants with needle fear related it to a previous traumatic experience with injections (Wright et al., 2009). Likewise in a qualitative

study adult participants typically attributed the onset of their needle phobia to a significant life event (Mathews, 2011).

Even though there is considerable evidence to suggest that classical conditioning can lead to the development of phobias, there have been some criticisms of this theory. Namely, it has become clear that traumatic experiences are neither necessary nor sufficient to explain the origins of all phobias for all people (Mineka & Sutton, 2006). For instance, some people report no conditioning event or cannot recall the event, that they have always been fearful, and are uncertain why (Öst, 1991). There are also methodological limitations to the way this phenomenon has been studied which relate to the reliability of retrospective reports to determine the onset of an event that occurred, in some cases, up to 50 years ago (see Kleinknecht, 1994; Öst, 1991). Many people simply cannot recall a history of traumatic classical conditioning in the origins of their phobia, although absence of memory cannot be taken as definite evidence for the absence of a relevant life event (Ayres, 1998). Some also argue that most retrospective studies investigating the origins of phobias have imposed preliminary constraints upon their results by limiting pathway options to various conditioning-based alternatives rather than incorporating all avenues (e.g., biological and evolutionary) (Poulton & Menzies, 2002). Due to these criticisms it became clear that two other associative pathways were also involved in fear acquisition.

Rachman (1977) identified vicarious and informational learning as indirect conditioning events that can lead to fear and phobias. In line with Bandura's (1986) social learning theory, it was suggested that vicarious conditioning was an important factor in phobia acquisition and that information and instructions from parents and other family members can influence the development of fear (Rachman, 1977). Therefore, vicarious conditioning can operate by observing the distress responses of others (e.g., carers) without experiencing direct conditioning (Blount et al., 2009), as reported in Öst (1991) whereby 24% of participants could trace their phobias to having seen another child experiencing a traumatic injection (vicarious fear acquisition has also been shown in primate animal models; Mineka, Davidson, Cook & Keir 1984). Studies focusing on this pathway among chronically ill children are scarce, however there is a large amount of literature that has focused on the impact carers and health professionals have on NRD more generally, indicating the possibility that multiple factors, including but extending beyond direct and vicarious classical conditioning, influence the acquisition and maintenance of fear and distress.

A well-established finding in the literature is that parental modelling in relation to distressing stimuli affects child responses (Ayers, 2011; Muris, Merckelbach, de Jong, & Ollendick, 2002). Modelling originated from the observational learning paradigm (Bandura, 1986) and is based on principles of vicarious conditioning and social learning theory (Ollendick & King, 1998). The premise is that behaviour can be acquired, facilitated, reduced or eliminated by observing others' behaviour (Ollendick & King, 1998). For instance, correlational and experimental research shows that carer anxiety, criticism, overprotectiveness, apologetic, and reassuring behaviours are associated with increased child distress (distress-promoting),

whereas distraction, humour and the use of non-procedural talk are associated with decreased distress (coping-promoting) (Blount et al., 2009; Claar, Simons, & Logan, 2008; Frank, Blount, Smith, Manimala, & Martin, 1995; Mahoney, Ayers, & Seddon, 2010; Schechter, 2007). The level of impact parental behaviour can have on child distress during injections can range from 53% (Frank et al., 1995) to 64% (Mahoney et al., 2010), while parent and nurse coping-promoting behaviours were seen to predict 40% of the variance in child coping (Frank et al., 1995). Several recent studies have replicated these results and shown that adult behaviours were found to influence child distress and coping during injections (Ayers, 2011; Silka et al., 2013; Taylor, Sellick, & Greenwood, 2011).

Alongside carers, the interaction between health professionals and the child can also impact on child distress and coping. While carer behaviours are more strongly correlated with child distress, health professionals' behaviours are strongly correlated with child coping (McCarthy et al., 2010). Coping-promoting behaviours of health professionals also reduce as the child gets older, regardless of the level of anxiety displayed (McCarthy et al., 2010). This could imply that children either cope more independently as they get older or health professionals tend to respond to the age of the child rather than clinical need. Ayers (2011) found that familiarity with hospital staff doing the needle procedure had a major influence on distress levels, to the point where a few children were reluctant to attend hospital if the familiar staff were not on duty. Trust in the health professional and their ability was also a factor associated with distress and coping. Taken together, research suggests that vicarious conditioning of distress responses from others potentially contributes to the development of NRD, although respondent and operant conditioning may also have some influence.

Respondent and Operant Conditioning

Skinner (1937) described the potential for interrelations between stimuli and responses, and outlined that interaction between various stimulus-response and response-stimulus relations are inevitable. In this paper he named the procedures and response types as respondent and operant. At the same time as Skinner's proposal, several other researchers had already studied this phenomenon. For example, Thorndike (1911) had already experimented with instrumental (operant) conditioning, Pavlov (1927) as mentioned earlier, had previously explored classically conditioned responses (respondents), and Miller and Konorski (1969) (this article was later translated and reprinted) had already proposed the existence of at least two categories of conditioned reflexes. However, it was Skinner's logical arguments that proved so successful in establishing the bi-conditional nature of responding.

Respondent conditioning, also known as stimulus-reinforcer, refers to inborn stimuli that automatically elicit certain responses without any prior learning or condition experience (Allan, 1998). For example, in humans a high temperature (US; unconditioned stimulus) leads to sweating (UR; unconditioned response). On the other hand, operant conditioning, also known as response-reinforcer, refers to behaviour that can be modified by its consequences (Allan, 1998). Consequences that cause behaviour to increase are called reinforcers, and those that

cause behaviour to decrease are called punishers (Martin & Pear, 2011). Even though respondent and operant conditioning have been proposed as two separate processes, Skinner outlined that behaviour is probably influenced by effects derived from the sometimes uncontrolled presence of *both* contingencies (Allan, 1998). Therefore, both processes may have some affect over the development and maintenance of NRD among chronically ill children.

Overall, while the accumulation of research over the past century suggests that childhood NRD is acquired through both associative and non-associative pathways (and influenced by respondent and operant principles), evidence suggests that these avenues are not sufficient to completely explain the etiology of phobias (Öst, 1991; Von Baeyer, McGrath, & Finley, 2008), so cognitive theories have also been proposed.

Cognitive Theory

Due to behavioural theories of fear acquisition dominating until the 1960's, it was not until the 1970's that the 'cognitive revolution' in psychology occurred and influenced the etiological theories of phobias (Davey, 2006; O'Donohue, 1998). From a cognitive theory perspective, it was argued that conditioning is not automatic and direct, but mediated by thought processes (Coelho & Purkis, 2009). These cognitive processes include attentional factors that bias toward prioritising threatening information, interpretational factors which allow rapid judgements to be made about the nature and intensity of the threat posed by the stimulus, and memory factors that prioritise potential threats for storage and retrieval at a later date (Merckelbach, De Jong, Muris, & Van den Hout, 1996). Outcome expectancy biases about the feared stimuli can also cause and maintain fear responses.

Attentional factors refer to a preferential allocation of attention to threatening verbal and visual material thus perpetuating the fear response (Coelho & Purkis, 2009; Merckelbach et al., 1996). For example in drawings, chronically ill children have reported the needle to be significantly longer than it actually is, which then penetrates the entire arm (Lewis, 1978), while others portray themselves as smaller than the needle in drawings (Rice, 1993). On the other hand, interpretational factors mean that when anxious individuals are presented with ambiguous information that can be interpreted positively, negatively or neutrally, they will tend to endorse a threatening or negative interpretation (Davey, 2006). Interpretational biases then maintain fear and anxiety by sustaining the range of potential threats the individual perceives (Davey, 2006). Equivocal results have been demonstrated for the influence of memory on fear responding, although some suggest that there is an enhanced coding and recall of threat-relevant information in anxious and fearful individuals (Davey, 2006).

The previous section describes how information processing can influence the fear response, but this can also be impacted by the beliefs and expectancies that individuals have acquired about the feared stimuli and potential outcomes (Davey, 2006). Research suggests that those with phobias tend to have beliefs related to potentially threatening outcomes associated with the feared stimuli. These beliefs form the basis for outcome expectancy

judgements. Coelho and Purkis (2009) also mention a similar process, but using a different term known as covariation, which is the tendency to overestimate the association between the phobic stimuli and aversive outcomes. For example, some children believe they will “Bleed to death” and that their “Arm will fall off and die when it runs out of blood” due to having a needle injection (Lewis, 1978, p. 21). Both concepts (e.g., expectancies and covariation) appear to explain the same phenomenon where individuals with phobias tend to overestimate the level of consequential danger associated with the phobic stimulus. It is further suggested that over-prediction of consequences arises from over-prediction of danger and under-prediction of available safety resources (e.g., escape routes) (Davey, 2006).

There is considerable evidence suggesting that outcome expectancy biases (or covariation) are causal elements in developing and maintaining fear responding (Davey, 2006; Merckelbach et al., 1996). For instance, individuals not only have outcome expectancies that maintain fear and trigger behavioural avoidance strategies, but they also possess reasoning biases that lead them toward using evidence to verify rather than disconfirm these beliefs. There are also a number of other appraisal processes that operate to maintain or inflate the aversive evaluation of the outcome rather than devalue it including post-conditioning experiences, vicarious information, interpretation of interoceptive cues, cognitive rehearsal and coping strategies that maintain the fear (Davey, 2006). As demonstrated behavioural and cognitive theories are pivotal to the etiology of phobias, which has led to a combined approach.

Cognitive-Behavioural Theory

The term *cognitive-behavioural* represents an amalgam of ideas involving the juxtaposition and partial integration of cognitive, behavioural and affective theories about how psychological problems may develop and be treated (O'Donohue, 1998). Prior to this, therapies for most psychological problems were typically developed within a framework of classical and operant principles leading to successful treatments such as exposure therapy, flooding, counter-conditioning, and systematic desensitisation. Several theories were suggested and modified before clinical practice started implementing cognitive-behavioural approaches for phobias; these theories were important tools to the foundation of CBT (Mowrer, 1939; Wolpe, 1958).

As discussed previously, Pavlovian conditioning was initially instrumental in shaping behavioural therapies, however limitations of this approach soon resulted in Mowrer's (1939) two-stage theory for the acquisition and maintenance of phobias. As elaborated by Mowrer (1960), this theory proposed that in the first stage (classical conditioning) a neutral event becomes associated with fear by being paired with a stimulus that evokes fear/anxiety. Through conditioning, these previously neutral objects, thoughts and images develop the ability to also elicit anxiety (i.e., as conditioned stimuli they elicit a conditioned response). In the second stage of this process (operant conditioning), instrumental escape or avoidance responses develop to reduce anxiety evoked by the various conditioned stimuli (e.g., objects, thought or images) because these responses are effective in reducing fear/anxiety (Ayres, 1998). Escape or

avoidance is then maintained as safety behaviours due to their success in relieving the person's discomfort (Lovibond, 2006). The second stage of Mowrer's theory is closely tied with principles of operant conditioning and the relationship between negative and positive reinforcement.

With regards to treatment, exposure therapy (e.g., systematic desensitization), as developed by Wolpe (1958) involves non-reinforced exposure to the conditioned stimulus (i.e., presentations of the conditioned stimulus without the occurrence of the unconditioned stimulus), thereby producing extinction of the conditioned response (Craske, Vansteenwegen, & Hermans, 2006). Once the capacity of the conditioned stimulus to elicit the conditioned response is reduced or eliminated through extinction, the motivation to emit the instrumental escape/avoidance response is reduced, and its reinforcement by fear reduction is pre-empted (Kehoe & Macraem, 1998; Mowrer, 1960). If extinction does not occur then phobic anxiety is maintained along with phobic escape and avoidance. This process has enormous clinical implications and forms the foundation for several key therapeutic strategies (Craske et al., 2006).

In the context of conditioned fears and phobias, safety behaviours interfere with and may prevent exposure, both in everyday life and in therapy, as individuals carry out these often very subtle behaviours that have been learned because they are thought to prevent perceived harmful outcomes (Lovibond, 2006). From a cognitive perspective, safety behaviours act to prevent the disconfirmation of irrational danger beliefs concerning the feared object, as the absence of harm is attributed to the safety behaviour rather than a lack of danger in the first place (Lovibond, 2006). The notion of safety behaviours is similar to that of safety signals, although in the latter case avoidance responding almost always leads to feedback stimuli which may then become learned safety signals (or in other words conditioned inhibitors) (Lovibond, 2006). These signals serve as an alternative source of positive reinforcement for avoidance behaviour (Lovibond, 2006). For example, in the case of NRD, safety behaviours may involve carrying out rituals to prevent fainting, while a safety signal may be the presence of another person, therapist, medication, food or drink. Furthermore, social concerns such as embarrassment and/or negative evaluation by others can also motivate safety behaviours. These concepts address some of the limitations of Mowrer's two factor theory, particularly in relation to extinction processes (Craske et al., 2006).

The limitations of two factor theory were addressed further by researchers who proposed that fear reactions comprise three components: cognitive, behavioural and physiological (Lang, 1971). The cognitive component includes irrational beliefs, catastrophic statements and erroneous interpretations. Catastrophic misinterpretation is particularly important and considered the central premise for panic attacks and other related anxiety disorders (e.g., NRD) (Westbrook, Kennerley, Kirk, & Centre, 2011). The supposition is that bodily or cognitive changes (e.g., increased heart rate or breathing difficulties), which are symptoms most often caused by anxiety, are interpreted as indicating some immediate and serious threat (e.g., "I'm going to die") (Westbrook et al., 2011). These thoughts cause more anxiety, and therefore more symptoms, confirming the individual's threat perception. Lang

(1971) then proposed that the behavioural component includes passive avoidance with anticipated confrontation of the object, escape and active avoidance (this includes safety signals and safety behaviours as previously discussed). The physiological component includes activation of the autonomic system and other bodily functions (e.g., increased blood flow to the amygdala and bodily changes just previously mentioned). It was proposed these response systems are partially independent, but interactive, resulting in feedback loops that maintain the anxiety (Lang, 1971). For instance, a child with anxious thinking regarding injections might have enhanced awareness of autonomic feedback that results, in turn, in more danger-laden thinking (Craske et al., 2006). Autonomic activity may then feedback to influence muscle reflexes which then disrupts the behavioural response system by producing unskilled performance. These behavioural impairments may then be perceived and contribute to an ascending spiral of verbal, behavioural, and autonomic activation (Craske et al., 2006).

Cognitive-behavioural theory also integrates other perspectives, most notably social learning theory (Bandura, 1986) and the idea of vicarious learning as discussed above. In particular, it places emphasis on the learning process and the influence of contingencies and models in the environment in the development and alleviation of psychological distress. Thus interventions using cognitive-behavioural theory focus on both the child's internal and external environment (Kendall et al., 1992). As an expansion of Lang's three systems theory, Greenberger and Padesky (1995) proposed the five part model for understanding various psychological problems. The basic assumption is that the five systems are interconnected (e.g., cognition, behaviour, physiology, emotion and environment), and altering any one of these can lead to systemic changes, in all five components and thus alleviate the presenting problem (Greenberger & Padesky, 1995). For example, the thoughts an individual has about the phobic stimuli tend to be irrational (e.g., "I'm going to die" or "It will hurt a lot"). Physiological reactions can then occur in combination with these thoughts (e.g., increased heart rate; thoughts about danger). These physiological and cognitive reactions then result in behavioural avoidance of the phobic stimuli, therefore the individual rarely finds themselves in situations where they encounter evidence that disconfirms the phobic beliefs, thus perpetuating the fear and anxiety (Davey, 2007). Other important maintaining factors include thoughts about the meaning or consequence of the physiological symptoms (e.g., I'm going to faint) or the anticipated social outcomes (e.g., I'm going to be embarrassed) as well as safety behaviours. External factors such as the actions of people close to the individual may also maintain NRD by assisting the individual to directly or indirectly avoid the feared stimuli.

In summary, behavioural theories initially provided the foundation for explaining phobic anxiety. These were later widened to include cognitive theories, resulting in the amalgam of the two domains to form cognitive-behavioural theory/therapy. Therefore, phobic anxiety can be conceptualised as being caused and maintained by cognitive and behavioural processes jointly interacting. These principles have formed the mainstay of interventions for NRD with children, a topic which will be examined next.

SECTION THREE: Treatment of Needle-Related Distress

Given the etiological factors described previously and their general focus on variants of social learning theory, cognitive and behavioural theory (except non-associative pathways for which no intervention exists yet), several treatments building upon these basic concepts have been developed for chronically ill children with NRD. Over three decades of research has been dedicated to developing effective interventions for these children possibly due to injections being a large part of their lives, and the amount of evidence pointing to the significant distress they elicit (Jay et al., 1985). Despite this, there are a number of controversial methods that continue to be used for childhood NRD and several limitations that exist in the treatment literature.

Physical Restraint and Pharmacotherapy

The need for efficient and cost-effective non-psychological interventions for childhood NRD has in some circumstances prevailed, resulting in controversial methods being used such as physical restraint and sedation (Pao & Bosk, 2011; Taddio et al., 2009). Historically, physical restraint was used with children displaying problematic and defiant behaviour during injections (Willemsen et al., 2002). This behaviour was seen to interfere with injection administration, usually resulting in numerous unsuccessful attempts and increasing the cost and utilisation of resources (Jay et al., 1985; Willemsen et al., 2002). Fairly recent articles suggest that physical restraint is still used (Harrison, 2005; Lynn, 2010), despite the negative implications it can have on the child such as increased anxiety, avoidance of healthcare, and non-compliance with medical treatment regimens (Willemsen et al., 2002). Several studies have found high levels of physical restraint being used with children ranging from 53-80% ($N = 23$) in one study (Manne et al., 1990) and 74% ($N = 2188$) in another (Papa, Morgan, & Zempsky, 2008). A recent qualitative study showed that the majority of 14 children taking part had been physically restrained in the past, leading to further distress for the child and carer (Ayers, 2011).

In contrast to other psychological problems, the efficacy of pharmacotherapy combined with psychotherapy for anxiety disorders is limited (Black, 2006; Foa, Franklin, & Moser, 2002; Hayward & Wardle, 1997; Jay et al., 1987; Otto, Smits, & Reese, 2005). Regardless, medication is still used in Europe and the United States for NRD, where it is routinely administered to children undergoing injection procedures (Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995; Pao & Bosk, 2011), ranging from local to topical anaesthetic, sedatives or analgesics (Blount et al., 2009; Willemsen et al., 2002). Children have also been medicated with antihistamines, antipsychotics, selective serotonin reuptake inhibitors (SSRIs), benzodiazepines, morphine and nitrous oxide to reduce distress during injections (Hamilton, 1995; Pao & Bosk, 2011; Taddio et al., 2009). Of the treatment trials that have investigated pharmacotherapy for chronically ill children with NRD, results have not been promising (Jay et al., 1995; Jay et al., 1987; Jay, Elliott, Woody, & Siegel, 1991). Generally results showed that children and carers rated more

behavioural adjustment symptoms following the injection (Jay et al., 1995) or no significant differences from the control condition in regards to distress, pain and pulse ratings (Jay et al., 1987). In some cases, although Valium demonstrated less effectiveness compared to CBT, it was helpful in reducing behavioural distress prior to the procedure (Jay et al., 1991). Results from the same study failed to support the value of combining both approaches. Side effects from these studies involving pharmacology methods ranged from confusion, behavioural disinhibition, paradoxical withdrawal, irritability, lethargy, appetite difficulties and tiredness. These are symptoms that could potentially impact on the habituation process.

Aside from more extreme pharmacological interventions, there are less intrusive methods that can be used such as topical anaesthetic creams (Eichenfield, Funk, Fallon-Friedlander, & Cunningham, 2002), vapocoolant cold spray (Farion, Splinter, Newhook, Gaboury, & Splinter, 2008), pinching, rubbing or vibration near the site (Fowler-Kerry, 1992). Topical anaesthetic cream is the preferred pharmacological method due to its non-painful and non-invasive nature (Koh et al., 2004). Even though there is no completely effective anaesthetic currently available, a eutectic mixture of local anaesthetic (“EMLA cream”) is commonly used. EMLA cream has shown to be effective at reducing pain associated with lumbar punctures, vaccinations and intravenous insertions (Nagengast, 1993; Robieux, Kumar, & Radhakrishnan, 1991). However, there are several limitations to this approach including a minimum application time of one hour to be effective (Medical Economics Company Inc, 2000), possibly leading to underutilisation due to time constraints and costs associated with busy hospitals. EMLA cream can also come off, be placed on an area not chosen for access by the procedure nurse, or be placed for an inadequate or excessive amount of time (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011). Other potential limitations include blanching of the skin (Buckley & Benfield, 1993), possibly making needle insertions even more difficult (Teillol-Foo & Kassab, 1991). Overall, pharmacotherapy interventions to alleviate injection pain for children have not gained wide acceptance due their controversial nature, expense and side effects (Jay et al., 1995; Jay et al., 1987; Jay et al., 1991; Taddio et al., 2009).

A Novel Intervention for Injection Pain and Fear (Buzzy)

As an alternative to physical restraint and pharmacotherapy, a novel battery-powered device (also known as Buzzy) has recently been developed and applied within paediatric care to alleviate injection pain (Baxter et al., 2011). The device is a reusable 8 x 5 x 2.5cm handheld plastic bee containing a battery-operated vibrating motor and blue ice-pack wings aimed to block pain receptors while providing distraction during the insertion process. Essentially it combines cold temperature, vibration and distraction, which together are thought to reduce sharp injection pain. Buzzy can be pressed in place or secured to a limb via a Velcro strap or tourniquet near the insertion site. Due to this device being relatively new research is limited, although Baxter et al. (2011) conducted a randomised controlled trial comparing Buzzy with standard care (vapocoolant spray) using 81 non-chronically ill children aged 4- to 18 years.

Results showed that Buzzy decreased venepuncture pain significantly more than standard care without compromising procedural success. A number of limitations were evident in the study including a lack of double blinding to the intervention groups (e.g., patients and coders), although it might have been difficult to blind conditions where a conspicuous device is buzzing on the patient's arm. Furthermore, despite the researcher using randomisation, there may have been small differences in the type of procedure used (e.g., blood draw versus IV), sex of the participants and their initial anxiety, potentially creating biased results in favour of the device. Additional research is also needed to determine whether the device provides pain relief for other procedures (intramuscular injections).

An unpublished study using Buzzy was carried out in New Zealand by Counties Manukau DHB (Russell, Nicholson, & Naidu, 2013). Children with rheumatic fever were being referred to the ward due to not coping in the community with their monthly Bicillin injections. As a result, in 2011 a pain management approach was introduced that combined Buzzy with Lignocaine (local anaesthetic); it was initially used with 10 children showing positive results and then implemented fully within the community in May 2011. It was offered to all 405 children and adults receiving monthly Bicillin injections. A pre- and post-injection survey (after three procedures) was conducted evaluating pain and fear scores. According to 119 participants with paired data pre- and post-intervention, pain and fear scores significantly reduced when using both Lignocaine and Buzzy, compared to just Lignocaine alone. Despite this study not providing methodology information or being formally published, it does provide insight into the usefulness of Buzzy within a New Zealand community. Alongside interventions for injection pain being developed, there are several behavioural and cognitive-behavioural interventions available for the treatment of childhood NRD.

Behavioural Therapy Packages

Of the psychological interventions that have been developed for chronically ill children with NRD, behavioural interventions are among the most empirically validated (see for example, Blount, Powers, Cotter, Swan, & Free, 1994; Kazak, Penati, Boyer, et al., 1996; Manne, Bakeman, Jacobsen, Gorfinkle, & Redd, 1994; Manne et al., 1990; Powers, Blount, Bachanas, Cotter, & Swan, 1993), possibly due to the evidence for learning theory in the etiology of NRD. Most of this research was conducted in the 1980-1990s with generally positive results, although there are several limitations to these studies. The studies that are discussed in this section are also primarily behavioural "packages", meaning that they combine two or more techniques into one intervention and evaluate the combination (Smith, 2013). It should also be noted that although distraction has been grouped under "behavioural therapy packages", it can be considered both a behavioural and cognitive technique considering both processes are being utilised (Westbrook et al., 2011).

Several studies have looked at a combination of behavioural techniques for chronically ill children with NRD, in particular a variation of distraction, breathing, contingent reinforcement, behavioural rehearsal/role-plays and parental or nurse coaching (Blount et al., 1994; Cohen et

al., 1999; Manne et al., 1990; Powers et al., 1993). Both controlled breathing and muscle relaxation have been demonstrated to be clinically effective for reducing the physiological responses of NRD in children (McGabe, Ashbaugh, & Antony, 2010; Öst, Fellenius, & Sterner, 1991). The rationale for relaxation training is that it teaches the child to perceive sensations of bodily tension and use these sensations as cues for them to relax. However, there is some debate that relaxation techniques may interfere with exposure due to the potential to develop as a safety behaviour (Abramowitz, 2013; Westbrook et al., 2011). Empirical evidence also suggests that contingent reinforcement meets the criteria for well-established interventions for phobic-type disorders (Ollendick & King, 1998) and has shown to be effective with childhood NRD (Jay et al., 1985). This technique derives from principles of operant conditioning, and aims to alter phobic behaviour through changing the consequences (O'Donohue, 1998).

In some cases, rather than treatment being conducted by health professionals, parents have been taught to coach their child (Powers et al., 1993). In these studies, child distress reduced (whether self-report or observed), and in some cases where coping behaviours were assessed they also improved (Blount et al., 1994; Cohen et al., 1999; Manne et al., 1990; Powers et al., 1993). However, child self-report of distress was not obtained in some cases (Blount et al., 1994; Powers et al., 1993), despite parent ratings of child distress having low to moderate agreement with child self-report of distress (Engel et al., 1994). In other cases, inter-rater reliability for the coding of behavioural observational measures was obtained for only 38% of sessions although the average percentage agreement was high at 93% (The Child Adult Medical Procedure Interaction Scale-Revised, CAMPIS-R) and 98% (Observational Scale of Behavioural Distress, OSBD) (Powers et al., 1993). Some studies collected even fewer inter-rater reliability scores, with only six sessions rated for consistency with an agreement of 75% (Jay et al., 1985). Furthermore, there were limitations including no long-term follow-up, a focus on only one procedure (e.g., venepuncture), uncontrolled timing of medication, and no clarity as to which components contributed most to a reduction in distress (Manne et al., 1990). In comparison, in another study, family members who participated in treatment differed in their enthusiasm for learning new behaviours (Powers et al., 1993). Certain nurses also delivered medical treatment in slightly different ways, for example some had difficulty with finding venous access, which has shown to correlate with higher levels of child distress (Richeimer & Macres, 2000). On a positive side, one study in particular offered a number of distraction options rather than trying to implement the same techniques with boys and girls across different age groups (see for example, Cohen et al., 1999).

A few other studies have also investigated behavioural interventions, although only incorporating two techniques. Tak and van Bon (2005) investigated the use of distraction during, and information provision before, venepuncture in 136 healthy children, whereas Cavender, Goff, Hollen and Guzzetta (2004) assessed distraction and parental positioning during venepuncture for 43 healthy children. The distraction technique utilised in the first study included a video of Walt Disney's *Beauty and the Beast* (Tak & van Bon, 2005), while the second study utilised an illusion kaleidoscope, lift-the-flap books, and questions during the

procedure (Cavender et al., 2004). Parental positioning included side-sitting or chest-to-chest, whereas information provision included the use of a photo book accompanied by simple text explaining what the venepuncture involved. Results from these studies were mixed, with procedural information and distraction showing no effect for distress or pain (Tak & van Bon, 2005), but replacing procedural information with parental positioning while including distraction may reduce fear as rated by parents and health professionals (Cavender et al., 2004). On the other hand, child self-reported fear and pain as well as distress were not significantly different when using distraction/parental positioning versus standard care, which included an explanation of the procedure and parental presence (Cavender et al., 2004).

Several limitations to these studies may explain the inconsistent results. For example, the distraction techniques may not have been appropriate for all children as Walt Disney's *Beauty and the Beast* video may be more suitable for girls. Moreover, although the illusion kaleidoscope and lift-the-flap books are age appropriate, these items can be easily ignored during a venepuncture. This may explain the negative results found in another study also using the illusion kaleidoscope (Carlson, Broome, & Vessey, 2000). Information provision was also given via a photo book with an eight year-old boy as a model, but the sample included girls as well and may have been difficult to understand for the three year-olds taking part in the study. The influence of age on the effectiveness of distraction has been supported by a meta-analysis carried out on pain and distress in children undergoing medical procedures (Kleiber & Harper, 1999). Furthermore, both studies excluded follow-ups, while one excluded child self-report measures (Cavender et al., 2004; Tak & van Bon, 2005).

Nonetheless, while behavioural interventions have gained empirical evidence, cognitive-behavioural interventions have also emerged with an increased emphasis on therapy being given immediately prior to needle insertion.

Cognitive-Behavioural Therapy Packages

As is true of behavior therapies, cognitive-behavioural therapies (CBT) have certain principles in common. For example they are short-term, with booster and maintenance sessions offered if required (Kendall, Marrs, & Chu, 1998). Treatment can be delivered in group and individual formats and used with children as well as adults. The therapist is active, directive, present-oriented and problem-focused (Ginsberg, & Walkup, 2004). Even though there is a significant amount of heterogeneity among the components of CBT, most researchers tend to agree that it combines at least one cognitive and one behavioural technique (Uman et al., 2008).

CBT for children undergoing traumatic medical procedures was first developed for dental procedures, surgical preparation and burn treatments (Elliott & Olson, 1983; Melamed & Siegel, 1975; Peterson & Shigetomi, 1981). Participants in these studies were typically drawn from populations of children with chronic medical conditions, particularly cancer. Generally, they showed that techniques such as systematic desensitisation, exposure, relaxation training, modelling, distraction, emotive imagery and positive reinforcement were effective at reducing

distress in chronically ill children (Elliott & Olson, 1983; Melamed & Siegel, 1975; Peterson & Shigetomi, 1981). An important aspect of systematic desensitisation (also known as graded exposure) is the construction of a fear hierarchy from least to most feared situations, which has been an important component of CBT interventions for phobias.

Cognitive-behavioural packages for chronically ill children with NRD were first demonstrated in 1985 (see for example, Dahlquist, Gil, Armstrong, Ginsberg, & Jones, 1985; Jay et al., 1985). The treatment package by Jay et al. (1985) is the most widely researched, and incorporated filmed and participant modelling, breathing exercises, muscle relaxation, emotive imagery, behavioural rehearsal, and positive reinforcement in the form of a trophy with the child's name engraved on it. The trophy was awarded for lying still during the procedure and completing breathing exercises while having a needle injection. Even though Dahlquist et al. (1985) included the same components (with the exclusion of filmed modelling and behavioural rehearsal), a cognitive component known as positive self-talk was also added, where children were taught the statements such as "If I relax it won't hurt as much" and "I can handle this" (Dahlquist et al., 1985, p. 327). Subsequently others have suggested alternative child-appropriate statements that are helpful may include "I can do it" and "This will be over soon" (Uman et al., 2008, p. 844). A number of other CBT packages have utilised a similar combination of techniques such as relaxation, distraction and emotive imagery (Broome, Rehwaldt, & Fogg, 1998), as well as relaxation, breathing and cognitive restructuring (Lioffi & Hatira, 1999). These studies were carried out with chronically ill children undergoing either BMAs or LPs.

Research shows it is beneficial to use emotive imagery to promote coping (Kendall et al., 1992). Emotive imagery was first introduced by Lazarus and Abramowitz (1962) and is a variant of systematic desensitisation. Other examples of emotive imagery used in the past include Superwoman, whereby the child developed a story about having 'special powers' to get through the injection. The child was then asked before and during the injection procedure "Remember Superwoman – what would she do right now?" (Jay et al., 1985, p. 516). Some researchers have also used Teenage Mutant Ninja Turtles, with the child's favourite being Leonardo who had 'weapons' to protect himself against the injection (Friedman, Campbell, & Evans, 1993). Principles of emotive imagery are similar to Bandura's (1986) social learning theory, in the respect that the superhero served as a model of fearless coping that the child could then mimic in real life. Unfortunately there is limited research on the effectiveness of this as a separate treatment component, and instead most research has included emotive imagery as part of a CBT package, which has shown positive results (Jay et al., 1995; Jay et al., 1987; Jay et al., 1985; Jay et al., 1991; Mclvor, 2011).

Soon after the research by Jay et al. (1985) and Dahlquist et al. (1985), a New Zealand Master's thesis was carried out by Albers-Pearce (1989) investigating CBT to reduce anxiety for chronically ill children undergoing venepunctures. A sample of 22 chronically ill children (e.g., asthma, diabetes, cystic fibrosis, or cancer) aged between 3 - 10 years were recruited from the Paediatric Outpatients Clinic at Christchurch Hospital. Participants were randomly assigned to

the treatment or placebo group. Treatment components included illness information (e.g., why they needed a venepuncture), procedural information (e.g., description of what would happen during the venepuncture), stress management strategies (e.g., calm breathing and positive self-talk) and behavioural rehearsal/exposure. Results were not successful, with the psychological intervention indicating anxiety did not reduce any more than in the placebo group. Results for a non-intervention control group could have provided insight into whether anxiety increased, decreased or stayed the same, but unfortunately this data was not available.

Other researchers have based their intervention on the CBT package developed by Jay and colleagues in 1985 (Mclvor, 2011; Tyc, Leigh, Mulhern, Srivastava, & Bruce, 1997). Even though the study by Tyc et al. (1997) was primarily aimed at chronically ill children undergoing magnetic resonance imaging, intravenous insertions were also included. The study by Mclvor (2011) was also based on the CBT package developed by Jay and colleagues, however it expanded on this research by developing a standardised six-session CBT treatment manual. The intervention was evaluated using four chronically ill children of New Zealand/European descent aged 7 to 14 experiencing NRD. This study addressed previous research limitations by incorporating cognitive restructuring and carer involvement in therapy sessions. In this case, cognitive restructuring was included to target maladaptive thoughts, which are considered to maintain fear and avoidance behaviour by preventing the child from obtaining new and accurate information (Powers, Jones, & Jones, 2005). The process involves firstly being able to identify and modify maladaptive thinking when confronted with the feared stimulus, and then being able to develop alternative, more adaptive thoughts based on coping rather than fear. Various strategies were used to do this, for example identifying information processing errors, finding the evidence for and against a thought (e.g., 'being a detective'), developing alternative thoughts and then learning how to communicate thoughts and feelings (Blackburn & Davidson, 1995).

With the exception of Albers-Pearce (1989), results from the majority of studies have shown that CBT packages are effective at reducing child distress during injections (Dahlquist et al., 1985; Jay et al., 1985; Lioffi & Hatira, 1999; Mclvor, 2011). More specifically, the OSBD showed a 50% reduction in distress from pre-intervention levels in one study (Jay et al., 1985), compared with a 46-68% reduction in observed behavioural distress in another (Dahlquist et al., 1985). For studies that did not show statistically significant changes in child distress at post-treatment, other benefits were reported including reductions in pain, increased positive mood (Broome et al., 1998), and reductions in distress on the basis of staff but not child or parent self-report ratings (Tyc et al., 1997). Research replicating the techniques used in the CBT package developed by Jay and colleagues has also shown it to be more effective than oral Valium (Jay et al., 1987; Jay et al., 1991), with mixed results when compared to general anaesthesia (Jay et al., 1995).

There are several limitations to the studies discussed above, as well as strengths. When putting aside behavioural observation measures and primarily assessing child, parent and health professional self-report measures, some results are incongruent. Dahlquist et al.

(1985) showed that at post-treatment, health professional ratings of child distress only decreased slightly (e.g., mean decrease ranged from 9-22%), whereas parent ratings of child distress did not change from baseline (Dahlquist et al., 1985). Child self-report of distress also only showed moderate reductions during venepuncture (e.g., mean decrease ranged from 13-36%). The same pattern of results was found by (Tyc et al., 1997) with child and parent self-report ratings of child distress differing somewhat to staff self-report ratings of child distress. All other studies utilised child self-report measures alongside other parent and/or health professional measures, which typically showed either consistent negative results (Broome et al., 1998) or consistent positive results for a reduction in child distress (Liossi & Hatira, 1999; Mclvor, 2011).

Other limitations to research investigating CBT packages include the absence of follow-up measures (Dahlquist et al., 1985; Liossi & Hatira, 1999; Tyc et al., 1997) or small follow-up timeframes ranging from one month (Mclvor, 2011) to five months (Broome et al., 1998; Jay et al., 1985). Furthermore, despite many researchers referring to their interventions as “cognitive-behavioural therapy”, cognitive elements that explicitly addressed maladaptive thoughts (e.g., cognitive restructuring) regarding injections were absent in the majority of studies. The exception to this was research by Liossi and Hatira (1999) and Mclvor (2011). In studies that claimed to include a cognitive component, cognitive restructuring was in actual fact absent, and more general cognitive strategies were used such as positive self-talk (Dahlquist et al., 1985) or emotive imagery (Tyc et al., 1997).

The exclusion of cognitive factors in past research may be due to them being considered unimportant to the onset and maintenance of phobia-type symptoms until the mid-1990's (Merckelbach et al., 1996; Thorpe & Salkovskis, 1995). Child self-reports of distress were also lacking in previous research, with parental self-report measures taking precedence despite evidence suggesting that this is not a reliable measure of child distress (Engel et al., 1994; Klein, 1991). Some have also criticised previous research due to the abundance of single-case research designs or group designs with small sample sizes (Uman et al., 2008; Varni, La Greca, & Spirito, 2000). The most frequently noted limitation of single-case research is the lack of external validity in terms of generality (Kazdin, 2003). However, some researchers argue that having a large sample and null hypothesis testing does not guarantee generality of results (Blampied, 1999; Krause, 2011; Rorer, 1991). For instance, even though we can infer that the average person is typical of all persons in the sample population, this reasoning is problematic unless the population mean has very small variance and we know where this particular person is distributed (Rorer, 1991). Furthermore, even though the aim of these studies was not to generalise to other cases, reducing the need for external validity, systematic replication in a single-case design has implications for generality. For instance, successful replications across diverse participants support generality to the extent that they are diverse along various dimensions (e.g., age, gender, ethnicity, and socio-economic status) (Blampied, 2013).

Lastly, there is a need for standardised, generic measurement instruments developed for various developmental age groups. As it stands, most researchers utilise behavioural observation methods such as the CAMPIS-R and OSBD, however child, parent and health professional self-report measures vary considerably. In the past, researchers have used VAS, Likert scales and faces pain scales, all with different question content, formats and severity thresholds. This variability can be problematic when it comes to assessing the literature and making comparisons across studies. The meta-analysis by Uman et al. (2008) is a good example of this phenomenon, in which tests for between-study heterogeneity were significant for the majority of interventions. In this case, heterogeneity is defined as any variance not explained by the experimental variables based on chi-square testing ($p < 0.01$). Differences between the results of each included trial were analysed using chi-square in order to determine whether the results were statistically similar enough to combine, in which case some of them were not. Despite this, where statistically significant heterogeneity was detected, the data were still pooled with a note of caution for the reader. There is also a lack of measures that can quantify the cognitive aspect of NRD, which may relate to why cognitive restructuring tends to be excluded from treatment packages (Pao & Bosk, 2011).

Alongside these limitations, there are a number of strengths that these studies possess such as inter-rater reliability checks for behavioural observation measures and the inclusion of parents in therapy sessions, although parents were only encouraged to coach their child, rather than be active participants in therapy and/or given training to promote generalisation outside of the session (Broome et al., 1998; Dahlquist et al., 1985; Jay et al., 1985; Lioffi & Hatira, 1999). There are two aspects of generality where parents may play an important role, including the extension of treatment effect to contexts and situations beyond those experienced in the intervention, as well as the maintenance of the therapeutic effect (i.e., durability) over time. This is an area that requires further research considering the influence parents have on child distress and coping. Other strengths were that CBT packages may be applicable to a range of procedures including BMAs, LPs, MRIs, intravenous insertions and venepunctures.

One Session Treatment for Needle-Related Distress

OST is a massed, cognitive-behavioural exposure therapy that progresses over the course of a single, three hour session (Davis III, Ollendick, Reuther, & Munson, 2012). It was first promoted by Öst (1987, 1989) as a treatment for phobias combining graduated in vivo exposure, participant modelling, psycho-education, cognitive challenges, and skills training in an intensive treatment model. The treatment was originally developed for adults, although the adaptation and use of OST has increased in the last decade including a total of six studies investigating a variety of phobias with children and adolescents (Davis III, Kurtz, Gardner, & Carman, 2007; Flatt & King, 2010; Muris, Merckelbach, Holdrinet, & Sijnsenaar, 1998; Muris, Merckelbach, Van Haaften, & Mayer, 1997; Ollendick, Öst, Costa, & Cederlund, 2009; Öst, 2001). However, only one study has focused on injection phobia ($N = 12$) with children, and those with injection phobia were combined into a miscellaneous category with five other phobias

(e.g., enclosed spaces, blood, thunderstorms, deep water and loud noises; $N = 18$) (Öst, 2001). Therefore, it is difficult to determine if the treatment was primarily effective for injection phobia or other specific phobias. Results showed that according to different measures, 73% (assessor rating of severity), 70% (behavioural test), and 66% (self-rated anxiety) of participants in the miscellaneous category improved. Despite the study limitations it did shed some light on the fact that NRD may be improved using intense exposure, and that other components such as cognitive restructuring may be less important.

Despite there being a large amount of research conducted on OST for specific phobias, very few studies have replicated the findings from Öst's (2001) research, other than previous studies Öst and others have carried out with adult samples (Ollendick et al., 2009). More research with children and adolescents primarily diagnosed with injection phobia is needed to gain more conclusive evidence, particularly given that two meta-analyses concluded that multiple exposure sessions (up to five sessions) are generally more effective than one-session exposure treatments for phobic and anxiety type disorders (Olatunji, Cisler, & Deacon, 2010; Wolitsky-Taylor, Horowitz, Powers, & Telch, 2008). This result may be due to having the opportunity for a longer extinction of the conditioned response and thus habituation of physiological arousal, while at the same time correcting maladaptive catastrophic beliefs (Powers et al., 2005). Therefore, treatments should be delivered in multiple sessions to enhance long-term treatment gains and prevent relapse. On the other hand, this conclusion conflicts with Öst's (2001) results where treatment gains were generally maintained at one year follow-up with one session of exposure therapy. Considering the age and distress levels of the children included in the present study, exposing them to an injection in one session without the establishment of a therapeutic relationship and/or coping strategies was not considered ethical practice. For example, some participants have rejected OST as they did not want to undergo such a rapid treatment and/or feared that the degree of anxiety would be too high during an intensive therapy session (Öst, 1989). Furthermore, a more systematic investigation into the types of techniques that are necessary for change was the primary goal of the present study.

In summary, cognitive-behavioural therapy for NRD among chronically ill children is largely based on the work of Jay, Elliot and colleagues in the 1980s (Dahlquist et al., 1985; Jay et al., 1985). Results from these studies generally show that the treatments are very effective in terms of behavioural observation measures, but at times results are inconsistent when other self-report measures are considered. Alongside cognitive-behavioural therapy emerging in the 1980s, there has been the development of one-session treatment (OST) for NRD.

Effectiveness of Individual Treatment Components

Compared to behavioural and cognitive-behavioural packages, as individual components delivered as treatments in themselves are the most widely researched interventions. The more common treatment components that have been individually investigated are distraction and hypnosis. Other techniques that have been researched in

relation to reducing NRD among children include coping skills, cognitive information and memory reframing.

Distraction

Distraction is one of the most widely researched techniques for NRD of which this research was extensively reviewed in the behavioural therapy “packages” section above. Even so distraction will primarily be discussed below considering the objectives of the present study. Hypnosis is the second most widely researched technique, which has been shown to be effective among children at reducing both pain and distress during injection procedures (Katz, Kellerman, & Ellenberg, 1987; Kuttner, 1987; Lioffi & Hatira, 1999, 2003; Lioffi, White, & Hatira, 2006).

Based on the majority of studies discussed previously, distraction is effective at reducing distress, pain and fear in chronically ill and healthy children undergoing injections. Two RCT's randomly assigned participants to either an interactive distraction technique (e.g., interactive toy or distraction from parent), a passive distraction technique (e.g., movie) or a control condition/standard care (Bellieni et al., 2006; MacLaren & Cohen, 2005). Both clinical trials showed that passive distraction was more effective at reducing distress or pain than interactive distraction and the control condition/standard care. Of the studies that revealed no effect when using distraction, small sample size, methodological issues or the distraction technique used not producing a distraction effect (e.g., illusion kaleidoscope, cartoon and parental distraction) may have explained these results (Carlson et al., 2000; Cassidy et al., 2002; Kleiber, 1999). Despite this, some suggest that distraction should primarily be a short-term strategy as it can develop into a safety behaviour and perpetuate NRD (Westbrook et al., 2011).

More recently two different types of distraction techniques (single interventions not packages) have been developed for injection anxiety. The first includes stress-reducing syringes decorated with colourful designs (Kettwich et al., 2007). Stress-reducing butterfly needles were also created by decorating the wings in a symmetrical manner using flowers, smiley faces, butterflies and fish. One of the few studies investigating this needle modification showed the devices effectively and significantly reduced aversion, anxiety, fear and overall stress. They were 76% effective in preventing overt needle phobia in children and 92% effective in adults (Kettwich et al., 2007). All participants recommended that the devices be made available in medical settings. Nonetheless, there are a number of study criticisms, perhaps most importantly the devices were only shown to participants rather than used in an actual injection procedure. The applicability of this intervention in real life is unknown until the relevant research is done. The outcome measures utilised included VAS, and although these are empirically validated, no other measures were utilised that incorporate clinical cut-offs. Needle phobia was also not defined according to DSM-IV criteria, but rather arbitrary scores on the VAS scales used. Overall, a larger sample and further replication of the device using an actual procedure would need to be carried out before more substantive conclusions can be made.

The second distraction intervention recently developed is known as diversionary therapy technology, also called “Ditto” (or in some cases multi-modal distraction), which is a portable console that reduces anxiety and pain for children during traumatic medical procedures (Miller, Buccolo, Patterson, & Kimble, 2008; Miller, Rodger, Buccolo, Greer, & Kimble, 2010). The device works by using colourful marker characters called ‘Dittens’ that are inserted into the Ditto. The children then choose between procedural preparation, stories and/or games. A touch screen and motion sensor is also built into the machine. Once the game or story is playing, the child can tip and turn the Ditto or control the scene as they wish. It is non-intrusive to medical practice while distracting the child. Several studies have exemplified the benefits of this distraction technology in relation to pain and anxiety, although primarily with reducing pain during burn injuries among young children (Miller et al., 2008; Miller et al., 2010). Outcomes also showed ease of use and improvements in the medical process. Further research would need to investigate the use of this technology with injection procedures before it could be verified as an effective intervention for NRD.

Coping Skills

Coping skills have also been an important component included in some interventions and tend to be defined as “the ability to deal with threatening, challenging, or potentially harmful situations” (Hodgins & Lander, 1997; Walco, 2008). In one particular study, coping skills were delivered by asking children to view a seven minute video that involved a child modelling deep breathing and positive self-statements during an injection (Cohen et al., 2002). Eventually, the children did not use the coping skills during the procedure, which may have been due to the lack of training and/or the need for parents or nurses to be more actively involved. Even so, previous research suggests that a child’s ability to cope effectively with injections can influence the effectiveness of the intended therapy (Antal, Wysocky, Canas, Taylor, & Edney-White, 2010).

A meta-analysis (Suls & Fletcher, 1985) and review of the literature (Roth & Cohen, 1986) with adults who experience NRD showed that for acute, uncontrollable stress (e.g., watching their child have a needle injection); avoiding threatening information is more beneficial. On the other hand, for enduring, controllable stress (e.g., having a child with a chronic illness); attending to threatening information is more advantageous². Findings are variable in relation to these two coping styles among children (Blount et al., 1989; Manne, Jacobson, & Reddm, 1992; Peterson & Tolor, 1986; Slifer et al., 2011). In general, every individual copes with threatening situations in different ways and the same anxiety-reducing intervention may not work for all individuals (Walco, 2008)³. Some suggest that matching interventions with a preferred style of

² Theories of coping have mainly focused on Miller’s (1981) monitoring (attending to threatening information) and blunting (avoiding threatening information) coping style framework.

³ Leventhal, Nerenz and Steele (1984) identified five components to illness representation that may also affect coping including (1) identity, (2) consequences, (3) timeline, (4) cause, and (5)

coping (e.g., distraction with avoidance coping and information provision with approach coping) may result in optimal outcomes during injection procedures (Bernard, Cohen, McClellan, & MacLaren, 2004). Despite this, there is no clear coping pattern that is consistently superior in promoting adaptation to distress associated with medical procedures for children (Bernard et al., 2004; Walco, 2008). As a result, most researchers suggest that a mixed-focus intervention is the better option for paediatric populations with NRD, although these are very rarely researched as individual components (Bernard et al., 2004; Blount, Davis, Powers, & Roberts, 1991; Walco, 2008).

Cognitive Information and Memory Reframing

Other individual techniques that have been researched include cognitive information and memory reframing. Eland (1981) is one of the only researchers to individually assess a cognitive component in relation to NRD. The goal was to compare a topical anaesthetic with altering information processes and the interpretation of the injection pain. Essentially these processes also operated to modify the child's expectation of the injection. Nurses were told to say "I'm going to spray something on your leg...the spray will make the shot hurt less than other shots you've had" (Eland, p. 365). Results showed that for children undergoing immunisations, pain can be reduced using cognitive information. Providing information to the child by explaining what will happen during the needle procedure (i.e., psycho-education) has also been shown to reduce distress and pain (Harrison, 1991; Tak & van Bon, 2005). Preparation in both cases involved the use of a story book that provided simple descriptions of the procedure and why it was carried out, explaining that "The pain is noticeable but not unbearable, and that they will experience less pain if they relax their arm and cooperate with the technician".

Much the same as cognitive techniques, memory reframing is also under-researched. It was utilised by Chen et al. (1999) with a sample of 50 chronically ill children undergoing LPs. Memory reframing was administered by encouraging the children to re-evaluate their reactions and enhance their beliefs about self-efficacy (e.g., reminding themselves that asking the nurse questions helped them), realistically appraise their responses (e.g., extent of crying, screaming, and protest), and increase the accuracy of their subjective memory (e.g., increase their memory of coping strategies they used). Reframing memories of a previous injection experience reduced children's anticipatory distress, with further reductions at one week follow-up (Chen et al., 1999).

