

Dental Anxiety Amongst Paediatric Cardiology Patients

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DEDICATION

This research project is dedicated to my mother for her endless support and encouragement, especially over the past 3 years.

ABSTRACT

Background: The dental health of paediatric cardiology patients has been shown to be poorer than that of healthy children. Multiple factors could be implicated with dental anxiety potentially playing a major role. However, there is no published research specifically looking at dental anxiety amongst paediatric cardiology patients.

Aims: The primary aim was to determine whether there was a difference in the level of dental anxiety between paediatric cardiology patients and a group of healthy children. The secondary aim was to establish whether dental anxiety was affected by previous medical history as measured by number of overnight hospital admissions, number of general anaesthetics and cardiac complexity category.

Materials and Methods: Fifty-four participants were recruited into the study group from the outpatient cardiology clinic at Leeds General Infirmary. The control group comprised 53 children who attended consultant-led new patient orthodontic clinics. All participants were aged 8-16 years old. The children completed the Modified Child Dental Anxiety Scale (faces version) and their parents completed the Modified Dental Anxiety Scale along with a questionnaire regarding their child's medical and dental histories.

Results: The mean level of dental anxiety was significantly higher in the study group ($p < 0.05$). Other significant findings between the two groups related to socio-economic status, exodontia experience, overnight hospital admissions and general anaesthetic history. Analysis of covariance indicated that only the admission history might have had an effect upon child dental anxiety in this study.

Conclusion: Paediatric cardiology patients had significantly increased levels of dental anxiety. It is likely that aspects of their medical history, notably overnight hospital admissions, are moderating factors but due to the multifactorial aetiology of dental anxiety, further research is required in order to identify specific factors involved.

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GLOSSARY

ANCOVA	Analysis of covariance
ASD	Atrial septal defect
CDFP	Children's dental fear picture test
CFSS	Children's fear survey schedule
CFSS-DS	Children's fear survey schedule dental subscale
CHD	Congenital heart disease
dmft	Decayed, missing and filled teeth (primary dentition)
DMFT	Decayed, missing and filled teeth (permanent dentition)
FIS	Facial images scale
GA	General anaesthetic
GDP	General dental practitioner
IE	Infective endocarditis
IQR	Interquartile range
LA	Local anaesthetic
LDI	Leeds Dental Institute
LGI	Leeds General Infirmary
MCDAS	Modified child dental anxiety scale
MCDAS _f	Modified child dental anxiety scale (faces version)
MDAS	Modified dental anxiety scale
n	Number
SD	Standard deviation
SFP	Smiley faces program
SPSS	Statistical package for the social sciences
VPT	Venham picture test
VSD	Ventriculo-septal defect
YH	York Hospital

1.00 INTRODUCTION

In spite of being high priority for dental care, studies consistently show that children with cardiac disease have dental caries levels that are at least as high as the general population. In addition they seem to have high levels of untreated disease although most of the children in these studies appeared to have regular access to dental care. One possible barrier to the appropriate provision of dental care is the concept that children with chronic illness or a history of medical intervention are dentally more anxious and therefore more intolerant of dental treatment. The evidence for this is sparse, however, and mostly dates from the 70s and 80s since when delivery of medical treatment for children has changed significantly. No published research exists into the dental anxiety levels of this specific group of children.

2.00 REVIEW OF THE LITERATURE

2.10 FEAR AND ANXIETY

Anxiety is defined as a vague unpleasant feeling which is accompanied by the premonition that something unpleasant is about to happen; a “non specific feeling of apprehension” (Klingberg, 2008). Mild fear and anxiety are accepted as normal stages of cognitive development, as is shown by stranger and separation anxiety amongst infants and is a normal physiological and cognitive response to stressful situations in adults. However when such symptoms are experienced in the absence of a real threat, the anxiety response is considered abnormal.

Anxiety can be divided into trait and state anxiety. Spielberger (1970) defined state anxiety as a “transitory emotional state or condition of the human organism that is characterised by subjective, consciously perceived feelings of tension and apprehension, and heightened autonomic nervous system activity” i.e. a temporary reaction to a stressful situation. In comparison to this, trait anxiety is the level of anxiety experienced by someone who has a heightened anxiety response so that they have a tendency to be more anxious and react less appropriately to anxiety-provoking situations. It is state anxiety that is of particular interest when studying dental anxiety as it has been shown that children with higher state anxiety scores were almost three times more likely to be dentally fearful. Trait anxiety scores were not shown to influence dental fear (Chellappah et al., 1990, Holmes and Girdler, 2005). However, a positive relationship between dental fear and general fear has been reported (Brown et al., 1986, Klingberg and Broberg, 2007, Winer, 1982). In his review, Winer (Winer, 1982) recognised that the data presented was conflicting but still concluded that dental anxiety was related to other signs of anxiety. Klingberg and Broberg (Klingberg and Broberg, 2007) reviewed literature published from 1982 to 2006 and found that four out of the five studies included in their review reported a positive relationship between dental anxiety and general fears. However, evidence regarding the relationship between dental behavioural management problems and general fear was conflicting. Brown et al (Brown et al., 1986) collected data from 243 children aged seven to 11 years old and found that general anxiety was the most important factor influencing dental anxiety. They suggested that a child’s perception of the dental environment had a greater influence on dental anxiety than the actual reality of the dental situation and that

dental anxiety reflected a more generalised anxiety behaviour as opposed to being acquired following a specific event.

Fears are mainly thought to arise through direct conditioning experiences. However, this cannot explain the acquisition of all fears and phobias as the source of the fear is not always identifiable. Rachman (Rachman, 1977) proposed three main pathways of fear acquisition. Firstly, direct conditioning where the fear develops after a specific event - for example, the use of local anaesthetic. The majority of the evidence to support this is derived from laboratory studies and classical conditioning does not explain the fears in children without previous negative experiences of the fear-provoking stimulus (King et al., 1998). The second method is vicarious acquisition, which occurs through modelling experiences. This is an indirect method of fear acquisition whereby the child acquires their fear through the observation of others. The final method involves informational acquisition, another indirect pathway, where the child acquires their fear after hearing about negative experiences from their peers. Despite the paucity of evidence to support informational fear acquisition, it remains a well accepted pathway as it offers an explanation for why people can fear something they have yet to experience (King et al., 1998). Stimuli that provoke high-anxiety responses are more likely to have been acquired through direct conditioning experiences although the pathways should not be viewed independently as they can all be present (King et al., 1998). Rachman's theory has been challenged by studies that have included parental reports of children that "have always been afraid" of particular stimuli, for example water (King et al., 1998).

2.20 DENTAL ANXIETY

2.21 Prevalence of dental anxiety

Dental anxiety is common. It is estimated to affect 31% of adults (McGoldrick P, 2001) with a prevalence in childhood ranging from 5.7 – 19.5% (Klingberg and Broberg, 2007). It differs from dental fear which is the response elicited to a specific threatening stimulus. In comparison, dental anxiety is more vague and often not associated with specific stimuli. However, these differences are often difficult to distinguish and the terms are often used interchangeably. The effects of dental fear and anxiety are not restricted to dentistry and have been shown to impact upon daily living in aspects such as interpersonal relations and sleep

patterns (Cohen et al., 2000). When fears impact significantly upon daily living, the term phobia can be applied.

2.22 Aetiology of dental anxiety

The aetiology of dental anxiety is multifactorial with temperament, age, maturity, and emotional status as well as dental and social factors being involved (Ten Berge M., 2002, Pollard and Curzon, 1992, Klingberg, 2008, Klingberg and Broberg, 1998). Different origins of dental anxiety were proposed by Weiner and Sheehan as either being exogenous, whereby the anxiety develops via conditioning experiences or endogenous where the anxiety is related to general psychological states and anxiety disorders (Weiner and Sheehan, 1990). In general, evidence supports the concept that childhood dental anxiety is more likely to be of exogenous origin rather than endogenous, the latter being more commonly associated with adult-onset anxiety (Locker et al., 1999). A longitudinal study by Klaassen et al (Klaassen et al., 2008) supported the theoretical framework of conditioning and demonstrated that fear in children can be prevented by gradual exposure to the dental environment over a period of time. There is also evidence (de Menezes Abreu et al., 2011) to suggest that gradual exposure of young children to the dental environment could also reduce children's dental anxiety even when operative treatment was performed, although local anaesthetic was not routinely used in this study. Furthermore, a previous positive or neutral dental experience prior to an invasive treatment may 'protect' against the development of dental anxiety (Milsom et al., 2003, Ten Berge M., 2002). This may explain the few studies where anxiety has been shown to be higher in children who have not undergone invasive procedures (Murray et al., 1989). This finding has been termed the Latent Inhibition Theory. In this way, patients who have greater experience of non-painful dental procedures prior to their first painful experience have been shown to have lower levels of dental anxiety (de Jongh et al., 1995). Vicarious learning has also been documented as a possible source of dental anxiety i.e. when negative personal experiences are described to the patient by peers (Tickle et al., 2009, Kleinknecht et al., 1973).

2.221 External Factors

Childhood dental anxiety has been associated with parental anxiety (Tickle et al., 2009, Nuttall et al., 2008, Milsom et al., 2003, Ten Berge M., 2002, Townend et al., 2000, Pollard and Curzon, 1992, Shaw, 1975) and lower socio-economic status (Nuttall et al., 2008, Townend et al., 2000, Wogelius et al., 2009). Patients with dental anxiety originating during childhood are more likely to have an anxious family member than those whose anxiety begins later on in life (Locker et al., 1999). The relationship between parental and child dental fear has been well researched. A meta-analysis including 43 studies confirmed the association between parental and child dental fear and reported that the relationship is most evident in children aged eight years and under (Themessl-Huber et al., 2010).

The dentist's management techniques and manner has also been shown to influence a patient's response to dentistry. Their fear response could be heightened if the patient believes their dentist is unsympathetic (Townend et al., 2000) or if they view the dentist negatively (Kleinknecht et al., 1973). A recent systematic review concluded that an empathic approach combined with an appropriate level of physical contact, such as a reassuring hand on the patient's shoulder, can reduce child dental anxiety (Zhou et al., 2011). The dentist's behaviour has been shown to be the most important factor in early-onset anxiety whereas fear of pain seems to be a major factor in adult-onset anxiety (Berggren and Meynert, 1984).

2.222 Factors relating to the child

Younger children display an inferior coping ability and are at a lower stage of psychological development. It is, therefore, understandable that younger children have been found to be more anxious (Buchanan, 2005, Klaassen et al., 2008, Klingberg and Broberg, 2007, Versloot et al., 2008). Anxiety should reduce with increasing age (Cuthbert and Melamed, 1982) although several studies have failed to show any impact of age (Klingberg and Broberg, 2007) and some reported an increase in dental anxiety with age (Murray et al., 1989, Tickle et al., 2009). Suggested explanations for increased dental anxiety in adolescents are increased awareness of the risks associated with dental treatment, an increased likelihood of previous negative invasive dental procedures and pubertal changes (Winer, 1982).

Temperament has also been shown to influence dental anxiety. Children who are shy or display negative emotionality have been reported to be at increased risk of dental anxiety (Klingberg, 2008).

