Will the Needle Make Me Bleed to Death?

The Development and Evaluation of a Cognitive-Behavioural

Therapy 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 cognitive-behavioural therapy for childhood needle-related distress (NRD), although there are significant gaps in the literature that need to be addressed. The aim of the present study was to develop and evaluate a six-session cognitive-behavioural therapy to alleviate NRD among chronically ill children. The research was designed to pilot this manualised approach, which was based on an existing therapy utilised at the Massey Health Conditions Psychology Service, relevant theory and empirical research. The therapy programme known as the "Coping Kids Treatment Manual" differed from previous research by incorporating cognitive components, carer involvement and multiple exposure sessions.

A single-subject multiple-baseline across participants design was used to assess the effectiveness of the treatment manual. Four chronically ill children (aged 6-14 years) of New Zealand European descent diagnosed with NRD and their carers participated in this study. Child and carer self-report measures were collected during baseline, treatment and once at one month follow-up. 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 needle injection situations. Follow-up data showed treatment gains were maintained and/or improved at one month. Most importantly, these gains were accompanied by three of the four children successfully receiving an in-vivo needle injection during session five of the intervention. Findings are interpreted in terms of previous literature, and implications are discussed according to theory, research and clinical practice. Limitations of the present study are highlighted and recommendations for future research directions are outlined. Suggestions for future research include evaluating the effectiveness of the treatment manual with a larger and more diverse group of children, extending follow-up periods and utilising more rigorous measures. Additional research is also required to investigate what components are most critical in producing meaningful change and to what extent carer involvement enhances treatment outcomes. Overall, preliminary findings offered support for the effectiveness of the Coping Kids Treatment Manual in treating four chronically ill children with NRD.

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Chapter 1: Introduction

Chronic Medical Conditions in Children and Needle Injections

Chronic medical conditions affect a large number of children and families 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). Research investigating the prevalence of chronic medical conditions show an estimated 10 - 20% of children in Western developed countries and 30.8% (i.e., 21 million) of children in the United States (US) are diagnosed with a chronic physical condition (Cadman, Boyle, Szatmari, & Offord, 1987; Newacheck & Taylor, 1992). Most recently, the 1994 National Health Survey in the US estimated 18% (i.e., 12.5 million) of children aged under 18 have a chronic health condition (Newacheck et al., 1998). Estimates vary considerably which could be due to the different approaches to defining chronic medical conditions, different severity thresholds and measures used to ascertain these thresholds (Newacheck, McManus, Fox, Hung, & Halfon, 2000). Nevertheless, there are several medical procedures associated with diagnosing and treating chronic medical conditions, one of the most common of these procedures are needle injections.

Many chronic medical conditions require needle injections including cancer, leukaemia, bowel syndromes, rheumatic fever, multiple sclerosis, diabetes, allergies and chronic infections (Mohr, Cox, Epstein, & Boudewy, 2002; Patel, Baker, & Nosarti, 2005). In part, this is due to medical treatment regimes and an increase in technology whereby medications can only be delivered via regular needle injections (Mohr et al., 2002). Moreover, there are several different types of needle injection procedures that chronically ill children have to endure such as bone marrow aspirations (BMAs), lumbar punctures (LPs), venepunctures and vaccinations. These procedures typically differ according to the type, location and frequency of needle insertion.

BMAs and LPs are considered the most painful and 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 or absence of cancer cells (Jay et al., 1985). LPs are similar, however the needle is inserted into the spinal column and fluid withdrawn to be examined for the presence or absence of cancer cells.

Alongside BMAs and LPs, there are more general needle 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 obtaining a blood sample. Some needle injections are also required as part of a world-wide public health care initiative to prevent the onset of certain

diseases, this includes vaccinations which are one of the most common injection procedures in New Zealand. Moreover, although it is important to distinguish between different types of needle injections for medical purposes, it is also necessary as some suggest they have different psychological effects on the child (Jay et al., 1985; Mohr et al., 2002).

Some degree of apprehension towards 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 a needle 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 adequately (Humphrey, Boon, Van den Heuvell, & 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 needle 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). Immunisation coverage in New Zealand is also considered to be marginally acceptable with parental and caregiver attitudes towards needle injections contributing to incomplete procedures (Grant, Turner, York, Goodyear-Smith, & Petousis-Harris, 2010). Furthermore, a recent study conducted in New Zealand showed a fear of needles and a previous negative experience with vaccinations were key factors that determined immunisation incompletion (Bland, Clear, Grogan, Hoare, & Waldock, 2009). Research shows chronically ill children also view venepunctures as one of the most feared needle injection procedures (Humphrey et al., 1992). Overall, needle injections are identified as one of the most distressing and fear-provoking experiences for children going to hospital (Humphrey et al., 1992; Menke, 1981; Schechter, 2007).

In summary, chronic medical conditions among children are increasingly diagnosed and treated using needle injection procedures. In some circumstances, these procedures can be a great source of distress to the child and their carer (Pao & Bosk, 2011). Needle injections may elicit certain 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 needle injections, making it difficult to identify a dominant term (Thurgate & Heppell, 2005). There are also inconsistencies regarding the definition of some terms, and disagreements regarding the use of certain terms in relation to children. General needle-related

terms used in the literature include *needle and injection phobia, needle and injection fear, needle-related anxiety, and needle-related distress* (see Table 1 for a summary)*.*

Table 1

Definitions of needle-related distress

Term	Definition
Needle and injection phobia	Full DSM-IV criteria met for specific phobia. Excessive fear in relation to needle insertion, which is unreasonable and causes significant functional impairment (American Psychiatric Association, 2000).
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-related anxiety	A physiological, behavioural and/or emotional response, in relation to the apprehension of needle insertion (Kendall et al., 1992; Sadock et al., 2007).
Needle-related distress	Full DSM-IV 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).

Phobia

The term *phobia* derives from the Greek 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 fact dangerous (Butler, 2001, p. 97; Stewart, 1994, p. 549). *Needle phobia* and *injection phobia* tend to be similarly defined, and used when attempting to classify specific phobia, blood-injection-injury type, which is a cluster of phobias that includes fear of blood, injury, injections, or any invasive medical procedure (American Psychiatric Association, 2000). The reaction of a person with needle/injection phobia is extreme and can include a vasovagal response with symptoms of dropping blood pressure and fainting during injections (Howe, Ratcliffe, Tuttle, Dougherty, & Lipman, 2011).

In the general psychological literature, needle phobia and injection phobia are also used as both lay and professional terms (Thurgate & Heppell, 2005) and are seen to cause significant distress and functional impairment (Antony, 1997). Needle phobia tends to be defined as "fear of medical procedures involving the insertion of needles into the body" (Thurgate & Heppell,

2005, p. 15). Similarly, injection phobia is defined as "fear of receiving various types of injections and having a blood sample drawn from venepuncture or pricking a finger" (Öst, 1992, p. 68). There is little difference between these two definitions, 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), and are often used interchangeably in the psychological literature (Wolman, 1994). 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 internal or external threat) and signal the person to take action (Kendall et al., 1992). On the other hand, some argue that fear and anxiety should be differentiated from one another. For example, fear is 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).

In relation to needle injections, fear and anxiety are defined quite similarly, and some authors even choose to use both terms in research (e.g., Simmons et al., 2007). Most recently, needle fear has been described quite simply in an Australian study as a positive response to the question "Are you afraid of needles?" (Yelland, Heathcote, & Ng, 2009); a process similarly used by Simmons et al. (2007). Needle fear has been used in a number of other studies (e.g., Agras, Sylvester, & Oliveau, 1969; Antony, 1997; Howe et al., 2011). In addition, anxiety-related terms are commonly used in the literature to describe the reaction children have towards needle injections, such as 'needle anxiety' (e.g., Howe et al., 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). These anxiety-related terms are typically defined according to the construct 'anxiety' as outlined above. Overall, fear and anxiety in relation to needle 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* to form a definition of distress, despite a lack of empirical evidence supporting the inclusion of this construct (Duff, 2003; Uman et al., 2008). In relation to needle injections, it has been suggested that *needle-related distress* should be reserved for individuals that do not meet full Diagnostic and Statistical Manual (DSM-IV) criteria for specific phobia, blood-injury-injection type (American Psychiatric Association, 2000), but present with significant fear and anxiety

regarding needle 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 needle injections.

There are several disagreements in the literature regarding the use of the term needle phobia in relation to children. For example, Humphrey et al. (1992) argue that needle 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". Therefore, it could be argued that needle injections are a legitimate threat, and distress is a normal response for children.

In light of these arguments, the term used in the current study is needle-related distress (NRD), which is defined as "distress occurring in relation to the expectation or experience of having a needle injection". There were two main reasons to focus on this construct, the first being that NRD is the most inclusive term making the present study relevant for a broader range of children. Second, considering the argument that needle injections are not benign stimuli for children, but rather a legitimate threat that may involve the distress response, terms such as phobia were ruled out.

Now the phenomenon of interest has been defined, the following sections describe why NRD is an important problem, alongside a brief review of the evidence regarding aetiology, carer and health professional influences on child distress and coping. These 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; to manualise and evaluate a cognitive-behavioural therapy for chronically ill children experiencing NRD that incorporates cognitive components, carer involvement and multiple exposure sessions.

Prevalence of Needle-Related Distress

Needle-Related Distress

There is limited data available on the prevalence of NRD among chronically ill children, instead researchers have focused on *healthy* children experiencing NRD and, more commonly, injection fear and needle phobia while having routine procedures such as immunisations and blood tests. Fradet, McGrath, Kay, Adams, and Luke (1990) are some of the few researchers

that have investigated NRD among chronically ill. In this prospective study of 171 chronically ill and healthy children aged 3 to 6 requiring venepuncture, 36 - 64% of children experienced moderate to high levels of distress during the procedure (Fradet et al., 1990). Age also accounted for 14% of the variance in distress, as did self-reported anxiety of the parent (*r* = 0.41, *p* < 0.001). Similarly, in a more recent qualitative study, an estimated 93% (*N* = 13) of children and adolescents diagnosed with cystic fibrosis (aged 7 to 17) had self-reported NRD (Ayers, 2011). Lastly, Humphrey et al. (1992) investigated the prevalence of NRD among healthy children and found 83% of toddlers (aged 2.5 to 6), 51% of preadolescents (aged 7 to 12) and 28% of adolescents (aged 12 to 18) were distressed while having a needle injection. There was also a strong relationship between distress and age, with younger children (aged 2.5 to 6) experiencing more distress. Gender was not correlated with distress levels.

Needle Fear and Needle Phobia

In comparison to research on NRD, there is somewhat more information on injection fear and needle phobia for healthy and chronically ill children. Research on childhood injection fear was first conducted in the late 1960's and was evident in 14% of 325 healthy children in a British community (Agras et al., 1969). Since then another study was conducted suggesting needle phobia was evident among 8.3% of children and adolescents diagnosed with diabetes attending a paediatric clinic in Sweden (Hanas & Ludvigsson, 1997). Results also showed that of those children, 16.8% of their mothers, and 17.7% of their fathers experienced needle phobia.

A more recent study assessed fear of injections and self-testing, in which 27% of children diagnosed with diabetes (*N* = 27 child/parent dyads) were found to be affected by needle anxiety (Simmons et al., 2007). Health professionals were also seen as relatively unreliable at diagnosing needle fear, as physicians, nurses and social workers only identified 50% of those with fear of self-injecting and self-testing. Meltzer et al. (2008) investigated injection fear in a large sample of 10,496 'healthy' children aged 5 to 16. Reports from the child, parent and teacher were gained as to whether the child's fear was "set off by an injection or some other medical procedure" (Meltzer et al., 2008, p. 783). The study showed injections were one of the most common fears in 10.8% of their large sample, although they did not define what was meant by "set off".

Most recently, the prevalence of fear, distress, pain and level of cooperation with needle injections has been investigated in children diagnosed with diabetes (Howe et al., 2011). Twenty-three children and their mothers were included with measures taken at diagnosis and six to nine months later. At diagnosis, more children reported fear of injections (40.9%) compared to pain of injections (22.7%). Six to nine months later, fear of injections reduced (9.5%), as well as pain with injections (9.5%). The percentage of mothers with self-reported fear and distress was also relatively high, with 43.5% reporting fear and 52.2% reporting distress when administering insulin injections to their child.

In summary, a wide range of terms (i.e., NRD, injection fear, needle anxiety and needle phobia) have been used to investigate the rate at which children have a negative reaction towards needle injections. This may have resulted in varying estimates from 8.3% (needle phobia) to 93% (NRD) (see Table 2 for a summary). This variability could be due to the restrictive definition of some terms in which full DSM-IV criteria must be met (i.e., needle phobia), in comparison to the broader definition of other terms whereby DSM-IV criteria does not need to be met (i.e., NRD). Therefore, 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 whereby everyday functioning is not necessarily impacted.

Table 2

Prevalence estimates for needle-related anxiety problems

	Construct	*N*	*Age*	*Prevalence*
(Fradet et al., 1990)	Needle-related distress	171	3-6	36-64%
(Humphrey et al., 1992)	Needle-related distress	233	2-18	28-83%
(Ayers, 2011)	Needle-related distress	14	7-17	93%
(Agras et al., 1969)	Injection fear	325	8-12	14%
(Meltzer et al., 2008)	Injection fear	10,496	5-16	10.8%
(Howe et al., 2011)	Injection fear	23	4-16	40.9%
(Simmons et al., 2007)	Needle anxiety	54	11-14	27%
(Hanas & Ludvigsson, 1997)	Needle phobia	159	10-18	8.3%

Several other factors can be attributed to such a wide range of prevalence rates. For example, needle phobia has only recently been defined according to DSM-IV thus diagnostic criteria have until recently been absent (Du, Jaaniste, Champion, & Yap, 2008; Hamilton, 1995; Silverman & Kearney, 1992). There are also inconsistencies regarding the definition of some terms used, which may have impacted on the design and theoretical framework of some studies. Different measures, procedures and age cohorts have also been used to investigate the same construct, potentially impacting on research outcomes (Silverman & Rabian, 1994). External validity is also compromised in some studies due to small sample sizes which restricts the generality of the results (see Table 2).

Despite this, some outline that an estimate of 10% prevalence for childhood needle phobia is credible (Agras et al., 1969; Hamilton, 1995; Hanas & Ludvigsson, 1997), with up to 50% of children experiencing significant levels of NRD (Fradet et al., 1990; Humphrey et al., 1992). However, an estimate of 10% for needle phobia should be interpreted with caution as prevalence rates vary considerably. For example, several other researchers estimate needle phobia to only have an incidence rate of around 2 to 4% for children and adults (Kleinknecht, 1987; Marks, 1988). Similarly, a more recent epidemiological study found that needle phobia was present in only 3.5% of 1920 healthy adults in a US community (Bienvenu & Eaton, 1998). Overall, the incidence of NRD appears to be common among children, which if left untreated can result in several short- and long-term implications.

Implications of Needle-Related Distress

NRD can have several short- and long-term psychological and social implications. While there is little research available on the clinical implications of NRD among chronically ill children, research has been conducted more broadly. Most studies have investigated the impact of childhood medical experiences (i.e., needle 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-Term Implications during Childhood

Initial short-term effects of NRD can include anticipatory nausea, insomnia, eating problems, anxiety, increased fear and pain responses, behavioural avoidance, non-adherence to treatment and less cooperation during subsequent needle injections (Ayers, 2011; Bush & Holmbeck, 1987; Howe et al., 2011; Jones et al., 2008; Kennedy et al., 2008; Young, 2005). NRD may also escalate over time with successive procedures (Ellis & Spanos, 1994; Young, 2005). A compelling example of this was demonstrated in children who received placebo instead of an oral analgesic agent during initial LPs and BMAs for the diagnosis of cancer. Children who received placebo for the initial procedures reported greater pain and distress compared to children who had received the active drug. Children continued to report higher pain and distress during subsequent procedures despite receiving oral analgesics (Weisman, Bernstein, & Schechter, 1998).

Long-Term Implications during Childhood

Childhood is a critical period for the development of health-related cognitions, attitudes and behaviours (Bush & Holmbeck, 1987). In particular, children who experience traumatic medical procedures may develop avoidant healthcare attitudes, which in turn can influence the likelihood of seeking healthcare in the future (Bush & Holmbeck, 1987; Pate et al., 1996).

Moreover, the relationship between negative memories of past traumatic needle injections and future behaviour and emotion states has been investigated in chronically ill children. Research shows children can recall between 59% (Chen, Zeltzer, Craske, & Katz, 2000) and 63% (Duff & Brownlee, 1999) of negative factual details about needle injections (e.g., the length of the needle), and over 46% rate their subsequent fear and anxiety of needle injections as "very" or "extremely" high (Duff & Brownlee, 1999, p. 8). Similarly, in a sample of 47 children hospitalised for surgical intervention, those with a history of more negative injection experiences showed 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). Results also revealed no effect between child distress and the *quantity* of negative experiences with needle injections, but rather the *quality* of the negative experience. As demonstrated, children's recollections of needle injections can be vivid, which may result in heightened distress during subsequent procedures, less cooperation and behavioural avoidance. However, more research is required to obtain more conclusive evidence.

Most recently, a qualitative study using semi-structured interviews explored the nature and management of NRD in children and adolescents (*N* = 14) with cystic fibrosis (CF) (Ayers, 2011). Participants identified previous needle experiences and pain as related to their current needle-related anxiety. NRD had a substantial impact on the children and their families, and led to treatment management problems and treatment refusal. More specifically, Howe et al. (2011) explored the level of pain, fear and cooperation in a sample of children newly diagnosed with diabetes (*N* = 23, children and mother pairs). Measures were taken at diagnosis, and six to nine months later. Results showed that, although fear and pain lessened over time, 9.5% of children continued to report fear and pain with needle injections nine months later. Self-report measures from mothers at diagnosis also showed that 21.7% of children did not cooperate, 26.1% gave verbal protest, and 17.4% showed physical protest during insulin injections. After nine months, 18.2% of mothers continued to report poor cooperation by children during needle injections, thus impacting on medical treatment adherence.

Childhood needle injections may be required for a variety of health-related issues. Therefore, it has been suggested anxiety and behavioural avoidance can generalise to other medical settings, such as seeing a physician when ill and/or dental treatment (Hamilton, 1995; Öst et al., 1992; Taddio et al., 2009). Children with NRD have also been reported to display increased pain and anxiety during oral injections (Poulton, Thomson, Brown, & Silva, 1998). Overall, NRD can be associated increased anxiety, behavioural avoidance and poor cooperation during subsequent needle injections, as well as generalise to a number of other medical settings.

Long-Term Implications during Adulthood

Research shows that anxiety and avoidance associated with needle injections are fairly stable across time, and may lead to health complications during adulthood (Bush & Holmbeck,

1987; Pate et al., 1996). For example, Pate et al. (1996) investigated the relationship between negative childhood medical experiences (including needle injections) on current fear and avoidance of medical situations among young adults. To determine a fear of needle injections, adults were asked questions such as "As a child, how afraid were you of having a shot…having an anaesthetic injection?" (Pate et al., 1996, p. 284). The study showed that child fear was a significant predictor of increased adult avoidance and fear of similar medical situations. Jones et al. (2008) also found similar results with a sample of college students, whereby those with more negative childhood healthcare experiences had the least adaptive healthcare behaviours and behavioural avoidance. This study also included needle injections, in which adults were asked "How afraid were you of getting an injection?" (Jones et al., 2008, p. 236). More recently, Yelland et al. (2009) found that, of 46.2% of adults who had a previous traumatic needle experience, at least 20.5% of them avoided medical treatment. This included a flu shot (64.1%), tetanus shot (30.8%), blood test (10.3%), pain relief (25.6%), and donating blood (76.9%). Therefore, childhood NRD can have long-term implications for the healthcare of adults.

Childhood NRD can also have several long-term psychosocial implications that may continue into adulthood, although few longitudinal studies have been conducted investigating this over time. Instead, most researchers simply report that "in their clinical experience and that of others treating this type of patient" (Öst et al., 1992, p. 263), NRD and phobia results in numerous problems. For example, patients typically avoid routine medical check-ups, see a physician when ill, and taking their children to medical check-ups or physician when ill (Hamilton, 1995; Marks, 1988; Öst et al., 1992; Taddio et al., 2009; Willemsen, Chowdhury, & Briscall, 2002). They may avoid going through a small operation, getting pregnant, receiving medication, blood tests, vaccinations and immunisations (Hamilton, 1995; Marks, 1988; Öst et al., 1992). Furthermore, an aversion to needle injections can affect plans for travel, as vaccinations are mandatory in some countries, as well as education and employment in medical-related professions (Hamilton, 1995; Marks, 1988; Öst et al., 1992). 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 et al., 2002).

Legal problems may arise as a result of needle phobia. For example, Marks (1988) reported that several patients had been charged by police for refusing to give blood specimens. In the past, the same patients had also refused local anaesthesia for dental operations and suturing, preferring to bear the pain instead. It was also 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). Most significantly, there have been at least 23 reported deaths during needle procedures due to needle phobia and the vasovagal reflex (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 consistently shows that negative experiences of needle injections in childhood can continue into adulthood, resulting in high levels of adult anxiety, increased procedural pain, avoidance and refusal of medical care (Pao & Bosk, 2011). Consequently, the need for effective psychological interventions to alleviate NRD in children is crucial so health complications in both childhood and adulthood can be mitigated. An in-depth understanding of the etiology of NRD is essential as it provides the foundation for the development of treatment models.

Etiology of Needle-Related Distress

A number of theories have been suggested in relation to the etiology of childhood NRD and phobic-type disorders (i.e., needle phobia), such as genetic predisposition (Ellinwood & Hamilton, 1991; Kleinknecht, 1987; Öst, 1991; Torgersen, 1979), premorbid temperament factors (Broome, Rehwaldt, & Fogg, 1998; Lee, 1996; Ollendick, Davis, & Sirbu, 2009), preparedness and neurohormones (Merckelbach, De Jong, Muris, & Van den Hout, 1996). However, NRD has predominantly been seen as part of a learned process, therefore it is widely recognised that behavioural theories play a significant role in the onset of this problem (Chen et al., 2000). In relation to cognitive theory, the majority of research has focused on needle phobia as opposed to other terms used in the literature. However, both behavioural and cognitive theories are thought to play a crucial role in the etiology and maintenance of phobic symptoms (i.e., anxiety and avoidance) (Coelho & Purkis, 2009; Merckelbach et al., 1996; Thorpe & Salkovskis, 1995). Given the focus of this study, the next section provides a brief overview of behavioural and cognitive theories of NRD (where available) and needle phobia.

Behavioural Theory: Classical, Vicarious and Informational Conditioning

Since the 1920's, classical conditioning has been suggested as a pathway to the acquisition of human fears and phobias (Watson & Rayner, 1920). Classical conditioning operates by pairing a conditioned stimulus (CS) to an unconditioned stimulus (UCS), after several pairing of the CS with the UCS, a conditioned response occurs (Davey, 2007). In contrast to adults, research investigating this pathway among children in relation to NRD or phobia is non-existent and instead focuses on how negative memories of past traumatic events can impact on future behaviour and emotion states. Due to this, evidence supporting the classical conditioning pathway in the onset of NRD among adults will be explored.

Öst (1991) showed in a sample of 56 adults aged 17 to 58 that 57% had a previous traumatic experience in relation to having a needle injection. This was replicated by Kleinknecht (1994) whereby 53% of 128 students (aged 17 to 76) attributed the onset of their injection fear to traumatic conditioning. Nevertheless, the reliability of these results are questionable as both studies used retrospective reports in order to determine the onset of an event that occurred, in some cases, up to 50 years ago. 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%).

Although research supports the classical conditioning pathway in the onset of needle phobia, there are methodological limitations to the way this has been studied, most notably due to the questionable reliability of retrospective reports of fear onset over time (Taylor, Deane, & Podd, 1999). For example, Taylor et al. (1999) found almost half (46%) of participants with a driving fear attributed the onset of their fear to different pathways after one year, with some participants moving from a conditioning event to 'cannot remember' or 'always been this way', and vice versa. Therefore, the reliability of research conducted using retrospective reports is questionable, particularly when test-retest results are not provided.

Vicarious conditioning is another pathway explaining the development of childhood NRD, which operates by observing the distress responses of others (e.g., carers) without experiencing direct conditioning (Blount et al., 2009). Studies focusing on this pathway among chronically ill children are scarce, however, a well-established finding in the adult literature is that parental modelling of behaviour in response to distressing stimuli affects behavioural responses in children (Ayers, 2011) and parental anxiety is positively correlated with child distress during needle injections (Fradet et al., 1990). Parental use of distraction techniques has also been shown to reduce NRD in children (Blount, Powers, Cotter, Swan, & Free, 1994; Manne et al., 1990). More recently, Askew and Field (2007) provided prospective and experimental evidence supporting the role of vicarious conditioning in the development of childhood fears. Taken together, literature suggests that vicarious conditioning of distress responses from others potentially contributes to the development of NRD among chronically ill children.

Regardless of personal experience, negative information about an object or situation can explain the development and maintenance of NRD (Blount et al., 2009). Information such as this may lead to maladaptive beliefs about the feared stimulus (e.g., needle injection), resulting in avoidance behaviour and reducing the chance of the child correcting these beliefs (Von Baeyer, McGrath, & Finley, 2008). For example, negative information regarding a needle injection can lead to short-term avoidance of the injection experience and facilitate persistent resistance (Blount et al., 2009). Overall, childhood NRD can be acquired through direct and/or indirect learning pathways. However, evidence suggests that associative pathways are not sufficient to explain the etiology of needle phobia (Öst, 1991; Von Baeyer et al., 2008), and cognitive theories have also been proposed.

Cognitive Theory: Attention and Information Biases

Until recently, cognitive factors have had relatively little impact on theories of the acquisition of needle phobia, this may be partly due to Seligman's (1971) conclusion that

specific phobias are 'non-cognitive' (Thorpe & Salkovskis, 1995). However, researchers are now suggesting that phobias are not only acquired through behavioural pathways, but also through cognitive processes, whereby the individual learns that a particular stimulus precedes an aversive outcome (Coelho & Purkis, 2009). From a cognitive perspective, phobic symptoms such as anxiety and distress are related to the attributions made regarding the safety and danger of the stimulus, perception of control over the situation and attribution regarding bodily reactions to the stimulus (Coelho & Purkis, 2009; Craske & Rowe, 1997). Phobic symptoms are seen as part of a learned expectation that adverse consequences will occur, which becomes exaggerated and leads the individual to overestimate the danger of the feared stimulus (Coelho & Purkis, 2009).

Moreover, individuals with phobias show evidence of dysfunction in attention and inferential (e.g., judgement) processes in relation to feared stimuli (Merckelbach et al., 1996). Beck (1985) states that biases in information processing arise from beliefs ingrained in schemata structures, which then cause dysfunctional behaviour and emotions. In relation to needle phobia, biases in information processes can include attentional and judgment bias (Merckelbach et al., 1996). Attentional bias refers to hyperattention to threatening verbal and visual material. For example, chronically ill children have reported the needle to be significantly longer than it actually is, which then penetrates the entire arm (Lewis, 1978). On the other hand, judgment biases include either covariation or emotional reasoning. Covariation is the tendency to overestimate the association between phobic stimuli and aversive outcomes, whereas emotional reasoning is when the individual assumes dangerous situations 'should' elicit anxiety, thus reinforcing the phobic fear (Merckelbach et al., 1996). For example, children are reportedly 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).

Cognitive restructuring is used to correct dysfunctional beliefs and informational biases that can contribute to the causation and maintenance of phobic symptoms. This in turn modifies maladaptive behaviour that contributes to the development and maintenance of phobic beliefs and therefore negative affect (e.g., distress). Evidence for the role of cognitions in the etiology and maintenance of specific phobias was supported by Öst, Salkovskis and Hellstrom (1991) who indicated that therapeutic change is unlikely due to exposure alone. This was supported by Thorpe and Salkovskis (1995) who reported that the majority of specific phobias are characterised by high levels of dysfunctional beliefs. More specifically, Öst (1992) found that 73% of people with injection phobia reported various negative cognitions. These findings have been replicated with adolescents (Thompson, 1999) and adults (Panzarella, 1999; White & Sellwood, 1995).

Cognitive-Behavioural Theory

While cognitive-behavioural theory (CBT) derives from social learning theory (Bandura, 1986), it also integrates other perspectives, most notably behavioural and cognitive theory

(Kendall, Marrs, & Chu, 1998). Thus CBT takes into account the relationship of cognition and behaviour to the affective state of the individual and the functioning of the individual in the larger social context. Thus interventions using cognitive-behavioural theory focus on both the child's internal and external environment (Kendall et al., 1992). Moreover, inaccurate and maladaptive cognitions (e.g., the needle will break in my arm) are seen to drive psychopathological affect (e.g., distress), physiology (e.g., increased heart rate) and behaviour (e.g., avoidance) (Ollendick et al., 2004). Therefore, interventions are targeted at modifying dysfunctional cognitions, which may in turn lead to changes in affect and behaviour.

In relation to NRD, cognitive-behavioural theory proposes that the reaction an individual has towards certain symptoms maintains the distress by creating a vicious cycle that perpetuates fear and anxiety. Figure 1 demonstrates the vicious cycle using a standard CBT model of phobic anxiety which has been taken from Butler (2001). The model has not been formally tested in relation to NRD or needle phobia.
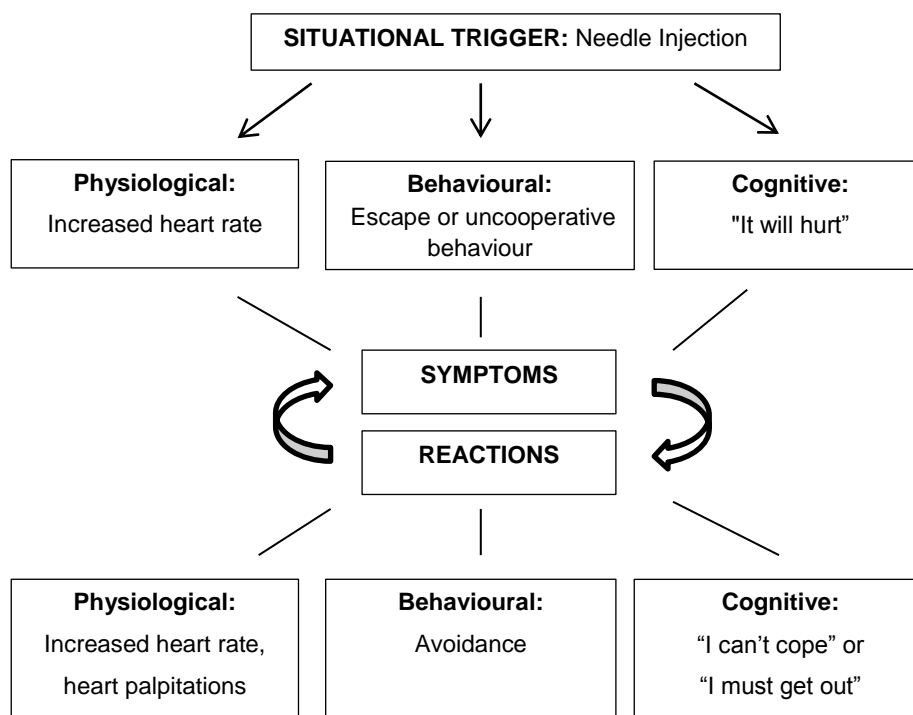
Figure 1. A vicious cycle model of phobic anxiety. Taken from "Phobic Disorders," by G. Butler, 2001, in K. Hawton, P. Salkovskis, J, Kirk and D. Clark (Eds.), *Cognitive behaviour therapy for psychiatric problems: A practical guide*, p. 97-128. Copyright 2001 by Oxford University Press.

As illustrated in Figure 1 several factors contribute to the maintenance of NRD. For example, the beliefs an individual has about the phobic stimuli tend to be dysfunctional and do not match the reality of the threat, which can result in behavioural avoidance of the phobic stimuli. As a result, 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 of the symptoms

(e.g., I'm going to faint) or the anticipated consequences of being exposed to the feared situation (e.g., I'll bleed to death). External factors such as the actions of people close to the individual, for example when they assist the individual to avoid exposure to feared stimuli, may also maintain NRD. Alongside cognitive and behavioural theories contributing to the etiology of NRD, carers and health professionals can also influence the onset and maintenance of childhood NRD, as will now be explored.

Carer and Health Professional Influences

Needle injections are not only a traumatic experience for the child, but can cause anxiety for carers and can be challenging events for health professionals (Kennedy et al., 2008; Mahoney, Ayers, & Seddon, 2010; Schechter, 2007). Therefore, carer and health professional behaviours can influence child distress and coping during needle injection procedures (Ayers, 2011; Mahoney et al., 2010; Schechter, 2007). Furthermore, it has been suggested that when situations such as needle injections are misconstrued, over-interpreted or over-emphasised by a carer and/or health professional, it may lead to a pattern of carer/health professional-child interactions that result in even more anxiety and distress for both. In relation to the present study the term "carer" will be utilised and is an inclusive term that incorporates the parent, caregiver and/or legal guardian(s) of the child. The term "parent" will be used where appropriate in terms of specific research outlined below.

Frank, Blount, Smith, Manimata and Martin (1995) demonstrated the level of impact parents have on child distress in a sample of pre-schoolers receiving immunisation injections. Parental behaviour accounted for 53% of the variance in child distress due to displaying distress-promoting behaviours. Parent and nurse coping-promoting behaviours were seen to predict 40% of the variance in child coping. Similarly, Mahoney et al. (2010) found that parental behaviour contributed to 64% of child distress during needle injections. In other cases, carers have reported avoiding immunising their child due to anxiety, which has serious health implications for the entire population (Samad, Butler, Peckham, & Bedford, 2006). Meyerhoff, Weniger and Jacobs (2001) attempted to quantify parental avoidance of child immunisations. According to their survey, of 294 families drawn from a random sample from 26 centres around the US, parents would pay an average of $57 to avoid a two-injection visit, and nearly $80 to avoid a three- or four- injection visit. This data indicates significant parental avoidance regarding immunisations, which is problematic as immunisations are seen as one of the largest worldwide initiatives in an attempt to prevent the onset of disease (Taddio et al., 2009).

In general, carers are seen to impact on child distress and coping due to children taking their cues for coping and adaption to illness mainly from their carer (Pao & Bosk, 2011). For example, correlational and experimental research shows carer anxiety, criticism, overprotectiveness, apologetic, empathetic 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 et al., 1995; Mahoney et al., 2010; Schechter, 2007). Nevertheless, there has been inconsistency surrounding these results as other studies have found that empathy and reassurance are coping-promoting behaviours (Ayers, 2011; Mahoney et al., 2010). In general, carers who are able to isolate their own fears and anxieties during crises are better able to enhance their child's psychological functioning.

A recent qualitative study investigated parental influences on NRD in children (*N* = 14, child and parent pairs) (Ayers, 2011). Results were consistent with previous research, whereby both children and parents outlined it was important for the parent to provide familiarity, reassurance, security and practical support during injections. Parents reported how upsetting it was to witness their child's distress, and tried to conceal this. However, in some cases, parents were so overwhelmed they left the room. The following quotes from parents illustrate these points (Ayers, 2011, p. 377):

I get upset, but I try not to do it in front of her. She looks at me, and I think she's the brave one and I'm not. I've learned over the years to try not to get upset in front of her because she's the one she should be worried about, not me. She's going through it, not me (Participant 10: Mother).

It was horrible, I was crying as well (Participant 13: Mother).

I had to literally walk off the ward. I couldn't stand it any longer. Was there no other way forward? (Participant 11: Mother).

The implications of this for the child were feeling abandoned and less supported during the procedure (Ayers, 2011). While the external validity of qualitative studies are limited by small sample sizes, they do provide rich data on the idiosyncratic features of individual children and their families. These features tend to be overlooked by standardised measures utilised in quantitative research.

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 to 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, implying health professionals tend to respond to the age of the child rather than clinical need. Ayers (2011) found that children who were more familiar with the health professional performing the needle injection reported less distress.

In summary, carers and health professionals can influence child distress and coping in relation to needle injections, and this is a factor that needs to be considered when developing effective psychological interventions. Despite this, the influence carer and health professional behaviours have on child distress and coping has not been given much consideration in treatment literature, as will now be explained.

Treatment of Needle-Related Distress

For chronically ill children, needle injections are a fact of life. Consequently, over 35 years ago, the need for interventions to alleviate distress for these children became evident (Jay et al., 1985). Despite this, there is still minimal research on psychological interventions for chronically ill children experiencing NRD, which has resulted 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 needle 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). Physical restraint is still used in present practice. For example, Manne et al. (1990) conducted a randomised controlled trial and found restraint was used with 53% of children in the intervention group and 80% of children in the control group. More recently, Papa, Morgan and Zempsky (2008) reported in a survey of 2188 paediatric nurses that children are physically restrained 74% of the time by another nurse, parent or caregiver during needle insertion. Restraint is frequently used despite the negative implications it can have on the child such as increased anxiety, avoidance of healthcare, and non-compliance with medical treatment regimes (Willemsen et al., 2002).

In contrast to other psychological disorders, it is generally accepted that pharmacotherapy is not an appropriate treatment for phobia-type symptoms (McGabe, Ashbaugh, & Antony, 2010). However, pharmacology is still used in Europe and the US for NRD, whereby anaesthesia is routinely administered to children undergoing needle 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 (SSRI), fast-acting benzodiazepines, morphine and nitrous oxide to reduce anxiety and distress during needle injection procedures (Hamilton, 1995; Pao & Bosk, 2011; Taddio et al., 2009). Of the treatment trials that have investigated pharmacology treatment for chronically ill children with NRD, results have been negative (Gothelf et al., 2005; Jay et al., 1995; Jay et al., 1987; Jay, Elliott, Woody, & Siegel, 1991). These studies also reported side effects ranging from confusion, behavioural disinhibition, paradoxical withdrawal, irritability, lethargy, appetite difficulties and tiredness (Jay et al., 1995; Pao & Bosk, 2011). Aside from these interventions, there are less intrusive methods that can be used such as topical anaesthesia in the form of an ointment which is applied at the injection site to minimise sensitivity to the skin (Willemsen et al., 2002). Overall, pharmacological interventions 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). As an alternative, a few behavioural and cognitive-behavioural interventions have been developed.

Behavioural Interventions

Of the psychological interventions that have been developed for chronically ill children with NRD, behavioural interventions are one of the most empirically validated (Blount et al., 1994; Kazak et al., 1996a; Manne, Bakeman, Jacobsen, Gorfinkle, & Redd, 1994; Manne et al., 1990; Powers, Blount, Bachanas, Cotter, & Swan, 1993), which could be due to the prominence of learning theory in the etiology of NRD. Behavioural therapy is based on principles of classical conditioning, operant conditioning, social and observational learning (Powers, Jones, & Jones, 2005). In regards to the influence of parents, most research has addressed the value of parental "coaching" of children during needle injections (Manne et al., 1990; Powers, 1999), although parents are rarely the primary interventionists or active participants in therapy. Behavioural research has mainly been conducted in the 1990s in which results were typically positive, although there are several limitations to these studies.

In a randomised controlled trial, Manne et al. (1990) investigated the effectiveness of parental coaching, distraction and positive reinforcement in reducing distress among chronically ill children undergoing venepunctures. Although child distress and parent distress reduced over the three intervention trials, both child self-report of pain and nurse-rated child pain were not significantly reduced. 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). It was also suggested that the distraction tool (e.g., party blower) was not effective and could account for insignificant results in relation to pain. Consequently, Manne et al. (1994) tried to rectify earlier shortcomings by conducting a study to determine the individual effectiveness of distraction via a party blower. Results were slightly positive, with the party blower associated moderately with less crying and weakly with less distress. Age may have played a role in the success of this therapy as older children (e.g., 8 years) were more likely to accept the party blower, whereas younger children appeared upset by parental coaching (Manne et al., 1994).

Around the same time, a single-subject design was used to investigate the effectiveness of an intervention which included 45 minutes of intensive training (e.g., distraction, breathing exercises, modelling, role-plays and rehearsal of child and parent coping) followed by 15 minutes of maintenance promotion (e.g., brief rehearsal of previously learned skills) (Powers et al., 1993). Rather than treatment being conducted by health professionals parents were taught to coach their child. Participants were four children aged 3 to 4.5 years, diagnosed with leukaemia; therapy for each child ranged from 9.5 to 17.5 days. Observed child distress reduced significantly at post-treatment, as well as nurse and parent ratings of child distress. However, child self-report of distress was not recorded, and parent-ratings of child distress have been found to have low to moderate agreement with child self-report of distress (Engel, Rodrigue, & Geffken, 1994). Furthermore, inter-rater reliability checks were conducted for only 38% of the sessions, family members differed in their enthusiasm for learning new behaviours, and different nurses delivered medical treatment in slightly different ways.

A similar study by Blount et al. (1994), also including children with leukaemia, aimed to coach parents to use coping promoting behaviours (e.g., distraction, positive reinforcement and behavioural rehearsal) in front of, and teach these, to their child. Results showed coping behaviours increased and observed distress decreased, however again, child-self report of distress was not obtained, session duration varied significantly (e.g., 10 to 45 minutes) and inter-rater reliability was obtained for only 31% of sessions.