In summary, results from the majority of studies point to the effectiveness of behavioural treatment packages (in particular distraction) in the reduction of child distress and pain when undergoing medical procedures. Technique most often incorporated into behavioural packages have included strategies such as books, toys, videos, and/or talking during the procedure. More recently, decorated needles and technology (Ditto) have been developed as single interventions

control/curability. There is some evidence to suggest that these five dimensions can be applied to children (Goldman, 1991; Paterson, Moss-Morris, & Butler, 1999).

and are popular strategies to reduce injection anxiety. Even though there are some promising results regarding distraction and hypnosis as individual treatment components, studies were primarily in relation to reducing pain rather than distress. In other cases, behavioural observation methods and/or follow-up data was not collected. Furthermore, the majority of individual techniques that have been researched are behavioural, with cognitive strategies generally overlooked. For instance, as shown in Table 4, very few studies have individually assessed the effectiveness of behavioural strategies such as exposure, muscle relaxation and breathing exercises, while none have assessed strategies such as cognitive restructuring, positive self-statements and thought-stopping. Therefore, it is unclear if these cognitive or behavioural strategies add significantly to the treatment outcomes gained in previous CBT packages.

In relation to studies assessing multiple components, none have specifically compared the effectiveness of cognitive *versus* behavioural techniques for chronically ill children with NRD. Research that has investigated the individual effectiveness of two or more cognitive and/or behavioural treatment components for NRD is minimal, although one randomised controlled trial investigated the use of distraction, coping skills and deep breathing (Blount et al., 1992). Children who used deep breathing (via a party blower) and distraction were less distressed, although it is not clear what technique led to the treatment outcome (Blount et al., 1992). Multi-component treatment packages may be able to provide some insight into what individual techniques work best, however to date no research has dismantled a CBT package for chronically ill children with NRD.

Table 4

Studies Investigating the Effectiveness of Cognitive and/or Behavioural Components for Children and Adolescents with NRD

Study Type	N	Age (years)	Condition	Procedure	Intervention
Randomised Controlled Trial					
Tak and van Bon (2005)	136	3-12	Non-chronically ill	Venepuncture	Distraction & IP
Cohen et al. (2002)	61	3.7–6.9	Non-chronically ill	Immunization	Coping Skills
Eland (1981)	40	4.9–5.9	Non-chronically ill	Intramuscular	Cognitive Info
Franurik, Koh, & Schmitz (2000)	160	2–16	Non-chronically ill	IV insertion	Distraction
Press et al. (2003)	94	6–16	Non chronically ill	Venipuncture	Distraction
Vessey, Carlson & McGill (1994)	100	3–12	Non chronically ill	Blood draws	Distraction
Blount et al. (1992)	60	3–7	Non chronically ill	Immunisations	B, D & CS
Öst (2001)	12	7–17	Non chronically ill	Injections	Exposure
Harrison (1991)	100	6–12	Non-chronically ill	Blood sample	IP
Bellieni et al. (2006)	69	7-12	Non-chronically ill	Venepuncture	Distraction
Carlson et al. (2000)	384	4-18	Non-chronically ill	Venepuncture/IV	Distraction
Cavender et al. (2004)	43	4-11	Non-chronically ill	Venepuncture/IV	Distraction & PP
Cassidy et al. (2002)	62	5	Non-chronically ill	Immunisation	Distraction
Chen at al. (1999)	50	3-18	Chronically ill	LP	MI
Wint et al. (2002)	30	10-19	Chronically ill	LP	Distraction
Katz et al. (1987)	36	6–11	Chronically ill	BMA	Hypnosis
Kleiber et al. (2001)	44	4–7	Chronically ill	IV	Distraction
Lioffi & Hatira (2003)	80	6–16	Chronically ill	LP	Hypnosis
Lioffi, White & Hatira (2006)	45	6–16	Chronically ill	LP	Hypnosis
Tyc et al. (1997)	55	6-18	Chronically ill	IV insertion	CBT
Lioffi and Hatira (1999)	30	5-15	Chronically ill	BMA	CBT
Experimental Design					
MacLaren & Cohen, (2005)	88	1-7	Non-chronically ill	Venepuncture	Distraction
Kazak et al. (1996)	162	0-17	Chronically ill	BMA & LP	D, B, GI
Manne et al. (1990)	23	3–9	Chronically ill	Venepuncture	D, PR, B
Manne et al. (1994)	35	3–9	Chronically ill	Venepuncture	D, PR, BC, B
Jay et al. (1995)	18	3–12	Chronically ill	BMA	CBT
Single-Case Design					
Blount et al. (1994)	3	4.5-7	Chronically ill	BMA & LP	D, B, CS
Powers et al. (1993)	4	3-5	Chronically ill	IV & IM	D, B, M & BR
Mclvor (2011)	4	6–14	Chronically ill	Injections	CBT
Jay et al. (1985)	5	3.5–7	Chronically ill	BMA and LP	CBT
Dahlquist et al. (1985)	3	11–14	Chronically ill	Venipunctures	CBT

Note. B = breathing, BC = behavioural coaching, BR = behavioural rehearsal/role plays, BMA = bone marrow aspiration, CBT = cognitive-behavioural therapy, D = distraction, GI = guided imagery, I = information provision, IM = intramuscular injection, IV = intravenous insertion, LP = lumbar puncture, MR = memory reframing, and PR = positive reinforcement.

Dismantling Multi-Component Treatment Packages

According to previous research, multi-component treatment packages can alleviate NRD, although a limitation of this approach is that it is not evident what techniques are creating the observed changes. The difficulty with not knowing the effectiveness of certain treatment components has been illustrated in a recent meta-analysis of randomised controlled trials investigating psychological interventions for NRD with healthy children and chronically ill children and adolescents aged 2-19 undergoing injections (Uman et al., 2008). Outcome measures included self- and observer report, and observational and physiological measures. Twenty-eight trials were included in the review with a total of 1,039 participants. Effect sizes were calculated using Standard Mean Difference (SMD) with a 95% confidence interval (CI). Interventions were only considered efficacious if the SMD and both anchors of the CI fell within the negative range (Petticrew & Roberts, 2006). That is, the intervention for a particular outcome is not considered efficacious if the CI includes zero. Results showed that hypnosis was the most efficacious intervention in relation to self-reported distress (SMD = -2.20, CI -3.69, -0.71) and behavioural measures of distress (SMD = -1.07, CI -1.79, -0.35). Distraction was also efficacious with regards to self-reported pain (SMD = -0.24, CI -0.45, -0.04), as well as combined cognitive-behavioural interventions for other-reported distress (SMD = -0.88, CI -1.65, -0.12) and behavioural measures of distress (SMD = -0.67, CI -0.95, -0.38).

Despite these promising results, the effect sizes should be interpreted cautiously as tests for heterogeneity were significant for all three interventions. This could have been due to a significant amount of variation in the study samples (e.g., healthy and chronically ill children), measures and/or the combination of cognitive and behavioural techniques utilised across studies were not similar enough to combine into one effect size calculation. Furthermore, although all of the interventions were considered cognitive-behavioural, they had very different theoretical underpinnings and targeted different underlying mechanisms of NRD. For example, Tyc et al. (1997) primarily focused on CBT for distress associated with MRIs, with intravenous insertions as a secondary objective. Therefore, the education phase of the research involved preparation for the MRI rather than the injection procedure. In contrast, Lioffi and Hatira (1999) focused on cognitive-behavioural coping skills for injection pain and distress. Strategies included were an abbreviated form of autogenic relaxation and cognitive restructuring based on the pain-control model alongside other techniques.

Overall, although Uman et al. (2008) showed which interventions are the most efficacious for needle pain and distress, the research also revealed that there was a significant amount of variability in the outcomes for components of CBT. Due to this variability, it was suggested that caution should be taken when making general conclusions regarding treatment outcome studies (for example, Dahlquist et al., 1985; Jay et al., 1985). Additionally, a more critical evaluation of the treatment literature regarding chronically ill and non-chronically ill children is needed. As it stands, research tends to combine both groups despite there being important differences between the two populations such as type, frequency and location of injections, the presence of medical complications and duration of illness/medical treatment,

which can all moderate levels of distress and coping (Drotar et al., 2006). To date, no study has dismantled a previously developed treatment package for NRD and determined whether cognitive and/or behavioural techniques are most effective. Very few studies have even assessed the effectiveness of two or more cognitive-behavioural treatment components, let alone the comparison of multiple techniques for NRD. Studies that have used a dismantling treatment design have primarily investigated the effectiveness of behavioural techniques such as applied tension, applied relaxation, exposure and tension only among an adult population with blood phobia rather than injection phobia (Hellstrom, Fellenius, & Öst, 1996; Öst et al., 1991; Öst, Sterner, & Fellenius, 1989). Therefore, it is difficult to determine what components of existing treatment packages have resulted in changes at what point, or are more effective than others. Addressing this gap in the literature could result in the elimination of unnecessary components, and shed light on what components are merely providing support for something else that may actually be producing the observed changes. For example, based on meta-analyses and treatment outcome studies, exposure techniques (e.g., practicing an in-vivo injection and systematic desensitisation) could be considered to produce the most changes in NRD symptoms, whereas psycho-education and positive self-talk may assist with the reduction in NRD (Öst, 2001; Wolitsky-Taylor et al., 2008). Overall, research into this phenomenon could provide insight into whether briefer treatments like cognitive or behavioural therapy are just as or more effective than CBT. This could have implications for delivering psychological services in a more effective and efficient way for chronically ill children with NRD.

In summary, research supports the use of cognitive-behavioural therapy packages for the treatment of chronically ill children with NRD. However, the identification of what components are the most effective is a significant gap in existing research. Clarification of which techniques work best may alleviate some of the heterogeneity among cognitive-behavioural therapies for NRD, primarily by identifying what techniques are more effective than others, thus guiding researchers and clinicians as to what strategies to utilise in on-going research and practice rather than incorporating an assortment of strategies. Moreover, considering that several treatment packages have been shown to be effective, some suggest the next step is to dismantle the treatments in order to determine what components are most effective (Plante, 2011; Spokas, Rodebaugh, & Heimberg, 2008). These gaps in the literature provide the impetus for the current research.

Chapter 2: RATIONALE AND AIM OF THE CURRENT RESEARCH

Chapter Outline and Aims

Chapter 2 presents the research rationale and purpose in three sections. The first section describes the rationale for the treatment manual development and subsequent dismantling of the components. The second section builds on the first, by explaining how the treatment manuals were evaluated using single-case methodology, combined with a comprehensive evaluation of why this strategy was used over alternative research methods. The second part of this section provides an overview of participant inclusion and exclusion criteria, data analysis strategies and finally a justification for the psychometric measures used. Section three presents the aims and objects of the current study.

SECTION ONE: Treatment Manual Development

Rationale for Dismantling the Treatment Manual

The literature review presented in Chapter 1 demonstrated that the frequency of NRD is fairly common among chronically ill and non-chronically ill children, and if left untreated NRD can have both short- and long-term implications. Treatment typically incorporates components of cognitive-behavioural therapy and has been administered with success in numerous studies, although researchers tend to exclude cognitive restructuring and carer involvement. In a pilot study for the present research, McIvor (2011) addressed previous limitations by developing a six-session CBT treatment manual incorporating these additional components. The manual was evaluated using single-case research with four chronically ill children and their carers. Results showed that, compared to pre-treatment levels, the majority of children and their carers demonstrated a reduction in distress and increase in coping behaviours related to injection situations. Nonetheless, it was unclear what components were the most effective. When a clinical problem has been conceptualised, tested and the procedures operationalised in a manualised form, the next step may involve a dismantling treatment design to determine which components of the treatment package are responsible for the observed changes (Spokas et al., 2008). Therefore, the 2011 pilot study provided the foundation for this study and resulted in the original treatment manual being dismantled to determine whether cognitive and/or behavioural techniques were more effective. The initial development of the manual will now be described followed by how it was modified for the present study.

The 'Original' Coping Kids Treatment Manual

The Coping Kids Treatment Manual (McIvor, Ross, & Taylor, 2011) was originally developed in 2011 as part of my Master's thesis, and utilised as a tool for clinicians working with chronically ill children aged 8 to 12 years who had experienced NRD. It was based on an existing therapy utilised at the Massey University Health Conditions Psychology Service (HCPS), and combined cognitive-behavioural theory and empirical research. The 59-page document incorporated a six-session format with four distinct phases: (1) psycho-education, (2) coping strategies, (3) gradual exposure, and (4) therapy completion. It outlined the purpose and rationale, goals, materials required, session format, optional worksheets and out-of-session activities (homework) incorporated into each session.

The primary goal of the manual was not to eliminate distress entirely, but to reduce it to a level that was manageable for the child and their carer while also increasing their ability to cope with injection situations. The rationale for not eliminating distress entirely is that research suggests a child's response to injections is not necessarily phobic, but can instead be a legitimate fear which involves the distress response (Duff, 2003; Ellis & Spanos, 1994; Humphrey et al., 1992). Therefore, it is when catastrophic misinterpretation of the distress response occurs in one or many instances and is generalised to all injection situations regardless of whether there are painful sensations and/or other complications or not, that the response can become maladaptive (Ollendick et al., 2002). It may also be argued that it is unrealistic for the child's distress to be eliminated completely considering injections can be painful and that a number of complications can occur such as venous collapse or difficulty with venous access leading to multiple injections (Emanuelson, 2013; Kuensting et al., 2009). Complications such as these had occurred with all of the participants who took part in the 2011 pilot study as well as the current study, either recently or at some point in the past. The secondary goal of the manual included a reduction in the child's and carer's level of behavioural avoidance toward injections, as well as assisting the child to develop more helpful thought processes.

The 'New' Treatment Manuals

For the purpose of the present study, the *Coping Kids Treatment Manual* was administered in its original form as well as modified by separating out as clearly as could be achieved the cognitive versus behavioural components, resulting in three treatment manuals (CBT, CT, and BT). The primary and secondary goals of the original manual outlined above remained unchanged and were consistent regardless of the treatment condition to which the child and carer were allocated. However, unlike the original version, the new manuals were not strictly phased according to the four areas described above (e.g., psycho-education, coping strategies, gradual exposure, and therapy completion). Instead, the new manuals had three phases, with each phase emphasising important elements identified in the introduction chapter

of this thesis, supplemented with aspects from local clinical practice. *Phase 1* focused on psycho-education, rapport and contextual factors. *Phase 2* involved the introduction of cognitive and/or behavioural components (depending on treatment allocation) derived from previous research including emotive imagery, cognitive restructuring, relaxation strategies and graded exposure. *Phase 3* provided a transition to life beyond therapy, relapse prevention and celebrating the child's therapy success. As discussed previously, these techniques have been empirically validated for children with NRD (see Dahlquist et al., 1985; Jay et al., 1985).

Another key difference between the original and new manuals was the fluidity between phases, in which case the new structure allowed for a considerable amount of overlap between sessions. For example, depending on the treatment condition, coping skills and psycho-education were combined together in session one, whereas in other cases coping skills and exposure were combined together in sessions two and three. A more detailed description of the programme is presented in the Method chapter. The reader is also referred to the introduction of the manual (refer to electronic compact disc) for a full rationale, description and structure of the three treatments.

Treatment Characteristics

Perhaps most importantly, the manuals were designed to be used flexibly. For example, some children may need certain techniques adapted to suit their developmental stage, whereas other may take longer to work through certain sessions and/or require booster sessions. Therapy session structure was relatively consistent though to enable some prediction of the therapeutic process. There was an emphasis on collaborative empiricism enabling the therapist, child and carer to form hypotheses about what might have caused the presenting problem and what might help the child to manage their symptoms. These hypotheses were tested out in therapy and monitored using outcome measures. Therapy was also designed to promote generalisation outside of session to everyday situations the child encountered, which was particularly important for chronically ill children considering their medical treatment was ongoing.

Other features of the three manuals included a collaborative therapeutic relationship, an ever-evolving case formulation of the child and the presenting problem within a cognitive and/or behavioural framework, working with the child's idiosyncratic perception of self, others and the world, active involvement and engagement from the child, and helping them to develop skills necessary to becoming their own therapist (in an age-appropriate manner). As delineated in the Introduction chapter, a contextual framework is particularly important when working with children. The five-part CBT model was used a foundation for the treatment with consideration for thoughts, feelings, behaviour and physical reactions within the context of the child's broader environment (Greenberger & Padesky, 1995).

Finally, the use of a treatment manual was designed to increase internal validity and treatment integrity by providing a standardised protocol for treatment implementation. "Treatment integrity (also known as treatment fidelity) refers to the extent to which the intervention was implemented as intended" (Perepletchikova, Treat, & Kazdin, 2007, p. 829). It

can include three components: therapist adherence, therapist competence, and treatment differentiation (Perepletchikova et al., 2007). Procedures used to assess treatment integrity will be explained in the Method chapter, in addition to the assessment procedures carried out prior to the intervention phase. Treatment manual evaluation will now be explored.

SECTION TWO: Treatment Manual Evaluation

Study Design Rationale

The present study was based on the scientist-practitioner model of clinical research, meaning that the attitude and knowledge of a scientist guide the clinician when they are confronted with problems in the therapy room (Barlow, Hayes, & Nelson, 1984; Stricker & Trierweiler, 1995). By utilising the scientist-practitioner approach, assessment and treatment techniques may gain empirical support, while the risk of unprofessional practice and harmful techniques being applied are reduced (Stricker & Trierweiler, 1995). The present study was an attempt to evaluate whether certain techniques are effective at alleviating NRD for chronically ill children, using single-case research design methodology, recommended by Blampied (2013) and Krause (2011) as particularly suited for the exploratory stage of clinical research.

One of the reasons for adopting single-case research design was due to the resource and time constraints of the study, as component studies undertaken with large-N, between-group designs require a considerably larger sample for tests of statistical and clinical significance. Design characteristics like this would also need more therapists in order to carry out the treatment within a suitable timeframe, however the funding allocated to this project would not have enabled the payment of a registered clinical psychologist as an additional therapist. Furthermore, with research requiring a large number of research participants, it would be unlikely that they would have been recruited and progressed through baseline, treatment and follow-up phases in the two-year timeframe within which this research needed to be completed.

Blampied (2013) also supports the utility of single-case research particularly in the early phases of therapy innovation due to its small scale and usefulness in evaluating novel ideas and new procedures with low cost and little risk. It is suggested that only once a novel therapy has shown to be effective using a series of single-case studies should any large-scale randomised controlled trials be carried out. This process eliminates any ethical issues inherent in standard group research protocols that require a large number of participants exposed to a potentially ineffective intervention. Therefore, based on the resources available, time restrictions and the need to reduce any ethical dilemmas, conducting a series of single cases was the most viable option for answering the present research question.

Justification for adopting a single-case research design was in some respects also based on the debate between efficacy versus effectiveness studies. Effectiveness research (i.e., single-case research) establishes the utility of the therapy in typical settings with typical therapists and typical clients (Blampied, 2013; Seligman, 1995). In contrast, efficacy research

(i.e., randomised controlled trials) use highly selected participants with a carefully selected single diagnosis (usually based on DSM criteria), and highly trained therapists working from a manual with a fixed number of sessions and usually in atypical settings (e.g., university research clinics) (Blampied, 2013; Seligman, 1995). These characteristics alone are problematic as exploration of every dimension and their variation including the participants, the therapy, the therapists and the therapy context can be lifelong and expensive in order to determine the effectiveness of a single intervention (Blampied, 2013; Staines, 2008). As Arnett (2008, p. 607) suggests “Are human beings across the world similar enough that one need only study them in one part of the world in order to make generalisations about the entire species?” Equally important, efficacy research using these strict criteria omits many crucial elements of what is actually done in clinical practice, thus limiting the generality of research findings (Arnett, 2008; Pilecki & McKay, 2013; Seligman, 1995). For instance, clients present with multiple problems, therapy is not always of a fixed duration and is just as concerned with improvement in general functioning as it is with the amelioration of disorders. Therefore, effectiveness studies are needed because the narrow sampling done in efficacy research can render them less than adequately generalisable to everyday clinical practice and clients (Arnett, 2008; Piaget, 1958; Pilecki & McKay, 2013). There were a number of design characteristics incorporated into the present study to ensure it was clinically relevant.

A certain number of participants was chosen due to single-case design requiring at least three replications in order to draw valid inferences from the data (Chambless & Hollon, 1998; Kratochwill et al., 2010), while working within the constraints imposed by the requirements of a Doctorate of Clinical Psychology, and the time available to complete the research. Single-case designs can provide rigorous experimental evaluation of intervention effects provided several evidence standards are met. Perhaps most importantly, internal validity can be improved in single-case designs through replication and randomisation (D’Alessandro & Burton, 2006; Kratochwill et al., 2010). According to these evidence standards, this includes three demonstrations of the experimental effect at three different points in time with a single case or across different cases (D’Alessandro & Burton, 2006; Kratochwill et al., 2010). These replications act as a reliability check on the relationships being studied and offer an opportunity for causal inferences to be drawn, as well as being cost-effective and practical (Morgan & Morgan, 2003). These reasons provided the rationale for having at least four replications (i.e., participants) within each therapy condition in the present study.

Further evidence standards that have been included in the present study are the use of continuous measures within and across different phases of the independent variable. The advantages of utilising this approach is that it increases confidence that the behaviour being sampled and measured is representative of that participant under those experimental conditions, conceptualises behaviour as an ever-evolving phenomenon, and permits individual variability to be examined directly rather than concealed in averages (Morgan & Morgan, 2003). A non-concurrent multiple baseline was used to allow for flexibility within an applied research setting (i.e., participants were assigned as they were naturally referred) while maintaining the

design parameters necessary for ruling out extraneous factors (Watson & Workman, 1981). Furthermore, this design allowed for data to be analysed from several participants seen at different times, despite them having varied baseline lengths. Note, however, when multiple referrals were made at once, there was at times a waiting list for the commencement of the assessment interview and baseline phase, which was primarily due to there being only one therapist, so for some participants the waiting for therapy phase was longer than the baseline phase. Even though there was no explicit control group or placebo condition, it should be noted that the baseline phase of single-case research acts as a placebo control for the effects of participating in assessment and receiving therapist attention. Furthermore, the treatment phase is not introduced until the baseline is stable, thus permitting each participant to act as their own control as comparisons are made across experimental conditions (Kazdin, 2011; Kratochwill et al., 2010). Given that treatment effects are detected in one or more participants, causal inferences about the effects of the intervention then depend on the extent of replication of treatment effects across participants (Barlow & Hersen, 1984; Blampied, 2013).

Considering the applied nature of this research, it was imperative that the study design allowed for clinical flexibility of treatment length and delivery. The single-case design was therefore ideal while closing at least some of the gaps between research and clinical practice. It also does not depend on withdrawing or suspending the intervention in order to show treatment effects, thus avoiding ethical and logistical issues (Blampied, 1999). Lastly, the multiple-baseline design accommodates relatively marked treatment effects (i.e., changes that are immediate and large), therefore reducing threats to internal validity such as maturation and history as these factors are unlikely to produce changes that are abrupt and large (Kazdin, 2011).

In summary, participants were randomly allocated to one of the three treatment conditions (e.g., cognitive-behavioural therapy, cognitive therapy alone, or behavioural therapy alone), such that each condition included four children ($N = 12$) and their carers. Kratochwill and Levin (1992) suggest that randomisation procedures incorporated into single-case design strengthens the internal validity of the study and represents a higher level of methodological soundness. Within each treatment condition, a single-case multiple-baseline/multiple probe design across participants was also used. Baseline lengths varied in duration and baseline conditions were concluded when the data from the child met a stability criterion (see below). Since the basic features of the study design have been described, the rationale for the inclusion of measurement probes will now be explained followed by variations in therapy dose.

The Inclusion of 'Probes'

Elements of the multiple-probe design (Cooper, Heron, & Heward, 2007) were incorporated into this study as a way to increase internal validity while avoiding the necessity of collecting continuous baseline data. This strategy was integrated mid-way through the research, therefore only two of ten participants who were placed on a waiting list completed probe assessments. This resulted in their baseline phase extending for two to three months. The

reason for utilising probe assessments for only two participants was that they were recruited in advance and only a maximum of six participants were allowed to be participating in therapy at once due to there being only one therapist.

The multiple-probe design is a method of assessing the independent variable with the dependent variable in much the same way as the multiple-baseline design (Cooper et al., 2007). However, the multiple-probe design differs in several ways such that intermittent measures or 'probes' are administered over a longer period of time to assess whether NRD is changing prior to the intervention. The benefit of the multiple-probe design is that, alongside increasing the internal validity of the research (i.e., behaviour does not change until the independent variable is introduced), it avoids the necessity of collecting continuous baseline data as the probes can be less frequent and spaced further apart (Cooper et al., 2007). This is a major advantage, particularly when dealing with chronic and long-established conditions (as was the case in this study), as extended baseline measurement under non-treatment conditions can prove aversive to some participants, and extinction, boredom, practice effects, or other undesirable responses can occur (e.g., ritualistic responses rather than answers that are influenced by actual change) (Cooper et al., 2007). Alongside the more practical benefits of utilising probes, they can also provide insight into the influence of therapist variables on treatment outcomes. That is, regardless of contact time the therapist has with participants throughout the baseline phase, it was anticipated that child and carer ratings of NRD would not improve until therapy was introduced. In summary, the multiple-probe design was an effective and efficient way of increasing the internal validity of the present study without threatening the integrity of the research, although there were some methodological constraints that were unavoidable.

Variations in Therapy Dose

The development of three treatment manuals such that there was the original manual and two representing dismantled components confronted the researcher with the issue of confounding treatment condition with treatment length. The rationale for using treatment manuals with different treatment dose (i.e., number of sessions) was due to a number of reasons and was consistent with a meta-analysis of other dismantling treatment studies (Ahn & Wampold, 2001). Perhaps most importantly, when developing the CT and BT manuals and separating the cognitive and behavioural components from one another, there were not enough activities to spread over a six-session format to be consistent with the treatment length of the CBT manual. It was also not possible to reduce the CBT manual to four sessions as this would have eliminated key techniques due to the restricted timeframe. Other solutions to the dose-treatment confound were considered, such as incorporating 'time fillers' (e.g., watching an educational video) or utilising an hours rather than number of sessions format. However, time fillers also posed a potential confound making it difficult to determine whether outcomes were due to the therapy techniques specified in the treatment manual or the activities that were newly added to the conditions. In addition, the *Coping Kids Treatment Manual* comes as a "package" therefore it is the package, and the individual techniques incorporated into that package which

are being assessed rather than the dose of therapy. There were also ethical issues with including time fillers as the majority of them have no empirical evidence for their effectiveness, not to mention the practical and ethical implications of wasting the participants' time by using techniques that are potentially non-therapeutic. Lastly, therapy dose versus content confound is inherent in all dismantling studies considering some parts will always take less time than the whole therapy combined. In fact, even two techniques of a similar nature will very rarely take the same amount of time (Bell, Marcus, & Goodlad, 2013).

Considering the variation in therapy dose could not be eliminated, psychometric measures were incorporated at certain stages of the treatment programme to monitor this confound. This was carried out by collecting psychometric measures weekly during the baseline and treatment phases and once at one- and three-month follow-up intervals. Alongside this, additional measures were administered during the assessment interview, after session four for all three conditions, and then again after session six for the CBT condition only. These measures were strategically placed after session four in an attempt to control for the extra two sessions in the CBT condition and act as a comparison point across all three conditions. An explanation of how the dose confound was controlled and the administration structure of these measures will be explained in the Method chapter.

Inclusion and Exclusion Criteria

The optimal age range for children administered the treatment was 8-12 years because the manual was originally developed for this age group. However, due to difficulty with participant recruitment during the 2011 pilot study, the age range was widened from the outset to 7-13 years. The rationale for including children as young as 7 years was that, according to Piaget's Theory of Cognitive Development, children progress through a series of stages, and that by age 7 they have reached the concrete operational stage allowing them to reason deductively and problem-solve (Piaget, 1958). For children under 7 years this may not be the case, and at this age learning is concrete (i.e., dependent on observable events) and marked by reductions in egocentricism (i.e., an understanding that others have different thoughts and feelings than their own). Recent developmental research also suggests it is more important to consider the developmental stage of the child rather than their chronological age (Bolton, 2005). Other researchers have taken the same stance, for instance Kendall's *Coping Cat Treatment Manual* was written for children aged 7-13 years (Kendall & Hedtke, 2006).

Additional inclusion criteria were that the child (1) displayed symptoms of NRD severe enough to warrant intervention, (2) had been diagnosed with a chronic health condition that required regular injections, (3) had a cooperative carer who was willing to participate in treatment, and (4) that both the child and carer were fluent in English. Children diagnosed with cancer were excluded due to often presenting with a number of psychological problems in addition to NRD, as well as the nature and frequency of their injections differing somewhat to other populations (i.e., long-term central catheters). Children were also excluded if they presented with significant mental health problems and safety issues which required immediate

attention. Both the child and carer were required to not be engaged in a psychological treatment plan through another agency or already receiving therapy as it could confound the study results. Children were also excluded if they were currently involved with Child Youth and Family Services (CYFS), as it potentially presented safety issues that were beyond the scope of this research. Based on the study design and rationale, there were certain ways the data was also analysed and displayed.

Data Analysis and Display

Measures produced data throughout all three phases of the intervention and the data were extracted using several methods. First, raw scores were compared for each participant across time to determine whether any changes occurred on the outcome variables. Second, time-series data was further examined using two non-regression algorithms including Standard Mean Difference all (SMDall) (Busk & Serlin, 1992; Olive & Smith, 2005) and Percentage of Non-Overlapping Data (PND) (Scruggs & Mastropieri, 1998). These were used to provide additional insight into treatment outcomes and to calculate effect sizes. The advantages and disadvantages of using these two algorithms and how they will be interpreted are explained below.

The Standard Mean Difference all (SMDall) is an effect size calculation used to measure the total effect size of the intervention based on the means of the dependent variable. In comparison to SMD (which uses the last three data points only), SMDall was used as it outlines an overall change from baseline through intervention by incorporating all raw data in the form of means. Furthermore, using only the last three data points may not capture data variability, resulting in an inflated effect size (Olive & Smith, 2005). The advantages of SMDall are that it is easy to perform and provides an actual effect size value. SMDall was interpreted using guidelines based on Cohen's *d* effect size, which is a statistic used to calculate the difference between means using the standard deviation (Cohen, 1988). According to Cohen's *d*, a small effect ranges between 0.2 – 0.3, a medium effect is between 0.4 – 0.7 and anything above 0.8 extending beyond 1.0 is a large effect (Cohen, 1988). The calculation for SMDall is below, where *i* represents each individual participant:

$$SMDall_i = \frac{Baseline_{mean,i} - Treatment_{mean,i}}{Standard\ Deviation\ of\ Baseline_i}$$

The second algorithm, Percentage of Non-Overlapping Data (PND) was used to show the number of intervention scores that fall below the lowest baseline score. PND was used to provide further insight into what stage of the intervention produced positive changes typically occurred and whether these changes occurred gradually or rapidly. The advantages of PND are that it is sensitive to changes in level and shown to be strongly related to qualitative 'expert' ratings (Scruggs & Mastropieri, 1994). On the other hand, PND has been criticised as it ignores all baseline data except one data point and is therefore subject to ceiling/floor effects whilst also

ignoring changes in slope (Scruggs & Mastropieri, 1998). This statistic can also not be calculated when zero data are present in the baseline, thus representing a major limitation. Despite these disadvantages, PND was used to provide insight into the degree of change across the three treatment groups. Interpretative guidelines according to Scruggs and Mastropieri (1998) propose PND scores below 50 indicate that the intervention is ineffective, scores between 50 to 70 are questionable, scores between 70 to 90 suggest an effective intervention, and scores above 90 represent very effective interventions. Therefore, a higher number indicates change occurred early in treatment, while a lower number indicates changes occurred towards the end of treatment. However, due to this study only incorporating four sessions for two of the groups of children, the likelihood for PND percentages to be above 50 was quite low, so these interpretive guidelines were used with caution in this study. The calculation for PND is below, where i represents each individual participant, n is equal to the total number of participants, k is for each session, and min is the minimum observation from the baseline phase:

$$PND_i = \left[\frac{\sum_{k=0}^n (intervention\ point_{k,i} < baseline_{min,i})}{Total\ Intervention\ Points_i} \right] \times 100$$

Once the data had been analysed using non-regression algorithms, treatment outcomes were displayed using two methods. The first included Brinley plots which are not widely used in psychology (but for a recent example, see Dye, Green, & Bavelier, 2009), although can be used as an additional way to display time-series data (Rucklidge & Blampied, 2011). Traditional Brinley plots were originally developed by Brinley (1965) as a way of displaying results from cognitive psychology experiments, whereby two groups were exposed to different conditions within one experiment (or family of experiments; Dye et al., 2009). However, in order to provide ideographic information (Barlow & Nock, 2009), Blampied (2007) modified Brinley's scatter plots by having them display individual rather than group average data, with each individual's data acquired and displayed as one point per person per phase, or aggregated to one point per person per phase (or sub-phase). Blampied (2007, August) further outlined that in the context of single-case research this visual display has considerable potential for detecting systematic effects of interventions while preserving the identity of each individual participant. This is an important feature that group mean data overlooks. When a baseline and post-treatment measure are available for each individual, systematic effects can be displayed in a scatterplot of these two scores revealing deviations from the diagonal, the line of no effect (e.g., if baseline score = intervention score, the data point lies on the diagonal) (Rucklidge & Blampied, 2011). Considering the amount of data obtained in the present study, modified Brinley plots were an effective and efficient method of data display for summarising findings for all three treatment groups across phases of the study.

Prior to analysing the data in the Results section via modified Brinley plots, an explanation for how they are interpreted and what averaging procedures were used is

necessary (Blampied, 2005; Blampied, 2007, August; Rucklidge & Blampied, 2011). As noted above, modified Brinley plots are scatterplots with the axes (scaled the same) where each point represents individual scores on a particular dependent variable at time 1 (X-axis) and time 2 (Y-axis). Therefore, each point on the graph represents one case. The diagonal line at 45° from the origin represents a line of no change, since if any X-value equals any Y-value, the data point will lie on the diagonal. If improvement over time is measured by reductions in scores, then data points lying below the diagonal represent improvement and those above the line signal deterioration, and vice versa if improvement is measured by increased scores. If the individual plots are close together, it indicates participants had similar results, while if individual plots are scattered apart, then participants had divergent results.

Averaging procedures were carried out to create all modified Brinley plots. For instance, in order to obtain a single data point to plot on the X-axis (e.g., baseline) and Y-axis (e.g., follow-up), all scores were averaged for each child across his/her total weeks in each phase to obtain the mean value, whereas for the treatment phase the final *two* sessions for CT and BT groups and final *three* sessions for CBT were averaged only. The rationale for averaging the final two or three therapy sessions only was due to very different results being reported at the start versus end of treatment. It was more important to show the level of performance at the end of treatment than take the average of this entire phase. Overall, all modified Brinley plots presented in this study were interpreted using the guidelines that points below the diagonal line represent improvement, with the exception of the coping domain, which was scored in reverse, therefore points placed above the line indicate the treatment was effective rather than ineffective. The same calculation procedures to obtain individual scores were used on all modified Brinley plots.

The second data display method (also presented after the modified Brinley plots in the Results chapter) included a time series, which is a set of observations recorded at specific points in time (Brockwell & Davis, 2009). These recordings can either be discrete or continuous depending on the nature of the research. The present study utilised the latter approach and displayed this data using line graphs. The methods used for data collection will now be explained.

Psychometric Measures

As part of the pilot study in 2011, a general literature review was carried out to assess what psychometric measures were currently being used for children with NRD. The review showed that a combination of behavioural observation methods and self-report measures were commonly used, although several limitations made them unsuitable including extensive administration time, irrelevant or inappropriate item content and lack of standardisation with children. Most of the psychometric measures also focused on general trait anxiety rather than NRD. Due to these limitations, the Needle Injection Questionnaire for Children (NIQ-C) and Needle Injection Questionnaire for Parents (NIQ-P) were developed by Mclvor in 2011. These

measures were utilised as the primary outcome measures to assess changes in distress and coping for both the child and their carer. The measures incorporated a multi-modal (i.e., behavioural observation method and self-report measure) and multi-informant approach (i.e., child and carer) as recommended in the treatment literature (Blount et al., 2009; Kendall et al., 1992). Due to the continued lack of appropriate measures, the NIQ-C and NIQ-P were refined further and utilised in the present study as some of the primary outcome measures.

Several improvements were made to the NIQ-C and NIQ-P for the present study. The Likert scale in each measure was replaced with an 11cm visual analogue scale for the distress, avoidance and cognition domains (VAS; Scott & Huskinsson, 1976) as they are the most widely used instrument in pain studies, are easily understood by children, and have well-established validity and reliability (McGrath, 1990; Vami, Walco, & Wilcox, 1990). The VAS is also popular for use among children due to its simplicity, versatility, insensitivity to bias effects and it tends to have less clustering of scores compared with categorical scaling methods (Price, McGrath, Rafii, & Buckingham, 1983; Uman et al., 2008). Administration of the VAS requires the child to mark on an 11cm line the point that represents the intensity of the target construct. The distance from the left end is then measured. Initially all questions were also modified in the present study to reference the child's "Most recent needle injection" because research suggests that memory recall is more reliable if the event is relatively current (Bijttebier & Vertommen, 1998; Fradet et al., 1990). However, feedback from Tamati (first pilot participant in this study) revealed that, regardless of the amount of treatment received, the perception of the most recent injection would not necessarily change if injections were relatively infrequent, attesting to the fact that the measure may not be sensitive to treatment effects. As a result, the question was reverted back to the original form of "In general" to encompass all injections.

Other modifications included the integration of extra questions to assess if the child's avoidance behaviours were typical of what they would normally do in injection-related situations. Some questions were excluded due to providing little to no information in the previous study, such as how many injections the child had in the past six months and whether medical appointments had to be cancelled and/or postponed due to child or carer distress. One of the three cognition questions was also excluded (i.e., distortions in visual perception of the needle) due to eliciting little to no response in the previous study. Instructions were also simplified to ensure ease of use and brevity of the measure. It should be noted that, although these measures were first piloted in 2011, reliability and validity information is still unknown. Despite this, self-report measures are seen as the best way to assess NRD for a number of reasons.

Why Self-Report?

Traditionally, the use of child self-report measures in treatment evaluation has been discounted. Social desirability of the child's willingness to express symptoms of psychological distress is a factor influencing these methods, as is recall bias, whereby children are asked to recall events over a prolonged period of time (weeks to months) (Logan, Claar, & Scharff, 2008). Self-report measures are also dependent on the child's social, cognitive and

communicative competence, such as their ability to read and follow instructions correctly (Huguet, Stinson, & McGrath, 2010). It is also possible the child is influenced by their context such as the person asking the question. Despite these limitations, this method of measuring psychological functioning was an important component of this study for three main reasons.

First, self-report measures can enable cognition content, intensity and frequency to be gathered, which cannot be obtained from behavioural observation measures. This is particularly important due to the increase in cognitive interventions, whereby thought intensity and frequency are used to assess treatment effectiveness (Huguet et al., 2010). Cognitions are also subjective personal experiences, therefore it is preferable to use measures that most accurately capture the perceptions of the child under study, rather than the perception of others (e.g., carers; Von Baeyer, 2007).

Second, child self-report is seen as a more valid and reliable measure of psychological functioning, particularly as carers and health professionals may over- or under-estimate the amount of distress or coping strategies the child displays during medical procedures (Klein, 1991). To counteract this, it is recommended to take measures from multiple sources (e.g., child, carer and clinician) for assessment and treatment evaluation (Engel et al., 1994; Kleiber & McCarthy, 2006; Klein, 1991). Therefore, carer self-report of their own distress, avoidance and coping, as well as carer self-report of their child in relation to these three domains was also obtained. This was important as one of the therapy goals was also to assist with the carer's distress, avoidance and coping while their child is having a needle injection. This recommendation has been incorporated into the present study and was the primary rationale for including a multi-informant approach.

Third, self-report measures have high clinical utility since most of them are convenient to use in everyday practice and are quick to administer (Huguet et al., 2010). Self-report measures are also cost-effective as they can be completed independent of the clinician, which also serves to eliminate contextual factors that threaten the internal validity of behavioural observation measures (Huguet et al., 2010).

Overall, to evaluate treatment effectiveness, child and carer self-report measures were used to assess NRD across baseline, treatment and follow-up phases of the intervention. Primary constructs investigated included distress, avoidance, coping and cognitions related to injections. The term "cognition(s)" refers to any changes in content, intensity and frequency during the intervention regarding both helpful and unhelpful thoughts. Cognitive measures were extensively reviewed in the literature prior to selecting suitable measures.

Rationale for the Cognitive Measures

Cognitive restructuring was an essential component of the treatment manual so it was equally important to utilise an appropriate measure. A review of the literature showed no relevant standardised cognitive measures for children with NRD, although there were a number available in other areas including the Dysfunctional Attitudes Scale for Children (D'Alessandro & Burton, 2006), Positive and Negative Affect Scale for Children (Laurent et al., 1999), and

Cognitive Triad Inventory for Children (Kaslow et al., 1992). However, these were mostly self-report inventories that incorporated on average 20-30 items and covered a broad range of areas related to cognition content rather than specific situations. There are methods used in clinical practice to elicit thoughts known as the downward arrow technique, although this is not typically classified as a measure per se but rather a clinical tool for eliciting thoughts in session (Westbrook et al., 2011). For instance, the downward arrow technique is a systematic questioning style that aims to unpack the three levels of thought (e.g., automatic thoughts, underlying assumptions and core beliefs) (Westbrook et al., 2011). Instead, two alternative measures were utilised including a cognitive component incorporated into the NIQ-C (explained in the Method chapter) and articulated thoughts in simulated situations (ATSS).

ATSS is traditionally an audio-recording of a conversation created to stimulate a complex event (Davison, Robins, & Johnson, 1983). Typically two audio-recordings are developed, one designed to be stressful and directly relevant to the event (experimental) and the second not directly relevant to the event (control). Participants are then asked to listen to the conversation and pretend that the event is actually happening and that they are part of the situation depicted in the conversation. They are then told to express what they are thinking and feeling during certain intervals as the situation unfolds. All verbalisations including the story are then audio-taped for later analysis. The data obtained is coded according to pre-determined categories (Davison et al., 1983).

Advantages of ATSS compared to other cognitive assessment approaches include providing an unstructured response format, prospective assessment, situational specificity and control, and flexibility of situation and cognitions (Davison, Vogel, & Coffman, 1997). It is also particularly well suited to children who have limited reading, writing and comprehension skills, and can be valuable in studying sensitive topics and reducing bias in self-disclosure (Davison et al., 1997). ATSS was also found to be superior to paper and pencil questionnaires in detecting cognitive changes from therapeutic intervention with children (Davison, Haaga, Rosenbaum, Dolezal, & Weinstein, 1991). Lastly, a variety of ATSS coding strategies have been reliably established with research providing evidence for its face, concurrent, predictive and construct validity (Davison et al., 1997).

In summary, ATSS was a desirable measure for exploring cognition content and frequency as it permits open-ended verbal responses, which reflect as much as possible, ongoing thought processes rather than retrospective reporting. Participants are also able to make self-reports with ease and minimal delay.

SECTION THREE: Aim and Objectives of the Present Study

Aim

The aim of the current study was to replicate previous research findings from Mclvor (2011), which developed and evaluated a manualised CBT programme known as the *Coping Kids Treatment Manual*. The present study dismantled this existing manualised treatment to

determine whether the cognitive and/or the behavioural components were more effective than no treatment (i.e., the baseline phase) for a reduction in NRD symptoms among chronically ill children. Treatment components were also assessed in relation to improving the carer's ability to manage their own reactions regarding their child's NRD symptoms. Three treatment manuals were used to conduct this research including (1) cognitive-behavioural therapy – 6 sessions, (2) cognitive therapy – 4 sessions, and (3) behavioural therapy – 4 sessions. The objectives of the present research were as follows:

Objective One: To evaluate the effectiveness of cognitive-behavioural therapy, cognitive therapy and behavioural therapy compared to no treatment (i.e., baseline phase) in relation to improving NRD symptoms (distress, avoidance, coping and cognitions related to injections) for chronically ill children.

- 1.1 It was expected that children in all three treatment conditions (CBT, CT and BT) would self-report a reduction in distress and avoidance, and an increase in adaptive coping behaviours both during treatment and at post-treatment. It was also expected these gains would be maintained over a one- and three-month follow-up period.
- 1.2 It was expected that children in all three conditions (CBT, CT and BT) would self-report improvements in cognitions related to injections. This may be demonstrated by a reduction in unhelpful cognition content, intensity and frequency, and/or an increase in helpful cognition content, intensity and frequency, both during treatment and at post-treatment. It was also expected that these gains would be maintained over a one- and three-month follow-up period.
- 1.3 It was expected that carers in all three conditions (CBT, CT and BT) would self-report reductions in their child's distress and avoidance-related symptoms and an increase in their child's ability to cope both during treatment and at post-treatment. It was also expected that these gains would be maintained over a one- and three-month follow-up period.

Objective Two: To evaluate the effectiveness of cognitive-behavioural therapy, cognitive therapy and behavioural therapy compared to no treatment (i.e., baseline phase) in relation to improving the carer's ability to manage their own reactions regarding their child's NRD symptoms.

- 2.1 It was expected that carers in all three conditions (CBT, CT and BT) would self-report a reduction in distress and avoidance symptoms, in addition to an increase in their own ability to cope as well as the ability to help their child cope both during treatment and at post-treatment. It was expected that these treatment gains would be maintained over a one- and three-month follow-up period.

Chapter 3: METHOD

Chapter Outline and Aims

The Method chapter describes how the study was implemented by outlining the participants involved in the research, the measures used, treatment manuals and materials, followed by modifications that occurred during research implementation. Study procedures and ethical considerations are then described.

Participants

Twelve chronically ill children (8 girls, 4 boys) aged 7 to 13 years who experienced NRD participated in the research, along with their available carer. The sample was drawn from primary and secondary healthcare settings, relevant organisations and the local community as will be explained later in this chapter. The sample was recruited from July 2012 to December 2012, while the intervention was conducted over the period August 2012 to June 2013 (including follow-up). Analysis of the participant profiles revealed all 12 children were very diverse and similar only in their experience of NRD as will be explained in the Discussion chapter.

A total of 26 chronically ill children with NRD meeting the 7 – 13 years age inclusion criterion were referred to the study, although 8 participants were identified during the screening interview as not meeting other study criteria (i.e., outside age band, residing in Dunedin, Child Youth and Family involvement and/or the presence of more complex issues). One participant dropped out of the study prior to the assessment interview due to other commitments, while a further participant was excluded due to ticking “No” on the consent document. There were also risk factors (e.g., suicidal ideation) with regards to one participant, although her treatment was delayed until this was alleviated, leading her to become fully accepted into the study at a later date. Moreover, despite four participants meeting research criteria, they were declined due to the maximum number of participants having been recruited into the study. As an alternative, they were referred to psychological services elsewhere.

The remaining 12 children referred were accepted into the study (see Table 5). However, for one of the participants (Flynn), distress and coping markedly improved during the assessment and baseline period from November 2012 to February 2013. Even though this participant was excluded from the treatment component of the study, he was still included in the baseline phase and so some results will be given for him in this chapter. A total of four participants resided in Palmerston North while eight resided in Wellington. All participants identified as New Zealand/European, although Tamati, Aroha and Wiremu also identified as Māori. The majority of participants were girls (8 out of 12; 67%), with mothers taking part more

often than fathers in the assessment and therapy process (9 out of 12; 75%). All carers who took part were the child's biological parent with the exception of one child (Sam - stepmother). The majority of participants were also self-referrals (9 out of 12; 75%), with the remaining participants referred by health professionals. To ensure confidentiality, pseudonyms were given to each child.

Table 5
Participant Characteristics

Participant	Sex	Age	Chronic Physical Condition	Frequency of Injections	Type of Injection
CBT					
Tamati	M	9.5	Eczema and Allergies	3 + injections per year	Blood test (intravenous)
Alyssa	F	12	Diabetes	4 to 5 injections daily, plus 1 annual blood test	Insulin (subcutaneous) and blood test (intravenous)
Lisa	F	13	Cystic Fibrosis	3 + injections per year	Blood test (intravenous)
Sam	M	13	Blood Condition	2 injections every 6 months	Blood test (intravenous) and BMA
CT					
Elena	F	10	Chronic Oral Condition	3 + injections per year	Local anaesthetic (intradermal)
Haley	F	10	Arthritis	1 injection per week and 1 per month	Methotrexate (intramuscular) and blood test (intravenous)
Jenna	F	12	Neurofibromatosis	1 injection every 2 months	IV infusion – pain relief (intravenous)
Aroha	F	10	Cystic Fibrosis	3 + injections per year	Blood test (intravenous)
BT					
Lyla	F	7.5	Food Allergies	1 injection every 3 and 6 months	Blood test (intravenous)
Wiremu	M	7	Heart Condition	3 + injections per year	Blood test (intravenous)
Kala	F	13	Arthritis	1 injection every month	Blood test (intravenous)
Flynn	M	9	Liver Condition	1 injection every 2 and 6 months	Blood test (intravenous)

Measures

The protocol for the research comprised a multi-modal, multi-informant battery of instruments as recommended in the treatment literature in relation to paediatric pain, distress and anxiety (Blount et al., 2009; Kendall et al., 1992). This included a semi-structured clinical

interview (for assessment purposes) and full battery of child and carer self-report measures designed to assess therapeutic outcomes across baseline, treatment and at one-month and three-month follow-up points according to a single-case design procedure. Some of the measures selected have known validity and reliability while others were piloted in the author's 2011 Masters research as will be explained.

Semi-Structured Clinical Interview

Prior to therapy, all children and carers were screened over the phone to assess research eligibility (refer to recruitment section). Participants were then seen face-to-face for a semi-structured clinical interview ranging from 60 to 120 minutes (see Appendix 6 for the assessment interview protocol). The assessment interview included four distinct stages: (1) completion of the consent process, (2) obtaining information about the nature of the problem including case formulation and functional analysis, (3) the development of a fear hierarchy, and (4) completion of the first week of baseline measures.

The first stage of the assessment included participants being given an overview of the study, the primary researcher answered any questions, and if the family agreed to participate, consent forms were completed. The interview also allowed the researcher to carry out a final screening to assess for any contraindications to participation in the research (e.g., mood symptoms or suicidal ideation). The second stage of the assessment was aimed at gathering information about the nature of the presenting problem (NRD), completion of a mood and safety screen plus collect additional information (e.g., history of the child's development, medical condition and carer mental health history). Case formulation (also known as case conceptualisation) was integrated into the assessment interview and involved a description of the presenting problem, an account of why and how these problems might have developed, and an analysis of key maintaining processes hypothesised that keep the problems going (Westbrook et al., 2011). In addition, a functional analysis of the presenting problem was conducted including identification of the antecedents, behaviour and consequences. These processes were completed within the framework of the CBT five-part model described in the Introduction chapter (Greenberger & Padesky, 1995).