Whether dental anxiety is more common in females is unclear. However, most research indicates that dental anxiety is higher amongst girls (Brown et al., 1986, Kleinknecht et al., 1973). Liddell (Liddell, 1990) postulated that the dentally anxious girls in his study were more influenced by internal factors, such as temperament, whereas the boys were more affected by external ones such as the extent of their hospital stay for dental treatment. He also reported that girls were rated significantly more fearful in relation to medical fears. Girls are perhaps more willing to discuss their concerns than boys who generally wish to be thought of as stoical. This could be a factor in studies that have shown an increase in dental anxiety amongst females (Tickle et al., 2009, Klaassen et al., 2008, Klingberg and Broberg, 2007, Winer, 1982). However, several studies have reported no difference in dental anxiety between the sexes (Versloot et al., 2008, Buchanan, 2005, Buchanan and Niven, 2003, Ten Berge M., 2002, Locker et al., 1999).

2.223 Dental Factors

Childhood dental anxiety is related to a greater experience of invasive dental treatment (Karjalainen et al., 2003, Milsom et al., 2003, Ten Berge M., 2002) and general anaesthetic (Howard and Freeman, 2007, Nuttall et al., 2008, Shaw, 1975). Anxiety has also been associated with an irregular pattern of dental attendance, an increased time interval since the last dental visit and a history of dental extractions (Bedi et al., 1992a, Bedi et al., 1992b, Milsom et al., 2003, Tickle et al., 2009). It is difficult to determine whether anxiety is the causative influence in poor attendance patterns and subsequent levels of treatment need or whether high treatment need results in increased dental anxiety.

Local anaesthetic and the drill have been shown to be the most anxiety provoking stimuli (Buchanan, 2005, Kleinknecht et al., 1973) although restorative treatment per se has not been associated with dental anxiety (Milsom et al., 2003, Tickle et al., 2009). An exception to this was discovered in 12 and 15 year old patients (Nuttall et al., 2008). Although the authors suggested no possible explanations for

this, the need for local anaesthetic for restorative techniques in these age groups could be a factor. Following their prospective study of dental anxiety in children, Tickle et al (Tickle et al., 2009) proposed that the lack of a relationship between restorative treatment and dental anxiety could be attributed to the use of the controversial atraumatic restorative technique by many general practitioners for the restoration of primary teeth.

Dental anxiety has been shown to be associated with the child's appreciation of their own treatment need (Bailey et al., 1973). Children who were aware that they needed some form of treatment were more dentally anxious. More negative behaviours were displayed by children who knew they had a dental problem (Wright and Alpern, 1971, Bailey et al., 1973). Wright and Alpern (Wright and Alpern, 1971) proposed the negative behaviours reflected a higher level of anxiety in these children.

2.224 Medical Factors

In a case-control study of children referred to a specialist centre due to behavioural management problems (Holst, 1988), 50% of the study group had a history of hospitalisation compared to 29% of the controls. Many were found to have medical problems and were afraid of doctors' visits. The authors linked these previous medical experiences to dental anxiety and their resultant behavioural management problems. Wright and Alpern (Wright and Alpern, 1971) similarly discovered an association between medical experiences, in particular painful experiences, and poor cooperation at the first dental visit. A more recent study (Colares and Richman, 2002) also related previous hospitalisation and health problems with behaviour in the dental setting.

There are also studies specifically examining dental anxiety (not solely behavioural management problems) and its relationship to previous medical experiences. These are important as behaviour management problems are not necessarily synonymous with dental anxiety. Dentally anxious children can display positive behaviour in the dental environment. Children who have experienced frequent medical experiences have been shown to have increased dental anxiety (Karjalainen et al., 2003). Furthermore, those who have experienced unpleasant

medical contacts are significantly more likely to have a high level of dental anxiety (Bailey et al., 1973, Majstorovic et al., 2001, Sermet, 1974).

2.23 Consequences of dental anxiety

The course and factors involved in anxiety progression or cessation are difficult to determine as there are few longitudinal studies investigating dental anxiety in children. However, a recent prospective study by Tickle et al (Tickle et al., 2009) which followed a cohort of children from age five to nine years showed that anxiety is not stable over time – half of the children who were categorised as anxious at age five were not anxious at age nine and 11.7% of children were found to be anxious at age nine despite being previously classed as non anxious at age five. This finding is supported by another three-year longitudinal study by Klaassen et al (Klaassen et al., 2008).

Evidence has suggested that childhood dental anxiety can continue through to adulthood (Locker et al., 1999) and can be severe enough to impact negatively upon dental attendance in 3-4% of children. Whilst this percentage may seem low, the increased number of general anaesthetics experienced by this group is significant (Nuttall et al., 2008).

Anxiety can lead to significant impairment. Anxious children can not only present with more behavioural management problems (Klaassen et al., 2008, Gustafsson et al., 2010a), but also significantly higher levels of caries experience (Milsom et al., 2003, Shaw, 1975, Townend et al., 2000). However, anxiety is not the only factor implicated in behavioural management problems (Blomqvist et al., 2006, Klingberg and Broberg, 2007) and it has been shown that there is only partial overlap in these conditions (Klingberg et al., 1995). It has been demonstrated that anxious children can achieve definitely positive Frankl ratings (Ramos-Jorge et al., 2006).

Caries experience was found to be 44% higher in dentally anxious children amongst a group of 14-year-old schoolchildren in Scotland (Bedi et al., 1992a). The same study also revealed that for the dentally anxious group, fewer fissure sealants had been placed, more caries was left untreated, and the children were

more likely to have received a dental general anaesthetic. However, only the findings related to the fissure sealants were significant. An increased number of restored teeth in the high dental anxiety group contributed most to the higher DMFT value. This may support the idea that anxiety results from increased dental experience. The notion that anxiety results in the avoidance of dental appointments was also supported by this study. Those with high dental anxiety or general fear were more likely to defer, cancel or fail to attend dental appointments. Such avoidance behaviour can result in poorer dental health (Bedi et al., 1992a, Berggren and Meynert, 1984). Bedi et al (Bedi et al., 1992a) illustrated that it is unclear whether anxiety results from an increased experience of dental care or whether anxiety manifests in dental avoidance, which subsequently leads to an increased need for treatment. Either way, dental anxiety is recognised as a considerable barrier to the access of oral health services.

2.30 MEDICALLY COMPROMISED CHILDREN

2.31 Dental Health

Poor oral health in chronically sick children is associated with significant morbidity and can have serious complications. Studies have indicated that paediatric dental patients with special needs, be it psychological or medical, also have poorer dental health despite being regarded as high priority for dental care (Roberts and Roberts, 1981, Shaw et al., 1986).

Chronically sick children have not only been found to have significantly higher caries levels (Roberts and Roberts, 1981, Welbury et al., 2003) but also a significantly greater amount of untreated caries (Pope and Curzon, 1991). Exceptions to this finding include children with cystic fibrosis (Kinirons, 1985) and chronic renal failure (Al-Nowaiser et al., 2003) and have been related to frequent antibiotic usage, significantly greater saliva buffering capacity and greater salivary pH seen in these groups. Others findings in this high priority population were poorer gingival health and restorations of a significantly lower standard when compared to healthy control children (Pope and Curzon, 1991).

Poor oral health not only leads to caries but also periodontal conditions, candidiasis and the risk of bacteraemia which can all have serious consequences,

especially in immunocompromised patients. In view of this, causal factors should be eliminated as much as possible. Such factors include the chronic use of cariogenic medication, xerostomia as a result of medication or radiotherapy, frequent ingestion of cariogenic foodstuff during oncology treatment and dental health being given a low priority by the families of chronically sick children (Roberts and Roberts, 1981).

Parry and Khan (Parry and Khan, 2000) distributed questionnaires and assessed the provision of dental care for medically compromised children by general dental practitioners (GDPs). They concluded that this patient population experienced barriers to care. Eighty percent of the GDPs felt they would benefit from further training in the provision of care for medically compromised children. In contrast, Mattila et al (Mattila et al., 2001) found that children with chronic illnesses accessed dental health services more frequently but their families were often less satisfied with the standard of care they received compared to the control population.

2.32 Dental anxiety of medically compromised children

There has been conflicting findings in studies examining dental anxiety in children with special needs. Blomqvist et al (Blomqvist et al., 2006) discovered that attention-deficit-hyperactivity disorder patients displayed more behavioural management problems, as would be expected, but found no significant difference in their dental anxiety levels measured using the Children's Fear Survey Schedule Dental Subscale questionnaire (CFSS-DS) when compared to a control group. Cancer and its treatment were also not associated with increased dental anxiety (Wogelius et al., 2009) although the sample population in this study was small. The authors suggested this could have been due to extra careful handling by the dentist as a result of the oncology diagnoses. Furthermore, they suggested that dental treatment is less invasive than some of the medical treatments the children would have experienced and, therefore, less anxiety provoking. It was also suggested that oncology patients have developed effective coping strategies (Wogelius et al., 2009). A Swedish study found no difference in the prevalence of dental anxiety between a group of 12-14 year old preterm adolescents when compared to a group of full-term controls matched for age, gender, ethnicity and dentist (Brogardh-Roth et al., 2010). This was despite a statistically significant

increase in reported general health problems in the preterm patients ($p=0.047$). Although it should be noted that only limited information on the medical health of the children was provided in terms of chronic illness, general health problems and medication. It has been shown that dental apprehension is associated with frequent exposure to invasive medical care (Karjalainen et al., 2003). A prospective study by Karjalainen et al (2003) took place over six years and examined children already enrolled in a randomised trial examining “Coronary Risk Factor Intervention” in Finland in which recurrent middle ear infections, pharyngitis, sinusitis, juvenile diabetes and thrombocytopenia were classed as invasive medical conditions. The authors found a significant association between dental apprehension and exposure to invasive medical conditions and their treatment at nine years of age.

Sermet in 1974 (Sermet, 1974) showed that 53% of anxious children in his study population of 100 children had some form of illness compared to 37% of children in the control group. Moreover, dentally anxious children were taking significantly more medication such as bronchodilators, antihistamines and tranquilisers. The anxious children had also experienced significantly more hospital admissions, outpatient appointments and traumatic medical experiences. Such experiences may have long-term psychological effects on the child.

2.40 PAEDIATRIC CARDIOLOGY PATIENTS

2.41 General health and Infective Endocarditis

Congenital heart disease (CHD) is one of the most common developmental anomalies affecting approximately 7:1000 (1 per 145) births in the UK (Peterson S., 2003) with increased survival rates due to advances in medical care. Over 80% of children born with CHD will survive into adulthood (Peterson S., 2003).