Overall, behavioural interventions for NRD have been positive, but have had several limitations. Moreover, in the early 1980s, cognitive-behavioural interventions began to emerge with increased emphasis on therapy being given immediately prior to needle insertion. There are also a number of significant limitations of cognitive-behavioural interventions developed in the past.

Cognitive-Behavioural Therapy

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

Cognitive-behavioural therapies (CBT) for children undergoing traumatic medical procedures were first developed for dental procedures, surgical preparation and burn treatments (Elliott & Olson, 1983; Melamed & Siegel, 1975; Peterson & Shigetomi, 1981). Samples from these studies were typically drawn from populations of children with chronic medical conditions, particularly those with cancer. Generally, they showed that techniques such as systematic desensitisation, exposure, relaxation training, modelling, distraction, emotive imagery and positive reinforcement are effective at reducing distress in chronically ill children (Elliott & Olson, 1983; Melamed & Siegel, 1975; Peterson & Shigetomi, 1981). Since then, a small number of studies have investigated the effectiveness of CBT for chronically ill children that experience NRD.

Cognitive-behavioural interventions for NRD were first demonstrated by Jay et al. (1985), who developed an intervention for children with cancer. A single-subject multiple-baseline design was utilised with five children aged 3 to 7. Children were referred due to displaying severe distress while undergoing BMAs and LPs. The treatment package was given in one session approximately 45 minutes prior to needle insertion and consisted of filmed and participant modelling, breathing exercises and muscle relaxation, emotive imagery, behavioural rehearsal and positive reinforcement. Using the Observational Scale of Behavioural Distress (OSBD), there was more than a 50% reduction in distress from pre-intervention levels.

Research replicating the techniques used in this study consistently showed the treatment package to be as effective as, or superior to, oral Valium (Jay et al., 1991) and general anaesthesia (Jay et al., 1995).

However, there were several limitations to this study, as well as strengths. For example, follow-up results were only reported 2 to 4 months later, with 1 out of 5 participants showing an increase in distress during follow-up sessions (20% relapse rate). Therefore, the long-term effectiveness of this intervention (past 2 to 4 months) is unknown. Child self-report of distress was also not obtained, and the treatment may only be applicable to BMA and LP procedures. Strengths of the study were the inclusion of parents in therapy sessions and inter-rater reliability checks for the OSBD. However, parents were only encouraged to coach their child, rather than active participants in therapy and/or given training to promote generalisation outside of the session. Furthermore, cognitive techniques that explicitly addressed maladaptive thoughts and beliefs regarding needle injections were absent. These cognitive factors are seen as important factors in the onset and maintenance of NRD (White & Sellwood, 1995).

Despite this, several components of this package have been replicated in a number of other studies with different needle injection procedures (Dahlquist, Gil, Armstrong, Ginsberg, & Jones, 1985; Manne et al., 1990). For example, Dahlquist et al. (1985, p. 327) investigated the effectiveness of muscle relaxation, controlled breathing, emotive imagery and positive-self-talk (e.g., "I can handle this" and "If I relax, it won't hurt as much") in reducing distress in a sample of three children with cancer aged 11 to 14. The intervention was administered during an assessment interview and subsequent venepunctures, although the total duration of the intervention was not given. OSBD scores showed a 46 to 68% reduction in observed behavioural distress during venepunctures. However, health professional ratings of child distress only decreased moderately (e.g., mean ranged from 9 to 22%), and parent ratings of child distress did not change from baseline. Child self-report of distress also only showed moderate reductions in distress levels during venepuncture (e.g., change ranged from -.13 to -.36%). A strength of this study was the use of positive-self talk (cognitive strategy), although maladaptive thoughts were not explicitly addressed via cognitive restructuring. More recently, Broome et al. (1998) showed in 19 children and adolescents aged 4 to 18 that relaxation, distraction, and emotive imagery significantly decreased pain at post-intervention. However, behavioural distress scores only marginally decreased. For example, the baseline mean distress score on the OSBD was 4.6, at five month follow-up the mean distress scores was 3.3 (23% change from baseline).

In summary, cognitive-behavioural therapy for NRD among chronically ill children is largely based on the work of Jay, Elliot and colleagues in the 1980's (Jay et al., 1987; Jay et al., 1985). Behavioural therapy then dominated in the 1990's, and during this time the emergence of one-session therapy (OST) for injection phobia became evident (Öst, 2001; Öst et al., 1992). Furthermore, common among all CBT interventions for NRD is the combined use of safety behaviours (e.g., relaxation training and emotive imagery) during exposure tasks. Research

regarding the use of safety behaviours during exposure is currently under debate and will now be explored considering the relevance to the present study.

Safety Behaviours during Exposure

Cognitive-behavioural theories suggest that safety behaviours are one of the primary maintaining factors of specific phobias and may interfere with exposure tasks (Helbig-Lang & Petermann, 2010; Hood, Martin, Koerner, & Monson, 2010). The rationale for this is that safety behaviours may allocate attention away from the feared stimuli during exposure and thus distract from disconfirming evidence (Sy, Dixon, Lickel, Nelson, & Deacon, 2011). Therefore, safety behaviours during exposure are seen to prevent the disconfirmation of core dysfunctional beliefs that contribute to the onset and maintenance phobic anxiety.

However, empirical studies investigating the effects of safety behaviour in exposure therapy have yielded mixed and inconclusive results (Helbig-Lang & Petermann, 2010). Dissatisfaction regarding the definition of safety behaviours and methodological differences among empirical studies could explain the equivocal findings. There is also a lack of a clear distinction between safety behaviours and adaptive coping behaviours (Helbig-Lang & Petermann, 2010). However, some suggest that these two responses can be differentiated from each other according to the situation (e.g., actual versus real threat) in which they occur and their function (e.g., preventing events that are unlikely to occur versus habitual behaviour) (Helbig-Lang & Petermann, 2010; Rachman, Radomsky, & Sharfran, 2008). Therefore, safety behaviours can be seen as dysfunctional emotion regulation strategies that are used when there is no real threat and may take the form of overt actions (e.g., behavioural avoidance) or subtle strategies (e.g., distraction, imagining being somewhere else or focusing on thoughts other than the feared stimulus) (Helbig-Lang & Petermann, 2010).

Empirical research also shows that the effective use of safety behaviours differs according to the type of anxiety disorder. For example, safety behaviours have shown to limit the effectiveness of exposure for social phobia (McManus, Sacadura, & Clark, 2008), panic disorder (Salkovskis, Clark, Hackmann, Wells, & Geldler, 1999) and obsessive-compulsive disorder (Salkovskis, Thorpe, Wahl, Wroe, & Forrester, 2003). Nonetheless, for some specific phobias (e.g., injection phobia), available evidence consistently points to the positive effects of safety behaviours during exposure tasks, which has shown to reduce anxiety and behavioural avoidance after exposure (Oliver & Page, 2008). From this perspective, the use of safety behaviours leads to feelings of controllability, tolerability and acceptability of exposure within a feared situation (Helbig-Lang & Petermann, 2010). Rachman et al. (2008) goes further and outlines a number of potential advantages including client cooperation with the treatment, exposure may be extended with ease, and a sense of safety may better enable the client to absorb corrective information.

Despite the on going debate on whether to tolerate or eliminate safety behaviours during exposure tasks, research shows that, for certain disorders such as needle phobia, safety behaviours can improve treatment outcomes. As a result, muscle relaxation, breathing

exercises, emotive imagery and positive self-talk have been incorporated into the current treatment manual.

Limitations of Previous Research

There are significant gaps in the literature on treatment for chronically ill children with NRD. Despite many researchers referring to their interventions as "cognitive-behavioural therapy", cognitive elements are lacking that explicitly address maladaptive thoughts (e.g., cognitive restructuring). This may be due to cognitive factors only recently being considered important to the onset and maintenance of phobia-type symptoms (Merckelbach et al., 1996; Thorpe & Salkovskis, 1995). Another major limitation of previous research is the use of short-term (10 to 45 minutes) one session therapy. Two recent meta-analyses concluded that multiple exposure sessions are more effective than one-session exposure treatments for phobic and anxiety type disorders, particularly at follow-up (Olatunji, Cisler, & Deacon, 2010; Wolitsky-Taylor, Horowitz, Powers, & Telch, 2008). Therefore, treatments should be delivered in multiple sessions to enhance long-term treatment gains and prevent relapse.

Child-self reports of distress are 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). There is also a primary focus on cancer patients that require BMAs and LPs, with other needle injection procedures overlooked (Patel et al., 2005; Powers et al., 2005). Furthermore, most studies have focused on single-subject research designs or group designs, with small sample sizes (Uman et al., 2008; Varni, La Greca, & Spirito, 2000). Treatment duration and follow-up periods are also non-existent or brief (Golda et al., 2004; Varni et al., 2000), with few exceeding six months (e.g.,Dahlquist et al., 1985; Jay et al., 1985). This is important considering the long-term implications of NRD, such as increased anxiety and avoidance of healthcare (Pate et al., 1996). Lastly, there is a need for standardised, generic measurement instruments developed for various developmental age groups. Unfortunately, several of these issues are also limitations of the present study.

Due to the heterogeneity of CBT packages in the literature, caution has been raised when making conclusions regarding treatment outcome studies (Ollendick & Davis, 2004; Varni et al., 2000). For example, a recent review of randomised controlled trials (RCTs) revealed that there is a significant amount of heterogeneity in the components of CBT (Uman et al., 2008), making it unclear what components are more beneficial than others. In addition, there are no RCTs assessing the efficacy of CBT for children with chronic medical conditions that experience anxiety disorders (Pao & Bosk, 2011). Few studies have examined CBT for chronically ill children that develop NRD as a result of past trauma (i.e., classical conditioning) from medical procedures (Willemsen et al., 2002), even though this was seen as one of the most significant etiological pathways. To conclude, a lack of cognitive components, inadequate treatment duration and carer inclusion appear to be the most significant limitations of previous research, and the present study aims to address these issues.

The Importance of Cognitive Restructuring

In 1986, Bandura emphasised the importance of cognitive processes in how environmental influences are perceived and interpreted, which in turn influences the individual's behaviour. Increasingly, models of the etiology, maintenance and treatment of anxiety and phobic disorders have emphasised the need to include a cognitive component (Alfano, Beidel, & Turner, 2002) and in some cases the "cognitive model" has been proposed (e.g., Beck et al., 1985). Treatment from a cognitive perspective usually involves identifying and modifying maladaptive cognitions and subsequently maladaptive behaviours (Powers et al., 2005). Findings to date are promising for incorporating cognitive techniques into treatments for chronically ill children with anxiety disorders (Alfano et al., 2002; Pao & Bosk, 2011; Powers et al., 2005).

Despite this, to date there are no studies that have specifically targeted the cognitions of chronically ill children with NRD. Consequently, cognitive techniques tend to be excluded from treatment packages, which is also reflected in the lack of measures that are able to quantify this phenomenon (Pao & Bosk, 2011). This is problematic as irrational beliefs, catastrophic consequences and fear of medical procedures can prevent the child from participating in needle injections or jeopardise treatment success (Catherine & Garlipp, 1999; White & Sellwood, 1995; Willemsen et al., 2002). Furthermore, by overlooking cognitions, it is unlikely the child will be able to realise that having a needle injection is a non-catastrophic event (Panzarella, 1999).

The presence of maladaptive cognitions in children undergoing needle injections has been demonstrated by a number of researchers (Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Rice, 1993). Research has mainly been qualitative, for example in 1978 an article titled "the needle is like an animal" was published (Lewis, 1978). This was a detailed first-hand description of the thoughts children have during needle injections. Some of these include "It feels like she's going to push it all the way in and leave it in", "It could go through my body", "It scratches my bones" and "I'm going to run out of blood" (Lewis, 1978, pp. 18-21). Many children also believe that the blood was tested to "See if it is good or bad" or "Doctors see what people are thinking by looking at their blood" and "Children get shots when they don't eat enough" (Fassler & Wallace, 1982, p. 59). Other children report that they "Felt the technician had intentionally tried to hurt them" (Fassler, 1985, p. 372) and expressed "The nurse, I hate" (Lewis, 1978, p. 18). In children's drawings of needles, the size was often exaggerated while the child was portrayed significantly smaller than the needle (Fassler & Wallace, 1982), and the needle was often piercing through the entire arm (Fassler & Wallace, 1982). Drawings reflected the feeling that the needle is "An attack, an intrusion, a threat to body integrity and something that hurts" (Rice, 1993, p. 11). Clearly, needle injections can be traumatic procedures for children and can be associated with maladaptive cognitions.

Despite the presence of maladaptive cognitions among children with NRD, modification of these have only focused on the adult population (e.g., Mohr et al., 2002; Panzarella, 1999; White & Sellwood, 1995). White and Shellwood (1995) described the case of injection phobia in a woman who, in the second trimester of her pregnancy, required testing for rhesus antibodies. Initial assessments of cognitions revealed she thought the "The needle will snap in my arm", and she rated the level of this belief as 49%. The belief was challenged by first asking her to break a needle on its own, and then when it was embedded in an orange. After this experiment, she rated the level of her belief as 3%. Moreover, she also believed that, during venepuncture, "The needle is inserted until the full length of the needle is embedded and that it remains in her arm for many minutes" (White & Sellwood, 1995, p. 58). To counteract this, she was asked to watch a video of the therapist undergoing venepuncture. Following this, she admitted "The needle doesn't really go *all* the way in" (White & Sellwood, 1995, p. 59). Another study found maladaptive cognitions in adults, such as "The needle will break" and "The needle will hit my bone" (Mohr et al., 2002, p. 42). Some of these cognitions are similar to the child cognitions discussed earlier.

Aside from the fact that cognitive restructuring is essential in order for the child to realise that having a needle injection is a non-catastrophic event, developmental factors need to be taken into consideration when implementing this technique with younger children (Kingery et al., 2006). 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 (11-16 years). It is suggested that children during the concrete operational stage can reason deductively and problem-solve. However, for children under 7 years, 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 was by Vygotsky (1981), which suggested cognition and action are fundamentally social, and that language has a key role in the regulation of action. The idea that thought and language are connected has implications for the age-appropriateness of CBT. Despite this, even though chronological age can determine the level of cognitive development, clinicians should carefully assess each child's cognitive, social and emotional skills and adapt manualised treatments accordingly.

Several ways the therapist could adapt the cognitive restructuring component of treatment is by engaging in more teaching about thoughts with younger children, using more concrete tools when identifying thoughts (e.g., cartoons and thought bubbles) or increasing the use of incomplete sentences (e.g., when I have to get a needle injection, I feel...and I worry that...) (Kingery et al., 2006). Moreover, if the child has difficulty with understanding cognitive restructuring components (e.g., thinking traps), the therapist may need to place more emphasis on another component (e.g., relaxation or emotive imagery).

In summary, cognitive processes impact on how needle injections are perceived and interpreted, and by overlooking these in treatment, exaggerated expectations and informational biases may not be corrected. Furthermore, developmental factors need to be taken into

consideration when implementing cognitive restructuring with children less than 7 years and manualised treatments should be adapted accordingly. As discussed previously, carers also impact on child distress and coping, and can contribute to the cognitive distortions and dysfunctional behaviour children can have towards needle injections. It is therefore critical to also consider the carer in the onset and maintenance of NRD so that treatment can be adapted accordingly.

The Importance of Carer Inclusion

Active carer involvement is beneficial for positive treatment gains in child therapy, perhaps due to carer behaviours that are potentially damaging being addressed in session (Kendall, 1994; Varni et al., 2000). Outside of therapy, children may also watch carers engage in fearful or avoidant behaviour and caregiving styles may be dysfunctional, therefore enhancing anxiety and avoidance behaviour in already distressed children (Kendall et al., 1992). Empirical evidence also suggests that carer behaviours impact on the level of distress a child experiences during needle insertion (Blount et al., 2009; Frank et al., 1995; Mahoney et al., 2010; Schechter, 2007). Carer involvement in therapy is therefore critical so that potentially damaging behaviours can be addressed.

Researchers have incorporated carers into treatment programmes at some level (e.g., Blount et al., 1994; Jay & Elliott, 1990; Jay et al., 1987; Jay et al., 1985; Manne et al., 1990; Powers et al., 1993). These studies showed that, by training parents to be less anxious and coaching their child in the use of coping behaviours, child distress can be reduced and coping improved (Jay & Elliott, 1990; Manne et al., 1990; Powers, 1999). In these studies, parents were mainly taught strategies such as prompting the child to use breathing and muscle relaxation techniques, distraction, positive reinforcement, and behavioural rehearsal of needle injections (Blount et al., 1992; Blount et al., 1994; Jay et al., 1987; Jay et al., 1985; Powers et al., 1993). Parents were taught to be coaches either by the experimenter or a trained professional, which usually occurred over a few sessions (Powers et al., 1993) or within a 45-minute session (Jay et al., 1985). Moreover, the experimenter/trained professional would either accompany the child and parent into the needle procedure and offer prompts when necessary, or allow parents to implement the techniques independently (Powers et al., 1993).

More recently, the impact of parental inclusion on the treatment of NRD was investigated in a randomised controlled trial where the intervention was carried out before and during the needle procedure in one session (Kleiber, Craft-Rosenberg, & Harper, 2001). Forty-four children (and their parents) with chronic conditions having intravenous catheters were randomised into two groups: distraction education prior to IV insertion (experimental group) and standard care (control group). There were no differences between control and experimental groups on the Perception of Procedures Questionnaire (PPQ) or the OSBD. This could be due to a small sample size which then resulted in a small effect size, thus insignificant results for the PPQ and OSBD. Despite this, further analysis revealed that more children in the experimental

group displayed decreased distress during procedures, compared to children in the control group who displayed increased distress. As demonstrated, there are multiple ways carers have been included in treatment. However, carer anxiety has not been addressed and the encouragement of them being an "at-home-coach" for the child is minimal. It would seem advantageous to incorporate carers as an active participant in therapy, particularly due to the impact they can have on child distress and coping during needle injections.

In conclusion, although research supports the efficacy of behavioural and cognitive-behavioural therapy for childhood NRD, there are significant gaps in the literature that need to be addressed (Olatunji et al., 2010). First and perhaps most importantly, this includes the lack of cognitive components that address maladaptive thoughts, which in turn drive maladaptive behaviour and therefore contribute to NRD. Second, it is widely recognised that carer behaviours impact on child distress and coping during needle insertion, thus there is a need to increase awareness of carer roles during needle injections. This awareness includes actively involving the carer in therapy, rather than just coaching them, so they also receive education and training on how to manage their own anxiety and cope while their child is having a needle injection. Third, previous cognitive-behavioural interventions have mainly focused on one exposure session (e.g., 45 minutes). However, research now suggests multiple exposure sessions are more effective in order to prevent relapse and maintain long-term treatment gains. Overall, these gaps in the literature have led to the development of the present study.

Aim and Objectives of the Present Study

Aim

The aim of this study was to develop and evaluate a six-session cognitive-behavioural therapy for chronically ill children experiencing NRD. The research was designed to pilot this manualised approach, which was based on an existing therapy utilised at the Massey Health Conditions Psychology Service (HCPS), relevant theory and empirical research. The therapy programme is known as the "Coping Kids Treatment Manual", and differed from previous research by incorporating cognitive components, carer involvement and multiple exposure sessions. The following objectives were determined:

Objectives

Objective One: To gather data to evaluate the effectiveness of a six-session cognitive-behavioural therapy on child anxiety and coping.

> 1.1 It was expected that children would show a reduction in anxiety-related symptoms and an increase in adaptive coping behaviours related to specific needle injection situations at post-treatment. It was also expected that children would show a reduction in subjective units of distress (SUD ratings) both during and following treatment. It was expected these gains would be maintained over a one month follow-up period.

> 1.2 It was expected that children would show a reduction in negative cognition intensity related to specific needle injection situations at post-treatment. It was also expected that these gains would be maintained over a one month follow-up period.

> 1.3 It was expected that carers would self-report reductions in their child's anxiety-related symptoms and an increase in their ability to help their child cope in relation to needle injection situations at post-treatment. It was also expected that these gains would maintained over a one month follow-up period.

Objective Two: To gather data to evaluate the effectiveness of a six-session cognitive-behavioural therapy on carer anxiety and coping.

> 2.1 It was expected that carers would show a reduction in anxiety-related symptoms and an increase in adaptive coping behaviours related to specific needle injection situations at post-treatment. It was also expected that these gains would be maintained over a one month follow-up period.

Chapter 2: Method

Outline and Aims

This chapter describes the study participants and rationale for the development and utilisation of the psychometric measures in this study. An outline of non-regression-based statistics that have been applied will also be given, followed by a discussion of the research design and an outline of the procedures used.

Rationale for Study Design

The present study was based on the scientist-practitioner model of clinical research and utilised a single-subject design. A multiple-baseline across participants approach was used to assess the effects of treatment on needle-related distress (NRD). The rationale for this design and small size was due to this being a pilot study of a newly developed treatment manual. The intention was to identify modifications that may be required for future research when utilising a larger and more diverse sample population. This study also required a design that was useful in applied research settings and enabled 'clinical' flexibility of treatment length and delivery. Single-subject designs also capture the idiosyncratic features of the participants and enable individual responses to therapy to be obtained thus guiding future research. A more in-depth analysis of the advantages and disadvantages of this research design will be provided later in this chapter.

Participants

Six chronically ill children aged 5 to 14 (4 boys, 2 girls) who displayed needle-related distress (NRD) participated in this research. Each child's available carer was also included. Due to two children still completing therapy data is only available for four children and their carer. Participant characteristics are summarised in Table 3. Analysis of the participant profiles revealed all four children were very diverse and similar only in their experience of NRD as will be explained in the discussion chapter. All four participants identified as being New Zealand European.

Table 3

Participant characteristics for study sample

Partici-pant	Sex	Age	Chronic Physical Illness	Severity of NRD	Type & Frequency of Injection	Baseline (weeks)
P.1	M	6	Blood Condition	Severe	Blood test, four weeks (arm); other injections (e.g., flu)	3
P.2	M	10	Fibrocystic Disease	Severe	Blood test, 12 months (arm); feeding tubes; regular check-ups, other injections (e.g., flu)	2
P.3	F	13	Hormone Deficiency	Moderate	Blood test, six months (arm); other injections (e.g., flu and oral injections)	4
P.4	M	14	Type 1 Diabetes	Mild	Two daily injections (body); blood tests every three months; other injections (e.g., flu)	2

The sample was drawn from children referred by MidCentral Health DHB to the Massey Health Conditions Psychology Service (HCPS) in Palmerston North, for psychological assessment and intervention for NRD. This service is a MidCentral Health DHB contracted service that works with children and families to assist in coping with chronic health conditions. The sample was recruited from May to July 2011, while the intervention was conducted over the period July to December 2011 (including follow-up).

The original inclusion criteria for this study involved children aged 8 to 12 who were diagnosed with a chronic medical condition and experienced some level of NRD. However, due to a lack of referrals from MidCentral Health DHB to the HCPS within the timeframes of this research, the age range was first widened to include children aged 5 to 12 and then later extended to include children aged 5 to 15. Additional inclusion criteria required the children to have a cooperative carer who was willing to participate in treatment, and it was essential that both the child and carer were fluent in English. Children and carers were 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 full treatment plan for the child's NRD through another agency or already receiving cognitive-behavioural therapy. Children were also excluded if they were currently involved in any care and protection issues through Child Youth and Family Services (CYFS).

In total, nine children and their carers were referred to the HCPS, although three were excluded as they did not meet the research criteria. For example, some children were under five years old and others had psychological problems beyond NRD. All of the six suitable

participants referred agreed to take part. However, as mentioned previously two are still currently completing therapy and will not be included in this thesis. This was due to missed appointments (participant five, P.5) and therapy sessions scheduled every three weeks due to the child's medical condition and geographical location (participant six, P.6).

Assessment and Measures

Initially, a semi-structured clinical interview as part of standard treatment at the HCPS was carried out by the clinical psychologist working in the service. This was carried out to determine if they were eligible for inclusion in this study and gather information about the child and their carer. To evaluate treatment effectiveness, a multi-modal, multi-informant battery of instruments was administered as recommended in the treatment literature in relation to paediatric pain, distress and anxiety (Blount et al., 2009; Kendall et al., 1992). This included child and carer self-report measures to assess NRD across baseline, post-treatment and at one month follow-up. Additionally, Subjective Units of Distress (SUD) tracked on-going progress and were completed by the children weekly across baseline, treatment and follow-up phases. This was carried out according to a single-subject design procedure as will be explained later in this chapter.

Semi-Structured Clinical Interview

A semi-structured clinical interview was carried out with the child and their carer for diagnostic and safety purposes, as well as determining their eligibility for research (i.e., inclusion/exclusion criteria). The clinical interview was not different from standard treatment received at the HCPS and would have occurred regardless of participation in this study. All assessment procedures were conducted by a registered clinical psychologist (KR) from the HCPS. The total assessment procedure continued for 60 minutes and included child, carer and clinician self-reports of the child's psychological functioning. Assessment measures during the interview included the Outcome Rating Scale (ORS) and SUD ratings ranging from 0 (not distressed) to 10 (very distressed) (imaginal). Results were then used to provide an overall summary of the child's current functioning across a range of domains. The ORS was not included in this study and was primarily HCPS protocol.

Alongside the semi-structured clinical interview and weekly SUD ratings across baseline, treatment and follow-up phases, child and carer self-report measures were also administered. These were completed weekly during baseline, once at post-treatment and once at one month follow-up to evaluate treatment effectiveness. Within the current literature, there were significant limitations of existing behavioural observation and self-report measures in relation to NRD. This provided the rationale for and led to the development of the measures utilised in the current study to capture NRD. As a result, the measures were either developed by the author or adapted from existing standardised psychometric measures, with the exception of the SUD ratings.

Limitations of Behavioural Observation Measures

An overview of the literature revealed that the majority of measures developed for NRD were behavioural assessment methods. These included either behaviour checklists (frequency) or behaviour rating scales (frequency, intensity and duration) (Blount & Loiselle, 2009). There are several advantages to behavioural assessment methods, but also several disadvantages. In relation to NRD, the most common behavioural observation measures utilised are shown in Table 4 (see below).

Behavioural assessment methods tend to rely on verbal (e.g., cry) and/or non-verbal (e.g., facial expression) cues about specific types of behaviours that have been associated with distress, to estimate the frequency and intensity of the child's distress. They are administered either in person, or voice- or video-recorded at the hospital before, during or after the needle injection. They can also be administered over the phone 24 hours after the procedure. The advantages of these methods include the degree of flexibility with which the scale can be used (Blount & Loiselle, 2009). There is also good evidence suggesting the validity of behavioural observation scales across a wide age range from early childhood to late adolescence.

Table 4

Common behavioural observation measures for needle-related distress

Psychometric Measure	*Author*
Observational Scale of Behavioural Distress (OSBD)/ (OSBD-Revised)	(Jay & Elliott, 1983)/ (Elliott, Jay, & Woody, 1987)
Procedural Behavior Rating Scale (PBRS)/ (PBRS-Revised)	(Katz, Kellerman, & Siegel, 1980)/ (Katz, Kellerman, & Ellenberg, 1987)
Child-Adult Medical Procedures Interaction Scale (CAMPIS)/ (CAMPIS-Revised)	(Blount, Corbin, et al., 1989)/ (Blount, Sturges, & Powers, 1989)
Behavioural Approach-Avoidance and Distress Scale (BAADS)	(Hubert, Jay, Saltoun, & Hayes, 1988)
Perception of Procedures Questionnaire (PPQ)	(Kazak, Penati, Waibel, & Blackall, 1996b)
Coping Behaviour Checklist (CBQ)	(Field, Alpert, Vega-Lahr, Goldstein, & Perry, 1988)

Despite evidence supporting the validity of behavioural observation methods across a range of needle injection procedures (e.g., BMAs and LPs), there are several limitations to these methods (Blount & Loiselle, 2009). For instance, behavioural observation may be subject to observer biases, whereby the relationship of the observer to the patient may affect the accuracy of the assessment (Von Baeyer, 2007). Therefore, an observer who is familiar with the child (e.g., carer) may be better able to identify distress-related behaviours than a clinician who is less familiar with the child. Contextual factors may also impact on behavioural distress (e.g., differences in physical activity prior to assessment) and cultural factors may result in different behavioural reactions (Von Baeyer, 2007).

The behaviour checklist approach is significantly limited as it does not allow for graduations in the intensity or frequency of behaviour. In relation to rating scales, some items may be unduly weighted more than others, for example facial expressions may be a more reliable index of distress than leg movement yet they may be weighted less (Von Baeyer, 2007). More generally, some suggest observational methods are sensitive to habituation effects, whereby behavioural signs of distress dissipate as time passes, making it difficult to observe the reliability of behaviour over time (Huguet, Stinson, & McGrath, 2010). Furthermore, although advantages of behavioural methods include quick administration and ease of use, they are expensive and labour-intensive due to observers being present during each needle injection, and multiple observers required to establish inter-rater reliability (Huguet et al., 2010; Kazak et al., 1996b). Lastly, cognition content or intensity cannot be assessed using behavioural observation.

In summary, behavioural observation methods are easy and fast to administer and provide an objective measure of behavioural distress, however, observer biases, contextual and cultural factors may threaten internal validity. Therefore, it is recommended that behavioural observation measures are used in combination with other approaches such as self-report measures which are obtained directly from the individual (Von Baeyer, 2007).

Limitations of Self-Report Measures

Traditionally, the use of 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 et al., 2010). It is also possible the child is influenced by their context such as the person asking the question. Despite these limitations, self-report of psychological functioning is an important component of this study for three main reasons.

First, self-report measures enable cognition content and intensity to be gathered, which would be unable to 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 a subjective experience, therefore it is preferable to obtain 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). This recommendation has been incorporated into the present study and is the 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. Due to these three major advantages, a number of self-report measures were investigated for use in this study. However, the majority of measures relating to NRD have been standardised with adults and, of the measures developed for children, several limitations restricted their applicability to the current study.

Psychometric measures most closely aligned to the present study are the Blood-Injection Symptom Scale (BISS) (Page, Bennett, Carter, Smith, & Woodmore, 1997) and the Injection Phobia Scale for Children (IPS-C) (Öst, 2008). However, neither BISS nor the IPS-C are relevant for this study. For example, the BISS has only been standardised with adults and primarily measures somatic responses in relation to needle injections such as "did you feel faint" and "did your heart pound" (Page et al., 1997, p. 464). The IPS-C has several advantages including being standardised with children, and the use of faces as a response format. Faces have proven to be a reliable and valid measure of child self-report of distress, cost-effective and usable among children of varying cognitive abilities (Keck, Gerkensmeyer, Joyce, & Schade, 1996). Despite these advantages, item content of the IPS-C was irrelevant to the present study, with questions addressing 'getting an ear pierced' and 'noticing the smell of a hospital' (Öst, 2008). In sum, although these measures are related to needle injections in some way, this study aims to identify and assess the intensity of cognitions the child experiences in relation to the visual perception of the needle injection, the actual injection, as well as the person administering the needle injection.

One of the more common inventories for children is the Revised Children's Manifest Anxiety Scale (RCMAS) (Reynolds & Richmond, 1997) which measures general trait anxiety. Revisions made to the CMAS include a reduction in length (37 items) as well as making the instructions and response format easier to follow and more appropriate for children. However, for the current study the measure was still too long and some items were irrelevant to needle

injections such as "I have trouble making up my mind" and "I have bad dreams" (Reynolds & Richmond, 1997, p. 17). Consequently, this measure was not appropriate for this study, leading to the investigation of other self-report inventories.

The Fear Survey Schedule for Children (FSSC) originally developed by Scherer and Nakamura (1968) and then revised by Ollendick (1983), is another common inventory utilised to assess a number of different fears in children. It is an 80-item self-report measure and has five domains including fear of death and danger, fear of the unknown, fear of failure and criticism, fear of animals and psychic stress-medical fears. The FSSC was revised in order to include a 3-point response format (e.g., none, some, a lot) and the length was reduced. Despite these modifications, the FSSC-R was not suitable for the present study due to the length of administration and inclusion of unrelated domains (e.g., animal fears). As a results, the State Trait Anxiety Inventory for Children (STAIC) (Spielberger, 1973), a well-known and frequently used instrument, was also considered. However, concerns have been raised about the STAIC as a measure of anxiety in children experiencing pain and distress from medical procedures, therefore this measure was also not appropriate for this study (Schisler, Lander, & Fowler-Kerry, 1998).

Due to the limitations of more common psychometric inventories, other measures were also investigated, including the Medical Fear Survey (MFS) (Kleinknecht, Thorndike, & Walls, 1996), Mutilation Questionnaire (MQ) (Klorman, Hastings, Weerts, Melamed, & Lang, 1974), and Fear Questionnaire (FQ) (Marks & Mathews, 1979). These measures had similar limitations to the anxiety inventories, most notably the lack of suitability and standardisation with children. For instance, the MFS is a 50-item self-report measure with a scale from *no fear or concern at all* (0) to *terror* (4) whereby the person rates how much fear or discomfort they would experience from "seeing a preserved brain in a jar" and "seeing the remains of bodies following an airline crash" (Kleinknecht, 1996, as cited in Antony, Orsillo, & Roemer, 2001, pp. 401-402). These items are inappropriate for children aged 5 to 15. The MQ is less explicit with 30 items using a yes or no format. Items include "when I see an accident I feel tense" and "watching people with sharp power tools makes me nervous" (Klorman et al., 1974, as cited in Antony et al., 2001, pp. 403-404). These questions were also unsuitable for the present study. The FQ is a more general measure and assesses the severity of common phobias. However, items were too broad and ranged from fear associated with needle injections to a fear of going to crowded shops.

As demonstrated, existing psychometric measures related to NRD were not suitable for the present study due to their extensive administration, irrelevant or inappropriate item content and lack of standardisation with children. Most of the psychometric measures also focus on general trait anxiety rather than NRD. Furthermore, due to the aims of the present study, it was essential that children could independently and easily complete the questionnaire in a short space of time. Limitations of existing measures led to the development of two psychometric measures for use in the present study 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), multi-informant approach (i.e., child and carer) as recommended in the treatment literature. It should be noted that these are pilot measures, thus reliability and validity information is unknown.

Child Self-Report Measures

*Needle Injection Questionnaire - Children (NIQ-C).*The NIQ-C was developed by the author and research supervisors for the present study (Appendix 4). Items were drawn from the literature as well as generated from previous research and clinical experience. The NIQ-C is a 7-item self-report measure that gathers both quantitative and qualitative information across four domains (1) distress, (2) behavioural avoidance, (3) cognition, and (4) coping. Quantitative questions are rated on either a 7-point (see Table 5, item 4.a) or 10-point Likert Scale (see Table 5, item 2, 3.a, 3.b, and 3.c) with varying anchors. An exception to the 7- or 10-point Likert Scale was question one which utilised the distress thermometer. Qualitative questions utilised an open-ended response format (see Table 5, 3.a, 3.b, 3.c and 4.b). Several characteristics were incorporated into the NIQ-C including easy-to-follow instructions, time efficiency, age-appropriate language and the inclusion of items that are sensitive to therapeutic changes in relation to NRD and coping.

Due to each participant acting as their own control, the NIQ-C is scored by comparing the baseline scores to post-treatment and follow-up scores of each individual child and carer. If there is a decrease in distress (i.e., decrease in distress scores) or increase in coping (i.e., increase in coping scores), then this is considered an improvement in psychological functioning. In this case, participants are compared against themselves rather than other participants. Furthermore, this study was the initial pilot for the NIQ-C as it was not able to be piloted before being included due to time restrictions. To counteract this, qualitative feedback from the participants was collected by the therapist during treatment and follow-up phases regarding the measure. An overview of each question in numerical order is now presented alongside supporting research.

Table 5

Needle injection questionnaire – child

Item	Question	Sub-category	Source
1.	How upset did you become during your most recent needle injection?	Distress	(Dahlquist et al., 1985; Kleiber & McCarthy, 2006)
2.	How sure are you that you will be able to have your next planned needle injection?	Behavioural avoidance	(Mohr et al., 2002)
3.a)	What thoughts come into your head when you think of or see a needle?	Cognition	(Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Mohr et al., 2002; Rice, 1993; White & Sellwood, 1995)
3.b)	What thoughts come into your head when you think of having a needle injection?	Cognition	(Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Mohr et al., 2002; Rice, 1993; White & Sellwood, 1995)
3.c)	What thoughts come into your head about the person giving you the needle injection?	Cognition	(Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Mohr et al., 2002; Rice, 1993; White & Sellwood, 1995)
4.a)	When you are having a needle injection, how much are you able to help yourself feel less upset?	Coping	(Kendall et al., 1992)
4.b)	When you are having a needle injection, what do you think or do in this situation to help yourself feel better?	Coping	(Kendall et al., 1992)

In order to measure self-reported distress during needle insertion, children were asked "How upset did you become during your most recent needle injection?" (Question one). This was then rated on a distress thermometer from *not upset* (0) to *very upset (*10). This question was developed as the main outcome variable for children. The distress thermometer is a modified visual analogue scale that resembles a thermometer and has been validated in British (Gessler et al., 2008) and Chinese (Tang, Zhang, Pang, Zhang, & Song, 2011) cancer populations. Gessler et al. (2008) demonstrated that the distress thermometer was acceptable

to 95% of 171 participants, while Tang et al. (2011) reported a test-retest correlation coefficient of 0.80 ($p < 0.01$) over a seven- to ten-day period in a sample of 106 Chinese patients. Research also shows a cut-off of four 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 et al., 2011).

Item content for question one originated from the Child Rating of Anxiety Scale developed by Clatworthy (1979, as cited in Kleiber & McCarthy, 2006), which was then adapted and piloted by Kleiber and McCarthy (2006). Adaptions were more concise item content and the inclusions of the distress thermometer. After piloting the measure, it was found that children understood the question and written instructions without complication. Other researchers have also used the distress thermometer as a measure of NRD for some time. For example, Dahlquist et al. (1985) used a similar approach by asking children to rate their distress in relation to needle injections on a thermometer marked with 7 evenly spaced lines from *I feel great, the best I've ever felt* (0) to *I feel terrible, the sickest I've ever felt* (7). Since then, a number of researchers have used the distress thermometer as a measure of psychological distress (Gessler et al., 2008; Lynch, Goodhart, Saunders, & O'Connor, 2011; Walco, Conte, Lebay, Engel, & Zeltzer, 2005). This research paved the way for the development of question one from the NIQ-C, one of the main outcome items utilised in this study.

Alongside gathering data on negative affect (e.g., anxiety), it was also important to assess changes in behavioural avoidance towards needle injections. This was carried out by asking children *"*How sure are you that you will be able to have your next planned injection?" (Question two). This was anchored on a scale from *would not avoid it* (0), *maybe avoid it* (5), to *definitely avoid it* (10). This 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 and adding a third anchor (e.g., maybe avoid it) to the 10-point Likert Scale. The original question was "How certain are you that you will be able to perform your next Avonex injection yourself?''. The MSSE has shown to have high test-retest reliability over a two-month period ($r = .75$, $p < .001$) and to yield stable scores over time. The MSSE has also shown to have convergent and divergent validity suggesting the scale is both sensitive and specific (Schwartz, Coulthard-Morris, Zeng, & Retzlaff, 1996). Anchors for question two originated and were adapted from the FQ (Marks & Mathews, 1979).

Cognitive restructuring is an essential component of the current treatment manual. Therefore an assessment of the content and intensity of cognitions in relation to needle injections was crucial. Due to the lack of measures assessing child cognitions in relation to needle injections, qualitative 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. This led to the development of three open-ended questions across three domains: (1) distortions in visual perception of the needle, (2) thoughts during the actual needle injection, and (3) thoughts regarding the person giving the needle injection. These three items were used to

elicit participant-specific thoughts in relation to needle injection situations. 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 each thought on a 10-point Likert Scale from *I do not believe it* (0) to *I absolutely believe it* (10). 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 percent scale of 0 (I don't believe this at all) – 100% (I am absolutely convinced this is true) how much they believed the thought.

The improvement of existing coping strategies is a key component of the current treatment manual, therefore an adaptation of the Coping Questionnaire-Child Version (CQ-C) by Kendall et al. (1992) 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* (1) to *not at all able to help myself feel comfortable* (7). For the purpose of the current study, the questionnaire format was simplified to include only one situation (i.e., having a needle injection), and *feel comfortable* was dropped from one anchor (7). An open-ended question was also added to the CQ-C (see Table 6, item 4. b) to capture other cognitive and behavioural coping strategies the child may be using that the restrictive response format of the original measure was unable to capture. 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 across treatment (Kendall et al., 1992).

Overall, the NIQ-C captures self-reported anxiety, behavioural avoidance, cognition content and intensity as well as coping strategies employed by the child in association with needle injections. Due to the impact carers can have on child distress and coping and their inclusion in therapy, it was imperative to also assess changes in carer distress and coping. This led to the development of the Needle Injection Questionnaire for Parents (NIQ-P), which was also a pilot measure in the present study.