The third stage of the interview involved a comprehensive and individualised fear hierarchy. Subjective units of distress (SUD) ranging from *not distressed at all* (0) to *the most distressed I have ever been* (10) were used to anchor the hierarchy items and teach the child to self-rate their own distress, and become more aware of their feelings and bodily reactions. The child was asked to identify what aspects of a needle injection elicited the least and most distress and then write these items on the fear hierarchy (see Appendix 10 for an example of the fear hierarchy). These items were then used to guide treatment sessions, in particular the incorporation of graded exposure tasks. Finally, the fourth stage of the interview included the completion of psychometric measures which took approximately 15 to 20 minutes depending on the child's pace.

Child Self-Report Measures

One of the primary outcome measures used in this study was the Needle Injection Questionnaire for Children (NIQ-C). Some items were developed by the author and her research supervisors through drawing on the literature and clinical experience. While other items were existing measures simply added to the NIQ-C to comprise a ‘measure set’, which will be explained later in this section.

Needle Injection Questionnaire - Child (NIQ-C; Mclvor, 2011) (Appendix 7). The NIQ-C is a 7-item self-report measure that gathers information across four domains: (1) distress (Table 6, item 1.1), (2) behavioural avoidance (Table 6, items 2.1-2.2), (3) cognitions related to injections (Table 6, items 3.1-3.2), and (4) coping (Table 6, items 4.1-4.2). Some questions were rated using an 11cm VAS with varying anchors or a 7-item Likert scale, while others utilised an open-ended response format. Several characteristics were incorporated into the NIQ-C including easy-to-follow instructions, time efficiency and age-appropriate language. Use of the NIQ-C as part of the pilot research showed this measure was sensitive to therapeutic changes and corresponded with other measures that were collected (e.g., SUD ratings) (Mclvor, 2011). An overview of each question is now presented in numerical order.

Table 6
Content of the Needle Injection Questionnaire – Child

Item	Question	Domain	Response Format
1.1	In general, how upset do you become when having a needle injection?	Distress	11cm VAS scale: <i>I do not get upset at all (0) to I get very upset (10)</i>
2.1	In general, how much do you want to avoid having a needle injection?	Behavioural Avoidance	11cm VAS scale: <i>I do not want to avoid it at all (0) to I definitely want to avoid it (10)</i>
2.2	What are the kinds of things that you think and/or do to try and avoid having a needle injection?	Behavioural Avoidance	Open-ended question
3.1	What thoughts come into your head when you think of having a needle injection?	Cognition	Open-ended question, and 11cm VAS scale: <i>I do not believe it at all (0) to I absolutely believe it (10)</i>
3.2	What thoughts come into your head about the person giving you the needle injection?	Cognition	Open-ended question, and 11cm VAS scale: <i>I do not believe it at all (0) to I absolutely believe it (10)</i>
4.1	In general, how much are you able to help yourself feel more comfortable when having a needle injection?	Coping	7 point Likert Scale: <i>I was not able to help myself feel comfortable at all (1) to I was completely able to help myself feel comfortable (7)</i>
4.2	When you are having a needle injection, what do you think and/or do in this situation to help yourself feel comfortable?	Coping	Open-ended question

Previous researchers have assessed NRD by simply asking the child pre-injection “How upset will you be during the shot?”, followed by the post-injection question “How upset were you during the shot?” (Cohen et al., 1999). The child responds using a VAS ranging from *not upset* (0) to *very upset* (10). Several other researchers have used a similar question and answer format (see Cassidy et al., 2002; Chen et al., 1999; Cohen et al., 2002; Dahlquist et al., 1985; Fanurik et al., 2000; Kleiber & McCarthy, 2006; Tak & van Bon, 2005; Wint et al., 2002). This research paved the way for the development of item 1.1 from the NIQ-C (see Table 6). Research shows a cut-off of four (on a 10-point scale) or five (on an 11-point scale) maximises sensitivity and specificity for identifying distressed patients and referring them for psychological consultation (Akizuki et al., 2003; Gil, Grassi, Travado, Tomamichel, & Gonzalez, 2005; Tang, Zhang, Pang, Zhang, & Song, 2011).

Alongside gathering data on negative affect (e.g., distress), it was also important to assess changes in behavioural avoidance regarding injections (Table 6, item 2.1). This item was adapted from the question utilised by Mohr et al. (2002), which originated from the Multiple Sclerosis Self-Efficacy Control Scale (MSSE). Modifications to the initial question were mainly in relation to simplifying the content. The original format was “How certain are you that you will be able to perform your next Avonex injection yourself?” Anchors for item 2.1 were adapted from the Fear Questionnaire (Marks & Mathews, 1979). An open-ended question was also added to capture other behavioural avoidance strategies the child may be using that the numerical question was unable to capture due to its restrictive format (Table 6, item 2.2). This question was developed by the author and her research supervisors.

Due to the lack of measures assessing children’s cognitions in relation to injections, written accounts from children were identified in the literature as an alternative (e.g., Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Mohr et al., 2002; Rice, 1993; White & Sellwood, 1995). These articles documented direct accounts from children with NRD leading to the development of two open-ended questions across two domains including: (1) thoughts during the actual injection, and (2) thoughts regarding the person giving the injection. After the child had identified specific thoughts and written these down in the space provided on the questionnaire, they were then required to rate the intensity of the thought (Table 6, items 3.1 and 3.2). The scale anchors originated and were adapted from the Dental Cognitions Questionnaire (DCQ) by de Jongh, Muris, Schoemakers and Ter Horst (1995). The original format of the DCQ included a thought whereby the respondent had to indicate on a scale from 0% (I don’t believe this at all) to 100% (I am absolutely convinced this is true) regarding how much they believed the thought.

NIQ-C Additional Measures

Coping Questionnaire-Child Version (CQ-C; Kendall et al., 1992 (Appendix 7). The improvement of existing coping strategies is a key component of the current treatment manual, therefore an adaptation of the CQ-C was utilised. The original format of the CQ-C identifies three areas as the most distressing by the child during the initial interview, which is then rated by the child on a 7-point Likert scale ranging from *able to help myself feel comfortable* (1) to *not*

at all able to help myself feel comfortable (7). For the purpose of the current study, instead of identifying the situation during the assessment interview, the questionnaire format was simplified to include only one situation: "In general, how much are you able to help yourself feel more comfortable when having a needle injection?" (Table 6, item 4.1). Content of the anchors were also slightly modified from the original format. Lastly, an open-ended question was added to the CQ-C (Table 6, item 4.2) to capture other cognitive and behavioural coping strategies the child may be using that the original measure was unable to capture. This was developed by the author and her research supervisors.

The CQ-C is treatment sensitive across a range of research settings in child anxiety, including New Zealand (Huzziff, 2004; Kendall et al., 1997). Research regarding the reliability and validity of the CQ-C has been positive, with internal stability estimated to be .70 (Kendall et al., 1997) and test-retest reliability for 20 children with anxiety disorders was .46 over a two-month period (Kendall, 1994). The CQ-C also provides a baseline for major target behaviours addressed in therapy, and is a useful measure of change in coping across treatment (Kendall et al., 1992).

Child Anxiety and Pain Scale (CAPS; Kuttner and Lepage, 1983 (Appendix 7). The CAPS consists of one set of five drawings of children's faces exhibiting increasing levels of pain, and a second set of five drawings indicating increasing levels of anxiety. The scale is presented on white cardboard and the child was asked to point to the face that shows how much pain or anxiety they feel about having an injection. The chosen face is converted to a numerical score by counting the faces from left to right, ranging from a neutral expression of *no pain/anxiety* (0) to a suffering face of *severe pain/anxiety* (4).

The CAPS (Appendix 7, items 1.2-1.3) has well-established psychometric properties and is a reliable and valid measure for evaluating paediatric pain and anxiety in research and clinical settings (Goodenough et al., 1997). Based on this and the fact that previous researchers outlined it was easy to administer and usable among children of varying cognitive abilities, it was included in this study (Keck, Gerkensmeyer, Joyce, & Schade, 1996). However, when the measure was administered during this study, several children had difficulty with understanding that the facial expressions were just an illustration of the pain or distress they might feel, compared to what they actually look like. As a result, scores from this measure are not presented in the Results chapter, but accessible upon request.

Articulated Thoughts in Simulated Situations (ATSS; Davison et al. 1983) (Appendix 9). Administration of ATSS in the present study was carried out by reading a non-injection-related story and then an injection-related story. The first story described a family that went to McDonalds with various obstacles occurring along the way to prevent them from reaching their destination and receiving their food. Scores for this story were not presented in this study as it was primarily a control condition and simply enabled the child to practice imagining themselves in a situation before presenting the experimental story, which included receiving a needle injection. Even though it is not standard practice to exclude control condition data (see., Davison et al., 1983), scores indicated that this story was producing more positive cognition

content and frequency compared to the experimental condition. Data for the control condition is available upon request.

There were four intervals within each story where the child was asked to say what they were thinking and/or feeling. Another segment of the story was then read followed by the child's self-report and so on until the story was completed. Coding categories used were mutually exclusive so it was not possible for a statement to be categorised in multiple ways, therefore preventing the inflation of frequency scores. Coding was based on categories outlined by Davison et al. (1983) (see Appendix 9 for coding descriptions).

Subjective Units of Distress (SUD; Wolpe, 1982) (Appendix 10, item 1) and Fear Hierarchy (Appendix 10). SUD ratings were obtained as an additional measure of child distress and were an effective way to help the child quantify their feelings (Mohr et al., 2002). The aim of this measure was to assess the intensity of distress regarding injections in general on a Likert scale from *I'm not distressed at all* (1) to *I'm the most distressed I have ever felt* (10). As part of treatment, SUD ratings were also obtained from the child using a basic 10-item fear hierarchy of injection-related situations that were customised for the individual child. SUD ratings for the hierarchy items were then checked throughout the intervention to assess any changes in distress.

Overall, items incorporated into the NIQ-C aimed to capture self-reported distress, avoidance, coping and cognitions related to injections including content, intensity and frequency. Due to the impact carers can also have on their child during injections, it was also imperative to assess these factors in relation to carers, leading to the development of the Needle Injection Questionnaire for Parents (NIQ-P).

Carer Self-Report Measures

Similar to the NIQ-C, the NIQ-P was a primary outcome measure used in this study. Some items incorporated into the NIQ-P were developed by the author and her research supervisors, whereas other items were based on existing measures.

Needle Injection Questionnaire - Parent (NIQ-P; McIvor, 2011) (see Appendix 8). The NIQ-P is an 8-item self-report measure that gathers information across three domains: (1) distress (Table 7, items 1.1-1.2), (2) behavioural avoidance (Table 7, items 2.1-2.3), and (3) coping (Table 7, items 3.1-3.3). The NIQ-P requires the carer to rate their own subjective experience as well as what they perceive their child to experience in relation to these three domains. Some questions were rated using an 11cm VAS with varying anchors or a 7-point Likert scale, while other questions utilised an open-ended response format. Much the same as for the NIQ-C, this measure was developed so that it is easy to follow, time efficient and sensitive to therapeutic changes in relation to NRD and coping. Scoring of the NIQ-P was the same as the NIQ-C.

Table 7

Content of the Needle Injection Questionnaire – Parent

Item	Question	Sub-category	Response Format
1.1	In general, how distressed is your child when having a needle injection?	Child Distress	11cm VAS scale: <i>My child is not at all distressed (0) to My child is extremely distressed (10)</i>
1.2	In general, how distressed are you when your child is having a needle injection?	Carer Distress	11cm VAS scale: <i>I am not at all distressed (0) to I am extremely distressed (10)</i>
2.1	In general, how much does your child want to avoid having a needle injection?	Child Behavioural Avoidance	11cm VAS scale: <i>My child definitely wants to avoid it (10) to My child does not want to avoid it at all (0)</i>
2.2	In response to the question above (2.1), is it typical of your child to react in that way. Please explain your answer.	Child Behavioural Avoidance	Yes or No, and open-ended question format
2.3	In general, how much do you want to avoid your child's needle injection?	Carer Behavioural Avoidance	11cm VAS scale: <i>I definitely want to avoid it (10) to I do not want to avoid it at all (0)</i>
3.1	In general, how much are you able to help your child feel more comfortable when they are having a needle injection?	Child Coping	7 point Likert Scale: <i>I am not able to help my child feel comfortable at all (1) to I am able to help my child feel comfortable (7)</i>
3.2	In general, how much are you able to help yourself feel more comfortable when your child is having a needle injection?	Carer Coping	7 point Likert Scale: <i>I am not able to help myself feel comfortable at all (1) to I am able to help myself feel comfortable (7)</i>
3.3	When your child is having a needle injection, what do you think and/or do in this situation to help yourself feel more comfortable?	Carer Coping	Open-ended question

Two items were included in the NIQ-P that assessed the level of carer distress, as well as carer perception of child distress during injections (Table 7, items 1.1 and 1.2). Both questions were adapted from McCarthy et al. (2010) and originated from the Perception of Procedures Questionnaire (PPQ) (Kazak, Penati, Waibel, & Blackall, 1996). As an indicator of construct validity, Kleiber (1999) reported a small positive correlation ($r = .33, p = .03$) between parents' answers on this question and observed distress scores for children during intravenous insertions. A number of other researchers have adopted very similar questions and response formats to capture parent self-report of child distress (e.g., Dahlquist et al., 1985; Kleiber & McCarthy, 2006; McCarthy et al., 2010; Powers et al., 1993; Walco, Conte, Lebay, Engel, & Zeltzer, 2005).

In order to provide a more objective and precise measure of child and carer behavioural avoidance, three questions were used (Table 7, items 2.1-2.3). Items were originally developed by the author and research supervisors as a result of clinical and research experience, although other studies have used similar strategies (Blount et al., 1992; Mohr et al., 2002). For example, Blount et al. (1992) used a similar format asking carers “How afraid is your child?” and “How much did the medical procedure hurt your child?”. The end points on the 10cm VAS were “no fear/pain at all” and “most fear/pain possible”. In addition to this numerical item, item 2.3 was included in the NIQ-P to determine whether it was typical of the child to be behaviourally avoidant. A *yes* or *no* response format was used for the first part of this question, with the second part requesting the carer to explain their answer. This item was developed by the author and her research supervisors. Other items that were incorporated into the NIQ-P included measures developed by other researchers, which were either left in their original form or modified for the present study, as will now be described.

NIQ-P Additional Measures

Coping Questionnaire - Parent (CQ-P; Kendall et al., 1992) (Appendix 8). The Coping Questionnaire-Parent Version (CQ-P) (Kendall et al., 1992) was integrated into the NIQ-P, and parallels the CQ-C described previously. However, it was adapted to include two numerical questions where the carer rated (1) their perceived ability to help their child cope, and (2) their own ability to cope (Table 7 items 3.1-3.2). Lastly, an open-ended question was added to the CQ-C (Table 7, items 3.3) to capture other cognitive and behavioural coping strategies the child may be using that the original measure was unable to capture. This was developed by the author and her research supervisors.

Outcome data supports the sensitivity of the Coping Questionnaire-Child and Parent versions to treatment (Kendall, 1994; Kendall et al., 1997). Due to the parent version being similar to the child version, the psychometric properties are the same as those reported earlier in which case reliability (e.g., test-retest) and validity (e.g., internal stability) have shown to be promising (Kendall, 1994).

Coping Behaviour Questionnaire (CBQ; Field, Alpert, Vega-Lahr, Goldstein, & Perry, 1988) (Appendix 8). The CBQ is a behaviour checklist that is completed by the carer in relation to observed behavioural distress and coping behaviours the child displayed during their most recent needle injection. The questionnaire comprises 15 items that are rated using a simple *true* or *false* response format (Appendix 8, item 3.4). Using the CBQ as an adjunct to other measures (e.g., NIQ-C and NIQ-P) addressed some of the limitations of behaviour checklists discussed earlier in this chapter.

There is no information available on the validity and reliability of the CBQ, apart from a pilot study conducted by Kleiber and McCarthy (2006) evaluating internal consistency. Participants were children aged 4 to 12 with a chronic medical condition that required repeated injections. Distress showed a positive correlation with the CBQ ($r = .55$), as did child state anxiety although this was a much smaller correlation ($r = .18$). Nurturance, parent state anxiety and child state anxiety accounted for 32% of the variance in CBQ scores. According to Field et

al. (1988) as well as Kleiber and McCarthy (2006), items indicating coping such as "followed instructions without complaining" and being "cooperative" are reverse-scored (e.g., questions 5, 6, 8, 9 and 15). The total score range is 0-15, with lower scores indicating more adaptive coping and/or a repressor coping style. Field et al. (1988) suggested children with a repressor versus sensitizer coping style will experience less distress and more coping. There is no normative data available for the CBQ.

Supplementary Measures

A number of supplementary measures were utilised to assist with explaining any unusual patterns in the data and provide a context for individual responses on the primary outcome measures. It also provided an opportunity for the families to give feedback about the therapy programme that was not restricted by pre-determined response formats. Information obtained from these measures can also be used to guide the development of future treatment programmes for children with NRD.

Treatment Component Rating Scale (Jay et al., 1987) (Appendix 11). Children and carers were asked to rank individual components of their allocated treatment condition at post-treatment using an 11cm VAS ranging from *not at all helpful* (0) to *very helpful* (10). The same rating system in relation to treatment components has been utilised in several other studies (Jay et al., 1987; Tyc et al., 1997).

Post-Therapy Feedback Questionnaire (Appendix 12). A questionnaire developed by the author was completed at post-treatment by the child and their carer. The questionnaire included five open-ended questions with sentence and/or paragraph answers. The purpose of this measure was to provide an opportunity for the child and carer to offer feedback about the therapy programme in general, what modifications they would suggest and whether they would recommend the treatment programme to other family and/or friends in a similar situation. Questionnaire responses were not analysed using qualitative techniques, but summarised according to key themes and reported verbatim in the thesis. This questionnaire was used as an adjunct to numerical measures and to provide anecdotal information about the effectiveness of the treatment programme. It also provided an opportunity for participants to provide feedback in their own words.

Session Rating Scale (SRS) and Child Session Rating Scale (CSRS) (Miller, Duncan, & Johnson, 2002) (Appendix 13). The SRS and CSRS were used to monitor therapeutic alliance across the three treatment conditions. Both scales were also used to identify treatment components that were producing changes by checking the scores against any fluctuations on the main outcome measures. This comparison provided information in relation to whether therapy needed to be adjusted in future research and clinical practice. The SRS and CSRS are easy to administer, score and interpret, while also remaining cost-effective.

Psychometric properties for SRS have shown excellent internal consistency, test-retest reliability and moderately strong concurrent validity with longer, more established measures of treatment outcome and therapeutic alliance (Campbell & Hemsley, 2009). Four studies

including three RCTs support the efficacy of using SRS as a client feedback intervention across various treatment approaches (Anker, Duncan, & Sparks, 2009; Miller, Duncan, Brown, Sorrel, & Chalk, 2006; Reese, Norsworthy, & Rowlands, 2009; Reese et al., 2009). Scoring the SRS (child and adult versions) is done using a centimetre ruler. Each of the visual analogue scales are 11cm (e.g., 0-10), so the score is the measurement length on the ruler (e.g., 3.3cm = score of 3.3) with 10 being the highest score for each scale. The scores of all visual analogue scales are then added together for an overall score (Miller et al., 2002). Due to only two of the four visual analogue scales being used in this study, the total possible score for both scales was 20 rather than 40, with a cut-off score of 18 rather than 36. When items are at the cut-off score of 18 or above, this indicates the client is satisfied with therapy, and when scores are below 18 (or one scale is significantly below 9), then it may be that the alliance needs repairing or adjustments to therapy are necessary (Miller et al., 2002).

Measure Sets

To determine what components of the treatment conditions were most effective and to control for the dose confound, a different “measure set” was administered at certain stages of the intervention (see Figure 1). A total of four measure sets were developed, with each one including a different combination of the measures mentioned previously. Due to some sets incorporating extra items, administration times varied with sets one and four taking approximately 15-20 minutes whereas sets two and three took approximately 5-10 minutes. See Table 8 for a content description of each measure set.

Measure sets corresponded to the four intervention phases: assessment interview, baseline, treatment and follow-up. Measure set one was administered in the assessment interview and follow-up phases for all treatment groups. Measure set two applied to the baseline phase only and was also administered to all treatment groups. Once the therapy phase began, administration became more complex. All treatment conditions completed measure set three at each therapy session except for the final session, in which measure set four was used. This meant that set four was completed in session four for the CT and BT groups, but session six for the CBT group. The other exception was that the CBT group completed measure set one again during session four (which was the CT and BT groups’ final session). The rationale for this was that results from the measures completed in this session could then be compared across all three treatment conditions.

Cognitive-Behavioural Therapy (N = 4)						
Assessment Interview	Baseline	S1	S2	S3	S4	S5
					S6	
Measure Set 1	Measure Set 2	Measure Set 3	Measure Set 3	Measure Set 1	Measure Set 4	Measure Set 1
Cognitive Therapy (N = 4)						
Assessment Interview	Baseline	S1	S2	S3	S4	
						1 Mo
Measure Set 1	Measure Set 2	Measure Set 3	Measure Set 3	Measure Set 4		Measure Set 1
Behavioural Therapy (N = 4)						
Assessment Interview	Baseline	S1	S2	S3	S4	
						1 Mo
Measure Set 1	Measure Set 2	Measure Set 3	Measure Set 3	Measure Set 4		Measure Set 1

Figure 1. Study Design and Administration Structure of the Measure Sets

Table 8

Content Description of Measure Sets

Set 1: Assessment and Follow-Up	
Child	Carer
1. Needle Injection Questionnaire-Child	1. Needle Injection Questionnaire-Parent
2. Subjective Units of Distress	2. Coping Behaviour Questionnaire
3. Child Anxiety and Pain Scale	
4. Articulated Thoughts in Simulated Situations	
5. Fear Hierarchy	
Set 2: Baseline	
Child	Carer
1. Needle Injection Questionnaire-Child	1. Needle Injection Questionnaire-Parent
2. Subjective Units of Distress	
Set 3: Treatment	
Child	Carer
1. Needle Injection Questionnaire-Child	1. Needle Injection Questionnaire-Parent
2. Session Rating Scale	2. Session Rating Scale
3. Subjective Units of Distress	
Set 4: Final Treatment Session, Only	
Child	Carer
1. Needle Injection Questionnaire-Child	1. Needle Injection Questionnaire-Parent
2. Session Rating Scale	2. Session Rating Scale
3. Subjective Units of Distress	3. Coping Behaviour Questionnaire
4. Child Anxiety and Pain Scale	4. Treatment Component Rating Scale
5. Articulated Thoughts in Simulated Situations	5. Post-Therapy Feedback Questionnaire
6. Fear Hierarchy	
7. Treatment Component Rating Scale	
8. Post-Therapy Feedback Questionnaire	

Treatment Manuals and Materials

As described in the introduction of the treatment manual (McIvor et al., 2011) and earlier in this chapter, children were allocated to receive either four structured sessions of CT or BT, or six structured sessions of CBT. The manual describes the purpose and goals for each session, materials required, format and activities, and out-of-session activities (homework).

Worksheets for the child were provided to accompany each session. Therapy comprised three phases as follows (although as discussed previously there was some overlap):

Phase 1: Psycho-Education. This phase involved the therapist building rapport with the child and carer, providing an overview to the programme, exploration of the child's history and introduction to the CBT five-part model outlined by Greenberger and Padesky (1995) (see pp. 23 for a description). Contingent reinforcement was also introduced at this stage and implemented throughout the intervention. Praise from the therapist and carer were used to reinforce helpful behaviours during session, while tangible rewards such as lollies, chocolate, toys, stationary and stickers were given contingent on the child's completion of the entire therapy session. These strategies were used regardless of the phase.

Phase 2: Cognitive and/or Behavioural Components

Cognitive components were based on techniques (e.g., emotive imagery and cognitive restructuring) that encouraged children to cope directly with their distress, rather than relying on avoidance behaviour. Emotive imagery was used to engage the child in the identification of superhero figures who then served as models for managing injections. This created a sense of understanding and active mastery over the anxiety/situation rather than passive submission during procedures. Cognitive restructuring involved firstly being able to identify and modify maladaptive thinking when confronted with the feared stimulus, and then being able to develop alternative, more adaptive thoughts based on coping rather than fear. Various strategies were used to do this, for example identifying information processing errors, finding the evidence for and against a thought (e.g., 'being a detective'), and developing alternative helpful thoughts associated with injections.

Behavioural components incorporated coping strategies such as controlled breathing and muscle relaxation, combined with exposure tasks (i.e., systematic desensitisation). Muscle relaxation was taught in session through imagery (e.g., floppy vs. robot game) and scripts that were presented in a playful and fun manner. Similarly, controlled breathing also involved the use of scripts in addition to structured exercises. The aim was to demonstrate and practice each new skill with the child, as well as show the difficulties that might be experienced, and the strategies to overcome these difficulties. Depending on the treatment condition several sessions were dedicated to in-vivo exposure (e.g., direct contact with the phobic stimuli) moving from least to most anxiety-provoking (Olatunji et al., 2010). Participant modelling was also incorporated into gradual exposure tasks (both imaginal and in-vivo). For example, the therapist acted as a coping model by first demonstrating the skill for the child (e.g., calm breathing), and the child was then invited to participate and eventually encouraged to carry out the skill independently. Depending on the fear hierarchy items, symbolic modelling was also incorporated and involved watching a video from YouTube of a child having a successful injection titled "Orion's Blood Test".

Phase 3: Completion of Therapy. The final session of each treatment condition was devoted to the closure of therapy and relapse management. Closure of therapy was signalled at an early stage of treatment and discussed more fully in this phase. Moreover, in order to

promote relapse management, possible setbacks and achievements in therapy were discussed in session six, as well as the child's strengths and weaknesses. Lastly, the therapist discussed with the carer how to support the child and coach them in other situations.

Treatment Integrity

To assess treatment integrity, all assessment interviews and therapy sessions were audio-taped and reviewed by either Dr Joanne Taylor or Dr Kirsty Ross to ensure that the treatment manual was being followed and to provide clinical supervision of assessment and treatment work. Audio recordings rather than video recordings were utilised as the equipment was portable and more conducive to the establishment of rapport. Slight deviations from the manual were identified as discussed below.

Treatment Manual Modifications

Therapy Content

As recommended in the literature, a flexible, clinically sensitive application of treatment manuals is the most appropriate (Lambert & Ogles, 2004). This includes the clinical psychologist adapting therapy to the developmental stage, cognitive and social development of the child (Kendall et al., 1992). Several modifications were made to the treatment manual during therapy including simplified cognitive restructuring, adaptation of reward systems, and worksheets were either included or excluded. There were also variations in the implementation of emotive imagery. For younger children, the use of metaphors (e.g., traffic lights rather than SUD ratings) as a way to monitor distress was used alongside the CBT five-part model. Lastly, at times low-level exposure for the CBT group was carried out during session three rather than session four, although the manual stipulated that the transition of exposure tasks between sessions was flexible.

Cognitive restructuring was simplified depending on the child's ability to understand abstract concepts. In circumstances where the child could easily find the evidence for and against the thought as well as identify maladaptive thought processes, cognitive restructuring was used as manualised (e.g., for participants Haley, Lisa, Elena, and Jenna). When the child struggled to understand cognitive restructuring, it was replaced by simply learning the difference between helpful and unhelpful thoughts (e.g., Tamati and Aroha). This was not strictly related to age as both children were between nine and ten years, an age identified as being capable of learning cognitive techniques. In general, cognitive restructuring was carried out as manualised for the majority of children randomised into the CBT and CT conditions.

Rewards and games were the most widely modified primarily due to the developmental stage and preference of the child. For younger children, a game was used either at the start, middle and/or end of each therapy session, whereby a reward was offered contingent on the child's success or completion of the task (e.g., lolly, chocolate or sticker). Games were structured so that the child succeeded the majority of the time. In comparison, rewards for older

children were mainly based on contingency reinforcement and offered in the final session. However, each child consistently received a reward of their choice up to the value of \$20 during their final therapy session. All food rewards were given with consideration to the child's medical condition and with the carer's verbal consent.

Some worksheets were excluded or included according to the developmental level of the child. For example, the worksheets "My Account" and "Reward Chart" that were incorporated into phase one were not used for any of the children that took part in this study. These contingency reinforcement strategies were too stringent for the treatment and a more flexible approach was required so that rewards could be adapted to the child's personal preference. The CBT five-part model (e.g., "My Experience" worksheet) was explicitly explained to all children and their carers using a whiteboard, although the content changed slightly with children less than 10 years old to ensure they understood the concept.

Several of the breathing worksheets were also not used due to them being age inappropriate. Instead, breathing exercises from the Anxiety and Phobia Workbook (Bourne, 2010, pp. 81-86) were applied for adolescents (Lisa and Kala). Muscle relaxation was rarely carried out due to time restrictions and lack of therapist experience when initially administering the programme. Therefore, it was administered toward the end of data collection (Sam and Lyla) or encouraged as homework, although few children practiced it outside of session. The rationale for prioritising controlled breathing over muscle relaxation was that, despite a significant amount of research attesting to the effectiveness of muscle relaxation (or applied tension) for blood or injection phobias, this exercise is usually used in order to raise blood pressure and prevent fainting (Wolitsky-Taylor et al., 2008). It was thought that the use of muscle relaxation during an injection could be counterproductive as it is easier to access the vein when the child is physically relaxed rather than switching between different states of tension. Another rationale is that controlled breathing rather than muscle relaxation is typically incorporated into existing treatment manuals and seen as one of the most effective techniques for NRD (Dahlquist et al., 1985; Jay et al., 1985). Despite this, the exclusion of muscle relaxation may have had implications for certain participants who could have found this helpful.

For the CBT and CT groups, emotive imagery was used for all participants, although how it was implemented and contextualised was dependent on the child. Each child chose a different hero with some children basing this on a real person (e.g., Maria Tutaia, Perrie Edwards and a school teacher), or conjuring up a superhero in their mind (e.g., Random Guy Bob, New Zealand's Hottest Home Baker, and Dr Sabrina the Vet). In particular, one child went further and wrote a poem about their superhero having an injection and using different coping strategies to be "less teary" during the injection. Another child imagined themselves as NZ Hottest Home Baker and when having unhelpful cognitions "re-mixed" their thoughts (or ingredients) in order to cope better during the injection. Lastly, one child drew two versions of themselves, one during the injection and the other after the injection. This process assisted the child to cope and think about what they needed to do in order to achieve their reward. Therefore, even though these superheroes did not necessarily deviate from the emotive

imagery technique, it is important to mention variations in the way different children approached this task to enable research replication.

Low- and medium-level exposure tasks switched between being implemented in sessions three and four for the CBT and BT groups. This was due to activities taking longer than expected, forcing exposure tasks to be transferred to the subsequent session. In some cases, this meant exposure only continued for one session (Lisa), compared to two sessions for other children (Tamati, Lyla and Aroha). Lastly, as a way to explain the distress response to younger children, traffic lights were used rather than SUD ratings. The red light indicated when the child felt very distressed, whereas the orange light indicated mild distress, and the green light showed that the child was not distressed at all. This metaphor was explained to younger children (Wiremu and Lyla) to assist them with understanding and articulating their emotions. This strategy was also used during exposure tasks to gauge the child's level of distress.

Treatment Length

Every measure was taken to ensure sessions occurred weekly and that all groups had the same treatment length. However, this was not always possible due to the availability of the therapist and family, cancelled sessions, and the child's next scheduled injection not aligning with sessions four or five. Therapy duration for the CBT condition ranged from 6 to 7 weeks, while durations for the remaining two groups ranged from 4 to 7 weeks. All sessions ranged between 50 to 90 minutes long, with the exception of the in-vivo injection session which took between 90 to 120 minutes. At times, session timeframes deviated from the treatment protocol for a number of reasons, including (1) the amount of activities incorporated into each session required longer than 50 minutes, (2) the completion of psychometric measures took an extra 15 to 20 minutes per session, (3) some children required further practice and consolidation of the information, and (4) the in-vivo injection in session took longer than expected. Participants also received follow-up measures one and three months after therapy completion, although these were not always completed on time as will be explained.

Study Procedures

Recruitment

As part of the recruitment process, an oral presentation about the study was given to the Hutt Valley DHB, Capital and Coast DHB, Mid Central DHB as well as community nurses in Palmerston North. Two flyers were handed out during the presentation; the first provided information for the families (see Appendix 3) and the second provided information for health professionals (see Appendix 4). Flyers were then able to be passed onto families and/or posted in hospital waiting rooms. Alternatively, health professionals were invited to more formally refer participants using the referral form developed for this research (see Appendix 5). Other relevant services were also approached including Cystic Fibrosis Association, Aotea Pathology and

Diabetes New Zealand. In this instance, flyer two was either emailed and/or posted to the service for them to pass onto the families, hand around at their team meetings and/or put in waiting rooms. Therefore, potential participants were invited to take part in the study using two methods. The first method included the health professional identifying suitable participants and formally referring them to the researcher. The second method included families contacting the researcher themselves via information provided on the flyer.

Once the health professional had passed on the referral form or contact from the carer was received, the researcher telephoned potential participants and carried out an initial screening interview over the phone. The screening interview was a chance to establish rapport with the family while also determining their eligibility for the research. If the family met research criteria and were interested in taking part, the researcher scheduled an assessment interview and posted an information sheet plus a map with directions to the appropriate Clinic in either Palmerston North or Wellington. Every effort was made to ensure that families were not interviewed face-to-face if they did not meet research criteria and were unlikely to participate in the study. If the family did not meet inclusion/exclusion criteria during the screening interview, the researcher explained why and suggested more appropriate services. There were no requirements on the number of participants recruited from each locality, although every effort was made to ensure an equal number of participants were from Wellington and Palmerston North.

Baseline Phase

Once the assessment interview was completed, participants were assigned non-concurrently to a baseline duration ranging from two to six weeks. An additional probe assessment was incorporated mid-way through the research for two participants (duration was approximately two months) and completed prior to starting the baseline phase. As a result, baseline durations differed within and across each condition (see Table 9 for a summary).

Table 9

Allocated Baseline Lengths According to Treatment Condition

	2 weeks	3 weeks	4 weeks	5 weeks	6 weeks	Probe
CBT	1	1	1	-	1	-
CT	-	2	1	-	1	1
BT	-	-	-	3	1	1

Random assignment of baseline lengths was not carried out for several reasons. For instance, although this process can prevent research confounds (Hsu, 2003), it did not guarantee that each treatment group had a range of baseline lengths which was essential for

the present study. Furthermore, prior to entering the study several participants had injections pre-booked, so a pre-determined baseline length was allocated to ensure the procedure aligned with session four or five (depending on the condition allocated). In some cases, the implication of not aligning the injection appointment with the correct session meant a six month delay in therapy (as that was when the child's next injection was scheduled) or exclusion from the study because of time constraints. The locality of the participant as well as therapy start and end dates in relation to other families also determined baseline allocation. The rationale for this was that it was more efficient to start families concurrently when they resided within the same region.

Before participants could proceed to the treatment phase, they had to demonstrate a stable baseline across all assessment measures. In this case, a stable baseline was characterised as no more than a 50% change in behaviour over three or more data points (Barlow & Hersen, 1984; Kazdin, 2011). Therefore, such baselines are characterised by relatively little variability and the absence of a slope (trend). In this study, two participants (Lyla and Flynn) presented with an unstable baseline on several measures. As a result, these participants continued on baseline until their variability was less than 50% on all measures. Both Lyla and Flynn were allocated to the behavioural condition, and were originally assigned two- and three-week baselines but these were extended to five and six weeks, respectively. This explains why the behavioural condition has longer baseline durations than the other two conditions. Baseline stability for all 12 participants will be further discussed in the Results chapter, while possible explanations for the variability in baseline duration for these two participants will be explained in the Discussion chapter.

Most Recent Injection Prior to Baseline

Table 10 provides a summary of each participant's most recent injection prior to the baseline phase. The most common procedure that participants required was a subcutaneous injection whereby blood was drawn for diagnostic purposes (i.e., blood tests). Other procedures included intramuscular, intravenous and oral injections. The most common insertion point was the arm, although some children required injections in the hand, mouth and buttock. Common health service locations for injection procedures were MidCentral DHB, Hutt Valley DHB, Aotea Pathology, dental surgeons, general practitioners or alternatively the injections were carried out at home (either self-injected or injected by the carer). As shown in Table 10, prior to therapy the majority of children took on average 10 minutes to complete the injection with either moderate to severe distress. Most of the children were physically restrained. Of particular note, alongside a distress reaction some children exhibited more extreme behaviours when exposed to injections. For example, prior to the baseline phase, Flynn required several people to physically restrain him in order to complete the injection. He would then become socially withdrawn and mute for up to four weeks following the procedure. While Elena had avoided up to seven injections in the past 18 months: three blood tests and four oral injections. She would refuse to open her mouth during oral procedures and to uncover her arm during blood tests. Injection procedures that were completed as part of treatment and follow-up will be briefly described in the results section.

Table 10

Description of Each Participant's Most Recent Injection Prior to Baseline

Participant	Type of injection	Baseline Description
CBT		
Tamati	Blood Test	1 hour to complete. Physically restrained
Lisa	Blood Test	10 minutes to complete
Alyssa	Pain Medication (Intravenous)	10 minutes to complete. Physically restrained
Sam	Blood Test	10 minutes to complete. Physically restrained
CT		
Elena	Anaesthetic (Intramuscular)	Not completed. Seven injections have been avoided over the past 18 months
Hayley	Blood Test and Methotrexate (Intramuscular)	Not completed. Avoided methotrexate injections in past so went on oral medication
Jenna	Blood Test	10 minutes to complete
Aroha	Blood Test	30 minutes to complete. Physically restrained
BT		
Wiremu	Blood Test	2 hours to complete. Physically restrained
Lyla	Blood Test	10 minutes to complete. Physically restrained
Kala	Blood Test	10 minutes to complete
Flynn	Blood Test	30 minutes to complete. Physically restrained. Became mute for four weeks post-injection

Note. All blood tests were subcutaneous.

Treatment and Follow-Up Phases

Once it was determined that the participant's baseline was stable, they were randomly allocated to one of the three treatment conditions. This procedure was carried out via a table of random numbers, with participants allocated in order of referral and only once they had been through the screening interview process and met research criteria. At the completion of the treatment phase, follow-up measures at one and three month intervals were completed during a face-to-face meeting with the researcher, although time periods differed across participants and

were sometimes reduced or extended depending on the availability of the family. For example, one-month follow-ups ranged from 0.8 to 1.8 months, with a mean of 1.3, whereas three-month follow-ups ranged from 3.2 to 4.3 months, with a mean of 3.5.

Setting

The assessment interview, first week of baseline measures, therapy sessions and follow-up measures were mostly carried out at the Massey Psychology Clinics in Palmerston North and Wellington. The remaining baseline measures were posted to participants and returned using a freepost envelope. During the treatment phase, all measures were completed immediately after the therapy session while at the Clinic. The assessor and therapist for this study was the researcher and author of this thesis, a Doctorate of Clinical Psychology student at Massey University. To ensure ethical practice, clinical supervision of all assessment interviews and therapy sessions was provided by on-site registered senior clinical psychologists at the Massey Psychology Clinics in Wellington (Ruth Gammon) and Palmerston North (Kirsty Ross and Joanne Taylor). All three senior clinicians have extensive experience in the assessment and treatment of children and their families presenting with a range of psychological problems.

Ethical Considerations

The present study was carried out according to the Code of Ethics for Psychologists Working in Aotearoa/New Zealand. Ethical approval to conduct this study was provided in June 2012 by the Central Region Human Ethics Committee, reference number CEN/11/03/019 (see Appendix 1). Ethical issues pertinent to the present study included providing adequate information to participants about the nature of the study (i.e., information sheet), obtaining written consent from both the child and carer, and ensuring confidentiality and no harm to the participants. Other key issues included training and regular clinical supervision for the therapist who was a Doctorate of Clinical Psychology trainee.

All potential participants were provided with information sheets and consent forms in age-appropriate language (see Appendix 2). Information sheets outlined the nature and purpose of the research and what would be expected of the participant if they took part. It explained what the treatment involved, and the names and roles of those concerned. The researcher expressed verbally and in written form that participation in the research was voluntary, and that participants had the right to decline to take part in the study at any time without treatment being withdrawn. It was also clearly outlined that participants had a right to ask questions, have them answered and to decline to answer questions at any time. Following this, written consent was obtained from both the child and their carer.

Confidentiality was maintained for all participants, although exceptions to this were explained at the outset (e.g., safety issues). To ensure confidentiality, pseudonyms were given to the child and their carer and were used in all research reports and publications. Much the same as standard practice, assessment, treatment and follow-up material was stored in a

locked filing cabinet only accessible to the researcher and supervisors. All data will be held for a period of ten years, after which it will be destroyed by the researcher.

As in all research, no harm should come to the participants. This research was considered to be of low risk to the participants, with the only potential harm occurring due to exposure activities inducing high levels of distress. Close monitoring of participant progress during treatment was carried out and the therapist could modify or discontinue treatment if any participants were placed at risk (which did not occur in this study). Initial screening of participants was completed in collaboration with two clinical supervisors. If safety issues were identified, the intervention was discontinued and an alternative service offered. It was also important that participants were recommended psychological services beyond the research if they were randomised into a treatment condition that had any aversive or less than desirable outcomes. In some cases, the ethical issues described above did occur such as suicidal ideation, the presence of more complex issues and children not giving written consent, resulting in the therapist offering an alternative service (see participant section on pp. 56 for examples).

Other ways in which these key issues were dealt with included the researcher receiving regular feedback and clinical supervision via audio recordings of all the assessment interviews and therapy sessions. The carer was also present in case of emergencies and the therapist followed their professional Code of Ethics (Code of Ethics Review Group, 2002) and Clinic policies and procedures. Lastly, once the final follow-up measures were collected, clients were referred to the Massey Psychology Clinics (or other appropriate services) if they felt the need to continue receiving psychological intervention at the completion of the research.

Chapter 4: RESULTS

Chapter Outline and Aims

Research results are presented in five sections. The first section provides an analysis of baseline stability across all participants. The second and third sections relate to child and carer reports, respectively, both of which are organised into the three treatment conditions (CBT, CT and BT) and then presented according to the main constructs of distress, avoidance and coping. The two types of graphic displays used are modified Brinley plots and time-series graphs. Written information obtained in relation to child and carer avoidance, cognitions and coping are also provided. The fourth section provides an in-depth analysis of the research results by displaying non-regression-based statistics relating to certain data. Fifth, therapy feedback and rapport are reviewed.

Baseline Stability

As described in the method chapter, a stable baseline is characterised as no more than a 50% change in behaviour over three or more data points (Barlow & Hersen, 1984; Kazdin, 2011). Therefore, it is characterised by relatively little variability and the absence of a slope. Participants did not proceed to the treatment phase until they had a stable baseline across all measures. Table 11 presents the baseline range and variability for the distress, avoidance and coping domains according to child self-reports (NIQ-C) and carer self-reports (NIQ-P). The cognition domain was excluded due to this item comprising verbal descriptions of thoughts rather than numerical data.

Overall, baseline stability was achieved for the majority of children and their carers, with the exception of two participants, Lyla and Flynn. Lyla, who was allocated to the behavioural condition, had an unstable baseline for the NIQ-C distress domain and SUD rating with a variability of 60% and 50%, respectively. Due to this, Lyla's baseline phase was extended by two weeks so that stability could be obtained for this domain. After three weeks, a consistent rating of 3.2-3.5 was attained for NIQ-C distress, and after four weeks a consistent rating of 5 was recorded for the SUD rating. Lyla proceeded to the treatment phase after completing five weeks of baseline measures.

The second child with an unstable baseline was Flynn, who was also allocated to the behavioural condition, and was one of the two participants to complete a probe assessment two months prior to starting the baseline phase. It was during this period that baseline ratings exceeded the recommended variability across NIQ-C distress (89% variability), avoidance (88% variability), and coping domains (64% variability). Likewise, carer ratings exceeded the recommended level also across NIQ-P distress (82% variability), avoidance (84% variability)

and coping domains (71% variability). The reason for such variability was due to over a 50% reduction in distress between completing the probe assessment (November 2012) and conducting the second initial assessment during baseline (January 2013). Due to this, and in consultation with the carer and my primary supervisor, it was decided that Flynn no longer required therapeutic intervention. To ensure that improvements were being maintained, the family were asked to attend a final assessment interview and complete another three measures at home. Taken across five weeks, results indicated a stable level of distress (NIQ-C range: 0-1.1; SUD range: 1-1), avoidance (NIQ-C range: 0-1), and coping (NIQ-C range: 7-7). Consequently, only baseline data for Flynn will be discussed in this chapter of the thesis, while possible explanations for the abrupt improvement during the assessment phase will be considered in the Discussion chapter.

In the remaining 10 cases (see Table 11), visual inspection of the baseline data suggested that it was stable enough to make a prediction that, without intervention, all participants would be likely to continue to experience NRD symptoms. An exception to this was Tamati, who despite reporting less than a 50% change during this phase, only completed two baseline measures. Research guidelines recommend that three data points should be collected to ensure baseline stability, and as will be illustrated, while the first two data points may be stable, subsequent scores can differ considerably. Tamati was also the first participant to complete the therapy programme and was incidentally a pilot for the study. Therefore, results from this participant should be interpreted cautiously as not only were there an inadequate number of measures completed, the measures were also changed halfway through the baseline phase as explained in the Method chapter.

Guidelines for Graphic Displays

The *lower* the distress and avoidance scores, the more adaptive behaviour the child is displaying, whereas the *higher* the coping scores, the more adaptive coping behaviour the child is displaying. All data illustrated in the tables and graphs represents the data returned in order of the dates recorded on the measures. Due to sessions being missed for practical reasons as discussed in the Method chapter, treatment phase points on the graphs represent *sessions* rather than *weeks*. Abbreviations on all time-series graphs refer to baseline number (B1), session number (T1) and one- and three-month follow-ups (1MO and 3MO).

Table 11

Baseline Range and Percentage of Change across the Primary Outcome Measures

	NIQ-C Child Distress	NIQ-C Child Avoid	NIQ-C Child Coping	Child SUD Rating	NIQ-P Child Distress	NIQ-P Carer Distress	NIQ-P Child Avoid	NIQ-P Carer Avoid	NIQ-P Child Coping	NIQ-P: Carer Coping
Tamati	5-5.5 (5%)	8.4-8.6 (2%)	3-4 (14%)	7-8 (10%)	9.6-9.7 (1%)	7-7.1 (1%)	9.4-9.6 (2%)	0.3-0.4 (1%)	4-4 (0%)	4-5 (14%)
Lisa	9.5-10 (5%)	9.5-10 (5%)	2-2 (0%)	8.5-9 (5%)	9.5-9.5 (0%)	4.3-7.6 (30%)	9.5-9.5 (0%)	0.3-0.5 (2%)	3-5 (29%)	5-6 (14%)
Sam	5-5.5 (5%)	8.4-8.6 (2%)	3-4 (14%)	7-8 (10%)	7.6-9.4 (16%)	1.5-2.2 (6%)	7.5-8.6 (10%)	1.8-2.9 (10%)	2-2.5 (7%)	5-6.5 (21%)
Alyssa	7.7-8.2 (5%)	5.5-9.3 (35%)	3-4 (14%)	6-7 (10%)	7.7-9.5 (16%)	5.9-6.8 (8%)	7-10 (27%)	0.1-0.5 (4%)	2-4 (29%)	3-5 (29%)
Hayley	9.6-10 (4%)	10-10 (0%)	1-1 (0%)	8.5-9 (5%)	8.4-10 (15%)	5.1-8.4 (30%)	8.5-9.8 (12%)	5.5-9.9 (40%)	2-4 (29%)	1-3 (29%)
Elena	9.5-9.8 (3%)	9.8-10 (2%)	1-2.5 (21%)	7.5-9.5 (20%)	9.5-10 (5%)	6.5-8.7 (20%)	10-10 (0%)	5.6-6.8 (11%)	1-2 (14%)	2-4 (29%)
Aroha	7.6-9 (13%)	10-10 (0%)	1-4 (43%)	7-8 (10%)	7-8.7 (15%)	5-7.6 (24%)	7.7-9 (12%)	4.7-7.6 (26%)	5-6 (14%)	4-5 (14%)
Jenna	6.7-8.5 (16%)	6.8-9.5 (25%)	3-4 (14%)	5-7.5 (25%)	8-8.8 (7%)	2.5-4.8 (21%)	8-10 (18%)	2.5-3.5 (9%)	2-2.5 (7%)	4-6 (29%)
Lyla	3.2-9.8 (60%)*	0-0.2 (2%)	4-7 (43%)	5-10 (50%)*	7.4-9.6 (20%)	0.4-3.4 (27%)	7.4-9.8 (22%)	0.3-1 (6%)	2.5-5 (36%)	6-7 (14%)
Wiremu	10-10 (0%)	10-10 (0%)	1-2 (14%)	8-10 (20%)	10-10 (0%)	10-10 (0%)	10-10 (0%)	1.5-3.6 (19%)	2-2 (0%)	1-2 (14%)
Flynn	0-9.8 (89%)*	0-9.7 (88%)*	2.5-7 (64%)*	1-5 (40%)	0.5-9.5 (82%)*	2.7-5.4 (25%)	0.1-9.3 (84%)*	0.3-1.4 (10%)	1-6 (71%)*	6-6 (0%)
Kala	8-9.5 (14%)	9-10 (9%)	2-3 (14%)	8.5-9 (5%)	8.3-9.5 (11%)	0-1.1 (10%)	6.2-9 (25%)	0-1 (9%)	3-5 (29%)	7-7 (0%)

Note. Percentages with an asterisk indicate an unstable baseline. Scores all ranged between 0-10 (total of 11 points), apart from the NIQ-C and NIQ-P coping domain which ranged from 1-7.

Child Reports

Modified Brinley Plots

The three figures below show the results for child reports across all three treatment conditions in relation to distress, avoidance and coping. Each figure compares different phases of the intervention, with Figure 2 comparing baseline to treatment, Figure 3 comparing baseline to follow-up, and Figure 4 comparing treatment to follow-up⁴. The rationale for assessing the differences across the various phases is due to each section of the intervention indicating largely different outcomes. Therefore all phases needed to be displayed in order to provide an accurate overview of the results.

A comparison of baseline to treatment data (see Figure 2) suggested that across the three conditions, CT was the most effective at reducing distress. CBT exceeded all other groups in terms of reducing avoidance, although all conditions were relatively effective at increasing coping. However, analysis of these results in comparison to follow-up data (see Figure 3) showed treatment gains for the CT condition were the least likely to be maintained. CBT was the most effective at maintaining treatment gains for distress and avoidance, while coping remained relatively stable at follow-up across all three treatment conditions.