Congenital heart disease results from an abnormality of heart structure or function, and encompasses lesions such as aortic or pulmonary stenosis, ventriculo-septal defects (VSD), atrial septal defects (ASD), coarctation of the aorta, Tetralogy of Fallot and transposition of the great arteries (Jowett and Cabot, 2000, Moore R.S., 1989). In 10-15% of cases, children have more than one cardiac anomaly and a similar percentage have an associated non-cardiac anomaly (Parry et al., 1998). In view of this, children with CHD are frequently exposed to the hospital environment for routine follow up and investigations, some of which are invasive. As a result, an

increased anxiety level in such situations is to be expected which can then impact upon dental anxiety and create barriers to dental intervention resulting in poorer dental health. There are already several potential complications of CHD with regards to dental treatment including anticoagulant medication, polycythaemia secondary to chronic hypoxaemia, bleeding abnormalities, immunosuppression (heart or heart/lung transplant recipients) and the effects of immunosuppressants such as gingival hyperplasia (Parry et al., 1998). In addition to this is the susceptibility to infective endocarditis as a result of oral bacteraemia which is associated with significant morbidity and can be fatal in 30% of cases (Scully and Cawson, 1998).

Infective endocarditis (IE) is infection of the heart valves or endocardium by bloodborne microorganisms. Although IE is rare in children (approximately 0.3 cases/100 000 children per year (Carmona et al., 2002), its incidence may be increasing (Ferrieri et al., 2002). This trend can largely be explained by the increased survival rate of children with CHD. Whilst prophylactic antibiotics prior to invasive dental treatment are no longer recommended by the National Institute of Clinical Excellence (NICE, 2008), children with CHD are still considered at risk and good dental health is imperative to reduce the risk of everyday bacteraemia.

2.42 Dental Health of Paediatric Cardiology Patients

Despite the need for optimum oral health, many children with CHD have significant levels of dental disease. A Swedish study (Stecksen-Blicks et al., 2004) showed that despite having more caries preventive interventions (based on fluoride use), patients with complex CHD had higher levels of caries than the control population. This increase was statistically significant in the primary dentition and supports the findings of Hallett et al (Hallett et al., 1992). However, the authors noted that the use of fluoride was often instigated after caries diagnosis and that this may have been a result of irregular dental care in the early years. Other studies have supported the finding of increased caries levels in children with congenital heart disease (Pollard and Curzon, 1992) although this increase is not always significant (da Fonseca et al., 2009, Tasioula et al., 2008). Either way, patients with CHD have at least similar caries levels as the general population. Factors such as cariogenic medicines (Hallett et al., 1992) and nutritional difficulties have been

implicated (Stecksen-Blicks et al., 2004) in the studies which have shown increased caries levels.

A worrying consistent finding is increased levels of untreated caries in cardiac patients (Balmer and Bu'Lock, 2003, Berger, 1978, Franco et al., 1996, Jowett and Cabot, 2000). In Berger's study (Berger, 1978), healthy children had the lowest treatment needs and cyanotic children had the greatest. The high levels of untreated caries could be due to patients being unable to access dental care or dentists being unable to meet their treatment needs. A retrospective study of 370 paediatric cardiology patients attending the Royal Hospital for Sick Children in Glasgow discovered that 32% of the participants had untreated decay and 5% of the parents admitted that their children never brushed their teeth (Busuttill Naudi et al., 2006).

2.43 Dental Attendance

In a postal questionnaire study by Gordon et al (Gordon et al., 1998) aimed at patients with special health care needs, dental fear/anxiety was rated as one of the most commonly reported barriers to accessing oral health care. Furthermore, the frequency of dental visits was significantly lower in those who reported increased levels of fear/anxiety. da Fonseca et al (da Fonseca et al., 2009) investigated the attendance patterns of children with CHD and discovered that almost half of the children with cardiac disease in their study had never seen a dentist. A low dental attendance was also found by Saunders and Roberts (Saunders and Roberts, 1997) where almost one fifth of CHD patients had not seen a dentist. The barrier to dental treatment that dental anxiety presents is a possible factor in this trend. Furthermore, studies have shown that even when patients do attend, they are not provided with adequate professional oral health education or preventive measures (Tasioula et al., 2008) and their knowledge of infective endocarditis is poor (Balmer and Bu'Lock, 2003, Hallett et al., 1992). However, it has been shown that patients registered with a general dental practitioner had significantly greater knowledge of IE compared to those who were not (Balmer and Bu'Lock, 2003). Even so a good dental knowledge and attitude does not always translate into good routine dental practices (Berger, 1978). Whilst antibiotic prophylaxis for endocarditis is no longer routinely practised, prophylaxis by means of effective preventive measures and education is still of paramount importance. Dental care is often complicated by the risk of IE associated with an oral bacteraemia resulting

in more radical treatment planning e.g. extraction of primary teeth instead of pulp treatments, the increased risk of general anaesthetic, and the risk of bleeding problems in those taking anticoagulants. This could explain why Parry and Khan (Parry and Khan, 2000) discovered that only 37% of general dental practitioners felt confident in providing treatment for children with cardiac disease.

2.44 Dental Anxiety of Paediatric Cardiology patients

There is no published data on dental anxiety amongst paediatric cardiology patients. However, da Fonseca et al (da Fonseca et al., 2009) discovered that parents of cardiac children believed their children became significantly more irritated and frustrated as a result of dental problems than the control group. Patients with dental anxiety may avoid attending resulting in less opportunity to instigate effective preventive regimes and identify caries and pathology at an early stage. The increased prevalence of caries which has been shown in medically compromised patients when coupled with dental anxiety and its potential adverse effect on dental attendance could have damaging effects.

2.50 MEASURES OF DENTAL ANXIETY IN CHILDREN

There are four main methods of measuring anxiety in children. These are behaviour ratings by observation of the patient, physiological measures, projective techniques and psychometric tests.

2.51 Behavioural Tests

The Frankl scale developed in 1962 (Frankl, 1962) is amongst the most frequently used behaviour scales. It consists of four behaviour categories ranging from definitely positive to definitely negative which are assigned by the treating clinician and can be applied at various stages during treatment. Other behaviour scales include Venham's scales and Melamed's behaviour profile-rating scale. One of the main problems associated with using behaviour ratings in anxiety assessment is that the absence of non-cooperative behaviour does not necessarily equate to the absence of anxiety. Behaviour ratings are subjective and their reliability and validity is heavily dependent on the training of the observer. Additionally, studies have shown only moderate agreement between the dentist's perception of a child's anxiety from clinical observation and the child's own rating (Buchanan and

Niven, 2003) which strengthens the need for a patient-assessed measure. However, behavioural measures may be the only practical method of assessing dental anxiety for some children.

2.52 Physiological Tests

Physiological measures require special monitoring equipment to assess physiological changes such as heart rate, blood pressure, respiration, muscle tension and basal skin temperature. Whilst these techniques gain objective results, they can be difficult to interpret. Studies have demonstrated increased pulse rates in children rated as anxious by their parents (Howitt and Stricker, 1970, Myers et al., 1972) but this increase may not solely be due to anxiety. It is impossible to exclude potential confounders such as the mere presence of the equipment or other external stimuli.

2.53 Projective Techniques

Projective techniques gain information on a child's anxiety levels through the interpretation of tasks such as figure drawing or story-telling. An assessment tool based on drawing, Child Drawing: Hospital (CD:H), has been proposed for the measurement of anxiety in hospitalised children (Clatworthy et al., 1999). The CD:H has also been used to assess children's dental anxiety and was shown to correlate with the Frankl behaviour rating scale (Aminabadi et al., 2011). However, a direct measurement of anxiety requires careful interpretation of the drawings and the use of a specific rating scale which is time-consuming. Furthermore, projective techniques often lack measures of reliability (Winer, 1982).

2.54 Psychometric Tests

There are various psychometric tests that have been used for measuring anxiety in children. The most commonly used measures are shown in table 1.

Table 1. Commonly used dental anxiety assessment methods

Measure	Description
Children's Fear Survey Schedule Dental Subscale (CFSS-DS)	Asks children to rate their fear of 15 situations from 1 (not afraid) to 5 (very afraid). Scores above 38 indicate significant dental fear (Newton and Buck, 2000) whilst scores below 32 are non-clinical (Versloot et al., 2008). Mainly used in 2 versions 1) self-reported 2) reported by parent.
Modified Child Dental Anxiety Scale (MCDAS)	8 questions asking how relaxed or worried the child is in different situations e.g. having a filling. Child rates how they feel from 1 (not worried) to 5 (very worried) (Buchanan, 2005).
MCDAS _f	8 questions asking how relaxed or worried the child is in different situations e.g. having a filling. Child rates how they feel from 1 (not worried) to 5 with a faces rating scale.
Venham Picture Test (VPT)	Consists of a series of 8 paired drawings of a child. 1 picture in the pair represents a fearful pose and the other non-fearful. The child is asked to pick the one that best describes how they feel.
Facial Images Scale (FIS)	Involves asking the child to point to 1 of 5 faces which represents how they feel. The faces range from very happy (scores 1) to very unhappy (scores 5).
Smiley Faces Program (SFP)	4 item computerised scale comprising of a series of faces which aim to describe the child's response to a range of dental interventions. The child is first presented with a neutral face then questions appear on the screen for a few seconds during which the child is asked to replace the neutral face with 1 of 7 faces that best describes how they feel about the dental item in question.
Children's Dental Fear Picture Test (CDFP)	Consists of 3 subtests 1) Dental setting pictures – 10 pictures of animals in different dental care situations 2) Pointing pictures – 5 pictures showing a child in different dentally related situations 3) Sentence completion task – 15 incomplete sentences which the child is asked to complete.

The Children's Fear Survey Schedule Dental Subscale (CFSS-DS) is a revised version of the Children's Fear Survey Schedule (CFSS), designed by Scherer and Nakamura. CFSS has good psychometric properties and assesses a range of general fears but is relatively long which prompted the development of the dental subscale (CFSS-DS). This revised scale included specific dental items and covered different aspects of medical and dental treatment situations (Blomqvist et al., 2006). It has correlated well with the full scale scores (Cuthbert and Melamed, 1982), has shown good reliability, validity and internal consistency (Klaassen et al., 2008, Ten Berge M., 2002) and is the most commonly used anxiety measure especially with younger patients (Klingberg and Broberg, 2007). However, CFSS-DS has received criticism for not having standardised cut off points and the level of agreement between parental and child versions has not been fully investigated (Klingberg and Broberg, 2007).

Both the Modified Dental Anxiety scale (MDAS) and MCDAS were based on Corah's Dental Anxiety Scale (Corah, 1969) but include an item regarding local anaesthetic. MDAS is the most frequently used scale for adults (Dailey et al., 2001) and has been shown to have good internal consistency (Humphris et al., 2000, Humphris et al., 1995, Newton and Edwards, 2005) good test-retest stability (Humphris et al., 1995, Newton and Edwards, 2005) and validity (Humphris et al., 2000). Scores range from five (no/little dental anxiety) to 25 (extreme dental anxiety) with a cut-off point at 19 to identify dentally phobic patients. MCDAS is more appropriate for use in children and has also shown good reliability and validity and assesses specific child dental fears. A faces version of the MCDAS (MCDAS_f) was developed to overcome possible comprehension difficulties of younger children when presented with a numerical scale as in the original version. Howard and Freeman (Howard and Freeman, 2007) concluded that MCDAS_f showed an acceptable internal consistency ($\alpha = 0.82$, similar to that of MCDAS and CFSSDS) and good reliability despite there being a significant decrease in the scores between the first and second administrations of the questionnaires after a 17-week time interval. The authors attributed this to familiarity with the scale resulting in a reduction of experimental state anxiety.