Carer Self-Report Measures

Needle Injection Questionnaire - Parents (NIQ-P). The NIQ-P was developed by the author and research supervisors for the present study (Appendix 4). Items were drawn from the literature as well as generated from previous research and clinical experience. The NIQ-P is an 11-item self-report measure that gathers both quantitative and qualitative information across three domains (1) distress, (2) behavioural avoidance, and (3) coping. Of note is that 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. Quantitative questions are rated on either a 10-point Likert Scale (see Table 6, 1.a, 1.b, and 2.d, 2.e) or a 7-point Likert Scale (see Table

6, 5.a, and 5.b) with varying anchors. Other questions involve the carer providing a more objective account of behavioural avoidance (see Table 6, item 2.a, 2.b, and 2.c). Qualitative questions utilise an open-ended response format (see Table 6, 4.c). As an indicator of observed behavioural distress and coping, a behaviour checklist known as the Coping Behaviours Questionnaire (CBQ) (Field et al. 1988) was also included in the NIQ-P. The CBQ was developed by Field et al. (1988) and published as a modification of the Coping Behaviour Checklist by Peterson (1982) and the Coping Rating Scale by Katz et al. (1980).

Scoring of the NIQ-P was done in much the same way as the NIQ-C, with the exception of the CBQ for which scoring instructions will be explained later in this chapter. Also similar to the NIQ-C, the NIQ-P was piloted in the present study. To counteract this, qualitative feedback from the participants during therapy and at follow-up phases will be obtained regarding the measure. An overview of each question in numerical order is now presented alongside supporting research.

Table 6

Needle injection questionnaire – parent

Item	Question	Sub-category	Source
1.a)	In general, how distressed is your child when having a needle injection?	Child distress	(Kazak et al., 1996b; McCarthy et al., 2010)
1.b)	In general, how distressed are you when your child is having a needle injection?	Carer distress	(Kazak et al., 1996b; McCarthy et al., 2010)
2.a)	How many needle injections has your child been scheduled to have in the last 6 months?	Child behavioural avoidance	Author
2.b)	How many needle injections has your child tried to avoid, but ended up having to get, in the last 6 months?	Child behavioural avoidance	Author
2.c)	How many needle injections has your child been successful at preventing from occurring in the last 6 months?	Child behavioural avoidance	Author
2.d)	In general, do you have to alter or cancel medical appointments because your child is too distressed to have a needle injection?	Child behavioural avoidance	(Quittner, Tolbert, & Regoli, 1996)
2.e)	In general, do you have to alter or cancel medical appointments because you are too distressed to see your child have a needle injection?	Carer behavioural avoidance	(Quittner et al., 1996)
3.a)	Coping behaviours questionnaire (CBQ) – Behavioural method	Child coping	(Field et al., 1988)
4.a)	When your child is having a needle injection, how much are you able to help your child feel less distressed?	Child coping	(Kendall et al., 1992)
4.b)	When your child is having a needle injection, how much are you able to help yourself feel less distressed?	Carer coping	(Kendall et al., 1992)
4.c)	When your child is having a needle injection, what do you think or do in this situation to cope?	Carer coping	(Kendall et al., 1992)

As carer behaviour impacts on child distress, several items were included that assessed the level of carer distress (see Table 6, 1.a, and 1.b) as well as child distress during needle injections. These questions were anchored on a 10-point Likert Scale ranging from *not at all distressed* (1) to *extremely distressed* (10). Both questions were adapted from McCarthy et al. (2010) and originated from the Perception of Procedures Questionnaire (PPQ) (Kazak et al., 1996b). As an indicator of construct validity, Kleiber (1999) reported a 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; Powers et al., 1993; Walco et al., 2005).

In order to provide a more objective and precise measure of child behavioural avoidance of needle injections, items 2.a, 2.b and 2.c were utilised. These 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 (Mohr et al., 2002). More subjective questions utilised to determine behavioural avoidance of needle injections for both children and carers were items 2.d, and 2.e, which are rated on a scale from *not at all* (1) to *all the time* (10). These questions were adapted from the Role-Play Inventory of Situations and Coping Strategies (RPSCS). The RPSCS has been shown to have inter-rater reliability in terms of the categorisation theme, as well as concurrent and predictive validity in relation to two well-known outcome measures (i.e., Center for Epidemiological Studies-Depression scale and the Who Does What? scale) (Quittner et al., 1996).

The CBQ was utilised alongside other measures (e.g., NIQ-C and NIQ-P), and provided an objective measure of how the child coped during their most recent needle injection. 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. A total of 15 items are incorporated into the questionnaire with a simple *true* or *false* response format. 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.

Due to limited information available on the validity and reliability of the CBQ, a pilot study conducted by Kleiber and McCarthy (2006) evaluating the internal consistency of the CBQ was consulted. The sample population was children aged 4 to 12 with a chronic medical condition that required repeated needle injections. Results showed that child state anxiety had a small but positive correlation with the CBQ, while nurturance, parent state anxiety and child state anxiety accounted for 32% of the variance in CBQ scores. Kleiber and McCarthy (2006) also reported a positive correlation (*r* = 0.55, *p* < .01) between the CBQ and one of the main outcome variables also included in this study (see Table 5, 1.a).

Lastly, 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 three questions where the carer rates (1) their perceived ability to help their child cope, (2) their own ability to cope, and (3) what they think or do to cope while their child is having a needle injection. This was administered on a scale ranging from *able to help myself* (1) to *not at all able to help myself* (7). Outcome data supports the sensitivity of the CQ-P to the effects of anxiety treatment for children and adults (Kendall, 1994; Kendall et al., 1997).

Clinician and Child Self-Report Measures

Subjective Units of Distress (SUD) (Wolpe, 1982). SUD ratings were obtained as an additional measure of child distress and are an effective way to teach a child how to quantify their feelings (Mohr et al., 2002). The aim of this measure was to assess the intensity of distress in relation to needle injections on a fear ladder from *no anxiety* (0) to *extreme anxiety* (10). As part of treatment, SUD ratings were also obtained from the child and clinician using a basic 10-item fear hierarchy of injection-related situations that were customised for the individual child. Alongside SUD ratings, non-regression-based statistics were carried out to obtain corroborative information regarding treatment outcomes.

Data Analysis: Non-Regression-Based Statistics

In addition to individually scoring and analysing the data collected from the NIQ-C, NIQ-P and SUD ratings for each child, data was further analysed using three non-regression algorithms. These algorithms included Standard Mean Difference all (SMDall), Mean Baseline Reduction (MBLR) and Percentage of Non-Overlapping Data (PND). These algorithms were used to provide additional insight into treatment outcomes and obtain effect size calculations. Regression-based statistics were considered but unable to be calculated due to a lack of assessment data collected during all three phases of the intervention (e.g., baseline, treatment and follow-up). The advantages and disadvantages of using these three 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 (Busk & Serlin, 1992; Olive & Smith, 2005). 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, by using only the last three data points it may not capture the variability in the data, resulting in an inflated effect size. 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. Therefore, 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:

$$SMDall = \frac{Baseline - Treatment}{Standard\ Deviation\ of\ Baseline}$$

The second algorithm, Mean Baseline Reduction (MBLR) was used to show the average reduction of behaviour from baseline (Campbell, 2000; Parker & Brossart, 2003). According to psychological literature, there are no interpretive guidelines for MBLR (Olive & Smith, 2005). Moreover, instead of using only the last three baseline and intervention points, all data was utilised to ensure a more accurate result. The calculation for MBLR is:

$$MBLR = \frac{Mean\ Intervention\ - Mean\ Baseline}{Average\ Baseline\ x\ 100}$$

The third algorithm, Percentage of Non-Overlapping Data (PND) (Scruggs & Mastropieri, 1998) was used to show the amount of intervention scores that fall below the lowest baseline score. PND was used to provide further evidence for at what point positive changes typically occurred in the intervention 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 effects whilst also ignoring changes in slope (Scruggs & Mastropieri, 1998). Despite these disadvantages, PND was used as it provides further analysis of the collected data. 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, and scores between 70 to 90 suggest an effective intervention. Lastly, scores above 90 represent very effective interventions. The calculation for PND is:

$$PND = \frac{\sum_{k=0}^{n}(intervention\ point(n) < baseline(min)\ )}{Total\ Intervention\ Points}$$

The outcome of non-regression-based statistics for each participant is provided in the results chapter. The rationale for utilising a single-subject research design will now be explained, alongside the advantages and disadvantages of this approach.

Research Design

The present study utilised a single-subject multiple-baseline across participants design. All four participants were randomly allocated to pre-determined baseline lengths, ranging from two to five weeks. Continuous measures were completed throughout baseline, treatment and

follow-up phases. The NIQ-C and NIQ-P were completed weekly during the baseline phase, once at post-treatment and one month follow-up. The rationale for one post-treatment measure was due to the age of some participants (e.g., 6 years). It was thought weekly assessments for children 7 years and under would be too challenging, and reduce the reliability and validity of the measure. As an alternative, SUD ratings were gathered weekly across baseline and treatment and then once at one month follow-up. This was because SUD ratings are easier to administer and less time consuming for younger children,

The use of a continuous measures approach was justified as it conceptualises behaviour as ever-evolving and treatment outcome as an unfolding phenomenon, rather than a single discrete observation that lacks a natural and full context (Kazdin, 2002). A non-concurrent procedure was utilised to allow for flexibility within an applied research setting (i.e., participants assigned to various baselines lengths as they are naturally referred) while maintaining the design parameters necessary for ruling out extraneous factors (Watson & Workman, 1981). Furthermore, it allows for data to be analysed from several participants seen at different times, despite participants having varied baseline lengths.

The rationale for this study design was to assess whether the intervention was responsible for a change in baseline functioning rather than extraneous factors, this increases the extent to which inferences can be drawn and threats to internal validity ruled out (Kazdin, 2011). For example, this design includes relatively marked treatment effects (i.e., changes that are immediate and large), therefore eliminating threats to internal validity such as maturation and history as these are unlikely to produce changes that are abrupt and large (Kazdin, 1982). Alongside this, single-subject multiple baseline designs have a number of advantages that make them useful in applied research settings. For example, they allow for 'clinical' flexibility of treatment length and delivery, closing at least some of the gaps between research and clinical practice. In fact, repeated single-case research designs, when carried out on similar clients where the same experiment (treatment) is carried out three or four times, have been said to have the potential to exceed experimental/control group designs in terms of external validity (Barlow & Hersen, 1984).

Further advantages of single-subject designs relate to the use of repeated measures, participants acting as their own controls, intra- and inter-participant replications and the acceptance of treatment variability (Morgan & Morgan, 2003). Many observational strategies in psychology rely on single observations of the dependent variable, whereas the single-subject design uses a repeated measures approach. This strategy is justified for two reasons; the first being that it increases confidence that the sample behaviour being measured is representative of that participant under those experimental conditions; and secondly, it conceptualises behaviour as an ever-evolving phenomenon (Morgan & Morgan, 2003).

Participants in single-subject designs act as their own controls, with comparisons being made across experimental conditions rather than across participants. This is seen as the only relevant comparison, as a change in the individual's behaviour relative to their own baseline is the most important, rather than compared to that of another person (Morgan & Morgan, 2003).

The multiple-baseline approach also controls for threats to internal validity (e.g., extraneous variables) otherwise present in pre-test–post-test designs. Single-subject designs rely on both intra- and inter-participant replications, although multiple-baseline designs primarily focus on the latter, which are practical and cost-effective (Morgan & Morgan, 2003). Inter-participant replications act as a reliability check on the relationships being studied and provide an opportunity for causal inferences to be made.

Treatment variability can be seen as an advantage in single-subject designs, as opposed to group designs whereby the reduction of error variance (usually due to individual differences) is critical. However, it is argued that reducing participants to single aggregate measures neglects the idiosyncratic variability of each individual, which is seen as pivotal regarding the impact of the independent variable on the dependent variable in single-subject research (Morgan & Morgan, 2003). Several other advantages to single-subject designs include participants being able to be assessed quickly and completing baseline measurements while on the wait-list. Additionally, an A-B single-subject design does not depend on withdrawing or suspending the intervention in order to show treatment effects, thus avoiding ethical and logistical issues.

The most widely recognised limitation of single-subject designs is the lack of external validity in terms of generalising to other groups and settings. Therefore, if population parameters are a necessary part of the research, then group designs may have more usefulness. Nonetheless, this is debated by some who suggest that using large groups does not necessarily mean greater generality (Ottenbacher, 1992). Moreover, by describing participants in as much detail as possible in single-subject designs, future researchers are able to replicate or apply treatment to similar cases.

Procedure

Recruitment

Potential participants were identified by referrals from MidCentral Health DHB to the HCPS in Palmerston North. In order to initiate these referrals, a meeting was held between the multidisciplinary team at MidCentral Health DHB, the primary researcher (JM) and a clinical psychologist (KR) from Massey University to inform the DHB team about the study. At the completion of the meeting, a flyer was given to the health professionals (see Appendix 2), which outlined the nature of the study and the inclusion and exclusion criteria.

Once a suitable referral was made to the HCPS, an information sheet about the study (see Appendix 3) was sent to the child and carer along with their appointment letter and other information about the service. The family then had their initial appointment and semi-structured clinical interview with KR as part of standard treatment offered at the HCPS. If they met the inclusion criteria, KR invited them to have a brief meeting with JM immediately following their initial appointment (consent was not obtained through the clinician to ensure free and informed

consent). The meeting with JM continued for approximately 30 minutes, during which JM explained the study, answered questions, and if the family remained interested in taking part, guided them through the consent process. However, if the children did not meet the study criteria or decided to not participate, they were provided feedback about their initial assessment and why they could not be included. They were then referred for appropriate treatment. Self-report measures including the NIQ-C and NIQ-P were also completed during this meeting for those who chose to take part. This accounted for the first week of baseline measures. The first week of baseline measures for the SUD ratings were gathered during the clinical interview by KR.

Setting

All assessment procedures, the first week of baseline measures (e.g., NIQ-C, NIQ-P and SUD ratings) and therapy sessions were carried out at the HCPS. The remaining baseline, treatment and follow-up NIQ-C and NIQ-P measures were posted to participants, with the exception of the post-treatment measure which was completed immediately after the sixth session at the HCPS. SUD ratings were obtained over the phone by KR across baseline, during/after therapy sessions and then once over the phone at one month follow-up.

Carers were expected to transport the children to and from assessment and therapy sessions. The HCPS was a purpose-built and child-focused facility. A range of therapy rooms were available and set up age-appropriately for children aged 5 to 15. A variety of media was also available including toys, games, colouring pens, scrapbooks, stickers and books.

Assessor and Therapist

The main assessor and therapist for the current research was KR, a registered clinical psychologist from the HCPS. KR has extensive experience working with chronically ill children displaying a range of psychological problems, and had a vast amount of professional knowledge in relation to this research project.

Informed Consent

If the child and their carer met research criteria, informed consent (see Appendix 3) for participation in this study was gained in writing from the child and their legally responsible carer. Potential participants were informed both verbally and in writing that participation was voluntary, and that if they declined they would still receive treatment at the HCPS. Before written consent was obtained, information sheets (Appendix 3) see were provided outlining the nature of the research and what would be expected if they took part.

Random Allocation

Once consent was gained, each child was randomly assigned by JM to a baseline of 2, 3, 4 or 5 weeks. However, it should be noted that clinical judgement and the needs of the child overrode research requirements when client safety and wellbeing was at risk. Clinical judgement overrode random assignment in one case due to clinical concerns regarding the frequency of injections (e.g., P.4, diabetic). There was no safety or suicidal issues.

Baseline Phase

All participants completed weekly measures during the baseline phase (e.g., NIQ-C, NIQ-P and SUD ratings). In all cases, the researcher attempted to collect all requisite baseline measures as planned and to follow the randomly assigned baseline lengths across participants. While it was planned baseline lengths would be 2, 3, 4, and 5 weeks, due to some measures not being returned some participants had a shorter baseline period (e.g., P.4). In single-subject research, the baseline data must be examined for stability (Kazdin, 2011). A stable baseline is characterised by relatively little variability and the absence of a slope (or trend). At least two or three data points are required to establish stability. For single-subject methodology in applied research, it is recommended that the variability in the baseline scores does not exceed 50% in any case (Barlow & Hersen, 1984). Details of baseline stability will be presented in the results section.

Treatment Phase

Once a stable baseline was established, the treatment phase began in which all participants received the Coping Kids Treatment Manual. As recommended in the literature, a flexible, clinically sensitive application of the treatment manual is the most appropriate. This includes the clinical psychologist adapting therapy to the developmental age, cognitive and social development of the child (Kendall et al., 1992). This resulted in several major modifications to the treatment manual during therapy including the use of filmed modelling (during sessions 2 to 4); simplified cognitive restructuring for children 8 years and under; reward systems were modified and worksheets were either included or excluded depending on the preference and developmental age of the child.

Emotive imagery was not used for P.1 and P.2 as both children struggled to understand this strategy and did not want to use it. This was replaced by filmed modelling using videos from Youtube in which a child of a similar age was seen having a needle injection and coping appropriately. Once the child had watched the Youtube video, the clinician asked the child "What would you do in this situation?", "What are you feeling?" and "What would you do to help them cope?". On the other hand, P.3 and P.4 responded well to emotive imagery. For example, P.3 chose a famous writer (Laura Ingalls) and P.4 a cartoon character from South Park

(Cartman). This was also slightly modified to "someone I admire" for P.4 due to developmental age.

Cognitive restructuring was simplified for P.1, due to their age and ability to understand abstract concepts. This was replaced with positive self-talk and helpful versus unhelpful thoughts. Cognitive restructuring was used as manualised for P.2, P.3 and P.4. The use of rewards was modified according to the developmental age of the child. For example, a reward (e.g., their favourite game) was used in every session for younger children (under 8 years), whereas rewards for older children were based on contingency reinforcement and offered in the final session.

Some worksheets were excluded or included according to the age level of the child. For example, the worksheets "My Account" and "Reward Chart" were not used for children 10 years and over. Several of the breathing and muscle relaxation worksheets were also not used with some children depending on their personal preference. Although, the "My Experience" worksheet was mainly aimed at children 8 years and over, utilising it with younger children was beneficial for the child and their carer.

Lastly, as per session five of the treatment manual, SUD ratings were not obtained from the child before, during and after the in-vivo needle injection due to this being inappropriate considering the child's distress levels. Instead, the clinician provided their own SUD rating of the child's distress during the in-vivo injection and then asked the child once this had finished how they would feel about their next injection using SUD ratings. Moreover, due to the nature of P.4's distress, informal SUD ratings were also gathered in relation to how the child would feel if they rotated their injection site (i.e., from their stomach to their leg).

Modifications to Treatment Length and Carer Involvement

Every measure was taken to ensure sessions were weekly, however this was not always the case due to cancelled sessions, the availability of the family and the next scheduled needle injection at the hospital (e.g., session five) not aligning with therapy timeframes. Therefore, the length of treatment ranged from 6 to 11 weeks (P.1, 6 sessions, 7 weeks; P.2, 6 sessions, 6 weeks; P.3, 6 sessions, 11 weeks; P.4, 6 sessions, 10 weeks). All six sessions were 50 minutes long, with the exception of session five (90 minutes) which required an in-vivo needle injection at a local health service as per the treatment manual.

The Coping Kids Treatment Manual is based on six sessions, although an additional booster session was provided for P.2 due to a pervasive pattern of NRD. This booster session was carried out after the follow-up data was collected to avoid any interference with the data collection phase. The booster session reviewed what past sessions had covered, addressed any potential relapses and the participant's medical condition in general. It should also be noted that P.2 received 12 sessions of cognitive-behavioural therapy from the HCPS in 2009. All participants received follow-up measures (e.g., NIQ-C, NIQ-P and SUD ratings) one month (e.g., 28 days) from therapy completion, although these were not always completed on time as will be explained in the results chapter.

In order to incorporate the carer into therapy, each session was structured so that the first 40 minutes was with the individual child and the last 10 minutes included the child and their carer. However, this was flexible and in some cases the carer was present for the whole session. For example, P.6 included the carer in the entire session whereas P.5 included their carer intermittently as required. Other participants included the carer in the final 10 minutes as stipulated in the treatment manual. The aim of carer involvement was to ensure that teaching components and coping strategies learned by the child were demonstrated and reinforced in front of the carer. Carers were also encouraged to model and coach their child outside of therapy sessions to consolidate the information and promote generalisation. However, it should be noted that some carers could be more motivated than others and coach their child more regularly out-of-session, therefore impacting on results. Children were brought to therapy by their carer who waited for the children to complete each session and then returned them to school or home.

Treatment Manual and Materials

Therapy was based on the Coping Kids Treatment Manual, which is a 59-page document that incorporates a six session format (see Appendix 9). The treatment manual is based on cognitive-behavioural theory and was developed as a tool for clinicians working with chronically ill children and their families with NRD. It is structured and directive and outlines the purpose, goals, materials required, session format, optional worksheets and out-of-session activities (homework) incorporated into each session. Each of the six sessions has been grouped into one of the four phases as follows.

Major phases of the treatment manual

Phase 1: Psycho-education. This phase involves the establishment of rapport and treatment orientation, exploration of the child's history and presenting problems (Session 1). This is followed by an introduction to the nature of anxiety, the development of a fear hierarchy and an explanation of SUD ratings. Out-of-session activities are also explained and the child taught to self-rate their own anxiety. Carers are included in the last 10 minutes to ensure that what is learnt is generalised outside of session.

Phase 2: Coping strategies. This phase includes the introduction and practice of coping strategies such as breathing and muscle relaxation training, as well as emotive imagery (Session 2). Coping strategies are also explained to and modelled in front of the carer at the end of the session.

Phase 3: Gradual exposure. This phase includes three sessions (Session 3 to 5) whereby exposure tasks and cognitive restructuring are introduced. Cognitive restructuring includes techniques such as identifying information processing errors, finding the evidence for and against a thought (e.g., 'being a detective'), developing alternative thoughts and positive

self-talk. Exposure tasks include imaginal, in-vivo and behavioural rehearsal, moving from least to most anxiety-provoking situations. SUD ratings are also completed by the child throughout exposure tasks. During these sessions, carers are included and coping strategies learnt in previous sessions are reviewed before exposure tasks.

Phase 4: Completion of therapy. The final phase reviews the overall treatment programme and puts strategies in place to prevent relapse (Session 6). A large part of this session is about awarding the congratulations certificate to the child, celebrating their success (e.g., with a cake) and saying goodbye to the child and their carer. Overall, in order to carry out these four phases, specific techniques were used.

Major techniques of the treatment manual

The major features of cognitive-behavioural therapy used in past research and incorporated into the present study included exposure (in the form of systematic desensitisation and role-plays), coping modelling, muscle relaxation and breathing exercises, positive reinforcement, emotive imagery, and cognitive restructuring (Pao & Bosk, 2011; Uman et al., 2008). A brief discussion about the use of distraction will also be given. Lastly, the rationale for including these techniques in the present study will be explained alongside supporting research.

Through behavioural rehearsal, modelling, role-play and perhaps most importantly, exposure, children practice in therapy how to cope with needle injections. Exposure can take the form of systematic (based on counterconditioning procedures), imaginal (e.g., imagery-based representations such as thinking about it) and in-vivo desensitisation (e.g., direct contact with the phobic stimuli) (Olatunji et al., 2010). Recent meta-analyses conclude that exposure techniques are the preferred treatment for phobia-type symptoms (Kendall & Ronan, 2003; Olatunji et al., 2010; Wolitsky-Taylor et al., 2008). The rationale behind exposure is that it 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). Exposure to or contact with needle injection situations is an effective and major component of CBT for chronically ill children with NRD (Uman et al., 2008).

Another technique useful in the treatment of chronically ill children with NRD is observational learning or modelling. Modelling originated from the observational learning paradigm (Bandura, 1986) and is based on principles of vicarious conditioning and social learning theory (Ollendick & King, 1998). It is based on the premise that behaviour can be acquired, facilitated, reduced or eliminated by observing others' behaviour (Ollendick & King, 1998). There are a number of different types of modelling including symbolic, live, and participant modelling (Ollendick et al., 2004). Symbolic modelling involves the child watching a video recording of someone having a needle injection, whereas live modelling includes the child watching a "live" model having a needle injection (Jay et al., 1985; Ollendick et al., 2004). On the other hand, participant modelling involves the child first observing and then copying, by having a needle injection using coping strategies exemplified during the first observation.

Empirical evidence is well established for participant modelling and probably efficacious for filmed or live modelling (Ollendick & King, 1998). Modelling was often combined with role-play in the current treatment programme.

In the 1990s, there was a great deal of interest in the development of coping strategies for children with chronic health conditions (Varni et al., 2000). Coping strategies mostly included controlled breathing and muscle relaxation. Controlled breathing involves the use of stories that are read to the child in order to help them slow their breathing and relax, whereas muscle relaxation involves tensing and relaxing specific muscle groups in the body; the individual then learns to perceive these bodily sensations and use them as cues to relax. When teaching these exercises to children, relaxation training scripts are typically used. These techniques have demonstrated to be clinically effective for reducing the physiological responses of NRD in children (McGabe et al., 2010; Öst, Fellenius, & Sterner, 1991). For the present treatment, this strategy was usually combined with exposure tasks (e.g., systematic desensitisation).

Contingency reinforcement derives from principles of operant conditioning, and aims to alter phobic behaviour through changing the consequences (Ollendick & King, 1998). It relies on the therapist and carer to ensure positive consequences follow the child's exposure to the feared stimulus (e.g., relaxation), and positive consequences (e.g., carer attention) do not follow negative behaviour (e.g., anxiety or avoidance) (Golda et al., 2004). Empirical evidence suggests that contingency 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).

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. It also involves the development of a fear hierarchy, however rather than using relaxation as the anxiety inhibitor, the child conjures a story about their favourite hero (Ollendick & King, 1998). Items from the fear hierarchy are interwoven into the story. Thus feelings of positive affect created by the story serve to counter the effects of anxiety created by the phobic object (Ollendick & King, 1998). The superhero also serves as a model for managing distressing situations. Emotive imagery has been used extensively with chronically ill children experiencing NRD, usually as a distraction technique to transform the meaning of distress for the child. For example, during medical procedures the child is asked "Remember Superwoman – what would she do right now?" (Jay et al., 1985, p. 516). Unfortunately the efficacy of emotive imagery as a separate component is limited (Ollendick & King, 1998), and instead most research includes 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).

Cognitive restructuring is a technique based on the assumption that maladaptive beliefs maintain fear and avoidance behaviour, thus preventing the child from obtaining new information and correcting the false belief (Powers et al., 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 are used to do this, for example finding the evidence for and against a thought, identifying information processing errors and positive self-talk (Blackburn & Davidson, 1995).

Gathering evidence for and against a thought might include the therapist asking questions like, "How many times has this happened before?" and "What is the likelihood of this occurring?" (Kendall et al., 1992). Information processing errors include overgeneralisation and catastrophising (Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978). Positive self-talk includes teaching the child statements like "I can do it" and "This will be over soon" (Uman et al., 2008, p. 844) or "If I relax it won't hurt as much" and "I can handle this" (Dahlquist et al., 1985, p. 327). Efficacy for this technique has been demonstrated by Kanfer, Karoly, and Newman (1975, p. 253) who showed self-talk such as "I am a brave boy/girl" can result in increased competence of the child when confronted with the feared stimulus. Cognitive restructuring is an important component in the treatment of childhood NRD (Kendall et al., 1992).

Despite distraction not being formally utilised in the treatment manual, its deserves to be mentioned as the majority of research on CBT techniques for NRD has focused on distraction techniques (Uman et al., 2008). First and foremost, distraction has been predominantly utilised in the past as focusing on anxiety in treatment makes the symptoms worse and perpetuates the vicious cycle of anxiety. Distraction can reverse this process for chronically ill children by shifting their attention away from distress-provoking procedures (Butler, 2001). Literature also suggests that it buffers memory and decreases distress and anxiety in later injections (McCarthy et al., 2010; Uman et al., 2008). Items used for distraction in past research include video games, party blowers, blowing bubbles and counting out loud (Manne et al., 1990; Willemsen et al., 2002). Despite all of these advantages, the rationale for excluding the use of distraction in this study was that it is a short-term strategy, and unhelpful if used as a way of avoiding symptoms in the long-term (Butler, 2001; Uman et al., 2008). Consequently, more adaptive coping strategies were alternatively taught to the child (e.g., breathing exercises, emotive imagery and coping thoughts).

Assessment and Treatment Integrity

The use of a treatment manual was designed to increase internal validity and treatment integrity by ensuring adherence to treatment procedures. Moreover, although the manual provided a standardised protocol for treatment implementation, it was designed to be implemented flexibly and as explained earlier there were some adaptations according to the developmental needs of the child. No treatment integrity measures were carried out due to time restrictions. However, the main assessor and therapist (KR) went through the treatment manual agenda before each session to ensure consistency, and also provided qualitative feedback to the primary researcher (JM) on the progress of therapy and treatment integrity. Cultural

consultation was also sought with an on-site Māori clinical psychologist to ensure treatment was implemented in a culturally sensitive way.

Ethical Considerations

The research was carried out according to the Code of Ethics for Psychologists Working in Aotearoa/New Zealand and the Massey University Human Ethics Committee Code of Ethics. Ethical approval to conduct this study was reviewed and approved by the Central Region Human Ethics Committee (see Appendix 1). Key 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.

All potential participants were provided with information sheets and consent forms in age-appropriate language (see Appendix 3). Information sheets outlined the nature and purpose of the research and what would be expected of the participants if they wished to take part. It explained what the treatment involved, and the names and roles of those involved were clearly described. 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 denied. 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 (e.g., safety issues). To ensure confidentiality, numerical codes were also given to the child and their carer. These numerical codes were participant one/carer one (P.1), participant two/carer two (P.2), participant three/carer three (P.3) and participant four/carer four (P.4). These codes were also used in all research reports and publications. As with all treatment carried out at the HCPS, assessment, treatment and follow-up material was stored in a locked filing cabinet only accessible to the researcher and supervisors. When the child turns 16, all data will then be held for a period of ten years, after which all data will be destroyed by the researcher and supervisors.

As in all research, no harm should come to the participants. This research was considered to be of a low risk to the participants, with the only potential distress induced by in-vivo exposure to anxiety-provoking stimuli (e.g., needle injections). However, there was close monitoring of how participants were progressing in treatment and the clinical psychologist would have modified or discontinued treatment if any participants were placed at risk. Treatment was also closely monitored by a senior clinician via clinical supervision and the carer was present in the case of emergencies. The clinician also followed their professional code of ethics and clinic policies and procedures.

Chapter 3: Results

Outline and Aims

Research results are presented below in five sections. The first section explains variations in the study design and provides an in-depth analysis of baseline stability across all four children and their carers. The second section relates to child reports, which shows the results according to the Needle Injection Questionnaire for Children (NIQ-C) and Subjective Units of Distress (SUD ratings). This is followed by a third section relating to carer reports, which presents the results of the Needle Injection Questionnaire for Parents (NIQ-C). Both sections are presented by initially outlining the combined mean scores of the measures across baseline, treatment and follow-up phases, followed by the individual case results for each participant in the form of quantitative and qualitative data. Fourth, non-regression-based statistics are utilised to provide an in-depth analysis of the research results. The fifth section gives a brief overview of the clinical significance of the present study in relation to the results presented.

Variations in Study Design and Baseline Stability

It was planned that post-treatment measures would be completed by the child and their carer immediately after the final session while at the Health Conditions Psychology Service (HCPS). However, for two participants this was unable to be carried out due to not having enough time to complete it after the final session. Instead, post-treatment measures were filled out at home by P.3 and P.4, which resulted in measures being completed 7 days (P.3) and 17 days (P.4) after the final therapy session. One month follow-up measures were distributed in the post and completed by all four participants, although time periods differed; P.1 (5.5 week follow-up), P.2 (6.5 week follow-up), P.3 (4 week follow-up) and P.4 (4.5 week follow-up).

All data illustrated in the tables and graphs in the following sections represent the data returned in order of the dates recorded on the measures. Treatment sessions were also intended to be weekly, but on occasion, weekly sessions were missed for practical reasons as discussed in the method chapter. As a result, treatment phase points on the graphs represent *sessions* rather than *weeks*. The child's mother completed all psychometric measures and attended the assessment interview and therapy sessions for all four participants.

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 (trend). Table 7 presents the baseline score ranges and variability for certain domains of the NIQ-C and NIQ-P, as well as SUD ratings. The NIQ-C cognition domain and NIQ-P avoidance

domain were excluded as baseline stability was not able to be calculated. Overall, baseline variability was within the recommended 50% level for each participant, with the exception of the NIQ-C and NIQ-P coping domains for P.1. In the majority of cases, the baseline data showed a downward trend following the initial assessment interview. Visual inspection of the baseline data returned suggested that it was stable enough to make a prediction that, without intervention, all participants would be likely to continue to experience NRD symptoms. The lower the NIQ-C and NIQ-P distress and avoidance, as well as SUD ratings, the more adaptive behaviour the child is displaying. NIQ-C and NIQ-P coping domains utilise the same format, therefore a reduction in coping scores indicates an increase in adaptive coping behaviours.

Table 7

Baseline stability across the NIQ-C, NIQ-P and SUD ratings

	NIQ-C: Distress	NIQ-C: Avoidance	NIQ-C: Coping	NIQ-P: Child Distress	NIQ-P: Carer Distress	NIQ-P: Child Coping	NIQ-P Carer Coping	SUD Ratings
P.1	7-10 (36%)	1-5 (45%)	1-6 (86%)*	8-10 (30%)	7-8 (20%)	3-7 (71%)*	1-1 (0%)	5-8 (36%)
P.2	8-8 (0%)	7-7 (0%)	4-5 (29%)	10-10 (0%)	3-4 (20%)	6-6 (0%)	1-1 (0%)	8-9 (18%)
P.3	7-8 (18%)	3-3 (0%)	3-5 (43%)	8-8 (0%)	3-6 (40%)	5-5 (0%)	2-2 (0%)	5-7 (27%)
P.4	0-0 (0%)	0-0 (0%)	1-2 (29%)	2-2 (0%)	2-4 (30%)	5-6 (29%)	2-3 (29%)	1-2 (18%)

Note. Numbers with no brackets = baseline score ranges. Numbers with brackets = percentage of change. Numbers with an asterisk indicate an unstable baseline. Score ranges: NIQ-C distress 0-10; NIQ-C avoidance 0-10 and NIQ-C coping 1-7; NIQ-P distress 1-10 and NIQ-P child and carer coping 1-7, SUD ratings 0-10.

Child Reports

Overall Mean Results

<u>NIQ-C: Distress, Avoidance and Coping Domains</u>

Figure 2 shows that the mean level of distress, avoidance and coping decreased following treatment, scores then decreased slightly further or remained stable over a one month follow-up period. Note the coping domain is on a reverse scale meaning a reduction in scores indicates an increase in adaptive coping behaviours.

The overall average self-reported NIQ-C distress for all four children decreased from 6.0 during baseline, to 2.8 over treatment and 2.5 over follow-up (on a scale of 0-10). The standard deviations were 4.0, 2.1 and 2.1 for the baseline, post-treatment and follow-up phases, respectively. The overall average self-reported NIQ-C avoidance for all four children decreased from 3.1 during baseline, to 1.5 over treatment and 1.5 over follow-up (on a scale of 0-10). The standard deviations were 2.9, 1.7 and 1.7 for the baseline, post-treatment and follow-up phases, respectively. The overall average self-reported NIQ-C coping for all four children decreased from 3.2 during baseline, to 2 over treatment and 1.5 over follow-up (on a scale of 1-7). The standard deviations were 1.4, 1.4 and 0.6 for the baseline, post-treatment and follow-up phases, respectively.

Figure 2. NIQ-C combined mean scores for child self-reported distress, avoidance and coping (average for all four participants) across baseline, post-treatment and follow-up phases.

SUD Ratings

Figure 3 shows that the level of SUD ratings slightly decreased during the treatment phase, and decreased even further over a one month follow-up period. The overall average self-reported SUD ratings for all four children slightly decreased from 5.6 during baseline, to 5.3 over treatment and 2.7 over follow-up (on a scale of 0-10). The standard deviations were 3.1, 2.5 and 2.5 for baseline, post-treatment and follow-up phases, respectively.
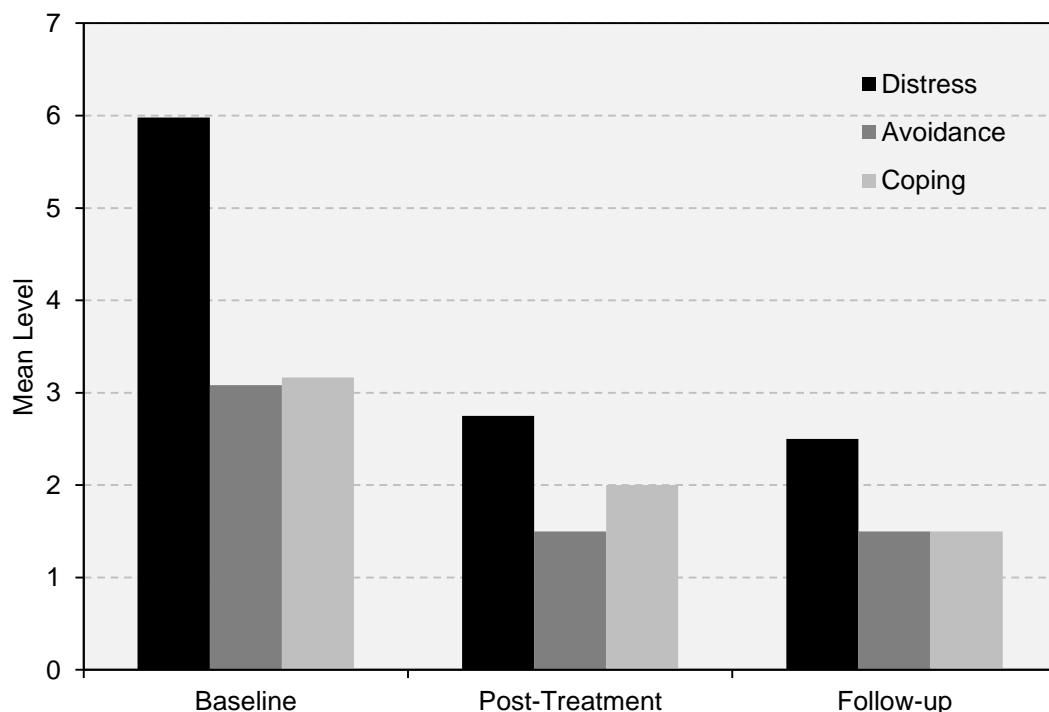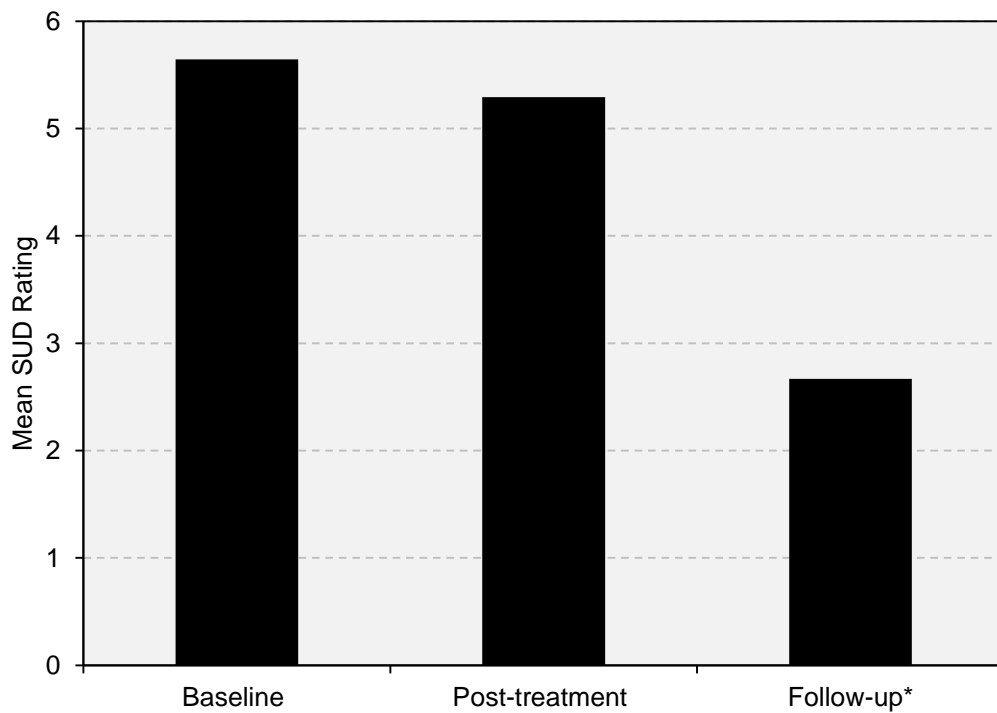

* Includes 3 children only.

Figure 3. SUD ratings combined mean scores for child self-reported distress (average for three participants only) across baseline, treatment and follow-up phases.

Individual Results

NIQ-C: Distress, Avoidance and Coping Domains

Figure 4 shows the results for all four participants on the NIQ-C distress, avoidance and coping domains across baseline, post-treatment and at one month follow-up. Due to the quantitative and qualitative nature of the NIQ-C cognition domain, it will be discussed separately to these three domains. Abbreviations on Figure 4 refer to baseline (B.1, B.2, B.3 and B.4), post-treatment (Post) and one month follow-up (Follow-up).

Each participant reported a unique pattern of baseline NRD symptoms as well as post-treatment and follow-up symptoms. This may reflect that NRD is a fluctuating experience depending on the chronic health condition and other developmental factors. P.4 scores were low on all three domains during the baseline phase so there was little room for improvement at post-treatment and one month follow-up.