Baseline to treatment scores revealed some promising results. It was only when treatment to follow-up phases were compared (see Figure 4) that results showed moderate to large relapses for several participants in terms of distress, avoidance, and coping. Figure 4 is also interpreted differently to the previous Brinley plots due to this figure measuring the amount of relapse following treatment. For this graph a successful therapy would show negligible change between these two phases since data points on or near the diagonal represent the maintenance of treatment gains. Therefore, points below the line indicate improvement from post-treatment and points above the line indicate deterioration relative to treatment gains.

A comparison of distress levels at treatment compared to follow-up indicated that the CT condition was again the most likely to indicate relapse (three of four participants). In comparison, the CBT and BT conditions were more likely to have mild relapses in distress (CBT = two participants; BT = one participant), with no more than a one to two point increase in distress on an 11 point scale. For other children in these two conditions, their treatment gains were maintained or improved further. When still comparing treatment to follow-up scores, scores for avoidance generally stayed the same across all three conditions, with the exception of one participant in the CT group who relapsed. Coping showed similar results across groups, with only small reductions evident for some participants and treatment gains maintained for others.

Overall, comparisons across baseline, treatment and follow-up showed that CBT was the most effective. CT was initially effective at post-treatment, however outcomes were the least likely to be maintained. BT showed large improvements, but for two of three participants only.

⁴ Modified Brinley plots relating to the BT group only show three data points due to one of the participants being excluded from the study as explained in the baseline stability section above.

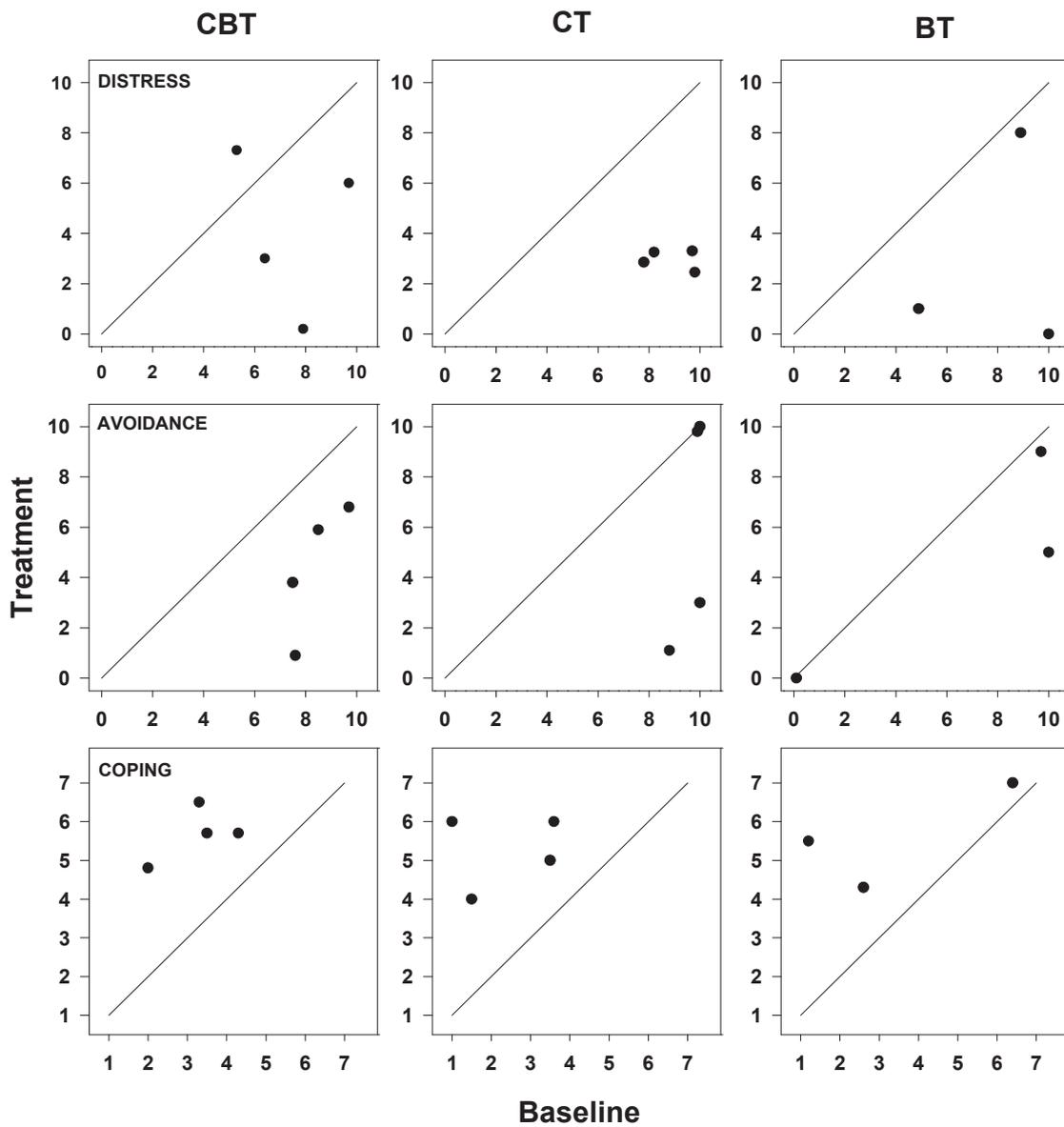


Figure 2. Modified Brinley Plots Showing Summarised Group Data for Child Self-Report of Distress, Avoidance and Coping across Baseline (X-axis) and Treatment Phases (Y-axis). (All domains indicate improvement if results decrease, aside from the coping results where interpretation is reversed.)

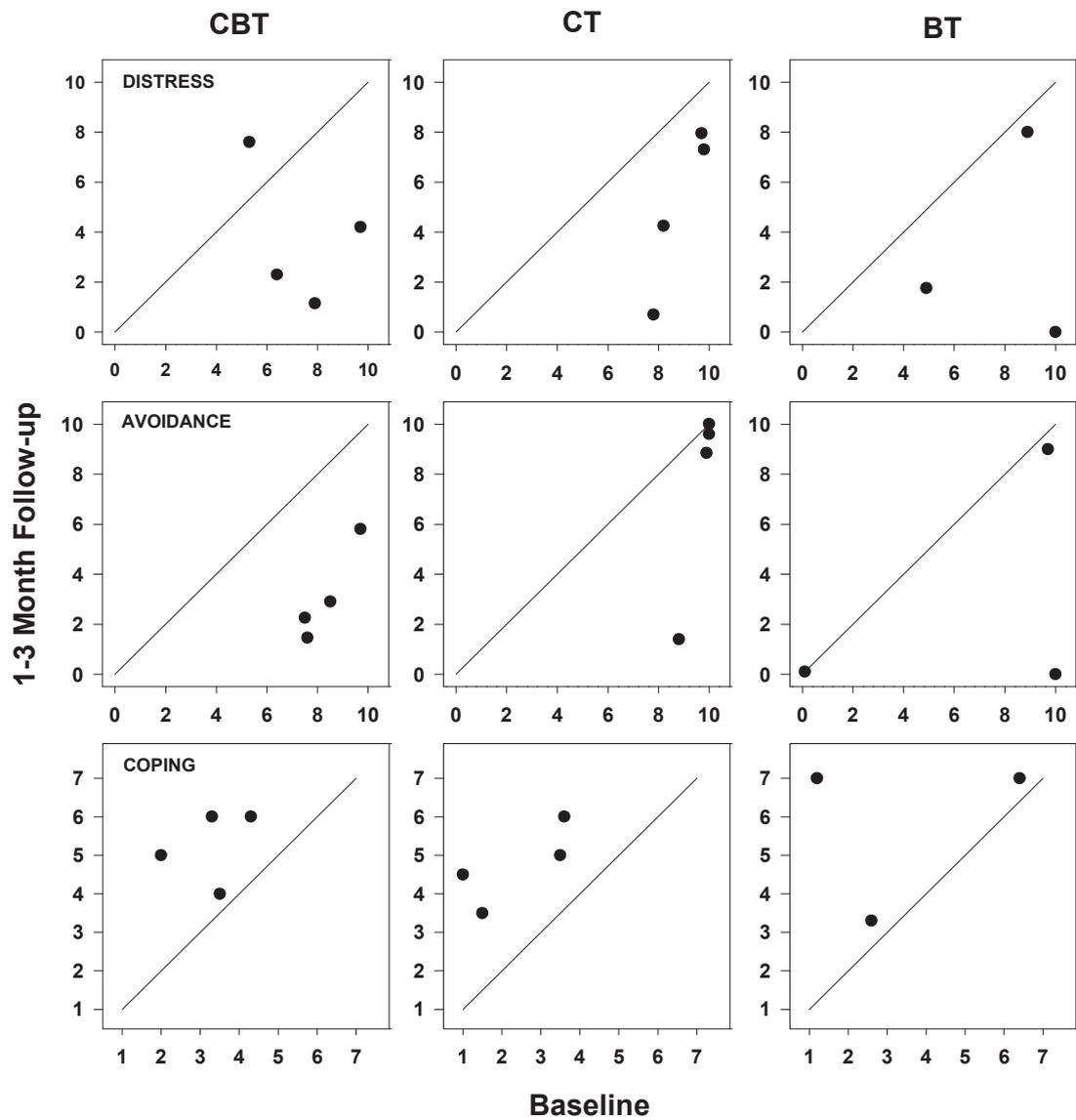


Figure 3. Modified Brinley Plots Showing Summarised Group Data for Child Self-Report of Distress, Avoidance and Coping across Baseline (X-axis) and Follow-Up Phases (Y-axis). (Direction of improvement indicated as for Figure 2.)

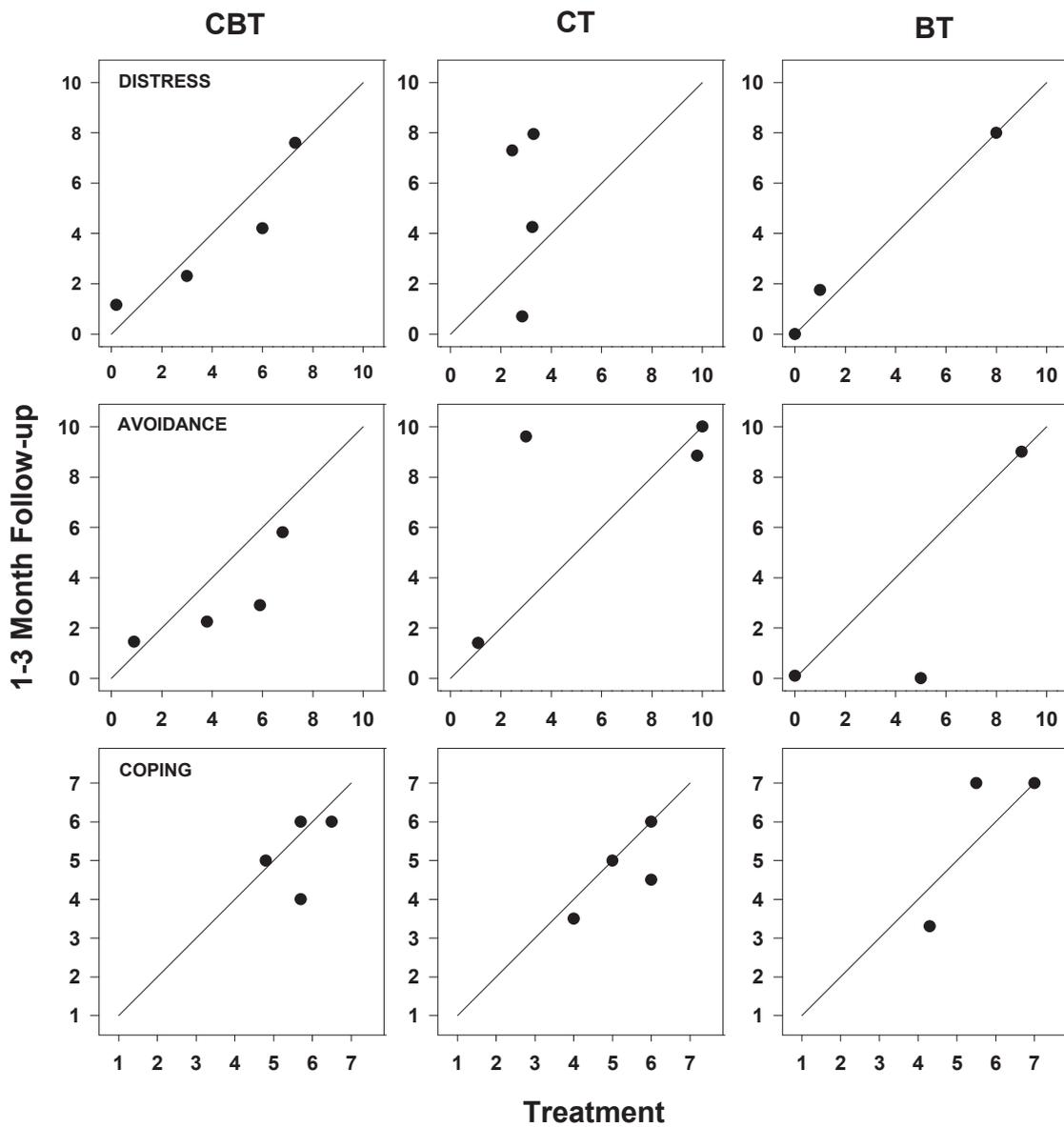


Figure 4⁵. Modified Brinley Plots Showing Summarised Group Data for Child Self-Report of Distress, Avoidance and Coping across Treatment (X-axis) and Follow-Up Phases (Y-axis). (Direction of improvement indicated as for Figure 2.)

⁵ As Figure 4 compares follow-up with treatment. Points on or near the diagonal represent maintenance of treatment gain, whereas points below the line indicate improvement from post-treatment and points above the line indicate deterioration.

Distress

Numerical Data (Time-Series)

Figure 5⁶ shows the results for all participants allocated to each treatment condition in relation to distress across baseline, treatment and follow-up phases. Both the NIQ-C and SUD rating measured distress and were used to increase the internal validity of the study. The NIQ-C ranged from *I do not get upset at all* (0) to *I get very upset* (10), whereas SUD ratings ranged from *I'm not distressed at all* (1) to *I'm the most distressed I have ever felt* (10).

From sessions one to three, distress remained consistently high for children allocated to the CBT condition. A reduction was reported in session four for all participants except Tamati. Improvements in distress were generally maintained in subsequent sessions, where the child received an injection followed by closure and relapse prevention. Follow-up data showed distress decreased even further for Sam and Lisa, and remained fairly stable for Alyssa. Follow-up distress levels for Tamati remained similar to baseline levels which were fairly high.

The CT condition differed from the other two groups in that participants completed an extra SUD rating prior to receiving a real injection in session four. This ensured that the effect exposure tasks had on cognitive outcomes could be closely monitored. These scores were not included in Figure 5 and instead are discussed separately below. Furthermore, Aroha was one of two participants to complete a probe assessment, which was carried out two months prior to starting the baseline phase. During this probe assessment, Aroha reported an NIQ-C distress and SUD rating of 8 and 7, respectively. This was consistent with her baseline scores.

Treatment and follow-up phases showed a consistent pattern across all four participants in the CT group. Similar to the CBT condition, sessions one and two produced very little reduction in distress, although these two conditions differed in session three when a large reduction occurred for the CT participants. Reductions ranged from 4.9 to 7, with an average decrease of 5 on an 11 point scale. As mentioned above, the CT condition participants also completed a SUD rating just prior to receiving their injection. Results showed that participants rated their anticipatory distress (before insertion) as much higher than their actual distress (after insertion). SUD ratings of 7 (Elena), 7 (Hayley), 8.5 (Jenna), and 5 (Aroha) were recorded prior to insertion, which later reduced to 4, 7, 4 and 5 respectively. However, these gains were not maintained at one- and three-month follow-up for three of four participants, and distress levels reverted back closely toward baseline levels.

Compared to the previous groups, distress for the BT group reduced more gradually across the treatment phase with no particular session producing the most change. The only exception to this pattern was Wiremu, who had a large reduction in distress in session three which was maintained in session four. Follow-up data showed treatment gains were maintained at one and three month follow-up for Lyla and Wiremu. Kala relapsed at one month, although improved slightly beyond baseline levels at three months.

⁶ Time series data relating to the BT group only show three data points due to one of the participants being excluded from the study as explained in the baseline stability section above.

Avoidance

Numerical Data (Time Series)

Figure 6 shows the results for all participants allocated to each treatment condition in relation to NIQ-C avoidance across baseline, treatment and follow-up phases. Scales ranged from *I do not want to avoid it at all* (0) to *I definitely want to avoid it* (10).

Data suggested that avoidance reduced during the treatment phase for the CBT group. Similar to distress, the point of change mostly occurred towards the middle or end of therapy in session three (Tamati and Sam) or session four (Alyssa and Lisa). However, the pattern of responding for distress and avoidance differed from this point on. For example, in cases where avoidance reduced in session three, levels initially increased in subsequent sessions and then reduced again beyond previous reports. On the other hand, if change occurred later in the therapy (session four), instead of avoidance initially increasing it continued to gradually reduce throughout the intervention. Follow-up results showed that avoidance increased by one to two points for some participants and then stabilised, while for others it reduced even further compared to post-treatment gains.

In relation to the CT group, treatment phase results showed divergent patterns across participants. Two of the four children displayed very little change in avoidance during therapy compared to baseline, and continued to report high levels at one and three month follow-up (Aroha and Elena). The remaining two participants had largely different outcomes, with the first (Hayley) showing a considerable reduction in avoidance from session one onwards, although this relapsed back toward baseline levels at follow-up. The second participant (Jenna) also showed a considerable reduction in avoidance from session one, although this differed to Hayley's outcomes as gains were maintained at the follow-up period. Overall, CT appeared to be effective at initially reducing avoidance, but these gains were typically not maintained.

Even though a stable baseline was indicated for all three participants in the BT group, Lyla's avoidance scores were so low (0 - 0.2 out of 11) during this phase that there was little room for improvement (see Figure 6). Avoidance levels for the other two participants were both high, suggesting that without intervention they would be likely to continue experiencing avoidance of injections. Wiremu showed the most change out of the three participants, which primarily occurred in session three. These gains were then maintained in session four and at follow-up. Similar to Wiremu, Kala also reported the most positive change in session three, although these outcomes were not maintained. Based on these divergent results, it is unclear if the BT condition was effective at reducing avoidance.

Written Data (Open-Ended Question)

Throughout the intervention, children were asked an open-ended question to determine the content of their behavioural avoidance. This was continually re-administered to assess whether avoidance content changed over the course of therapy. The question was “What are the kinds of things that you think and/or do to try and avoid having a needle injection?” The child was then asked to write their answer in the blank space provided.

The most common avoidance strategy that children utilised included verbal protests. For example, saying out loud (usually to their mum) “I don’t want to do it” and “Can we not do it this one week”. Alternatively, they would cry, scream or yell at their carer and the nurse (Elena, Tamati, Hayley, Jenna, Lisa and Kala). Using physical force to postpone or stop the injection from happening was the second most common strategy. This usually included behaviours whereby children pulled away or crossed their arms in order to restrict access to the insertion site (Elena, Sam, Wiremu, Hayley, Tamati, Jenna and Lyla). Extreme physical behaviours included struggling, kicking, punching and swearing (Kala, Wiremu and Aroha). Lastly, some children used more creative strategies such as trying to distract the nurse by talking off subject so that they would ‘forget’ about the injection (Jenna).

As therapy progressed, avoidance behaviours changed in several ways including (1) the behaviour discontinued (e.g., “Didn’t do anything” during session five, Alyssa) (2) the frequency of behaviour changed (e.g., “scream” went from 80% during baseline to 25% during treatment, Wiremu), and/or (3) the content of behaviour changed (e.g., “No I don’t want to do this” during baseline to “Be calm” during session three, Jenna).

Sessions that appeared to initiate the most change for some children involved the in-vivo injection, resulting in avoidance behaviours being discontinued (Wiremu, Alyssa, Sam and Jenna). In subsequent sessions and at follow-up, these children tended to exhibit adaptive coping behaviours which were replicated in the numerical data. Change in the content and frequency of behaviours was more subtle. For example, Lisa simply wrote “cry” during baseline, which changed to “sometimes cry” during follow-up. Data also indicated the frequency of this behaviour reduced by 50% during the treatment phase. Elena exhibited a similar pattern whereby she would initially cry without hesitation, but during follow-up wrote “maybe cry”. The content for other children changed more dramatically from “punching and kicking” to “trying to postpone it” (Aroha). A change from avoidance to coping behaviours was also a common occurrence. For example, at post-treatment Sam changed from jerking his hand away and becoming tense to asking questions and breathing calmly. Wiremu also expressed that he now “Talks with mum about it a lot and it helps, especially about the different types of injections I might have in the future”. In comparison, Alyssa changed her avoidance statement during therapy from “I don’t want it” to “I don’t want it, but the next one I do”, and then proceeded to list only coping behaviours during the final therapy sessions and follow-up phases including distraction, rewards and using her emotive imagery poster.

Despite many children displaying improvements in behavioural avoidance, this was not the case for other children who continued to exhibit these behaviours at post-treatment and

follow-up. For instance, Kala expressed fairly extreme behaviours during the baseline and treatment phases (e.g., crying, screaming and swearing). There was some improvement at post-treatment such as “Didn’t really say or do anything leading up to the injections”, however this later changed to “Shaking, covering my arm and running away” at follow up. These results were replicated in her numerical data on the NIQ-C with an avoidance score of 8 out of 11. Similarly, Aroha continued to make excuses or postpone the injection, which was also replicated in her numerical data with an avoidance score of 10 out of 11 at follow-up.

In summary, children who no longer reported avoidance behaviours displayed more effective treatment outcomes across various domains, in comparison to children that reported more subtle changes in the content/frequency of behaviour.

Coping

Numerical Data (Time Series)

Figure 7 shows the results for all participants allocated to each treatment condition in relation to the NIQ-C coping domain across baseline, treatment and follow-up phases. Scales ranged from *I was not able to help myself feel comfortable at all (1)* to *I was completely able to help myself feel comfortable (7)*.

Coping gradually improved throughout therapy for the CBT group. These outcomes are in contrast to distress and avoidance, which showed that changes mostly occurred in particular sessions. At follow-up coping behaviours were maintained or showed slight reductions, but not beyond baseline levels.

CT treatment phase results showed that, similarly to the CBT condition, once the intervention was introduced, coping improved gradually rather than rapid changes occurring during particular sessions. Treatment gains slightly relapsed at the one-month follow-up for the majority of participants, while the three-month follow-up resulted in an increase in coping either above (Jenna), equal to (Elena) or just less than post-treatment levels (Hayley). Aroha’s coping relapsed close to baseline levels, although it should be noted that she reported a probe score of 1 out of 7 in November 2012, which improved to an average of 3.5 out of 7 during the baseline phase from January to February 2013.

Baseline scores for the BT condition showed that Lyla reported high levels of coping and required very little improvement. However, for Wiremu and Kala coping levels were low at baseline, although they gradually improved during treatment much the same as the CBT and CT groups described earlier. These treatment gains were maintained for Wiremu, but slightly reduced for Kala at follow-up.

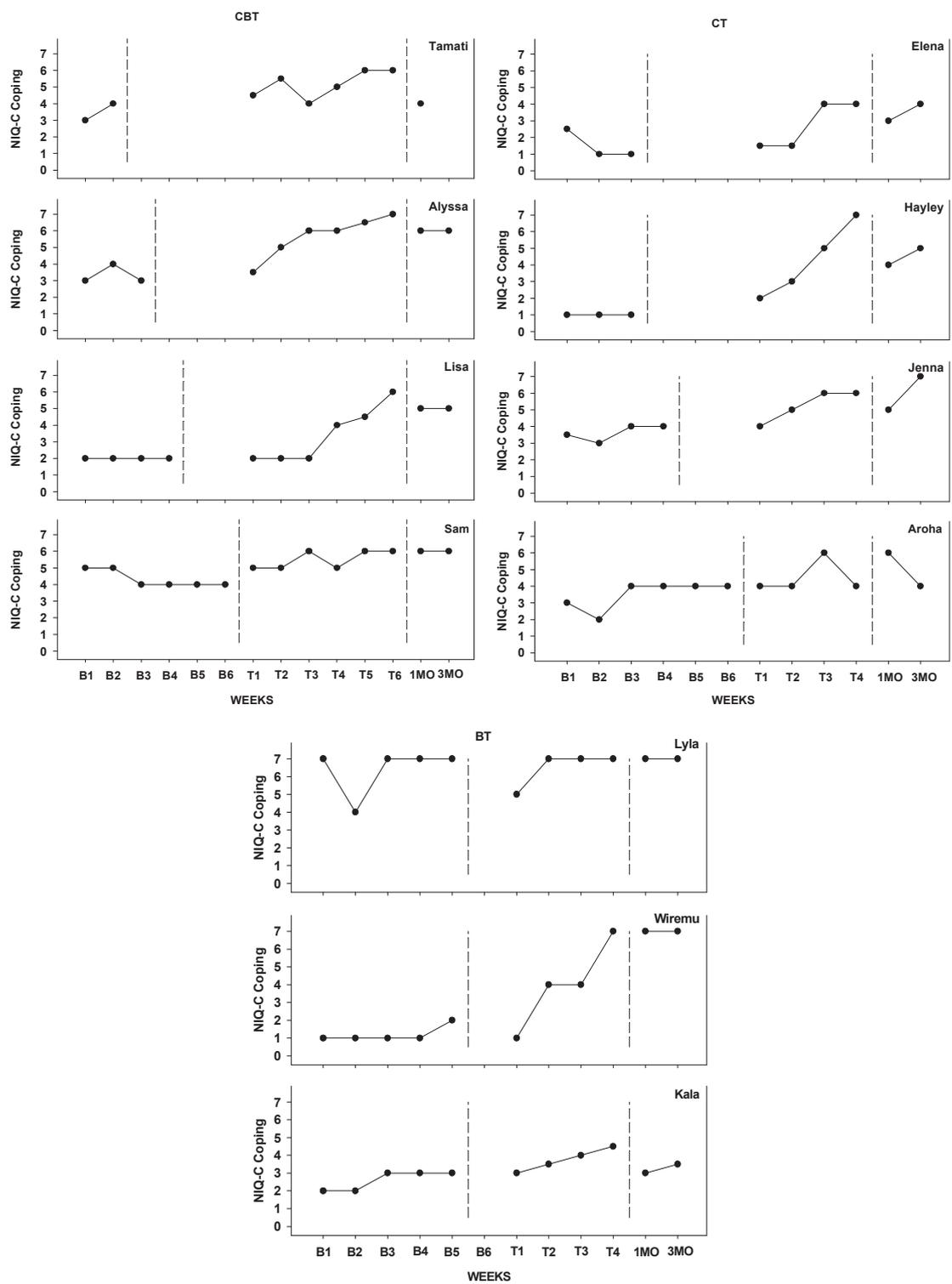


Figure 7. Time-Series Individual Data for Child Self-Report of Coping for All Treatment Conditions across All Intervention Phases. (Direction of improvement indicated as for Figure 2.)

Written Data (Open-Ended Question)

Throughout the intervention, children were asked an open-ended question to determine the content of their coping behaviours, and assess whether these changed over the course of therapy. The question was “When you are having a needle injection, what do you think and/or do in this situation to help yourself feel comfortable?” The child was then asked to write either a behaviour or thought in the blank space provided. The majority of coping strategies that were listed during the baseline phase consisted of receiving support from their carer (e.g., squeeze/hold mum’s hand), distraction (e.g., watch a movie or chew on something), avoidance (e.g., look away, don’t think about it, and pull my arm away), and crying or screaming. Some children also used quite imaginative distraction techniques such as “Count the hairs on Dad’s hand” (Lyla).

New coping strategies that participants listed during therapy were either behavioural (e.g., breathing, muscle relaxation, distraction and giving themselves control over the situation) or cognitive (e.g., helpful thoughts, emotive imagery and information provision). Some children also used the idea of impressing their sibling as motivation to do well. For example, “My sister will go mental with congratulating me afterwards” (Lyla – BT condition session four), while other children thought about it more abstractly and summarised that “I’m going to have it the hard way or the easy way, so I might as well get it done” (Aroha – CT condition, one-month follow-up).

In some cases, children also transferred from an avoidant coping style to an approach coping style mid-way through the therapy. For example, during the baseline period, Elena preferred to “Stare at the ground” during the procedure, whereas at post-treatment she wanted to be “Given information about the procedure, such as who, when, where, what and how it is going to happen”. Instead of looking away or counting in their head, some children also chose to watch the procedure while making comments on the process. Calm breathing, muscle relaxation, talking and asking questions were also common coping strategies. This more adaptive coping style was evident among a number of other children including Wiremu, Lyla, Sam, Jenna and Alyssa, and appeared to result in the most improvements in coping. Numerical data displayed provides further evidence for these conclusions. On the other hand, some children continued to prefer an avoidant coping style regardless of therapy, including Kala who expressed throughout all three phases of the intervention that not looking or thinking about the injection was more helpful. However, numerical data suggested that the continuation of an avoidant coping style resulted in minimal improvements across all domains.

Cognition

NIQ-C Numerical and Written Data

Child cognitions were assessed using two types of measures throughout the intervention including the NIQ-C and ATSS, both of which had numerical and written formats. Results for these measures in relation to the three treatment conditions will be discussed below.

Tables 12, 13 and 14 summarise the results for all participants in each treatment condition according to the NIQ-C cognition domain across baseline, treatment and follow-up phases. The response format for this domain differed to others as it incorporated both numerical

and written answers. Initially the child reported their thought content in relation to two open-ended questions (see Appendix 7, NIQ-C items 3.1 and 3.2), and then rated the intensity of thoughts using a VAS from *I do not believe it at all* (0) to *I definitely believe it* (10). For display purposes, both baseline and follow-up intensity ratings were averaged, while treatment ratings were not. The rationale for not averaging the intensity of treatment phase results was that the same cognition was sometimes recorded at the start and end of therapy with different ratings. Therefore, averaging treatment scores would not provide an accurate indication of the change in cognition intensity at the end of therapy. Instead, intensity ratings of the last time the cognition was recorded were utilised. All questions, response formats and scoring procedures were consistent across treatment conditions.

Table 12 shows the cognition content and intensity for the CBT condition, which indicated that unhelpful thoughts usually related to pain (e.g., “This is going to hurt” – Tamati), avoidance (e.g., “I don’t want to” – Lisa), that something will go wrong (e.g., “They might miss the vein/stuff up” – Sam) and/or incompetence of the health professional (e.g., “She’s not qualified or not good enough” – Lisa).

During the baseline phase, the intensity of unhelpful cognitions typically remained high (above 5 out of 11), with cognitions relating to pain showing the highest intensity scores (ranged from 3.4 to 9.7 out of 11). All other unhelpful cognitions improved with either small or large reductions in intensity. With regards to cognition content, examples include change from “Stupid little pointy needle” (8.6) to “Good little pointy needle” (10). Another child also changed his cognition content from “Might stuff up” (2.9) to “Unlikely to stuff up” (9.3), and reduced the intensity he thought the injection would hurt from 3.4 to 0.2. On the other hand, children also came to therapy with helpful thoughts such as “It will be fine” (Lisa) and “He/she is a pro doctor” (Tamati). The reverse occurred for helpful cognitions whereby the intensity increased, however compared to unhelpful thoughts these were very minor changes. Follow-up data suggested that treatment gains were maintained or improved further.

Table 13 shows that similar to the CBT condition, all children in the CT condition had unhelpful thoughts related to pain. This was the only similarity between the two groups apart from selected thoughts related to something going wrong (“What if it doesn’t work” – Jenna) and avoidance (“Don’t touch me” – Aroha). Instead, children in this condition had cognitions related to hopelessness (“Why me...?” – Hayley, and “Lots of people have injections every day, why can’t I?” – Elena), and feeling negative towards the health professional (“I wish you weren’t here” – Elena, “Will they make fun of me?” – Jenna and “I hate them” – Aroha). Other cognitions were also evident that related to their body becoming harmed (“Will I get a lump” – Jenna) and the visual appearance of the needle (“It’s really sharp” – Aroha). Not only were the cognitions in this group more unhelpful than those in the CBT condition, but their intensity ratings were also consistently higher (average rating of 9.2 out of 11 across all participants).

Treatment phase data suggested that for the majority of children there were more changes in cognition content than cognition intensity. New cognitions related to receiving a reward such as “Do it and you will get a therapy reward” (Hayley) and “I’m going for a swim

afterwards” (Aroha). Others reassured themselves “It will be okay” (Lyla) and resigned themselves to that fact that “they are going to give it to me anyway, so just get it over with” (Aroha). Some children also replaced unhelpful thoughts with more balanced thoughts from “Ouch, this is going to hurt” to “It hurts, but not as long, and as much as I think” (Hayley). For Elena, cognition intensity related to pain decreased by 50% (8.5 to 3 out of 11), and the belief that she could *not* do it reduced by 30% (8.8 to 5.5 out of 11). She also reported minor changes in cognition content from wishing that she could do it, to stating that she *can* do it. For other children, changes in cognition content were more obvious (see Table 13).

Follow-up results indicated that some of the improvements children showed during treatment either relapsed, maintained or improved further. In relation to children who maintained gains or improved further, cognitions that appeared to be resilient were receiving a reward and the continued belief that the injection would not hurt forever.

Table 14 shows the cognition content and intensity for all children allocated to the BT condition. Consistent with the CBT and CT groups, thoughts related to pain were the most prevalent with a high intensity for the baseline phase of the BT group. Thoughts related to avoidance were also prevalent, alongside catastrophic ideas about the consequences (“I’m going die” and “All my blood is gone” – Lyla). Cognitions about the visual appearance of the needle were also evident such as “the needle is big, really long and sharp” (Wiremu), although these types of cognitions were mainly present among younger children below 8 years.

Compared to the CBT and CT conditions, cognition content and intensity for the BT group was relatively unchanged. Cognitions that exhibited some variation related to pain which reduced in intensity by just less than 50% for Wiremu and Lyla. All other thoughts remained relatively similar to baseline levels, other than Lyla who developed a new helpful cognition (“It will be okay”). Follow-up results showed a similar pattern, whereby cognition content and intensity remained the same as the baseline, although improvements were evident for Lyla and Wiremu in relation to pain content (e.g., “It might hurt a little”).

Table 12

Child Cognition Content and Intensity for the CBT Condition across Baseline, Treatment and Follow-Up Phases

Baseline	I	Treatment	I	Follow-up	I
Tamati (9.5 years)					
Ahhhhhh!	8.6	Oohnooo	0.2	-	
This is going to hurt	5	This is going to hurt	3.7	It might hurt	5
He/she is a pro doctor	8.1	He/she is a pro doctor	6.9	-	
Alyssa (12 years)					
Stupid little pointy needle	8.6	Good pointy needle	10	Good point	10
It hurts	9.7	It hurts	3	I know it does not hurt	10
Liar (nurse/doctor)	10	Liar (nurse/doctor)	5.2	Good and dumb doctors	10
Get on with it	9.3	I can do it	10	Thinking about medicine life line	10
Lisa (13 years)					
It will hurt	9.5	It will hurt	7.2	-	
It won't work	8.3	It won't work	6.1	It won't work	5.8
I don't want to	10	I don't want to	6.8	I don't want to	5.6
It will be fine	4.2	It will be fine	6.7	It will be fine	7.2
She'll mess up/not qualified	8.3	She'll mess up/not qualified	5.2	She'll mess up/not qualified	5.5
She'll do a good job	5.1	She'll do a good job	6.5	She'll do a good job	6.3
Sam (13 years)					
It will hurt	3.4	It's unlikely to hurt a lot	9.5	I will hurt	0.2
Miss the vein/stuff up	2.9	Unlikely to stuff up	9.3	Might stuff up	0.9
She's kind/caring	8.5	She's kind and calms me	9.1	The person is kind and explains everything	9.8

Note. I = intensity score ranging from *I do not believe it at all* (0) to *I definitely believe it* (10).

Table 13

Child Cognition Content and Intensity for the CT Condition across Baseline, Treatment and Follow-Up Phases

Baseline	I	Treatment	I	Follow-Up	I
Elena (10 years)					
I wish I could do this	10	I can do it	7.8		
I wish I wasn't here	9.4	It won't hurt forever	9.6	It won't hurt forever	9.5
It will really hurt	8.5	It will really hurt	3	It will hurt really bad	2.5
I don't think I can do it	8.8	I don't think I can do it	5.5	-	
I wish you weren't here (dentist)	8.2	I wish you weren't here (dentist)	5	-	
Lots of people have injections every day, why can't I?	10	Happy that she (dentist) was nice	10	She was really nice (dentist)	10
Hayley (10 years)					
Ouch, this is going to hurt	10	It hurts, but not as long and as much as I think	10	It's going to hurt	9.8
Get it done	10	Get it done	10	Get it done	10
Nothing. Zone out	9.8	Nothing. Zone out	10	-	
Why me...?	9.9	Why me...?	9.6	-	
This isn't that bad	9.1	It won't be too bad. The first went well	9.3	I really don't want to do it	9.2
-		I get a therapy reward	10	I get a chocolate bar	10
Jenna (12 years)					
Will it hurt	8.3	Will it hurt	5.8	It won't hurt that much	9.2
Will I get a lump	9.4	Will I get a lump	9.6	Only hurts for 3 sec	8.5
Will it bleed	9.3	It will be okay	9.8	-	
What if it doesn't work	8.6	-			
Will they make fun of me (think I'm a "wiss"/"wimp")	9.6	I'm calm when the nurse is nice	9.7		
Aroha (10 years)					
Don't hurt me	9.2	I don't want it to hurt	10	I want that surprise	8.2
I hate them	8.7	I don't like them for this	10	I want to do it first	10
Don't touch me/go away	10	They are going to give it to me anyway	10	Don't you dare rush me, I'll take longer	10
The needle is really sharp	9.1	I'm going for a swim afterwards	5	The quicker I do it the faster I can go home	10
Run away/punch them	6.7	Playing on ginger island	5	You're doing your job	10
Scared, angry and sad	9.2				

Note. I = intensity score ranging from *I do not believe it at all* (0) to *I definitely believe it* (10).

Table 14

Child Cognition Content and Intensity for the BT Condition only across Baseline, Treatment and Follow-Up Phases

Baseline	I	Treatment	I	Follow-Up	I
Lyla (7.5 years)					
I'm going to die	0.6	I'm going to die	0	-	
All my blood is gone	0.2	All my blood is gone	0	-	
It's going to hurt	10	It's going to hurt	6	It might hurt a little	1.6
Aaaaahhhh (scared)	10	Aaaaahhhh (scared)	10	Oh no	5.3
Nice, kind, gentle (nurse)	10	Nice, kind, gentle (nurse)	10	Nice, kind, generous	10
		It will be okay	10	I'm okay	10
Wiremu (7 years)					
I don't want to do this	10	I don't want to do this	10	-	
It will hurt	10	It will hurt	5.8	-	
The needle is big, really long and sharp	10	It's not going to hurt	10	It's going to hurt, but it doesn't	10
Kala (13 years)					
It's going to hurt	9.7	It's going to hurt	10	It's going to hurt	9
I don't want it	10	I don't want it	7	I don't want it	10
They enjoy giving me pain	4.8	They enjoy giving me pain	4	They enjoy giving me pain	3
They are horrible/mean	4.7	They are horrible/mean	5	They are mean	6

Note. I = intensity score ranging from *I do not believe it at all* (0) to *I definitely believe it* (10).

Articulated Thoughts in Simulated Situations (ATSS)

Tables 15, 16 and 17 show the frequency of various thoughts in response to an injection-provoking scenario across all three groups. Six categories were used to classify thoughts and emotions in order to determine whether there were changes in frequency. The six categories were positive feeling, positive anticipation, negative feeling, negative anticipation, resignation and problem solving (Davison et al., 1983). Improvements were indicated when scores for the negative categories (negative anticipation, negative feeling and resignation) decreased in frequency and the positive categories (positive anticipation, positive feeling and problem solving) increased in frequency. A seventh category known as "Other" was also included, however this was not scored as it was for thoughts and/or emotions that could not be assigned to an existing category.

The injection-provoking scenario was administered across the three intervention phases including baseline, treatment and follow-up, and abbreviations in the tables relate to these phases (B, T, and F). In terms of administration, ATSS was completed once during the baseline

phase for all groups, twice for the CBT group during treatment (sessions four and six) and once for the CT and BT groups during treatment (session four). All treatment conditions completed it twice at follow-up (one and three months). Due to multiple administrations within one phase, scores in this instance were averaged to obtain an absolute frequency.

ATSS frequencies (see Table 16) showed that CT was the most effective at increasing positive statements and reducing negative statements. These changes tended to occur in the treatment phase and slightly relapsed during the follow-up phase, but not beyond baseline levels. Table 15 and 17 shows that in relation to ATSS frequencies, CBT was the second most effective treatment, followed by the BT group. Further analysis showed that more changes were seen in relation to negative statements compared to positive statements regardless of the treatment group. For instance, large reductions in negative feelings and anticipations were recorded, but only minor increases in positive feelings and anticipations were recorded. Across conditions, problem-solving and resignation were the least reported thoughts.

Table 15

Frequency of Articulated Thoughts in Response to an Injection-Provoking Scenario for the CBT Condition across Baseline, Treatment and Follow-Up

Participant	Phase	PF	PA	PS	NF	NA	R	Positives	Negatives
Tamati	B	1		4	7	4			
Alyssa		1		2	6	1	1		
Lisa		1	1		3	5			
Sam		2	1		4	4			
Average		1.3	1.0	3.0	5.0	3.5	1.0	1.8	3.2
Tamati	T	3	3		3	3			
Alyssa		2	2	3	3	2			
Lisa		1.5	1		4.5	1.5			
Sam		2.5	1.5		4.5	1.5			
Average		2.3	1.9	3.0	3.8	2.0		2.4	1.9
Tamati	F	2			2				
Alyssa		1.5			2.5	2			
Lisa		2	3		3.5	1			
Sam		2.5	2		2.5	1.5			
Average		2.0	2.5		2.6	1.5		1.5	1.4

Note. B = baseline, T = treatment, F = follow-up, NA = negative anticipation, NF = negative feeling, PA = positive anticipation, PS = problem solving, PF = positive feeling and R = resignation.

Table 16

Frequency of Articulated Thoughts in Response to an Injection-Provoking Scenario or the CT Condition across Baseline, Treatment and Follow-Up

Participant	Phase	PF	PA	PS	NF	NA	R	Positives	Negatives
Elena	B	1	2		2	3	6		
Hayley			2	2	7	5			
Jenna					1	10	10		
Aroha				2		3.5	3		
Average		1.0	2.0	1.5	5.6	5.3	6.0	1.5	5.6
Elena	T	3	3	1	2	3			
Hayley		4	2	2	1	2			
Jenna		4	4		1				
Aroha		1	2		4	2			
Average		3.0	2.8	1.5	2.0	2.3		2.4	1.4
Elena	F	2	2	1	2.5	3	2		
Hayley		1		3	3.5	1			
Jenna		3.5	3.5	3	3		1		
Aroha		1			5.5	2.5			
Average		1.9	2.8	2.3	3.6	2.2	1.5	2.3	2.4

Note. B = baseline, T = treatment, F = follow-up, NA = negative anticipation, NF = negative feeling, PA = positive anticipation, PS = problem solving, PF = positive feeling and R = resignation.

Table 17

Frequency of Articulated Thoughts in Response to an Injection-Provoking Scenario for the BT Condition across Baseline, Treatment and Follow-Up

Participant	Phase	PF	PA	PS	NF	NA	R	Positives	Negatives
Lyla	B	2	1		2	1			
Wiremu			1		2	4			
Kala					1	11	10		
Average		2.0	1.0	1.0	5.0	5.0		1.3	3.3
Lyla	T	4	4			3			
Wiremu		2	4						
Kala		2			4	3			
Average		2.7	4.0		4.0	3.0		2.2	2.3
Lyla	F	1.5	1.5		4	4			
Wiremu		3	3	1	3				
Kala		1		2	4	6.5	2		
Average		1.8	2.3	1.5	3.7	5.3	2.0	1.9	3.6

Note. B = baseline, T = treatment, F = follow-up, NA = negative anticipation, NF = negative feeling, PA = positive anticipation, PS = problem solving, PF = positive feeling and R = resignation.

Summary of Child Reports

CBT displayed the most stable improvements in distress and avoidance over time, closely followed by BT and then CT. More specifically, improvements in distress for the CT condition were the least likely to be maintained at follow-up and often relapsed close to baseline levels, whereas the BT condition showed a large amount of treatment outcome variation across participants. For instance, some children showed large improvements which were maintained across all three domains, while for other children minimal improvements were evident. Coping consistently increased across all three treatment conditions with no particular treatment being better than another. Cognition frequency showed slightly different results in that the CT group was the most effective, closely followed by the CBT group. BT showed little change in cognition frequency of adaptive and maladaptive thoughts.

Carer Reports

Modified Brinley Plots

The three figures below show the results for carer self-report across all three treatment conditions in relation to distress, avoidance and coping. Each figure compares a different phase of the intervention in relation to another, with Figure 8 comparing baseline to treatment, Figure 9 comparing baseline to follow-up, and Figure 10 comparing treatment to follow-up⁷. All aspects of the modified Brinley plots are consistent with that described in the child section above.

When comparing baseline to treatment data (Figure 8), results suggested that the majority of carers reported moderate to large improvements in their own and their child's distress, with CBT showing the most improvement. The CT and BT conditions were less effective and showed that two carers in each group reported similar or worse distress levels compared to baseline. This differed to carer avoidance which was low from the outset and required little improvement. On the other hand, child avoidance was rated as high but carers indicated little reduction during treatment with the exception of a few children in each group. Carer coping improved by relatively the same degree across all treatment conditions, although these changes were minor compared to the child self-reports. There were also some outliers in each group suggesting coping did not improve at all compared to baseline for these participants.

When comparing baseline to follow-up (Figure 9), distress levels for most of the children and carers allocated to the CT condition remained relatively high, as was the case for a number of children in the CBT group. Avoidance scores showed a similar pattern where the CT condition continued to have higher levels than the other two groups. On the other hand,

⁷ Modified Brinley plots relating to the BT group only show six data points due to one of the participants being excluded from the study as explained in the baseline stability section on pages 78-79.

although coping showed that some participants improved more than others, there were no large differences between the groups.

Unlike the child results, a comparison of treatment and follow-up scores (Figure 10) showed very promising results. Carers reported that treatment gains were maintained across the three domains regardless of the treatment condition. In some cases, follow-up assessments also resulted in further improvements, particularly for CT participants' distress scores. More general analysis showed that, in contrast to the children, carers tended to show larger improvements during the one- and three-month follow-up phases.

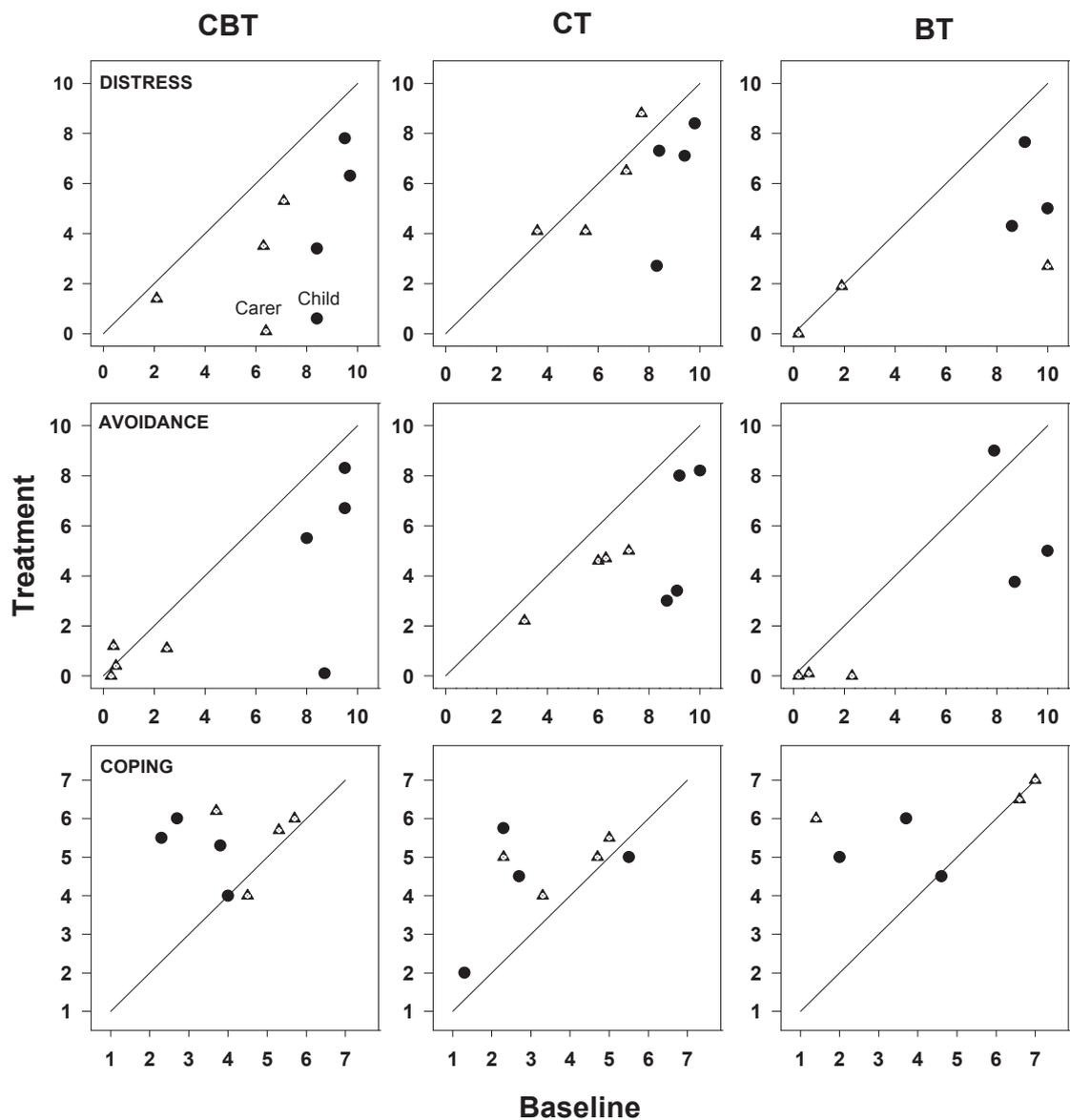


Figure 8. Modified Brinley Plots Showing Summarised Group Data for Carer Self-Report of Themselves and Their Child's Distress, Avoidance and Coping across Baseline (X-axis) and Treatment Phases (Y-axis). (Direction of improvement indicated as for Figure 2.)