Other measures incorporating the use of faces include the Venham Picture Test (VPT), Facial Images Scale (FIS) and Smiley Faces Program (SFP). The VPT is a measure of situational anxiety which is quick and easy to administer and can be applied to a wide age range. However more data is needed to show its validity and reliability (Aartman et al., 1998, Newton and Buck, 2000). FIS is strongly correlated with the VPT and has been shown to be a valid indicator of child state anxiety in the dental setting (Buchanan and Niven, 2003). The computer-based design of the SFP adds an enjoyable interactive element to the scale and may engage the child more but computer access could be a limiting factor. However the use of a computer would simplify data collection. Another advantage is that it is a relatively short measure and has obtained improved completion rates when compared to MCDAS and CFSS-DS (Buchanan, 2005). The recently revised version of the SFP includes an item regarding tooth extraction and has also demonstrated good reliability and validity (Buchanan, 2010).

Finally the CDFP is a detailed scale which requires training to enable the investigator to interpret the children's responses appropriately. Its validity is still to be reported on. Currently, no scale is viewed as the 'gold standard' which explains the great variation in the designs of the existing scales and makes comparisons between studies difficult.

2.60 CONCLUSIONS OF THE LITERATURE REVIEW

The dental health of paediatric cardiology patients is of concern as it has been shown to be poorer than that of healthy children. It is likely that there are multiple factors implicated in this trend with dental anxiety potentially contributing. It is well accepted that dental anxiety acts as a barrier to the provision of dental care, which can then lead to higher levels of untreated caries. With the serious complications of poor oral health in this patient group, it is imperative that all potential barriers to dental care are acknowledged and addressed.

Few studies have examined dental anxiety amongst children with special medical needs and there is no published research specifically looking at dental anxiety in children with congenital heart disease. Paediatric cardiology patients generally have a greater experience of invasive medical procedures than healthy patients

which could sensitise them to further exposures in the health care setting with possible implications on their dental anxiety status and subsequently their dental health.

2.70 AIMS OF THIS STUDY

The primary aim of the study was to:-

1. Determine whether the level of dental anxiety was different in children who have been diagnosed with cardiac conditions.

The secondary aims were to establish whether dental anxiety was affected by previous medical history as reflected by the following outcomes:-

1. Number of overnight hospital admissions experienced.
2. Number of general anaesthetics experienced.
3. Cardiac diagnosis category for the children with structural defects.

2.80 HYPOTHESES

The null hypotheses were as follows:-

1. There was no difference in the level of dental anxiety amongst paediatric cardiology patients when compared to healthy children.
2. There was no relationship between the MCDAS_f scores and the number of overnight hospital admissions experienced by the children.
3. There was no relationship between the MCDAS_f scores and the number of previous general anaesthetics experienced.
4. There was no difference in the level of dental anxiety between the three structural cardiac diagnosis categories.

3.00 MATERIALS AND METHODS

This study considered the level of dental anxiety amongst patients attending cardiology outpatients' clinics at Leeds General Infirmary and compared this to a group of healthy (ASA I) children attending orthodontic consultations as new patients. Dental anxiety levels of all parents/guardians were also considered. Other potential confounders, for example social factors and previous dental experience, were also investigated. Ethical approval was obtained from the Research Ethics Committee of the Leeds Teaching Hospitals NHS Trust (appendix I). Appropriate Research and Development approval was also granted (appendices II and III).

Children who met the inclusion criteria along with their parent/guardians were asked to complete the Modified Child Dental Anxiety Scale (faces version) and the Modified Dental Anxiety Scale, respectively. In addition to this, the parents completed a short questionnaire regarding the child's medical and dental histories in order to determine whether there were any significant differences between the medical and dental experiences between the two groups. The study population was recruited from the paediatric cardiology outpatient clinic at Leeds General Infirmary (LGI), a tertiary referral centre, between September 2011 and February 2012. The severity of the cardiac diagnoses of the children with structural cardiac defects recruited into the study group was classified according to the complexity of the defect as simple congenital heart disease, moderate severity or great complexity (Warnes et al., 2001) to enable subgroup analysis (appendix IV). The control group was recruited from the new patient orthodontic clinics at Leeds Dental Institute (LDI) and York Hospital (YH) between September 2011 and June 2012.

3.10 SELECTION OF THE STUDY AND CONTROL GROUPS

3.11 Inclusion criteria for study group

- Children attending the paediatric cardiology clinic at LGI
- Children aged 8-16 years old
- Children with informed consent from parent/guardian with parental responsibility

3.12 Inclusion criteria for control group

- Children aged 8-16 years old
- Children with no relevant medical histories i.e. ASA I
- Children attending the orthodontic clinics at LDI and YH as new patients
- Children with informed consent from parent/guardian with parental responsibility

3.13 Exclusion criteria

- Children under the age of 8 years
- Children over the age of 16 years
- Children with comorbidity
- Those not wishing to participate

3.14 Subject withdrawal criteria

- Any participant could withdraw from the study at any stage of the research
- Children or parents who showed visual signs of distress

3.20 INFORMED CONSENT AND ASSENT

All children and their parents/guardians who met the inclusion criteria were informed of the research by cardiology or orthodontic members of staff on the respective clinics. Families who were identified as potential participants were then approached by the chief investigator. All those recruited were provided with an information sheet (tailored to their age) to ensure that they made an informed choice regarding their participation. There were separate information sheets for the children in the study group and their parent/guardian (appendices V-VII), and for the children and parent/guardian of those recruited to the control group (appendices VIII-X). Potential participants were allowed sufficient time to consider the information sheets and ask any questions. Following this, written consent was

obtained from all parents/guardians (appendix XI) and the children signed assent forms (appendix XII). Children aged 16 years old completed modified consent forms. The consent process included obtaining consent to inform the child's dental practitioner of their involvement in the study (appendices XIII-XIV).

3.30 STUDY DESIGN

3.31 Sample size calculation

Sample size was determined based on the primary objective of this study, which was to compare the level of dental anxiety amongst paediatric cardiology patients with a group of healthy children from the orthodontic clinic. The formula used to determine the sample size is shown below:-

$$n = \frac{2 \times (\text{standard deviation})^2 \times \text{magic number}}{(\text{difference in means})^2} + 1$$

Using estimates from a previous study (Howard and Freeman, 2007) a standard deviation of 8 was used. The magic number was determined by the power and significance level. Using a power of 80% and a significance level of 0.05, the magic number was 7.8.

Aiming to detect a minimum clinically significant difference in the anxiety levels of 5, the formula above produced a sample size of 42 in each group. Allowing 15% to enable the use of non-parametric tests and 10% for subject withdrawal, the final sample size was 53 for each group.

3.32 Pilot study

The study was piloted on 10 patients and their parents/guardians. The pilot sample was a convenience sample taken from a group of patients attending for routine dental appointments and included both those with and without cardiac defects. Patients and their parents were asked to consider and complete the paperwork that was being piloted before use in the full study. All pilot participants were fully aware that their data would not be analysed as part of the research.

The purpose of the pilot study was as follows:-

- 1) To devise an efficient method of identifying potential participants
- 2) To determine the approximate length of time participation would take
- 3) To identify the most suitable way of distributing the questionnaires
- 4) To enable feedback regarding the questionnaire

Following the pilot study, it was agreed with the reception staff that an extra clinic sheet would be available in order to identify potential participants using the patients' dates of birth. It was a requirement that all new patients attending LDI completed medical questionnaires and therefore, the medical histories of potential participants could be easily checked before the clinic staff approached the patients. From the pilot study, it was found that participation would take approximately five minutes. The feedback from pilot participants was positive and there were no major amendments to the questionnaires following the pilot study.

3.33 Data Collection

3.331 Study group

Potential participants at the outpatient cardiology clinic at LGI were identified and informed of the study by the receptionist or the paediatric cardiology clinician. Following this, the chief investigator provided more detailed information about the study both verbally and through the distribution of the participation information sheets. Once the participants were satisfied with the information provided and had asked any questions, informed consent was obtained from the parent/guardian and the child. Copies of the information sheets, consent forms and assent forms were given to the participants. The following paperwork was then completed:-

- 1) A questionnaire regarding the child's medical and dental history was completed by the parent/guardian (appendix XV)
- 2) The child was asked to complete the MCDAS_f to assess their dental anxiety (appendix XVI)
- 3) The parent/guardian was asked to complete the MDAS (appendix XVII)

Where parents were unsure of aspects of their child's medical history, the medical notes were reviewed. In six cases, parents could not recall either how many general anaesthetics their child had received or how many times they had been admitted to hospital. In these circumstances, the parents were asked to recall general anaesthetics and admissions at other hospitals and the patient's LGI general anaesthetics and admissions were counted with the aid of the LGI medical notes. With regards to the cardiac diagnosis categories, the cardiologist resolved any difficulties in classifying patients with structural cardiac defects. Study group recruitment was carried out at a range of outpatient cardiology clinics from September 2011 until the sample size was achieved in February 2012.

3.332 Control group

Control recruitment commenced at LDI in September 2011. Families who met the inclusion criteria for the control group were identified and informed about the study by the orthodontic receptionists at LDI before being approached by the chief investigator. The paperwork completed was identical except for minor differences in the medical and dental questionnaire (appendix XVIII).

Due to there being fewer potential control participants attending the new patient orthodontic clinics at LDI than anticipated, a decision was made to add a second research site for control recruitment. Recruitment at YH followed a similar process to recruitment at LDI, the only difference being that in York, potential participants were identified and informed of the study by the orthodontic consultants and nurses.

3.34 Deprivation Indices

Participants' postcodes were entered into GeoConvert, an online geography matching and conversion tool (Economic and Social Research Council, 2012). Using the National Statistics Postcode Directory 2010 (Office for National Statistics, 2010) and the Index of Multiple Deprivation 2007 (IMD 2007) (The National Archives, 2012), each postcode was converted to a social deprivation score and allocated a deprivation quintile. The most deprived areas were ranked 1 and the least deprived were ranked 5. Data relating to two of the postcodes in the study group and one of the postcodes in the control group was not available as

these areas were not geo-coded. Therefore three participants were omitted from the deprivation analysis.

3.40 DATA ANALYSIS

The data was entered in to an electronic database and analysed using SPSS Statistics software (version 19). Summary statistics were calculated to include frequencies and means and standard deviations, where appropriate. Comparisons between the study and control groups were carried out with the use of independent t-tests, Mann-Whitney U tests and Chi-Square after checking the assumptions of the tests had been met. Further analysis of the data was performed by correlations and analysis of covariance (ANCOVA). P-values equal to or less than 0.05 were considered statistically significant. Statistical tests were performed following advice and support from a statistician.