Baseline scores remained relatively stable for all participants with the exception of P.1's coping domain where change exceeded 50%. The avoidance domain for P.1 also appeared unstable, although change did not exceed 50%. Results for this participant should be interpreted with caution. Additional visual inspection of P.2, P.3 and P.4 scores indicates a relatively horizontal trend in their baseline data. P.2 and P.4 also only completed two baseline measures, although the slope over the two points remained stable across all domains except for the coping domain which shows a slight reduction following assessment for both participants. Despite this, it is recommended that three data points are collected to ensure baseline stability, and as illustrated with P.1's coping domain, even though the first two data points may be stable the third data point can differ considerably. Therefore, although P.2 and P.4 both have stable baselines, due to these children only completing two pre-treatment measures results should also be interpreted with caution.

Visual inspection of the NIQ-C distress and avoidance domain scores suggests a reduction at post-treatment for P.1, P.2 and P.3. Scores on the coping domain suggest P.2 and P.3 had improved coping strategies post-treatment, while P.4 showed no improvement following treatment. Due to the instability of baseline scores for P.1, it is not certain if there was an increase in coping post-treatment. Overall, reductions in one domain of the NIQ-C appeared to parallel reductions/improvements in the other two domains.

One month follow-up data shows distress and coping decreased even further for P.1, while avoidance remained stable. Distress, avoidance and coping remained stable for P.2 and P.3. Follow-up data for P.4 shows distress, avoidance and coping remained consistent with baseline and post-treatment scores.

NIQ-C: Distress Domain

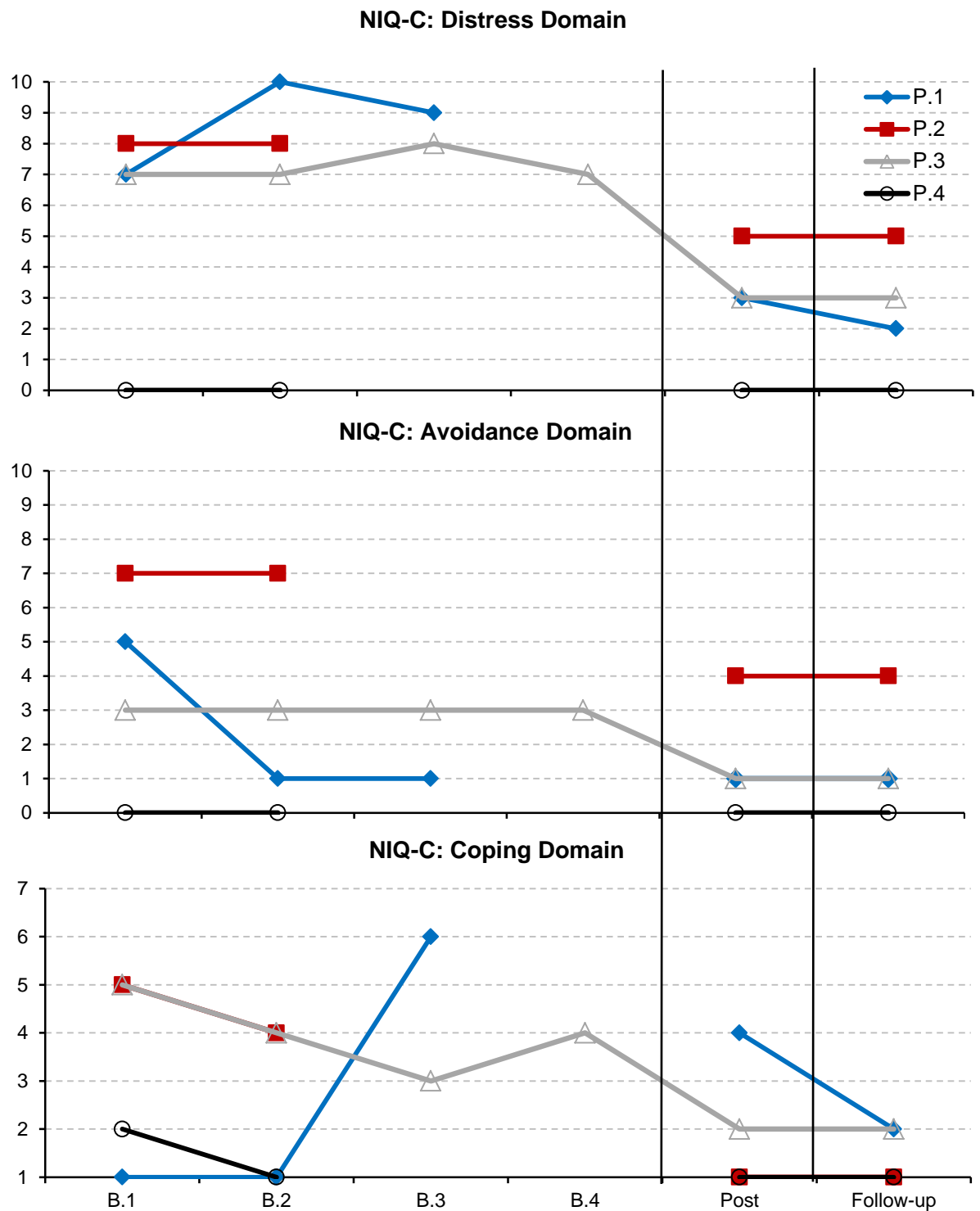## NIQ-C: Avoidance Domain

NIQ-C: Coping Domain

Figure 4. Child self-reported distress, avoidance and coping across baseline, post-treatment and follow-up phases. NIQ-C distress: 0 *(not upset)* – 10 *(very upset).* NIQ-C avoidance: 0 *(would not avoid it)*, 5 *(maybe avoid it)* - 10 *(would definitely avoid it)*. NIQ-C coping: 1 *(able to help myself)* – 7 *(not at all able to help myself)*.

NIQ-C Cognition Domain

Table 8 shows the results for all four participants on the NIQ-C cognition domain across baseline, post-treatment and at one month follow-up. The cognition domain has a qualitative and quantitative response format, therefore the child first wrote on the NIQ-C their thoughts in relation to three open-ended questions (see 3.a, 3.b and 3.c of the NIQ-C). The child then rated the intensity of their thought on a Likert Scale from 1 (*I do not believe it*) to 10 *(I absolutely believe it).* Cognitions in Table 8 have also been summarised and raw data is provided in Appendix 5.

Visual inspection of the baseline data shows that the majority of children had cognitions that related to hurt/pain (e.g., It might hurt a bit/lots – P.1); invasion of their body (e.g., it's going into me – P.5); avoidance (e.g., I want to run away, kick or punch – P.2) and lastly the visual appearance of the needle (e.g., I hope it's sharp – P.4). During the baseline phase, the intensity of negative cognitions typically remained high (above 5 out of 10). The hurt/pain cognitions had some of the highest intensity scores and was reported the most consistently across all four participants (average intensity score was 8 out of 10).

At post-treatment, the cognition content for P.1 changed from negative thoughts about the needle injection to positive thoughts about their carer, toys (Ted) and household pet (Sammie). The intensity of these cognitions remained relatively stable. At post-treatment, the cognition content for P.2 remained consistent with baseline data. However, the cognition intensity reduced considerably post-treatment, particularly in relation to pain/hurt cognitions which decreased by 45% and avoidance cognitions (e.g., kick, punch and go away) which decreased by 30%. On the other hand, cognition intensity for P.2 in relation to the person carrying out the needle injection increased by 45%. This is because the nurse had difficulty finding P.2's vein during the in-vivo needle injection in session five of the treatment programme. In relation to P.3, two out of three cognitions remained consistent with the content reported during baseline. However, one of these cognitions reduced in intensity by 26% (e.g., the needle is yuck), while the intensity of the other cognition remained high. The third cognition reported was more adaptive (e.g., "I don't want to have one, but I'll be okay") with a high intensity of 10 out of 10. Post-treatment thoughts for P.4 changed from negative thoughts about the procedure during the baseline phase, to being less concerned about the procedure and having the attitude "it's just another needle" at post-treatment. The intensity of these cognitions remained high (above 5 out of 10).

One month follow-up results for P.1 showed cognition content reverted back to negative cognitions reported during baseline, although the intensity of similar cognitions reduced by 20 - 40%. The cognition content for P.2 became slightly negative at follow-up, although the intensity was lower than baseline scores. P.3 cognition content that the needle is "yuck" was again repeated at follow-up, and the intensity had reverted back to baseline levels (8 out of 10). The remaining cognitions included new positive thoughts with a high intensity score of 10 out of 10. Follow-up results for P.4 showed cognition content and intensity was consistent with post-treatment gains.

Table 8

Child cognitions and intensity across baseline, post-treatment and follow-up phases

Pre-treatment	I	Post-treatment	I	Follow-up	I
Participant 1 (6 years)					
It might hurt a bit/lots	8	Think about Sammie	10	It's going to hurt	6
A bit scared	10	I think about Mum and Dad	10	I'm scared	6
It will feel like a pinch	10	Playing with Ted	7	It's going to prick me	8
She's going to put it into me or somebody else	6.75	Feeding Sammie	8	Take deep breaths	7
I don't want to have it	7.5	-	-	Need to take deep breaths	6
Participant 2 (10 years)					
The needle hurts	9	Oh they hurt	4.5	Do not like	6
I want to run away, kick or punch	8	Go away	5	Oh no	6
They're doing their job	5.5	If they do it good they're good, if they do it bad, they're bad	10	Hate you (person injecting needle)	6
Participant 3 (13 years)					
I hope it doesn't hurt	10	-	-	-	-
The needle is yuck!	7.6	Yuck, then I'd look away	5	Yuck, then I'd look away	8
I don't want to think about it	8	I don't want to see it	10	I don't want to have one but it will be okay	10
I think about me getting upset	7	I don't want to have one but I know I have to and I'll be okay	10	I don't worry about this until I need to	10
Thinking about the needle going in	8	I want them to get it over with	10	I want them to get it over with	10
I just want them to get it over with and not tell me what's happening	9.75	I don't want them to tell me when the needle is in	10	I don't want them to tell me when the needle goes in	10
Participant 4 (14 years)					
It's going to hurt	6.5	It's just another needle I don't care	10	I don't care	10
I don't want to have another one	5.6	I don't care, it's a daily thing for me	10	-	-
I hope it's sharp and hasn't been used before	3	-	-	-	-
They better do it well/properly	7	Do it properly	5	Get it over with	3

Note. I = intensity score. NIQ-P cognition: Qualitative response format: Written answer in the form of thought 1, 2 and/or 3; Quantitative response format: 1 (*I do not believe it*) – 10 (*I absolutely believe it*).

Table 9 shows the results for all four participants on the NIQ-C coping domain across baseline, post-treatment and at one month follow-up. These coping behaviours have been summarised, and raw data is provided in Appendix 6. Visual inspection of the baseline data indicates the majority of participants were either doing "nothing" (P.2) or using cognitive (e.g., "think about something else" – P.4) and/or behavioural distraction (e.g., "look away" – P.2) techniques to cope with the needle injection prior to therapy. At post-treatment, P.1 was using relaxation and breathing exercises, while P.2 was using behavioural rehearsal/exposure and applied tension. There were improvements in the coping strategies used by P.3 including both behavioural (e.g., calm breathing) and cognitive strategies (e.g., good self-talk). P.4 continued to report distraction techniques, although it appears more adaptive coping thoughts were being used (e.g., "realise it's just another needle"). Follow-up results suggest coping strategies for P.1 and P.3 remained stable, whereas the NIQ-C coping domain for P.2 was unanswered. P.4 reported few coping strategies at follow-up other than one distraction technique.

Table 9

Child coping behaviours across baseline, post-treatment and follow-up phases

Pre-treatment	Post-treatment	Follow-up
Participant 1 (6 years)		
Hug mum or my teddy bear	Take deep breaths and relax	Take deep breaths
Tell myself stop crying	Cuddle/sit on mum's knee	Sit on mum's knee
Playing with Ted my dog	Playing with Ted and Sammie	Think of cuddling Ted
Participant 2 (10 years)		
Look away or look at something else	Pinch my hand to make it less sensitive	-
I was so upset I did nothing	Practise an injection on one hand before I go in	-
Participant 3 (13 years)		
This will be over soon	Calm breathing and eyes shut	Calm breathing
I can cope if I choose to cope	Mind pictures and good self-talk	Mind pictures and I'll be okay
Participant 4 (14 years)		
Close my eyes	Look away	Ignore everything
Relax and think about something else	Think of something else	-
Not think about the pain	Realise it's just another needle	-

Note. NIQ-C coping: Qualitative response format: Written answer in the form of thought/action 1, 2 and/or 3.

SUD Ratings

Figure 5 shows the level of SUD ratings collected during each session for all four participants across the baseline, treatment and follow-up phases. Abbreviations on Figure 5 refer to baseline (B.1, B.2, B3 and B.4), treatment (T.1, T.2, T.3 and so on) and one month follow-up (1 mo). Each participant reported a unique pattern of baseline distress, an idiosyncratic response to treatment and a relatively stable response at one month follow-up. Visual inspection of the baseline data suggests that initial monitoring (e.g., session 1 and 2) produced little changes in SUD ratings with the exception of P.4 who showed a slight increase in distress from baseline scores. During the treatment phase, distress remained stable for the majority of participants until session three in which case there was a slight reduction in distress. Session four and five resulted in a rapid increase in distress which could be due to these sessions involving medium to high level imaginal and in-vivo exposure to needle injection situations. SUD ratings reduced for all four participants upon completion of therapy (e.g., session six). Follow-up results for P.1, P.2 and P.4 suggest treatment gains remained stable at one month follow-up. Overall, distress for the majority of participants gradually reduced over the course of treatment.
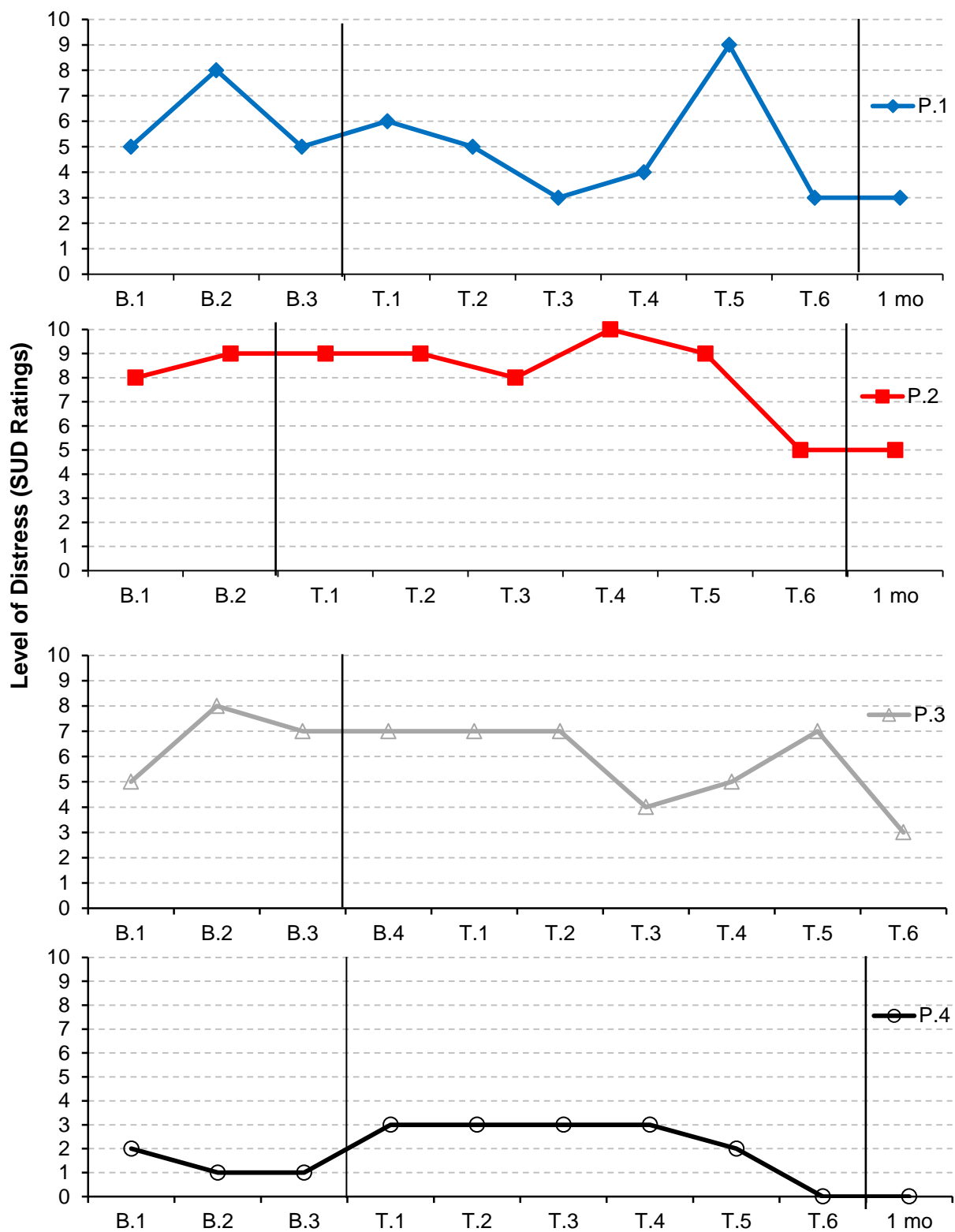
Figure 5. Child self-reported SUD ratings across baseline, treatment and follow-up phases. SUD rating: 0-10.

Carer Reports

Overall Mean Results

<u>NIQ-P: Child and Carer Distress and Coping Domains</u>

Figure 6 shows that the mean level of carer self-report of child distress decreased with treatment, and decreased even further over a one month follow-up period. The carer's ability to help their child cope decreased at post-treatment with further reductions reported at one month follow-up. The coping domain is on a reverse scale meaning a reduction in scores indicates an increase in adaptive coping behaviour. The overall average of carer self-report of child distress for all four participants decreased from 7.3 during baseline, to 4.3 over treatment and 2.8 over follow-up (on a scale of 1-10). The standard deviations were 3.7, 2.2 and 1.7 for baseline, post-treatment and follow-up phases, respectively. The overall average of the carers ability to help their child cope for all four participants decreased from 5.2 during baseline, to 3.5 over treatment and 3.3 over follow-up (on a scale of 1-10). The standard deviations were 0.7, 1.9 and 2.2 for baseline, post-treatment and follow-up phases, respectively.

In addition, Figure 6 also shows that the mean level of carer distress decreased with treatment, and decreased slightly further at one month follow-up. There were only slight reductions in carer coping at post-treatment, which then remained stable over at one month follow-up. The coping domain is on a reverse scale meaning a reduction in scores indicates an increase in adaptive coping behaviours. The overall average of carer distress for all four participants decreased from 4.4 during baseline, to 2.3 over treatment and 1.8 over follow-up (on a scale of 1-10). The standard deviations were 2.0, 0.5 and 1.0 for baseline, post-treatment and follow-up phases, respectively. The overall average of carer coping for all four participants decreased from 1.6 during baseline, to 1.5 over treatment and 1.5 over follow-up (on a scale of 1-10). The standard deviations were 0.8, 0.6 and 0.6 for baseline, post-treatment and follow-up phases, respectively.
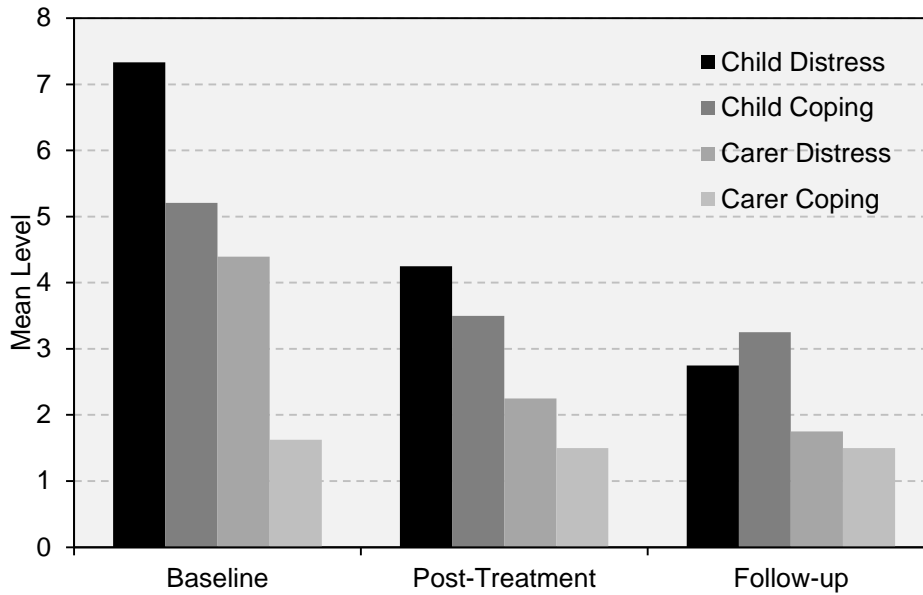
Figure 6. NIQ-P combined mean scores for child and carer distress and coping (average for all four participants) across baseline, post-treatment and follow-up phases.

Individual Results

<u>NIQ-P: Distress and Coping Domains</u>

Figures 7 and 8 show the results for carer distress and coping, as well as carer self-report of child distress and coping according to the NIQ-C across baseline, post-treatment and at one month follow-up. The coping domain is on a reverse scale so a reduction in scores indicates an increase in adaptive coping behaviours.

Visual inspection of baseline data suggested a stable baseline for all four participants with the exception of P.1 child coping domain where variability exceeded 50%. Carer self-report of child distress (with the exception of P.4) and the carer's ability to help their child cope (child coping) were moderately high during baseline. Carer distress during baseline was moderate for all four participants, with the exception of P.1 which was relatively high. Baseline scores for carer coping revealed there was little improvement required.

Post-treatment scores suggested that there were reductions in child and carer distress for all four participants. The exception to this was carer self-report of child distress for P.4, in which case any further reductions would be minimal. Results also suggested a decrease in the carer's ability to help their child cope during needle injections at post-treatment. Carer coping remained consistent with baseline scores.

Follow-up results for P.1, P.3 and P.4 showed further reductions in carer distress, while P.2's distress increased slightly but remained at a level below baseline scores. Carer coping for all four participants remained stable at follow-up. Child distress for P.1 and P.4 reduced further, while P.2 and P.3 remained stable. The carer's ability to help their child cope reduced further for P.1 and P.2, whereas scores remained stable for P.3 and increased for P.4 at follow-up.

NIQ-P: Carer Distress Domain

NIQ-P: Carer Coping Domain
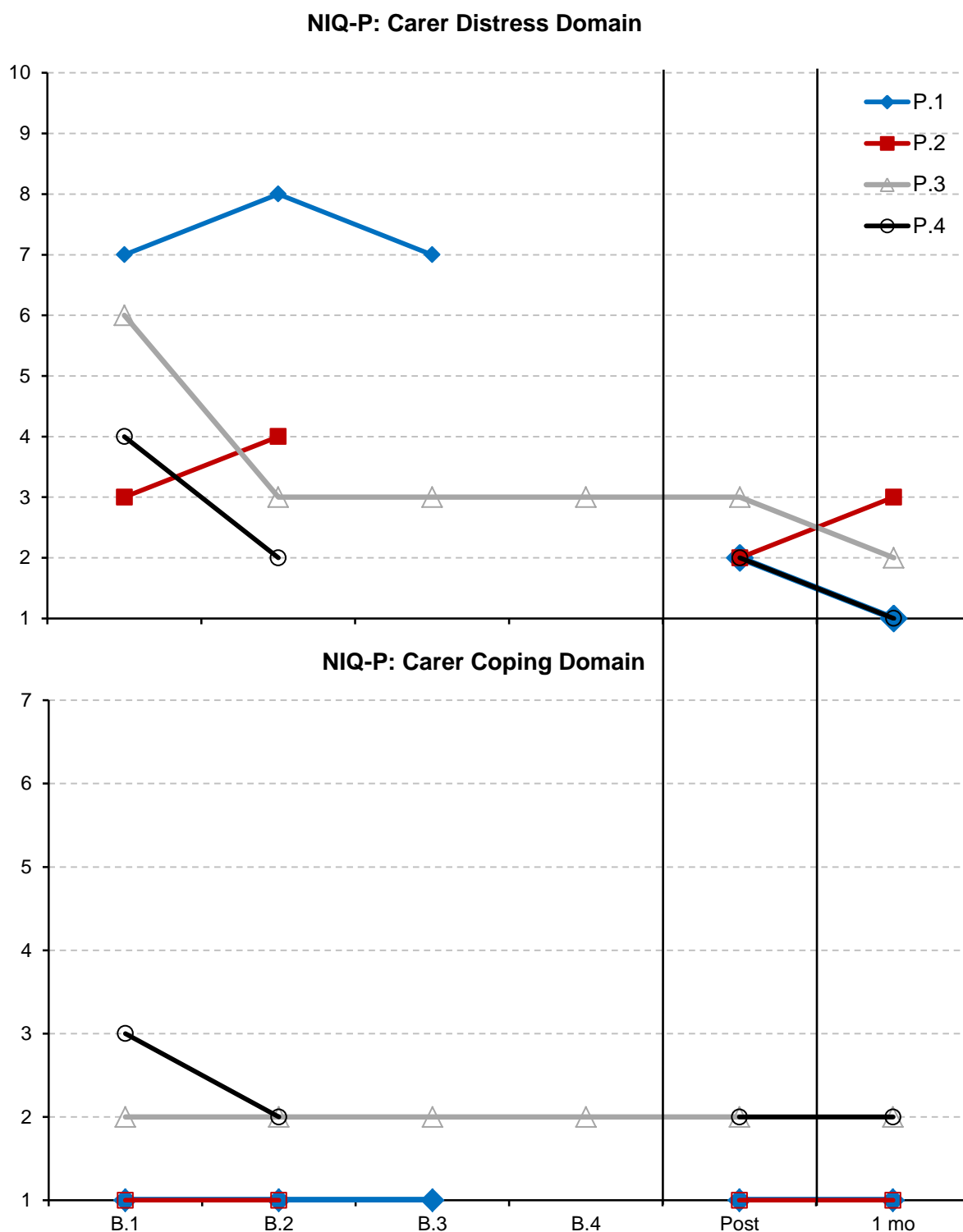
Figure 7. Carer self-reported distress and coping across baseline, post-treatment and follow-up phases. NIQ-P carer distress: 1 *(not at all distressed)* – 10 *(extremely distressed).* NIQ-P carer coping: 1 *(able to help myself)* – 7 *(not at all able to help myself).*

NIQ-P: Child Distress Domain

NIQ-P: Child Coping Domain
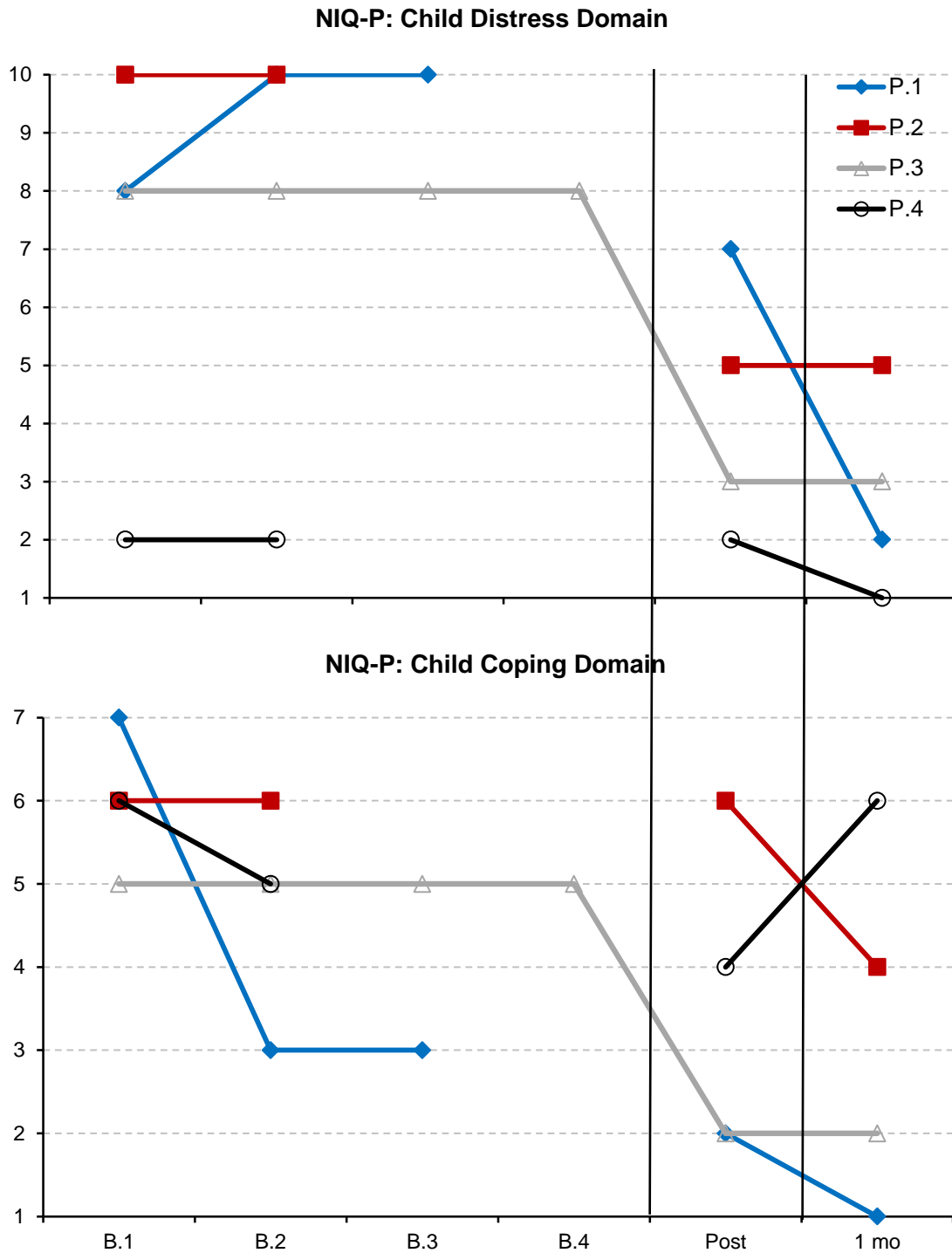
Figure 8. Carer self-report of child distress and coping across baseline, post-treatment and follow-up phases. NIQ-P child distress: 1 *(not at all distressed)* – 10 *(extremely distressed)*. NIQ-P child coping: 1 *(able to help my child)* – 7 *(not at all able to help my child)*.

Table 10 presents data gathered from the NIQ-P avoidance domain across baseline, post-treatment and follow-up phases. Data collected did not provide additional information about the effectiveness of the treatment programme, although it has been included as it offers information about the frequency of needle injections the child has had over the past six months and provides feedback about the usefulness of the NIQ-P as a measure of NRD. As shown, P.2 and P.4 are reporting the same amount of needle injections from baseline to post-treatment, despite the child receiving more injections during this period. The limitation of this domain will be outlined in the discussion chapter. Overall, results suggest P.2 was the only participant to show a change from baseline, in which case the number of medical appointments that were altered or cancelled due to child and carer distress reduced at post-treatment. At post-treatment and follow-up, there were no successful attempts at avoidance of needle injections for P.2. The number of attempts to avoid needle injections for P.1 also reduced at one month follow-up.

Table 10

Carer self-report of avoidance across baseline, post-treatment and follow-up phases

No.	Question	P.1	P.2	P.3	P.4
		Pre/Post/1mo	Pre/Post/1mo	Pre/Post/1mo	Pre/Post/1mo
2.a)	**Number of injections in last six months**	10/12/12	1/1/1	2/3/3	336/336/336
2.b)	**Attempted to avoid injection**	10/12/0	1/1/1	0/0/0	0/0/0
2.c)	**Successful at avoiding injection**	0/0/0	1/0/0	0/0/0	0/0/0
2.d)	**Alter/cancel appointment due to child distress**	1/1/1	3/1/1	1/1/1	1/1/1
2.e)	**Alter/cancel appointment due to carer distress**	1/1/1	2/1/1	1/1/1	1/1/1

Note. NIQ-P avoidance 2.a, 2.b and 2.c response format: *Numerical value.* NIQ-P avoidance 2.d and 2.e response format: 1 *(not at all)* – 10 *(all the time)*.

<u>*NIQ-P: Coping Domain*</u>

Table 11 presents the results for all four carers in relation to coping behaviours across baseline, post-treatment and follow-up phases. These coping behaviours have been summarised and raw data is provided in Appendix 7. Baseline data suggests that rewards, physical restraint and distraction were the main strategies used by carers to help their child cope. Results for P.4 were more related to how the carer coped during the needle injection and reassuring themself that injections are necessary for their child to stay healthy.

Visual inspection of the post-treatment data indicates the majority of carers were using more muscle relaxation, breathing exercises and reassurance following therapy. Negative behaviours present during baseline (e.g., physical restraint – P.2, and blackmail – P.1) were no longer present post-treatment. Feedback from the clinician also suggested carers were using more distraction techniques (e.g., iPad or favourite toy) during the in-vivo needle injection in session five of the treatment programme. Follow-up results for P.1, P.2, P.3 suggest muscle relaxation, breathing exercises, distraction and reassurance were maintained at one month. There were no significant changes in follow-up results for P.4 compared to baseline and post-treatment.

Table 11

Carer self-report of coping across baseline, post-treatment and follow-up phases

Pre-treatment	Post-treatment	Follow-up
Participant 1 (6 years)		
Try to reason with him	Talk to him and try to get him to relax and do his breathing	Get him to sit on my knee
Try offering him a reward/treat/present (e.g., he can sit on my knee) or blackmail him	Give him a cuddle and reassure him	Tell him to take deep breaths
Explain the sooner it's over the better and he can have a treat	Offer a reward	Tell him to keep calm and reassure him it's ok
Participant 2 (10 years)		
Restrain him or hold him down so that it happens quicker	Deep breathing/relaxation	Tell him to use his breathing techniques
Explain to nurse he has needle phobia and try to reassure him	-	-
Distract him with talking or an item (e.g., i-pod)	-	-
Participant 3 (13 years)		
Try to engage her in conversation and think about other things	Try to think about something else and get her to talk about something else	Include her in conversation
Use calm breathing and try to be calm myself	Breathe deeply and slowly	Breathe deeply and slowly
Remind myself that she has done this before and survived	Explain to the doctor with my child's permission that she will cry but that's okay just keep going	Try to think about other things
Tell myself it will be over soon and tell her	-	-
Participant 4 (14 years)		
Reassure myself that he needs the injection to get better and stay alive	He is getting older, the necessity for his jabs will sink in for him soon	I know that he needs insulin to survive
Hope that he is rotating his jab site	It is necessary - he is diabetic and he will feel better and be healthier	I know that I have done my best to help and support him

Note. NIQ-P coping: Qualitative response format: Written answer in the form of action or thought 1, 2 and/or 3.

Table 12 shows the results for carer self-report of their child's coping according to the Coping Behavior Questionnaire (CBQ). The lower the CBQ score the more adaptive the child's coping behaviour, therefore the percentage is shown in a negative direction. Overall results show that the baseline data for the CBQ remained relatively stable in terms of variability and trend for three of the four participants. The exception to this was P.3, in which case baseline data exceeded a change of more than 50%. Caution should be taken when interpreting P.3's results.

At post-treatment, child coping behaviours reduced compared to baseline scores for all four participants. This reduction ranged from -14 to -52% at post-treatment. Follow-up results remained stable and/or reduced further with a change in scores ranging from -16 to -81%. Further analysis of the results suggests that the magnitude of change is small for some participants despite the percentage of change suggesting otherwise. For example, P.4 changed from 3.5 during baseline to 2 at follow-up with a percentage reduction of -43%. Practically, this is a small change in behaviour. In addition, due to normative data being unavailable a clinically significant change is not able to be determined.

Individual results showed that prior to therapy and during the most recent needle injection, three of the four children gave verbal protest (e.g., "ouch", and "it hurts"), whereas three cried and were afraid during the procedure. Two of the four children screamed and/or yelled, were physically restrained and aggressive including biting and kicking during the procedure. Post-treatment and follow-up results showed no children gave verbal protest, were physically restrained or aggressive during their most recent needle injection. Instead all of the children were cooperative, followed instruction without complaining, engaged in conversation and asked questions about the procedure.

Table 12

Carer self-report of child coping on the Coping Behavior Questionnaire

Treatment phase	P.1	P.2	P.3	P.4
Baseline 1	13	11	8	3
Baseline 2	13	10	3	4
Baseline 3	13	-	4	-
Baseline 4	-	-	4	-
Post-treatment	9 (-31%)	5 (-52%)	4 (-16%)	3 (-14%)
Follow-up	5 (-62%)	2 (-81%)	4 (-16%)	2 (-43%)

Note. Numbers with no brackets = CBQ score. Numbers with brackets = percentage reduction to more adaptive coping behaviours.

Data Analysis: Non-Regression-Based Statistics

As mentioned in the method section, non-regression algorithms were used in order to provide additional insight into treatment outcomes and obtain effect size calculations. These algorithms included the Standard Mean Difference all (SMDall), Mean Baseline Reduction (MBLR) and Percentage of Non-Overlapping Data (PND). SMDall and MBLR were calculated for all participants according to three of the four domains of the NIQ-C (e.g., distress, avoidance and coping) and two of the three domains of the NIQ-P (e.g., distress and coping). SMDall, MBLR and PND were also calculated using SUD ratings collected weekly across baseline, treatment and once at follow-up for all four participants. PND was not calculated for the NIQ-C and NIQ-P due to the calculation requiring more than one intervention point.

The rationale for calculating only three of the four domains of the NIQ-C was that the cognition domain (e.g., questions 3.a, 3.b and 3.c) contained both quantitative and qualitative response formats, making non-regression-based statistics difficult to perform. One domain of the NIQ-P (i.e., avoidance) was also not calculated as it collected information that was unsuitable for calculation. This was mainly because the NIQ-P avoidance domain collects discrete numbers and showed no change from baseline to post-treatment with the exception of P.1 and P.2. Furthermore, for some participants SMDall and MBLR was unable to be calculated for certain domains of the NIQ-C and NIQ-P because the standard deviation during baseline was zero (i.e., no variation in their baseline scores) and/or there was no change from baseline to post-treatment scores.

Interpretative guidelines for these three algorithms are as follows. According to Cohen's *d*, a SMDall 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. There are no interpretative guidelines for MBLR (Olive & Smith, 2005). PND scores below 50 suggest 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 (Scruggs & Mastropieri, 1998). Results of these analyses for each participant will now be provided.

Child Reports

Table 13 presents the SMDall scores utilising data collected from the NIQ-C distress, avoidance and coping domains, as well as SUD ratings for all four children. Results show that there was a significant amount of variability in the effect sizes across participants, although this may be due to some calculations being unable to be performed. Despite this, for the participants in which SMDall could be calculated, effect sizes according to Cohen's criteria (Cohen, 1988) showed very large reductions in distress (P.3, SMDall = 8.5; P.1 SMDall = 4.0). P.1 avoidance domain showed a moderate reduction (SMDall = 0.6). Coping was also calculated for all four participants, which showed a negative result for P.1 and a moderate to very large increase in

adaptive coping for P.2, P.3 and P.4. SMDall effect sizes for SUD ratings showed either negative (P.4), moderate (P.1) or large reductions in distress (P.2 and P.3).

Table 13 also presents the MBLR scores utilising data collected from the NIQ-C distress, avoidance and coping domains, as well as SUD ratings. Results show that, for the majority of participants, there was a reduction in distress by 38 - 71% from baseline scores. Avoidance also reduced for the majority of participants by at least 43%, whereas coping improved by at least 33% with the exception with P.1 who had a reduction in coping of 13%. SUD ratings reduced the least across all four participants, which may due to the majority of scores during treatment remaining consistent with baseline scores until at least session six after exposure tasks.