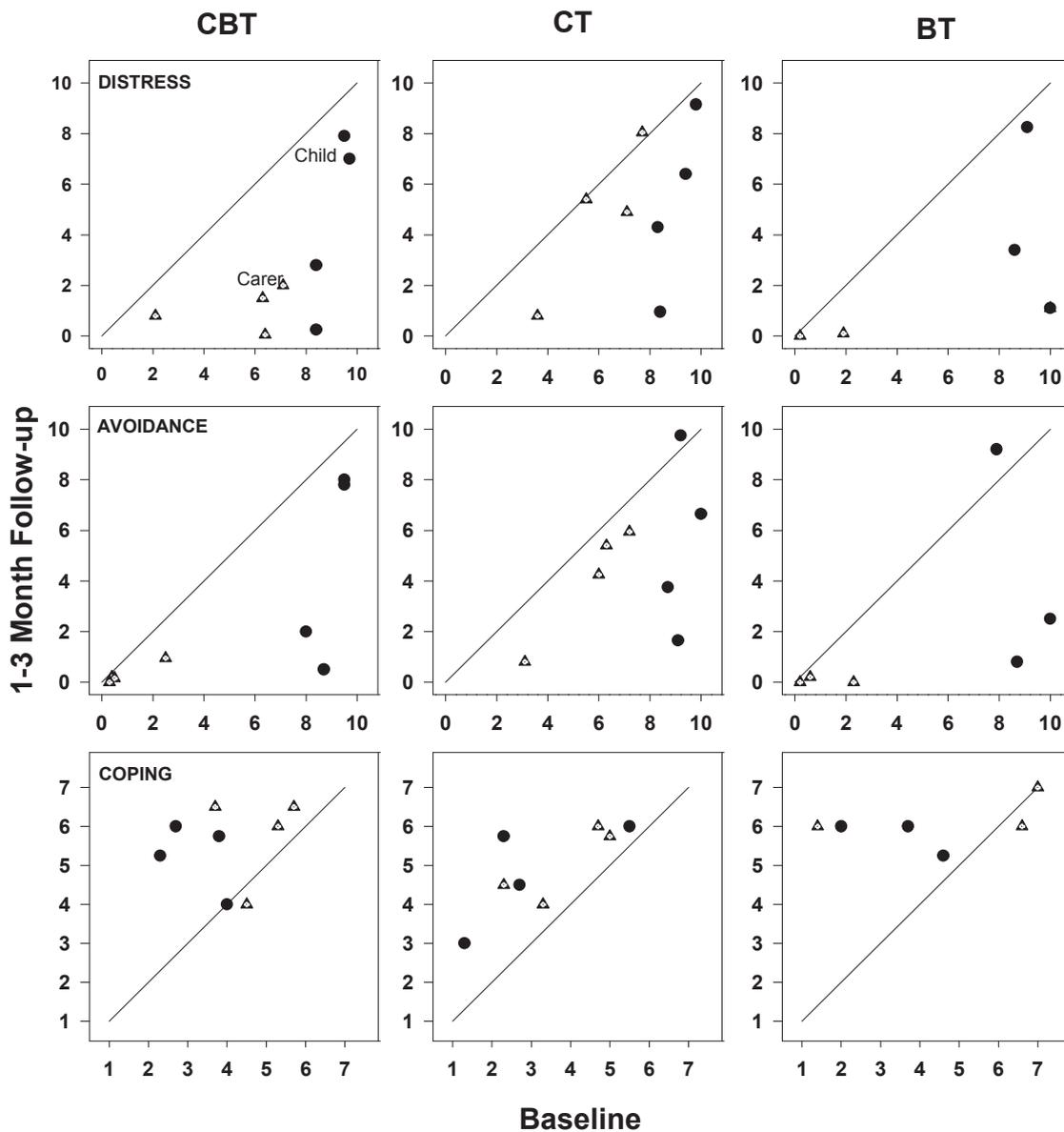


Figure 9. Modified Brinley Plots Showing Summarised Group Data for Carer Self-Report of Themselves and Their Child’s Distress, Avoidance and Coping across Baseline (X-axis) and Follow-Up Phases (Y-axis). (Direction of improvement indicated as for Figure 2.)

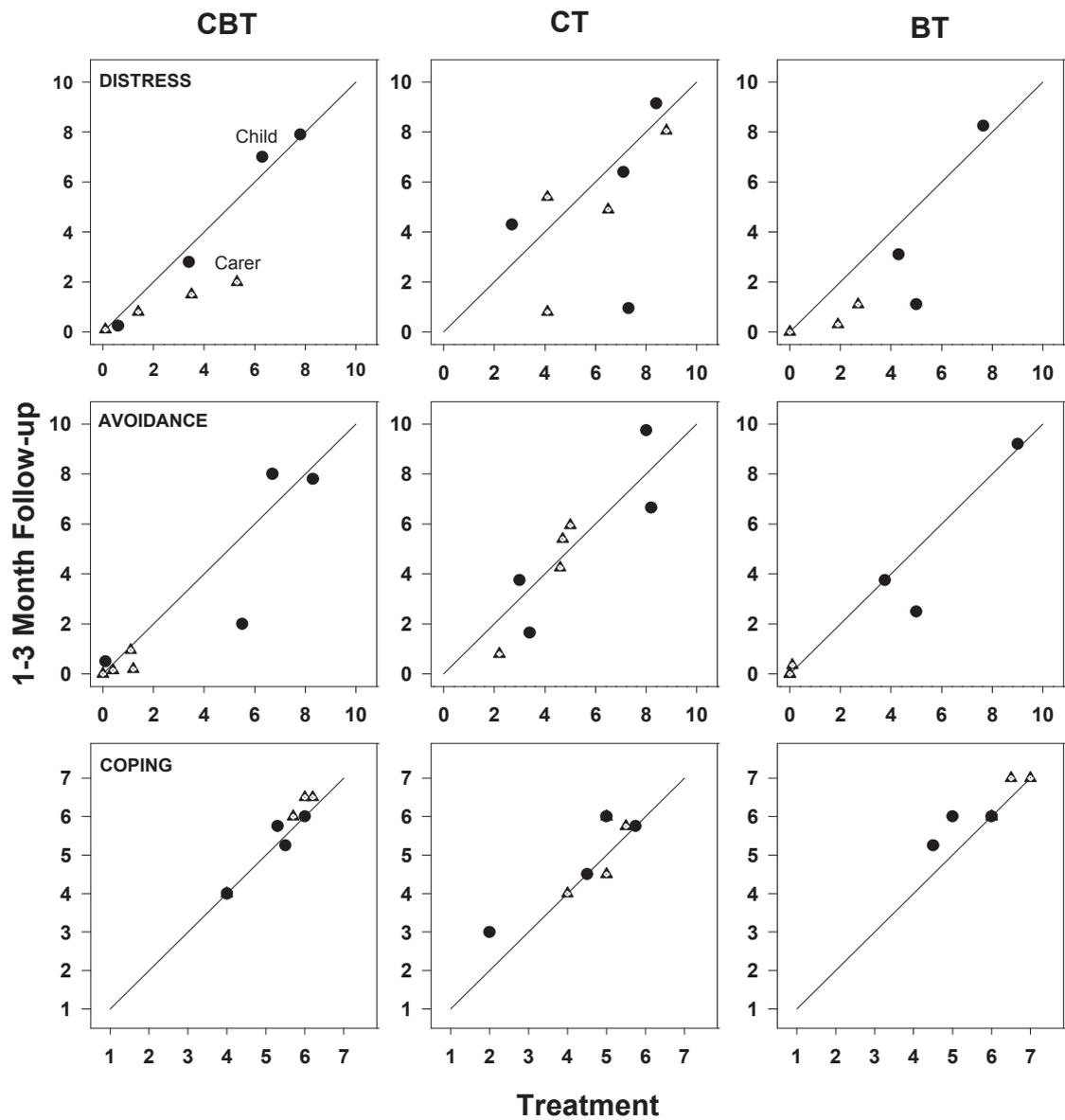


Figure 10⁸. Modified Brinley Plots Showing Summarised Group Data for Carer Self-Report of Themselves and Their Child's Distress, Avoidance and Coping across Baseline (X-axis) and Follow-Up Phases (Y-axis). (Direction of improvement indicated as for Figure 2.)

⁸ Figure 10 compares follow-up with treatment. Points on or near the diagonal represent maintenance of treatment gain, whereas points below the line indicate improvement from post-treatment and points above the line indicate deterioration.

Distress

Numerical Data (Time Series)

Figure 11⁹ displays the results for carer self-report of their own and their child's distress across baseline, treatment and follow-up phases for all treatment conditions. The NIQ-C distress scale ranged from *I am/my child is not at all distressed* (0) to *I am/my child is extremely distressed* (10). Abbreviations on the figure refer to baseline number (B1), session number (T1) and one and three month follow-ups (1MO and 3MO).

Assessment of baseline data for the CBT condition showed that carers consistently reported their distress levels to be lower than their child's. Change during the treatment phase occurred gradually across the first three sessions and then continued to reduce in subsequent sessions. The exception to this was Tamati's carer who reported an increase in distress in sessions four and five during the exposure tasks, although session six showed a reduction exceeding previous gains. When contrasting carer self-report of their own and their child's distress, it became apparent that reductions were reported at similar points in the intervention. All treatment gains were maintained at one- and three-month follow-up for carer distress.

Scores for the CT group showed that the treatment phase resulted in smaller distress reductions compared to the CBT group. There were also two distinct patterns across the four participants. Two carers reported large reductions in session three with an increase in session four (Hayley and Jenna), while the other two carers reported reductions in session two, with an increase in session three, and then decrease again in session four (Elena and Aroha). No particular pattern of responding (e.g., change in session three or four) resulted in better outcomes, as Jenna was the only participant to maintain treatment gains. Consistent with the CBT condition, changes in both child and carer distress occurred at similar points in the intervention.

Results for the BT group showed that, compared to the CT and BT conditions, carers tended to have lower levels of distress during baseline (with the exception of Wiremu's carer). Carers also reported that child distress levels continued to be higher than their own. Scores during the treatment phase showed rather divergent patterns across the three participants, the first carer reported that their child showed rapid reductions in distress during session four (Wiremu), the second carer reported more gradual reductions (Lyla), and the third carer reported little to no reductions at all (Kala). Follow-up data suggested that treatment gains were maintained for Wiremu and Lyla, although Kala relapsed close to baseline levels.

⁹ Time series data relating to the BT group only show three data points due to one of the participants being excluded from the study as explained in the baseline stability section above.

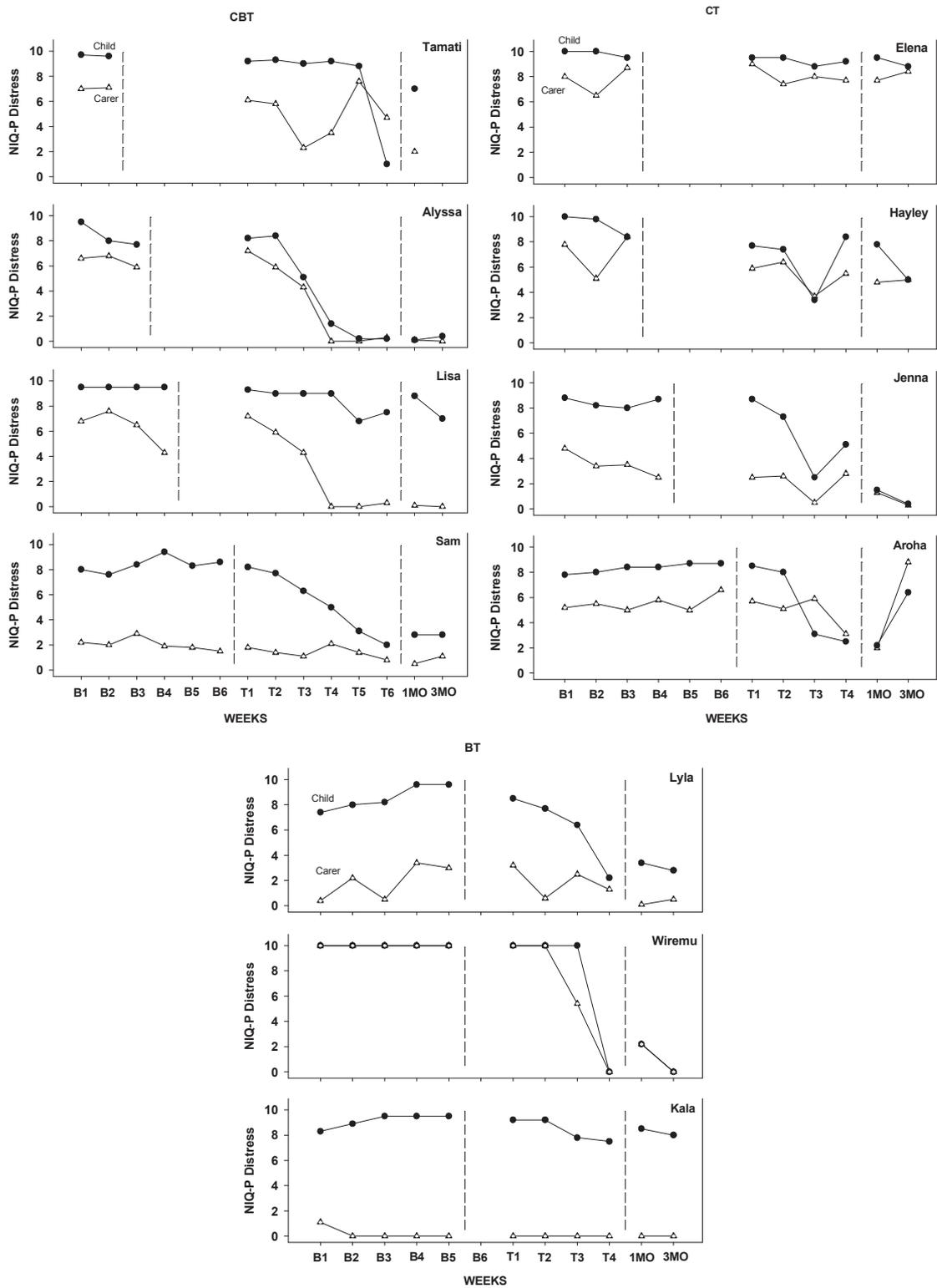


Figure 11. Time-Series Individual Data for Carer Self-Report of Themselves and Their Child's Distress for All Treatment Conditions across All Intervention Phases. (Direction of improvement indicated as for Figure 2.)

Avoidance

Numerical Data (Time Series)

Figure 12 displays the results for carer self-report of their own and their child's avoidance allocated to each treatment condition across baseline, treatment and follow-up phases. Abbreviations are the same as previous figures, but the NIQ-P rating scale changed from *I/my child definitely wants to avoid it* (10) to *I/my child does not want to avoid it* (0). With the exception of the CT condition, all carers reported that child avoidance was relatively high, while carer avoidance was relatively low. As a result, child scores will be predominantly discussed.

Analysis of baseline and treatment phases for the CBT group suggested that carers reported little to no avoidance of injections, while the perception of their child's avoidance was consistently high across all four participants. As a result, carer self-report of child avoidance will be predominantly discussed. Not only was there a large amount of variation between child and carer avoidance levels, but the point of change also differed considerably within the group. Some carers reported child avoidance reduced largely in session five (Sam and Tamati), while others reported the most change occurred in sessions four (Alyssa) and six (Lisa). This was in comparison to the distress domain, where reductions occurred at similar points in the intervention within and across therapy conditions. Follow-up data suggested divergent results ranging from major to minor reductions, while other participants slightly relapsed.

Treatment phase results showed that for the CT group, for two participants (Jenna and Hayley), child and carer avoidance levels mirrored one another with changes occurring at the same stage in the intervention. For the other two participants (Aroha and Elena), changes in child and carer avoidance did not parallel one another. Instead, there was a large reduction in either sessions three (Aroha) or four (Elena). Follow-up results showed that post-treatment gains were generally maintained at one- and three-month follow-up.

Results for the BT condition showed that some children had gradual improvements during therapy (Lyla), while others had large reductions in session four only (Wiremu). The third child fluctuated between an increase and decrease in avoidance (Kala), with little to no reductions at post-treatment. Follow-up results suggest that reductions in child avoidance for Wiremu were maintained, while Lyla relapsed. Kala's avoidance remained similar to baseline levels. There were no changes in carer avoidance throughout all three phases of the intervention, which was due to carers exhibiting low levels of avoidance from the outset (i.e., a floor effect).

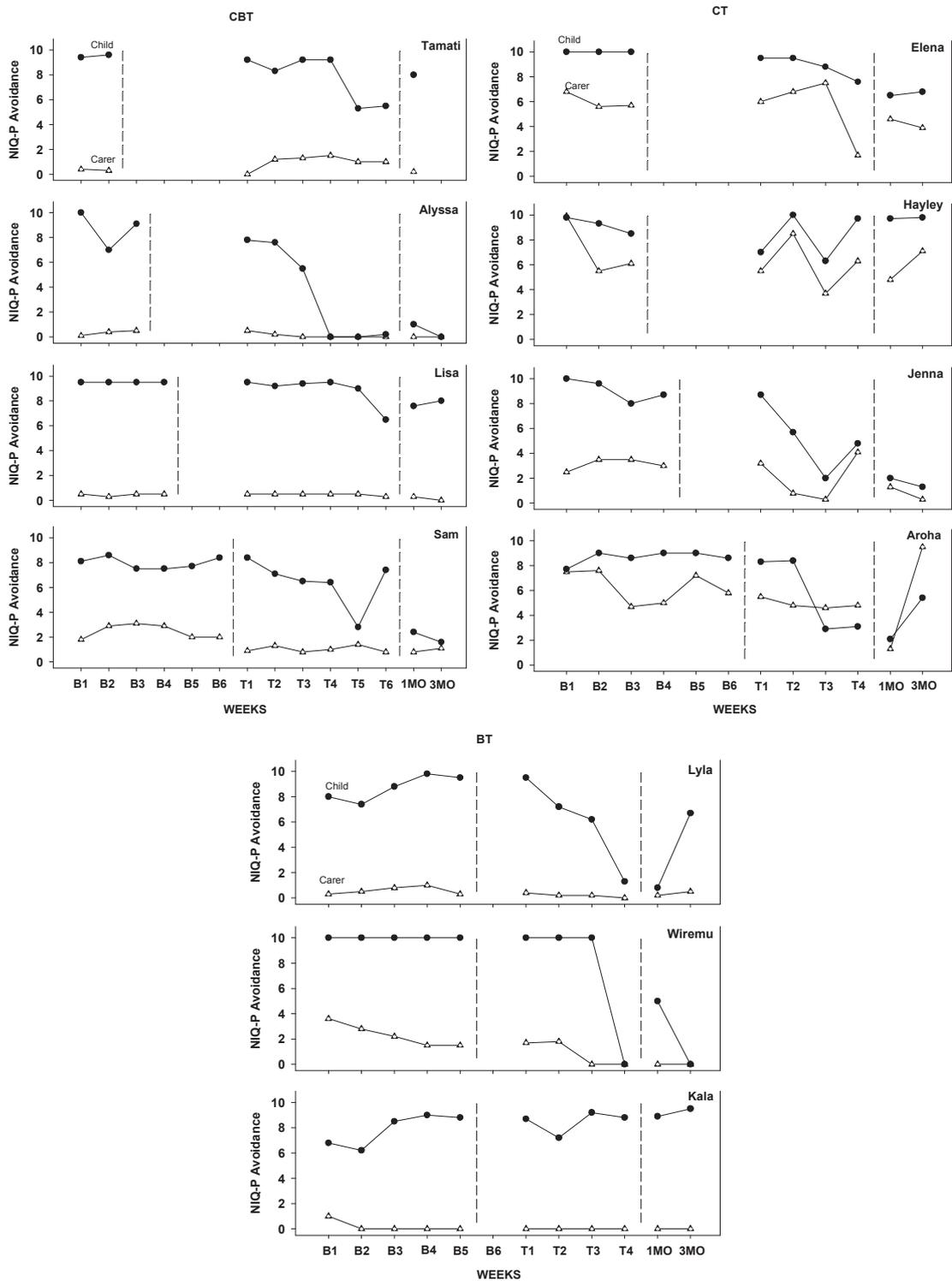


Figure 12. Time-Series Individual Data for Carer Self-Report of Themselves and Their Child's Avoidance across All Treatment Conditions and All Intervention Phases. (Direction of improvement indicated as for Figure 2.)

Written Data (Open-Ended Question)

Tables 18, 19 and 20 present the results for carer self-report of child avoidance in relation to all three treatment conditions across baseline, treatment and follow-up phases. In this case they were asked the following “In response to the question above (e.g., In general, how much does your child want to avoid having a needle injection?), is it typical of your child to react in that way?” Answers to the second part of the question have been summarised verbatim in the following three tables.

According to carers, there was some change in child behavioural avoidance whether it was small (e.g., “he really wanted to succeed this time” – Tamati’s carer) or large (e.g., “this is a vast improvement, previously he was hysterical” – Wiremu’s carer). Changes in the CBT condition appeared to occur mid-way through and towards the end of therapy, in sessions three (Alyssa), four (Sam), five (Tamati) and six (Lisa). A similar pattern was seen with the remaining two conditions and paralleled those obtained by the written component of the NIQ-P avoidance domain. For instance, Wiremu’s carer reported change occurred in session four, similar to child self-reports displayed in Figure 6.

Table 18

Carer Self-Report of Child Avoidance across Baseline, Treatment and Follow-Up Phases for the CBT condition (responses are verbatim)

Initial Behaviour	Change	Final Behaviour (including follow-up)
Tamati (9.5 years)		
He’s okay until actual injection. Always does this	Session 5	He really wanted to succeed this time
Alyssa (12 years)		
She hates having them	Session 3	This has vastly improved since doing sessions with Jess
Lisa (13 years)		
She is always distressed and keen to avoid injections	Session 6	Does appear to have gotten much better, this therapy has had a positive effect
Sam (13 years)		
Sam has always had a fear of injections	Session 4	The change in Sam's attitude and reaction to having injections has changed drastically since the start of therapy

Table 19

Carer Self-Report of Child Avoidance across Baseline, Treatment and Follow-Up Phases for the CT condition (responses are verbatim)

Initial Behaviour	Change	Final Behaviour (including follow-up)
Elena (10 years)		
She does not react like this in other situations, only needles	No Change	-
Hayley (10 years)		
Usually brave/good	Session 4	This was a much better injection than normal
Jenna (12 years)		
Will always avoid if possible	Session 2	She has improved since therapy and would generally be avoidant/fearful
Aroha (10 years)		
She hates needles, we have to hold her down sometimes	Session 4	Yes, but definitely better this time around thanks to the needle therapy

Table 20

Carer Self-Report of Child Avoidance across Baseline, Treatment and Follow-Up Phases for the BT condition (responses are verbatim)

Initial Behaviour	Change	Final Behaviour (including follow-up)
Lyla (7.5 years)		
She is always fearful/avoidant	Session 4	Today she was very much more relaxed and less anxious. Very different from past times
Wiremu (7 years)		
He has gotten progressively worse with every injection	Session 4	This is an amazing turn around. Previously he has been hysterical
Kala (13 years)		
Does not like needles	No Change	-

Coping

Numerical Data (Time Series)

Figure 13 displays the results for carer self-report of their own coping, as well as their ability to help their child cope across baseline, treatment and follow-up phases for all treatment conditions. Abbreviations on the figures are the same as described for previous domains, although the NIQ-P scale ranged from *I am able to help my child/myself feel comfortable* (1) to *I am not able to help my child/myself feel comfortable at all* (7). Baseline results across conditions indicated that the carer's ability to help their child cope was lower than their own ability to cope. However, treatment showed that, aside from a few carers, most reported similar levels of coping for themselves and their ability to help their child, with data points predominantly remaining the

same across therapy sessions particularly in session six. Follow-up results suggested that treatment gains were maintained at one- and three-months for the majority of participants.

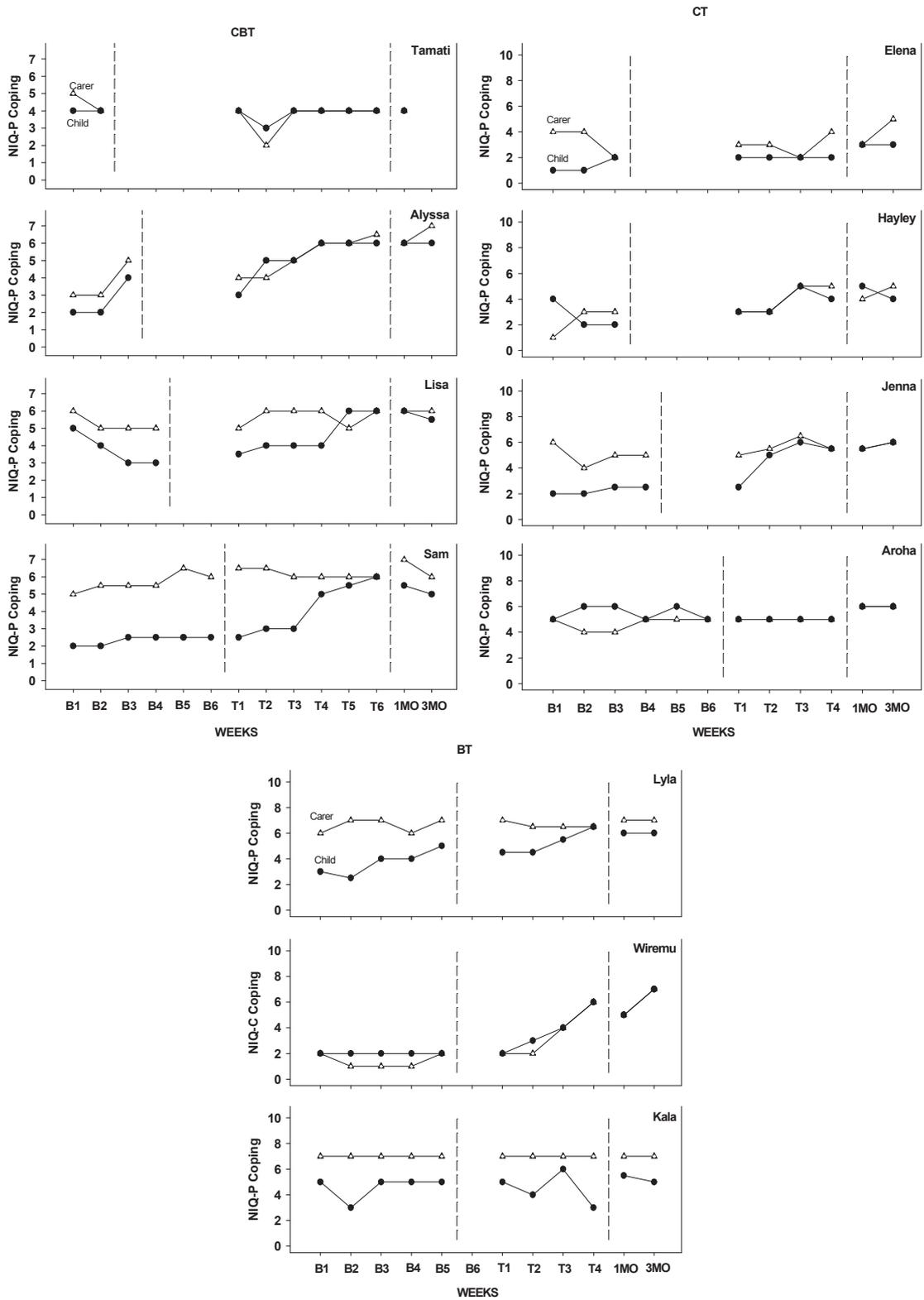


Figure 13. Time-Series Individual Data for Carer Self-Report of Themselves and Their Child's Coping for All Treatment Conditions across All Intervention Phases. (Direction of improvement indicated as for Figure 2.)

Written Data (Open-Ended Question)

Throughout the intervention, carers were asked an open-ended question to determine the content of their coping behaviours, and to assess whether these changed over the course of therapy. The question was “When your child is having a needle injection, what do you think and/or do in this situation to help yourself feel more comfortable?” The carer was then asked to write either a behaviour or thought in the blank space provided.

Baseline phase results showed that the utilisation of coping thoughts was the most widely reported strategy for carers regardless of treatment condition. In particular, thoughts related to the rationalisation and/or justification that the injection procedure was necessary for health reasons. It might be the case that thoughts such as these eased the carer’s discomfort when seeing their child distressed, as they could anticipate the short- and long-term benefits of the injection. Common coping thoughts included “It has to be done” (Tamati and Hayley’s carers), “It’s the best thing for her” (Lisa and Lyla’s carers), and “It’s absolutely necessary” (Jaden’s carer). Others justified the health benefits by suggesting “It will keep her well and stop arthritis (Hayley’s carer), and “We need to know the result” (Lyla).

In other cases carers described coping strategies that were aimed to benefit themselves, their child or both. For example, a common strategy included physical support such as holding their child’s hand, cuddling them and/or letting their child lean on them during the procedure. Some carers also described more advanced coping strategies that were beneficial for both of them by reminding themselves to be “supportive”, “encouraging”, “helpful” and “calm” (Aroha, Jenna, Lisa and Lyla’s carers). Concentrating on their child’s distress rather than their own needs was also common (Lyla’s and Lisa’s carer). Less adaptive coping strategies were “Pretending to bang my head on the wall” (Tamati’s carer) which was an act of frustration toward their child when they were unable to complete the procedure. Some carers also used “Bribery and persuasion, as well as offered a reward and/or monetary gain” (Elena and Hayley’s carers).

New adaptive coping strategies reported during the treatment and follow-up phases were aligned to the content of the treatment programme. For example, changes included more instances of calm breathing (Wiremu, Tamati and Lisa’s carers), challenge their child’s unhelpful thoughts while suggesting more helpful ones (Jenna’s carer), and providing information about and preparation for the procedure (Wiremu and Jenna’s carers). More specific strategies that were reported during treatment included giving themselves permission to have a break, or leave the room, as well as wearing comfortable clothes (Tamati’s carer). Certain carers also realised that it is best to let their child do it their way (Hayley’s carer), give them more time (Jenna’s carer), and have faith that their child can do it (Alyssa and Jenna’s carers). Follow-up data showed that for the majority of carers, adaptive coping strategies were maintained including calm breathing, challenging unhelpful thoughts, being relaxed and supportive, offering rewards, and reassuring themselves about their child’s ability to cope.

Key points of change ranged from session one (Wiremu’s carer – BT condition) to session five (Alyssa’s carer – CBT condition), indicating that adaptation to more effective coping

varied across all carers regardless of treatment condition. However, changes in carer coping for the CBT condition consistently occurred later in the treatment programme, compared to child coping. For the other two treatment conditions, change tended to be more wide-ranging. For example, the majority of carers in the CBT group (3 of 4) reported that their child's coping changed the most in session four. The fourth carer reported change in session five once they had seen their child receive an injection. For carers in the other two treatment groups, the point of change varied substantially with some reporting no large changes at all, while others indicated that change occurred anywhere from sessions one to three.

Coping Behavior Questionnaire

Alongside data gathered from the NIQ-P, a behavioural observation method, known as the Coping Behavior Questionnaire (CBQ), was utilised in relation to carer observations during the child's most recent injection procedure. Scores ranged from 0 (adaptive coping) to 15 (maladaptive coping). Depending on the treatment condition, the measure was administered once throughout the baseline phase and multiple times during treatment and follow-up. Therefore, scores cannot be attributed to specific sessions as a continuous measures approach was not used. Baseline results presented have also not been averaged as they relate to only one administration. Lastly, the lower the CBQ score, the more adaptive the child's coping behaviour, therefore the percentage is shown in a negative direction.

Table 21 shows the results for carer self-report of their child's coping. Baseline results showed that coping ranged from 6 (Hayley) to 15 (Wiremu), with an average score of 11 out of 15 (the higher the score, the less adaptive the coping). In relation to the CBT condition, sessions one to four had little effect on child coping, yet session six had an average change of 35%. Follow-up results showed even more promising results, in which case coping improved by 50% for some participants. Results for the CT and BT groups showed a different pattern where coping had an average increase of 42% by session four, with an even larger change for certain children (e.g., Wiremu – 87%; Kala – 64%). For the majority of children across the CT and BT groups, treatment gains were maintained at follow-up. The exception to this was Hayley who, compared to baseline levels, coping levels relapsed by 20%. This pattern of responding was consistent with Hayley's results on other measures of coping, distress and avoidance, which will be explored in the Discussion chapter. In summary, taken at the three-month follow-up, the CBT group showed the most positive changes in adaptive coping behaviour.

Table 21

Carer Self-Report Scores of (And Percentage Reduction In) Child Coping on the Coping Behavior Questionnaire over the Course of the Intervention

	Baseline	T4	T6	1MO	3MO
CBT condition					
Tamati (9.5 years)	13	13 (0%)	8 (-38%)	10 (-23%)	-
Alyssa (12 years)	8	5 (-38%)	6 (-25%)	3 (-63%)	4 (-50%)
Lisa (13 years)	13	13 (0%)	7 (-46%)	6 (-54%)	7 (-46%)
Sam (13 years)	7	5 (-29%)	5 (-29%)	5 (-29%)	6 (-14%)
CT condition					
Elena (10 years)	11	8 (-27%)	-	5 (-55%)	7 (-36%)
Hayley (10 years)	6	4 (-33%)	-	8 (33%)	9 (50%)
Jenna (12 years)	13	7 (-46%)	-	8 (-38%)	4 (-69%)
Aroha (10 years)	14	7 (-39%)	-	6 (-48%)	7 (-39%)
BT condition					
Lyla (7.5 years)	7	7 (0%)	-	7 (0%)	8 (14%)
Wiremu (7 years)	15	2 (-87%)	-	3 (-80%)	4 (-73%)
Kala (13 years)	11	4 (-64%)	-	8 (-27%)	8 (-27%)

Note. T4 and T6 = treatment sessions four and six; 1MO and 3MO = 1 month and 3 months.

Summary of Carer Reports

Due to carer avoidance being low during the baseline period, it was primarily carer distress and coping that could be improved during treatment. Results showed that CBT was the most effective at reducing distress at post-treatment. CT and BT displayed less than promising outcomes during treatment, although this was due to some carers exhibiting low levels of distress from the outset (i.e., a floor effect). Similar to child self-reports, coping gradually improved across all three groups with no particular condition showing better results than another at post-treatment.

Analysis of follow-up results revealed that, in most cases, carers tended to rate little to no change until they had seen their child receive an injection in real life. Therefore, scores at one and three months post-treatment showed more promising results, with carer self-report of

their own and their child's distress improving further for the CBT and BT groups. Even though distress levels for carers allocated to the CT condition reduced, they continued to remain fairly high at follow-up. Little change was reported for child avoidance across groups, although there were several changes in coping with the majority of treatment gains in the CBT group being maintained, CT improving even further and the BT condition slightly relapsing for two carers at follow-up.

Non-Regression-Based Statistics

Non-regression algorithms were used in order to provide information on the magnitude of treatment effects. These algorithms included the Standard Mean Difference all (SMDall) and Percentage of Non-Overlapping Data (PND). SMDall was calculated for all 11 children according to three of the four NIQ-C domains (e.g., distress, avoidance and coping) and SUD ratings. It could not be calculated for certain domains and participants where the standard deviation during baseline was zero (i.e., no variation in baseline scores). In an attempt to rectify this, slight adjustments (i.e., 0.1) were initially made to enable baseline variation. However, this resulted in inflated effect sizes. Instead it was decided that effect sizes would not be calculated for participants who indicated zero deviation in baseline scores. Treatment data was also only used in the calculation, rather than including follow-up data, because follow-up scores showed a different pattern to the final therapy session as previously discussed. Lastly, the PND statistic was only calculated using SUD ratings collected across intervention phases, and calculations were not performed for the carer self-report measures as these were not the main outcome measures for the study.

Table 22 presents the results for SMDall and PND. Interpretative guidelines for these two algorithms were described in Chapter 2 under data analysis and display (see pp. 49-51). Scores showed that there was a significant amount of variability in effect sizes across and within treatment groups. There was also a large degree of effect size variation across the different domains. For instance, effect sizes for distress ranged from 18.8 (Elena) to -4.0 (Tamati).

More specifically, with the exception of two participants (Tamati and Kala), all children showed very large effects in relation to distress regardless of treatment condition. Behavioural therapy generally showed the lowest effect sizes. Effect sizes for avoidance were variable with some groups showing large effects (CBT) and others showing medium effects (BT). Nonetheless medium effects were due to some children showing low levels of avoidance during the baseline phase. Coping showed the least amount of variability in effect size across groups, with most of the participants showing large effect sizes of approximately -2.5 (reduction = improvement). Lyla was the only participant to display a small effect size of -0.1, although this was due to her reporting high levels of coping during baseline.

For other participants such as Kala, coping appeared to be the only area of improvement, with small to medium effect sizes obtained for distress and avoidance, respectively. Even though her SUD rating indicated a large effect size (SMDall = 4.6), this may

be overstated given the minimal deviation in baseline scores, thus creating a small denominator and inflated effect size. In other words, statistically this effect size is a meaningful change, but in reality it has very little value considering the average difference between Kala's baseline (SUD = 8.9) to treatment score (SUD = 7.9) was minimal. This is a common occurrence when working with small standard deviations, and should be made transparent when interpreting data.

Analysis of the PND statistic showed an obvious pattern of change was evident for the CBT group, with three of four participants indicating that 67% of their treatment session (first half) scores remained below their minimum baseline score. This provides further evidence for the conclusion that change does not occur until mid-way through therapy once medium-level exposure tasks have been completed. Subsequent sessions then stayed below the minimum baseline score up until therapy finished. PND scores for the cognitive and behavioural groups ranged for the most part between 50% and 75%. This indicates that approximately half of the treatment sessions were below the minimum baseline score, suggesting that two of four sessions produced the most change. When combining this information with time-series data presented previously, it is apparent that session three as well as session four produced the most change in the target constructs in distress levels for both treatment conditions.

Overall, treatment sessions produced large effect sizes across distress, avoidance and coping domains for all three conditions. CBT showed the largest effects in relation to distress and avoidance, with coping displaying similar results across all groups. PND scores supported previous conclusions in that changes did not occur until approximately mid-way through therapy for the CBT group, and towards the end of therapy for the CT and BT groups.

Table 22

SMDall and PND for All Participants According Distress, Avoidance and Coping across Baseline, Treatment and Follow-Up Phases

	Tamati	Alyssa	Lisa	Sam	Elena	Hayley	Jenna	Aroha	Lyla	Wiremu	Kala
SMDall	CBT				CT				BT		
Distress	-4.0	13.4	9.1	3.5	18.8	17.3	3.4	4.7	1.1	*	0.3
Avoid	14.3	1.2	7.7	1.8	1.5	*	2.8	*	0.7	*	0.4
Coping	-2.4	-4.0	*	-2.0	-1.4	*	-3.4	-1.2	-0.1	-6.3	-2.1
SUD	0.1	5.8	9.5	1.4	1.0	9.8	3.6	1.2	1.7	4.4	4.6
PND	CBT				CT				BT		
SUD	33	67	67	67	50	75	25	50	75	50	50

Note. * = no standard deviation in baseline scores.

Post-Therapy Feedback

Child and Carer Numerical Feedback

An 11cm VAS was used to determine what treatment components the child found the *most helpful* (10) or *least helpful* (0) during therapy. The carer then rated the same treatment components using the same scale, but in relation to how helpful they thought it was for their child. Due to a variable number of children allocated to each condition, data was averaged and then weighted to ensure that scores could be compared across treatment components. Muscle relaxation was also a component incorporated into the CBT and BT groups, although it was only administered with two children so will be discussed separately. Figure 14 shows that child and carer self-report ratings of treatment components were so similar that any differences between helpful versus unhelpful techniques were negligible. Therefore, based on this data the following information is limited and relates to very minor fluctuations in scores.

Overall, children rated breathing as the most helpful component, followed very closely by coping thoughts and receiving a reward. In contrast, carers thought that receiving a reward was slightly less helpful for their child (although they still rated it as 8 out of 11), and instead rated the in-vivo needle injection as the most effective component (9.7 out of 11). This was consistent with scores on the carer distress, avoidance and coping domains discussed earlier, which showed that large improvements occurred only once the carer had seen their child have a successful injection. The second and third highest rated components that the carers thought were the most helpful for their child included role-plays and breathing, respectively.

While still considering the fact that differences in ratings of helpful versus unhelpful techniques were minor, children and carers consistently rated emotive imagery as less helpful compared to other components. On the other hand, there was also some divergence with children rating role-plays/in-vivo injections as less helpful and carers rating coping thoughts and rewards as less helpful. Therefore, while remaining attentive to the fact that there were very small differences in the ratings of components, both children and carers regarded calm breathing as one of the most helpful and emotive imagery as one of the least helpful components (although this was a one point difference). The most discrepancy between child and carer ratings was evident with the perceived helpfulness of rewards and the in-vivo injection.

When comparing the treatment components specific to each condition, there was more consistency between child and carer self-report ratings. Treatment feedback from participants allocated to the CBT and CT groups showed that learning new coping thoughts was more helpful than emotive imagery, whereas treatment components received primarily by the CBT and BT groups showed that learning calm breathing was more helpful than role-playing a mock injection. Furthermore, a comparison of these ratings to the outcomes described earlier showed there are some discrepancies, making it difficult to determine what components to exclude in future research and clinical settings. In particular, improvements in distress, and at times

avoidance, suggested that the most change occurred in sessions three and/or four which included exposure based activities (e.g., role-plays), rather than session one which taught calm breathing. However, it might be the case that session one produced little change as it precluded an opportunity for the child to practically use these skills in the feared situation.

Overall, based on the fact that components were scored 8 out of 11 or higher, it might be suggested that all of them were helpful, but that the highest scoring components (e.g., calm breathing and exposure), were also some of the most effective techniques for participants.

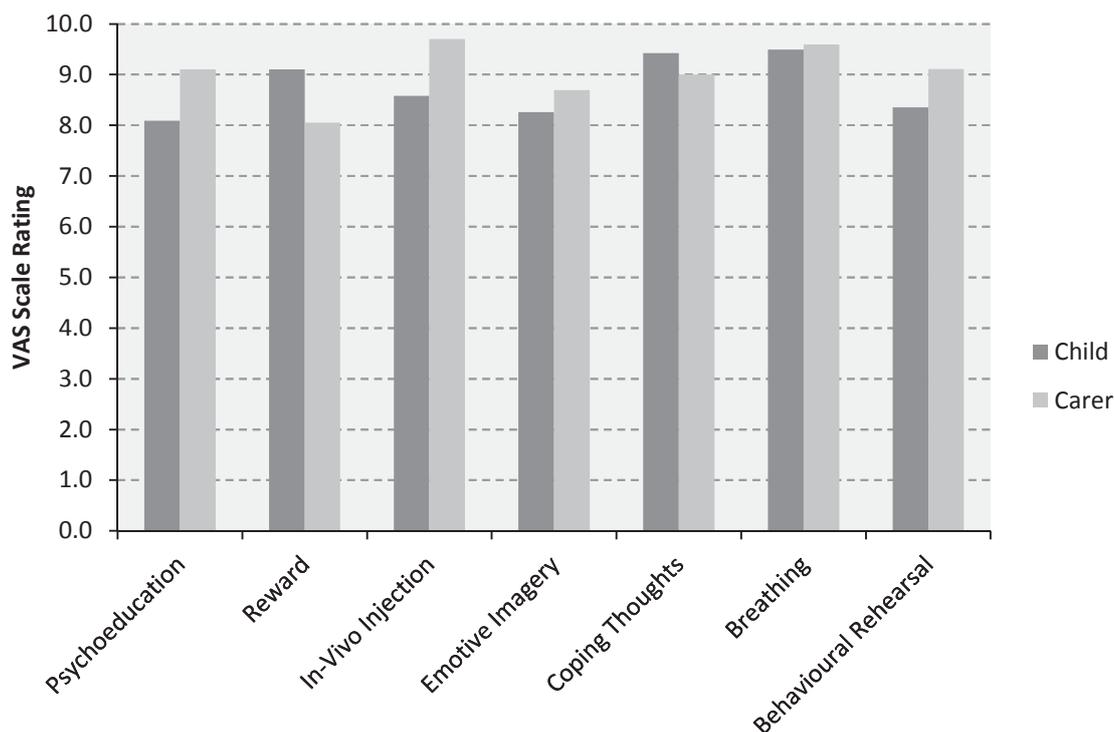


Figure 14. Child and Carer Ratings of Therapy Components across All Three Treatment Conditions.

Child and Carer Written Feedback

Two 5-item open-ended questionnaires (child and carer version) were developed in order to obtain therapeutic feedback. Questionnaires were completed at post-treatment for all treatment conditions. Responses to the items were summarised according to key themes and, where appropriate, participants' answers were copied verbatim. Responses from the two questionnaires were used to interpret the data presented thus far and/or provide anecdotal information about the effectiveness of the treatment programme.

Child Feedback

For the majority of children, the most enjoyable aspect of therapy included educational games, role-playing mock injections, learning about calm breathing and earning rewards. Again there was some discrepancy in relation to how children rated the helpfulness of these

components, although this might be due to this question relating to how *enjoyable* rather than how *helpful* the child found it, which are two different concepts. Games that were incorporated into therapy sessions were guess the emotion the other person is acting out, name the emotion hidden under the lolly, and chocolate basketball. Preparing for the injection by simply talking about it, knowing in advance when it's going to happen and how, plus learning about different strategies to help themselves cope during the procedure were also important aspects for many children (Aroha, Sam, Kala, Tamati and Jenna). Specific activities that were enjoyable for some children included drawing (Aroha and Alyssa), learning about thoughts (Elena), and watching videos of injections (Alyssa and Kala). Three children "Enjoyed everything" instead of favouring one activity (Lyla, Elena and Hayley)!

Less enjoyable aspects of therapy were coming straight after school when they were tired and hungry (Haley), completing the ATSS measure (Lisa and Alyssa), looking at the same pictures of needles during therapy exposure tasks (Kala), as well as having a real injection as part of therapy (Kala and Aroha). Lastly, many children wrote "Nothing" in answer to this question or left it blank when filling out the questionnaire (Tamati, Wiremu, Elena and Jenna). Others wrote "It was too short" (Lyla).

Suggested modifications to therapy was the inclusion of sporting activities (Tamati), playing more emotion games (Sam), and having additional resources during role-plays (e.g., cotton balls, swabs, a tourniquet and a variety of needles) (Alyssa). Other children reported that "Emotive imagery needed to be developed and utilised further in therapy, particularly the part about being Maria Tuatia (sic) and having a coach to help with the injection" (Lisa's carer). Others reported that there needed to be more role-plays, breathing and distraction exercises to reinforce further learning (Alyssa), whereas some thought "Role-plays/pictures of needles were good, but not that helpful" (Kala). Nonetheless, Kala did report that watching videos of needle injections assisted with her feelings of disgust and reduced her distress. Aroha, who was allocated to the CT condition, suggested that instead of having the injection, she would rather just pretend. Behavioural exposure activities were commonly recommended by families in the cognitive condition. Lastly, most of the children wrote "None/nothing" when it came to therapy modifications (Hayley, Wiremu, Elena and Jenna), while Lyla expressed that the therapy needed to be longer and include other phobias such as a fear of spiders.

Nine out of eleven children thought that more therapy sessions would have been helpful (three children from each group). Suggestions ranged from one to 11 more sessions, with the majority of children recommending another two to three sessions. Activities that children wanted to incorporate into these extra sessions were mainly behavioural. For example, Jenna was allocated to the cognitive condition and expressed that she would like to "See more needles, and medical equipment (tourniquet, swabs, and needles) to get familiar with the gear that you were going to use". She also expressed that "Practicing the injection, but not actually doing the procedure" would also be helpful. This suggestion appeared to not only relate to children in the cognitive condition, as children allocated to the behavioural condition also wanted to do more role plays of mock injections (Lyla – BT condition). Two older children made more abstract

suggestions and outlined that follow-up sessions that included additional blood tests would be beneficial to ensure that the therapy has worked (Alyssa and Sam). Despite this, other children indicated that the number of sessions were adequate (Lisa – CBT, Hayley – CT, Kala – BT). In particular, Haley expressed “I really liked the amount and I thought it was helpful enough for me and I didn’t think I could be helped anymore”.

All 11 children outlined that they found it helpful having their mum or dad with them in therapy. Two male children, one child of Māori descent and the other Pākehā, reported that alongside their mum, they would have liked additional family/whānau to be in therapy (e.g., dad) (Tamati and Sam). Children reported a number of different reasons for why they found it helpful having their carer in therapy, although it was mainly in relation to them providing support. However, for other children it was for more practical reasons whereby Hayley expressed that “she (Mum) is the one doing the injection and it’s good for her to know what to do”. Lastly, it was also important as it gave their carer insight into how they felt (e.g., “Mum learnt about the therapy activities as well as my situation” – Lisa).

Overall, feedback suggested that children would enjoy the therapeutic process more if fun activities are incorporated into sessions where they can then earn rewards. Games that are active also appear to be important. Completing the assessment measures and carrying out activities after school hours was the least enjoyable aspect of therapy, otherwise the majority of children reported nothing. Suggested modifications were mainly based around making therapy more fun. There was no clear pattern indicating that certain treatment conditions required more or less sessions over another. Instead a relatively equal number of children in all three conditions outlined they would like more sessions, while at the same time many other children found the number suitable. It might be the case that therapy duration is dependent on the individual child, rather than having a prescribed number of sessions for everyone. All children found it helpful having their mum or dad in therapy with them due to the support they provided, perhaps suggesting that only in certain circumstances should the carer be excluded from the therapeutic process.

Carer Feedback

All carers expressed the opinion that cultural modifications to therapy were unnecessary. Families from both Māori and Pākehā descent wrote “N/A as we don’t have any specific cultural needs” (Aroha) and “Our family does not really have a culture as such, so nothing needs to change” (Kala). Instead, more general modifications were recommended. For example, Elena’s carer expressed that the “Office was a bit stuffy and hard to stay alert” and Aroha’s carer thought it would be good to have even more games in therapy. On the other hand, Tamati’s carer recommended something entirely different by outlining the need for an individual session with the therapist, and that a phone call after each session would have been helpful as she could not always be honest in front of her child. This illustrates certain circumstances where the structured format of treatment manuals and/or research settings are not suitable for some families, particularly when clinical issues that need attention are unable to be addressed due to research protocols.