4.00 RESULTS

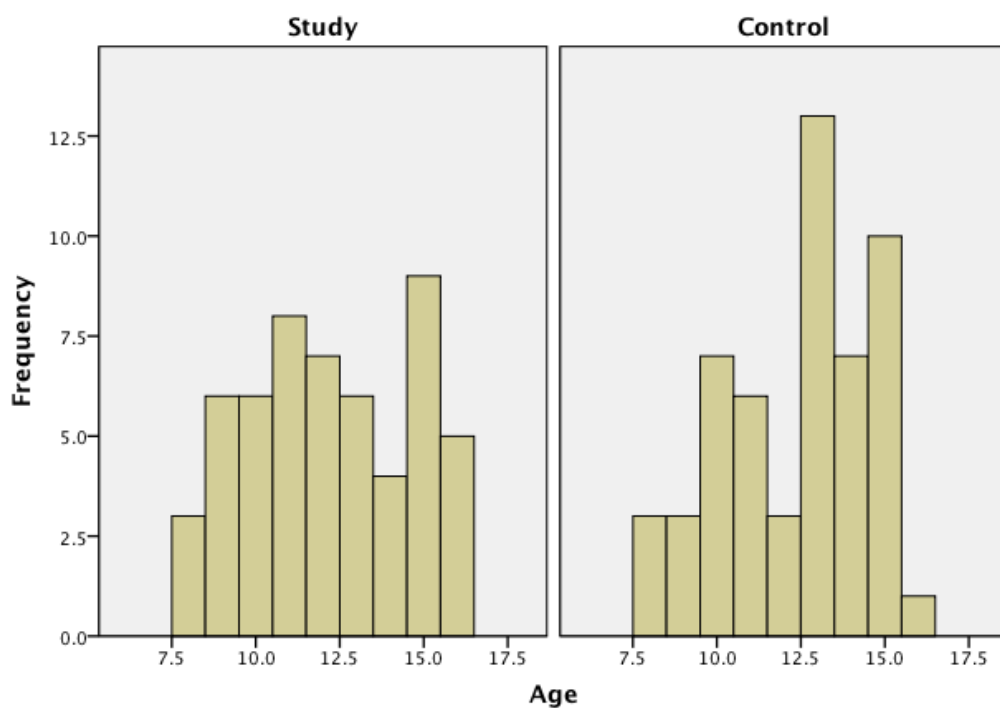
4.10 COMPOSITION OF THE GROUPS

The sample size was 54 in the study group and 53 in the control group. During the recruitment process, five families declined to participate. Four of these were potential control subjects and one was a potential participant for the study group. Within the control group, 22 participants were recruited from LDI and 31 participants were recruited from YH.

4.11 Age

The age of the participants in each group was not normally distributed according to normality plots and Shapiro-wilk (figure 1). The median age in the study group was 12 (IQR 10-15) and the median age in the control group was 13 (IQR 10.5–14). The difference was not significant according to a Mann-Whitney U test ($p=0.70$). The mean ages were 12.2 years and 12.38 years, respectively. The minimum age in each group was 8 years and the maximum age was 16 years.

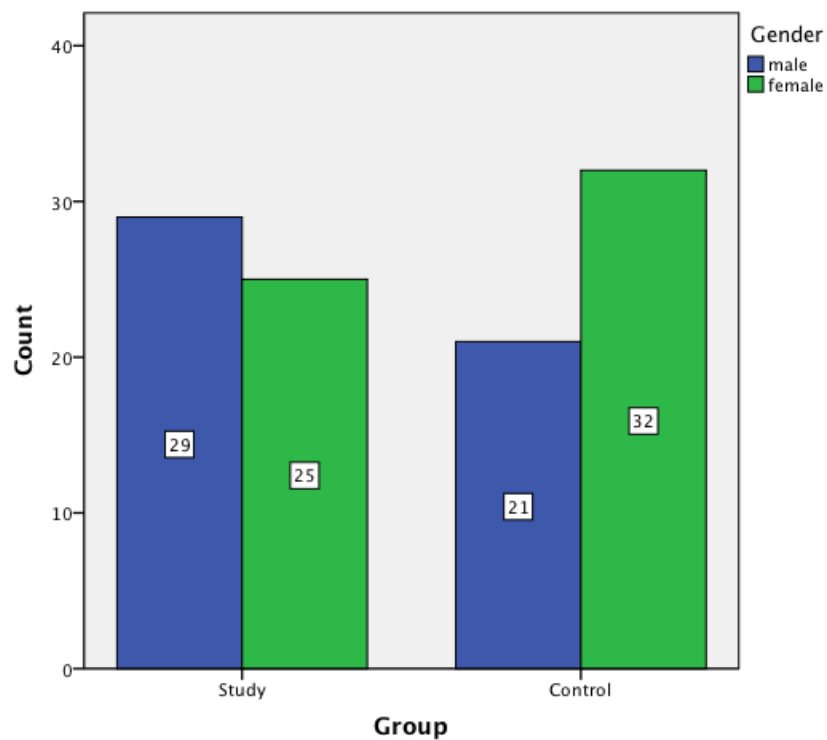
Figure 1. Age distribution in the study and control groups



4.12 Gender

In the study group, 53.7% (n=29) of the participants were male compared to 39.6% (n=21) in the control group (figure 2). Although there were more females in the control group than in the study group, there was no significant difference in the genders between the study and control groups ($p=0.144$, according to Chi-Square test).

Figure 2. Gender distribution in the study and control groups



4.13 Deprivation quintiles

Using the IMD 2007, there was a significant difference in the deprivation quintiles between the two groups (table 2). The control group was significantly less deprived according to Chi-square test ($p=0.002$).

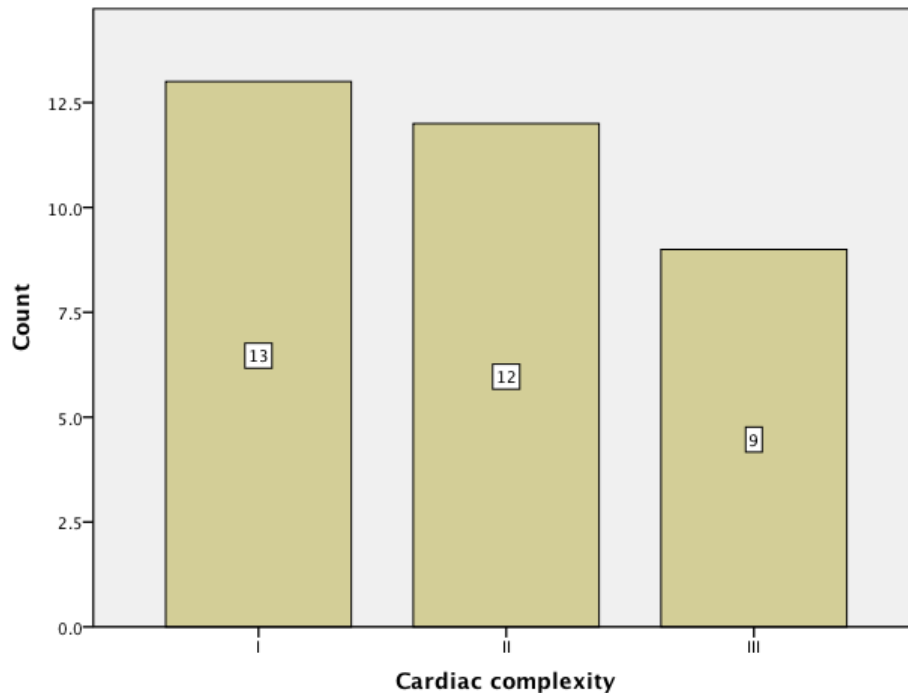
Table 2. Deprivation quintiles in the study and control groups

		Deprivation Quintile					Not Geocoded	TOTAL
		1	2	3	4	5		
Group	Study	17	9	12	9	5	2	54
	Control	5	9	6	13	19	1	53
TOTAL		22	18	18	22	24	3	107

4.14 Type of cardiac defect and cardiac complexity rating

In the study group, 34 children (63.0%) had structural cardiac defects, 18 children (33.3%) had conductive defects and there were two children (3.7%) with unknown diagnoses. The distribution of the cardiac complexity rating of the children with structural cardiac defects is shown in figure 3.

Figure 3. Cardiac complexity rating of children with structural cardiac defects



I = simple complexity

II = moderate complexity

III = great complexity

4.20 CHILD DENTAL ANXIETY

4.21 Comparison of child dental anxiety between the study and control groups

The MCDAS_r scores for the study and control groups were normally distributed according to Shapiro-wilk test, Q-Q-plot and Box-whisker plot. The distributions are shown in figures 4 and 5. Therefore, parametric analysis was used for comparison. The mean MCDAS_r score was 21.96 (S.D. 5.673) for the study group and 18.48 (S.D. 6.489) for the control group. An independent t-test revealed that the mean level of dental anxiety in the study group was significantly higher than the mean level of dental anxiety for the control group ($p=0.004$). According to Levene's test for equality of variances, $p=0.298$ ($p \geq 0$) and therefore, equal variances were assumed. The magnitude of the differences in the means (mean difference = 3.472, 95% CI: 1.14 to 5.81) was moderate (eta squared = 0.08).

In the study group, an outlier was identified who had a MCDAS_f score of 8, which is the lowest possible score recorded for this scale. In the control group, an outlier with a MCDAS_f score of 39 was identified. The maximum score of the MCDAS_f is 40.