Table 13

SMDall and MBLR for all four children according to the NIQ-C and SUD ratings across baseline, post-treatment and follow-up phases

	SMDall (effect size)	MBLR (percent)
Participant 1		
Distress	4.0	71
Avoidance	0.6	57
Coping	-0.1	-13
SUD ratings	0.7	11
Participant 2		
Distress	No standard deviation	38
Avoidance	No standard deviation	43
Coping	4.9	78
SUD ratings	0.9	2
Participant 3		
Distress	8.5	59
Avoidance	No standard deviation	67
Coping	2.4	50
SUD ratings	1.0	19
Participant 4		
Distress	No change	No change
Avoidance	No change	No change
Coping	0.7	33
SUD ratings	-1.2	-25

Figure 9 presents the PND scores utilising data collected from the SUD ratings for all four participants. Results show that the PND score for P.2, P.3 and P.4 was 33%, which according to interpretive guidelines suggests the intervention was ineffective. The PND score for P.1 was 67%, although still interpretive guidelines suggest the intervention was questionable. Perhaps the reason for such negative results is because the majority of SUD ratings remained considerably high throughout the intervention until session six. P.1 also had a large PND score (67%) compared to other participants because distress steadily decreased over the course of treatment for this participant. However, P.2, P.3 and P.4's distress reduced only after session six. It may be the case that change does not occur until the end of therapy after medium to high-level exposure tasks have been completed.
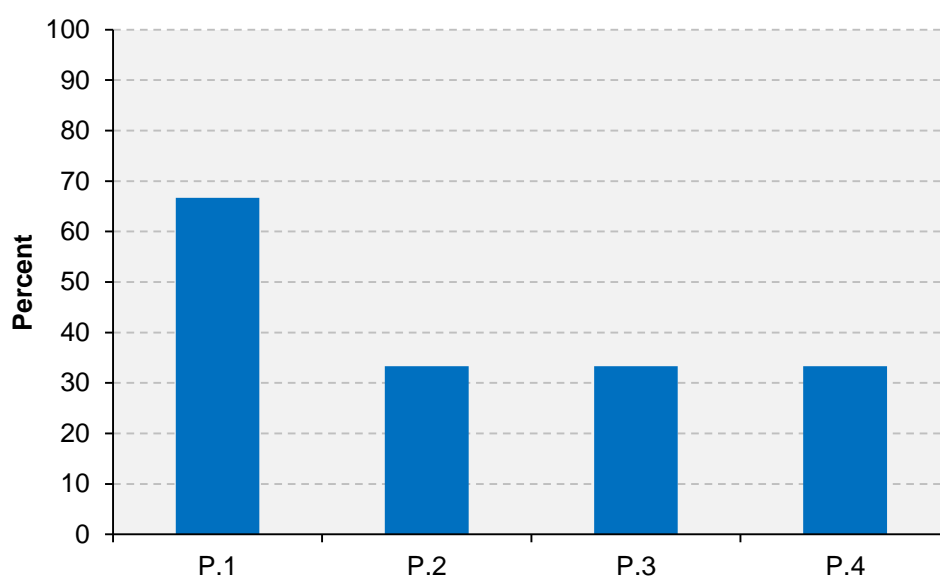
Figure 9. PND for child self-reported SUD ratings across baseline, treatment and follow-up phases.

Carer Reports

Table 14 presents the SMDall scores utilising data collected from the NIQ-P child and carer distress and coping domains. Results show that a significant amount of calculations could not be performed due to either a zero standard deviation or no change from baseline to post-treatment scores. Despite this, for the participants in which SMDall could be calculated, effect sizes according to Cohen's criteria (Cohen, 1988) showed very large reductions for child distress (SMDall = 4.2; P.1). Carer distress showed large (SMDall = 0.8; P.3) to very large (SMDall = 10.1; P.1) reductions for all four participants. For calculations that were able to be performed, child and carer coping had medium (SMDall = 0.7; P.4 child and carer) to very large effect sizes (SMDall = 1.2; P.1 child).

Table 14 also presents the MBLR scores utilising data collected for the NIQ-P child and carer distress and coping domains. Results show that, for the majority of participants, there was a reduction in child distress by 50 - 63% and a reduction in carer distress by 29 - 80% compared to baseline scores. The carer's ability to help their child cope improved by 9 - 77% compared to baseline scores. There was no change in carer coping from baseline scores with the exception of P.4, which improved by 20%.

Table 14

SMDall and MBLR for carers across baseline, post-treatment and follow-up phases

	SMDall (effect size)		MBLR (percent)	
Participant 1				
Child distress/Carer distress	4.2	10.1	52	80
Child coping/Carer coping	1.2	No change	77	No change
Participant 2				
Child distress/Carer distress	No deviation	1.4	50	29
Child coping/Carer coping	No change	No change	17	No change
Participant 3				
Child distress/Carer distress	No deviation	0.8	63	33
Child coping/Carer coping	No deviation	No change	60	No change
Participant 4				
Child distress/Carer distress	No change	1.1	No change	50
Child coping/ Carer coping	0.7	0.7	9	20

Clinical Significance

Clinical significance is an important part of assessing treatment outcomes, particularly in single-subject research (Kazdin, 1982). In relation to this study, 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 (e.g., meaningful changes observed by important people) or specifying level assessments using normative comparisons (e.g., behavioural observations and self-report instruments). Due to this

research using assessment measures with no validity, reliability and normative information available, it is difficult to determine if the results showed clinically significant change according to specifying level assessments. Instead, the level of clinical significance was obtained using anecdotal feedback from the carer and therapist regarding treatment outcomes (general impact level assessments). These sources of information are also recommended as important for determining clinical significance (Kendall & Grove, 1988).

Feedback from the therapist regarding the clinical significance of the treatment manual was positive. For example, it was reported post-treatment that P.3 had increased "bravery behaviour" and was generally less anxious when encountering everyday situations rather than just needle injections. It was also reported that P.3 and their carer found the treatment programme very useful. Further feedback from participants showed that, although they had learned skills to cope with needle injection situations, these could be used in other circumstances (e.g., fear of dark and test anxiety). Perhaps most importantly, three of the four participants completed the in-vivo needle injection during session five and none required physical restraint. This is despite two participants being restrained prior to therapy and during their most recent needle injection. P.4 did not complete an in-vivo injection due to not bringing their insulin kit to session five. It was also observed during this in-vivo needle injection that P.2 used coping behaviours learnt in therapy to cope with the procedure. P.1 has also shown significant improvements at follow-up, and as reported by the family and therapist, he has had two needle injections since therapy completion, both of which have been very successful compared to pre-treatment levels.

Chapter 4: Discussion

Outline and Aims

This chapter presents the overall findings of the present study with reference to the four research objectives delineated in Chapter One. The results are interpreted in terms of past literature, with implications discussed in key areas. Limitations of the present study and suggestions for future research are outlined. A final conclusion is presented.

Summary of the Findings

The aim of the current research was to develop and evaluate a six-session cognitive-behavioural therapy (CBT) for chronically ill children experiencing needle-related distress (NRD). The research was designed to pilot this manualised approach, which was based on an existing therapy utilised at the Massey Health Conditions Psychology Service (HCPS), relevant theory and empirical research. The treatment manual differed from previous research by incorporating cognitive components, carer involvement and multiple exposure sessions. The main outcome measures were also piloted: the Needle Injection Questionnaire for Children (NIQ-C) and the Needle Injection Questionnaire for Parents (NIQ-P). The treatment manual and measures were evaluated using a single-subject design with multiple baselines across participants. Participants included four chronically ill children presenting with NRD who were referred from MidCentral Health DHB to the HCPS.

Results indicated that, compared to pre-treatment levels, the majority of children and their carers demonstrated: a) a reduction in distress, b) an increase in coping behaviours related to needle injection situations, and c) that treatment gains were generally maintained and/or improved over a one month follow-up period. Overall, preliminary results of the present study are promising in suggesting the effectiveness of the Coping Kids Treatment Manual with four chronically ill children of New Zealand European descent. Specific objectives met with respect to this study are as follows:

1.1 It was expected that children would show a reduction in anxiety-related symptoms and an increase in adaptive coping behaviours related to specific needle injection situations at post-treatment. It was also expected that children would show a reduction in subjective units of distress (SUD ratings) both during and following treatment. It was expected these gains would be maintained over a one month follow-up period.

Results relating to Objective 1.1 showed there were reductions in distress and avoidance, and an increase in coping at post-treatment. For a number of participants, large effect sizes provide corroborative evidence for a reduction in distress (P.1 and P.3), avoidance (P.1) and an increase in coping (P.2, P.3 and P.4) at post-treatment and one month follow-up. Results also showed a reduction in SUD ratings following treatment, with medium to large effect sizes providing corroborative evidence for a reduction in distress for the majority of participants (except P.4). These results were also reflected in the percentage reduction between baseline and post-treatment scores calculated for distress, avoidance and coping. The exception to these improvements was P.4, where distress and avoidance were at the lowest point during the baseline phase so post-treatment scores could not reduce any further. This result was unexpected in the context of this study. Therefore, an explanation as to why P.4's scores were so low throughout the intervention is discussed later in this chapter. Coping behaviours changed considerably from baseline with the following strategies reported post-treatment: muscle relaxation, breathing exercises, behavioural rehearsal, applied tension, mind pictures and positive self-talk. Follow-up results showed that post-treatment results were maintained and/or improved further at one month follow-up.

1.2 It was expected that children would show a reduction in negative cognition intensity related to specific needle injection situations at post-treatment. It was also expected that these gains would be maintained over a one month follow-up period.

Results relating to Objective 1.2 showed post-treatment cognition content changed by revealing new positive cognitions, rather than primarily reducing negative cognitions as seen in the baseline phase. New cognitions learnt and applied included "I don't want to have one, but I know I have to and I'll be okay" (P.3) and "I think about Mum and Dad, and take deep breaths" (P.1). These new positive cognitions usually presented with a high intensity score. Negative cognition content present during baseline and repeated at post-treatment generally decreased in intensity compared to baseline scores. Follow-up results indicated post-treatment results were maintained.

1.3 It was expected that carers would self-report reductions in their child's anxiety-related symptoms and an increase in their ability to help their child cope in relation to needle injection situations at post-treatment. It was also expected that these gains would maintained over a one month follow-up period.

Results relating to Objective 1.3 showed carer self-report of child distress generally reduced, whereas carer self-report of their ability to help their child cope slightly improved post-treatment. For several participants, large to medium effect sizes provide corroborative evidence for a reduction in carer self-report of child distress (P.1) and increase in the carers ability to help their child cope (P.1 and P.4) at post-treatment. Carer self-report of child behavioural avoidance was low during the baseline phase, so there were no considerable changes post-treatment. Follow-up data indicated post-treatment results were generally maintained and/or improved further at one month follow-up.

2.1 It was expected that carers would show a reduction in anxiety-related symptoms and an increase in adaptive coping behaviours related to specific needle injection situations at post-treatment. It was also expected that these gains would be maintained over a one month follow-up period.

Results relating to Objective 2.1 showed there were reductions in carer distress post-treatment. For all four participants, large effect sizes provide corroborative evidence for a reduction in carer distress at post-treatment. Carer coping was low during the baseline phase, thus there were no changes at post-treatment. This was reflected in the effect size calculations whereby no change from baseline to post-treatment was reported for three of four carers. The coping strategies, reported by carers generally remained consistent with baseline strategies which mainly included relaxation and breathing exercises. In addition, carer behavioural avoidance was low during the baseline phase, thus there were no substantial changes post-treatment. Follow-up data indicated post-treatment results were generally maintained and/or improved further at one month follow-up.

Interpretations and Implications

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

Interpretation of Distress Domain

Distress Response Patterns: SUD Ratings

In general, results in relation to SUD ratings showed similar treatment response patterns for all four participants across baseline, treatment and follow-up phases. The exception to this was P.4, as will be explained later in this chapter. Scores from the psycho-education phase (session one) and coping strategy phase (session two) of treatment stayed consistent with baseline scores. Low-level exposure tasks (session three) showed a slight reduction in distress. In comparison, medium to high-level exposure sessions (session four and five) were associated with an increase in distress, while the child became desensitised to the needle injection. SUD ratings then reduced during session six and remained stable at post-treatment for all four participants. Calculation of the percentage of non-overlapping data (PND) gave further insight into the pattern of treatment responses in relation to the SUD ratings collected. Calculation of PND showed that change did not occur until the end of therapy after medium to high-level exposure tasks were completed. It could be suggested that the first three to four sessions of the Coping Kids Treatment Manual were unnecessary for positive changes to occur.

Previous research investigating the effectiveness of psychological treatments has shown NRD in children can be alleviated in one session of exposure therapy (Öst, 2001). However, as mentioned previously, the rationale for six sessions instead of one session was that research shows treatments should be delivered in multiple exposure sessions to enhance long-term treatment gains and prevent relapse (Olatunji et al., 2010; Wolitsky-Taylor et al., 2008). Furthermore, considering the age and distress levels of the children included in this study, exposing them to an injection in one session without the establishment of a therapeutic relationship and/or coping strategies was not recommended. Lastly, a more systematic investigation into the ideal number of sessions and the types of techniques that are necessary for change to occur is recommended.

Distress Response Patterns: NIQ-C

The NIQ-C distress domain suggested that for the majority of participants, treatment response patterns were also similar across the intervention. For instance, distress was considerably high during baseline and rapidly reduced at post-treatment (with the exception of P.4 as will be explained). Similarities in treatment response patterns may be due to all of the children experiencing some level of NRD. Despite this, there were also distinct differences in treatment responses across participants, which may be due to differences in participant profiles and the case history of each child.

Interpretation of the distress domain for P.1 showed that this participant had the highest distress during baseline and showed the largest reduction at post-treatment compared to other participants. An explanation for this could be that P.1 is only 6 years old and previous research

shows that younger children (aged 2.5 to 6 years) typically exhibit higher distress levels than older children (aged 7 to 12 years) (Humphrey et al., 1992). P.3 also received needle injections more frequently compared to other participants (e.g., scheduled injections every three weeks). Research shows that the more frequent the needle injections (i.e., exposure) the more quickly the individual can habituate to the procedure over time (Marks, 1988). P.1 was also the only participant whereby distress reduced further at follow-up, although this could be due to being the only participant exposed to injections during the follow-up phase. It may also be the case that due to P.1 being recently diagnosed with a chronic medical condition (one year ago) there have been several other changes in the child's life. For instance, P.1 has been absent from school since the diagnosis and has had difficulty integrating back into normal life. As a result, P.1 might have benefitted more than other participants from the psycho-education phase of treatment (e.g., about the impact of chronic medical conditions and anxiety), and in such a way that NRD reduced quite rapidly.

The case history of P.1 differed considerably to the case history of P.2, who was 10 years old, had been diagnosed with a chronic condition since birth and required injections every 12 months. Interpretation of the distress domain for P.2 showed that scores were considerably high during baseline and only moderately reduced at post-treatment. It may be the case that P.2's distress reduced only moderately due to receiving injections every 12 months and therefore had less opportunity to adjust to the procedure while using skills learnt in therapy (Marks, 1988). P.2 also presented with a more pervasive pattern of NRD, which could be due to having a history of needle phobia and the vasovagal response in the family. This was illustrated in the reaction this participant had towards needle injections which included biting, kicking, screaming and eventually physical restraint. It may be the case that for P.2, large changes are unlikely to occur in six sessions of CBT as behaviours are more severe. Research suggests that a pervasive pattern of needle phobia in children/adolescents may require up to 13 sessions of CBT (Thompson, 1999). This is further illustrated by the fact that P.2 had previously received treatment for NRD at the HCPS in 2009, and was the only participant to receive a booster session in this study.

The case history of P.3 was similar to P.2 as both children were diagnosed with a medical condition at a young age. However, P.3 was 13 years old and had injections every six months rather than once a year compared to P.2. P.3 also presented with a less pervasive pattern of NRD, although has experienced NRD since a young age which has recently generalised to oral injections. Over the course of the intervention distress levels for this participant gradually reduced post-treatment, although remained stable at follow-up. Similar to P.2, this response pattern may be due to having fewer opportunities to gradually habituate to the procedure and practice skills learnt in therapy.

Lastly, the pattern of distress exhibited by P.4 differed the most considerably from other participants over the course of the intervention. For example, P.4 had such a low level of distress during baseline that there was little area for improvement at post-treatment and follow-up phases. This may be due to being diagnosed with type 1 diabetes at birth and since then

being exposed to insulin injections up to two times a day. As a result, P.4 who is now 14 years old, may have developed coping strategies to deal with NRD at a relatively young age. Alternatively, distress associated with diabetic injections could have been an element of NRD not captured by the NIQ-C. A further explanation for the difference in NRD symptoms between P.4 and other children will be explained later in this chapter.

Overall, several factors may explain why some participants had better treatment outcomes than others. Some of these factors may be due to differences in participant profiles and case history including age, frequency of injections, length of chronic medical condition diagnosis, disruptions in everyday life (e.g., absence from school) and personal history.

Child versus Carer Distress

Consistent with previous research, the NIQ-P revealed that to some extent carers were distressed while their child was having a needle injection (Smith, Shah, Goldman, & Taddio, 2007). In general, there were some differences in child self-report and carer self-report of their own distress, although the majority of the time children reported higher distress than their carer. At post-treatment, reductions in carer distress appeared to parallel reductions in child distress (and vice versa). This may be due to carers utilising distress-promoting behaviours (e.g., physical restraint and bribery) during the baseline phase, which were eliminated and replaced with coping-promoting behaviours (e.g., reassurance, encouragement, relaxation and breathing exercises) at post-treatment. Research suggests that coping-promoting behaviours tend to reduce child distress and that children model behaviour from their carer, which may explain some of the parallels in child and carer distress reductions (Kleiber & McCarthy, 2006; Mahoney et al., 2010; Pao & Bosk, 2011). However, these more anecdotal findings require further research, which may be done by administering the Child-Adult Medical Procedure Interaction Scale (CAMPIS). The CAMPIS is a behavioural observation measure that assesses the influence of the immediate social environment (e.g., carer) on child distress and coping during needle injections (Blount, Corbin, et al., 1989). Alternatively, a question could be incorporated into the NIQ-C with the intention of asking the child if having their carer present during the injection does or does not reduce their distress and/or coping.

In summary, children were less distressed when having a needle injection post-treatment and at one month follow-up suggesting children continued to experience relief from NRD symptoms as a result of treatment. Carers also exhibited less distress at post-treatment and one month follow-up suggesting that the carer may have also benefited from treatment.

Interpretation of Avoidance Domain

A negative implication of NRD is behavioural avoidance of subsequent needle injections and healthcare in general (Ayers, 2011; Howe et al., 2011). Furthermore, NRD can lead to behavioural avoidance of other medical settings, such as seeing a physician when ill and/or dental treatment (Hamilton, 1995; Öst et al., 1992; Taddio et al., 2009). Anecdotal feedback

from P.3 revealed dental care has been avoided in the past due to oral injections. Research shows carers have also reported avoiding appointments which involve their child having a needle injection due to self-reported anxiety (Samad et al., 2006). These issues provided the rationale for the inclusion of an avoidance domain for both the child and carer.

Overall results showed child behavioural avoidance of subsequent needle injections lowered post-treatment. This is consistent with previous research investigating the effectiveness of CBT in alleviating behavioural avoidance of needle injections (Mohr et al., 2002). All four children successfully completed their in-vivo and imaginal needle injection during session five with little to no behavioural avoidance exhibited. This is a considerable improvement as baseline results of the NIQ-P avoidance domain showed P.1 and P.2 had attempted to avoid all of their scheduled injection appointments in the last six months. P.2 was successful in one of these attempts.

Despite previous research suggesting carers tend to avoid situations that involve their child having a needle injection (Ayers, 2011; Samad et al., 2006), baseline results showed behavioural avoidance was non-existent for the majority of carers. This may be due to the NIQ-P not capturing this construct rather a lack of behavioural avoidance. The exception to this was P.2, for whom the number of medical appointments that were altered or cancelled due to carer distress was 3 out of 10 during baseline and reduced to 1 out of 10 at follow-up (on a scale of 1-10). There were also reductions in the NIQ-P avoidance domain in relation to the number of appointments that were altered or cancelled due to child distress.

The implications of these findings are that child behavioural avoidance of subsequent needle injections should continue to be addressed in therapy and future research, particularly considering that avoidance of general healthcare can progress into adulthood (Yelland et al., 2009). Furthermore, CBT theory suggests avoidance is one of the key factors in the maintenance of phobic-type disorders such as NRD (Ollendick et al., 2004). Carer behavioural avoidance due to self-reported anxiety should also continue to be investigated, although the NIQ-P avoidance domain should be modified to more accurately capture changes in this construct over time. For example, rather than primarily capturing child and carer avoidance in relation to "altering or cancelling medical appointments", the question could focus on avoidance more generally. Therefore, questions 2.a, 2.b and 2.c could be deleted entirely and replaced with the following two questions: "How much did your child try to avoid their most recent needle injection?" and "How much did you try to avoid your child's most recent needle injection?" The response format for these two questions could be on a 10-point Likert Scale. The rationale for these modifications is that carers had difficulty remembering all of the injections their child had in the past six months resulting in unreliable data. This was illustrated by P.4's carer, who reported 336 injections in the last six months across baseline, post-treatment and follow-up phases despite their child having at least two injections per day.

Interpretation of Cognition Domain

The content of cognitions reported throughout the intervention was consistent with previous research (Fassler, 1985; Fassler & Wallace, 1982; Lewis, 1978; Rice, 1993; White & Sellwood, 1995). Children primarily expressed that physical pain/hurt, being "scared" and the actual appearance of the needle (e.g., it's sharp, metal and pointy) as well as the thought of it invading their body contributed to their distress. Previous research suggests 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). On the other hand, possible reasons for why hurt/pain cognitions cause distress is that the needle actually *does* hurt, making this cognition legitimate rather than unrealistic (Lewis, 1978). However, in this case, perhaps it is not the content of the cognition that is maladaptive, but the intensity at which the child believes the needle injection will cause hurt/pain.

According to CBT theory, the tendency for children to believe catastrophic consequences (e.g., intense pain) will follow an injection can increase distress and avoidance (Catherine & Garlipp, 1999; White & Sellwood, 1995; Willemsen et al., 2002). Findings from this study suggested this may be the case, as for the majority of participants, the intensity of the hurt/pain cognitions reduced post-treatment upon realisation that injections do not hurt as much as they initially thought. Research shows that the introduction of cognitive restructuring, whereby thoughts are challenged and the evidence for and against a thought are gathered, can result in such changes (Thompson, 1999).

Negative cognitions children had towards the person giving them the needle injection primarily related to the child wanting them to "do their job properly/good" (P.4, P.2). This was consistent with previous research and could be due to the person injecting them more than once if they failed to insert it correctly the first time (Lewis, 1978). Consequently, the child's distress increases upon being submitted to more injections than initially thought. Findings also revealed that the autonomy to choose whether to monitor the situation (e.g., "I want them to…not tell me what's happening" – P.3) and the choice to cry without feelings of disapproval from medical staff (e.g., "explain to the doctor…that she will cry but that's okay" – P.3 carer coping content) may have influenced distress and coping levels. The need for autonomy over the situation and opportunity to express their feelings freely without judgement is consistent with previous research investigating needle injections (Lewis, 1978).

Despite similar themes emerging across participants, thought content was also very different, which could be due to the diversity among participants. For example, P.1 may not have understood the cognition questions considering some of the responses given at post-treatment (e.g., "feeding Sammie", and "playing with Ted"). This may be due to his age (6 years) and therefore level of cognitive functioning. P.2 presented with the most pervasive pattern of NRD, and perhaps had the most negative cognitions for example, "I want to run away, kick or punch" and "oh no, this is very bad". P.2 was also the only child to express "hate" towards to the person injecting them. On the other hand, P.3 had the most thoughts with the highest intensity

in relation to the person giving the needle injection. This may be due to P.3 reporting a fear of injections during early childhood ever since a nurse failed to insert the needle properly and instead tried multiple times on her hands, arms and legs. P.4 had cognitions that differed the most from the other three participants, although this will be discussed later in this chapter.

Overall, children had a more adaptive attitude toward needle injections following treatment as exemplified by some of the post-treatment cognitions. An unexpected finding was that children reported *new positive cognitions* with a high intensity at post-treatment, rather than repeating negative cognitions with a lowered intensity. Adaptive changes in relation to the cognition domain at post-treatment may be attributed to the incorporation of cognitive restructuring, however this requires further investigation. The effectiveness of utilising positive-self-talk with NRD is consistent with previous research (Dahlquist et al., 1985; Kanfer et al., 1975; Uman et al., 2008) and current perspectives on the etiology of NRD (Coelho & Purkis, 2009). Anecdotal feedback from participants outlined the usefulness of cognitive components, as skills learnt in therapy could be used not only for current and future needle injections, but other situations as well (e.g., test anxiety and fear of the dark). Cognitive components that children found useful were finding the evidence for and against a thought, developing alternative thoughts such as "I can do this" and "I can cope" (P.2, P.3 and P.4) and positive self-talk. Other cognitive activities that were useful included emotive imagery (P.3 and P.4), the 'thought people' worksheet (P.1) and the 'my experience' worksheet (five-part cognitive-behavioural model), which was useful for all four children and carers.

Interpretation of Coping Domain

In general, child coping during injections and the ability of their carer to help them cope improved following treatment. Compared to distress, the case history of each child appeared to have less of an influence on coping scores, although age appeared to negatively impact the stability of baseline scores for P.1 (6 years). It could be suggested that this is due to P.1 not understanding the target construct (i.e., coping). In relation to qualitative data, children reported very few coping strategies prior to therapy. However, this changed post-treatment as children were better able to cope during injection procedures and reported more adaptive coping behaviours including behavioural rehearsal, applied tension, cognitive and behavioural distraction, mind pictures and positive self-talk. Similarly, previous research showed children find the following techniques the most helpful: breathing exercises (40%), imagery/distraction (23%), behavioural rehearsal (15%), filmed modelling (13%) and a reward (9%) (Jay et al., 1987). Uman et al. (2008) also found relaxation and distraction techniques to be one of the most effective strategies for children to cope with during needle injections. Lastly, these techniques differed to the techniques utilised prior to therapy which mainly included the child "doing nothing" (P.2), "hoping it will be over soon" (P.3) and perhaps most commonly behavioural distraction (e.g., "hugging mum or my teddy bear", P.1; "look away", P.2) and/or cognitive distraction (e.g., "think about something else", P.4).

An explanation for why relaxation and breathing techniques are seen as the most useful is that behavioural strategies are typically easier for children to master, and problems (e.g., 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., P.1) who primarily reported behavioural coping strategies across the intervention (e.g., hugging mum or my teddy, take deep breaths and sit on mum's knee). The implications of these findings suggest the continued use of muscle relaxation and breathing exercises within clinical settings for chronically ill children with NRD. However, the effectiveness of specific techniques utilised in the Coping Kids Treatment Manual require further investigation. Examples of how this could be carried out will be given later in this chapter.

Results from the Coping Behavior Questionnaire (CBQ) also showed child coping improved post-treatment. For example, compared to baseline levels, all of the 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 needle injections (Kleiber & McCarthy, 2006).

Coping strategies reported by carers prior to therapy were in some cases quite negative, for example, physical restraint and bribery. However, these were eliminated post-treatment and, in most cases, the carer was utilising positive behaviours to help their child cope during an injection such as distraction, reassurance and calm breathing. Previous research shows carers typically find the following techniques the most helpful (in order of preference): rewards, modelling, breathing exercises, distraction and behavioural rehearsal. There is some consistency in the types of techniques carers found useful in this study compared to previous research . Overall, baseline scores of the NIQ-P coping domain suggested carers had pre-existing coping strategies to deal with injection situations. However, the carer's ability to help their child cope improved post-treatment, suggesting it was important for the carer to be involved in therapy.

CBT theory and techniques

The outcomes in this study are convergent with previous treatment outcome research, which has shown the effectiveness of conceptualising and treating NRD according to CBT theories and models (Dahlquist et al., 1985; Jay et al., 1987; Jay et al., 1985). Also convergent with previous research is the effectiveness of systematic desensitisation and exposure in resolving NRD symptoms in children (Jay et al., 1987; Jay et al., 1985; Ollendick, Öst, Costa, & Cederlund, 2009; Öst, 2001). This was primarily exemplified by the SUD ratings collected weekly across the treatment phase and NIQ-C/P post-treatment results, which revealed that change mostly occurred after exposure tasks. CBT theory also suggests children with NRD tend to avoid situations where they encounter the phobic stimuli, thus maintaining the distress

(Davey, 2007). Therefore, by exposing the child to a needle injection (imaginal and in-vivo), dysfunctional beliefs can be corrected while also desensitising physiological and associated behavioural responses (Davey, 2007; Ollendick et al., 2004).

Key techniques incorporated into the treatment manual included exposure (in the form of systematic desensitisation and role-plays), coping modelling, muscle relaxation and breathing exercises, emotive imagery, cognitive restructuring and positive reinforcement. This differed from previous research which tended to also include filmed modelling and distraction (Jay et al., 1987; Jay et al., 1985). The rationale for why these two techniques were excluded was that a meta-analysis revealed filmed modelling had no efficacy in reducing child distress (Uman et al., 2008), and distraction is a short-term strategy and unhelpful if used as a way of avoiding symptoms in the long-term (Butler, 2001; Uman et al., 2008). However, as the treatment programme progressed it became clear that distraction was a natural coping strategy that both the child and carer utilised. Furthermore, two of the four children did not find emotive imagery helpful, in which case filmed modelling was applied instead. The implications of this are that future research should continue to investigate filmed modelling and distraction either individually or collectively, rather than eliminating them from therapy as this study has done.

Overall, this study revealed that therapy needs to be individualised to each child, and that a flexible, clinically sensitive application of the treatment manual is the most appropriate (Kendall et al., 1992). The clinical implications of these findings are that therapy should focus on a "tool box approach" whereby a range of techniques are available and utilised depending on the child's developmental age, cognitive and social development. As exemplified in the current study, perhaps most important is to also allow for the child's personal preferences and to utilise rewards that motivate the child in therapy.

Developmental Factors

Treatment responses varied with developmental age/level, particularly in relation to younger children (P.1, 6 years). As a result, several modifications were made to the treatment manual to allow for these differences, particularly in relation to the cognitive restructuring components which were simplified for younger children. Moreover, feedback from the therapist suggested that younger children struggled with the cognitive component, however rather than it being eliminated it was recommended that simplified strategies should be utilised instead (e.g., helpful vs. unhelpful thoughts). Children aged over 10 appeared able to identify thoughts, grasp the concept that thoughts were under their control and could use thoughts to regulate their behaviour, consistent with more recent research in this area (e.g., P.2, P.3 and P.4) (Bolton, 2005).

There is a large amount of scepticism about applying CBT to younger children (Kingery et al., 2006). This may be due to the fact that treatment responses varied with developmental age/level, which could be explained by the degree of cognitive development required to assimilate and understand certain elements of the Coping Kids Treatment Manual. Other factors

related to language development may have also contributed to difficulty with understanding concepts, for example younger children found it hard to answer certain questions on the NIQ-C, in particular the cognition domain (e.g., 3.a, 3.b and 3.c). A theoretical rationale for this finding is provided by the developmental theories of Piaget (1958) and Vygotsky (1981) which suggest cognitive capabilities may develop at different ages and stages. Furthermore, according to Piaget's Theory of Cognitive Development, the link between cognition and action (i.e., meta-cognition) is attained during adolescence, and language is crucial to the development of meta-cognition.

Despite the scepticism surrounding the use of CBT with younger children, recent developmental research suggests it is more important to consider "what cognition is involved in the production/maintenance of the problem" rather than whether the child is under 7 years and is or is not capable of meta-cognition involving theory use (Bolton, 2005, p. 17). Developmental research since the period of Piaget also indicates there are likely to be large individual variations at any given chronological age. These tend to be dependent on many factors including temperament, social and family context (Bolton, 2005). Therefore, the applicability of CBT to younger children should be assessed based on what kind and content of appraisals are implicated in the generation and maintenance of clinical problems rather than just chronological age. It appears that this is the case in the present study, as some children grasped onto cognitive concepts much easier than others and found certain cognitive techniques more useful, regardless of their chronological age. For example, younger (P.1, age 6) and older children (P.2, age 10) had difficulty utilising emotive imagery and were not as interested in this technique as other participants (P.3, age 13 and P.4, age 14). Similarly, the five-part model was also useful for younger (P.1) and older children (P.3), even though this was a challenging activity. Basic activities (e.g., 'my difference faces') and learning the difference between emotions and feelings were also beneficial for older children. Despite this, more abstract cognitive restructuring, for example finding the evidence for and against a thought was too difficult for younger children (P.1) and is a good example of how *some* cognitive strategies are hindered by developmental level.

Overall, the implications of these findings are that the Coping Kids Treatment Manual should be administered to children aged 8 to 12 years, which was the initial inclusion criteria of this study. This is because during the initial development stages of the manual, activities/techniques were mainly targeted towards this age group. However, with slight modifications the treatment manual can be adapted to include children aged 5 to 14 years, and depending on the child's personal preferences and developmental level, can be administered successfully. It is suggested that further research formally adapt the treatment manual according to the following age groups: 'young', 'middle' and 'late childhood/early adolescence'.

Carer Involvement

The level of carer involvement in this study varied according to the individual child. Some carers were present for the last 10 minutes of the session (as per the treatment manual), whereas others were present for the entire session. Inevitably, carer involvement out-of-session may have also differed, with some carers more motivated than others to encourage and coach their child. The possible impact carer involvement had in-session and out-of-session on treatment outcomes was not formally assessed or captured in this study. Future research could investigate this by gathering formal feedback from the carers at post-treatment to assess their level of involvement in- and out-of-session. An observational measure and/or the carers formally interviewed following therapy could also be utilised to provide more in-depth analysis. Alternatively, a between-subjects experimental design with carers present (experimental group) and without carers present (control group) could be conducted. The aim would be to then assess if there are significant differences between these two groups provided that confounding variables were controlled for. Despite the lack of formally assessing the impact of carer involvement, the carer appeared to be an important factor in therapy, as to some extent carers were distressed while their child was having a needle injection which reduced post-treatment. Distress-promoting behaviours (e.g., physical restraint and bribery) exhibited by the carer were also eliminated following therapy.

Diabetic Population

Results from the present study indicated distress levels for children diagnosed with diabetes ($N = 2$, only one child with results so far) were low compared to children diagnosed with other medical conditions. Diabetic children in this study presented with a negative view of their medical condition, and distress associated with injection site rotation rather than with the needle itself. For example, it was reported that P.4 would only allow insertions on certain parts of his body (e.g., leg and stomach) which tended to change every few years. Additional information confirming these issues was given from the therapist and revealed during the assessment interview. It should be noted that injection site rotation is important to prevent lipodystrophy and promote better absorption and metabolic control (Patton, Eder, Schwab, & Sisson, 2010).

Research suggests that common reasons for not rotating injection site include a fear of pain when rotating, new sites are awkward and conspicuous and just being comfortable with the current routine (Patton et al., 2010). The measures used in this study were not designed to specifically assess these types of changes. Despite this, the NIQ-P revealed some of the carer's concerns related to this phenomenon (e.g., "I hope that he is rotating his jab site" – P.4 carer) (see Appendix 7). In order to address this problem in therapy, the therapist adapted certain techniques and gathered SUD ratings related to how the child would feel if they rotated their injection site. Post-treatment and follow-up SUD ratings reduced, although due to this not

formally being assessed it was not outlined in the results section. This should also be interpreted with caution as it was an anecdotal finding but still important for this child.

Psychological literature suggests that, rather than a fear of injections influencing compliance with insulin regimes, it is psychosocial factors that should be addressed. For example, Nascimento et al. (2011) found that children respond more positively if they have support from their parent/caregivers as well as receive knowledge about their illness and its treatment. Therefore, educating the parents/caregivers and supporting them to accept the illness are important, as difficulty with the child carrying out their insulin injections may result in a more negative attitude towards diabetes in the family (Hanas & Ludvigsson, 1997). Even though assessment measures did not specifically measure these outcomes, it was reported during the assessment interview that the carer of P.4 placed high expectations on their child and became quite anxious if insulin injections were not adhered to. During the intervention it was reported that education about the psychological impact of diabetes on the child and family was particularly useful for P.4 and their carer.

Possible explanations as to why needle injections may not cause distress for diabetic children is that they may be exposed to injections up to five times a day, and therefore habituate to the procedure while also developing natural coping strategies (Marks, 1988). It may also be the case that the cognitions of diabetic children differ slightly from children receiving other injections. For example, P.4 outlined "I hope it's sharp and hasn't been used before" and "I don't care it's a daily thing for me", none of which were repeated by the other three participants. These cognitions also differ from existing research which implies children actually dislike the needle being sharp (Fassler & Wallace, 1982). Furthermore, rather than being distressed about the needle itself, P.4 presented with a more negative view of having to have another insulin injection and his medical condition in general (e.g., "Why do I need another injection" and "Wow! Another needle" – P.4) (see Appendix 5).

Overall, this study was not designed to deal with these issues, which may explain some of the different results for participants diagnosed with diabetes (e.g., P.4). Possible reasons for this may be due to the nature of distress being different for diabetic children and added issues associated with their condition (e.g., injection site rotation). It has been suggested psycho-education, relaxation and distraction may help children and adolescents with new injection sites (Patton et al., 2010), although results from this study suggest these techniques may not be addressing the issues diabetic children are faced with. In hindsight, diabetic children should have been excluded from the present study, and it is recommended future research investigate this population separately to other chronically ill children with NRD.

Assessment Measures

The present study extends previous research through the use of child self-report measures (i.e., NIQ-C) to assess changes in NRD. The lack of self-report measures utilised with children in past research could be due to the variable nature of reporting, perhaps indicating self-report measures may not be a reliable source of symptom monitoring for this age group

(Huguet et al., 2010; Logan et al., 2008). Findings from this study confirm this may be the case for children under 8 years, and as mentioned previously could be due to a lack of language and cognitive development (Piaget, 1958). To counteract this, the inclusion of a carer self-report measure and behaviour checklist were included in this study. Furthermore, due to previous research primarily utilising behavioural observation measures (Blount & Loiselle, 2009; Jay et al., 1985) or one to two self-report questions (Jay et al., 1995), this study has implications for the way future research may assess changes in NRD symptoms among children. It is recommended future research use both child and carer self-report measures and behavioural observation measures.

More specifically, when considering the results of this study, the NIQ-C and NIQ-P appear to be measuring the target construct (NRD). Evidence to support this claim includes the general consistency of scores over time on the child distress domain of the NIQ-C and NIQ-P. Similarly, a low level of distress was consistently reported by P.4 (who was diagnosed with diabetes) across the NIQ-C, NIQ-P and SUD ratings. The test-retest reliability of these measures may also be acceptable considering the general stability of baseline scores across participants. Nonetheless, these are preliminary findings and more rigorous testing of the reliability and validity of the NIQ-C and NIQ-P needs to be conducted. Several modifications to these measures are also necessary as will be discussed in the limitation section.

Consistency between Child and Carer Self-Reports

While multi-modal, multi-source evaluations are recommended in psychological literature to obtain thorough information (Klein, 1991), results of this study highlight some of the problems with this approach. Findings showed carers had a tendency to over- and/or under-estimate the amount of child coping across baseline, post-treatment and follow-up phases. There were also some differences between child self-reported distress and carer self-report of child distress, for example carers had a tendency to over-estimate their child's distress during the baseline phase. At post-treatment, child and carer reports of distress were more consistent for P.2 and P.3 carers, while P.1 and P.4 carers continued to over-estimate their child's distress. This finding is consistent with previous research in which the incongruity between child and carer self-reports has been noted (Engel et al., 1994; 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 (Klein, 1991). For example, carers may be distressed themselves or believe their child to be more distressed than they actually are during the procedure, leading them to over- and/or under-report symptoms. Previous research shows that carers consider needle injection procedures involving their child as one of the most distressing events in hospital settings (Ayers, 2011). Furthermore, Smith et al. (2007) found physiological and anxiety responses activated in persons who observed a loved one receiving a needle injection. Overall, the discrepancy between child and carer self-reports validates the need to directly question 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 symptomology.

Clinical Validity

One of the main goals of this study was the attempt to bridge the research to practice gap by basing the treatment manual on empirical research and clinical practice carried out at the HCPS. Furthermore, by examining the usefulness of a manual-based approach with clinically 'complex' cases and naturally referred clients, the present study provides a platform to investigate the effectiveness of certain methods in real world settings. This is particularly important given common criticisms that psychotherapy research fails to transfer to clinical settings (Ollendick & Davis, 2004). While there are limitations to the present study, which are covered in the following section, the Coping Kids Treatment Manual has shown to be feasible in a day-to-day setting such as the HCPS, and could perhaps be applied in other clinical settings. See Appendix 8 for an article published in *Psychology Aotearoa* as a result of presenting preliminary findings of this study at the New Zealand Psychological Society Conference in Queenstown 2011.

Limitations of the Present Study

The present study is limited by a range of methodological constraints related to carrying out research in a day-to-day clinic setting. Other limitations relate to the research design, procedures used, the treatment manual and assessment measures.

Research Design

The most frequently noted limitation of single-subject research is the lack of external validity in terms of generality. However, the aim of this pilot study was not to generalise to other cases, reducing the need for external validity. Instead, variations in the research design provided several limitations 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 the pre-determined baseline lengths assigned prior to therapy as some participants did not return measures and/or therapy started earlier due to participant safety issues. This resulted in shorter baseline periods for some children (e.g., two weeks) despite research suggesting a minimum of three weeks is required to establish baseline stability (Kazdin, 2011). Inevitably, a stable baseline was not established for P.1 on the NIQ-C and NIQ-P coping domains, thus it cannot be determined if treatment was responsible for change in baseline functioning or other extraneous factors. Moreover, due to time restrictions and the ethical issues of withholding treatment from a child for the sake of research, P.1 started therapy despite having an unstable baseline for the coping domains.