Of particular note is that two carers made comment regarding the first few sessions. The first carer suggested that they could be “Snappy and fast-paced, with more age-appropriate stories for teenagers” (Lisa’s carer), while the second carer reported they “Found it interesting although I was slightly sceptical during the first half of the first session. That soon passed and I found the whole process effective and enjoyable” (Lyla’s carer). Despite this, the majority of carers (8 out of 11) reported that no modifications were required with some expressing that “This was perfect!” (Wiremu’s carer), “Really enjoyed it, learnt a lot and it was beneficial for us” (Jenna’s carer), and “It worked really well for my daughter” (Kala’s carer). Sam’s carer also thought that “The therapy was child focused, so ensuring that it was a good fit with the child was really great”.

Similarly to the child feedback, the majority of carers also wanted more therapy sessions. Suggested activities that could be covered in the extra sessions included anxiety reduction (Kala’s carer - BT), role-playing a mock injection (Jenna’s carer – CT), and a follow-up needle injection to reinforce what has been learnt in therapy (Sam and Tamati’s carers - CBT). Despite this, five carers all from different treatment groups reported that the number of sessions was enough and that therapy was very successful in a short amount of time. Some carers wrote “I cannot believe the difference after only four sessions of therapy!” (Wiremu’s carer - BT) and “Today was proof that it worked very well” (Lyla’s carer – BT). For other carers, the number of therapy sessions was correct for reasons other than effectiveness. For example, Lisa’s carer thought that in no way had they mastered the techniques, but more therapy sessions may have lost the interest and/or motivation of the child.

All 11 carers outlined that they would recommend this therapy programme to another friend and/or family member. In particular, Tamati’s carer had already recommended it to another family during therapy, while Elena’s carer expressed that they would “Absolutely recommend it – the method is non-threatening, encouraging, wonderful and it worked!” Aroha’s carer thought beyond injections and stated that “The techniques she has learnt are useful to overcome distress in relation to needles, but also other aspects of her life she might find upsetting”. For other families they acknowledged that it has “Given us a way forward when there was none before” (Jenna’s carer), and that “If it can work for her (Alyssa’s carer), then I’m sure others would also see the amazing change in their child!” Some simply stated that “You really did make a difference” (Wiremu’s carer). Table 23 provides a list of informal comments that carers wrote at post-treatment (verbatim).

Overall, no major modifications to the therapy programme were recommended. Despite this, two carers noted that they were sceptical during the first therapy session which suggests it may need to be revised to some extent. The majority of carers would have liked more therapy sessions to consolidate information further; this is despite some of them reporting that their child showed major improvements after only four sessions. Similarly to the children’s suggestions, carers would have included behavioural activities into the extra sessions.

Table 23

Post-Treatment Feedback from Carers (Verbatim)

Participant	Comment
Tamati's Carer	"Thank you for the opportunity to be involved. You rock Jess!☺ "
Alyssa's Carer	"Thanks for everything, Jess. It was really worth it!"
Wiremu's Carer	Jessica – we can't thank you enough ☺ Wiremu has been telling everyone at school about his experience and the fact that it didn't really hurt and he didn't cry. Thanks again for everything. You really did make a difference.
Elena's Carer	Thank you, thank you, thank you so much, Jess!!! Thank you so much it was so amazing to get it done. Hopefully has had such a huge impact on Elena that future injections will not be so bad.
Lisa's Carer	This has been a very helpful process for me, by giving me strategies to focus on. I think Lisa will realise more and more it has also been helpful for her over the next few years
Lyla's Carer	Thanks Jess, for your approach and the help you have given Lyla and us.
Sam's Carer	Thank you for all your time and effort that you have put into the programme and Sam. Good luck with your studies and your future. It would be great to read your research once it has been completed. Could you please email me or send me a copy.
Aroha's Carer	I can't thank you enough for what you have done for Aroha. I'm so proud of Aroha, she did for the first time in her life, she didn't have the huff as I'm texting you I have a tear. Aroha was very scared, we talked about ginger island and captain ginger. She asked the nurse the three questions, she then told her mum to be quiet, so proud, she told the nurse I will tell you when I'm ready, I will say "yes". She did it so easy it only took 4.5 minutes. I had a tear, her nurse had a tear, like I said you have changed her life. What is small for others, is huge for Aroha, so after the injection I took Aroha up to the pool for a swim she is so proud of herself. Thank you so much Jessica.

Therapeutic Alliance and Treatment Outcomes

The session rating scale (child and adult versions) were used to monitor therapeutic alliance across the three treatment conditions. The opening question used for children included "How was our time together today?" They were then asked to rate this item according to two responses using a VAS scale. The first was *I did not like what we did today* (0) to *I liked what we did today* (10), and the second was *I wish we could do something different* (0) to *I hope we do the same kind of things next time* (10). Similarly, another opening question was used for

carers where they were asked to “Please rate today’s session by placing a mark on the line nearest to the description that best fits your experience”. This related to two items, the first being *the therapist’s approach is not a good fit for me* (0) to *the therapist’s approach is a good fit for me* (10). The second item was *there was something missing in the session today* (0) to *overall, today’s session was right for me* (10). Items on both scales were added together and then interpreted using a cut-off score of 18, where a score below this point was considered an opportunity to repair ruptures to the alliance and make necessary adjustments in therapy to improve outcomes. The rationale for a cut-off score of 18 was that the original measure had a cut-off of 36 when using all four questions (Miller et al., 2002). This value was halved to account for only two questions that were included in this study.

Results indicated that a strong therapeutic alliance was formed for both children and carers allocated to the CT and BT conditions (all scores were above 18 out of a possible 20). Specifically, therapy rapport was consistently reported across all four sessions with no particular component requiring adjustment to ensure positive outcomes. The exception to this was Kala, who was allocated to the BT condition and reported a low level of alliance in three of four sessions. Nonetheless, carer rapport was well established for this participant and showed no indication of being ruptured. As expected, therapeutic results for this child were less than promising, with distress, avoidance and coping showing minor improvements or remaining fairly similar to baseline levels.

The therapeutic alliance established for the CBT condition showed very different results, not only in relation to the other two treatment conditions but also between children and carers. Analysis revealed that, during each session, either two or three of the four participants indicated a low level of therapeutic alliance (average 13 out of 20). Session five which involved the child having an injection at a local medical setting showed the lowest results, with all four children reporting scores under 18. This might have related to the child confronting the thing they feared the most (injections), rather than the therapeutic relationship being damaged, particularly considering one of the questions asked whether they would like to do the same kind of things next time in therapy. In contrast, all carers allocated to the CBT condition reported a strong therapeutic alliance throughout all six sessions.

Closer analysis of individual sessions across all treatment conditions indicated that, if rapport was established immediately within the first session, it was consistently maintained at a high level throughout the intervention. Exceptions to this were children that initially rated a high level of rapport, and then rated very low levels in certain sessions (e.g., CBT group). These sessions typically included exposure-related activities such as an injection at the local medical setting, video, pictures and/or role-plays of injection related stimuli. For other children, if therapy rapport was not obtained in the first session, this relationship built slowly over time, a pattern that was particularly evident for adolescents. A final observation was that, of the four participants reporting low alliance levels, three were adolescents aged 13 years.

The relationship that alliance scores had with treatment outcomes showed that, out of the four participants in all three groups, two had less than positive results, providing some

evidence for the importance of therapeutic rapport. The two participants included Tamati, a 9½-year old boy allocated to the CBT condition, and Kala, a 13-year old girl allocated to the BT condition. An explanation for such low alliance levels established in the CBT group despite the positive outcomes may be related to a number of factors. Lastly, it might also be the case that questions were rating therapy content rather than therapy rapport (as only two of four SRS questions were used). Possible explanations will be explored in the Discussion chapter.

Overall, scores obtained by the SRS (child and adult versions) suggested that, with the exception of one participant (Kala), a strong therapeutic alliance was consistently obtained for both children and carers allocated to the CT and BT conditions. However, this was not the case for the CBT group, which showed alliance ruptures were evident with three of four child participants. All carers allocated to this group showed very strong alliance scores. Across all groups, the association these therapeutic ruptures had with treatment outcomes showed two of the four participants had less than promising results (Tamati and Kala), either suggesting that (1) rapport is important half of the time, (2) children were rating items in relation to therapy content, rather than therapy rapport, or (3) the entire SRS measure rather than just two items are needed in order to provide a more accurate indication of therapy alliance. Further research would need to be carried out in order to obtain more conclusive evidence.

Overall Summary of Results

Based on the number of replications recorded in each treatment condition, CBT was the most effective intervention with *three* of four participants showing positive results. BT showed *two* of four replications were positive, while CT only showed *one* of four replications were positive. These conclusions were based on post-treatment and follow-up assessment points across all domains (distress, avoidance, coping and cognitions related to injections). More specific analysis revealed that both children and carers reported CBT was the most effective at reducing distress and avoidance, while all conditions were relatively effective at increasing coping. Analysis of follow-up results revealed that, in most cases, carers tended to rate little to no change until they had seen their child receive an injection; therefore follow-up results were promising for this group. CT was the most effective at improving cognition content, followed by CBT and then BT. As indicated, although CBT superseded the other two therapies in relation to distress and avoidance, CT and BT were just as, if not more, effective in other areas for some participants. Therapy feedback indicated that children and carers rated all treatment components as helpful, but that calm breathing and exposure were considered the most helpful. No major modifications were suggested other than an increase in the number of therapy sessions including the use of more behavioural strategies. Children reported that playing games was the most enjoyable aspect of treatment and all outlined it was helpful having their carer participate in therapy. High levels of rapport were reported for all carers regardless of treatment condition, although several children in the CBT condition reported low alliance scores despite indicating the most effective results.

Chapter 5: DISCUSSION

A Child's Description Of Needle-Related Distress Post-Treatment:

- *Therapist: "How are you feeling about having an injection today?"*
- *Child: "Fine, just normal – I could eat a chocolate bar if I wanted to. I feel like I could hang upside down on that rail and juggle needles while I'm at it! That's how much better I feel".*

Lyla – 7½ years old, February 2013

Chapter Outline and Aims

The Discussion chapter reviews the overall findings of this study with reference to the hypotheses delineated in the Introduction chapter and the clinical significance of the treatment outcomes. The results are interpreted in terms of previous literature, with implications discussed in key areas. Limitations of the present study and suggestions for future research are outlined before a final conclusion is presented.

Summary of the Findings

The aim of this study was to dismantle an existing manualised CBT programme to determine whether cognitive and/or behavioural components were more effective than no treatment (i.e., the baseline phase) for reducing NRD symptoms among chronically ill children. Treatment components were also assessed in relation to improving the carer's ability to manage their own reactions regarding their child's NRD symptoms. Three treatment manuals were used to conduct this research, namely (1) a cognitive-behavioural therapy manual, (2) a cognitive therapy manual, and (3) a behavioural therapy manual. The original therapy programme was based on the *Coping Kids Treatment Manual* developed from a pilot study in 2011 with four chronically ill children aged 6 to 14 years. In the present study, a single-case multiple-baseline across participants design was used to assess the effectiveness of the treatment manuals with 12 chronically ill children aged 7 to 13 of New Zealand European/Pākehā and Māori descent. Participants were either self-referred or referred by a health professional within the Palmerston North and Wellington regions. Two main outcome measures were used including the Needle Injection Questionnaire for Children (NIQ-C) and the Needle Injection Questionnaire for Parents (NIQ-P).

Results indicated that six sessions of CBT was more effective than four sessions of BT or four sessions of CT for chronically ill children with NRD. This conclusion is based on the magnitude of change displayed in relation to distress, avoidance and coping, as well as the number of single-case replications that showed positive results. For instance, compared to pre-

treatment levels, *three* children in the CBT group, *two* in the BT group and *one* in the CT group demonstrated a) a reduction in distress and avoidance, b) improvements in cognition content, intensity and frequency related to injections, c) an increase in coping behaviours, and d) that treatment gains were maintained and/or improved over one- and three-month follow-up periods. Nonetheless, when assessing individual case results in certain areas (e.g., distress and cognition content, intensity and frequency), CT and BT were just as effective as CBT for some children. Treatment was also characterised by particularly low dropout rates with all 12 participants attending assessments and/or four or more therapy sessions. Overall, the results of the present study are promising in suggesting the effectiveness of combining cognitive and behavioural components for chronically ill children with NRD. Returning to the study hypotheses, the following points can be made.

1.1 It was expected that children in all three treatment conditions (CBT, CT and BT) would self-report a reduction in distress and avoidance, and an increase in adaptive coping behaviours both during treatment and at post-treatment. It was also expected these gains would be maintained over a one- and three-month follow-up period.

There were reductions in distress and avoidance and an increase in coping both during and at post-treatment for the majority of children. Large effect sizes (ranged from -0.4 to 18.8 for distress, 0.4 to 14.3 for avoidance, and -0.1 to -6.3 for coping) provided corroborative evidence for improvements in these three domains at post-treatment. One- and three-month follow-ups showed that six participants (Lyla, Wiremu, Sam, Alyssa, Lisa and Jenna) maintained or improved treatment gains, whereas four participants relapsed. This included three participants from the CT group (Aroha, Hayley and Elena) and one from the BT group (Kala). Lastly, one child from the CBT group (Tamati) also continued to report NRD symptoms during the follow-up period, but these were consistent with treatment scores which were similarly high. Relapse was not expected, and possible reasons for this outcome for these four children are discussed later in this Chapter.

Differences across treatment groups showed that CBT was the most effective at reducing NRD symptoms, while also maintaining these gains at follow-up. In comparison, only one participant from the CT and two from the BT conditions continued to show positive results at follow-up. All three conditions were equally effective at gradually improving coping throughout the treatment phase and maintaining these gains at follow-up. More generally, there were also two major patterns evident in the data. First, distress primarily improved in sessions three (CT and BT) and/or four (CBT) for the majority of children. Techniques incorporated into these sessions included medium-level exposure (BT and CBT) and the development of helpful thoughts (CT and CBT). Second, unlike distress and avoidance which reduced rapidly in certain sessions, coping gradually improved throughout the treatment phase.

1.2 It was expected that carers in all three conditions (CBT, CT and BT) would self-report reductions in their child’s distress and avoidance-related symptoms and an increase in their child’s ability to cope both during treatment and at post-treatment. It was also expected that these gains would be maintained over a one- and three-month follow-up period.

Compared to baseline levels, approximately half of the carers reported that their child’s distress and avoidance showed small to moderate reductions at the end of the treatment. The other half of the carers reported large reductions in these areas. The majority of carers reported that their child’s coping gradually improved throughout the intervention. Follow-up data was more promising; with carers indicating that treatment gains were generally maintained and/or improved further, particularly for children who reported positive changes during therapy. This may be due to carers rating large improvements only once they had seen their child receive an injection. Carers also tended to over- and under-report their child’s distress, avoidance and coping in relation to what their child was self-reporting.

1.3 It was expected that children in all three conditions (CBT, CT and BT) would self-report improvements in cognitions related to injections. This may be demonstrated by a reduction in unhelpful cognition content, intensity and frequency, and/or an increase in helpful cognition content, intensity and frequency both during treatment and at post-treatment. It was also expected that these gains would be maintained over a one- and three-month follow-up period.

Three major changes were assessed including changes in cognition content, intensity and frequency of helpful and unhelpful cognitions related to injections. Regardless of the condition, the most common thought related to the physical pain of the injection and that something will go wrong. As an example of each change, baseline results showed that Elena reported “It will really hurt” with an intensity score of 8.5, which changed to 3 at post-treatment and 2.5 at follow-up. Others replaced this unhelpful thought altogether with something like “It hurts, but not as long and as much as I think” (Hayley), whereas some thought “It will be okay” (Lyla and Jenna) and “I’m going for a swim afterwards” (Aroha). Cognitions that were the most resilient at follow-up related to receiving a reward and the continued belief that the injection will *not* hurt forever. Group analysis showed that CT was the most effective at improving cognition content, intensity and frequency related to injections, closely followed by CBT. BT showed minor changes in cognition content, intensity and frequency.

2.1 It was expected that carers in all three conditions (CBT, CT and BT) would self-report a reduction in distress and avoidance symptoms, in addition to an increase in their own ability to cope as well as the ability to help their child cope both

during treatment and at post-treatment. It was expected that these treatment gains would be maintained over a one- and three-month follow-up period.

Compared to baseline scores, treatment resulted in large improvements for some carers. The exception to this included those who reported low distress and avoidance levels (this was the majority) during baseline and therefore required very little improvement. Therefore, the following interpretation relates only to those carers that required improvement. General group analysis indicated CBT showed the most improvements in carer distress. The CT condition showed very little improvement for this domain, and only one of three carers allocated to the BT group showed positive changes, although this was due to the other two carers exhibiting low distress levels from the outset. Follow-up results showed that carers in all groups tended to display small improvements, with the exception of carers in the CT group where levels remained fairly high for avoidance and in some cases distress. Similarly to child reports, carer coping and their ability to help their child cope improved gradually across all three treatment conditions.

Consideration of clinical significance is an important aspect in assessing treatment outcomes in psychological research (Comer & Kendall, 2013), so it was imperative that the study results were also interpreted within this context.

Clinical Significance of the Findings

Clinical significance refers to the magnitude of intervention effects in relation to the difference treatment makes in the everyday functioning of the client (Kendall & Grove, 1988). According to Kendall and Grove (1988), clinically significant change can be evaluated using general impact level assessments, for instance meaningful changes observed by important people such as parents, thus providing a strong rationale for the inclusion of carer data. Another indication of clinically significant change involves the use of assessment target levels such as normative comparisons (e.g., clinical cut-offs, behavioural observations and self-report instruments). Jacobson, Follette, and Revenstorf (1984) defined this type of clinically significant change as the extent to which therapy moves someone outside the range of the dysfunctional population or within the range of the functional population.

Assessment of target levels using clinical cut-offs were not used in the present study for a number of reasons. Due to this research using non-normed assessment measures, it was difficult to determine if the results showed clinically significant change. Instead, cut-offs based on previous research were used for the VAS scale as explained in the Method chapter (i.e., five on an 11-point scale). The possibility of using data from the pilot study as a way to estimate clinical cut-offs was also not viable due to the assessment measures being modified. For instance, not only were questions re-structured, included or excluded, but the scales were changed, making comparisons difficult. Instead, the level of clinical significance was obtained using anecdotal feedback from the child and carer regarding treatment outcomes (general

impact level assessments). Observations from the therapist were also used to identify meaningful change in the participants. These sources of information are also recommended as important for determining clinical significance (Kendall & Grove, 1988).

Perhaps most importantly for judging clinical significance, all 11 families stated that they would recommend this treatment to other friends and/or family members, with some having already endorsed the treatment programme resulting in several additional referrals. Furthermore, all 11 participants completed the injection procedure during sessions four and five, with none requiring physical restraint. This is despite over half of the participants (6 of 11) having been physically restrained for injections prior to therapy. During one- and three-month follow-ups, many of the children (8 of 11) also continued to receive regular injections, most of which were successful compared to pre-treatment. Additionally, many of the children had avoided injections for many years or taken between 45 minutes to two hours to complete the procedure, but these aspects improved considerably at post-treatment. As an illustration, Elena had avoided up to seven injections over the past 18 months, although as part of therapy completed two oral injections. Hayley was extremely distressed by methotrexate injections and refused to receive them prior to therapy. However, during session four, she completed the procedure in less than 10 minutes with mild distress and continued to receive methotrexate injections on a weekly basis during follow-up. These two cases perhaps provide some of the most compelling evidence for the clinical significance of this study.

For other children, instead of overcoming their behavioural avoidance toward injections, they reduced the time it took for them to complete the procedure. For example, Wiremu took two hours to complete the injection prior to therapy, but as part of the programme completed it in less than five minutes with little or no distress. In other cases, there were more minor improvements such as the child displayed less disruptive behaviour (swearing, screaming and hitting), watched the procedure for the first time (instead of looking away) and/or went into the procedure really wanting to do well rather than trying to avoid it.

Further feedback from participants showed that, although they had learned skills to cope with injections, these skills were transferred to other medical procedures and situations in their everyday life. As an illustration, prior to therapy Jenna took approximately 20 minutes to complete insulin injections with a SUD rating of 3 out of 11 (11 being the highest distress). At the three-month follow-up, her SUD rating had reduced to 1 out of 11, and the injection took approximately one minute to complete. Insulin injections are also no longer disruptive to the entire family whereas prior to therapy, evening dinners would be delayed and/or the family had to cease all activity while Jenna self-injected (e.g., turn off the television or stop talking). During the three-month follow-up, she also reported that therapy had “helped with my self-confidence in medical situations”, which was supported by her carer who outlined that her daughter’s “whole demeanour was less ‘stressy’ and that when she came to this counselling, it was a turning point for her”. Lastly, the family stated that they saw their paediatric endocrinologist in February 2013 (two months post-treatment), and that he reported a change in Jenna whereby she was taking more of an active role in her diabetes treatment and looked more relaxed.

Other improvements that were not formally assessed but were observed and reported throughout the intervention included an enhanced relationship between the child and carer. Carers described during therapy and at follow-up that they were talking more with their child about health topics and that they had an increased understanding of psychological processes. For example, “very helpful process for me, by giving me strategies to focus on” (Lisa’s carer). Similarly, other carers came to understand their child’s situation more and exhibit feelings of empathy rather than frustration including Elena’s carer who developed alternative coping thoughts like “Calm down, she can’t help it” and “Tell myself I know she is unable to control her fears of needles” (Elena’s carer). Some children had also become more accepting of other medical encounters including routine check-ups at the hospital (Lyla, Lisa and Jenna) and dental appointments involving oral injections (Lyla). Lastly, Aroha’s carer reported that using the same therapy method when it comes to taking oral medication has been very effective.

Aside from these benefits gained by the families, health professionals including general practitioners, nurses, paediatricians and dental assistants were all interested in the research and enquired about referring more children for therapy. Observations regarding the role of health professionals in these children’s lives revealed a crucial need for teamwork. Chronically ill children receive medical treatment for a substantial amount of time, therefore working as a team with the family, health professional and clinical psychologist is essential. Effective and open communication is essential for this group, successful and collaborative relationships within medical health settings.

Overall, general feedback from the families regarding the treatment manual was positive, with some describing it as giving them hope, and a way forward when there was none before. Furthermore, not only have the positive impacts of this study been seen in relation to injections, but also in other medical encounters, child-parent relationships and the carers’ increased understanding of psychological processes and empathy for their child’s situation.

Interpretations and Implications of Intervention Phases

The following section discusses the findings in relation to common themes that emerged in the data, relative to past literature. Implications for research and clinical practice are also noted.

Baseline Improvements: Assessment as an Intervention

Psychological assessment interviews may have therapeutic effects for clients. Traditionally, clinical assessments are focused on identifying presenting problems and collaboratively developing treatment goals (Westbrook et al., 2011). Therefore, assessment and intervention activities are inextricably linked through diagnosis, case formulation, treatment planning and monitoring (Hunsley & Mash, 2010). Some researchers have placed emphasis on the therapeutic effect the assessment process can have for clients and important others in their

lives (Finn & Martin, 2013). Evidence accumulating over the past 20 years suggests that this effect can be substantial.

Finn and Tonsager (1992) were one of the first researchers to demonstrate the therapeutic effects of assessment. They showed that assessments can produce a significant drop in symptoms and increase in self-esteem. More recently, a meta-analysis of outcome studies suggested that psychological assessment procedures have positive and clinically meaningful effects on treatment when they are personalised, collaborative and involve test feedback (Poston & Hanson, 2010). Five key processes of assessment may explain these powerful therapeutic effects, including that assessment can (1) dramatically change the way clients view themselves, (2) incorporate empathy and the experience of being understood, (3) the use of psychological tests can act as empathy magnifiers, (4) carers see their child more accurately and understand their needs, and (5) facilitate change without overwhelming the client (Finn & Martin, 2013). These phenomena may have been present in this study, and although the exact processes that led to these changes are unknown, several hypotheses are suggested.

Three children who participated in this study substantially improved following the assessment interview process. The first such child was Flynn, who showed large reductions in NRD symptoms following a second assessment in January 2013. After this process and to ensure that changes were being maintained, four additional weeks of baseline measures were collected which showed a consistently low level of distress. The child also completed a successful blood test during this time. Several explanations for this change are possible.

Unlike participants who did not improve following the initial assessment, Flynn had a finger prick on the 21st December 2012 and an injection on the 29th January 2013 during the baseline period. The second procedure was not without complications, where the nurse injected him three times (arm, elbow and hand) due to being unable to find the vein. Despite this, feedback from his carer and the psychometric measures showed that he coped effectively as these injections provided an opportunity for him to practice using the procedure. Flynn's carer attributed the change in distress levels to a number of other factors that were not present prior to taking part in the study.

Factors not present prior to treatment included acknowledging and normalising Flynn's feelings (in particular being scared) as well as, obtaining more information and having an increased understanding about the procedure. The carer also expressed that completing the questionnaires was helpful as they initiated discussions about injections and associated thoughts and feelings within the home environment. Flynn's carer also had an injection prior to his procedure on the 29th of January and modelled adaptive coping strategies while remaining calm. The carer ensured there was no physical restraint of Flynn and provided some positive reinforcement afterwards (e.g., going to the park or eating pizza). It was also reinforced that he was brave and the carer was honest with him regarding the possibility of pain. For instance, it was explained that "It will hurt just a touch", whereas in the past nurses have told him that it would not hurt at all. Further investigations revealed that, this time, the nurses were informed about Flynn's distress, so they explained clearly what was going to happen, and allowed extra

time to ensure that he was breathing calmly and was relaxed. Lastly, the child's coping style changed. Flynn no longer monitored the injection, but utilised an avoidant coping style where information associated with injections was replaced with less distressing stimuli (e.g., looking out the window). Even though an avoidant coping style is traditionally seen as maladaptive and perpetuates the fear cycle, some researchers suggest that there is no clear coping pattern that is consistently superior in promoting adaptation to distress (Bernard et al., 2004; Walco, 2008).

The second child to considerably improve after the assessment interview was Lyla. Enquiries about this abrupt change indicated that she "Feels much better about having an injection after having talked about it". Another reason could be due to her rating anticipatory distress as lower than actual distress. This was supported by her carer who expressed that Lyla would be highly distressed if she was required to have an injection, upon which Lyla agreed.

Similarly, Sam also expressed that he improved during baseline because "Talking about injections made me feel better and completing the measures each week helped me to cope". Several other reasons could also have contributed to this change. For example, due to being diagnosed with mild Asperger's syndrome, inclusion in this study was contingent on the child's ability to engage in therapy and develop a collaborative relationship with the therapist. It was determined during the assessment that Sam's diagnosis was not a barrier to him taking part in the study or overcoming NRD, which was immediately explained to the family during the same session. These comments alone may have enhanced the child's self-efficacy and changed the way he viewed himself. Lastly, although Aroha did not improve following the assessment interview, her carer expressed that completing the measures was helpful as they initiated 'needle talk' within the home environment.

Overall, rather than one specific factor of the assessment interview resulting in therapeutic effects, a number of processes may have been operating including exposure by talking about injections, changing the child's view of themselves and their ability to cope, as well as acknowledgement of the child's feelings. More complex processes such as case conceptualisation was also evident during the assessment interview, in which case the therapist provided some explanation about how the problem developed and why the child was experiencing symptoms at that point in time. Treatment options were also discussed during the assessment stage, with the therapist offering suggestions to alleviate distress while providing test feedback on initial assessment measures. An accumulation of these factors may have resulted in the assessment becoming more of an intervention for some families.

Distress Domain

Between-Group Distress Patterns

Distress patterns provided the greatest insight into which therapy components resulted in changes at what point in the programme and were the most effective. Even though these patterns were not evident for the avoidance, coping and cognition domains, they were noteworthy in guiding future research.

Distress measures from the first two (BT and CT) or three sessions (CBT) stayed relatively consistent with baseline scores for distress. Depending on the treatment, session content included either psycho-education, emotive imagery, calm breathing, muscle relaxation and/or low-level exposure tasks. Thereafter, distress mostly improved in session three (CT and BT) and/or four (CBT) for the majority of children. Due to the CBT condition involving six sessions and the other two conditions comprising four sessions, this represents just over mid-way through therapy for each case. Techniques incorporated into these sessions varied depending on the treatment condition and included a mock needle injection with medical equipment (CBT – session four; BT – session three), and cognitive restructuring (CT – session three).

Since distress reduction appeared to be concurrent with the introduction of active treatment elements, based on the results it might be suggested that the first one or two sessions of all three conditions could be excluded from treatment, assuming there is no accumulation of effect over earlier sessions potentiating the effect of the later sessions. These results are consistent with the pilot study carried out in 2011, which developed and evaluated a six-session CBT for chronically ill children experiencing NRD (McIvor, 2011). A continuous measures approach was used in this study, showing that change did not occur until the end of therapy after medium to high-level exposure tasks were completed (McIvor, 2011). Further research to support these conclusions is limited as the majority of studies within this area focus on a single session excluding the use of continuous measures to indicate where change occurred most (Jay et al., 1985; Tyc et al., 1997). As an alternative, adult research literature was consulted which showed that exposure tasks alone can reduce adult needle distress from 38.3 (pre-exposure) to 15.4 (post-exposure) on a SUD scale from 0 (no anxiety) to 100 (maximum anxiety) (Thompson, 1999). One-session therapies based on exposure principles also support these conclusions with child and adult populations (Öst, 2001; Öst et al., 1992).

Regardless of the treatment, improvements during sessions three or four were large and rapid and were generally maintained in subsequent sessions. In most cases, gains in subsequent sessions led to further improvements during follow-up by enabling an opportunity for techniques to be implemented in multiple injection situations. This is consistent with previous single-case research which shows that child distress reduces even further when the child is repeatedly exposed to injections over time (Dahlquist et al., 1985; Jay et al., 1985). It is also consistent with the general principle in behavioural research that generality and durability of treatment effects only occurs when systematically planned rather than hoped for (Baer, Wolf, & Risley, 1989). The exception to this was the CT group where results clearly showed that although session three resulted in a large reduction in distress, this increased again in session four (which included the first exposure to injections during therapy). Initial reductions may indicate that therapy had a large influence on actual distress levels, but these gains were unlikely to be maintained for three of four children as discussed below.

Patterns of distress also differed in other ways across the three groups. Even though particular sessions produced more change than others, distress tended to reduce more

gradually for the BT group. The reason for more gradual reductions in distress may be due to therapy being structured so that exposure tasks were introduced across a number of sessions according to the child's fear hierarchy from least to most distressing. Therefore, habituation occurred over a longer period of time in contrast to the CBT and CT conditions, where therapy was structured around cognitive and/or behavioural tasks with session content switching between these two modalities. Results for the BT group showed that two of the three participants had large reductions in distress and that these treatment gains were maintained at follow-up.

Overall, sessions that produced the most change incorporated medium-level exposure tasks as well as cognitive restructuring. These patterns of distress were consistent with previous single-case research using a continuous measures approach described earlier (McIvor, 2011). Receiving continuous injections during follow-up also appeared to reinforce treatment gains, perhaps due to prolonged practice effects. Regardless of the treatment, improvements were large and rapid and were generally maintained in subsequent sessions with the exception of those receiving cognitive therapy. Reductions in distress were most likely to be maintained or improved further in final therapy sessions and follow-up assessments.

Within-Group Distress Patterns

In addition to between-group distress patterns, there were also different patterns within treatment groups, which may be due to variations in participant profiles and the case history of each child. In relation to the CBT group, three participants reported a similar pattern of distress reduction. However, this was not the case for Tamati, who showed an entirely different pattern where distress levels remained high during treatment and follow-up. Carer self-report of child distress also showed that distress relapsed during the follow-up phase close to baseline levels. This may have been influenced by a number of different factors including the therapy being piloted with this participant, the child having a traumatic injection during therapy, carer distress already being quite high, and the presence of carer-child relational difficulties. Finally, Tamati was the only participant to not complete homework tasks.

Within-group variations for CT were non-existent during the baseline and treatment phase. This may be due to these children all being female and of a similar age (three aged 10 years, and one aged 12 years). However, one- and three-month follow-ups revealed a clear divide within the group, with three of four participants relapsing close to baseline levels. There are six factors that might provide an explanation for these results.

First, cognitive components alone may not be sufficient to reduce NRD once therapy has finished and the child is in their natural environment without therapist support. Even one of the very few studies in this field to research cognitive factors also incorporated applied tension and basic exposure to assist with restructuring maladaptive thoughts (White & Sellwood, 1995). Second, families may be less likely to practice cognitive strategies compared to behavioural strategies outside of therapy. Blackburn and Davidson (1995) state that behavioural techniques are typically used at the start of treatment as problems best treated with these techniques are distressing for the client and can prevent therapy from progressing. It is also generally easier for

the client to master behavioural techniques (Blackburn & Davidson, 1995). Third, previous research suggests that in order for exposure to be effective in the long-term, habituation needs to occur over multiple exposure sessions (Olatunji et al., 2010; Wolitsky-Taylor et al., 2008). However, the cognitive group only received one exposure session, perhaps explaining why distress initially reduced and then relapsed when no further exposures were provided. Fourth, variations in the children's injection schedules could explain some of these divergent findings as different injections can have a different impact on distress (Thurgate & Heppell, 2005).

A fifth reason for why some participants in the CT group maintained treatment gains may be due to factors such as injection type and frequency, as these appeared to be one of the main variables that differed between the participants that succeeded in therapy and those that did not. For example, Jenna was one of the only participants to show successful results in the CT group. Her injection type and frequency included daily insulin injections and regular blood tests, thus differing considerably from the other participants who received different types of procedures (e.g., intramuscular injections – Hayley) and in some cases only a few times per year. It may also be directly related to the type of injection the child received once therapy had finished. For instance, some children received a number of different procedures during follow-up that were equally distressing, but for which they were unprepared (e.g., Hayley – methotrexate injections, Aroha – wart treatment, and Elena – went from an oral injection to a blood test at follow-up).

The sixth explanation is that it appears when certain children underwent cognitive therapy and key cognitions were restructured, then positive treatment outcomes were more likely to occur. Some suggest that client factors (e.g., motivation, attachment style, coping style, psychological mindedness and more) are crucial to influencing the relative efficacy and outcome of different types of therapeutic interventions (Blatt & Felsen, 1993; Bohart & Wade, 2013). Therefore, certain clients may be better suited to certain therapies. These factors will be further discussed later in this Chapter.

Of the three treatment groups, BT showed the most divergence across participants. This may be related to the broad age range of children that took part in this therapy group (7 to 13 years). Research shows that age and developmental stage strongly influence distress levels, with younger children exhibiting more distress (2 to 6 years; 83%) than older children (12 years and older; 28%) (Humphrey et al., 1992; Mclvor, 2011). This might explain why the two younger children in this group showed larger reductions in distress, as it was initially much higher and therefore had more room for improvement. Furthermore, due to these younger children receiving early intervention, their NRD may have been less pervasive over time and was perhaps less resistant to change. Differences in the type of medical condition, projected length of diagnosis and consequences of the condition may have also impacted on treatment outcomes by promoting barriers to therapy or influencing the child's motivation to change (Leventhal et al., 1997). These factors are likely to interact with age, as younger children may not understand the diagnosis and its implications regarding chronic treatment, particularly with regards to the implications for them and their distress and coping. Other children had been

diagnosed just prior to entering this study, therefore the length and consequences of their medical condition may have been unknown. This is combined with the fact that these children may have had less time for distress and avoidance to grow through experience and practice.

Carer Self-Report of Distress

Consistent with previous research, several carers were distressed while their child was having a needle injection (Smith, Shah, Goldman, & Taddio, 2007). Unlike child self-reports, patterns of carer responding were fairly consistent across groups. For instance, carers tended to rate their child as having higher distress than themselves, and that their child had larger treatment gains in terms of distress. Most carers also reported large reductions in their own and their child's distress only once they observed their child receiving an injection. Feedback from carers supported this interpretation indicating that they were initially sceptical of the treatment, although were convinced once they had witnessed the large change in their child when having an injection (and other medical encounters).

More general findings were that carers tended to self-report more gradual improvements compared to child self-reports, which were abrupt and usually resulted in key changes occurring in a single session. This may suggest that carers were more sensitive to changes in their affect without the need for external stimuli to provide some level of change. That is compared to children who tend to be more state-orientated and responsive to concrete observable stimuli. Therefore, instead of psycho-education resulting in positive changes for the child (as might be the case for the carer), they responded to specific sessions only such as role-plays and videos of mock injections.

Carer self-report of themselves and their child also showed very similar patterns of responding during the treatment phase. For example, when analysing data for the CT and BT conditions only, reductions in carer distress appeared to parallel reductions in child distress (and vice versa) at similar points in the intervention. Congruent with other research, this may suggest that, as the carer's distress reduced, so did the child's distress or vice versa (Mahoney et al., 2010). Alternatively it might be that when the carer was completing the measure they had difficulty separating their own distress from their child's distress (Keene et al., 2003).

Each treatment group also indicated patterns among individual participants. Most carers in the CBT group showed large reductions in their distress, the exception to this was Tamati's carer who reported an increase in sessions four and five during exposure tasks. The abrupt change in reporting may suggest that the child's injection was particularly distressing for this carer, however once this event was processed during the follow-up session, misconceptions were corrected leaving the carer with a more positive perception than previously held. This pattern was repeated in the CT group where certain carers reported a large reduction in distress in session three (Hayley and Jenna), followed by a large increase in session four, suggesting that, as well as the child being distressed by the injection, so was the carer.

Avoidance Domain

Results for the CBT condition showed child behavioural avoidance reduced during treatment and at follow-up. This was consistent with previous research investigating the effectiveness of CBT in alleviating behavioural avoidance of injections (McIvor, 2011; Mohr et al., 2002). All four children successfully completed their in-vivo injection during session five, with three exhibiting little to no behavioural avoidance. This was a considerable improvement, as carers reported during baseline that all four children had attempted to avoid their most recent injection. Closer inspection of avoidance patterns for the CBT group revealed that, for some children, a reduction occurred mostly in session three (Tamati and Sam), while for other children it occurred in session four (Alyssa and Lisa). These patterns do not differ greatly but may suggest that the habituation process can occur at different stages in the therapeutic process or at slightly different rates for each individual child.

Results were not so promising for the cognitive group, which initially appeared to effectively reduce avoidance, but these gains were not maintained. Specifically, one participant showed reductions in avoidance that were maintained during follow-up, whereas the other three children either relapsed or showed no change at all compared to baseline levels. An explanation for the relapse in avoidance levels for Hayley may be due to her injection schedule altering substantially during session four and follow-up as mentioned previously. The BT condition showed a similar pattern, with only one child showing considerable improvements. These changes primarily occurred in session three when mock injection role-plays were carried out. These results are incongruent with previous research, which suggests that behavioural therapy is particularly effective at reducing avoidance (Wolitsky-Taylor et al., 2008).

Previous research suggests that carers tend to avoid situations that involve their child having an injection (Ayers, 2011; Samad, Butler, Peckham, & Bedford, 2006), which make intuitive sense considering that taking a highly resistant child to regular injections may induce avoidance of the situation. However, consistent with previous research (McIvor, 2011), baseline results showed avoidance was non-existent for the majority of carers in this study. An explanation for this may be that the consequences of avoidance for this particular population (chronically ill children) are fairly significant, thus motivating carers to overcome any tendency to avoid medical appointments. Furthermore, the small number of carers that did report some level of avoidance also reported high levels of distress and an aversion to injections on their own part. Carer changes in avoidance levels tended to occur at the same point in the intervention as their child. It might be the case that child and carer avoidance levels correlated with one another, or carers could not objectively rate their child's avoidance.

Cognition Domain

In psychological research, especially research into psychotherapy, children are not commonly included in the samples studied, and if children are included their thoughts are ignored or seen as unimportant. A key component of this research was to focus on the fact that

children do have thoughts and that they can be pertinent and realistic. As is the practice in cognitive therapy with adults (Westbrook et al., 2011), when the children's thoughts were deemed unrealistic or unhelpful, they were tested in therapy and work was undertaken towards restructuring them. At the same time, the tendency for children to experience unhelpful thoughts was normalised. Ultimately, even though this research showed that exposure activities were superior in reducing distress, cognitions should not be overlooked but asked about, validated when accurate, and techniques which provide helpful coping thoughts included in therapy.

NRD can be related to the attributions made regarding the safety and danger of the stimulus, perception of control over the situation and attributions regarding bodily reactions to the stimulus (Coelho & Purkis, 2009; Craske & Rowe, 1997). Congruent with previous research (Fassler, 1985; Fassler & Wallace, 1982; McIvor, 2011; Rice, 1993), these themes were consistently reported in the present study. An unexpected finding in the 2011 pilot study was that new helpful cognitions with a high intensity were reported at post-treatment, rather than the repetition of unhelpful cognitions at a lower intensity. Therefore, the goal of this study was to not only restructure unhelpful thoughts but purposefully develop new helpful thoughts. The effectiveness of utilising positive self-talk with NRD is consistent with previous research (Dahlquist et al., 1985; Kanfer, Karoly, & Newman, 1975; Uman et al., 2008) and current perspectives on the etiology of NRD (Coelho & Purkis, 2009; Craske et al., 2006).

CT showed the most improvements in cognitions related to injections, which was closely followed by the CBT group. Consistent with previous research, which suggests that in order to achieve cognitive change, treatment must directly focus on cognitive restructuring techniques, BT showed only minor changes (Butler, 1985; Heimberg & Barlow, 1991). On the other hand, this does not mean that only treatments that incorporate cognitive components result in cognitive changes as several studies have shown that this can be obtained with purely behavioural therapies (Mattick & Peters, 1988; Newman, Hofmann, Trabert, Roth, & Taylor, 1994), although this was not the case with the present study.

The content of cognitions was relatively consistent across treatment groups with only slight variations, perhaps due to the diversity among participants and the variation in therapies. Regardless of the condition, the most common thought related to the physical pain. This was closely followed by cognitions associated with procedural avoidance and something going wrong. Cognition content specific to the CBT group was related to health professional incompetence, while children in the CT group reported a negative attitude towards the health professionals. Other cognitions reported in the CT group were about their body being harmed and feeling hopeless. Due to cognitive development, younger children in the BT group typically reported thoughts related to catastrophic consequences and the visual appearance of the needle. Helpful cognitions that were the most enduring during follow-up related to receiving a reward and the belief that the injection will not hurt forever. This suggests that, once therapy has ended, one of the ways in which carers can maintain treatment gains for their child is to continue providing incentives and restructuring thoughts related to pain.

The suggestion that cognitions (of the maladaptive kind reported above) contribute toward child distress is consistent with previous research (Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Lynn, 2010; Mathews, 2011; Rice, 1993; Thurgate & Heppell, 2005; White & Sellwood, 1995). Possible reasons for why pain cognitions cause the most distress is that injections actually do hurt, making this cognition realistic (Lewis, 1978). However, within the context of working with chronically ill children, it may not be the content of the cognition that is maladaptive, but the intensity at which the child believes the injection will cause pain. The present findings support this hypothesis, with the majority of participants reporting cognition intensity related to pain reduced at post-treatment once thoughts were challenged directly through exposure. For instance, the CT group completed a pre- and post-injection SUD rating showing anticipatory pain was much higher than actual pain. Likewise, the thought about something going wrong may be legitimate considering procedural complications can occur.

Consistent with previous research, rather than a fear of the injection itself, it can also be a fear of the consequences that increases NRD symptoms (Mathews, 2011; Olatunji et al., 2010). For example, results from the 2011 pilot study and other research showed that the choice to cry without feelings of disapproval from medical staff was very important for some children and reduced their distress (McIvor, 2011; Öst, 1992). As an illustration, in the present study, Jenna (10 years) expressed during therapy “Will they make fun of me?” and “Will they think I’m a wuss or wimp?”. Anecdotal feedback from an adult in a previous case study traced his needle phobia back to childhood inoculations in which he reported “I was treated like a baby and a wimp – doctors insulted me for being so uncooperative and I distinctly remember being restrained” (Lynn, 2010, p. 46). Mathews (2011) also showed among adults that there is a sense of shame and embarrassment over the inability to master something as simple as a needle injection. Loss of trust in health professional competence was also a factor and may be due to children’s concerns or choices being ignored (Thurgate & Heppell, 2005; Willock, 2004). Lastly, the presence of biases in information processing including attentional and inferential judgements was also consistent with previous research (McIvor, 2011; Merckelbach et al., 1996). For instance, younger children (8 years and under) tended to report catastrophic consequences (e.g., “I’m going to die”) or report cognitions related to the visual appearance of the needle being significantly longer and larger than it actually was (Lyla and Wiremu).

Despite similar themes emerging across treatment conditions, thought content was also very different for some children, which could be due to the diversity among the sample. For example, less common themes were related to feeling hopeless about their situation and thoughts related to their body becoming harmed. For some children, feelings of hopelessness might have been related to their chronic health condition (Hayley), while for others could be due to their severe phobia of injections (Elena). Results suggested that children who exhibited this emotion were less likely to show improvements at post-treatment and follow-up. Thoughts related to their body becoming harmed were reported by some children, with previous research suggesting children may feel an invasion of their body due to a foreign object penetrating their skin, feeling overwhelmed, attacked and/or uncertain about the integrity of their bodies (Fassler

& Wallace, 1982). These thoughts occurred irrespective of the developmental stage as children aged 8 to 13 years reported these fears.

Overall, several changes in cognitions were evident. Even though a reduction in the intensity of unhelpful thoughts resulted in some positive outcomes, the development of helpful thoughts appeared to be an important component for change. During treatment, the most common cognitions across groups were related to pain, procedural avoidance and something going wrong. The need for autonomy and opportunity to express thoughts and feelings without judgement from health professionals was also important and consistent with previous research (Lewis, 1978). In order to maintain treatment gains, findings showed that it is beneficial for carers to continue providing incentives and restructuring thoughts related to pain. Anecdotal feedback from participants outlined the usefulness of cognitive components, as skills learnt in therapy could be used for other situations as well (e.g., hospital check-ups and dental appointments).

Coping Domain

Treatment phase data suggested that coping gradually improved over a number of sessions across all three therapies. These outcomes are in contrast to distress and avoidance, which predominantly improved in particular sessions. It may be the case that as children progressed through treatment their confidence and self-efficacy to cope with injections increased as new strategies were introduced, rather than distress which tended to reduce only once they were exposed to injection-related stimuli. The minor increases that occurred in certain sessions were also at different points in the intervention across participants, perhaps suggesting that each child responds differently to various types of coping strategies. Research provides further evidence for this conclusion as coping styles tend to vary across individual characteristics (e.g., temperament, gender and age) and situations (Walco, 2008). Due to coping improving gradually regardless of the treatment condition, it might also be suggested that using either cognitive or behavioural techniques rather than a combination of both is enough to improve coping. This is in contrast to previous research which suggests that a mixed-focus intervention is the superior option for paediatric populations with NRD (Bernard et al., 2004; Blount et al., 1991; Walco, 2008).

Treatment gains across all groups were also very stable across time, with coping being maintained or improved further at one- and three-month follow-ups. This may be due to the gradual increase in coping ability and generalisation outside of session, rather than rapid and session-specific improvements as was seen with distress and avoidance. Improvements in these areas also typically occurred towards the end of treatment. Research suggests that early and (within the first three sessions) positive changes in therapy are strong predictors of final treatment status as well as follow-up status (Haas, Hill, Lambert, & Morrell, 2002).

When comparing these results to the Coping Behavior Questionnaire (CBQ), there were some discrepancies, however this might be influenced by administration timing. For example, due to the observational nature of this measure and it primarily being administered in sessions

four and six, changes were mostly seen towards the end of therapy after the in-vivo injection (session six only). Follow-up results showed even more change once the carer had seen their child have multiple procedures. Compared to baseline levels, the majority of children were cooperative, followed instructions without complaining, engaged in conversation and asked questions about the procedure. These findings are consistent with previous research utilising the CBQ to assess changes in child coping behaviours in relation to injections (Kleiber & McCarthy, 2006).

Written information obtained from the NIQ-C showed children reported very few coping strategies prior to therapy other than receiving support from their carer, using distraction or crying/screaming. These are all pre-treatment coping strategies seen in other studies (Hodgins & Lander, 1997). Adaptive coping behaviours that children reported were either behavioural (e.g., breathing, muscle relaxation, rewards and distraction) or cognitive (e.g., helpful thoughts, emotive imagery and/or information provision). These are all consistent with the coping strategies reported in previous research (Hodgins & Lander, 1997; Willock, 2004). Similar to Buzzy Bee (Baxter et al., 2011) and Dittens (Miller et al., 2008; Miller et al., 2010) described in previous research, some children also utilised iPads and iPods as distraction devices. Less concrete strategies such as having control over the situation, being able to ask questions, knowing about the consequences of the procedure and how long it will last also helped many children to cope (Thurgate and Heppell, 2005). For instance, offering the child control over the injection environment is important such as where they will sit in the room, who they want to be present and the type of support they want (Thurgate & Heppell, 2005). Similar to previous research when children also rated what component they found the most helpful, behavioural tasks were favoured such as breathing and rewards (Jay et al., 1987; Uman et al., 2008).

An explanation for why breathing techniques were seen as the most helpful could be that behavioural strategies are typically easier for children to master and problems, such as anxiety, that are treated with this technique can be quite distressing for the child, therefore resulting in rapid improvements (Blackburn & Davidson, 1995). In particular, this may have been the case for younger participants (e.g., Tamati, Lyla and Wiremu) who primarily reported behavioural coping strategies across the intervention (e.g., sit behind mum, count the hairs on dad's hand and calm breathing). The implications of these findings, combined with the direct feedback from children regarding the helpfulness of calm breathing, provided evidence for the continued use of this technique within clinical settings for chronically ill children with NRD.

Coping strategies reported by carers prior to therapy were in some cases unhelpful, such as physical restraint, bribery or pretending to bang their head on the hospital wall. However, these were eliminated towards the end of therapy and, in most cases, carers were utilising positive behaviours aimed to benefit themselves, their child or both. For example, more instances of calm breathing were reported, as well as challenging their child's unhelpful thoughts and suggesting more helpful ones, information provision, letting their child do it their way and having faith that their child can do it. Some of these changes were consistent with previous research, which showed that carers reported increased instances of reassurance and

calm breathing at post-treatment (McIvor, 2011). However, the components that carers found most helpful in this study were in contrast to other research. For example, Jay et al. (1987) found that carers thought receiving a reward was the most helpful technique with behavioural rehearsal being the least effective (injection role-plays), whereas these preferences were reversed in the present study.

Overall, baseline scores of the NIQ-P coping domain suggested that carers already had pre-existing coping strategies to deal with injection situations. However, the carer's ability to help their child cope improved at post-treatment, suggesting it was important for them to be involved in therapy. Lastly, compared to distress and avoidance where child and carer scores differed considerably in the final therapy session, coping scores tended to end at the same level on the VAS scale.

Explanations for Relapse at Follow-Up

Demonstrating that treatment benefits are maintained over time is extremely important for the practice of clinical psychology (Lambert, 2013). At one- and three-month follow-up, four participants had relapsed including Aroha, Hayley and Elena (CT – 10 years), and Kala (BT – 13 years). Tamati (CBT – 9.5 years) continued to report NRD symptoms throughout therapy so technically did not relapse during follow-up. Several factors contributing to relapse need consideration with respect to these results, some of which are general and others specific to the participant.