Figure 4. Child dental anxiety scores in the study group

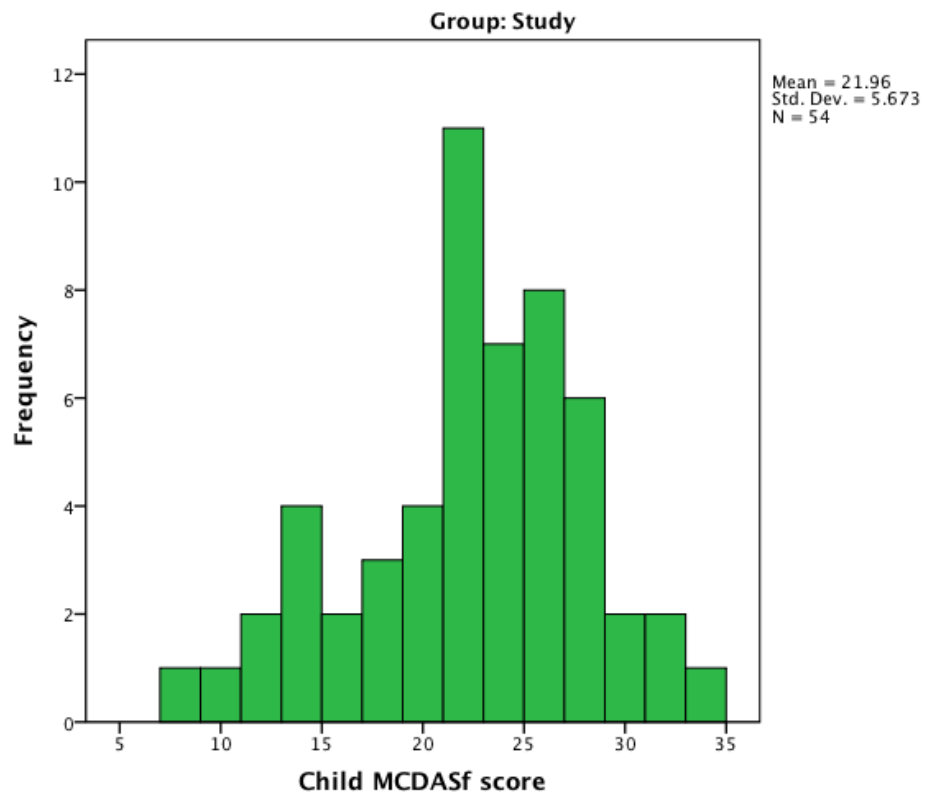
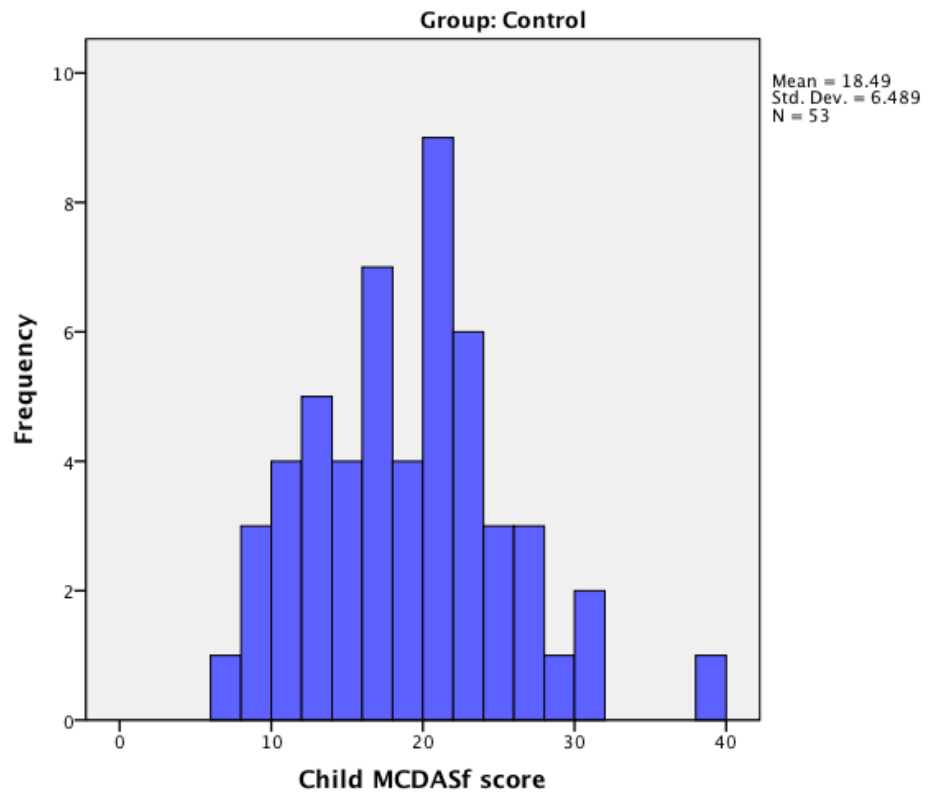


Figure 5. Child dental anxiety scores in the control group

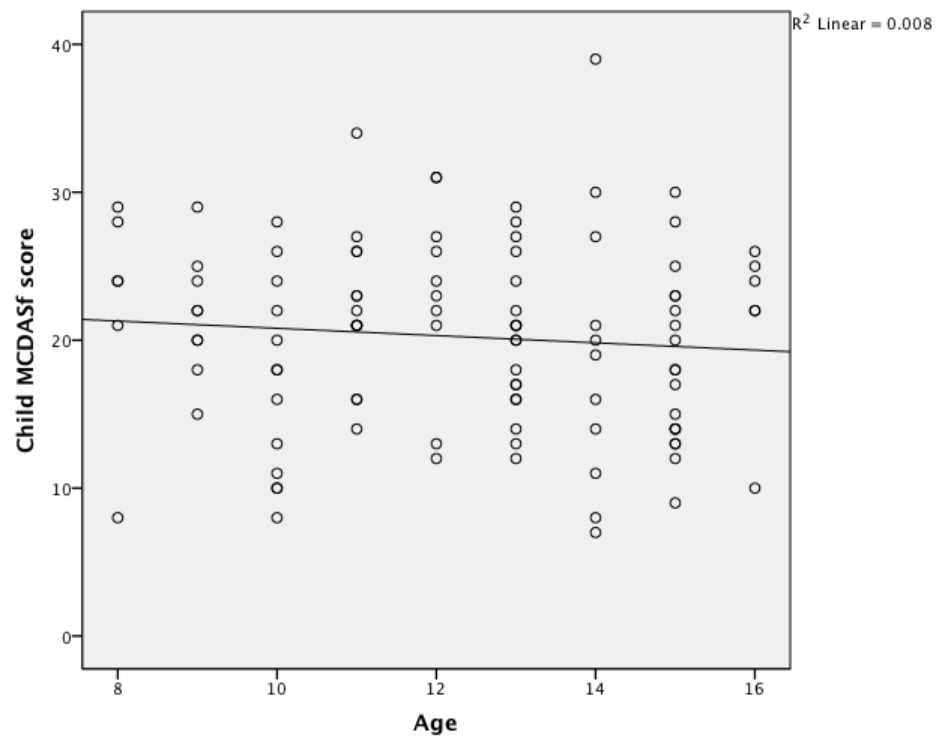


4.22 Child dental anxiety and demographics

4.221 Age

The relationship between age and the MCDAS_r scores was investigated using Pearson correlation coefficient. There was a very weak, negative correlation between the two variables, $r=-0.09$, $n=107$, $p=0.358$, with a reduction in dental anxiety with increasing age (figure 6).

Figure 6. Scatterplot showing the correlation between child dental anxiety and age



4.222 Gender

No significant difference in the mean level of dental anxiety was demonstrated between the genders ($p=0.734$). The mean MCDAS_f score for the boys was 20.02 (SD 6.33) and the mean MCDAS_f score for the girls was 20.44 (SD 6.34).

4.223 Deprivation

A one-way between-groups analysis of covariance was conducted to determine the impact of the participants' deprivation quintiles on the MCDAS_f scores between the two groups. The independent variable was the group (control/study) and the dependent variable consisted of the MCDAS_f scores. After adjusting for the deprivation quintiles, there was still a significant difference in the MCDAS_f scores between the two groups, with the study group being more anxious ($F(4, 94) = 8.78$, $p=0.004$, according to analysis of covariance). There was a medium – but not statistically significant - relationship ($F(4,94) = 2$, $p=0.101$) between the MCDAS_f scores of the combined study and control group and the deprivation quintiles, as indicated by a partial eta squared value of 0.78 ($p=0.10$).

4.23 Child dental anxiety and past medical history

4.231 Experience of overnight admissions

The data for the children's number of overnight hospital admissions was not normally distributed and therefore, non-parametric tests were used for analysis. The median number of overnight hospital admissions in the study group was 2 (IQR 1-4) and in the control group was 0 (IQR 0-1). A Mann-Whitney U test revealed a significant difference in the number of overnight hospital admissions between the two groups ($U = 528.0$, $z = -5.95$, $p=0.001$). The mean number of hospital admissions was 3.06 in the study group and 0.51 in the control group (table 3).

Table 3. Summary of overnight hospital admission history in the two groups

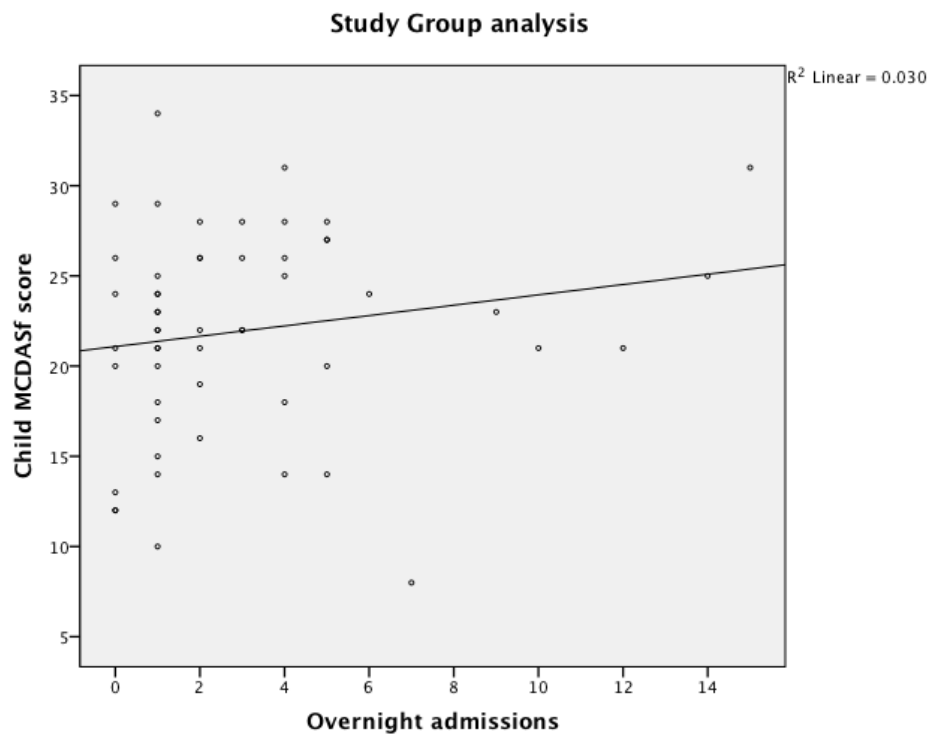
		Overnight admission history			
		Mean	Median	Minimum	Maximum
Group	Study (n=54)	3.06	2 (IQR 1-4)	0	15
	Control (n=53)	0.51	0 (IQR 0-1)	0	4

n = number

IQR = interquartile range

The difference in the mean MCDAS_f scores almost reached statistical significance when adjusting for the difference in overnight hospital admissions ($p=0.054$). However the covariate of overnight hospital admissions was not significant ($p=0.127$), suggesting that admissions is not an independent predictor of MCDAS_f scores when group membership is taken into account ($F(1,104)=3.794$, $p=0.054$, according to analysis of covariance). There was a small, non-significant relationship ($F(1,104)=2.364$, $p=0.127$) between the MCDAS_f scores and the overnight admission history when all the participants were considered, as indicated by a partial eta squared value of 0.022 ($p=0.127$).

Figure 7. Scatterplot showing child dental anxiety in relation to overnight hospital admissions in the study group



Given that the difference in the level of child dental anxiety between the groups was no longer significant when adjusting for the difference in overnight hospital admissions, the relationship between child dental anxiety and overnight admission history in the study group was investigated (figure 7). There was a positive correlation between the MCDAS_f scores and the number of overnight admissions in the study group. The Pearson correlation coefficient revealed a weak, non-significant correlation between the two variables ($r= 0.174$, $p=0.209$). Therefore, the difference in the admission history between the two groups did not explain the higher level of dental anxiety in the study group.

4.232 General anaesthetic experience

With regards to the number of general anaesthetics (not normally distributed), in the study group the median number was 1 (IQR 1- 3) and the mean was 1.87. For the control the median number of general anaesthetics was 0 (IQR 0-1), with a mean of 0.34 (table 4). The difference in the number of general anaesthetics each group had experienced was significant ($p=0.00$).