The main objective of this study was to develop and evaluate a cognitive-behavioural therapy for NRD, and not to identify specific techniques that may or may not add to the effectiveness of the treatment. However, it is widely recognised that there is a significant amount of heterogeneity among the components of CBT, making it unclear what components are more beneficial than others (Uman et al., 2008). It could be suggested that a limitation of this study is that a multiple baseline design does not assess the contribution each technique has in relation to treatment effectiveness. To put this in context, SUD ratings revealed distress reduced only after session five, although it not clear whether this was due to exposure or some other technique introduced earlier. This is perhaps highlighted in the present study as the NIQ-C and NIQ-P were only administered post-treatment rather than every session. More frequent monitoring would have been able to track changes in functioning more closely. As it stands, it is difficult to determine what techniques resulted in changes at what point, or which ones were more useful than others. In order to explore this further, future research could administer all assessment measures (e.g., NIQ-C and NIQ-P) weekly throughout the treatment phase as well as video-record therapy session in order to closely monitor therapeutic changes according to when techniques are introduced. At post-treatment, it is also suggested that the child and carer rank each of the therapy components (e.g., emotive, imagery, relaxation and exposure) on a scale from 1 (least helpful) to 5 (most helpful). This may provide a more accurate overview of what components contributed to treatment outcomes.

Procedures

Carer involvement in therapy was an important component of this study, particularly as carers can influence child distress and coping (Mahoney et al., 2010). Therefore, a major aspect of therapy was the inclusion of carers to provide them with psycho-education as well as facilitate and encourage coping behaviour in their children. However, 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 as time-efficient as possible for the children and their carers so that they would and could participate. Instead, less formal methods of attaining the level of carer involvement were used, which included the clinician outlining to the primary researcher 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 the impact carer involvement has on therapy outcomes.

A further limitation of the present study relates to some of the procedures used, in particular the lack of any formal method (e.g., video recording of the therapy session) of measuring treatment integrity. This was a significant limitation as it is unclear to what extent the treatment manual was adhered to during therapy, thus 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. Feedback from

the therapist also revealed a significant amount of modifications to the treatment manual were necessary in order to accommodate the child's developmental age and personal preference for certain activities. A full list of treatment manual modifications is provided in the methodology section in an attempt to enable replication of this study.

It has been suggested that therapist variables and a positive therapeutic relationship have a significant impact on treatment outcomes (Beutler et al., 2004). 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. 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 eliminate therapist variables that influence treatment outcomes.

Another limitation is the lack of standardisation when it came to the administration of post-treatment and follow-up measures, thus impacting on the comparability of results across participants. For instance, some post-treatment measures were completed immediately after session six while still at the HCPS (P.1 and P.2), whereas others were completed weeks after the final session while at home (P.3 and P.4). Some measures were also completed weeks past the one month follow-up period, although this may provide further evidence that post-treatment gains were being maintained longer than the one month follow-up.

The decision to not include a behavioural observation measure in this study (e.g., Observational Scale of Behavioral Distress) is another limitation. It would have been useful to collect observational data independently during the baseline and treatment phases of the research. Direct observations can provide reliable data not influenced by problems such as poor recall or social desirability (Blount & Loiselle, 2009). Furthermore, observation of NRD symptoms can assist in treatment planning, setting goals and monitoring progress throughout the intervention. Direct observations also allow for the measurement of antecedents and consequences of anxious behaviour. It may have also been beneficial to include physiological measures of anxiety (e.g., heart rate/pulse) to supplement self-report measures, particularly due to this being a medically related disorder. A structured diagnostic interview was also not utilised, therefore assessments were not standardised across the sample and may have resulted in different outcomes. A structured interview may have revealed early in the recruitment process, certain participants that should have been excluded from the study.

Lastly, the present study did not allow for the investigation of differential outcomes for a range of non-anxiety based diagnoses. Although the children were natural referrals to the clinic and were "real world" clients, the children did not typically have comorbid diagnoses or additional issues (exclusion criteria) which are not realistic in clinical practice. Despite this, the sample population was clinically representative of the referrals received at the HCPS.

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 for this, although this was expected which is why a flexible' component was incorporated into the manual. Moreover, 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. 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).

One specific limitation of the treatment manual identified was the inclusion of too much information in session one that resulted in some activities being omitted due to a lack of time. It is suggested that the treatment programme be expanded to range between six to eight sessions depending on the needs of the child to ensure activities are not rushed or left out due to time restrictions. Further criticisms of the treatment manual relate to the clinical validity of session five which incorporates an in-vivo needle injection at a local health service. Session five may limit generalisation out-of-session as having the clinician present during future injection procedures is not realistic. In some clinical settings having the clinician present during even one injection procedure may not be possible. 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.

Another issue related to session five is the lack of standardisation in terms of injection procedures. For example, it was intended that children diagnosed with diabetes (P.4) would practice an insulin injection during session five as an alternative to a needle injection as the other children received. However, it may be that insulin injections are less anxiety-provoking (e.g., smaller needle) than other injections perhaps impacting on the results. Moreover, P.4 forgot to bring their insulin kit to session five, thus imaginal injections were practiced instead. Long-term follow-up data investigating the generalisation of session five with or without the therapist and/or the differences across different injection procedures could be an area of further research.

Assessment Measures

There were several limitations recognised in relation to the assessment measures utilised in this study. In particular, 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). An example 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).

The fact that the NIQ-C and NIQ-P were only administered pre- and post-treatment is another limitation of this study. This is because changes that occurred at different stages of the intervention cannot be determined. A continuous measures approach also provides further validation for the effectiveness of the treatment programme. One month is also a very limited follow-up period. Moreover, the inclusion of multiple exposure sessions was a significant contribution this study made to existing research, the rationale for this being that it promoted long-term treatment gains. However, due to the short-term follow-up period utilised in this study, the contribution multiple exposure sessions made to long-term treatment gains is unknown. A short-term follow-up was implemented due to time restrictions.

A major contribution the present study made to existing literature was the development and initial pilot of child and carer self-report measures in relation to NRD (NIQ-C and NIQ-P). However, perhaps one of the greatest limitations is that these were newly developed for this study and therefore lack reliability, validity and normative information. Furthermore, due to the measures lacking normative data, it was not clear how much change from baseline to post-treatment scores was necessary to signify a *clinically significant* change. Despite these limitations, the development of the NIQ-C and NIQ-P was necessary as there were significant limitations of existing psychometric measures such as extensive administration, irrelevant or inappropriate item content and lack of standardisation with children. In an attempt to counteract the lack of reliability, validity and normative information, the measures could have been piloted prior to being incorporated into this study. However, this was overlooked due to the time restrictions of the research. Instead, this study was a pilot for the measures in which case during the research process, it was clear there were several limitations of the measures.

The NIQ-C and NIQ-P were originally developed for children aged 8 to 12 years. Therefore, some of the younger participants (P.1) were unable to complete the measures independently and required assistance from their carer and/or the primary researcher (JM). In particular, participants struggled with answering the cognition domain of the NIQ-C (e.g., 3.a, 3.b, and 3.c). Feedback from participants revealed behaviour-based questions were easier to answer compared to cognitive questions, although this was expected as they tend to be more concrete rather than abstract, making them easier for children to understand. Moreover, a lack of language development and meta-cognition may have been the reason why younger children struggled with answering the cognition domain. This was exemplified in some answers given by P.1 (6 years) who wrote for question 3.c) "she is going to inject someone else", which is similar to 'magical thinking' seen in the pre-operational stage of Piaget's (1958) Theory of Cognitive Development. Furthermore, it was clear from the beginning that younger children were more

state-driven with their emotions, and answered the questions according to how they are feeling in the present moment (i.e., if they're hungry or tired), rather than having the ability to answer the questions using retrospective or prospective memory. This may explain the inconsistency in some of the answers given by younger participants (e.g., P.1, NIQ-C avoidance and coping domains). In general, it is suggested that the NIQ-C is only administered to children aged over 8 years and/or is restructured and re-worded so that younger children can more adequately understand the questions.

Initially the cognition domain of the NIQ-C should be re-structured as it consistently had missing data, and questions 3.a and 3.b had similar thoughts listed with instances where the child would simply repeat the same thought across both questions. It is suggested that future research combine these two questions together and/or continue with 3.a which appeared to produce the most thoughts. The avoidance domain of the NIQ-C (e.g., question two) also needs to be modified as several children struggled to understand the concept of "avoid". It is suggested that this is either re-worded to "do not want" or facial pictures are used as an indication of whether the child would or would not avoid the injection. The use of facial pictures is similar to the response format utilised for the Injection Phobia Scale-Children developed by Ost (2008).

Several other changes to the NIQ-C and NIQ-P would be to ensure all questions utilise a 10-point Likert Scale to facilitate ease of use, which would also simplify scoring and interpretation procedures. A generic response format may also allow comparisons across domains and between the two measures. Instructions under each question could also be deleted and made universal at the beginning of the questionnaires in order to simplify administration. In relation to the NIQ-P, questions relating to the child and questions relating to the carer should also be separated (e.g., Section A and Section B) so that respondents are not rapidly switching between a self-report of their own behaviour and a self-report of their child's behaviour. Lastly, due to the limitations of the CBQ it should be replaced with the OSBD, which is a more validated measure of child distress and coping in relation to needle injections.

Recommendations for Future Research

There are a number of suggestions for future research that arose from the limitations outlined above and the initial findings of the current study. This section outlines first and foremost what future research should focus on to address the limitations of the current study. It then provides a number of options for future research that would be possible with fewer constraints on time and resources.

Initially, future research should carry out a larger series of single-subject research designs. Alternatively, there could be a systematic replication of this study with a large and diverse sample of children that is applicable to treatment outcome research in clinical settings. A sample of *all* children, rather than primarily chronically ill children, could also be incorporated into future research to focus on children undergoing more general injections (e.g., vaccinations and flu injections) that also experience distress. This could increase external validity in terms of

generalising to other groups and settings as well as provide support for the effectiveness of the Coping Kids Treatment Manual. More specifically, due to all four children identifying as New Zealand European, 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 and Pacific Island children and families, and other migrant and refugee populations.

In terms of adapting the treatment programme to other cultures, language use and preference should be ascertained at the start of therapy, as well as the level of involvement from their culture of origin and the host culture (Paniagua, 2000). Other modifications to allow for cultural differences 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 also need to 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, whereby 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 whereby the wider family/whanau have a large role in bringing up the child (Paniagua, 2000).

Even though the preliminary results of this study show the treatment manual was useful for four chronically ill children, it is not clear to what extent carers and the wider family have in facilitating treatment outcomes. Therefore, the level of carer involvement in-session and out-of-session should be investigated. This area of research is crucial considering the influence carers have on child distress and coping. In general, research should also exclude and/or investigate separately children diagnosed with diabetes due to the findings suggesting their mechanism of NRD and/or distress overall differs to other chronically ill children.

In terms of assessment measures, more rigorous psychometrics should be utilised in future research. This may include further development and evaluation of the NIQ-C and NIQ-P while incorporating the suggested modifications to these measures outlined in the limitations section. Further testing of these measures is also necessary in order to gather reliability, validity and normative data. In addition, validated observational measures (e.g., OSBD) administered by trained clinicians should be utilised to obtain a comprehensive view of treatment effectiveness. Research should also continue to use child self-report measures, as shown in this study simply collecting carer assessment data is not a reliable measure of child functioning.

The development of culturally sensitive outcome measures for this population is also important. Lastly, the administration intervals of psychometric measures should also be modified and follow-up periods extended. For example, a continuous measures approach (i.e., weekly assessment across baseline and treatment phases) with *all* psychometric measures should be carried out rather than primarily pre- and post-treatment measures. While follow-up periods should be extended to include 3-, 6- and 12-month intervals, this will provide further insight into the long-term effectiveness of the treatment manual.

A formal method of measuring treatment integrity should be carried out in future research by video-recording therapy sessions which are then checked for integrity by an external psychologist. This is required to determine to what extent the treatment manual is adhered to during therapy, making it easy to replicate this study in future research and clinical practice. Future research should also investigate the influence of therapist variables on treatment outcomes, which may be done through the use of multiple therapists delivering the treatment manual that differ in clinical experience and personal characteristics (e.g., age and gender).

Future research should focus on what techniques were active in bringing about positive change and the relative contribution of each of these techniques to treatment outcomes. Some questions remain unanswered, for example were positive changes due largely to behavioural strategies, cognitive strategies or a combination of both and at what age are these strategies more effective? It is recommended future research investigate what individual techniques are the most effective so that certain techniques can either be included or excluded. This could be carried out by isolating two components of the treatment manual (e.g., emotive imagery and exposure) and then individually assessing these using a between-subjects experimental design with two similar groups of participants, one with each technique.

Other areas of future research that could be conducted with more time and resources includes the replication of the Coping Kids Treatment Manual using single-subject designs in other clinical settings in New Zealand where chronically ill children may also be referred (e.g., non-university settings, hospitals and/or private clinics). The development and modification of the treatment manual to incorporate distress associated with all medical procedures rather than primarily NRD (e.g., insertion of feeding tubes and catheters) is also a significant gap in the literature. Moreover, this study included a broad age range of 5 to 15 years, which conferred significant limitations as mentioned previously. More systematic investigation into the effectiveness of the treatment manual with particular developmental levels/age groups could to be explored by adapting the manual for 'young', 'middle' and 'late childhood/early adolescence'. Eventually in order to determine whether the Coping Kids Treatment Manual is "efficacious", randomised controlled trials in at least one and/or two clinical settings would be required.

Conclusions

The current research involved the development and evaluation of a six-session cognitive-behavioural therapy to alleviate needle-related distress (NRD) among chronically ill children in a day-to-day clinic setting. This study was an initial pilot of the intervention known as the Coping Kids Treatment Manual, and was evaluated using a single-subject, multiple-baselines across participants design. Considering the limitations discussed, preliminary findings offer support for the effectiveness of the Coping Kids Treatment Manual with four chronically ill children experiencing NRD. The main outcomes of this study were that children were less distressed and better able to cope when exposed to needle injection situations. The child's carer was also less distressed and better able to help their child cope during needle injections following therapy.

The implications of this study relate to three major gaps in the literature. Firstly, the treatment manual incorporated a cognitive restructuring component which other researchers had not included in previous treatment programmes for NRD. Preliminary finding of this study suggest that addressing the negative cognitions children have in relation to needle injections may assist in alleviating their distress. Results showed that not only did therapy reduce the intensity of negative cognitions; new positive cognitions were evident post-treatment suggesting that therapy resulted in the development of more adaptive alternative thoughts. Secondly, although the inclusion of carers was not formally assessed, preliminary findings showed that it was important to incorporate carers into therapy for NRD. Following treatment, carers were less distressed during needle injections and distress-promoting behaviours (e.g., physical restraint) that were evident prior to therapy were eliminated. The inclusion of carers as active participants in therapy was overlooked in previous research. Thirdly, due to previous research primarily addressing NRD with one therapy session combined with little to no follow-up data, the present study utilised multiple exposure sessions in an attempt to improve long-term treatment gains. The implication of this was that findings showed distress tended to reduce after the completion of exposure sessions, suggesting that this technique was central to the alleviation of NRD. However, alongside previous research, the lack of follow-up data past one month was a significant limitation of this study.

In general, this study showed that although the key features of NRD can be similar across children, it is more a fluctuating experience that is dependent on the child's chronic health condition, frequency of needle injections, case history and developmental factors. Due to this, therapy should be tailored to the specific needs of the child and their family, rather than applied universally. Furthermore, findings showed a considerable amount of inconsistency between child and carer self-report measures. Consequently, a wide range of psychometric measures such as behaviour rating scales, direct observations and child and carer self-reports, need to be used in future research to gain an accurate indication of the child's presenting problems.

Many critical issues concerning NRD in children remain unresolved, and in order to obtain more conclusive evidence regarding the main outcomes of this study, further research is required. In particular, the precise role of carers in the exacerbation of NRD with a larger and more diverse group of children should be investigated. Furthermore, in order to broaden the study even more, all children rather than primarily chronically ill children should be included. An investigation of which components in the multifaceted programme are most critical in producing meaningful change is required, alongside extended follow-up periods (e.g., 6- and 12-months) and utilising more rigorous measures.

In conclusion, this study has provided a unique contribution to treatment outcome research in the field of NRD with four chronically ill children in 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 on-going coping skills to be integrated into the lives of the children and their carers who participated in this study. Overall, while no generalisations can be made due to the single-subject nature of this research, as a 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

Letters of Ethical Approval

Health
and
Disability
Ethics
Committees

Central Regional Ethics Committee
c/- Ministry of Health
PO Box 5013
1 the Terrace
Wellington
Phone: (04) 816 2405
Email: central_ethicscommittee@moh.govt.nz

10 May 2011

Dr Joanne Taylor
School of Psychology
Manawatu Campus, Massey University
Private Bag 11 222
Palmerston North

Dear Dr Taylor –

Re: Ethics ref: CEN/11/03/019   (please quote in all correspondence)
     Study title: Brief Cognitive-Behavioural Therapy for Chronically Ill Children with
                      Needle-Related Distress

The documentation has been reviewed and approved by the Chairperson of the Central
Regional Ethics Committee under delegated authority.
This study was given ethical approval by the Central Regional Ethics Committee on 3 May 2011.

<u>Approved Documents</u>

  — Letter in response to the Central Regional Ethical Committee's review of the above study
    dated 17 March 2011
  — National Application Form
  — Participant Information Sheet
  — Consent Form
  — Comment Sheets

This approval is valid until 3 May 2016, provided that Annual Progress Reports are submitted (see
below).

<u>Access to ACC</u>
For the purposes of section 32 of the Accident Compensation Act 2001, the Committee is satisfied
that this study is not being conducted principally for the benefit of the manufacturer or distributor of
the medicine or item in respect of which the trial is being carried out. Participants injured as a result
of treatment received in this trial will therefore be eligible to be considered for compensation in
respect of those injuries under the ACC scheme.

<u>Amendments and Protocol Deviations</u>
All significant amendments to this proposal must receive prior approval from the Committee.
Significant amendments include (but are not limited to) changes to:
  — the researcher responsible for the conduct of the study at a study site

— the addition of an extra study site
— the design or duration of the study
— the method of recruitment
— information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports
The first Annual Progress Report for this study is due to the Committee by May 2012. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

Requirements for the Reporting of Serious Adverse Events (SAEs)
SAEs occurring in this study must be individually reported to the Committee within 7-15 days only where they:
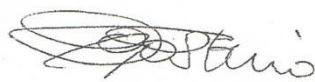— are *unexpected* because they are not outlined in the investigator's brochure, and
— are not defined study end-points (e.g. death or hospitalisation), and
— occur in patients located in New Zealand, and
— if the study involves blinding, result in a decision to break the study code.

There is no requirement for the individual reporting to ethics committees of SAEs that do not meet all of these criteria. However, if your study is overseen by a data monitoring committee, copies of its letters of recommendation to the Principal Investigator should be forwarded to the Committee as soon as possible.

Please see www.ethicscommittees.health.govt.nz for more information on the reporting of SAEs, and to download the SAE Report Form.

We wish you all the best with your study.

Yours sincerely

Elise Agostino
Administrator
Central Regional Ethics Committee
Email: elise_agostino@moh.govt.nz

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Letter of Ethical Approval - Amendment One

Health
and
Disability
Ethics
Committees

Central Regional Ethics Committee
c/- Ministry of Health
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Email: central_ethicscommittee@moh.govt.nz

13 July 2011
Amended 21 July 2011

Dr Joanne Taylor
School of Psychology
Manawatu Campus
Massey University
Private Bag 11 222
Palmerston North

Dear Dr Taylor

Ethics ref: **CEN/11/03/019**   (please quote in all correspondence)
Study title: Brief Cognitive-Behavioural Therapy for Chronically Ill Children with
                 Needle-Related Distress

Thank you for your email dated the 8 July 2011 enclosing documentation relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Central Ethics Committee under delegated authority.

Approved Documents

- Inclusion of Children aged from 5-12 years in the study.
- Information Sheet, Version 2, dated 8 July 2011

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

Yours sincerely

AWHINA RANGIWAI
ADMINISTRATOR
Central Ethics Committee

Letter of Ethical Approval – Amendment Two

Health and Disability Ethics Committees

Central Regional Ethics Committee
c/- Ministry of Health
PO Box 5013
1 the Terrace
Wellington
Phone: (04) 816 2405
Email: central_ethicscommittee@moh.govt.nz

4 August 2011

Dr Joanne Taylor
School of Psychology
Manawatu Campus
Massey University
Private Bag 11 222
Palmerston North

Dear Dr Taylor

Ethics ref: CEN/11/03/019   (please quote in all correspondence)
Study title: Brief Cognitive-Behavioural Therapy for Chronically Ill Children with
                     Needle-Related Distress

Thank you for your email dated the 22 July 2011 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

- To advise the CREC that since the first amendment was accepted on the 8th of July, we have still had very few referrals. Therefore, I have attached a second amendment to include children aged 5 to 15, rather than aged 5 to 12. Therefore are no other amendments, however further details are in the attached letter alongside a revised information sheet (Note: the only modification made on the information sheet is the number '12' changed to '15' on page one)

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

Yours sincerely

AWHINA RANGIWAI
ADMINISTRATOR
Central Regional Ethics Committee

Appendix 2

Information Flyer

Note: This document have been modified slightly (margins) in order to fit on bound pages.

Brief Therapy for Chronically Ill Children with Needle-Related Distress

SCHOOL OF PSYCHOLOGY   MASSEY UNIVERSITY

SPECIAL POINTS OF INTEREST:

- **Needle-related distress affects up to 50% of children.**

- **Health professionals can impact on child distress and coping during needle injections.**

- **Carers can become distressed when seeing their child injected.**

- **Treatment is based on six sessions of cognitive-behavioural therapy.**

- **Results will be available January 2012. Contact details on page 2.**

About this study...

- Thank you for your interest in this study being conducted at the Massey Health Conditions Psychology Service in Palmerston North.

- This is an information sheet for health professionals so they are informed about this study, and are aware we are accepting referrals for chronically ill children experiencing needle-related distress.

- Potential benefits for children are acceptance of needle injections within medical settings (e.g., general injections, vaccinations and dental care), reduced anxiety and avoidance of future healthcare.

What does the intervention involve?

- The aim of the intervention is to reduce anxiety and distress associated with needle injections, as well as improve coping strategies for chronically ill children and their carer.

- Therapy is based on a 61-page cognitive-behavioural manual, which was developed for this study.

- Therapy will continue for six, 50 minute sessions, while the intervention will take approximately 12 to 17 weeks.

- As part of this study, children and families will be expected to commit between 2 to 5.5 hours, in addition to the treatment they would otherwise receive at the Massey Health Conditions Psychology Service.

SCHOOL OF PSYCHOLOGY, MASSEY UNIVERSITY

We need referrals for children who...

• Are aged 5 to 15 years.

• Currently experience needle-related distress.

• Are not engaged in a full treatment plan through another agency or receiving cognitive-behavioural therapy.

• Have a cooperative carer who is willing to participate in treatment.

• Experience a chronic medical condition that requires them to have needle injections.

We *cannot* include referrals for children who...

• Present with significant mental health problems and safety issues that need immediate attention.

• Have a carer who experiences significant mental health problems such as depression.

• Are currently experiencing care and protection issues.

• Are not fluent in English.

B R I E F T H E R A P Y   F O R N E E D L E - R E L A T E D D I S T R E S S

How many referrals?

• We need between four to six children and their carers.

• At the completion of this study, if children and their carers still require therapy they will continue to receive treatment.

Contact

Jessica McIvor, Primary Researcher

Phone: 027 696 2336; Email: mcivormassey@gmail.com

Joanne Taylor, Academic Supervisor

Phone: 356 9099, ext. 2065; Email: j.e.taylor@massey.ac.nz

Kirsty Ross, Clinical Supervisor

Phone: 350 5799, ext. 2879; Email: k.j.ross@massey.ac.nz

**S C H O O L   O F   P S Y C H O L O G Y ,   M A S S E Y   U N I V E R S I T Y**

Appendix 3

Participant Information and Consent 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.

MASSEY UNIVERSITY

Brief Therapy for Chronically Ill Children with Needle-Related Distress
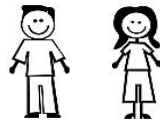
Information Sheet for Parents/Caregivers

Aims of the study

The aim of this study is to develop and evaluate a six-session therapy for chronically ill children experiencing needle-related distress. The treatment aims to reduce anxiety-related symptoms and improve coping strategies associated with needle injection situations among children and their parent/caregiver(s). Brief child and parent/caregiver self-report measures will be used to monitor the outcome of therapy; these will be completed before, during and after treatment. Six chronically ill children aged 5 to 15 that experience needle-related distress will be invited to take part. Therapy will be carried out by a registered clinical psychologist from Massey University. This study is being completed by Jessica McIvor as part of a Master of Arts degree, majoring in Psychology at Massey University.

Participant selection

You and your child are invited to take part in this project because your child has been referred from Mid-Central Health DHB to the Massey Health Conditions Psychology Service for the treatment of needle-related distress. Participation in this study will take approximately 2 to 5.5 hours, in addition to the time required for therapy at the Health Condition Psychology Service.

Initially a clinical psychologist will approach each family to make an assessment appointment, in which case you will have received this information sheet along with your appointment letter in the mail. At the initial assessment appointment, the clinical psychologist will discuss this study with you and if you are interested in taking part, the researcher (Jessica McIvor) will be available to answer your questions and discuss the study further. It is important that the child's parent/caregiver can also participate in treatment; there are no major mental health problems that need urgent assistance, and no current involvement with child, youth and family services.

You and your child are under no obligation to accept this invitation. If you and your child do not take part in this study, your child will still receive the standard treatment available at the Massey Health Conditions Psychology Service appropriate to his or her needs.

If you decide to take part in this study, you have the right to:

- Decline to answer any particular question.

- Withdraw from the study at any time without giving a reason and without affecting your child's access to treatment.

- Withdraw should any harmful effects appear.

- Ask any questions about the study at any time during participation.

- Understand that your child's name will not be used in any reports about the study.

- Be given a summary of the findings when the study is concluded (tick the appropriate box on the consent form if you wish to have a copy of this summary).

Please note 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 has the right to decline participation, unless there is no medically acceptable alternative for treatment, or if the anticipated benefits outweigh the risks.

Time commitment

If you agree to take part in this study, you and your child will take part in approximately 2 to 5.5 hours in addition to the time required for therapy at the Health Conditions Psychology Service. This includes an initial meeting (1 hour) with Jessica McIvor to go through the information sheet and complete consent forms. If you consent to participate, you will also complete questionnaires to track the progress of therapy. These questionnaires (approximately 30 minutes to complete) will be carried out before therapy begins, directly after therapy is completed and again 1 month later. All questionnaires will be mailed to you to complete at home (except for questionnaires completed at the initial meeting with Jessica), with a free post envelope included for you to mail the questionnaire back to the researcher. The study will be completed in December 2011.

Benefits, risks and inconveniences

The benefits of this study include your child potentially exhibiting less needle-related distress during future medical encounters, and improving their coping strategies to deal with their distress. This could lead to healthy behaviours in adulthood and future health care may be improved due to acceptance of needle-related situations. The potential risks associated with this study include your child becoming increasingly distressed during some parts of the therapy. However, the benefit is likely to be better than any available alternative. Children and their families may also be inconvenienced due to therapy perhaps progressing longer than one hour. However, due to children being referred to the Health Conditions Psychology Service as part of their original treatment, the inconvenience due to taking part in this study is potentially minimal.

Compensation

Taking part in this study will not incur any personal costs, other than those associated with transport to and from the Health Conditions Psychology Service. In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act, 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on partial reimbursement of costs and

expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator. You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

Confidentiality

No material that could personally identify you or your child will be used in any reports about this study. In addition, 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/whanau 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 will continue to receive treatment from the Health Conditions Psychology Service. Future care will not be compromised in any way.

- If an interpreter is required, this can be provided upon request.

- You may also request the results of this research (please tick the box on the consent form). Results will be published in a journal and stored at the Massey University library. Please note there may be a delay between data collection and the publication of results.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050; Free fax: 0800 2 SUPPORT (0800 2787 7678); Email: advocacy@hdc.org.nz. Please feel free to contact the researcher if you have any questions about this study: 027 696 2336

Thank you for taking the time to consider participation in this exciting research project! ☺

Yours sincerely
Jessica McIvor

Statement of approval: This project has received ethical approval from the Central Region Ethics Committee. Ethics reference number: CEN/11/03/019.

MA candidate: Jessica McIvor, Massey University, Wellington, can be contacted by phoning (04) 475 4003 or 027 696 2336. Alternatively you can email me at: mcivormassey@gmail.com.

Academic Supervisor: Dr Joanne Taylor, Senior Lecturer, School of Psychology, Massey University, PO Box 11-222, Palmerston North, can be contacted by phoning (04) 356 9099, extension 2065.

Clinical Supervisor: Dr Kirsty Ross, Clinical Psychologist, School of Psychology, Massey University, PO Box 11-222, Palmerston North, can be contacted by phoning (04) 350 5799, extension 2879.

MASSEY UNIVERSITY

Brief Therapy for Chronically Ill Children with Needle-Related Distress
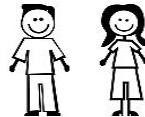
Parent/Caregiver Consent Form

I have read and understand the Information Sheet (version 3) for volunteers taking part in this study 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 family/whanau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary and I have the right to withdraw my child from the study at any time and this will in no way affect my future health care or my child's.

I understand that my child's participation in this study is confidential and that no material that could identify my child or my family will be used in any reports in this study.

I understand that the treatment will be stopped if it should appear to be harmful to 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.

☐   Yes, I wish to receive a copy of the results *(Please note there may be a significant 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 my child to take part in this study.

Date:

Participant signature:

Full name of researcher(s):

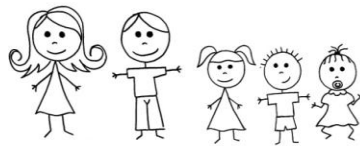Contact phone number for researcher(s):

Project explained by:

Project role:

Researcher's signature:

Date:

MASSEY UNIVERSITY

Brief Therapy for Chronically Ill Children with Needle-Related Distress

Information Sheet 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 already carried out at the Psychology Clinic at Massey University, but we want to know how helpful it is for children that are sick and need to have needle injections regularly.

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

If you don't want to take part you will still come to the Psychology Clinic at Massey University and still receive therapy from a clinical psychologist.

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

Your therapist will be Kirsty. You will come to the clinic and see Kirsty for about 1 hour, once a week or every two weeks for six sessions of therapy. You will be doing a lot of different activities that help with your fear of needle injections.

Kirsty also has a helper called Jessica. Jessica's job is to answer any questions you and your parent/caregiver has about the research. She will also ask you some questions and get you and

your parent/caregiver to fill in some forms before therapy starts, immediately after therapy and 1 month from when your therapy finishes. This will help Kirsty and Jessica know whether this therapy is helpful for you.

No one will know that you took part in this project because your name will be changed. Kirsty and Jessica will keep what you tell them private. If they are worried about something, they will tell you first before they talk to your parent/caregiver 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.

Brief Therapy for Chronically Ill Children with

Needle-Related Distress
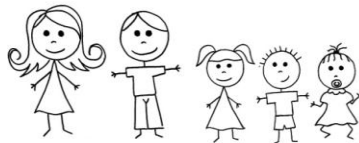
Child Consent Form

I have read the Information Sheet (version 1) 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 researchers 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 no matter what I decide, I will still be given therapy sessions at the Psychology Clinic at Massey University.

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………………………………………………………………………………………………
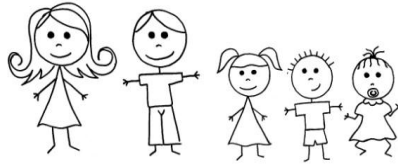
Appendix 4

Assessment Measures

Note: Measures have been modified slightly (margins and font size of items) in order to fit on bound pages.

Needle Injection Questionnaire – Child

Hi! Thank you for filling out our questionnaire. Please answer each question as honestly as you can – remember there are no right or wrong answers. ☺

Most of the questions ask about what you think and do when having a needle injection. Please circle the number that <u>best</u> describes your answer.

First, what is today's date?_____ (dd/mm/yy)

Question One

Pretend that all your feelings are in the thermometer. If you are not upset, the feelings might be at the bottom of the thermometer. If you are very upset, the feelings might go all the way to the top of the thermometer.

1. **How upset did you become during your most recent needle injection?** (Circle a number on the thermometer that best shows your answer)

Very upset - 10 9 8 7 6 5 4 3 2 1

Not upset - 0
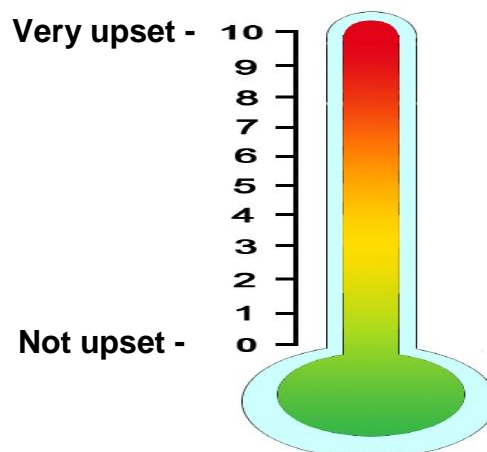
Question Two

2. **How sure are you that you will be able to have your next planned needle injection?** (Circle a number on the scale below that best shows your answer).

0———1———2———3———4———5———6———7———8———9———10

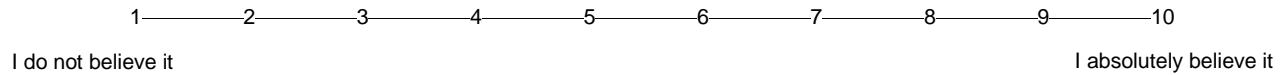Would not avoid it   Maybe avoid it   Definitely avoid it

Question Three

3.a) **What thoughts come into your head when you think of or see a needle?** (Write these thoughts below and then circle a number on the scale that best shows how much you believe these thoughts).
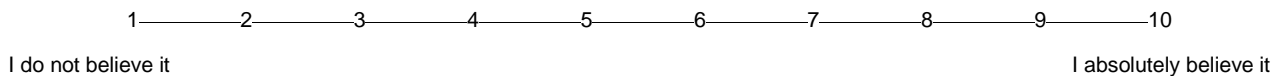
Thought 1………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 2………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 3………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

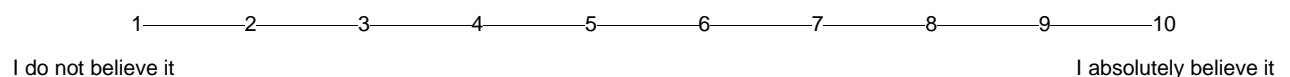**3.b)** **What thoughts come into your head when you think of having a needle injection?** (Write these thoughts below and then circle a number on the scale that best shows how much you believe these thoughts).
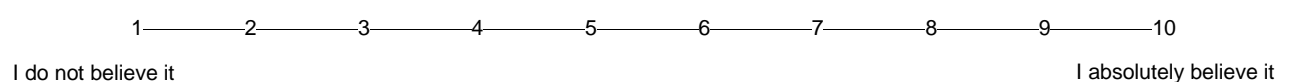
Thought 1………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 2………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 3………………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

3.c) **What thoughts come into your head about the person giving you the needle injection?** (Write these thoughts below and then circle a number on the scale that best shows how much you believe these thoughts).

Thought 1……………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 2……………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Thought 3……………………………………………………………………………………

1————2————3————4————5————6————7————8————9————10

I do not believe it   I absolutely believe it

Question Four

4.a) **When you are having a needle injection, how much are you able to help yourself feel less upset?** (Circle a number on the scale below that best shows your answer).
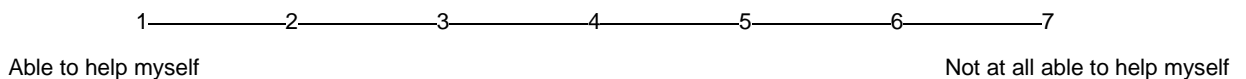
1————2————3————4————5————6————7

Able to help myself   Not at all able to help myself

4.b) **When you are having a needle injection, what do you think or do in this situation to help yourself feel better?** (Write this in space provided below).
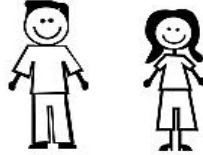
Action or Thought 1……………………………………………………………………………

Action or Thought 2……………………………………………………………………………

Action or Thought 3……………………………………………………………………………

The end - thank you for your help!

Needle Injection Questionnaire – Parent

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

First, what is today's date? _____ (dd/mm/yy)

Question One

1.a) **In general, how distressed is your child when having a needle injection?** (Circle a number from the scale below that best describes your answer).

1————2————3————4————5————6————7————8————9————10

Not at all distressed   Extremely distressed

1.b) **In general, how distressed are you when your child is having a needle injection?** (Circle a number from the scale below that best describes your answer).

1————2————3————4————5————6————7————8————9————10

Not at all distressed   Extremely distressed

Question Two

2.a) **How many needle injections has your child been scheduled to have in the last 6 months?** _____ Injections

2.b) **How many needle injections has your child tried to avoid, but ended up having to get, in the last 6 months?** _____ Injections

2.c) **How many needle injections has your child been successful at preventing from occurring in the last 6 months?** _____ Injections

2.d) **In general, do you have to alter or cancel medical appointments because your child is too distressed to have a needle injection?** (Circle a number from the scale below that best describes your answer)

1————2————3————4————5————6————7————8————9————10
Not at all   All the time

2.e) **In general, do you have to alter or cancel medical appointments because you are too distressed to see your child have a needle injection?** (Circle a number from the scale below that best describes your answer).

1————2————3————4————5————6————7————8————9————10
Not at all   All the time

Question Three

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

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

Question Four

4.a) **When your child is having a needle injection, how much are you able to help your child feel less distressed**? (Circle a number from the scale below that best describes your answer).

1————2————3————4————5————6————7

Able to help my child   Not at all able to help my child

4.b) **When your child is having a needle injection, how much are you able to help yourself feel less distressed?** (Circle a number from the scale below that best describes your answer).

1————2————3————4————5————6————7

Able to help myself   Not at all able to help myself

4.c) **When your child is having a needle injection, what do you think or do in this situation to cope?** (Write this in the space provided below).