More general factors relate to variations in exposure to injection-related situations outside of therapy. Recent meta-analyses conclude that exposure techniques are the preferred treatment for phobia-type symptoms (Olatunji et al., 2010; Wolitsky-Taylor et al., 2008), as they may result in extinction of the conditioned response and habituation of physiological arousal, while at the same time correcting maladaptive catastrophic beliefs (Powers et al., 2005). As an illustration, Kala was diagnosed with rheumatoid arthritis a few months prior to entering this study thus had only just started monthly blood tests (she had received two in total). This time period provided little opportunity for habituation, particularly due to some of the injections being traumatic for Kala and perpetuating her fear of injections. In comparison, several participants who received injections on a more frequent and long-term basis had positive treatment outcomes (Alyssa, Jenna and Lyla). It might be that differences in injection frequency and therefore the habituation process could account for some participants relapsing. A number of other individual child factors may have been influential.

As mentioned above, Kala's (13 years – BT) relapse could have been due to being newly diagnosed with rheumatoid arthritis in September 2012, upon which she began having monthly blood tests, an otherwise unfamiliar procedure for her. This diagnosis also led to subsequent changes in her life. For instance, she had been absent from several school activities (especially sport-related) and experienced a sudden increase in medical appointments. Therefore, rather than NRD being the primary problem, perhaps dealing with her recent diagnosis and subsequent grief over the loss of her existing life actually needed to be the

therapy focus. During the one-month follow-up assessment, she also expressed many unhelpful thoughts related to her inability to have the injection as well as the belief she was “Not that sick” and “Does not require injections”. The last thought in particular could explain why Kala behaved the way she did towards health professionals (e.g., angry, non-compliant, non-committal, abrupt, and intolerant of the injections). Some of Kala’s barriers to recovery may also be understood using Leventhal and colleagues’ (1997) description of illness perception, including factors such as illness cause, the predictive belief about how long the condition will last for, the consequences of the condition, and whether it can be kept under control. When considering these factors, it might be the case that behavioural therapy was unsuitable for this adolescent, and instead a therapy approach aimed at illness perception and grief may have been more beneficial.

The first child to show relapse in the CT condition was Hayley, perhaps due to her injection schedule being unexpectedly modified in session four. Prior to entering this study, Hayley received oral medication for arthritis, so the goal of therapy was to cope with an upcoming blood test instead. However, once it was perceived by her parents that she was less distressed, she resumed weekly arthritis injections which enabled better absorption than oral medication. These procedures are intramuscular and for some patients physiologically cause more pain due to the depth of insertion (Mohr et al., 2002). Baseline measures were also rated in relation to Hayley receiving a blood test and the initial goal of therapy aimed towards this procedure. Therefore, session four and follow-up results are not comparable to baseline scores. Hayley’s increased distress levels may also be attributed to the high level of actual pain she experienced upon exposure to this procedure, which could also provide a rationale for her not habituating. Nonetheless, despite Hayley’s distress relapsing, adaptive coping gains were maintained.

Elena (10 years) was the second participant allocated to the cognitive condition who showed considerable relapse at follow-up. The injection schedule for Elena was not modified, nor was she diagnosed with a chronic condition just prior to entering this study. The relationship she had with her carer was also adaptive and no other psychological issues were reported during therapy. However, the NRD symptomology that Elena presented with was more pervasive compared to other participants, and may have met the DSM-5 criteria for blood-injury-injection phobia. There were seven circumstances in the past where she had successfully avoided injection procedures: three blood tests and four oral injections. Furthermore, the success of the injection during therapy was not completely without complications; although her first oral injection took less than five minutes, her second injection took approximately one hour to complete. This was due to Elena believing that the second injection was going to hurt more than the first. After therapy, she expressed that, although she is now able to have oral injections, she continues to be fearful of having a blood test (SUD rating = 10 out of 11). Literature suggests that a pervasive pattern of specific phobia in children/adolescents may require more exposure and therapy (e.g., up to 13 sessions of CBT) (Thompson, 1999). This might explain why four sessions of cognitive therapy was initially effective, but resulted in

relapse once Elena was in her natural environment and presented with different types of injection procedures.

Aroha was the third child in the CT group to relapse, although this primarily occurred at the three-month follow-up. Relapse scores were also replicated in the carer's self-reports. Investigation revealed that at the one-month follow-up Aroha had successfully received an injection with little to no distress, however during her three-month follow-up received burn treatment for warts. Due to this being a different procedure to injections, her carer outlined that no preparation was made prior to the medical appointment. However, Aroha reported that the high level of distress experienced from this procedure transferred onto injections, increasing her NRD symptoms. Similar to Elena, it might also be the case that Aroha met the DSM-5 criteria for blood-injury-injection phobia.

Patterns of distress and coping for Tamati (9.5 years – CBT) were considerably different to other participants. For instance, Tamati reported no change from baseline levels during treatment, while his carer reported relapse at follow-up. Reasons for this may be due to several factors. Not only was the therapy piloted with Tamati, but he also completed draft assessment measures, which were later modified and then completed twice again within a one-week period. This process may have impacted on obtaining an accurate level of distress during the baseline phase (Kazdin, 2011). Tamati also had a particularly distressing experience during the therapy injection in session five, this is significant as previous trauma experiences can be very memorable for children (Duff & Brownlee, 1999; Noel et al., 2012). There were also few opportunities for the procedure to be corrected once therapy had finished due to no follow-up injections scheduled for this child.

Relational difficulties between Tamati and his carer may have also impacted on treatment outcomes, particularly because these issues were not addressed in therapy due to research protocols. An abundance of literature points to the importance of carer-child interactions and how they can result in even more anxiety and distress for both if they are problematic (Blount et al., 2009; Claar et al., 2008; Frank et al., 1995; Mahoney et al., 2010; Schechter, 2007). Compared to other carers, distress levels for Tamati's carer were in some cases over 50% higher in sessions five and six. Lastly, Tamati was the only child to not complete homework activities, nor did the child and carer practice techniques outside of therapy. Research suggests that those who complete homework tasks show greater improvement than those who do not, partly due to the increased opportunity to generalise session content into everyday life (Broome et al., 1998; Westbrook et al., 2011). There is also the possibility that the therapist was less proficient with therapy for Tamati due to this child being the first participant to take part in the study.

Overall, the severity of NRD (or DSM-5 diagnosis of blood-injury-injection phobia), variation in injection type and frequency, family dynamics, success of the injection during therapy and overlooking issues aside from NRD may be strong risk factors for relapse. Nonetheless, more conclusive evidence is required for these hypotheses to be supported.

Interpretations and Implications of Other Variables

Consistency between Child and Carer Self-Reports

While multi-source evaluations are recommended in the psychological literature in order to obtain thorough information (Klein, 1991), results of this study highlight some of the problems with this approach. Findings showed that the majority of carers had a tendency to over-estimate child distress and avoidance and under-estimate child coping during the intervention, particularly in relation to their child's levels of distress during the injection session. Furthermore, for some participants, carer self-reports were opposite to child self-reports (e.g., Aroha and Lyla's carers on the avoidance domain), whereas for others, both self-reports were fairly consistent (e.g., Wiremu's carer for distress and avoidance).

When making comparisons between child and carer self-reports for specific participants, there were a number of discrepancies. Some carers also reported that child treatment gains were maintained at one- and three-month follow-ups despite the child indicating completely opposite results. For example, Hayley reported a large relapse in her distress scores at one- and three-month follow-ups, while her carer reported improvements. This inconsistency may be related to Hayley's carer being pleased that her child is now able to complete methotrexate injections, a procedure that the child was opposed to, but was unexpectedly required to have towards the end of the treatment.

These findings are consistent with previous research in which the incongruity between child and carer self-reports has been noted (Engel et al., 1994; Keene et al., 2003; Klein, 1991). Possible explanations as to why there was such a large amount of over- and under-reporting may be that carer distress influences responses given on self-report measures. For example, Keene et al. (2003) found a strong positive correlation between carers' anticipatory anxiety and their perceptions of pain, fear and distress. This indicates that, the more anxious the carer was about the procedure, the more painful they perceived the injection was for their child, as well as the more fearful and distressed they thought that their child would be. More recent research supports this by indicating that carers consider injections that involve their child to be one of the most distressing events in hospital settings (Ayers, 2011), perhaps due to other procedures such as surgery typically not being witnessed by family members.

Overall, the discrepancy between child and carer self-reports validates the need to directly ask children regarding their own symptoms and behaviours. Future research should include the use of child self-report measures in order to cross-check carer self-reports of child NRD symptoms.

Different Therapies for Different Ages

Treatment responses varied according to developmental stage. For instance, children less than 8 years struggled with the cognitive component of therapy while older children were able to identify thoughts, grasp the concept that thoughts were under their control and then use

these to regulate their behaviour. Symptom reporting also varied, with younger children (Lyla, Wiremu and Tamati) sometimes reporting large and abrupt polarised changes, meaning scores were either at one end of the scale or the other. The same reporting pattern was displayed in the pilot study (McIvor, 2011). Even though children in the middle of the age-range reported more gradual changes, variations continued to be quite abrupt (Aroha, Elena, Hayley, Alyssa and Jenna). In contrast, children in late childhood/early adolescence (Sam, Lisa and Kala) reported more gradual changes with none moving from opposite ends of the scale within a single session or across two sessions.

Younger children also tended to report more behavioural symptoms compared to cognitive symptoms. When they did report thoughts, they were characterised by a mix of non-natural concepts of causation seen during the pre-operational stage of Piaget's Cognitive Development theory (e.g., "I'm going to die" and "All my blood is gone" – Lyla, 7.5 years) (Piaget, 1958). On the other hand, it might be the case that children in late childhood/early adolescence need both exposure and cognitive restructuring in order to alleviate NRD. For instance, Kala who was 13 years and randomised into the BT group showed less than promising results despite being continually exposed to injections during therapy, whereas Sam and Lisa were also both 13 years, but allocated to the CBT group and showed positive results.

The developmental theories of Piaget (1958) and Vygotsky (1981) provide an explanation for these patterns. According to Piaget's (1958) Theory of Cognitive Development, children progress through a series of stages: sensorimotor (0-2 years), pre-operational (2-7 years), concrete operational (7-11 years) and formal operational thought (11-16 years). Children during the concrete operational stage can reason deductively and problem-solve, while for children in the pre-operational stage, learning is concrete (i.e., dependent on observable events) and marked by reductions in egocentricism (i.e., an understanding that others have different thoughts and feelings than their own). Another influential development model is that of Vygotsky (1981), which suggested cognition and action are fundamentally social, and that language has a key role in the regulation of action. Therefore, the consistent and stable self-reporting observed by older children in this study may be explained by the fact they have developed the language skills crucial for the development of meta-cognition, and so can understand the questionnaires more adequately (Piaget, 1958; Vygotsky, 1981).

The idea that thought and language are connected has implications for the age-appropriateness of CBT (Kingery et al., 2006). Combined with the results of the present study, it is likely that different therapies are more suitable for different ages. Further research could formally adapt the treatment manuals according to the following age groups: BT for young children (less than 7 years), and CBT for middle (8-12 years) or late childhood/early adolescence (over 13 years). However, this should not be considered a prescribed and inflexible approach as more recent developmental research indicates there are likely to be large individual variations at any given chronological age (Bolton, 2005). These tend to be dependent on many factors, including temperament, social and family context.

The Art of Doing Therapy: Therapist Experience

Literature on the effectiveness of experienced versus inexperienced clinicians has been debated for several decades. This disagreement combined with the lack of research since the 1990s, and the use of inappropriate designs to adequately address differential effects between these two constructs, has made definitive conclusions difficult (Lambert & Ogles, 2004). It has been suggested that with the exception of a few superior studies, little empirically solid data has been added to the debate over whether clinical experience makes a difference in client outcome (Hill & Knox, 2013; Lambert & Ogles, 2004). Nonetheless, promising findings from Stein and Lambert's (1995) meta-analysis suggest that training may make a difference in terms of client satisfaction, drop-out rates, and pre-post testing on psychological measures.

Results from the present study suggest that therapist experience in terms of hours/months of client contact time and familiarity with implementing the treatment manual may have impacted on treatment outcome. In order to provide more information in this regard, results for the first and last half of participants were analysed (i.e., two groups of six). Participants were separated into either group based on their assessment, baseline and therapy start date. In order of start date, the first six participants included Tamati, Alyssa, Lisa, Elena, Wiremu and Hayley, and the last six participants included Kala, Jenna, Flynn, Aroha, Lyla and Sam.

At follow-up, three of six children (Tamati, Elena and Hayley) within the first half of the treatment had less than promising results, whereas only one of six children (Kala) in the second half of the treatment showed the same pattern. The remaining children who participated in the second half indicated relatively promising treatment results (Jenna, Flynn, Aroha, Lyla and Sam), with three of them improving considerably following the initial assessment interview. This pattern may suggest that, as the therapist gained more clinical experience and became more proficient with the assessment process, as well as administration of the treatment manual, that participants were more likely to show encouraging results early in the treatment process. This is particularly important considering the therapist was in the second year of clinical psychology training, and that her continuing exposure to assessment and therapeutic processes may have had more of an impact on proficiency than might be the case for an experienced clinician who had already established these skills. A study by Driscoll et al. (2003) supports this hypothesis and showed that *trainee* therapist experience, in terms of client contact time and exposure to therapeutic processes, was positively correlated with treatment outcome.

Therapeutic Alliance and Treatment Outcome

In the past three decades research findings have repeatedly demonstrated the therapeutic relationship as perhaps the most important common factor to the therapeutic process (Christoph, Gibbons, & Mukherjee, 2013). Despite this, there are mixed views on the influence of therapeutic rapport in treatment outcome research (Christoph et al., 2013). Even though, meta-analytic reviews indicate there is substantial evidence for a link between the

alliance and treatment outcome across disorders for adult populations (Horvath, 2001; Horvath & Symonds, 1991; Horvath, Del Re, Flückiger, & Symonds, 2011; Martin, Craske, & Davis, 2000), in terms of child and adolescent literature, the therapeutic relationship has been viewed as a pivotal change mechanism for behavioural and cognitive-behavioural therapies (Kendall, 2012).

Results from the present study showed that a strong therapeutic alliance was consistently obtained for both children and carers allocated to the CT and BT conditions, with the exception of one participant (Kala). This was not the case for the CBT group where, during each session, either two or three (Tamati, Sam, and Lisa) of the four participants indicated a low level of rapport, while all carers allocated to this group showed very strong alliance scores. Considering the CBT group showed the most positive changes on outcome variables, the lack of child therapeutic alliance for this group was not consistent with previous research, which suggests that treatment outcomes are largely dependent on the establishment of rapport (Lambert & Ogles, 2004).

Four participants in the CBT group reported ruptures in the therapeutic relationship, even though only two of them showed less than promising results (Tamati-CBT and Kala-BT). Generally, several factors might explain the low level of rapport as the majority of participants were adolescents (3 of 4) which, consistent with previous research, can mean that alliance formation is more challenging for this age group (Shirk & Russell, 1998; Shirk & Saiz, 1992). In relation to participants who reported low alliance but showed positive results, several hypotheses are suggested. Specifically, Sam was diagnosed with mild Asperger's syndrome, a condition that is known to produce difficulty with understanding and establishing relationships, while Lisa outlined she was only taking part due to being compelled by her parent. This is an example of how certain factors such as lack of autonomy regarding treatment referral and disagreements with carers about treatment goals can impact on the formation of rapport (Shirk & Russell, 1998). In particular, the tendency for adolescents to want autonomy from adults also represents an additional obstacle to the formation of a positive therapy relationship among this age group, all of which are factors that may have been present for these particular participants (DiGiuseppe, Linscott, & Jilton, 1996).

For children who reported low alliance levels combined with less than promising treatment outcomes, several other hypotheses are suggested. For instance, Kala's barriers to recovery may have related to her externalising rather than internalising behaviour and inability to recognise the existence of problems. Research suggests that rapport is likely to be more challenging among adolescents with externalising behaviour, as they tend to have less motivation to reduce internal discomfort and have more problems with authority figures (DiGiuseppe et al., 1996). On the other hand, Tamati was the first participant who completed treatment with the trainee psychologist; therefore rapport might have been impacted by therapist competence and ability to adequately address the problem. For instance, a review of the therapy session audio recording showed that the mock injection role-plays needed to be extended for longer than they were in therapy. This was especially important for the habituation

process to occur, which most likely explains why this child took 45 minutes to complete their in-vivo injection during therapy. Overall, these factors may all have had some impact on the establishment of rapport with these specific participants.

Different Types of Injections and Distress

Even though it is important to distinguish between different types of injections for medical purposes, it is also necessary as some suggest they can have different psychological effects on the child (Jay et al., 1985; Mohr et al., 2002). Claims that different injections cause different levels of distress is consistent with views regarding disease control which state that intramuscular injections (e.g., vaccinations and methotrexate injections) are considered one of the more painful injection routes compared to dermal or subcutaneous routes (e.g., blood tests) (Centers for Disease Control and Prevention, 2012). Research also suggests that correlates of child distress during injections are influenced by the different types of venous access (Jacobsen et al., 1990). Despite this phenomenon not being formally assessed in the present study, distress ratings and anecdotal feedback from the participants indicated that different types of injections elicited different levels of distress, therefore impacting on treatment outcome.

During therapy, Hayley stated that methotrexate injections and blood tests elicited different levels of distress and so she could not provide a general distress score for the two procedures. Likewise, Jenna outlined that blood tests were more distressing than insulin injections, and that even different insulin injections can elicit varying levels of distress. Some children stated that geographical location can also result in different levels of distress, with hospital settings being much worse than procedures completed in community settings. These instances may be related to previous trauma experiences associated with that environment. Most of the children expressed that vaccination injections hurt the most due to the insertion of fluid rather than withdrawal of blood (Lyla, Lisa, Elena, Hayley and Kala).

Due to the treatment injection included in this study not necessarily being the most distressing procedure participants had received, it is unknown if this study is generalisable across different injection types. On the other hand, children who received injections during follow-up that differed to their treatment procedure, and continued to report low levels of distress may provide some support for the generality of this study. However, there were mixed outcomes with some children habituating to a range of injections (Alyssa and Wiremu), whereas others did not (Hayley and Elena). It might be best if the child's most distressing procedure is incorporated into future research to promote more long-term treatment gains. This was considered in the present study, but for ethical reasons only injections that were part of the child's treatment plan could be used in therapy.

Limitations of the Present Study

Even though this study addressed some of the major limitations of the 2011 pilot study, there continued to be a range of methodological constraints. These related to research design,

procedures and assessment measures, while other more general issues included the dose-effect relationship, contamination of treatment conditions and impact of therapist experience. These limitations mainly arose due to resource and time constraints.

Component versus Single-Case Designs

The most frequently noted limitation of single-case research is the lack of external validity in terms of generality to the same population (Flyvbjerg, 2006). However, single-case research is not hypothetico-deductive so does not specify hypotheses at the population level (Blampied, 2013). Participants are not regarded as samples from a population, and no attempt is made to draw inferences from them as a sample to a population (Blampied, 2013). Therefore, criticising single-case research for a lack of this kind of external validity is meaningless as this is not what it is designed to accomplish. Instead, single-case research is concerned with detecting the effect of an intervention on an individual participant and determining whether the independent variable is reliable (e.g., by baseline-intervention phase comparisons). In this case, direct replication is the basis for inference and the mechanism for establishing generality within a specific domain (Blampied, 2013). For example, researchers might examine NRD severity as a factor in determining treatment effectiveness by replicating the treatment over individuals ranging in severity across the dimension of interest, with other factors remaining similar. If the treatment was effective, then an assumption can be made that the treatment has generality across the investigated dimension, whereas if the treatment was systematically ineffective for one or more cases then inferences can be made that generality has reached its limit (also known as generality mapping) (Blampied, 2013).

The main objective of this study was to identify specific techniques that may or may not contribute to the effectiveness of NRD treatment for chronically ill children. Research questions such as these are typically investigated using component studies including dismantling or additive treatment designs, which are intended to identify the active ingredients of a particular treatment package after it initially has been determined to be effective (Nathan, Stuart, & Dolan, 2003; Plante, 2011). For example, a conventional paradigm might involve the test of a behavioural therapy component for anxiety such as relaxation. The comparison treatment would mimic all elements of the experimental treatment including amount and frequency of contact, although it would not include the relaxation component.

A limitation of the present study may be that a single-case multiple baseline design was used to answer a research question that is traditionally investigated using dismantling or additive studies. For a number of reasons, the nature of this design makes it difficult to identify the specific contribution of both, including (1) individual components were not isolated and compared to a control condition, (2) a range of treatment components were grouped together as either behavioural, cognitive or a combination of cognitive-behavioural techniques, (3) each treatment condition was compared to another despite the fact that they differed in relation to amount and frequency of therapist contact, and (4) each treatment incorporated a range of different techniques all administered in different ways to account for the individuality of each

child. As a result of these four characteristics, it is difficult to identify what specific techniques individually contributed to treatment outcome, particularly due to several variables not being held constant. Despite this, these limitations potentially apply even when using a traditional between-groups design, therefore rather than being a criticism of the current research design, limitations may have actually arisen due to the way in which components were dismantled in the first place.

To put this into context, ratings of distress reduced mid-way through therapy for the CBT condition and towards the end of therapy for the CT and BT conditions. However, it is not completely clear whether this was due to videos, role-plays, helpful versus unhelpful thoughts, emotive imagery and/or breathing, all of which were used in these sessions at some stage. Instead, focusing on one or two key techniques (e.g., emotive imagery versus exposure) might have provided a more accurate overview of what contributed most to treatment outcomes. As it stands, only general conclusions can be made regarding this study, rather than specific inferences about what treatment techniques worked best.

It might also be the case that different techniques were effective for different purposes and that this was not captured by the outcome measures. For instance, research shows that some therapy processes impact treatment outcome such as rapport (warmth, empathy and friendliness), client engagement, identification with the therapist, and the development of client-therapist trust (Lambert & Ogles, 2004). These common factors may have all been obtained through less distinctive techniques like games, stories, developing emotive imagery posters and psycho-education. Children described these less distinctive techniques as “fun” and were the most memorable activity. It could be that without these core processes established early in therapy that the client is less likely to take risks in session by facing their fears via exposure-based tasks (Lambert & Ogles, 2004). Future research possibly needs to explore this facet of therapy before fully eliminating treatment components not seen to be contributing towards alleviating the problem. As is the case with most studies, the fit of research design to research question was an obvious limitation, however there were several reasons why a single-case design was utilised over other methods as has been described in Chapter 2.

Variations in Research Design

Throughout the course of the intervention, variations in the research design were unavoidable and were a limitation to the present study. This mainly related to pre-determined baseline lengths not being adhered to and therapy starting prior to the establishment of a stable baseline. For example, it was impossible to adhere to pre-determined baseline lengths assigned prior to therapy as some families did not return measures within the allocated timeframe and others did not complete the measures on a weekly basis, thereby overlooking the need for a certain amount of time to lapse before each administration. Instead, participants either completed them over the space of a few days just prior to therapy or completed up to two or three measures within the first therapy session due to arriving with incomplete measures. In these circumstances, the prospect of extending the baseline phase further was not viable due to

the limited availability of the family and/or the child's next scheduled injection aligning with planned treatment sessions. This resulted in some children completing multiple measures within a one-week period (Hayley) and shorter baseline durations for other children (Tamati-two weeks).

A lack of variation in baseline lengths across treatment conditions was also a limitation. Not only did each child have a pre-determined baseline length, but each condition was allocated a variety of durations to ensure that the same lengths were not allocated to the same treatment condition. However, due to some participants presenting with an unstable baseline and having to complete additional measures beyond their pre-determined length, this resulted in all three children allocated to the BT condition completing five weeks of measures. This is a limitation of the research as will be discussed below.

Procedures

Carer involvement

Carer involvement in therapy was an important component of this study, particularly as they can influence child distress and coping (Mahoney et al., 2010). A major aspect of therapy was carer psycho-education and facilitating them to encourage coping behaviour in their child and themselves. No formal method of measuring carer involvement inside or outside of therapy was undertaken in the current study, thus the level of impact carers had on treatment effectiveness is unknown. The rationale for not measuring carer involvement related to making this study time-efficient to ensure participation. Instead, less formal methods of attaining the level of carer involvement were used including a monitoring schedule to attain how much time each carer spent in session. It was not possible to determine the level of carer involvement out-of-session. Additional research is needed to formally evaluate this phenomenon.

Treatment integrity

Procedural limitations are also evident, in particular, a lack of treatment integrity measurement. Protocol variations may have been present due to sessions being individually tailored. For example, the behavioural condition included children aged 7 to 13 years, so certain activities were modified to account for developmental differences. Muscle relaxation was also not introduced to all participants. Therefore, treatment outcomes within certain conditions could be due to the different ways that particular condition was administered, rather than the treatment being more effective for certain participants. This was a significant limitation as the extent to which the treatment manual was adhered to during therapy was not formally measured, making it difficult to replicate this study in future research and clinical practice. This is despite the treatment manual being specific enough to enable standardisation and the therapist reviewing it before each session. A significant number of modifications to the treatment manual were also necessary in order to accommodate the child's developmental stage and personal preference for certain activities. A list of treatment manual modifications is provided in

the Method chapter to enable replication of this study. Even though these variations are strengths of the manual clinically, they are limitations of the research.

Random Assignment to Baseline Lengths

Random assignment to different baseline lengths can be an important way to attain pre-treatment equivalence of contrasted groups in psychological research (Hsu, 2003). The rationale for using this method is that it can equate groups on several nuisance variables simultaneously without the researcher being aware what the nuisance variables are or how they might impact on treatment outcomes (Hsu, 2003). Carrying out this method can also control for internal validity threats such as maturation and selection bias, as well as the interaction between these two variables (Hsu, 2003). Randomisation of baseline lengths did not occur in this study and is a limitation. There are several reasons for this including selection bias, where the researcher may have allocated less distressed families to shorter baselines or vice versa. This may have resulted in highly distressed families allocated to longer baselines thus receiving a somewhat more experienced therapist. Longer baselines could also result in increased boredom from completing more measures and less motivation due to therapy delays. On the other hand, allocation to longer baselines did result in more exposure to the measures, which according to participants was effective at reducing their distress levels. The rationale for non-randomisation of baseline length was that it ensured the same durations were not allocated to the same treatment condition. In particular, when using a small sample, the final distributions of baseline lengths can be very unbalanced when using randomisation (Hsu, 2003). Alongside a number of limitations arising from the procedures, there are other factors that need to be considered when interpreting study results including the dose-effect relationship.

Dose-Effect Relationship

A connection between dose response and treatment effectiveness has been claimed in previous research (Castonguay, Barkham, Lutz, & McAleavey, 2013). Similarly to the adult literature, child and adolescent studies of dose-response show a mixed pattern of results (Bickman, Andrade, & Lambert, 2002). For instance, two meta-analytic studies found no significant relationship between treatment duration and clinical outcomes (Casey & Berman, 1985; Schneider & Byrne, 1985). In fact, both studies indicated that shorter interventions had a tendency to produce larger effect sizes compared with longer interventions. Two more recent studies also found no evidence of a general dose-effect relationship (Bickman et al., 2002; Salzer, Bickman, & Lamber, 1999). Nonetheless, other researchers have showed evidence for a dose-effect relationship in child and adolescent therapy (Angold, Costello, Burns, Earkanli, & Farmer, 2000; Fonagy & Target, 1994). Due to these mixed results, the potential for a dose-effect relationship in the present study must be considered, particularly due to the variation in therapy dose which ranged from four to six sessions depending on the treatment condition. Based on the results, it could be hypothesised that participants randomly allocated to the longer

treatment (i.e., CBT) should have larger improvements due to receiving more exposure to treatment components and increased therapist contact time.

In order to combat confounding factors such as treatment dose, the study was designed so that full measure sets (as described in the Method) were completed in session four regardless of treatment condition. This full assessment occurred so that treatment groups could be compared at the same therapy dose point. The treatment injections were also isolated for the CBT and CT conditions so that the impact this technique had on therapy effectiveness could be assessed without contamination from other techniques. However, a limitation of this approach is that it did not account for the fact that session content also varied widely across the three groups at these points in time. Therefore, comparing scores across the groups at session four may show differences in treatment outcome, but it is unknown if these were due to therapy dose or therapy content. Nonetheless, this is a problem intrinsic to dismantling therapy research in general and a goal of this research was not to compare session duration but session content, so the therapy dose effect is of less importance compared to other limitations such as the contamination of techniques into other conditions.

Contamination of Treatment Conditions

Despite participants being randomly allocated into certain treatment conditions and these remaining distinctly separate, there were instances where cognitive and/or behavioural techniques contaminated another condition. In particular, the transference of behavioural techniques into the cognitive condition was evident. During session four for CT, where children received a needle injection at a local health service, it was observed that calm breathing and relaxation were naturally utilised by some children or at the instruction of the carer and health professional. For example, Elena had an oral injection and was instructed by the surgeon to do calm breathing, which she carried out a number of times for approximately five minutes. It is therefore uncertain if calm breathing or cognitive skills resulted in the treatment outcomes.

Other examples of when behavioural techniques contaminated the cognitive condition were when both Jenna and Elena wrote "Calm breathing" in response to the NIQ-C coping domain "What do you say or do to help yourself feel more comfortable when having a needle injection?" The utilisation of calm breathing was only noted by both participants during the treatment and follow-up phases of the intervention, despite the therapist never introducing this technique to the child or carer. It would have also been unethical for the therapist to instruct the child to discontinue this activity considering research has shown it to be effective for anxiety-based problems (Wolitsky-Taylor et al., 2008). Therefore, some contamination of behavioural strategies into the cognitive condition was unavoidable.

Another example of when behavioural techniques contaminated the cognitive condition was in Aroha's case. During the therapy sessions, it became apparent that when she became upset during injections she could become verbally and physically abusive towards the nurse (e.g., swear, kick and punch). As a result, alternative behaviours were suggested. In this case, a stress ball was introduced that Aroha took home with her between sessions. She was

encouraged to squeeze the ball to release tension when feeling angry. During the in-vivo injection, she also used this muscle relaxation strategy.

The reverse also happened whereby cognitive strategies contaminated the behavioural condition despite the therapist excluding this technique. For example, during the one-month follow-up, Kala expressed some unhelpful thoughts. She also reported at the one-month follow-up that breathing did not help her, but talking about injections and learning how to deal with her thoughts was useful. Considering the fact that Kala's results suggested therapy was not successful and she relapsed further, the therapist made a decision to provide some psycho-education and basic strategies for alleviating unhelpful thoughts. These are some of the limitations of doing research within a clinical setting, whereby research versus clinical ethics need to be considered. Despite these limitations, it is encouraging to see how children can spontaneously problem-solve and recognise areas where they need support. These skills appear to be dependent on developmental stage.

In certain circumstances, other less distinctive techniques were introduced into a treatment condition that should have been excluded. For example, Hayley was allocated to the cognitive condition and during her in-vivo injection was encouraged by the therapist to cover up the needle so that she could not observe the procedure. However, this was essentially a form of behavioural and/or cognitive distraction, and cognitive strategies could have been encouraged instead (e.g., helpful thoughts and used emotive imagery).

Finally, it might be the case that more general components introduced to all children were actually cognitive-behavioural. For instance, psycho-education about the nature of anxiety and correcting misconceptions about injections is a cognitive component but was administered to all groups. Furthermore, the use of rewards (i.e., contingent reinforcement) is traditionally a behavioural component but was also incorporated into the cognitive condition. Nonetheless, these components were kept constant throughout all three conditions, therefore any effect they had on treatment outcome would be seen across all therapies.

Common Factors and Treatment Outcome

Research suggests that common factors influence a substantial amount of the treatment variance, independent of the techniques used (Beutler, Forrester, Gallagher-Thompson, & Thompson, 2012; Nathan et al., 2003). Two factors that are of particular importance to this study include therapeutic alliance and therapist experience. The Session Rating Scale (SRS) – adult and child version was used throughout the treatment phase to assess the impact of therapeutic alliance on treatment outcomes. However, a limitation of this study is that only two items from each version were used. Results also showed that even though the children understood the question, it appeared that some were rating state anxiety levels and therapy content rather than rapport. For example, Kala rated a low level of rapport during the in-vivo injection and outlined that this was due to it eliciting high levels of distress. In session one, she rated rapport as very high due to it incorporating no exposure tasks.

Another hypothesis is that rapport was more important for younger children, whereas older children recognised the need to receive therapy and completed it regardless of relational factors. Alternatively, rapport could have been more easily established with certain participants compared to others. Future research should utilise the entire SRS measure to ensure a comprehensive assessment of rapport is obtained. The difference in therapist skill is also a potential limitation of this study and must be considered when interpreting results. Ways to prevent this common factor from confounding future research would be to either train the therapist in the treatment manual protocol prior to initiating the study or utilise an already experienced clinician. Overall, results suggested that therapeutic rapport did not impact on treatment outcome, but therapist experience may have had some influence. Even though more conclusive evidence is required, the present study does provide some support for the likelihood that, alongside who the therapist is, it is what they do that is also important (Beutler et al., 2004).

Assessment Measures

The assessment measures utilised in this study were a source some of the major limitations. This related to both the child and carer self-reports.

NIQ-C and NIQ-P limitations

A major contribution the present study made to existing literature was further development of the Needle Injection Questionnaire for Children (NIQ-C) and the Needle Injection Questionnaire for Carers (NIQ-C). These measures were initially piloted as part of the 2011 study and modified in the present study to address previous faults. They were developed due to significant limitations of existing psychometric measures such as extensive administration, irrelevant or inappropriate item content and lack of standardisation with children. However, although the NIQ-C and NIQ-P contribute significantly to previous literature, they are, for now, also one of the greatest limitations of this study as there is no information about reliability, validity and norms. Perhaps most importantly, it is also unclear how much movement was necessary to signify a *clinically significant* change.

Despite correcting faults, it was clear during the research process that several limitations continued to exist with the measures. Initially the measures were structured so that the child rated their distress, avoidance and coping in relation to their *most recent injection*. The rationale for this was that research suggests individuals are more likely to retrospectively recall events if the episode occurred a short time ago (Poulton & Menzies, 2002). However, Tamati (pilot participant) identified that rating the most recent injection inadequately captured distress levels and would be insensitive to therapeutic changes. Tamati's carer explained that her responses on the measures would not change regardless of therapy, as the child's experience of their most recent injection was unchangeable. The most recent injection was also different to the type of injection procedure incorporated in treatment, which was problematic as both injections elicited different levels of distress so ratings were not comparable. Furthermore, other

children (Alyssa and Hayley) struggled to recall details of their most recent episode (e.g., if it hurt and what they were thinking). Perhaps as previous research suggests, it is the *quality* of the injection experience that influences memory recall rather than *quantity* or how recent the event was (Bijttebier & Vertommen, 1998; Fradet et al., 1990). For instance, all children could very descriptively recall and describe a traumatic experience that occurred years ago, but struggled to recall an injection that occurred a few weeks or months prior to therapy.

For the reasons mentioned above, the measures were modified to include distress *in general*, which encompassed all injections. As a result, Tamati, Hayley and Alyssa who had already completed their assessment interview measures needed to complete baseline measures again. This was a disadvantage as extended baseline measurement of a skill under non-treatment conditions can prove aversive to some participants, and extinction, boredom, practice effects, or other undesirable responses can occur (Cooper et al., 2007). For example, Aroha and Hayley expressed during session one that they were simply repeating the same answers from the baseline phase, and that this was due to them already completing two other copies of the measures that day. Not only does this show that repetitive testing can result in ritualistic answers rather than actual change, but that some families were not completing the measures weekly as requested in the assessment interview. Results also showed a clear difference between ratings of the most recent injection compared to distress in general. For example, Hayley's baseline SUD rating for her most recent injection was 5.5, compared to her general rating of 8.5. This was because, alongside blood tests, the higher self-report included methotrexate injections (which are more painful), thus inflating the SUD score.

Once the measures had been modified, there continued to be a number of limitations. The NIQ-C and NIQ-P were originally developed for children aged 8 to 12 years. Therefore, some of the younger participants were unable to complete the measures independently and required assistance from their carer and/or the primary researcher. In particular, participants struggled with answering the cognition domain of the NIQ-C (see Appendix 7, NIQ-C items 3.1 and 3.2) and tended to rate their distress in relation to how they were feeling at the present moment (state anxiety), rather than how they were feeling during the injection (trait anxiety). It might also be the case that some children did not understand the questions, resulting in inaccurate responses.

ATSS limitations

Even though ATSS is useful in assessing complex cognitions in a variety of investigator-controlled situations, there are a number of limits to this approach. These limits mainly related to the coding system and the restriction this placed on identifying changes to participant responses. A universal coding system developed by Davison et al. (1983) was utilised, however the categories only identified changes in frequency and content of thoughts, rather than thought intensity or minor changes in the meaning of a statement. For example, many children gave statements during the baseline phase such as "I'm really scared" or "It's really going to hurt". Once therapy had finished, these statements changed to "I'm a bit scared" or "It might hurt a

little". However, due to these statements still containing a negative component they had to be coded as such, even though the intensity of that thought had changed considerably.

Another limitation is that, due to the nature of some thoughts, they could have been coded into two categories (e.g., "I'm happy that it is over, but my arm feels floppy, it feels not as strong and it's taken all the muscle off and I can't move it properly" - Hayley). To counteract this, a decision was made that no statements would be coded twice due to the likelihood that it may inflate frequency ratings, which were the primary indicators for therapeutic change. Nonetheless, this strategy may have resulted in some statements being coded incorrectly. Some participants also provided incomplete sentences which were difficult to score. In these instances, it was left to the discretion of the coder, although there might have been a difference between what was said by the participant and how it was interpreted by the researcher (Zanov & Davison, 2010). The accuracy of response coding or inter-rater reliability checks were not carried out.

A further limitation may have been a failure to create an adequately realistic situation to elicit target cognitions (Zanov & Davison, 2010). Some children also found the manipulation scenario developmentally inappropriate, improbable and/or unaligned to what realistically happens. The same story was also used regardless of the child's age and older children found the story "Childish" or "silly". This is another example regarding the difficulty of balancing clinical versus research requirements. The contextual relevance of the injection story was also questionable as it described an injection whereby medication was going into the body, although many of the children that took part in this study had a blood test whereby blood was taken out of the body. Moreover, some aspects of the injection story were unrealistic including the nurse "Flicking the tip" and "squirting some liquid out". Environment may have also impacted on some responses because final assessments for the CT and BT groups were usually carried out within the medical setting, which can be particularly noisy and disruptive. Several modifications could be made to the ATSS stories such as making them more injection-specific and including more common procedures (e.g., blood tests). They also need to be age-appropriate and realistic in terms of the injection stages.

Lastly, ATSS may have been receptive to extinction, boredom, practice effects, or other undesirable responses from participants due to many of the children outlining they were tired of listening to the same story sometimes up to five times. Generally, in ATSS research neutral and active stories are available for use (e.g., alternative versions of a test, that have been independently validated as equivalent test measures), but this was not applied in this study. Therefore, it may be the case that these children had fewer negative statements as the intervention progressed due to boredom effects rather than therapy effects, perhaps explaining why many of them stated they were thinking "nothing" during follow-up periods.

Other measure limitations

The Coping Behavior Questionnaire (CBQ) had a number of items that could have been adaptive coping items, yet they were not indicated as this according to the scoring instructions of the original author (Field et al., 1988). Examples of this were items such as "Did he/she

engage in conversation on his/her own accord?" (Item 10), and "Did your child ask questions about the instruments or how the procedure would feel?" (Item 11). It may be the case that these items could either be seen as coping (repressor coping style) or not coping (sensitiser coping style). Furthermore, due to it being identified in the 2011 pilot study that younger children had difficulty with answering questions, a more concrete visual task was included in the questionnaire known as the Faces Pain and Anxiety Scale (CAPS; Kuttner and Lepage, 1983). Nonetheless, as explained in the Method chapter, some children had difficulty with answering this measure so scores were not presented in this study.

Treatment Manual

Treatment manuals can limit external validity as most therapists have to deviate from manualised approaches to account for the 'complexities' of the client (Goldfried & Wolfe, 1998). The list of modifications to the treatment manual in the present study is evidence of this, although this was expected which is why a 'flexible' component was incorporated. The development of flexible treatment manuals also has some advantages, especially because adhering to a strict session format regardless of whether it is meeting the client's needs or not is unethical and could lead to poor treatment outcomes (Wilson, 1996). Treatment manuals are also useful for less experienced clinicians that require a more directive session format. Taking into consideration these advantages and disadvantages, treatment manuals play an important role in research and the development of more effective and efficient treatment programmes. They also enable the transfer of knowledge from research to clinical practice, which was identified as a major limitation of previous research (Ollendick & Davis, 2004).

Specific limitations of the treatment manual were that certain activities were rushed or left out due to time restrictions. The clinical validity of sessions four (CT and BT) and five (CBT) was questionable as they incorporated an in-vivo injection at a local health service. These sessions may limit generalisation out-of-session as having the clinician present during injection procedures is sometimes not realistic. Furthermore, it may promote dependence on the therapist or encourage the client to believe that they can only cope with the therapist present. On the other hand, by having the therapist present, the child and carer can have at least one successful injection to model from and gain confidence for future injection procedures. Data obtained from several participants showed that treatment strategies were being transferred to other injection and/or medical procedures, although more conclusive evidence would need to be obtained. Long-term follow-up data investigating the generalisation of the injection session with or without the therapist and/or the differences across different injection procedures could be an area of further research.

While the use of a manualised treatment was utilised to address the contribution of therapist variables to treatment outcomes, the fact that therapy was carried out by a single therapist is a limitation of this study. Two therapists administering the treatment manual would have been preferable, although this was not carried out due to time and resource restrictions. On the other hand, the use of a single therapist reduced therapist variability, a relative strength

of this study given the small sample size. The pilot study in 2011 also utilised an experienced clinician showing promising results with the same CBT manual. Overall, future research should focus on administration of the treatment manual with multiple therapists to enable the specificity of this approach to be determined and reduce the impact of therapist variables that influence treatment outcomes.

Other limitations

Alongside the limitations discussed above, treatment gains over a longer period of time are unknown. The existence of dual roles including the therapist also being the researcher and assessor may be a further limit due to risks of experimenter bias when collecting measurement data (Plante, 2011). Furthermore, in order to exclude the possibility that improvements were due to exposure to feared situations, participants were asked not to increase or decrease the extent to which they went into situations which they would tend to avoid (anti-exposure instructions). However, due to ethical reasons, the child's medical schedule was not allowed to be discontinued while taking part in the research, resulting in more exposure for some children and posing a large risk for the CT group. It was also observed that due to the child participating in a research project they tended to receive more attention from medical staff (e.g., two to three nurses compared to one). For example, Lyla had three nurses assisting with the injection in session four. Observation showed that nurses with more skill/experience appeared less likely to miss the vein and have less difficulty with insertion. An increase in the number of nurses also resulted in more distraction (due to increased conversation), support, encouragement and rewards (e.g., children received a certificate). Lastly, the study did not allow for the investigation of differential outcomes as the children did not typically have comorbid diagnoses or additional issues, which is not always realistic in clinical practice.

Recommendations for Future Research

Based on consideration of the study's strengths and limitations, a number of adaptations, extensions, and improvements for future research are suggested. Several intervention strategies are suggested to illustrate how this research could be adapted for clinical practice.

Improvements for Future Research

Even though this study addressed some limitations of previous research, results mainly provided *preliminary* evidence for the positive contribution of behavioural strategies over cognitive strategies in alleviating NRD among chronically ill children. Some questions also remain unanswered, for example at what age are these strategies most effective? More rigorous research methods aligned to a dismantling or additive treatment design and/or case studies designed to systematically examine these and other variables may be necessary to

provide conclusive evidence. This could be carried out by specifically isolating one or two components of the treatment manual that were identified as pivotal to the change process in this study (e.g., cognitive restructuring versus in-vivo exposure) which could then be individually assessed using similar groups of participants, one with each technique. Further research could also identify whether four or six sessions of therapy are necessary for change to occur as this could have major implications for clinical practice. As it stands, there is some evidence to suggest that both therapy durations produce beneficial outcomes.

Diversity among children across many dimensions (e.g., age, gender, ethnicity, medical condition, chronicity and severity) could also be established by systematically mapping generality using a series of single-case research designs. In this way, systematic replication can be the mechanism for establishing generality as mentioned previously. Other areas that could be assessed include non-chronically ill children that experience distress undergoing more widespread injections such as vaccinations. The development and modification of the treatment manual to incorporate distress associated with other medical procedures (e.g., insertion of feeding tubes and catheters) is another significant gap in the literature. Lastly, although a strength of this study was the recruitment of participants not only from university settings but also hospitals and private clinics, future research could widen the geographical area. This could potentially increase external validity in terms of generalising to other medical procedures, clinical settings and groups.

Cultural adaptations may be important for two reasons (1) the therapy effectiveness may be enhanced, or (2) the *acceptability* of an effective therapy may be enhanced. Unless an existing therapy is either not effective for a particular cultural group and /or not sufficiently acceptable to a particular group, in which case those who need the therapy don't participate, then a cost to benefit analysis about cultural modification may need to be explored. Despite this, cultural modification is particularly important considering several chronic medical conditions such as rheumatic fever most often affect Māori and Pacific children aged 4 – 19 years, which they require monthly Bicillin injections as part of treatment (Ministry of Health, 2013). A New Zealand study implemented a psychological intervention for people experiencing injection pain and fear due to monthly Bicillin injections with successful outcomes (Russell et al., 2013). Therefore, cultural adaptation of the manual needs to be examined, although three families that identified as Māori in this study indicated no need for this with some outlining "We don't have any specific cultural needs" and "Our family does not really have a culture as such, so nothing needs to change". Such views have to be respected, along with those that indicate that recruitment needs to specifically target culturally diverse groups. Service providers that work with culturally divergent populations could also be approached to assist with both design and implementation of such studies. Lastly, culturally orientated therapists could be included in the development (and subsequent) stages of the research (Macfarlane, Blampied, & Macfarlane, 2011).

Future research could focus on adapting the treatment manual *prior* to administration in the following key areas. Language use and preference should be ascertained, as well as the

level of involvement from the culture of origin and the host culture (Paniagua, 2000). Other modifications to allow for cultural differences might include the inclusion of extended family/whanau for Māori clients rather than just the primary carer (Herbert & Morrison, 2007). Cultural practices such as the sharing of food/kai and a more extensive welcome/karakia may potentially be incorporated into session one. Asian cultures also tend to be more somatic in their manifestation of psychological distress (Williams & Cleland, 2007), which may lead to modifications in the way the nature of anxiety is explained in session one and/or the development of fear hierarchies.

Cultural differences in definitions of fear-provoking circumstances such as needle injections, modes of coping and carer management style/skills are also particularly important. For example, Māori models of health that encompass a holistic view of the individual may need to be considered such as *Te Whare Tapa Whā* (Durie, 1994). In contrast, Asian cultures may define mental illness according to three schools of thought: Buddhism, Taoist beliefs and the balance of *yin* and *yang* forces. The family structure of Asian families also tends to have clearly defined roles, where the father is the head of the household, disciplinarian of the children and decision maker (Williams & Cleland, 2007). Māori and Pacific Island families tend to have parental management styles where the wider family/whanau have a large role in bringing up the child (Paniagua, 2000). Overall, future research needs to investigate to what extent this programme is appropriate, and what adaptations may need to be made when working with other cultures including Māori, Pacific Island and Asian families, as well as other migrant and refugee populations.

Even though the results of this study show the treatment manual was useful for 11 chronically ill children, it is not clear to what extent carers and the wider family have facilitated treatment outcomes. Therefore, the specific level of carer involvement in-session and out-of-session could be investigated by conducting session monitoring or end of therapy assessments. For example, session monitoring questions might include “Do you encourage your child to complete therapy homework?”, “Did you help your child with their homework?”, “Did you practice any of the therapy exercises with your child at home?”. Other questions might relate to “Did you talk with your child about the therapy activities/topics or talk about upcoming injections with them?”. Alternatively, more general questions could be completed at the end of each session such as “Approximately how much time did you spend on homework activities/general therapy topics (e.g., 15 minutes, 30 minutes, 1 hour or 2 hours)?”. Another area of research could be to investigate the influence carers have on child distress, avoidance and coping during the injection procedure. During the research process, consultation with health professionals revealed that they identified carers as the main catalysts for child distress. However, children rarely criticised their carer’s behaviour during the intervention, either due to it being non-existent or their reluctance to openly disclose this.

On the other hand, consultation with carers revealed that they identified health professional competence as the main catalyst for child distress. This was further supported by feedback received from children, where they identified “Good versus bad nurses/doctors”.

Mathews (2011, p. 110) indicated that nurses tend to focus on “Getting the job done” rather than the patient, causing a dissonance between these two components of medical practice. It might also be the case that some health professionals were more effective and better trained than others, leading to smoother injections (Mathews, 2011). It is recommended that future studies assess the influence that carer and/or health professional behaviours have on child NRD. Research into this topic could enable preventative measures to be implemented thus avoiding the need for therapeutic input. Alternatively, health professionals could be given a more pivotal role in the research process. For example, a sample of each child’s injection could be videoed during baseline and follow-up, experienced medical personnel could then rate the level of distress shown and how problematic the injection appears from the practitioner’s point of view. Otherwise, the frequency and duration of physical restraint could be measured at baseline combined with the injection procedure length. This information could then be compared to treatment data and provide compelling evidence for the generalisation of treatment gains to the medical context. Above all else, this study highlighted the importance of ensuring health professionals are psychologically responsive to distressed children during medical procedures.

A formal method of measuring treatment integrity could be carried out in future research by audio- or video-recording therapy sessions which are then checked for integrity by a clinical psychologist external to the research. The influence of therapist variables on treatment outcomes could also be investigated, which may be done through the use of multiple therapists delivering the treatment manual that differ in clinical experience (e.g., trainee versus senior clinician) and personal characteristics (e.g., age, gender and ethnicity). Perhaps in future research where resources are limited and the payment of a scorer is unfeasible, research supervisors listening to the audio recordings could rate to what extent the manual was being followed as prescribed.

More rigorous psychometrics should be utilised in future research. This includes formal testing of the NIQ-C and NIQ-P to obtain psychometric information while incorporating the suggested modifications outlined in the limitations section. A large sample of chronically ill and non-chronically ill children variable in age, gender and ethnicity could also be used to ascertain whether the measures are applicable to a range of groups. Child self-report measures are particularly important, as simply collecting carer assessment data may not be a reliable measure of child functioning as shown in this study. Lastly, follow-up periods should be extended to include 6- and 12-month intervals to provide further insight into the long-term effectiveness of the treatment manual. Alongside these methodological improvements to future research, several therapeutic interventions are suggested.