Table 4. Summary of general anaesthetic history in the two groups

		General anaesthetic history			
		Mean	Median	Minimum	Maximum
Group	Study (n=54)	1.87	1 (IQR 1-3)	0	9
	Control (n=53)	0.34	0 (IQR 0-1)	0	3

n = number

IQR = interquartile range

There was a very weak, non-significant relationship ($F(1,104)= 0.011$, $p=0.918$) between the MCDAS_f scores and the children's experience of general anaesthetic, as indicated by a partial eta squared value of 0.009. There was still a significant difference in the mean MCDAS_f between the groups when adjusting for the difference in the number of general anaesthetics the children in each group had experienced ($F(1,104)=4.342$, $p=0.04$).

4.233 Child dental anxiety according to type of cardiac defect and cardiac complexity (study group only)

There was no difference in the mean levels of dental anxiety between children with structural defects and children with conductive cardiac defects ($U=265.5$, $z=-0.781$, $p=0.435$, according to Mann-Whitney U test). The mean MCDAS_f scores for the children with congenital heart disease categorised as simple, moderate severity and great complexity are shown in table 5.

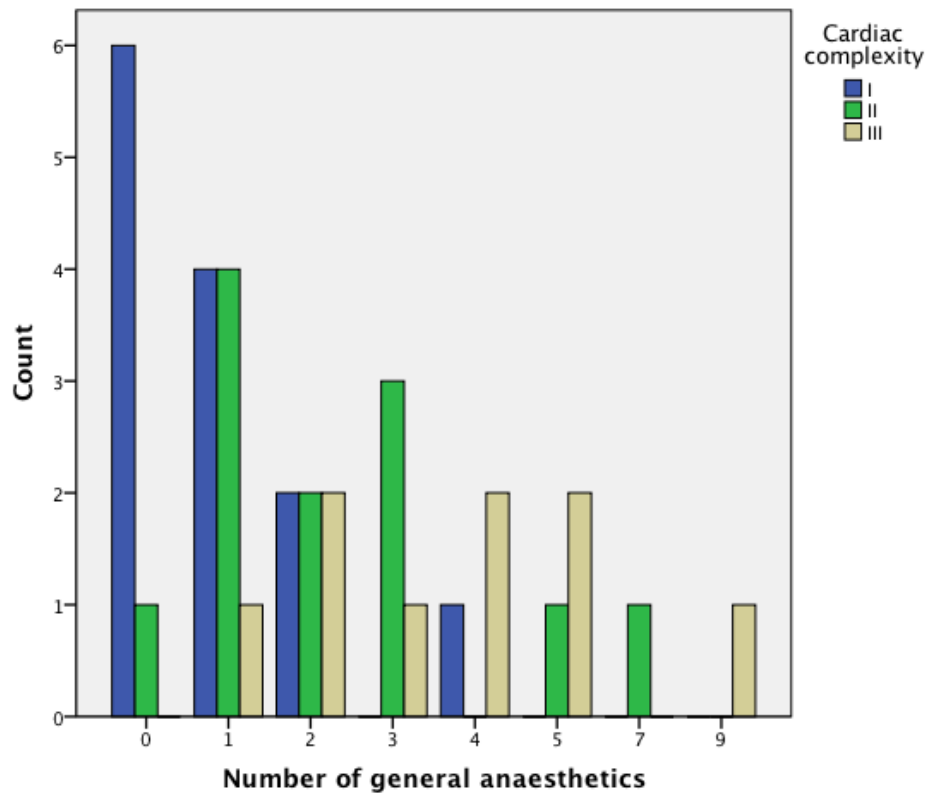
Table 5. MCDAS_f scores according to cardiac complexity category

		MCDAS _f scores	
		Mean	Standard Deviation
Cardiac complexity category (n=34)	Simple (n=13)	22.38	6.29
	Moderate (n=12)	20.50	6.45
	Great (n=9)	24.4	5.82

n = number

A one-way between-groups analysis of variance was conducted to explore the impact of cardiac complexity category on levels of dental anxiety. There was no significant difference at the $p < 0.05$ level in the MCDAS_f scores between the cardiac diagnosis categories ($p = 0.314$). This was in spite of a significant difference in the number of general anaesthetics between diagnosis categories I and II ($U = 37.0$, $z = -2.299$, $p = 0.21$, according to Mann-Whitney U test), and I and III ($U = 11$, $z = -3.237$, $p = 0.001$, according to Mann-Whitney U test) with the more severe categories experiencing a greater number of general anaesthetics (figure 8). There were no other significant differences in relation to overnight hospital admissions or general anaesthetic history between children with conductive and structural defects, or between the cardiac diagnosis categories of those with structural defects (according to Mann-Whitney U test). However, due to the small numbers in the subcategories, these results should be interpreted with care.

Figure 8. Number of general anaesthetics according to cardiac complexity category



I = simple complexity

II = moderate complexity

III = great complexity

4.24 Past dental history

4.241 Dental local anaesthetic (LA) experience

There was no significant difference in the number of times the children in the study and control groups had received dental local anaesthetic ($\chi^2 = 0.092$, $p=0.955$, according to Chi-Square). These results are summarised in table 6 which shows that the frequencies of LA experience between the two groups was very similar.

Table 6. LA experience according to group

		LA experience			
		None	Once	More than once	TOTAL
Group	Study	30	10	14	54
	Control	29	11	13	53
TOTAL		59	21	27	107

4.242 Restorative Experience

There was no significant difference in the number of times the children in the study and control groups had received a "filling" at the dentist ($\chi^2 = 0.419$, $p=0.811$, according to Chi-Square). These results are summarised in table 7.

Table 7. Restorative experience according to group

		"Filling" experience			
		None	Once	More than once	TOTAL
Group	Study	29	7	18	54
	Control	31	5	17	53
TOTAL		60	12	35	107

4.243 Experience of dental extractions under local anaesthetic

Although the children in the control group appeared to have a greater experience of dental extractions with LA (table 8) this difference was not statistically significant ($X^2 = 4.475$, $p=0.107$, according to Chi-Square).

Table 8. Experience of dental extractions under LA

		Experience of dental extractions under LA			
		None	Once	More than once	TOTAL
Group	Study	42	5	7	54
	Control	32	12	9	53
TOTAL		74	17	16	107

4.244 Experience of dental extractions under general anaesthetic (exodontia)

With regards to the exodontia experience between the children in the study and control groups, ten children in the study group had experienced dental extractions under GA compared to only three children in the control group. These results are shown in table 9 and according to Chi-Square test, the study group had a significantly greater experience of exodontia ($X^2 = 4.143$, $p=0.042$).

Table 9. Experience of exodontia

		Experience of GA for dental extractions		
		No	Yes	TOTAL
Group	Study	44	10	54
	Control	50	3	53
TOTAL		94	13	107

The only significant difference in the dental experiences of the children between the study and control groups related to a greater experience of exodontia in the study group. Therefore, a one-way between-groups analysis of covariance was conducted to investigate the impact of the children's exodontia experience on the MCDAS;

scores between the two groups. The independent and dependent variables were as for the deprivation ANCOVA. After adjusting for the exodontia experience, there was still a significant difference in the MCDAS_f scores between the two groups, with the study group being more anxious ($F(1, 104) = 8.396, p=0.005$, according to analysis of covariance). There was not a strong relationship between the MCDAS_f scores and the children's exodontia experience, as indicated by a partial eta squared value of 0.001.

4.25 Toothache

Only three children reported that they were experiencing toothache at the time of participation. One child was in the study group and the other two were controls. There was an insufficient number of participants with toothache to enable further analysis.

4.26 Access to dental care

All the children in the control group had access to dental care. However, four children in the study group did not have a dentist. Due to the small number of children without regular access to dental care, statistical analysis was not possible.

4.30 PARENTAL ANXIETY

According to the tests of normality, the parental MDAS scores in the study and control groups were not normally distributed (figures 9 and 10). Both distributions were positively skewed. In both groups, the median MDAS score was 11 ($p=0.973$ according to Mann-Whitney U) and the interquartile ranges were similar (IQR 8-16 in the study group and IQR 8-16.5 in the control group). The mean MDAS score in the study group was 12.83 and 12.64 in the control group.

Figure 9. Distribution of parental dental anxiety scores in the study group

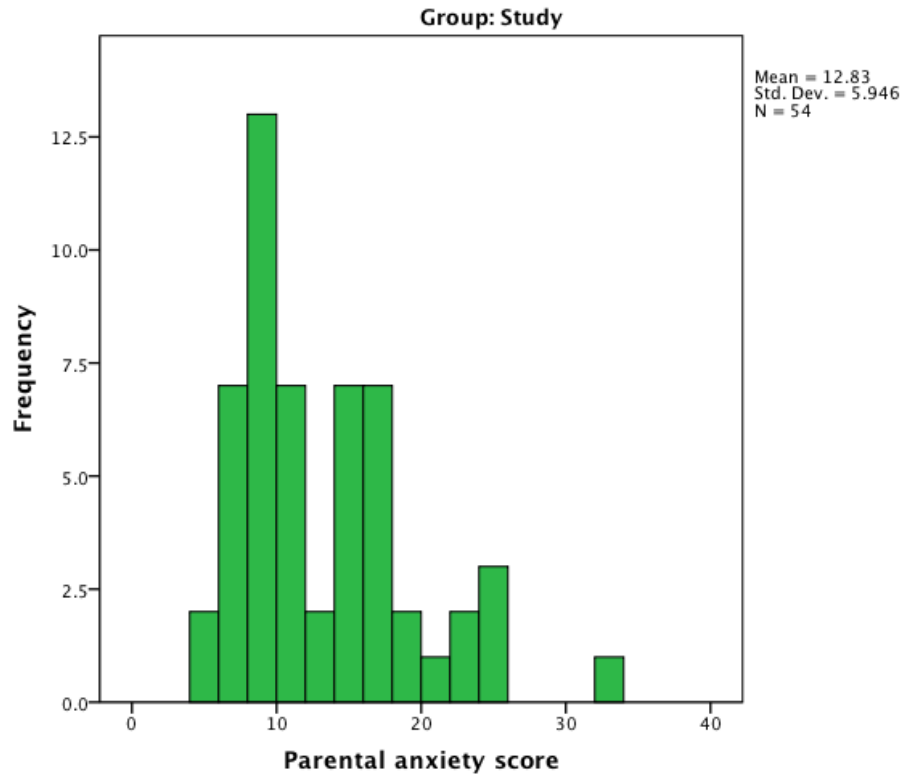
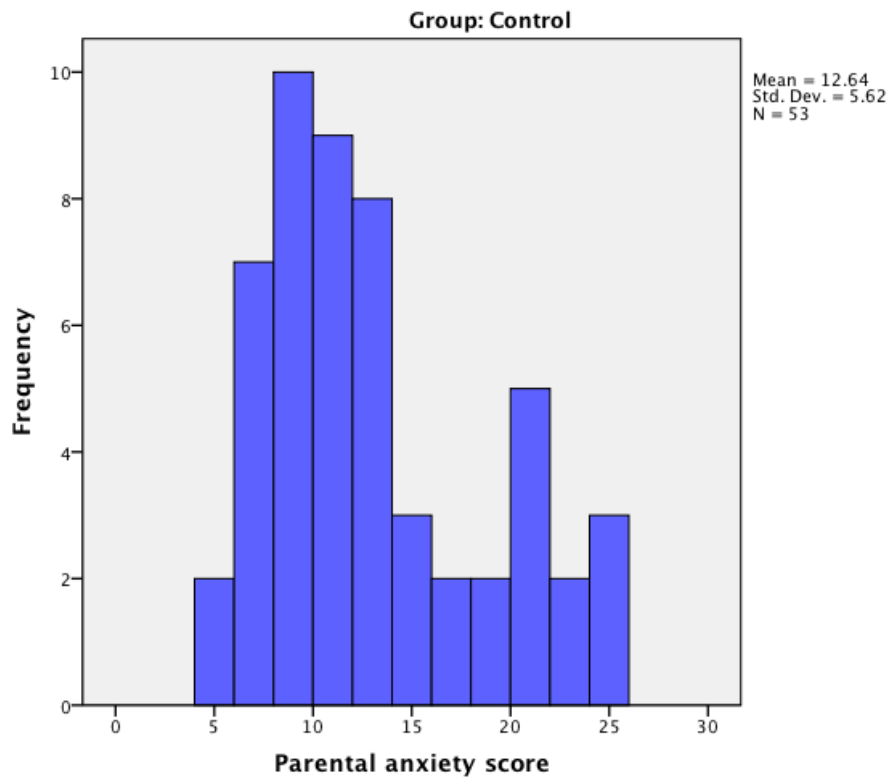