Action or Thought 1……………………………………………………………………………

Action or Thought 2……………………………………………………………………………

Action or Thought 3……………………………………………………………………………

All done – thank you for your help! :-)

Appendix 5

Child-Identified Cognitions and Intensity (in their own words)

Participant One

Baseline 1		Baseline 2		Baseline 3		Post-treatment		Follow-up	
3.a)									
She's going to put it into me	5	Oh no, she's going to put it into me	8	Oh no, she's going to put it into me	8	Think about Sammie	10	Take deep breaths	7
It might hurt a little bit	4	It might hurt	8	It might hurt	10	I think about mum and dad	10	It's going to hurt	6
She might put it into somebody else	6	A bit scared	10	A bit scared	10	-		I'm scared	6
3.b)									
-		It will feel like a pinch	10	It will feel like a pinch	10	Playing with ted	7	It's going to prick me	8
-		I don't want this	5	I don't want to have it	10	Feeding Sammie	8	Need to take deep breaths	6
-		It might hurt lots	9	It will hurt a bit	9	-		It's going to hurt	6

Participant Two

Baseline 1		Baseline 2		Post-treatment		Follow-up	
3.a)							
I want to run away from it	8	Kick, punch, run away	8	Oh they hurt	4	Oh no	6
-		-		Go away	5	Do not like	6
3.b)							
The needle hurts	9	Oh no, this is very bad	7	They hurt bad	5	-	
3.c)							
They're doing their job	6	They're doing what they're supposed to be doing	5	If they do it good they're good	10	Hate you	6
-		-		If they do it bad they're bad	10	-	

Participant Three

Baseline 1		Baseline 2		Baseline 3		Baseline 4		Post-treatment		Follow-up	
3.a)											
The needle is yuck	5	Yuck!	8	Yuck! But then I try not to think of it	9	Yuck!	10	"Yuck", then I'd look away	5	Yuck then I'd look away	8
I don't want to see it so I look away	10	I don't want to look at it - at all	10	-		Hurry up, get this blood test over with	9	-			
3.b)											
Me crying lots because of having a needle injection	7	I don't want to think about it, I'll think about it when I need to	7	I hate those!	10	I'll think about it when I need to	8	I don't want to have one but I know I have to and I'll be okay	10	I don't want to have one but it will be okay	10
Thinking about the needle going in	7	I think about me getting upset	7	I hope it doesn't hurt at all next time	10	-		-		I don't worry about this until I need to	10
3.c)											
I just want them to get it over with!	10	I just want them to get it over with	9	I just want them to get it over with	10	Hurry up!	10	I want them to get it over with	10	I want them to get it over with	10
I don't want them to talk about what's happening, just do it	10	I don't want them to tell me when the needle is going in	9	Hurry up! I want this to be over!	10	I don't want them to tell me what's happening	10	I don't want them to tell me when the needle is in	10	I don't want them to tell me when the needle goes in	10

Participant Four

Baseline 1		Baseline 2		Post-treatment		Follow-up	
3.a)							
Hope it's sharp and hasn't been used before	3	-		It's just another needle I don't care	10	-	
3.b)							
Wow! Another needle	6	I don't want to have another one	5	I don't care, it's a daily thing for me	10	I don't care	10
Why do I need another injection	6	-		-		-	
It's going to hurt	6	-		-		-	
3.c)							
Are they going to do it quickly and is it going to hurt	7	They better do it well/properly	7	Do it properly	5	Get it over with	5

Appendix 6

Child-Identified Coping Strategies (in their own words)

Baseline 1	Baseline 2	Baseline 3	Baseline 4	Post-treatment	Follow-up
Participant 1					
Tell yourself stop crying	Patting ted my dog	Giving mum some hugs	-	Take deep breathes and relax	Take deep breaths
Playing with Ted	Hugging my teddy bears	Patting my dog	-	Cuddling mum	Sit on mum's knee
Patting Ted	Mummy giving me hugs	Cuddling teddy bear	-	Playing with ted and Sammie	Think of cuddling Ted
Participant 2					
Look away	Usually nothing	-	-	Pinch one hand - to make it less sensitive (applied tension)	-
Look at something else	-	-	-	Practise an injection on one hand (exposure/behavioural rehearsal)	-
I was so upset I did nothing	-	-	-	-	-
Participant 3					
This will be over soon	It'll be over soon	This will be over soon	I can cope if I choose to cope	Calm breathing and eyes shut	Calm breathing
I can cope if I choose to cope	I can cope if I choose to cope	I will cope if I choose to cope	This will be over soon	Mind pictures and good self-talk	Mind pictures
				Conversation with Mum	-
Participant 4					
Relax and think about something else	Not think about the pain (that probably won't event happen)	-	-	Look away or think of something else	Ignore everything
Close my eyes	-	-	-	Realise it's just another needle	-

Appendix 7

Carer-Identified Coping Strategies (in their own words)

Participant One

Baseline 1	Baseline 2	Baseline 3	Post-treatment	Follow-up
Try to reason with him	Try offering a treat	Offer him to sit on my knee	Talk to him and try to get him to relax and do his breathing	Get him to sit on my knee
Blackmail, offer him a reward	Offer a present or surprise	Offer a treat at the end	Give him a cuddle and reassure him	Tell him to take deep breathes
Explain to him sooner its over have a treat	Explain the sooner it's over the better it will be and offer to cuddle him or sit on my knee whilst having it done	Give him something to look forward to: present	Offer a reinforcement (reward)	Tell him to keep calm and reassure him it's ok

Participant Two

Baseline 1	Baseline 2	Post-treatment	Follow-up
Try to reassure him	Know he needs it	I'm fine, just need to be able to help him	Distraction technique for child
Have told nurse he has a phobia	Try to help by holding so it happens quicker	Deep breathing and relaxation	Tell him to use his breathing techniques
Restrain him so it can happen quickly. Once over he's fine.	Try to distract him with talking or i-pod though neither worked	-	-

Participant Three

Baseline 1	Baseline 2	Baseline 3	Baseline 4	Post-treatment	Follow-up
Tell myself it will be over soon and she will be okay	Remind myself it will be over soon and remind Nadia too	Remind myself and her that she has them before and survived	Remind myself she has done this before and survived	Explain to the doctor with Nadia's permission that she will cry but that's okay just keep going	Include Nadia in conversation
Try to reassure her that it will be over soon, she has done it before and survived	Talk to the nurse and try to include Nadia in the conversation	Try to think about other things	Breathing long and slow	Try to think about something else and get Nadia to talk about something else	Breathe deeply and slowly
I remember to breathe too and I have probably talked to Nadia about breathing in and then slowly out her nose	Try not to look worried or distressed myself by breathing deeply and trying to stay grounded	Try to engage Nadia in conversation to take her mind off it	Try to talk about other things with the doctor and include Nadia in the conversation	Breathe deeply and slowly	Try to think about other things

Participant Four

Baseline 1	Baseline 2	Post-treatment	Follow-up
He needs the jab (insulin) to be well	He's a diabetic, he'll die without it	It is necessary - he is diabetic	I know that he needs insulin to survive
Talk to him about the importance of rotation	He has started rotating his jab site	He will feel better and be healthier	I know that he will feel better with controlled blood sugars
Cross my fingers and hope that he is rotating his jab site	He is feeling better because the insulin is working	He is getting older, the necessity for his jabs will sink in for him soon	I know that I have done my best to help and support him

Appendix 8

Article published in November 2011 Issue of *Psychology Aotearoa*

student forum

Will the needle make me bleed to death? Cognitions of chronically ill children

Jessica McIvor
Contributing authors: Joanne E. Taylor and Kirsty J. Ross

Jessica McIvor is currently a Masters psychology student at Massey University in Wellington and will be starting the Doctorate of Clinical Psychology programme in 2012. She is passionate about working with all children and adults experiencing anxiety disorders and has an interest in working cross-culturally. She enjoys mountain biking and running with friends in her spare time.

Abstract

Needle injections are required for vaccinations, blood donations, dental care and medical treatment. For some chronically ill children, having an injection is a regular occurrence and can result in distress and avoidance behaviour for both the child and their family. There can also be negative health implications of these children not having their injections. This study aims to manualise and evaluate a brief cognitive-behavioural therapy to alleviate needle-related distress among chronically ill children. The study will be completed later this year in collaboration with the Massey Health Conditions Psychology Service, and this paper briefly describes the rationale for and approach used in the research.

For most children, having a needle injection does not invoke any significant trauma and they have adequate coping strategies to deal with these types of procedures (Blount & Loiselle, 2009). However, for a number of other children the process of having a needle injection is one of the most distressing and fear-provoking experiences when going to hospital (see Figure 1) (Humphrey, Boon, van Linden van den Heuvell, & van de Wiel, 1992). A frequently asked question by children about to enter hospital is "Am I going to get a shot?" (Schechter, 2007, p. 1185).

Figure 1. Fear of Injections

Several terms are used to describe the reaction children can have towards needle injections, and there are inconsistencies regarding their definition (Thurgate & Heppell, 2005). Needle-related distress (NRD) was used in the present study and broadly defined as "distress occurring in relation to the expectation

or experience of having a needle injection". There were two reasons to focus on this construct as opposed to other terms such as needle phobia and needle anxiety. First, this study aims to investigate any experience of distress, anxiety and avoidance rather than primarily needle phobia which requires Diagnostic and Statistical Manual (DSM-Fourth Edition) criteria for specific phobia (American Psychiatric Association, 2000). Furthermore, by focusing on the broader construct NRD, the study will be relevant for a wider range of children, as needle phobia affects approximately 10% of the population, while NRD affects at least 50% (see Table 1) (Agras, Sylvester, & Oliveau, 1969; Hanas & Ludvigsson, 1997; Humphrey et al., 1992; Meltzer et al., 2008).

Table 1

Prevalence Rates for Needle-Related Anxiety Problems
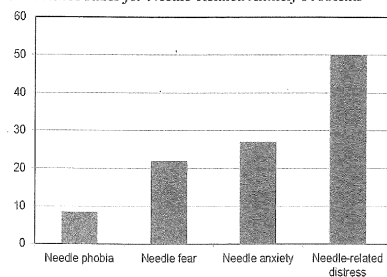
Second, needle injections are not benign stimuli for children, but unpleasant sensory and emotional experiences that threaten the child's sense of control (Humphrey et al., 1992). Therefore the child's response is not necessarily phobic, but can instead be a normal fear which involves the distress response.

The implications of NRD remaining untreated are significant. Initial short-term effects can include anticipatory nausea, insomnia, eating problems, anxiety, increased fear and pain responses, behavioural avoidance, and less cooperation during subsequent needle injections (Howe, Ratcliffe, Tuttle, Dougherty, & Lipman, 2011; Jones, DeMore, Cohen, O'Connell, & Jones, 2008).

This study aims to manualise and evaluate a brief cognitive-behavioural therapy to alleviate needle-related distress among chronically ill children.

Long-term implications include increased anxiety and behavioural avoidance of future healthcare, as well as not receiving necessary medical treatment (Jones et al., 2008). For example, Yelland, Heathcote, and Ng (2009) found that, of 46.2% of adults who had a previous traumatic needle injection, at least 20.5% of them avoided medical treatment (e.g., flu shot, tetanus shot and donating blood).

The aetiology of needle phobia is predominantly based on classical conditioning, vicarious conditioning and negative information provision (Blount et al., 2009; Watson & Rayner, 1920). However, cognitive factors have also been recognised in theories of the acquisition and treatment of needle phobias (Thorpe & Salkovskis, 1995). For example, research shows that children may

Figure 2. *Child drawing exaggerating the size of the needle*
Note. Reproduced from Children's fear of needles," by D. Fassler and N. Wallace, 1982, *Clinical Pediatrics, 21*, p. 59.

believe the needle is significantly larger than it actually is (see Figure 2) and that the needle will penetrate their entire arm (Fassler & Wallace, 1982) (see Figure 3).

Figure 3. *Child drawing of the needle penetrating the entire arm*
Note. Reproduced from Children's fear of needles," by D. Fassler and N. Wallace, 1982, *Clinical Pediatrics, 21*, p. 60.

Alongside behavioural and cognitive factors, parents and health professionals also influence child distress and coping during injection procedures (Ayers, 2011). Research shows that carer anxiety, criticism, overprotectiveness, and apologetic behaviours are associated with increased child distress, whereas distraction, humour and the use of non-procedural talk are associated with decreased distress (Mahoney, Ayers, & Seddon, 2010). For example, Mahoney et al. (2010) found that parental behaviour contributed to 64% of child distress during needle injections, whereas parent and nurse behaviours predicted 40% of the variance in child coping. However, these factors have not been incorporated into published research on treatment for needle-related distress.

A range of interventions have been used to treat needle-related distress including physical restraint, sedation and behaviour therapy. Papa, Morgan, and Zempsky (2008) reported in a survey of 2188 paediatric nurses that children are physically restrained

74% of the time by another nurse, parent or caregiver during needle insertion. Sedative techniques range from anaesthetics, antipsychotics, selective serotonin reuptake inhibitors, morphine, benzodiazepines and nitrous oxide (Hamilton, 1995; Pao & Bosk, 2011). Recent research shows, in a group of children aged 1 to 18 undergoing needle insertion, that morphine does not give any additional reduction of fear, distress or pain compared with placebo when combined with topical anaesthesia (Heden, Essen, & Ljungman, in press).

This treatment manual [Coping Kids Treatment Manual] was evaluated by comparing treatment to no treatment (i.e., the baseline phase). It was expected that child and carer anxiety would reduce and adaptive coping strategies improve following treatment and at one-month follow-up.

Alternative and less intrusive interventions include behavioural therapy, which is also the most empirically validated (Kazak et al., 1996; Manne, Bakeman, Jacobsen, Gorfinkle, & Redd, 1994; Manne et al., 1990). Followed by this, cognitive-behavioural therapy for needle distress was developed by Jay, Elliot, Ozolins, Olson, and Pruitt (1985) for five children aged 3 to 7 diagnosed with cancer. However, there are three significant limitations of these psychological interventions. First, although many researchers refer to their interventions as "cognitive-behavioural", cognitive elements that explicitly address maladaptive thoughts are absent. Second, there is a lack of active parental involvement in therapy, despite the influence they can have over child distress and coping (Mahoney et al., 2010). Third, interventions are based on one 10 to 45 minute therapy session, however

research now shows that multiple exposure sessions are more effective than one-session exposure treatments for specific phobias, particularly at follow-up (Olatunji, Cisler, & Deacon, 2010; Wolitsky-Taylor, Horowitz, Powers, & Telch, 2008).

Due to the limitations of previous research, the aim of this study was to manualise and evaluate a six-session cognitive-behavioural therapy for chronically ill children experiencing needle-related distress that incorporates cognitive components and carer involvement called The Coping Kids Treatment Manual. This treatment manual was evaluated by comparing treatment to no treatment (i.e., the baseline phase). It was expected that child and carer anxiety would reduce and adaptive coping strategies improve following treatment and at one-month follow-up. It was also expected that child cognition intensity and content would improve following treatment and at one-month follow-up.

The Coping Kids Treatment manual
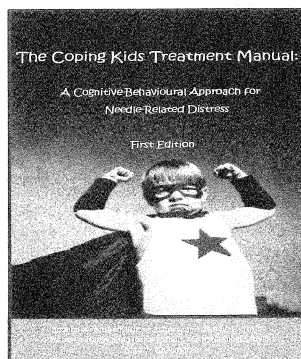
Figure 4. *The Coping Kids Treatment Manual*

(see Figure 4) is based on previous research and empirically validated techniques. Key features of the treatment manual are that it is short-term (six-sessions), structured (purpose, agenda, materials required and session format), flexible and easy to use. Several important techniques incorporated into the manual are relaxation, emotive imagery, cognitive restructuring and behavioural rehearsal. Also included are worksheets which have been utilised from previous treatments.

Method

A single-case, multiple-baseline across participants design was used to assess the effects of treatment on needle-related distress and coping in six chronically ill children (see Table 2). The children and their

Table 2

Participant Characteristics

Partici-pant	Sex	Age	Chronic Physical Condition	Type & Frequency of Needle Injection
P.1	M	5	Immune Deficiency	Blood test every 3 weeks
P.2	M	6	Blood Condition	Blood test every 4 weeks
P.3	F	6	Type 1 Diabetes	Insulin, four daily injections
P.4	M	10	Cystic Fibrosis	Blood test every 12 months
P.5	F	13	Thyroid Deficiency	Blood test every 6 months
P.6	M	14	Type 1 Diabetes	Insulin, two daily injections

families were referred by MidCentral Health to the Health Conditions Psychology Service and treatment was delivered by a Senior Clinical Psychologist. This service is a MidCentral Health DHB contracted service that works with children and families to assist in coping with chronic health conditions. Upon referral participants were randomly allocated to different baseline lengths ranging from two to four weeks. A non-concurrent procedure was utilised to allow for flexibility within an applied research setting, while maintaining the design parameters necessary for ruling out extraneous

student forum

factors (Watson & Workman, 1981). Continuous measures were completed throughout baseline, treatment and follow-up phases. Self-report measures included subjective units of distress (SUD) as well as two questionnaires developed for the study, the Needle-Injection Questionnaire for Children (NIQ-C) and the Needle Injection Questionnaire for Parents (NIQ-P). The NIQ-C and NIQ-P were developed and individualised for this study by the author and her supervisors because no existing measures were appropriate as indicators of child distress related to needles and injections. The measures are based on previous research and existing psychometric measures.
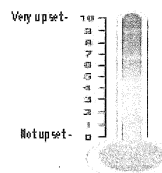
Figure 5 – *Sample item from the Needle Injection Questionnaire for Children (NIQ-C)*

The NIQ-C (see Figure 5 for example item) is a 7-item measure completed by the child that collects both quantitative and qualitative data and has four domains: (1) distress, (2) behavioural avoidance, (3) cognition, and (4) coping. The NIQ-P (see Figure 6 for example item) is an 11-item self-report measure completed by the carer that also collects quantitative and qualitative data and has three domains: (1) distress, (2) behavioural avoidance, and (3) coping. Also included in the NIQ-P is the Coping Behaviours Questionnaire (CBQ) developed by Field, Alpert, Vega-Lahr, Goldstein and Perry (1988), which is a 15-item behaviour checklist.

Preliminary results

Preliminary qualitative results will be presented here since therapy is underway and data for all participants is not yet completed. Qualitative information collected during the baseline phase of the intervention suggests children exaggerate the size of the needle. Other cognitions include "the needle is going into me" and "invading my body", "it looks scary and sharp", and "the needle is going to hurt me - a lot"! These thoughts are similar to those found in previous research in which children express physical pain contributes to their fear of injections (Fassler & Wallace, 1982). Furthermore, research shows the actual appearance of the needle (e.g., it's sharp, metal and pointy) and misunderstanding regarding its purpose may heighten the intensity of the child's reaction, particularly in younger children (Fassler & Wallace, 1982). Preliminary results of this study also show children focus on the needle penetrating the skin. It is suggested in previous research that children may consider this to be similar to a balloon and a sharp object, in which case to the child, having an injection represents frightening possibilities (Fassler & Wallace, 1982). Results also show that, prior to therapy and during the most recent needle injection, five of the six children gave verbal protest (e.g., "ouch", and "it hurts"), five cried and were afraid during the procedure. Two children were physically restrained and two were aggressive including biting and kicking, while four screamed and/or yelled during the procedure. Further quantitative and qualitative results regarding the effectiveness of the treatment manual will be available at the end of the year.

Conclusion

Needle injections have been administered for more than half a century. While there is no question that many children dislike injections, some children have a distress reaction that is more severe and can impact adversely on their health if they are not able to tolerate the procedure. Such reactions have not been examined in depth (Schechter, 2007), which has resulted in significant gaps in psychological research and clinical practice. This study aims to address some of these gaps regarding needle-related distress in chronically ill children, particularly the inclusion of cognitive elements in treatment along with carer involvement.

Preliminary results of this study also show children focus on the needle penetrating the skin.

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Appendix 9

Treatment Manual

Note: The treatment manual has been modified slightly (margins) in order to fit on bound pages.

Appendix 9

The Coping Kids Treatment Manual

Cognitive-Behavioural Therapy for Needle-Related Distress

First Edition

Jessica A. McIvor, Kirsty J. Ross, and Joanne E. Taylor

Massey Health Conditions Psychology Service

Contents

Acknowledgements

It is with pleasure that I acknowledge all those who have been instrumental in bringing this treatment manual together. I hope that this resource will contribute to the work of, and be a valuable resource, for health professionals (both clinical psychologists and medical staff) working with chronically ill children experiencing needle-related distress.

A number of people have been central to the development of this manual, most importantly Dr Kirsty Ross and Dr Joanne Taylor. The following people have also provided brief advice, and allowed me access to their own treatment manuals: Jacqueline S. Feather; Robyn D. Girling-Butcher and Louise J. Woolf. The therapist manual, cognitive-behavioural therapy for anxious children (third edition), by Phillip C. Kendall, and Kristina A. Hedtke, was also instrumental in the development of this manual.

Introduction

This manual describes a cognitive-behavioural therapy (CBT) programme for children and adolescents (aged 8 to 12 years) who experience needle-related distress as the result of needle injection procedures, and related traumatic experiences. The approach is presented in a six-session format, designed to be adapted for the idiosyncrasies of each individual child. Therefore, the present treatment manual is a guiding template, rather than rigid and inflexible instructions that must be adhered to.

The overall goal of this treatment manual is to enable chronically ill children to improve their medical treatment adherence, primarily by reducing anxiety and behavioural avoidance associated with needle injections. Consequently, the treatment manual is designed to teach children to recognise signs of unwanted anxiety and behavioural avoidance, and use this as a cue for the use of adaptive coping strategies. Emphasis within the treatment manual is placed upon the following techniques:

- Psycho-education
- Relaxation and breathing exercises
- Emotive imagery
- Gradual imaginal and in-vivo exposure
- Cognitive restructuring
- Positive reinforcement

Cognitive-Behavioural Therapy Essential Elements

General characteristics of cognitive-behavioural therapy have been incorporated into this treatment manual. This is demonstrated by the short-term, structured format of this treatment manual, whereby the therapist is active and directive (Blackburn & Davidson, 1995). Each session is also structured by the use of an agenda (i.e., goals) and homework (i.e., out-of-session tasks). Goals tend to be problem-orientated, and are focused on the 'here and now', with little reference to the client's past history. The therapist and client work collaboratively to solve problems, with an explicit and open approach to therapy. Techniques such as socratic questioning and scientific methods are used, in which the client collects 'data' (e.g., thoughts), formulates a hypothesis(s) (e.g., the needle will hurt me), sets up an experiment (e.g., in-vivo exposure task) and then evaluates the results. Dysfunctional behaviour is attributed to maladaptive thoughts, therefore, relearning more functional thought processes, and therefore behaviour, is the goal of treatment (Blackburn & Davidson, 1995).

Overview of Research

There is a significant amount of empirical evidence for CBT approaches, in preference to other forms of psychotherapy for resolving needle-related distress in chronically ill children (Uman, Chambers, McGrath, & Kisely, 2008). CBT is also the recommended treatment for children with chronic medical conditions experiencing procedural-related pain and distress (Willemsen, Chowdhury, & Briscall, 2002). Essentially this treatment manual is built upon the work of the following researchers, who have evaluated the current CBT components in a series of single-case design treatment outcome studies, with promising results.

Cognitive-behavioural therapy for chronically ill children experiencing needle-related distress was originally developed by Jay and colleagues in 1985 (Jay, Elliott, Ozolins, Olson, & Pruitt, 1985). Treatment was aimed towards children with cancer undergoing bone marrow aspirations (BMA's) and lumbar punctures (LP's). Components included filmed and participant modelling, breathing and muscle relaxation exercises, emotive imagery, behavioural rehearsal and positive reinforcement. The efficacy of these techniques for BMA's and LP's has been repeated in other studies (Blount, Powers, Cotter, Swan, & Free, 1994), as well as other needle-related procedures, such as venepunctures (Manne et al., 1990) and routine immunisations (Blount et al., 1992). These researchers included a combination of the following techniques; modelling (e.g., role plays), behavioural rehearsal (e.g., exposure), distraction (e.g., toys and books), breathing (e.g., using a party blower), muscle relaxation and positive reinforcement (e.g., stickers and certificate). Dahlquist et al. (1985, p. 327) also showed, in a sample of children with cancer, that muscle relaxation, controlled breathing, emotive imagery and positive-self-talk (e.g., "I can handle this" and "if I relax, it won't hurt as much"), had a significant reduction in observed behavioural distress during venepunctures. Overall, the six-session format in the present treatment manual was inspired by and adapted from this research. The present intervention model focuses on exposure, and the acquisition and practice of coping skills, to help the child manage needle injection situations.

Overview and Theoretical Rationale

This brief CBT programme comprises a comprehensive clinical assessment and four phases that are presented within a structured six-session format: (1) psycho-education, (2) coping strategies, (3) gradual exposure, and (4) therapy completion. The rationale for the inclusion of these components will now be presented.

Clinical assessment

It is expected that, prior to beginning the CBT programme, information and consent forms will be completed, as well as any other forms that are required from the Psycho-Oncology and Health Conditions Service. Alongside this, a comprehensive assessment of the child and

family will be carried out in order to establish that this is the most appropriate treatment option. This assessment also enables the therapist to obtain information on the presenting problem(s), prior interventions, current distress and functioning. Immediate concerns will be addressed such as suicidal ideation, low mood, eating problems and/or sleep problems. Additionally, a brief overview of the treatment programme and techniques will be given to parents, and their role as an "at-home-coach" explained before therapy starts. Outcome measures can also be administered to assess the effectiveness of therapy. For the purpose of this manual, the "Needle Injection Questionnaire for Children" (NIQ-C) and the "Needle Injection Questionnaire for Parents" (NIQ-P) has been developed.

Phase One: Psycho-Education

One session (session 1) is separated into two parts; treatment orientation and the nature of anxiety. Part one (treatment orientation) involves the therapist providing an introduction to the programme, building rapport, learning about the child and family and exploring the child's history of chronic illness and psychological problems. Out-of-session tasks are discussed and goals for therapy established. The rationale for part one is to set the context for therapy. This is because children with chronic medical conditions have complex medical and psychological histories, which is necessary for the therapist to understand in order to tailor therapy to the individual needs of the child (Drotar, Witherspoon, Zebracki, & Peterson, 2006). It also provides an opportunity for the therapist to establish a relationship with the child and parents(s).

The second part of this session involves the therapist introducing the nature of anxiety. This includes identifying feelings and somatic responses to anxiety-provoking situations (e.g., needle injections). The rationale for this is to enable the child to recognise signs of anxious arousal and let these serve as cues for the use of coping strategies. This is followed by the construction of a fear hierarchy; the aim of this is anxiety-provoking situations can be gradually introduced from most basic to more difficult. Lastly, the subjective units of distress (SUDS) rating scale is introduced, this teaches the child to self-rate their own anxiety, and become more aware of their feelings and bodily reactions.

Phase Two: Coping Strategies

Two sessions (session 2 and 3) are based on cognitive-behavioural techniques which encourage children to cope directly with their anxiety associated with needle injection situations, rather than relying on avoidance behaviour to reduce distress (Kendall et al., 1992). Coping strategies introduced in session two include breathing and muscle relaxation as well as emotive imagery. 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. Some ways this has been taught in session is through imagery (e.g., floppy vs. robot game). This is because, when it is

presented in a playful and fun manner, the images help the child to remember how to relax. Emotive imagery is also used as a coping strategy in session; this engages the child in the identification of superhero figures who then serve as models for managing needle injections. This creates a sense of understanding and active mastery over the anxiety/situation rather than passive submission during procedures (Jay et al., 1985; Kendall et al., 1992).

In session three, other coping strategies are also taught including positive self-talk, communicating feelings, finding the evidence for and against a thought and developing alternative thoughts. These techniques are based on the rationale that maladaptive thoughts are related to maladaptive behaviour (Kendall et al., 1992). Therefore, by changing faulty cognitive functioning, thoughts can be realigned so they serve to help the child function more effectively.

Overall, the rationale for the introduction of coping strategies is that the way the child is currently dealing with needle injections may seem helpful, but could also be maintaining the symptoms. Instead, more adaptive coping strategies are taught in therapy that will enable to the child to know when they are upset, and know what to do about it to feel better. These coping strategies are also taught using role-plays and the therapist acting as a coping model. The aim is 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.

Phase Three: Gradual Exposure

Three sessions (sessions 3 to 5) are dedicated to imaginal, in-vivo and behavioural rehearsal exposure tasks, moving from least to most anxiety-provoking situations. In addition to exposure, cognitive restructuring is also introduced in session three including techniques such as identifying information processing errors, finding the evidence for and against a thought (e.g., 'being a detective'), developing alternative thoughts and positive self-talk. This phase progresses from cognitive restructuring to practicing imaginal low-level anxiety situations (in-office), followed by actual in-vivo low-level anxiety situations (in-office). This continues until moderate-level exposure (session four, in-office) and high-level exposure (session five, in-vivo situations) are completed successfully.

The rationale for including cognitive restructuring techniques is that maladaptive beliefs are thought to maintain fear and avoidance behaviour, thus preventing the child from obtaining new information and correcting the false belief (Powers, Jones, & Jones, 2005). This is also usually combined with exposure tasks, which enable cognitive changes to occur, as when the child is exposed to needle injection situations or associated thoughts (which do not result in threat or anxiety), beliefs that maintain the anxiety and avoidance may also change (Pao & Bosk, 2011). Therefore, the rationale for using exposure is that, by gradually exposing the child to upsetting situations, anxiety decreases (habituation). When habituation has occurred, the child develops new associations that replace old ones. For example, instead of being anxious and tense during needle injections, a calm relaxed state becomes connected to previously

upsetting situations or thoughts associated with needle injections. In addition, gradual exposure prevents avoidance, and reinforces to the child that anxiety can decrease without using avoidance strategies (Kendall et al., 1992). Coping skills learnt in sessions two and three are used to manage symptoms throughout the exposure phase.

Throughout gradual exposure tasks (both imaginal and in-vivo), in much the same way as coping strategies, the therapist acts as a coping model. The therapist first demonstrates the skill for the child, then the child is invited to participate with the therapist in role-plays, and eventually the child is encouraged to role-play the scene independently. Finally, the child is taught to self-evaluate and reward themselves, even if they do not complete the task.

Phase Four: Completion of Therapy

One session (session 6) is devoted to the closure of therapy and relapse prevention. Closure of therapy can be upsetting for the child and family, and to counteract this, the therapist should explain that therapy will end soon. This should be done at an early stage, for example session one, rather than primarily in session six. Moreover, in order to promote relapse prevention, possible setbacks and achievements in therapy should be discussed in session six, as well as the child's strengths and weaknesses. Lastly, the therapist should discuss with the parent how to support the child and coach them in other situations. Follow-up is arranged or booster sessions offered if required.

Treatment Flexibility   FLEXIBLE

Although the content in this treatment manual is intended to be standardised across all participants, the way it is implemented will be different for each individual child. This is due to the individual needs and characteristics of each child, such as temperament and developmental age. To encourage therapists to apply this technique, this treatment manual has incorporated a "flexible" (see symbol above) element to sessions (even though all sessions can be implemented flexibly). This primarily acts as a reminder for the therapist, that this task can be implemented flexibly.

Parental Inclusion   PARENT

Although this CBT programme is delivered primarily as individual therapy, the parent is included in sessions. Parental involvement varies according to each child. However, the following format is recommended for this treatment manual: 40 minutes with each individual child, with the last 10 minutes of the session, including the parent-child working collaboratively together. Nonetheless, this is flexible, and in some cases the parent may need to be present the entire session, or not at all, if the child chooses this option. In addition, throughout the treatment manual, some activities in particular can be completed with both the child and parent, in which

case the symbol above will appear. Furthermore, an exception to the recommended (40/10 minute) format is in session five. This session is 90 minutes long, and the parent(s) are included before or after the behavioural rehearsal task. The parent(s) also accompany the child and therapist to a local health service for the in-vivo exposure task.

One aim of the parent-child section (10 minutes) is to explain and demonstrate techniques learnt in therapy, and obtain parent involvement as the "at-home-coach" for the child. A second aim is to enhance parental competency, reduce anxiety and behavioural avoidance that the parent may also be experiencing. A third aim is that parental inclusion ensures teaching components and coping strategies the child has learnt are modelled in front of, and taught to, the parent. Lastly, the therapist will also provide psycho-education and support to the parent. Overall, this allows the transfer of what is learned in therapy to the child's home environment, promoting generalisation and continued practice when therapy finishes.

Worksheet Options

Throughout this treatment manual, "worksheet options" are provided in relation to certain activities. These may or may not be appropriate for the individual child and their current situation. However they are provided as an option for the therapist to utilise. The therapist may also choose worksheets from other sources, provided they are covering the same content.

PHASE 1: PSYCHO-EDUCATION

SESSION 1

Treatment Orientation and the Nature of Anxiety

PURPOSE

Get to know the child and family and explain basic information about the treatment. Begin to gather information about situations that make the child distressed and the child's reactions to signs and feelings of anxiety. Help the child to understand the nature of anxiety. Develop exposure hierarchy and explain subjective units of distress ratings (SUDS).

GOALS

1. Build rapport with child
2. Orient to programme
3. The nature of anxiety
4. Construct a hierarchy of anxiety-provoking situations and explain SUD ratings
5. Summary and feedback
6. Engage in fun end-of-session activity
7. Child-parent section (10 minutes)

MATERIALS REQUIRED

- Large scrapbook to be used as a workbook (for gluing worksheets, pictures and drawing etc.)
- Art materials: crayons, colouring pencils, paints etc.
- Collage materials: glue, scissors, glitter, magazine and/or newspaper pictures
- A variety of age-appropriate games, activities and/or books
- Photocopy appropriate worksheet(s) options: All about me; I would like help with; My account; Reward chart; Feelings chart; My different faces; My body reactions; My experience
- Stickers for reward chart

SESSION FORMAT

1. Build rapport with child

FLEXIBLE

Begin with opening conversation for about 10 minutes; this should present as no threat to the child. The therapist suggests activities that the child can select as an end-of-session activity.

Get to know one another, play 'personal facts game' e.g., "How old are you?" "What is your favourite colour?" Alternatively, the child can choose a game to play.

Worksheet options:

1. All about me (pg.38)
2. I would like help with… (pg.39)

2. Orient to programme

Give a brief overview of the programme (e.g., meeting once per week or once every two weeks, for 50 minutes), and that treatment will continue for six sessions. Explain what booster sessions are, and that these may also be available if necessary. Provide an overview of reasons for the programme (e.g., "help children with having needle injections"). Mention the goals for treatment, including being able to identify thoughts, and use coping strategies to make yourself feel better. Invite the child to ask questions about treatment. Emphasise that you want to know their point of view.

Reward chart

Discuss the concept of reward as something you receive when you have done well. Rewards can be given by other people (e.g., presents, certificates, trophy), or we can decide whether we are pleased with our own actions and can rate and reward ourselves (e.g., telling oneself you did a good job, sharing it with a friend, or spending time doing your favourite activity). The therapist gives some examples of how they have been rewarded in the past, and then encourages the child to think of some examples to share.

The child is told they can earn stickers every session when they have done well. These can be awarded by the therapist, or the child (to promote self-reward). Once these stickers have reached a certain number, they can be used to purchase 'rewards' during the programme. Options for rewards include playing a game, or access to toys and/or books etc. (dependent on the child's preference).

Worksheet options:

1. My account (pg.40)
2. Reward chart (pg.41)

Out-of-session activities

Workbook assigned to the child and therapist explains 'out-of-session' activities. As an example of an out-of-session activity, the therapist can ask the child to write a brief example of a time when they felt good – not anxious or upset. The child is asked to focus on what made them comfortable and what they thought at the time, the child then brings this to the next session. The therapist may need to give an example. Alternatively, the child can do a 'worksheet option' as an out-of-session task.

3. The nature of anxiety

FLEXIBLE

Feelings - help the child recognise that different feelings are associated with different facial expressions and body postures.

- Game 1 – Feelings dictionary - use pictures from magazines and newspapers of people showing different expressions, both facial and the entire body that reflect different emotions. Have the child cut these out and paste them in their workbook while naming the emotions.

- Game 2 – Role-play feelings - one person acts the emotion, and the other person guesses what the emotion is.

Worksheet options:

1. Feelings chart (pg.43)
2. My different faces (pg.44)

Somatic responses – The therapist tells a story about a child excited about something (e.g., having a birthday party), and together identify what some of the body reactions might be (e.g., heart beating fast, butterflies in stomach, red face, trembling and sweating).

Normalise the anxiety response - Reassure the child that all people become anxious or scared at times, including adults who are brave. The purpose of this programme is to help the child to learn to recognise these emotions, and help themselves feel better.

- Game 1 – Role-play somatic responses - Ask the child to describe some experiences they have had and identify their own body reactions. If this is too hard, the therapist can describe the experiences of other people and identify somatic responses.

Worksheet options:

1. My body reactions (pg.45)
2. My experience (pg.46)

PARENT

4. Begin to construct a hierarchy of anxiety-provoking situations and explain subjective units of distress (SUDS)

Begin to discuss situations that can be upsetting for the child, including feelings and somatic responses. If this becomes too upsetting for the child, use imaginal situations, or do something less threatening.

Explain to the child the subjective units of distress, and that this can be used to help determine which situations are more anxiety-provoking for them. The therapist models this first using the SUDS scale and then asks the child some questions, for example "how upset did you feel when…?" Now give it a number.

From information gathered so far, the therapist and child then begin to develop a 10-item fear hierarchy of injection-related situations that provoke anxiety in the child. Write this down on a fear ladder from 0 (no anxiety) to 10 (extreme anxiety). This does not need to be perfect, as it will be re-introduced in sessions three, four and five. However, be as specific as possible regarding situations, for example 'seeing someone else getting an injection'.

5. Summary and feedback

Provide a brief summary of the session. Ask the child if they have any questions, how they are feeling, and what was helpful and/or unhelpful.

FLEXIBLE

6. Engage in fun end-of-session activity

Take 5 minutes to play a game or engage in an activity. Finally children are given a reward (e.g., stickers) for effort and participation, which can be added to the child's 'reward chart'. Example of games: Fish, memory, hungry hippo, hang-man, connect four, colouring inn, reading a story and sing a song.

7. Child-parent section (10 minutes)

Therapist provides a brief overview of what the session involved, and psycho-education about the nature of anxiety. Child demonstrates her 'new' ability to recognise feelings by playing game two practiced in session (e.g., one person acts the emotion (parent), and the other person (child) guesses what the emotion is) and/or role-play somatic responses. As well as this, the child could also show and explain worksheets they completed during the session, or have been given as an out-of-session activity. Parents also have the opportunity to ask any questions about the treatment programme.

PHASE 2: COPING STRATEGIES

SESSION 2

Coping Strategies: Relaxation and Emotive Imagery

PURPOSE

To introduce relaxation training and emotive imagery, and develop these strategies into steps the child can use to cope during needle injection procedures.

GOALS

1. Build rapport and review previous session
2. Increase the child's awareness of relaxation
3. Introduce breathing exercises
4. Introduce relaxation exercises
5. Practice relaxation via modelling and role-play
6. Practice relaxation with the child's parents (optional)
7. Introduce emotive imagery
8. Review fear hierarchy and discuss exposure tasks in next session
9. Out-of-session activity, summary and feedback
10. Child-parent section (10 minutes)

MATERIALS REQUIRED

- Child's workbook
- A piece of paper, HB pencil and eraser
- A variety of age-appropriate games, activities and/or books
- Photocopy appropriate worksheet(s) options: Calm breathing; Magic breathing; The dandelion story; The floppy Vs. robot game; Going to the beach; Muscle relaxation; Mind pictures; Busy brainwaves
- Stickers for reward chart

SESSION FORMAT

1. Build rapport and review previous session

Answer any questions from the previous session and review the goals for therapy. Allow more time for questions, or a game if rapport still needs to be established.

Review the out-of-session task from session one; if it was completed, reward with stickers. If it was not completed, the therapist and child spend time at the start of session to complete the task. The child can also talk about how they felt, and what they thought about over the past week.

2. **Increasing the child's awareness of relaxation**

Discuss the idea that, when someone is upset, some parts of their body may be tense. Introduce the concept 'calm down tricks' (e.g., controlled breathing and muscle relaxation) which can used as a way to calm oneself down. Explain that these can be used in real-life during anxiety-provoking situations.

3. **Introduce breathing exercises**

Deep breathing

FLEXIBLE

The child is taught a simple breathing exercise which gives them an active attention-diversion strategy during the needle injection procedure. This also provides a sense of mastery over anxiety, rather than passive submission. Exercise one can be used or refer to worksheet options.

- Exercise 1 – Blowing up a tyre - The child pretends they are a tyre, they breathe in to fill the tyre with air, and then slowly breathing out, making a hissing sound as the air leaks out of the tyre (mouth). Let all the air out very slowly. Then pump it back up again and start over (this can also be glued into the child's workbook).

Worksheet options:

1. Calm breathing (pg.46)
2. Magic breathing (pg.47)
3. The dandelion story (pg.48)

FLEXIBLE

4. **Introduce muscle relaxation**

Introduce muscle relaxation in the same way as breathing; either do exercise one or two, and/or choose from the worksheet options below. The therapist acts as a coping model in both exercises, and then asks the child to try it.

- Exercise 1 - Ask the child to tighten their fist, count to 5, and then relax it to the count of 5, focusing on the relaxed warm feeling in their hand, following it into her arm and continuing to follow it as it works its way through their body.

- Exercise 2 – Ask the child to imagine feeling 'floppy', then imagine feeling like a 'robot' (see pg. 49 for script). This enhances awareness of tension states versus relaxed states.

Worksheet options:

1. The floppy vs. robot game (pg.49)
2. Going to the beach (pg.50)
3. Muscle relaxation (pg.51)

5. Practice relaxation via modelling and role-play

The therapist describes a situation and models recognition of anxious feelings and accompanying tension by talking about their somatic responses. The therapist aims is to be a coping model. The therapist should also show coping by modelling unwanted stress and thoughts, then using the deep breaths and muscle relaxation. Describe carefully to the child what is being done. The child then 'tags along' with the therapist during a similar scenario, or the child can role-play a similar sequence while the therapist provides prompts as required.

PARENT

6. Practice relaxation with child's parents (optional)

When the child and therapist have gone through the exercise, the therapist invites the parent to join in so the child can "show-off" these skills. The therapist explains the rationale to parents and outlines how it can be practiced at home and during needle injection procedures.

PARENT

7. Introduce emotive imagery

Explain to the child that we can also do things to distract ourselves from feeling anxious during needle injections. For example, use images in our head of our favourite cartoon or super hero. First, the therapist asks the child about their favourite cartoon or super hero. Second, the child makes up a story (with the help of the therapist) about the cartoon character or super hero, helping them to cope with needle injection situations using special powers (the child can write this in their workbook). Note, the superhero or cartoon character should be applied to needle injection situations in a realistic way (see example of emotive imagery using a superhero below). Third, they imagine help from the cartoon or super hero to stay still, use breathing skills and muscle relaxation during needle injection procedures.

The therapist and parent can then remind the child of the story during practice exercises and exposure tasks by asking questions like "Remember Wonderwoman - what would she do right now?" This transforms the meaning of anxiety for the child and elicits motivation related to mastery of anxiety. The parent is also encouraged to prompt the child while at home in real-life situations.

An abbreviated <u>example</u> of a story is below. Each story will be different depending on the child.

Example of emotive imagery using a Superhero: Pretend that Wonderwoman has come to your house and told you that she wants you to be the newest member of her Superpower Team. Wonderwoman has given you 'special powers'. These 'special powers' make you <u>very strong</u> and <u>tough</u> so that you can stand almost anything! She asks you to take some tests to try out these superpowers. The tests are called needle injections. These tests can be really scary, but with your new superpowers, you can take <u>deep breathes</u> and <u>lie very still</u>. Wonderwoman will be <u>very proud</u> when she finds out that your superpowers work and you will be the newest member of the <u>Superpower Team!</u> ☺ (Jay et al., 1985, p. 516).

<u>Worksheet options:</u>

1. Mind pictures (pg.52)
2. Busy brainwaves (pg.53)

8. Review fear hierarchy and discuss exposure tasks in next session

The therapist informs the child that the next session involves practicing the skills that have been learnt in this session and session one, and review the fear hierarchy developed in session one. The practice will start in a gradual way, for example low-level exposure to high-level exposure. Explain that this can be stopped at any time if the child feels uncomfortable. Coping strategies learned in this session will also be practiced repeatedly throughout exposure tasks.