Research to Clinical Practice

Based on treatment outcomes from the present study it is suggested that relapse prevention strategies are considered for clinical practice. It is recommended that in order to prevent children from experiencing traumatic procedures and subsequent long-term distress, basic education for children, carers and health professionals could be provided. Some families

suggested that collaboration between themselves, clinical psychologists and health professionals also needs to occur in order to prevent traumatic incidents. Implementation of this could be through the use of an information sheet (see Figure 15) distributed to appropriate services, posted in waiting rooms or given directly to families. The 10 processes that are identified in the information sheet are based on results from this study and previous research (Jaaniste, Hayes, & Von Baeyer, 2007; Kendall et al., 1992; Lewis, 1978; McIvor, 2011; Powers et al., 2005). Information sheets such as this were requested from hospitals (e.g., Hutt Valley DHB) and families during the data collection phase of this research attesting to their usefulness.

In some circumstances, it is unrealistic for children to receive six sessions of CBT when displaying symptoms of NRD. Situations like this arise in the hospital where there are constraints on time and resources. In this event, a very brief intervention (30 minutes) could be carried out involving elaboration of the 10 tips outlined in Figure 15. However, in circumstances where children present with more extreme symptoms of NRD, and there are no constraints on time and resources, a comprehensive therapeutic intervention could be implemented. As shown in this study, even though positive results can be obtained with four sessions of either CT or BT, it is recommended that a combination of these therapies are utilised, due to less than promising follow-up results obtained when incorporating only one of these components. It is also suggested that particular emphasis is placed on exposure tasks, while addressing the child's understanding and acceptance of their chronic medical condition.

10 Tips for Making Bad Injections Good

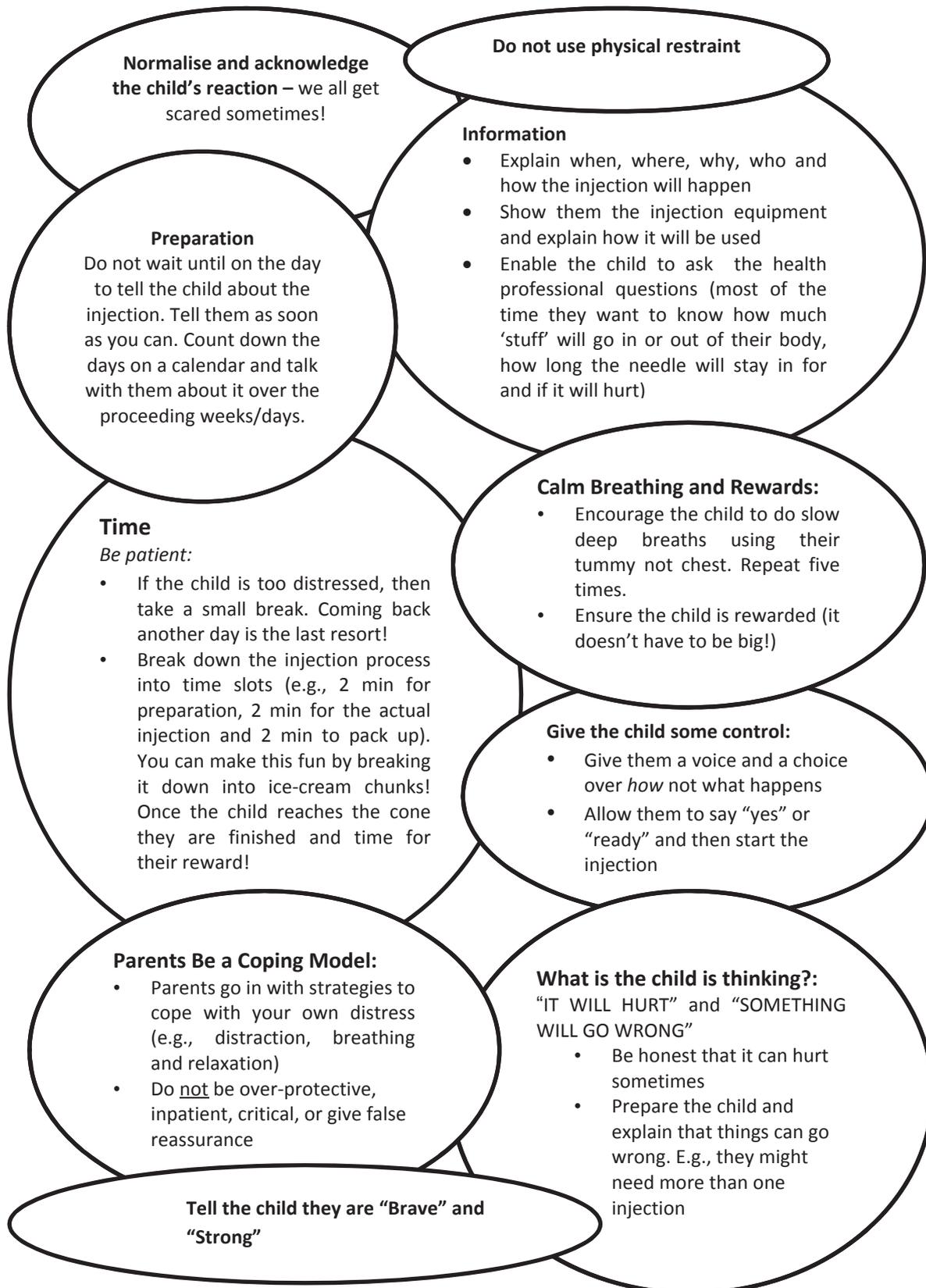


Figure 15. Tip Sheet for Health Professionals and Families.

Study Conclusions

This study dismantled an existing manualised CBT programme to determine whether cognitive and/or behavioural components were more effective than no treatment (i.e., the baseline phase) for reducing NRD symptoms among chronically ill children. Three treatment manuals were evaluated using a single-case, multiple-baseline across participants design including three groups: (1) CBT, (2) CT, and (3) BT. The original therapy programme was based on the *Coping Kids Treatment Manual* developed from a 2011 pilot study. Considering the limitations discussed, findings offer support for the effectiveness of six sessions of CBT. Combined with the replications carried out in the pilot study, a total of seven single-cases have shown that this therapy is effective at alleviating NRD among chronically ill children. Three additional single-case replications from the present study offer support for the effectiveness of a four-session CT (one girl, aged 12 years) and a four-session BT (one boy and one girl, both aged 7-7.5 years). Furthermore, it should be noted that when assessing individual case results in certain areas (e.g., coping and cognitions related to injections), CT and BT were just as effective, if not more effective, than CBT for some children.

Specifically, CBT was the most effective at maintaining treatment gains related to distress and avoidance, while CT showed the most improvements in cognition content, intensity and frequency. Results related to carer functioning showed that CBT was again the most effective at reducing distress. Carer avoidance required very little improvement. All three conditions were equally effective at increasing coping for child and carer participants. Carer changes mostly occurred once they had observed their child receive a successful injection. Previous research suggests that the more painful the carer perceives their child's injection, the more distress they can experience (Mahoney et al., 2010).

Study implications relate to both research and clinical practice in several key areas. Evidence suggested that assessment interviews can produce therapeutic effects and that several factors can influence the likelihood of relapse during follow-up. Proposed risk factors include symptom severity, variation in injection type and frequency, family dynamics, additional psychological problems and the success of exposure tasks during therapy. In particular, despite the impact of injection type on distress not formally being assessed in the present study, distress ratings and anecdotal feedback provided some evidence for the influence on treatment outcome. Coping also tended to improve gradually for both children and carers regardless of therapy. Unlike previous research, this may suggest that either cognitive or behavioural techniques rather than a combination of both are enough to improve coping (Bernard et al., 2004; Blount et al., 1991; Walco, 2008).

Another important finding was the identification of which cognitions were the most resilient at follow-up, including the knowledge that children would receive a reward and the continued belief that the injection will not hurt forever. This suggests that once therapy has ended, ways in which carers can maintain treatment gains for their child is to continue providing

incentives and restructuring thoughts related to pain. In addition, this study highlighted that children do have thoughts and that they can be pertinent and realistic.

Perhaps one of the most influential outcomes was that distress reduced mid-way through (CBT) or towards the end of therapy (CT and BT) after the completion of medium-level exposure tasks, or in the case of cognitive therapy when helpful thoughts were reviewed. This suggests that these techniques were central to the alleviation of NRD, and that components carried out in sessions one and two (and perhaps three) produce little if any therapeutic benefit. Even so, caution should be taken when eliminating less distinctive techniques as these could be essential for the development of common factors that also impact on outcome (e.g., rapport and client-therapist trust). These processes may need to be established in order for the child to take risks in therapy and attempt exposure tasks. Children also described these less distinctive techniques as fun and the most memorable part of therapy.

Treatment outcomes also showed that, although the key features of NRD can be similar across children, it is a heterogeneous experience that varies according to the child's case history, developmental stage and medical treatment regime. Due to this, the treatment manual should be tailored to the needs of the child, rather than applied universally. Anecdotal feedback from children also revealed that some of the most effective components of therapy were being listened to and receiving empathy, rather than specific treatment techniques. Improvements to the quality of the child and carer relationship appeared to have a flow-on effect for reducing distress. More general implications were that child and carer self-reports were fairly divergent, validating the need to directly ask children about their own symptoms. Lastly, unlike previous research, this study showed that trainee experience was related to therapeutic outcomes.

Many critical issues concerning chronically ill children with NRD remain unresolved, and in order to obtain more conclusive evidence, further research is required. In particular, the precise role of exposure versus cognitive restructuring techniques could be explored. Alternatively, different types of exposure tasks could be compared to determine which one is the most effective (e.g., low- versus high-level exposure). Research questions such as this could address limits of this study including the contamination of treatment conditions and the dose-effect relationship. A series of single-cases with a diverse sample of children could answer this question by systematically mapping generality of the target intervention. Extended follow-up periods (e.g., 12-months) and empirically validated measures that signify a clinically significant change are also necessary.

In conclusion, this study has provided a unique contribution to treatment outcome research in the field of NRD with chronically ill children in Aotearoa New Zealand. In addition to providing a valuable foundation for future evidence-based practice and research in this area, involvement in this project alleviated distressing symptoms and enabled ongoing coping skills to be integrated into the lives of the children and their carers who participated in this study. While no generalisations can be made due to the single-case nature of this research, as an extension of the 2011 pilot study it offers useful insights into an area much in need of empirical research, both in New Zealand and internationally.

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Appendices

Appendix 1

Letter of Ethical Approval



Central Regional Ethics Committee
c/- Ministry of Health
PO Box 5013
1 the Terrace
Wellington
Phone: (04) 816 2403
Email: central_ethicscommittee@moh.govt.nz

14 June 2012

Ms Jessica McIvor
4/66 Northland Road
Northland
Wellington 6012

Dear Ms McIvor

Ethics ref: CEN/11/03/019 (please quote in all correspondence)
Study title: What Part of Treatment Works Best? Cognitive and/or Behavioural Components for Chronically Ill Children with Needle-Related Distress.

Thank you for your email dated the 5 June 2012 enclosing documentation relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Central Regional Ethics Committee under delegated authority.

Approved Documents

- Amended Study Protocol
- Locality Assessment Form signed and dated Dr Ruth Gammon dated 8 May 2012
- Maori Consultation - Massey University
- Information for Caregivers, Version 4 dated 5 June 2012
- Information Sheet for Children Version 2 dated 28 May 2012
- Caregiver Consent Form Version 2 dated 5 June 2012
- Child Consent Form Version 2 dated 5 June 2012
- Flyers 1 & 2
- Measure 1 - Full Assessment - One CBT, CT and BT
- Measure 2 - Half Assessment - Baseline CBT, CT and BT
- Measure 3 - Half Assessment - Treatment CBT, CT and BT
- Measure 4 - Full Assessment - Two, CBT only
- Measure 5 - Full Assessment - Two, CT and BT only
- Measure 6 - Full Assessment - Three, CBT only
- Measure 7 - Full Assessment - Follow Up, 1 Month and 3 Months, CBT, CT and BT

Ongoing ethical approval is reconfirmed until the 14 June 2013.

We look forward to receiving your next annual report before this date. Instructions on how to file a report after 1 July 2012 can be found at our new website www.ethics.health.govt.nz.

Please do not hesitate to contact me should you have any queries.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Emma Phelan'.

Emma Phelan
Administrator
Central Regional Ethics Committee

Appendix 2

Consent and Information Documents

Note: Information sheets for children and their parent/caregiver were printed on official Massey University Letterhead. Documents have been modified slightly (margins) in order to fit on bound pages.



Therapy for Children with Needle-Related Distress Information for Children



What is the research project about?

This research is about a special therapy to help children that are scared of needle injections. This therapy is being carried out at the Massey Psychology Clinic, and we want to know how helpful it is for children that are sick and need to have needle injections.

What happens if you don't want to take part in this project?

If you don't want to take part that is okay, you will still receive health care.

What happens if you want to take part in the project?

- Your therapist will be Jessica. You will come to the clinic and see Jessica for about one hour (weekly or fortnightly), for either four or six sessions of therapy. You will be doing a lot of different activities that help with your fear of injections. Each session you have with Jessica will be audiotaped so that we can check if therapy is being carried out according to a special book that she follows.
- Jessica's job is also to answer any questions you have about the research. She will also ask you some questions and get you to fill in some forms before therapy starts, immediately after therapy and a few months from when your therapy finishes. This will help Jess know if the therapy was helpful for you.
- No one will know that you took part in this project because your name will be changed. Jessica will keep what you tell her private. If she is worried about something, she will tell you first before she talks to your carer or any other person.

If you want to take part in this research project you can:

- Ask any questions at any time,
- Decide to stop taking part in this project at any time without giving a reason,
- Say you don't want to answer a question or fill in a form, and you can still come to therapy,
- Find out how helpful the therapy has been for you, and other children, once the research is finished.

If you would like to take part in this research project, or have any questions, you can talk to Jessica now, or tell your parent/caregiver, who can call her on 027 696 2336 or 04 475 4003.



Therapy for Children with Needle-Related Distress Information for Caregivers



What is this study about?

You and your child are invited to take part in this project, which aims to assess the effectiveness of a brief therapy for chronically ill children with needle-related distress. The goal of treatment is to reduce distress and increase coping behaviours among children and their carers. Therapy will be carried out by Jessica McIvor as part of a Doctorate in Clinical Psychology at Massey University. The invitation for families to take part in therapy will run from July 2012 to May 2013, although this is subject to change.

How will my child and family be selected?

Either you may contact me directly or a health professional will approach you and your child to take part in this study (approximately 12 families will be invited). If you are interested in participating, you will receive a phone call from the primary researcher to determine your eligibility for the research. It is important that the child's carer can also participate in treatment, that there are no major mental health problems that need urgent assistance and no current involvement with Child, Youth and Family services. Your participation is entirely voluntary (your choice).

Time commitment

Therapy will continue for 4 or 6 one-hour sessions (either weekly or fortnightly) at the Massey Psychology Clinic. In some circumstances therapy may be held at a place convenient for the family. Aside from therapy, families will also attend an assessment interview (approximately 1 hour) to complete the consent process and allow time for Jessica to understand how needle injections are impacting on your child. If you consent to participate, you and your child will complete questionnaires to track the progress of therapy. These questionnaires will be completed before, during, and after therapy has finished, and will take either 10 or 30 minutes to complete each time. In addition to the time required for therapy, participation in this study will take approximately 3.5 to 5.0 hours spaced over 18 to 23 weeks.

You and your child are under no obligation to accept this invitation, and if you choose not to take part, this will in no way impact on your future health care. If you decide to take part in this study, you have the right to:

- Withdraw from the study at any time without giving a reason and without penalty,
- Withdraw should any harmful effects appear,
- Ask any questions about the study at any time during participation and/or decline to answer any particular question.

Your child has the right to consent to participate in this study when they are capable of understanding what the study involves and the risks. If your child is unable to fully understand, their assent must be obtained unless your child is unable to communicate. Your child also has the right to decline participation, unless there is no medically acceptable alternative for treatment, or if the anticipated benefits outweigh the risks.

Benefits, risks and inconveniences

Treatment will be of no cost to the participants, and all travel costs to the Massey Psychology Clinic in Palmerston North and Wellington will be reimbursed. Other benefits of this study include your child exhibiting less needle-related distress and having improved coping strategies during future medical encounters. The potential risks associated with this study include your child becoming increasingly distressed during some parts of the therapy. Children and their families may also be inconvenienced due to therapy perhaps progressing longer than one hour.

Confidentiality

The initial assessment interview and all therapy sessions will be audiotaped. No material that could personally identify you or your child will be used in any reports about this study. All study data will be stored for 10 years in a locked filing cabinet, after which it will be destroyed.

General

- You may have a friend, family/whānau member to help you understand the risks and/or benefits of this study and any other explanation you may require,
- At the end of this study, if it is necessary your child may continue to receive treatment from the Massey Psychology Clinic, although this will not be free of charge,
- You may request the results of this research (please tick the box on the consent form).

Advocacy Statement

If you have any queries or concerns regarding your rights, or your child's rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health and Disability Commissioner Act: Telephone (NZ wide): 0800 555 050; Free fax (NZ wide); 0800 2787 7678 (0800 2 SUPPORT); or Email: advocacy@hdc.org.nz

Thank you for taking the time to consider participation in this exciting research project! Please feel free to contact the project leader if you have any questions about this study 😊

Jessica McIvor, Project Leader
Doctorate of Clinical Psychology Candidate
Massey University, Wellington
Telephone: 027 696 2336
mcivormassey@gmail.com

Joanne Taylor, Project Supervisor
Senior Lecturer, School of Psychology
Massey University, Palmerston North
Telephone (04) 356 9099, extension 2065
j.e.taylor@massey.ac.nz

This project has received ethical approval from Central Region Ethics Committee: Ref: CEN/11/03/019



MASSEY UNIVERSITY

Therapy for Children with Needle-Related Distress Child Consent Form



- I have read the Information Sheet (Version 2) for children and have had the research explained to me in a way I understand.
- My questions have been answered in a way I can understand, and I know that I can ask further questions at any time.
- I know that whatever I tell the primary researcher is private (confidential).
- I know that I can decline participation and withdraw from this research project at any time without giving a reason. I also do not have to answer any questions I feel uncomfortable with.
- I know that the initial assessment interview and all therapy sessions will be audiotaped.

Please tick one:

Yes, I want to take part in this project

No, I don't want to take part in this project

Your name

Today's date



MASSEY UNIVERSITY

Therapy for Children with Needle-Related Distress
Caregiver Consent Form



- I have read and I understand the Information Sheet for volunteers taking part in this study that is designed to alleviate needle-related distress in chronically ill children. I have had the opportunity to discuss this study and am satisfied with the answers I have been given.
- I have had the opportunity to use whānau support to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice), and that I may withdraw myself or my child from the study at any time, and that this will in no way affect my child's future health care.
- I understand that my participation and my child's participation in this study are confidential and that no material that could identify me or my child will be used in any reports on this study.
- I understand that the treatment will be stopped if it should appear to be harmful to myself or my child.
- I understand the compensation provisions of this study and have had time to consider whether to take part in the study. I know who to contact if I have any harmful effects from the study, and know who to contact if I have any questions about the therapy or questions in general.
- I understand that the initial assessment interview and all therapy session will be audiotaped.

- Yes, I wish to receive a copy of the results (*Please note there may be a delay between data collection and publication of results*).
- Alternatively, I would like the researcher to discuss the outcomes of the study with me.

I.....hereby give consent for myself and my child to take part in this study.

Signature.....Date.....

Project explained by.....Project role.....

Signature.....Date.....

THANK YOU

Jessica McIvor, Project Leader
Doctorate of Clinical Psychology
Massey University, Wellington
Telephone: 027 696 2336
mcivormassey@gmail.com

Joanne Taylor, Project Supervisor
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Appendix 3

Information Flyer for Families

Free Therapy For Children with Needle Distress

SCHOOL OF PSYCHOLOGY

MASSEY UNIVERSITY

- Do you have a child who is scared of needle injections? and,
- Your child is aged 8 to 12 years? and,
(Children aged 5 to 15 years may be included on a case by case basis)
- Diagnosed with a chronic medical condition? and,
- You are a parent/caregiver willing to take part in therapy?

This study aims to assess the effectiveness of a **Brief Cognitive-Behavioural Therapy (CBT) For Chronically Ill Children/Adolescents with Needle-Related Distress**. Needle-Related Distress is when the individual experiences mild, moderate or severe levels of fear and/or anxiety when exposed to a needle injection.

- **Therapy will continue for 4 or 6, one-hour per week sessions** at the Massey Psychology Clinic either in Wellington or Palmerston North. In some circumstances therapy may be held at a place convenient for the family.
- **Treatment will be of no cost to the family, and all travel costs will be reimbursed** to the Massey Psychology Clinic in Palmerston North and Wellington.
- In addition to the time required for therapy, **children/adolescents and their parents will need to commit between 3.5 to 5.0 hours spaced over 18 to 23 weeks** in order to complete treatment outcome measures.
- A **maximum of 12** and a **minimum of 9 children/adolescents and their parents** will be invited to participate. Therapy will be held at a **time convenient for the family**, and is **flexible to allow for family commitments**.

Please contact Jessica (see below) if you would like more information or to participate in this study ☺

Jessica McIvor, Project Leader

Cell: 027 696 2336

(Option: Text the Cell Number Above and Jessica Can Call You Back)

Telephone: 04 475 4003

Email: mcivormassey@gmail.com

Appendix 4

Information Flyer for Health Professionals

Free Therapy (CBT) For Children with Needle Distress

SCHOOL OF PSYCHOLOGY

MASSEY UNIVERSITY

You are invited to identify children/adolescents and their carers who may wish to participate in this project run by Jessica McIvor, as part of a Doctorate in Clinical Psychology at Massey University.

This study aims to assess the effectiveness of a **Brief Cognitive-Behavioural Therapy (CBT) for Chronically Ill Children/Adolescents with Needle-Related Distress**. Needle-Related Distress is when the individual experiences **mild, moderate or severe levels of fear and/or anxiety** when exposed to a needle injection.

Therapy will continue for 4 or 6, one-hour per week sessions at the Massey Psychology Clinic either in Wellington or Palmerston North. In some circumstances therapy may be held at a place convenient for the family. **Treatment will be of no cost to the family, and all travel costs will be reimbursed** to the Massey Psychology Clinic in Palmerston North and Wellington. Therapy will also be held at a **time convenient for the family**, and is **flexible to allow for family commitments**.

In addition to the time required for therapy, **children/adolescents and their parents will need to commit between 3.5 to 5.0 hours spaced over 18 to 23 weeks** in order to complete treatment outcome measures. We need a **maximum of 12 and a minimum of 9 children/adolescents and their parents** to participate.

Children are invited to take part if they are:

- ✓ Aged 8 to 12 years (children aged 5 to 15 years may be included on a case by case basis),
- ✓ Currently experience Needle-Related Distress,
- ✓ Currently experience a chronic medical illness that requires them to have regular needle injections,
- ✓ Have a cooperative parent/caregiver who is willing to participate in treatment,
- ✓ Not already receiving cognitive-behavioural therapy.

Children cannot take part if they are:

- ✗ Diagnosed with cancer,
- ✗ Presenting with significant mental health problems that require immediate attention,
- ✗ Have a parent/caregiver who presents with significant mental health problems,
- ✗ Currently experience care and protection issues,
- ✗ Not fluent in English.

Who can refer? = Any health professional and/or the family themselves. Referrals can be made by simply contacting Jessica (see below)

Jessica McIvor, Project Leader

Cell: 027 696 2336

(Option: Text the Cell Number Above and Jessica Can Call You Back)

Telephone: 04 475 4003

Email: mcivormassey@gmail.com

Appendix 5

Referral Form



MASSEY UNIVERSITY

Needle Therapy Referral Form

1. CLIENT DETAILS:

Surname: _____ First names: _____

Gender: M F DOB: _____

Ethnicity

Māori – tribal affiliation: _____ New Zealand European/Pākehā

Pacific Island (*please specify*) _____ Other (*please specify*) _____

2. PARENT/CAREGIVER :

Name: _____ Ph: (H) _____ Ph: (M) _____

Address: _____ Fax: _____ Ph: (W) _____

Email: _____

Postal Address: (*if different from above*) _____

3. PERSON MAKING REFERRAL: *If different from 2 above (e.g. health professional)*

Name: _____ Ph: (H) _____ Ph: (M) _____

Address: _____ Fax: _____ Ph: (W) _____

Email: _____

4. REASON FOR THE REFERRAL:

Needle-Related Distress? No Yes Frequency of Injections? Weekly Monthly

Other (*please specify*) _____

What chronic health condition is the child diagnosed with?

Please provide a brief description of the child's distress in relation to needle injections.

Are there any other agencies currently involved with your child? (please list them below)

Please submit the completed referral form by mail, email or fax as follows:

J. A. McIvor, Project Leader

WELLINGTON

mcivormassey@gmail.com (*preferred method of submission*)

Fax: (04) 801 0493

Psychology Clinic, Massey University, PO Box 756, Wellington, 6140 (Attention: Jessica McIvor)

If you have any enquiries, please call: 027 696 2336

Appendix 6

Assessment Interview Protocol



MASSEY UNIVERSITY

Child Name: _____

Parent Name: _____

Parent present during interview: Yes No

Interviewer: _____ Date and time of interview: _____

Location of interview: _____ Duration of Interview: _____

Severity of Needle-Related Distress: Low Medium High

Risk of harm to self or others: Low Medium High

**To be completed at the end of the assessment*

Note: The order outlined in the following interview schedule is a guideline only, therefore in practice items will be discussed when appropriate rather than in a tick box fashion.

Tip: Be aware of timing and pace, language and rapport!

The Opening

1. "What brings you here today...?"
2. "What do you understand about being here today...?"
3. "Do you know why you are here?"

Establish rapport

- Conversation and small talk
- Put the family at ease
- Build rapport with the child and family
- Establish rapport and small talk (topics: school, favourite game, friends, hobbies...)
- Get to know the child not just the problem
- Be warm, kind and genuine
- Play a quick game

Presentation (note only important items)

- Engagement and insight into condition
- Eye contact and posture
- Hygiene / Dress
- Quality / quantity of speech
- Thought process
- Emotional state
- General cognitive functioning
- Behavioural observations

Explain Purpose of Interview and Confidentiality

- (Purpose) Provide a brief introduction and explanation of the purpose of the interview, for example what we will talk about today
- (Medical doctor) It is very important to explain that we are going to talk about feelings and behaviours. That no medical procedures (e.g., needle injections) will occur with me and that I am not a medical doctor.
- (Psychologist) Ask the child if they know what a psychologist is, and then explain to them what we do and how we are not medical doctors.
- (Make a deal) Explain to the child and carer that we do an in-vivo at the end of therapy, and that no physical restraint will occur. Explain the difference between cuddle (mum) and restraint (stranger). Be honest and transparent about the injection and my stance on physical restraint.
- (Confidentiality) Explain confidentiality and its limitations

Explain Research

- Give a brief overview of the research,
- Obtain written consent to participate in the research
- Provide an opportunity to ask any questions about the research

Chronic Health Condition

Health and Medical:

- Medical history
- Mental health history
- Medications

What is the child's level of illness perception?

What chronic health condition is the child diagnosed with?

How long has the child been diagnosed with a chronic health condition?

How severe is the chronic condition?

Mood Screen (anxiety and depression)

- Use five-part model as a guide (e.g., cognition, emotion, behaviour and physical symptoms)
- Sometimes sadness/depression can present as irritability in children
- Assess for other areas of the child's life where they experience anxiety, as children with NRD are typically quite anxious in general. These factors are important to obtain as this could impact on

Five-part model:

Physical:

- Sleep
- Appetite
- Sore tummy
- Energy level
- Sore neck
- Concentration

Cognition:

- Negative thoughts about self, others and future

Behavioural:

- Pleasant events
- Motivation
- Effort
- Effectiveness
- Social withdrawal

Emotion:

- Tearful/crying
 - Elevated mood
 - Anxiety
 - Anger
 - Irritability
-
-
-
-

Safety Issues (Risk Assessment)

Are there any safety issues?

- Suicidal ideation
 - Previous self-harm
 - Risk to others
 - Abuse (self / others)
 - Threats (self / others)
-
-
-
-

Background Information: Personal and Family history

Socio-cultural factors:

- Education/School
- Cultural beliefs and practices
- Religion / Spirituality

Family and other social relationships:

- Psychological history of family members
 - History of NRD in the family
 - Friendships at school or home
-
-
-
-

Guideline for Next Section: "Paint Me A Picture" – if I was looking through a window and saw you having an injection what would I see?). Use most recent needle injection (ask if that reaction is normal)

Q: Question to assess for other anxiety: "are there other situations that you feel scared?"

Nature of Needle Injections

What are the type, frequency and location of needle injections?

Development of NRD

Onset – When did the NRD first start? What happened at the time (e.g., trauma)?

Fluctuations – Is the NRD lifelong or re-occurring? Is the NRD static or has it changed over time?

Frequency, Intensity and Duration of the NRD

Extra factors to consider (Five W's):

- What is the nature of the distress?
- Where does the problem occur?
- When does the problem occur?
- Why (what is the feared belief or consequence)?
- With whom does the problem occur?



Use the 5 W's as a guideline for assessing the nature of distress

What is the frequency of the NRD? Does it occur every time the child has a needle injection?

How intense is the NRD (0 - not intense at all – 10 - very intense)

How long does the NRD last during one episode?

Modifiers – what makes the NRD better or worse (e.g., having mum present)?

ABC Analysis

Assess the cognition, emotion, behaviour and physical symptoms of NRD (five-part model). Tip: Use the most recent needle injection to determine what the ABC's are for each participant. Then ask the child if what they have described is what typically happens when they have an injection. Can also use *Paint Me A Picture* technique if the child is struggling with the exercise

Antecedents – What are the triggers to the problem, these can be internal or external. What physical symptoms are present? Emotions: anger, guilt, shame, fear, embarrassment, shame. Children tend to express feelings of distress emotionally/behaviourally rather than cognitively.

Behaviour – What does the child do when distressed? Examples include avoidance, gains reassurance, restraint and safety behaviours etc.

Consequences – What happens afterwards in terms of reduced or increased anxiety, improved or worsened mood, others reactions, rewards given?

Development of a Fear Hierarchy (Ladder)

Instructions: Draw a vertical picture of a ladder on a piece of paper anchored 1 (no distress) to 10 (extreme distress). Explain to the child that it is a ladder and that in order to get to the top we cannot jump 5 steps but need to go up it slowly in order to get to the top. The top step is the toughest step to get to and the bottom step is the easiest step to get to. Use *Paint Me A Picture* technique if the child is struggling with the exercise.

Prompt and offer suggestions to the child if necessary. Do not ask what might be a “2”, “5” or 10” as children response to more concrete questions and examples. I do not need 10 items on the hierarchy, and in some cases will have one three items (e.g., low, medium and high). Items suggestions may include: a picture of a needle, picture of a hospital, watching someone else have a needle injection (video), touching a needle, having a pretend injection with a fake needle, have a real needle injection.

Describe any extra information that may be revealed during the fear hierarchy.

Coping strategies – What does the child do to cope, and what coping skills/assets do they have?

Strengths and protective factors:

- Motivation to change
- Intelligence
- Insight into their condition
- Family / Whānau support
- Community support
- Spirituality / religion
- Talents / abilities
- Interests / hobbies
-

Previous interventions/strategies – What has worked well and what has not worked well.

Research Psychometrics

- Administer research measures (approximately 20-30 minutes each). Ask the child and carer to complete them at the same time.

The Closing

- Summarise crucial themes and provide interpretation of information
- Reassure and support the family (instil hope)
- Reinforce that therapy will be successful and helpful for them in the short- and long-term
- Offer an opportunity for any further questions or comments.

Appendix 7

Needle Injection Questionnaire - Child

Child Questionnaire



Hi! Thank you for filling out this questionnaire. Please answer each question as honestly as you can – remember there are no right or wrong answers! Please place a mark on the line that best describes your answer or write in the space provided. 😊

What Is Today's Date? _____

When was your most recent injection? _____

Section One

1.1) In general, how upset do you become when having a needle injection? (Place a mark on the line below that best shows your answer.)



1.2) Circle the face that best shows how much it hurts you when having a needle injection.



1.3) Circle the face that best shows how scared you are when having a needle injection.



Section Two

2.1) In general, how much do you want to avoid having a needle injection? (Place a mark on the line below that best shows your answer.)

I definitely want to avoid it |-----| I do not want to avoid it at all

2.2) What are the kind of things that you think and/or do to try and avoid having a needle injection? (This may include crying, telling mum that you don't want the injection, or someone holding you down while having the injection etc.) Write your answer in the space provided below.

.....

.....

Section Three

3.1) What thoughts come into your head when you think of having a needle injection? (Write these thoughts below and then place a mark on the line that best shows how much you believe each thought.)

Thought 1.....

I definitely believe it |-----| I do not believe it at all

Thought 2.....

I definitely believe it |-----| I do not believe it at all

Thought 3.....

I definitely believe it |-----| I do not believe it at all

3.2) What thoughts come into your head about the person giving you the needle injection?

(Write these thoughts below and then place a mark on the line that best shows how much you believe each thought.)

Thought 1.....

I definitely believe it |-----| I do not believe it at all

Thought 2.....

I definitely believe it |-----| I do not believe it at all

Thought 3.....

I definitely believe it |-----| I do not believe it at all

Section Four

4.1) In general, how much are you able to help yourself feel more comfortable when having a needle injection? (Circle a number on the scale below that best shows your answer.)

1-----2-----3-----4-----5-----6-----7
I am not able to help myself feel comfortable at all |-----| I am completely able to help myself feel comfortable

4.2) When you are having a needle injection, what do YOU think and/or do in this situation to help yourself feel comfortable? (Write this in the space provided below.)

Action or Thought 1.....

Action or Thought 2.....

Action or Thought 3.....

Appendix 8

Needle Injection Questionnaire - Parent

Carer Questionnaire



Hi! Below are some questions relating to needle injections. Some questions ask about your child's reaction to needle injections, while others ask about your own reactions to your child's needle injections. Answer each question as honestly as you can, and remember there are no right or wrong answers!

Date _____

Section One

1.1) In general, how distressed is your child when having a needle injection? (Place a mark on the line below that best shows your answer.)

My child is extremely distressed |-----| My child is not distressed at all

1.2) In general, how distressed are you when your child is having a needle injection? (Place a mark on the line below that best shows your answer.)

I am extremely distressed |-----| I am not distressed at all

Section Two

2.1) In general, how much does your child want to avoid having a needle injection? (This may include them telling you that they don't want to have an injection, leaning away, or physical restraint etc.) (Place a mark on the line below that best shows your answer.)

My child definitely wants to avoid it |-----| My child does not want to avoid it at all

2.2) In response to the question above (2.1), is it typical of your child to react in that way?

Yes No

Please explain your answer.....

.....

2.3) In general, how much do you want to avoid your child's needle injection? (This may include cancelling appointments etc.) (Place a mark on the line below that best shows your answer.)

I definitely want to avoid it |-----| I do not want to avoid it at all

Section Three

3.1) In general, how much are you able to help your child feel more comfortable when they are having a needle injection? (Circle a number on the scale below that best shows your answer.)

1-----2-----3-----4-----5-----6-----7

I am not able to help my child feel comfortable at all

I am completely able to help my child feel comfortable

3.2) In general, how much are you able to help yourself feel more comfortable when your child is having a needle injection? (Circle a number on the scale below that best shows your answer.)

1-----2-----3-----4-----5-----6-----7

I am not able to help myself feel comfortable at all

I am completely able to help myself feel comfortable

3.3) When your child is having a needle injection, what do YOU think and/or do in this situation to help yourself feel more comfortable? (Write this in the space provided below.)

Action or Thought 1.....

Action or Thought 2.....

Action or Thought 3.....

3.4) These questions relate to the most recent needle injection that your child has had. Circle the word "TRUE" if you think it is true about your child. Circle the word "FALSE" if you think it is not true about your child.

- | | | |
|---|------|-------|
| Was your child afraid during this procedure? | True | False |
| Did he/she say "ouch" or "it hurts"? | True | False |
| Did your child cry? | True | False |
| Did he/she physically hold on to you or the nurse? | True | False |
| Was your child quiet during the procedure? | True | False |
| Did he/she follow instructions given by the nurse without complaining? | True | False |
| Did your child have to be held down by force? | True | False |
| Did he/she look away or close his/her eyes during the procedure? | True | False |
| Was your child cooperative? | True | False |
| Did he/she engage in conversation on his/her own accord? | True | False |
| Did your child ask questions about instruments or how the procedure would feel? | True | False |
| Was he/she aggressive, biting, kicking, etc.? | True | False |
| Did your child ask you to hold or comfort him/her during the procedure? | True | False |
| Did he/she scream or yell? | True | False |
| Did your child talk about topics unrelated to hospital i.e., family, friends or home? | True | False |

Appendix 9

Articulated Thoughts in Simulated Situations (Coding and Stories)

ATSS coding description (Taken from Davison et al. 1983)

Category	Description of Category
Positive Feeling	A statement that expresses a positive affective state of the subject.
Negative Feeling	A statement that expresses a negative affective state of the subject.
Negative Anticipation	A statement expressing anticipation of an event that would result in a negative outcome for the self.
Positive Anticipation	A statement expressing anticipation of an event that would result in a positive outcome for the self.
Resignation	A statement that expresses perceived hopelessness or an intention not to attempt to have influence in a situation.
Problem Solving	A statement that specifies and/or evaluates a possible course of action or solution to a problem. These solutions or courses of action must be generated by the subject and not by the taped speaker(s).
Other	Any statement that cannot be placed into one or more of the above categories.

McDonalds Story (Control Story)

1. Information about going to McDonald's

"We're off to McDonald's" mum says! Your brothers and sisters all jump up in down in excitement and start getting ready. Mum is searching around for her keys – "Ekkkk" she says.

“Where are my keys!” She gets everybody to look around for her keys. (15-30 second interval)
(Prompt question – “What are you thinking and feeling right now?”).

2. Just before McDonald’s

Finally mum finds her keys and everyone jumps into the car. “We’re off” mum says! But just as you get down the road, your younger sister Jenny starts crying. Your brother has taken her favourite teddy off her. She is crying so loudly you have to cover your ears – it hurts. Mum stops the car to find out what is going on. She turns around and asks Jenny what is wrong, and your brother gets told to give the teddy back or else he will get nothing at McDonalds. Mum keeps talking to your sister to try calm her down... (15-30 second interval)
(Prompt question – “What are you thinking and feeling right now?”).

3. During McDonald’s

Your sister has stopped crying and your younger brother finally leaves her alone. Mum starts the car and keeps going down the street. Gosh this street goes on forever! Finally Mum turns the corner and there it is, “McDonalds!” you and your brother yell loudly together. “Yay we’re finally here!” Mum parks the car. McDonalds is really busy and the line has lots of people. You run in and start waiting. People have to wait in lines that twist back and forwards behind black tapes. Suddenly your brother stands on your foot – “ouch!” “Get off my foot!” you yell at him. Your brother laughs at you. The line gets smaller and smaller until suddenly it is your turn to order. “A Big Mac with fries please”, you say very excitedly. The girl smiles at you and then says, “Sorry but there is a 20 minute wait on Big Mac’s” – “Would you like to order something else?” ... (15-30 second interval) (Prompt question – “What are you thinking and feeling right now?”).

4. After McDonald’s

Mum puts her hand on your shoulder and says “It’s okay, just order something else. Next time we come to McDonald’s we’ll get you a Big Mac, I promise”. You end up ordering a McChicken burger instead and it looks just as big as a Big Mac! Your brothers and sisters are smiling now and mum looks happy. (15-30 second interval) (Prompt question – “What are you thinking and feeling right now?”).

Having a Needle Injection (Experimental Story)

1. Information about the injection

One day after school you were feeling sick, so your mum took you to see a nurse at the hospital. The hospital is big and busy with lots of different people. The nurses and doctors are

all wearing uniforms and have badges with their names on them. The hospital also has lots of equipment and machines to help doctors and nurses find out why you're sick.

As you arrive, you meet the nurse who will look after you. Her name is Annabel. Annabel tells you, that today you will have an needle injection. She explains that needle injections are used to help people feel better and get special medicine into their body. Annabel shows you where the needle will go and how long it is. As you look at it, you can see that it's quite shiny and very sharp at one end. You then realise that the needle is going to poke deep into your skin... (15-30 second interval) (Prompt question – "What are you thinking and feeling right now?").

2. Just before the injection

Annabel smiles encouragingly at you, while leading you into a room. You notice that the room is white and bare, with maybe a few pictures on the wall. She begins to set up the equipment, makes sure the needle is clean, that there are cotton balls ready, and plasters just in case! Annabel then tests that the needle is working by flicking the tip and swirting some liquid out. It must be working fine – because the liquid squirts out as if waiting to be set free! Annabel slowly comes toward you with the needle in her hand... (15-30 second interval) (Prompt question – "What are you thinking and feeling right now?").

3. During the injection

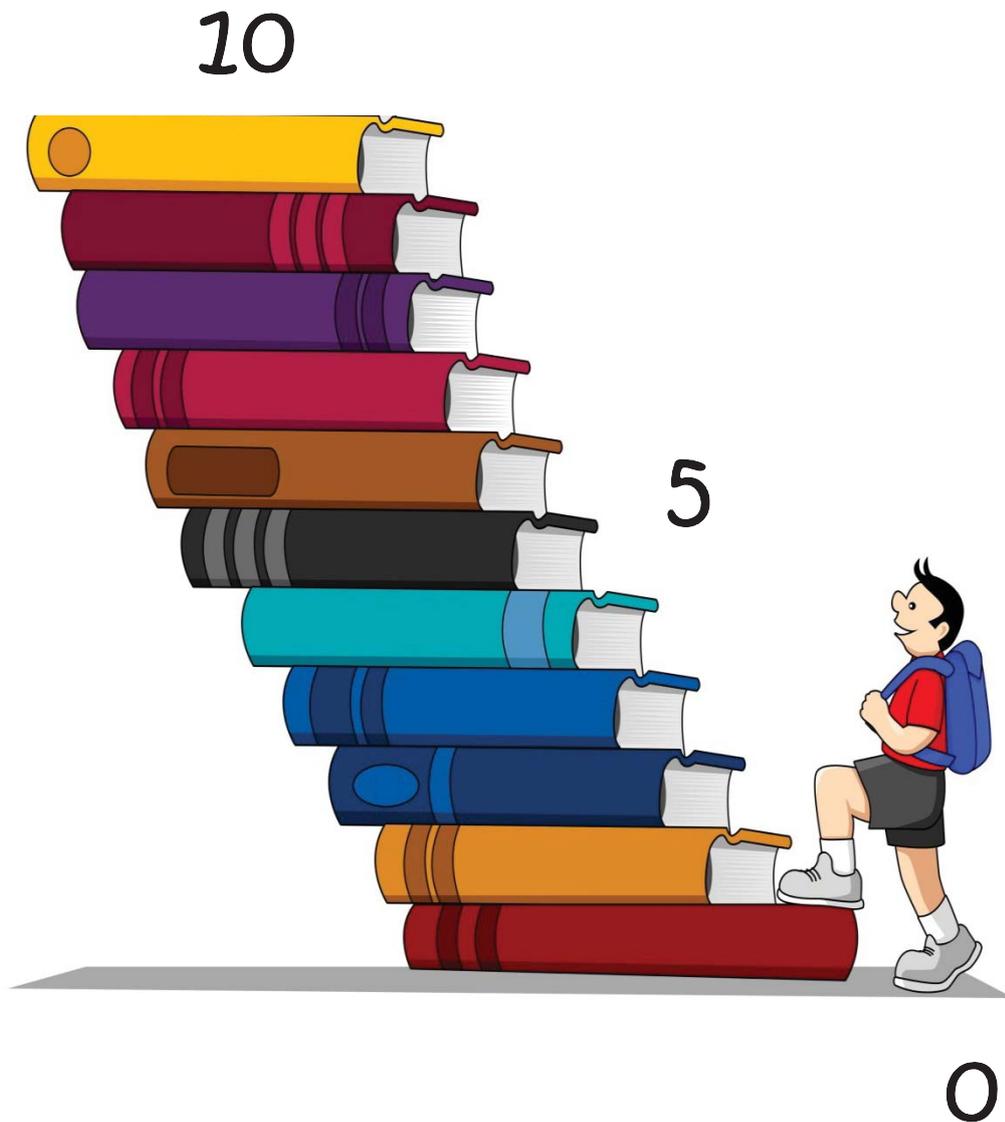
Annabel holds your arm and makes sure your sleeve is rolled up. She then starts to wipe a small area on the upper part of your arm with a white cotton ball. The cotton ball is wet on your skin and it smells really strong. Annabel puts the cotton ball down and picks up the needle. She raises the needle and places it on your skin, and you can feel the cold sharpness of the metal lying there. Annabel then slowly pushes the needle into your arm, and then you can feel it, that part where it very sharply pricks your skin... (15-30 second interval) (Prompt question – "What are you thinking and feeling right now?").

4. After the injection

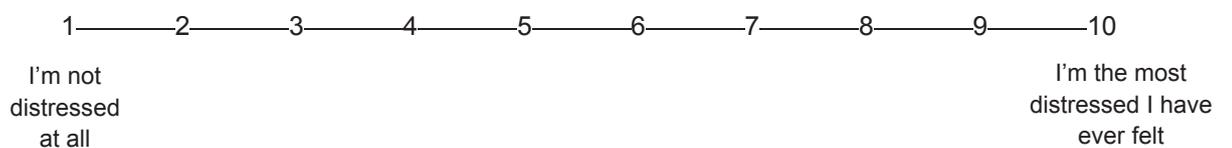
As Annabel begins to carefully pull the needle out, you look at your arm and see that it has gone slightly red. You don't want to, but you look once again, now a small area has a little bit of blood on it where the needle came out! Annabel quickly begins to wipe it away with another white cotton ball. She gently places a plaster on your arm. At last Annabel says to you "It's finished" and mum smiles. You look down again and see that the white cotton ball has gone a little red as it soaks up your blood... (15-30 second interval) (Prompt question – "What are you thinking and feeling right now?").

Appendix 10

Fear Hierarchy and Subjective Units of Distress



On the scale below, where 0 means you're not distressed at all, and 10 means you're the most distressed you have ever felt. **In general, how distressed are you about having an needle injection?** (Circle a number on the scale below that best shows your answer.)



Appendix 11

Treatment Component Rating Scale

Child Questions



The next section includes the last set of questions for you to fill out. You have not answered these questions before so they may seem unfamiliar. Please be as honest as you can – remember there are no right or wrong answers!

Section Six

We would like to know what activities were most helpful to you during therapy. Please read the question below and place a mark on the line that best shows your answer.

6.1) How helpful was it to learn about **anxiety (e.g., different feelings and body reactions)** during therapy?

Not at all helpful  _____  Very helpful

6.2) How helpful was it to **receive an award/prize** during therapy?

Not at all helpful  _____  Very helpful

6.3) How helpful was it to learn **breathing exercises** during therapy?

Not at all helpful  _____  Very helpful

6.4) How helpful was it to learn **muscle relaxation** during therapy?



6.5) How helpful was it to **practice having a needle injection (e.g., role plays)** during therapy?



6.6) How helpful was it to **have a real needle injection** during therapy?



6.7) How helpful was it to learn **emotive imagery** during therapy?



6.8) How helpful was it to **learn new coping thoughts** during therapy?



Carer Questions



The next section includes the last set of questions for you to fill out. You have not answered these questions before so they may seem unfamiliar. Please be as honest as you can – remember there are no right or wrong answers!

Section Six

We would like to know what activities you think were most helpful for your child during therapy. Please read the question below and place a mark on the line that best shows your answer.

6.1) How helpful was it for your child to learn about **anxiety (e.g., different feelings and body reactions)** during therapy?

Not at all helpful |-----| Very helpful

6.2) How helpful was it for your child to **receive an award/prize** during therapy?

Not at all helpful |-----| Very helpful

6.3) How helpful was it for your child to learn **breathing exercises** during therapy?

Not at all helpful |-----| Very helpful

6.4) How helpful was it for your child to learn **muscle relaxation** during therapy?

Not at all helpful |-----| Very helpful

6.5) How helpful was it for your child to **practice having a needle injection (e.g., role plays)** during therapy?

Not at all helpful |-----| Very helpful

6.6) How helpful was it for your child to **have a real needle injection** during therapy?

Not at all helpful |-----| Very helpful

6.7) How helpful was it for your child to learn **emotive imagery** during therapy?

Not at all helpful |-----| Very helpful

6.8) How helpful was it for your child to **learn new coping thoughts** during therapy?

Not at all helpful |-----| Very helpful

Appendix 12

Post-Therapy Feedback Questionnaire

Child Questions



Section Seven

Now you can tell me in your own words what you thought about therapy. Remember there are no right or wrong answers!



7.1.1) What did you not enjoy about therapy

.....

.....

7.1) What did you enjoy about



.....

.....

7.2) What activities would you have liked to do differently in therapy? Please explain your answer.

.....

.....

7.3) Would you have liked more or less therapy sessions? Please explain your answer.

.....

.....

7.4) Did you find it helpful having your Mum or Dad in therapy with you? Would you have liked any other family/whānau to be in therapy with you?

Yes

No

Please explain your answer.....

.....

Do you have any other comments?

.....

.....

Thank You! 😊

Carer Questions

Section Seven

Below are some open-ended questions about what you thought of therapy in general, and how you might make adaptations to improve the therapy programme. Please be honest, and remember there are no right or wrong answers.

7.1) What modifications would you make to the approach used in therapy to meet your cultural needs? (This may include but is not limited to, culturally appropriate icons, pictures, language, introductions/welcome and/or environment).

.....
.....

7.2) Was the number of therapy sessions enough to meet your needs? Please explain your answer.

.....
.....

7.3) In general, are there any modifications you would make to therapy?

.....
.....

7.4) Would you recommend this therapy programme to any friends and/or family that also have a child distressed by needle injections? Please explain your answer.

.....

.....

7.5) Do you have any other comments?

.....

.....

Thank You! ☺

Appendix 13

Session Rating Scales

Child Questions

Section Five

How was our time together today? (Place a mark on the lines below to let me know how you feel.)

5.1) What We Did Today

I did not like what we did today  _____  I liked what we did today

5.2) Overall

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

Carer Questions

Section Four

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

4.1) Approach and Method

The therapist's approach is not a good fit for me  _____  The therapist's approach is a good fit for me

4.2) Overall

There was something missing in the session today  _____  Overall, today's session was right for me