9. Summary, feedback and out-of-session activity

Ask the child if anything was not clear, how they are feeling and if they have any questions. If any new topics are raised, add to the goals for the next session. For out-of-session activities, the therapist has the option of giving the child a breathing, muscle relaxation or emotive imagery exercise, as well as worksheet options.

10. Child-parent section (10 minutes)

Therapist provides a brief overview of what the session involved, then the child chooses a muscle relaxation and/or breathing exercise to demonstrate to their parent. The child also shows their parent the emotive imagery story created with their favourite super-hero or cartoon character. The therapist explains the parent can prompt the child to use these coping strategies outside of therapy (e.g., "remember Superwoman - what would she do right now?"). Parents also have the opportunity to ask any questions about the treatment programme.

PHASE 3: GRADUAL EXPOSURE

SESSION 3

Cognitive Restructuring and Low-Level Exposure

PURPOSE

To help the child recognise the role of thoughts in perpetuating symptoms, and learn how to turn negative self-talk into positive self-talk. As well as this, practice low-level exposure tasks and SUDS ratings.

GOALS

1. Review previous session
2. Introduce thoughts
3. Being a 'detective'
4. Introduce positive self-talk
5. Reward for imaginal and exposure tasks
6. Practice using imaginal exposure in low-level anxiety-provoking situations
7. Practice using in-vivo exposure in low-level anxiety-provoking situations
8. Out-of-session activity, summary and feedback

MATERIALS REQUIRED

- Child's workbook
- A copy of the fear hierarchy and SUDS scale from session one
- Collage material: glue, scissors, glitter, pictures cut out of magazines
- Cue cards for the child to write on
- Props for exposure tasks
- Photocopy appropriate worksheet(s) options: Thought people; Positive self-talk; What skills I will use; What I did when I had to have a test or procedure.
- Stickers for the reward chart

SESSION FORMAT

1. Review previous session

Briefly review the content of session two. Discuss child's experiences when practicing breathing and muscle relaxation in therapy and at home, noting the parts that went well and those that did not. Review the out-of-session task from session two; if it was completed, reward with stickers. If it is not completed, the therapist and child spend time at the start of session to complete the

task. Lastly, take 5 minutes to practice relaxation, and 5 minutes to imagine a scenario with their favourite cartoon character.

2. Introduce thoughts

FLEXIBLE

Introduce the idea that when things happen we have feelings and bodily reactions, as well as thoughts.

- Game 1 – Identifying thoughts – using the 'thought people' worksheet (pg.54), the child and therapist make up a story (e.g., self-talk) about what might be happening for each figure.

- Game 2 – Role play – the therapist asks the child to describe a situation, for example you have to go to hospital. The child is then asked to give some examples of thoughts that might accompany these events. Explore what thoughts someone else might have, to help the child recognise their own self-talk, and identify different thoughts that are possible in the same situation.

- Game 3 - Using a favourite cartoon character or super hero presented in a situation, the therapist asks the child to think of thoughts that would help the character to be less upset (e.g., practicing emotive imagery with thoughts).

3. Being a 'detective'

FLEXIBLE

Introduce the idea that some thoughts can help us to feel better, whereas other thoughts can make us feel worse. Depending on the child's developmental age engage in more teaching about thoughts rather than hypothesis testing. This should be done using concrete tools such as cartoons with thought bubbles (e.g., game 1 or 'thought people' worksheet) and incomplete sentences (e.g., "when I have a needle injection, I feel_____and I worry that_____").

- Game 1 – The child can gather two pictures of people (from a magazine or newspaper) and fill in their thoughts, one with helpful thoughts, and one with unhelpful thoughts. The child can then glue these into their workbook.

- Game 2 – The child chooses a situation that was upsetting and describes unhelpful thoughts that they had. The therapist then asks the child to gather evidence for and against the thought (be a detective!). Below are some questions the child can ask. The child is then asked to write these good detective questions on cue cards or in their workbook, which can be taken with them into needle injection situations.

  1. What has happened before in this situation?
  2. Are there any other ways of thinking about this situation?
  3. What else might happen?

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4. Has it happened before?
5. Has it happened to anyone I know?
6. What would someone I admire think in this same situation?
7. What would I tell a friend who was in this same situation and had the same unhelpful thought?

Alongside being a 'detective', the therapist should introduce the idea of 'thinking traps'. These can 'trick' people into having bad feelings (e.g., anxiety) before they have a chance to collect evidence, especially in scary situations such as needle-injection procedures. The child is encouraged to reflect on thinking traps that might trick them into having these feelings during needle injections. Below are some examples of thinking traps:

1. Focusing on the negative and overlooking the positive
2. It happened before, it's always going to happen that way
3. Always thinking the worst is going to happen
4. Staying away from situations that are scary
5. Jumping to conclusions about a person/thing/situation
6. Telling the future
7. I should always be perfect
8. Setting expectations that are too high

8. Introduce positive self-talk

PARENT

Therapist explains positive self-talk such as "I can do it" and "I'm a brave boy/girl", and uses a situation to model how and when to use positive self-talk. The child is then asked to write down (on cue cards or in their workbook) some positive self-talk statements (or use an image to represent a coping thought) and to practice saying them out loud using a similar situation. Once the child has mastered the activity, the parent can be asked to join in.

Communicating my feelings

PARENT

Introduce the idea that it is okay for children to tell people (e.g., friends and family) how they are feeling. The therapist models this using the script below and a situation that is familiar to the child. The child is then invited to practice using the script with a situation that is similar. Once the child has mastered this, the parent can be asked to join in. The therapist may also invite the child to write this on a cue card or in their workbook.

- When_____I feel_____because_____so I would like_____.

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Worksheet options:

1. Positive self-talk (pg.55)

9. Reward for imaginal and exposure tasks

This is an incentive for the child to practice their coping strategies during imaginal and in-vivo exposure. While they practice, the therapist encourages the child to act "bravely" and "do the best they can". The situation is structured so that the child will succeed. The therapist and child can choose the reward (e.g., stickers or a game).

10. Practice using imaginal exposure in low-level anxiety-provoking situations

Preparation

FLEXIBLE

Describe the chosen practice situation and review coping strategies learnt in previous sessions (the child can write this down in her workbook). Make the imaginal situation as real as possible and actual items that would be part of the situation are used as props. In preparation, the therapist pretends she is the child, and models thinking through the situation out loud, while using coping strategies developed in previous sessions (be a coping model).

Practice

The child is then asked to think through a similar, but different, situation using the same props. During the imaginal exposure, the child provides a 0 (no anxiety) to 10 (extreme anxiety) SUDS rating before, during and after the exposure task. The therapist records the child's SUDS rating, and also rates how they feel, how anxious the child was before, during and after exposure.

FLEXIBLE

11. Practice using in-vivo exposure in low-level anxiety-provoking situations

In therapy and using props as appropriate, the therapist asks the child to use their new skills in an actual situation that had been practiced through the imaginal procedure. If the child cannot proceed at any point, the therapist encourages self-reward for the partial success achieved. The therapist then joins the child in the exercise, providing prompts as needed. Once the child has mastered the exposure task, with prompts from the therapist, they are asked to try again, but this time carries out the task independently. Throughout the procedure, the child and therapist provide SUDS ratings before, during and after exposure. The therapist records the child's SUDS rating, and also rates how they feel, how anxious the child was before, during and after exposure. The child is rewarded for effort and completing in-vivo.

12. Out-of-session activity, summary and feedback

Summarise the session and provide an opportunity for the child to ask questions. The therapist has the option of giving the child the out-of-session activity below, a positive self-talk exercise and/or getting the child to practice a low-level exposure activity at home. The child is encouraged to continue practicing coping strategies out-of-session.

Worksheet options:

1. What skills I will use (pg.56)
2. What I did when I had to have a test or procedure (pg.57)

13. Child-parent section (10 minutes)

Therapist provides a brief overview of what the session involved, and the child chooses one of the thought games practiced in session to role-play with her parent(s). Following this, the child and parent can practice 'communicating my feelings' using the script provided in therapy, and practice positive self-talk statements (using cue cards) created in session. Lastly, an imaginal and in-vivo exposure task can be attempted using the coping strategies learnt in previous sessions. Parents also have the opportunity to ask any questions about the treatment programme.

SESSION 4

Medium-Level Exposure

PURPOSE

The purpose of this session is to practice applying coping strategies to imaginal and in-vivo exposure situations that produce medium-level anxiety.

GOALS

1. Review previous session
2. Review coping strategies
3. Reward for imaginal and exposure tasks
4. Practice imaginal exposure in medium-level anxiety-provoking situations
5. Practice in-vivo exposure in medium-level anxiety-provoking situations
6. Out-of-session activity, summary and feedback
7. Child-parent section (10 minutes)

MATERIALS REQUIRED

- Child's workbook
- Props for exposure tasks
- Photocopy appropriate worksheet(s) options: What I did when I had to have a test or procedure
- Stickers for reward chart

SESSION FORMAT

1. Review previous session

Discuss previous session and answer any questions. Review the out-of-session task from session three; if it was completed, reward with stickers. If it is not completed, the therapist and child spend time at the start of session to complete the task.

FLEXIBLE

2. Review coping strategies

Remind the child that today's session will include them practicing their newly acquired skills in imaginal or real-life situations. Instead of learning about coping strategies, the focus will shift to practicing these skills in session/office and sometimes out of office.

Before progressing to imaginal and in-vivo exposure tasks, briefly practice coping strategies (e.g., relaxation, emotive imagery, positive self-talk and 'being a detective') using role-plays and the games learnt in previous sessions. Ensure the child has their cue cards and workbook when practicing these, and remind them these coping strategies can be used as a first response when becoming upset, and that learning new skills takes practice.

3. Reward for imaginal and exposure tasks

This is an incentive for the child to practice their coping strategies during imaginal and in-vivo exposure. While they practice, the therapist encourages the child to act "bravely" and "do the best they can". The situation is structured so that the child will succeed. The therapist and child can choose the reward.

4. Practice using imaginal exposure in medium-level anxiety-provoking situations

FLEXIBLE

Preparation

Describe the chosen practice situation that will cause moderate-levels of anxiety. Actual props that would be part of the situation are used this time. In preparation, the therapist acts as a coping model (acting as the child), thinking out loud and using coping strategies practiced in previous sessions.

Practice

The child is then asked to think of a similar, but different, situation using the same props. Throughout the situation the child provides SUDS ratings before, during and after, using the same scale employed in session three. The therapist records the child's SUDS rating, and also rates how they feel, how anxious the child was before, during and after exposure.

5. Practice using in-vivo exposure in medium-level anxiety-provoking situations

FLEXIBLE

Preparation

Prepare the child for the in-vivo exposure task, the therapist and child review coping strategies, and ensure cue cards and the child's workbook are readily available before proceeding. The therapist and child also talk about what might, or might not happen, and prepare for different outcomes.

Practice

The therapist acts as a coping model using a real-life situation (still within the office), while thinking out loud, and allowing the child to comment on the situation, and provide suggestions for the therapist to cope better. Before the child is asked to do the same, using a similar but different real-life situation, they are asked to describe their feelings, somatic reactions and anxious self-talk. Furthermore, several minutes before exposure, relaxation exercises can be practiced, and may also occur after exposure. The child now completes the in-vivo exposure task, while giving SUDS ratings before, during and after exposure. The therapist also provides SUDS ratings before, during and after exposure of how anxious they feel the child is. Following the exposure task, the child is rewarded for effort and completing the in-vivo exposure task.

6. Out-of-session activity, summary and feedback

Ask the child if anything was not clear, how they are feeling and whether they have any questions. If new topics are raised, add to the goals in the next session. The therapist has the option of giving the child an out-of-session activity, for example, practice coping strategies or positive self-talk exercise. The therapist also informs the child that the next session involves high-level exposure where "we will leave the office and practice a real needle injection". It is important the clinician is honest about this to maintain trust with the client.

Worksheet options:

1.   What I did when I had to have a test or procedure (pg.57)

7. Child-parent section (10 minutes)

Therapist provides a brief overview of what the session involved, and the child demonstrates to their parent(s) an imaginal and/or in-vivo exposure task while using coping strategies learnt in previous sessions. Parents also have the opportunity to ask any questions about the treatment programme.

SESSION 5

High-Level Exposure

PURPOSE

Practice applying the skills for coping with anxiety in imaginal and in-vivo situations that produce in high-levels of anxiety. Please note, this session is 90 minutes long to allow for in-vivo exposure at a local health service.

GOALS

1. Review previous session
2. Review coping strategies
3. Reward for imaginal and exposure tasks
4. Practice using imaginal exposure in high-level anxiety-provoking situations
5. Practice behavioural rehearsal of needle injection situations
6. Practice using in-vivo exposure in high-level anxiety-provoking situations
7. Out-of-session activity, summary and feedback
8. Child-parent section (10 minutes)

MATERIALS REQUIRED

- Child's workbook
- Props for exposure tasks
- Photocopy appropriate worksheet(s) options: What I did when I had to have a test or procedure
- Stickers for the reward chart
- Liaison with medical staff to set up an in-vivo needle injection procedure at a local health service. Organise transportation, medical staff (e.g., nurse), time and day. The child and parent go together in their own car, while the therapist meets them at the scheduled location. Ensure this is organised so that factors such as waiting times are not present, which tend to increase anxiety further.

SESSION FORMAT

1. Review previous session

Discuss with the child anxiety-provoking situations practiced last week, and ask the child to describe how they coped with being upset. Review the out-of-session task from session four; if

it was completed, reward with stickers. If it is not completed, the therapist and child spend time at the start of session to complete the task.

2. Review coping strategies

FLEXIBLE

Remind the child that today's session will include them practicing their newly acquired skills in imaginal or real-life situations. Instead of learning about coping strategies, the focus will shift to practicing these skills in session/office and sometimes out of office.

Before progressing to imaginal and in-vivo exposure tasks, briefly practice coping strategies (e.g., relaxation, emotive imagery, positive self-talk and 'being a detective') using role-plays and the games learnt in previous sessions. Ensure the child has their cue cards and workbook when practicing these, and remind them these coping strategies can be used as a first response when becoming upset, and that learning new skills takes practice.

3. Reward for imaginal and exposure tasks

This is an incentive for the child to practice their coping strategies during imaginal and in-vivo exposure. While they practice, the therapist encourages the child to act "bravely" and "do the best they can". The situation is structured so that the child will succeed. The therapist and child can choose the reward.

4. Practice using imaginal exposure in high-level anxiety-provoking situations

Preparation

FLEXIBLE

At this point, the child should be able to use coping strategies, cue cards and her workbook without assistance. However, this part may be challenging and they may still require encouragement and prompts every now and again.

Practice

The child decides on a practice situation (imaginal) that will cause high levels of anxiety, using actual props to make the situation as real as possible. Have the child complete SUDS ratings before, during and after imaginal exposure. The therapist records the child's SUDS rating, and also rates how they feel, how anxious the child was before, during and after exposure.

5. Practice behavioural rehearsal of needle injection situations

Preparation for in-vivo exposure

PARENT   FLEXIBLE
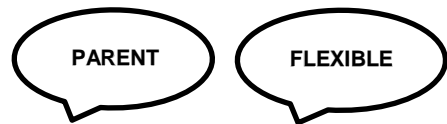
In preparation for the in-vivo exposure task, the therapist and child carry out the following behavioural rehearsal stages. The aim of this exercise is to challenge dysfunctional beliefs. It is important to reiterate to the child that needle injections are necessary to get well, that physicians are their friend, and that although the procedure may be painful, their bodies will be fine as soon as the procedure is over.

- Behavioural rehearsal, stages 1 to 3 described below:

  1. The child is allowed to play doctor and give a doll a needle injection with actual medical equipment. As the child administers the procedure, the doll is coached to stay still and do their coping strategies (e.g., positive self-talk, emotive imagery, muscle relaxation and breathing exercises). As well as this, the child encourages the doll to use their workbook and cue cards to get them through the difficult situation.

  2. The child practices administering a mock needle injection on the psychologist who models these coping strategies (out loud) as the child plays doctor.

  3. The child and the psychologist actually practice a mock needle injection procedure. The child is coached to lie still and use coping strategies while the psychologist pretends to administer the needle injection.

6. Child-parent section (10 minutes)

Therapist provides a brief overview of what the session involved, and the child demonstrates to their parent(s) an imaginal and/or behavioural rehearsal task while using coping strategies learnt in previous sessions. Next the therapist explains that a real-life needle injection procedure will be carried out at the local health service, and that it is critical the parent(s) accompany them. Parents also have the opportunity to ask any questions about the next task.

7. Practice using in-vivo exposure in high-level anxiety-provoking situations

Preparation

FLEXIBLE   PARENT
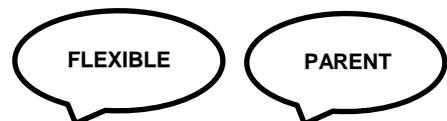
In preparation for the high-level in-vivo exposure task, the therapist and child discuss the behavioural rehearsal task practiced above. They then discuss the high-level anxiety-provoking situation they will practice in real-life (e.g., a needle injection at a hospital or clinic). They talk

about coping strategies that can be used, and arrange a reward for effort and completion of in-vivo exposure. The therapist also explains to the child and parent that he/she will accompany them into the procedure to advocate for the child, and not allow any adverse practices to occur such as restraint. In addition, the therapist also goes over what could/couldn't go wrong with the procedure. It is important the parent is present during this stage of therapy so that advocacy and techniques can be modelled to them by the therapist.

Practice

The therapist and child leave the office and go to a location in which the child can practice using coping strategies in a real-life needle injection procedure (as just practiced in the behavioural rehearsal task above). If transportation is necessary, this is arranged prior to the session.

Before in-vivo exposure, the child describes their feelings, somatic reactions and anxious self-talk. The therapist describes how to make their self-talk more positive. A few minutes before the actual situation (e.g., needle injection), the child practices a breathing and/or muscle relaxation exercise and this helps the child develop coping strategies within the actual situation.

Throughout the in-vivo exposure, the child provides a SUDS rating before, during and after exposure. The therapist also provides SUDS ratings before, during and after exposure of how anxious they feel the child is. The therapist records the child's SUDS rating, and also rates how they feel, how anxious the child was before, during and after exposure. Following the in-vivo exposure task, the child is rewarded for effort and completion.

8. Out-of-session activity, summary and feedback

Ask the child if anything was not clear, how they are feeling and whether they have any questions. Therapist has the option of giving the child an out-of-session activity, for example, an exposure task and/or a worksheet option.

Worksheet options:

1. What I did when I had to have a test or procedure (pg.57)

PHASE 4: THERAPY COMPLETION

SESSION 6

Relapse Prevention and Closure

PURPOSE

Review and summarise the training programme. Make plans with parents to help the child maintain and generalise newly acquired skills. Bring closure to the therapeutic relationship and celebrate the child's success!

GOALS

1. Review previous session
2. Summarise the treatment programme
3. Relapse prevention
4. Congratulations certificate
5. Saying good-bye and arranging follow-up

MATERIALS REQUIRED

- Completed workbook with copies of artwork and activities done in therapy
- Materials required for celebration activity, e.g., small cake with a candle, etc.
- Cue cards to take home
- Photocopy appropriate worksheet(s)
- Congratulations certificate

SESSION FORMAT

1. Review previous session

Discuss with the child the anxiety-provoking situations practiced in session five. Check how the child is and respond to concerns about therapy ending.

2. Summarise the treatment programme

PARENT   FLEXIBLE

- The therapist and child (and the parent, if invited by the child) go through the child's workbook. The aim is to ensure the child recognises strengths they have, and things they are proud of and achievements in therapy.

- Outline that it is important to identify when you do well, and be proud of this. It is also important to celebrate and share your achievements with others.

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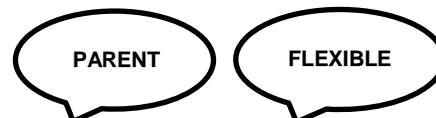
- Recap with the parents and child what has been accomplished over the course of treatment. Review with the parents coping strategies. Note that there have been gains, as well as areas for improvement.

- Encourage parents to share their feedback about their child's progress, ask any questions, or share any concerns that they may have about concluding treatment. The therapist also discusses with the parent how to support the child with what they have learned, and to encourage coping strategies during future medical procedures (e.g., needle injections).

3. Relapse prevention

PARENT   FLEXIBLE
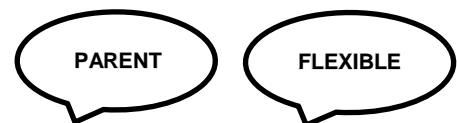
- The therapist reminds the child that they can use the coping strategies, cue cards and workbook to be 'their own therapist'. Talk about how they can use these strategies to manage future needle injection situations. Remind the child to take their cue cards, with positive self-talk statements, ready to use next time they get upset during a needle injection.

- Acknowledge that relapse is possible, but is a controllable event. Explain to the parents that there may be times that are difficult in terms of coping with needle-related distress. Encourage the child to continue practice coping strategies.

- Highlight to the parent(s) the need to advocate for the child during needle injection procedures, and the value of setting up appointments to avoid anxiety-provoking factors inherent in health services (e.g., wait times).

4. Congratulations certificate

- In the final session, present the child with a 'congratulations certificate' as a final reward for participation in the programme. Another reward could also be offered; it is suggested this be a social reward, such as playing a favourite game with the therapist, going out for ice-cream, or sharing some other activity.

5. Saying goodbye and arranging follow-up

- The parents and the child are given the therapist's card and are invited to call if they have any further questions, but they are also told to call to inform the therapist as to how the child is progressing, therefore, inviting the child to contact them around future successes.

- Inform the parents that you will call to "check in" and see how the child is doing. If appropriate, schedule a meeting for booster sessions. Booster sessions content and length vary according to each child, but can include revision of past sessions, information provision, problem solving and behavioural rehearsal.

- "You've gotten on top of your anxiety". As an out-of-session activity for children to complete before their next booster session(s), the clinician can ask the child to put together some kind of summary (i.e., "tip sheet") for other kids on how to manage needle injections. Explain to the child that not only are they managing their anxiety associated with needle injections, they are an "expert" on it, so we want to use that expertise and help other kids just like them. The child can use ideas from their workbook or anything else they can think of. It can be something they have written or typed on the computer (e.g., poem or story) or it could be something they have drawn. It could also be a mixture of drawings and words.

  FLEXIBLE

- Remind the family that a follow-up letter to the referrer saying the therapy is complete will be sent out, alongside a customer satisfaction questionnaire (CSQ) for the family to fill out. Outcome measures can also be administered at this point, or at follow-up, such as the "Injection Questionnaire for Children" and the "Injection Questionnaire for Parents".
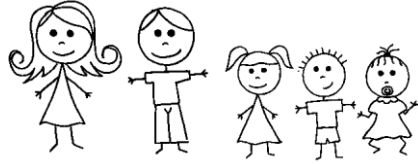
THERAPIST RESOURCES

All About Me

Five words that describe myself are:

☺ ....

One thing that makes me very special is

☺ ....

My favourite animal is

☺ ....

My favourite food is

☺ ....

My favourite sport is

☺ ....

My favourite music is

☺ ....

My favourite book is

☺ ....

My favourite movie is

☺ ....

My favourite super-hero/cartoon character is

☺ ....

I Would Like Help With…
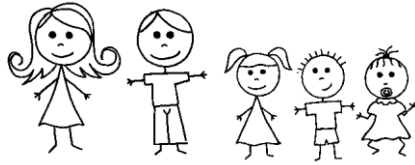
First, let's do an example: I would like help with knowing what to do when I'm upset:

☺ ....

☺ ....

Now your turn

☺ ....

☺ ....

☺ ....

☺ ....

☺ ....

☺ ....

☺ ....

☺ ....

My Account
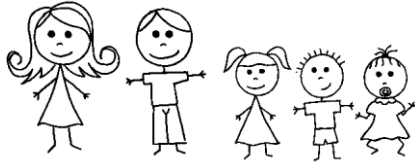
Date	Session #	Points

Reward Chart
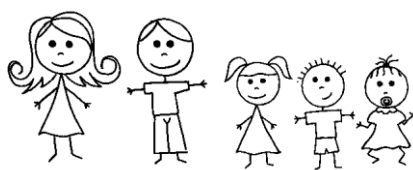
Reward Options (presents and/or activities)	Number of points needed

Feelings Chart

Worried	Caring	Confused	Bored
Annoyed	Angry	Ashamed	Anxious
Jealous	Lonely	Happy	Surprised
Relaxed	Frustrated	Depressed	Guilty
Hurt	Sad	Disgusted	Scared
Crazy	Hopeful	Spaced Out	Excited

My Different Faces

My Happy Face
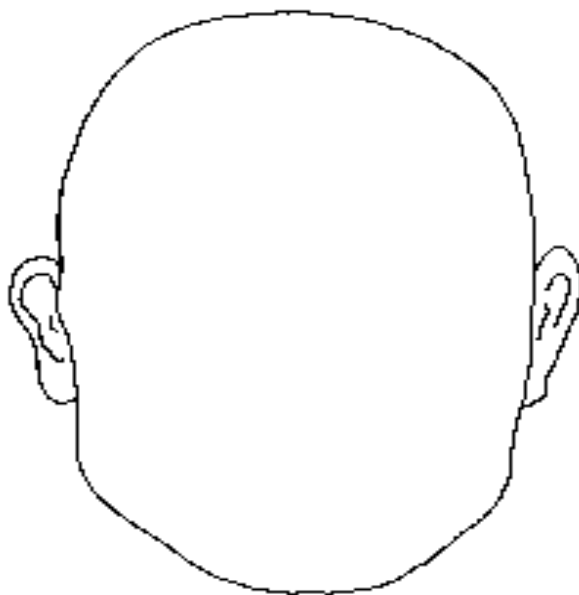
My Sad Face
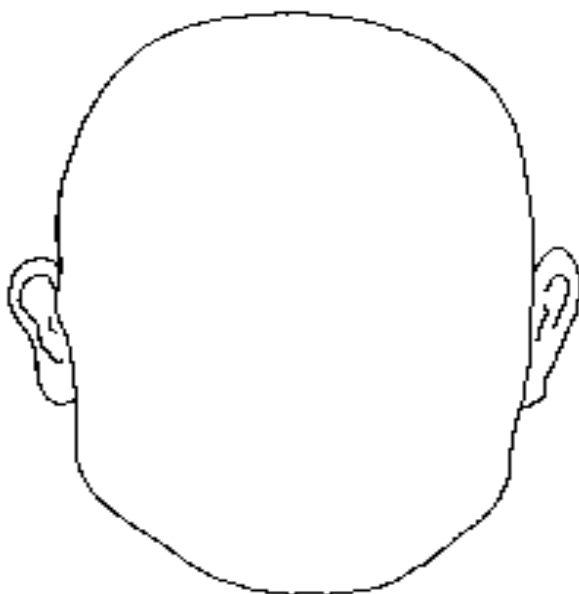
My Angry Face
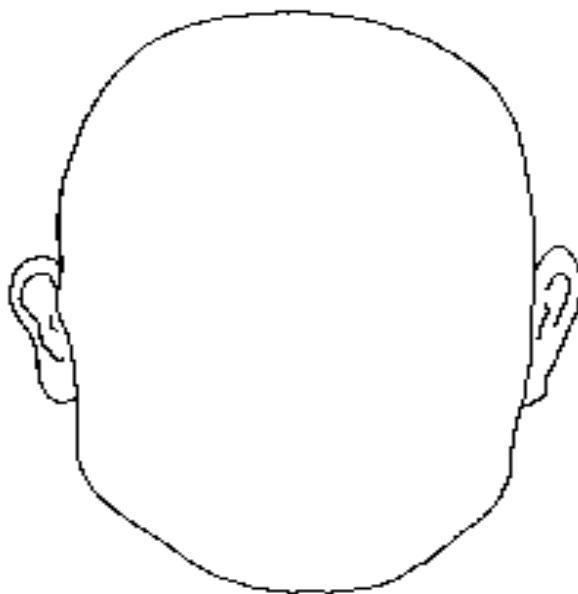
My Scared Face

Taken from "Cognitive behavioural therapy for child trauma and abuse: A step-by-step approach," by J. Feather and K. Ronan, 2010, Copyright 2010 by Jessica Kinsley Publishers.

My Body Reactions

Draw on the picture what happens when you are:

☐ **Relaxed and Calm**

☐ **Tense and Upset**

My Experience

What Happened…?

My Body Reactions

My Thoughts

My Actions

My Feelings

Calm breathing.

Hi there, Zoobi here! Can you remember what calm breathing is? Calm breathing helps you to focus on your breathing and forget what is happening around you. This may be a useful skill to use when you are feeling scared, sad or worried. Can you remember how to do calm breathing? If you are not sure, read through Steps 1-6 to refresh your memory.

Step 1:
To do calm breathing, you need to sit or lie in a comfortable position. Close your eyes and relax.

Step 2:
Take a deep breath in by breathing in through your nose.

Step 3:
Let it out slowly through your mouth. You can make a hissing sound (sssssssssss) if you like. Try and relax your body while you are doing this.

Step 4:
You may want to say the word "calm" in your mind while you are breathing out.

Step 5:
Another way of doing calm breathing is to blow bubbles with a bubble blower. You will need to open your eyes to do this one!

Step 6:
Take a long, slow breath in and blow out slowly through the bubble blower. You may notice that as you breathe out, the scary feelings seem to go away.

Magic Breathing
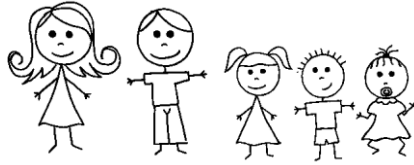
☺ **First of all, close your eyes… and just pat your legs and your tummy and your arms and your head…**

☺ **Then give your head a little massage, just by rubbing gently behind your ears, and you put your arms slowly, slowly by your side and you start to take big deep breaths.**

☺ **You breathe with your stomach, so that your stomach moves out and in. Just gently – ever, ever so softly.**

☺ **As you breathe, you imagine that you have holes in your feet.**

☺ **As you breathe in through your nose or your mouth, the air moves all the way down through your body and then out of the holes in your feet.**

☺ **Just imagine that the cool air around your nostrils is fresh air and then the air goes in through your nose or mouth all the way down your body, and comes out as warm, lovely… feet breath!!!**

☺ **It's like a nice big circle that goes from your feet, up to your head, through your middle and out again.**

☺ **Your can do 'Magic Breathing' any time, even in the daytime.**

☺ **If you are waiting for someone or if you are a little bit scared, you can do 'Magic Breathing'.**

Adapted from Janet Hall (2001)

The Dandelion Story
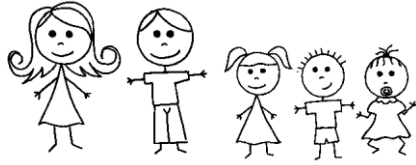
☺ **First of all, close your eyes and wiggle your body around so you are comfortable.**

☺ **Imagine you are sitting on your front step waiting for your friend to arrive.**

☺ **The sun is shining and you're nice and warm.**

☺ **Take a deep breath and hold it (1 – 2 – 3).**

☺ **Now imagine you are holding a dandelion flower and you want to blow it gently so that the flower floats away in the breeze.**

☺ **You sound like a balloon letting the air hiss out.**

The Floppy Vs. Robot Game
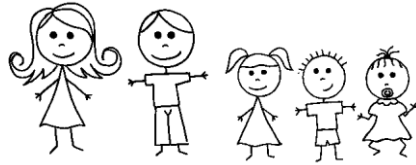
Being floppy (relaxed):

- ☺ **Imagine you are becoming loose and floppy.**

- ☺ **Imagine that your feet can be flopped from side to side and that there is a ripple of rubbery stuff that moves all the way up through your legs, into your body, through your neck and into your head.**

- ☺ **The rubbery stuff makes you feel a bit like jelly. All loose and floppy, just like a floppy rag doll.**

- ☺ **You take a great BIG deep breath and you relax and you feel really good, just like a big bowl of jelly, all loose and floppy.**

- ☺ **You take another deep BIG breath and you are feeling good; relaxed and comfortable.**

Being a robot (tense):

- ☺ **Do you know what a robot looks like and how they walk?**

- ☺ **Therapist models this to the child, while pointing out how stiff the movements are compared to being floppy.**

- ☺ **Now, can you show me how a robot moves?**

- ☺ **Therapist points out this is the difference between tension and relaxation.**

Adapted from Janet Hall (2001)

Going to the Beach
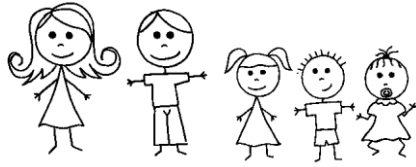
It is a lovely sunny day.

A really good day to go to the beach to look at shells and build sand castles.

You take off your socks and shoes and roll up your pants legs.

You decide to go for a paddle in the water.

The water is nice and warm where the sun has been.

The sand is wet and warm and squishes under your feet.

The sand is oozing between your toes.

The water is nice and warm as it splashes you up to your knees.

You decide to collect shells so you can build a sandcastle.

You find some really pretty shells, all different shapes and colours.

You find a really sunny spot in the sand to build your sand castles.

The sand is nice and dry and the sun is really warm.

You make some really big sandcastles and decorate them with shells that you found along the beach.

You decide to lie down on the sand because the sun is nice and warm and you are feeling all relaxed.

The sky is clear, clear blue, and above you, you can see a small white cloud that is floating away into the distance.

It is getting smaller and smaller.

And you are feeling more and more relaxed.

The clouds have floated away and you are feeling more relaxed.

You are feeling like a big bowl of jelly all floppy and relaxed.

Muscle Relaxation. ∞

Some situations you experience in hospital may make you feel nervous. I am going to teach you some special relaxation exercises that can help you to feel calmer. You can use these exercises whenever you are feeling uptight or nervous. It is best if you are able to sit in a comfortable chair, but you can also do them while in bed. You will need to squeeze tight the muscles in each of the following body parts, hold it while you count to 8 and then relax it.

How do I relax my hands?
Pretend you have a tennis ball in your left hand. Squeeze the ball really hard. Feel the tightness in your hand and arm. Count to 8 while you squeeze, then let go and relax. Let your hand and arm go all floppy and soft. Doesn't it feel good now?! Take the ball in your right hand and do the same.

How do I relax my arms and shoulders?
Pretend you are a weight lifter in the Olympic Games. Your arm muscles are very strong. Flex your muscles and show us how big they are. Hold this position while you count to 8, then relax. See how good your arms feel when they relax.

How do I relax my shoulders?
Now pretend that you are just waking up and you are having your morning stretch. Stretch your arms right up to the sky, as far as you can reach. Count to 8, then relax. Let your arms drop down to your sides and relax. Notice how good they feel when they are soft and floppy.

How do I relax my jaw?
Pretend that you have just bitten into a hard biscuit. It is really hard. Bite down on it. Use your neck and jaw muscles. Then relax. You still haven't managed to bite some off. Have another go and bit really hard. Harder! Yes, you have managed to bite some off. Now relax as the biscuit melts in your mouth.

How do I relax my face?

Pretend that a little butterfly has landed on your nose. Try to get him off without using your hands. Screw up your nose and try to get him to fly away. Screw your nose up really tightly and count to 8. Great, he has flown away. Oh, no, he has landed on your forehead! Wrinkle up your whole face and count to 8. Great, he has gone for good now. Relax. Your face now feels smooth and relaxed.

How do I relax my stomach?

Pretend that you are trying on a pair of jeans that have been given to you. You are trying to do the button up, but they are too tight around the waist. You squeeze your tummy muscles in while you try to do up the button. You just can't get them done up. Relax. Try again. Suck your tummy in tightly and count to 8. Relax. You decide that it is not worth trying to do them up any more as they are too small for you. See how good your stomach feels when it is relaxed!

How do I relax my legs and feet?

Pretend that you are lying on the soft sand at the beach. Wriggle your toes in the sand. You can feel the warm sand moving between your toes. Dig your toes into the sand. Push your heels down into the sand and count to 8. Relax. Squish your toes into the sand again and press your feet into the sand. Relax. See how good they feel when they are relaxed.

Well done!

You have relaxed all your body parts. Try to stay relaxed now. Let all your muscles go soft and floppy.

Keep your eyes closed while you let all your muscles relax. Think about how good it feels to work hard then relax. If you feel sleepy, let yourself drift off to sleep.

If you are not sleepy, open your eyes and gently start to wriggle.

Congratulations, you are a really good relaxer!

Mind Pictures.

Mind pictures are fun and easy to use! You can make a Mind picture by using your imagination to focus on pictures in your mind. Mind pictures can help you to relax.

You can use this skill when you are having a procedure done or when you can't sleep. If you use it while having a procedure done, you may be concentrating so hard on your mind pictures that you do not notice that the procedure is happening.

Lets have a go! Firstly, you need to lie or sit comfortably. Close your eyes and let your muscles go all soft and floppy. Imagine a place that is warm, safe and makes you feel happy. You could imagine that you are at the beach, swimming under water, in a garden, in fairyland, at the circus, on an island, in space, at the zoo or in a jungle. Let's practice by imagining that you are in a jungle.

What can you see?
What are you wearing?
Who is with you?
What are you doing?
What can you smell?
What can you touch?
What can you hear?

Busy Brainwaves.

Hi, Zoobi again! Can you remember what *busy brainwaves* are and why this skill might be useful? Keeping your mind busy or having 'busy brainwaves' helps you to focus on something pleasant around you other than the things that worry you.

You can use this skill when you are having a procedure done, when you are alone or even when you are bored.

There are a number of ways to keep your mind busy.
Here are some suggestions which can all be done while you are in bed:

★ Look at the pictures and paintings on the walls and ceiling and think of a story to go with them.
★ Read a book
★ Watch television
★ Listen to music
★ Draw a picture
★ Write a letter or story
★ Play a game or do a puzzle
★ Play cards
★ Blow bubbles
★ Play with your toys
★ Talk to the nurses or other children

These are just some ideas. Can you think of any other activities you can do to keep your mind busy?

1._____

2._____

3._____

4._____

Thought People

Positive Self-talk.

Howdy, Zoobi here. Can you remember learning about positive self-talk in the CD? Positive self-talk or coping thoughts can help you to handle difficult situations while you are in hospital.

When you feel scared, nervous or angry you can help yourself to feel better by using coping words or thoughts.

Let me give you some examples:

Instead of saying "I don't like this doctor because he put a drip in me" you could say, "This doctor did a good job. I needed to have a drip so that I can have the medicine to make me better."

Another example might be:

"Hospital is ok, there are some fun things to do here" rather than "I don't like hospital."

These children are learning to change their thoughts into positive thoughts. Can you work out which are the coping thoughts? Colour in the thoughts that you think are positive thoughts.
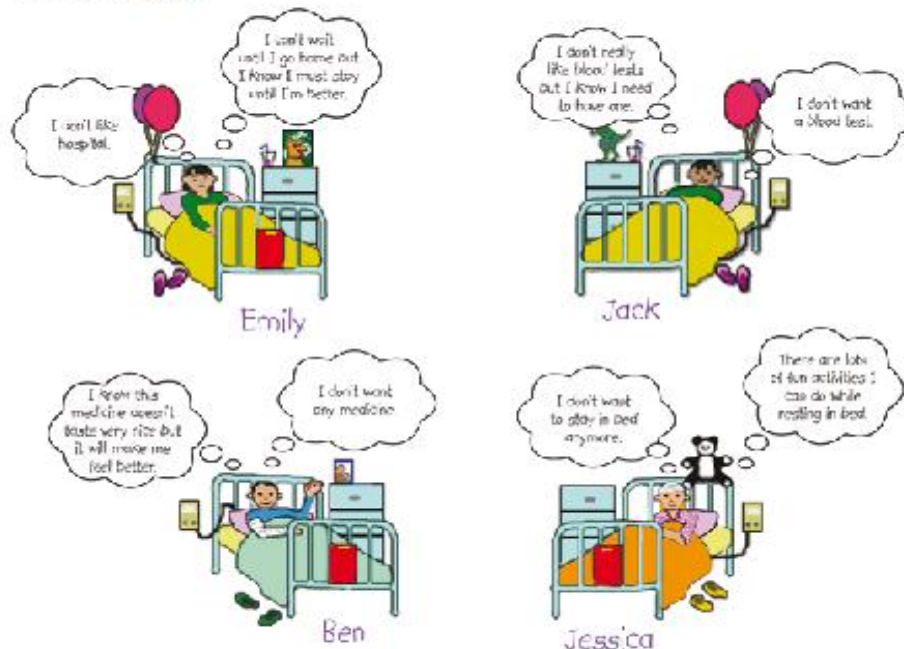
See how easy it is to say positive things! Can you think of any times when changing your thoughts would have made you feel better?

Practice using positive thoughts and write down some of your favourite positive thoughts.

What skills I will use.

Write in the skill(s) you plan to use if you:

can't sleep_____

feel worried_____

feel bored_____

feel sore_____

feel sick_____

have to have a test or procedure_____

calm breathing   busy brainwaves

muscle relaxation   positive self-talk

mind pictures

What I did when I had to have a test or procedure.

Keep a record of the tests you had and the skills that you used to make you feel less worried about them:

	8 muscle relaxation	+ positive self talk	mind pictures	busy brainwaves	calm breathing

TESTS TAKEN:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

CONGRATULATIONS

This certificate is awarded to:

for excellent participation in the

"Coping Kids Treatment Programme"

Date:…………

Signature:…………

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