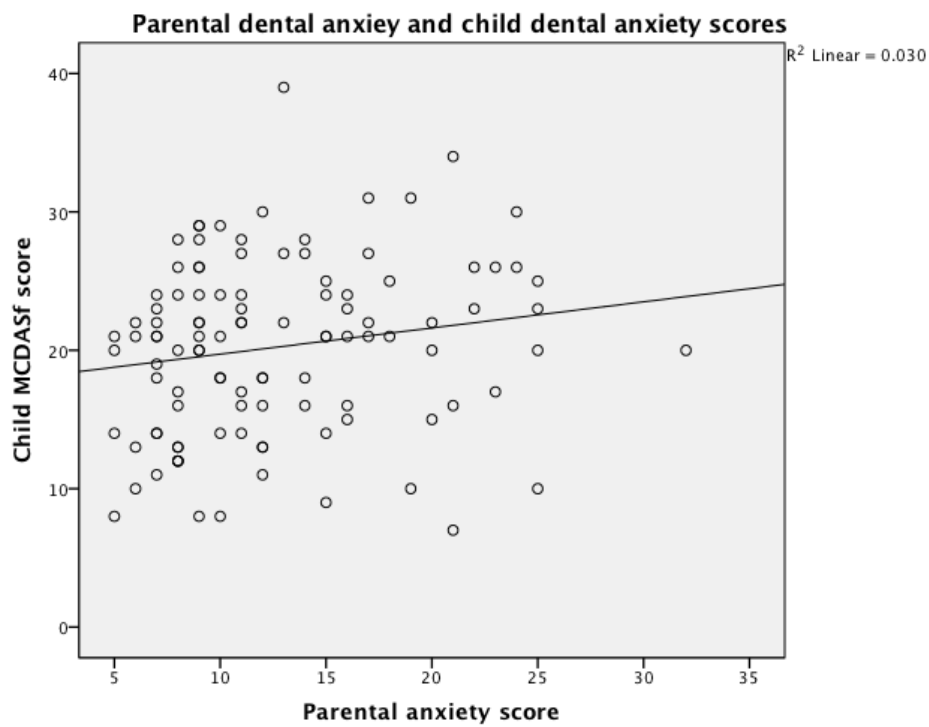
Figure 10. Distribution of parental dental anxiety scores in the control group



4.40 CORRELATION OF PARENTAL DENTAL ANXIETY AND CHILD DENTAL ANXIETY

Figure 11 demonstrates a positive relationship between the parental and child dental anxiety scores. The correlation was further investigated using Spearman's correlation coefficient which revealed a weak correlation ($r=0.21$, $p=0.03$).

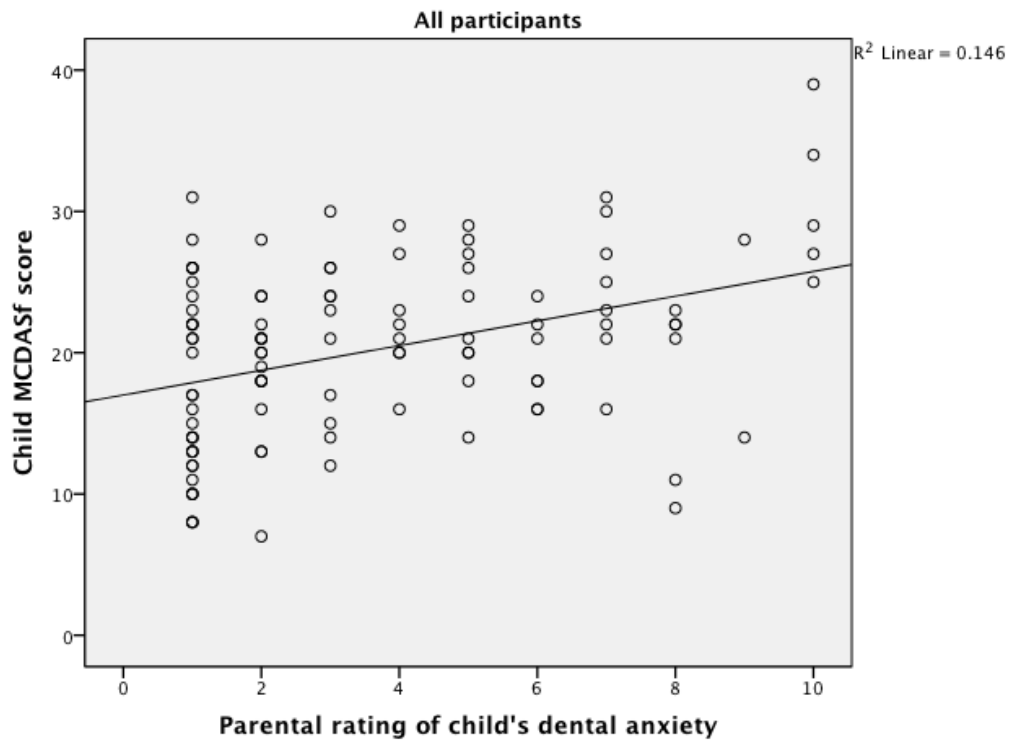
Figure 11. Parental dental anxiety scores against child dental anxiety scores



4.50 PARENTAL RATING OF CHILD DENTAL ANXIETY

There was a medium positive correlation (figure 12) between the parental rating of the children's dental anxiety (measured on a scale on 0-10) and the children's MCDAS_f scores when all the participants were included ($r=0.354$, $p=0.00$).

Figure 12. Parental rating of their child's dental anxiety against self-reported child dental anxiety



5.00 SUMMARY OF SIGNIFICANT FINDINGS

- 1) In this study, children with cardiac diagnoses were significantly more dentally anxious than the control group.
- 2) The study group was significantly more deprived than the control group, as measured by IMD 2007.
- 3) The study group had a significantly greater experience of extractions under general anaesthetic.
- 4) With regards to medical history, the children with cardiac defects had experienced a greater number of overnight hospital admissions and general anaesthetics. These findings were significant.
- 5) The difference in the level of dental anxiety between the study and the control group remained significant when controlling for deprivation, exodontia experience and number of general anaesthetics.
- 6) Within the group of children with structural cardiac defects, children classified as having simple defects had experienced a significantly fewer number of general anaesthetics than those with moderate or great complexity defects.

6.00 DISCUSSION

6.10 INTRODUCTION

This study aimed to determine whether there was a difference in the level of dental anxiety amongst children with cardiac defects and a group of healthy (ASA I) control patients taken from children attending new patient orthodontic clinics. The study design was cross-sectional and involved convenience samples. There was no previous research specifically investigating dental anxiety amongst paediatric cardiology patients. Extensive research has, however, investigated the dental health of children with cardiac defects and a consistent finding has been poorer dental health in paediatric cardiology patients. A possible explanation for this is increased dental anxiety which is a well documented barrier to dental care. The secondary aim was to determine if there was a correlation between the children's medical histories, in terms of general anaesthetic history, number of overnight hospital admissions and cardiac complexity category, and dental anxiety.

6.20 DISCUSSION OF THE METHODOLOGY

6.21 Anxiety scales

There are numerous anxiety scales described in the literature but an ideal scale has yet to be identified. When considering dental anxiety scales, the reliability, including the test-retest reliability, and validity of the scales need to be examined. The faces version of the Modified Child Dental Anxiety scale (MCDAS_f) was chosen because it is an adapted version of MCDAS which has correlated highly with both CDAS and DFSS for children and has been shown to have high reliability (Wong et al., 1998). Furthermore, Howard and Freeman (Howard and Freeman, 2007) concluded that MCDAS_f showed an acceptable internal consistency ($\alpha = 0.82$), similar to that of MCDAS and CFSS-DS. Children aged 8–16 years old were chosen as the MCDAS_f has been shown to be a valid measure of dental anxiety levels in children as young as eight years old (Howard and Freeman, 2007). Whilst there was data missing in the initial validation for MDAS, the MCDAS_f was distributed on an individual basis in this study which ensured completion of the entire scale.

Although the CFSS-DS appears to be more commonly used than MCDAS_f, it was not used in this study. This was because the CFSS-DS is almost twice as long and would have proved difficult to complete in the clinical setting used during this study.

Furthermore, the faces version of the MCDAS is a more child-friendly scale. The increased length of the CFSS-DS is the most likely explanation for the higher return rate of incomplete scales in comparison to the MCDAS reported in previous studies (Wong et al., 1998, Christophorou et al., 2000).

The Modified Dental Anxiety Scale (MDAS) was used to measure the parental level of dental anxiety as it offered a simple and quick method of measuring dental anxiety in adults and has been recommended for research purposes (Freeman et al., 2007). It has been widely used and tested for reliability and validity (Humphris et al., 2000, Humphris et al., 1995, Newton and Edwards, 2005).

Although there was no formal training in the use of the anxiety scales, the pilot study increased the chief investigator's familiarity of the scales. Furthermore, this method of anxiety assessment was chosen as minimal training was required. All the participants were recruited by the chief investigator and were given as much time as needed to complete the anxiety scales. Reading difficulties were encountered during the recruitment of one family. Therefore, the chief investigator assisted by reading the questions but did not influence any of the responses.

The intention was to test reliability with 10% of the research participants. However, due to time constraints, this was not possible. The aim of testing reliability was to investigate any potential impact that the chief investigator may have had on reliability, not to specifically test the reliability of the anxiety scales as this has been reported elsewhere (Freeman et al., 2007, Howard and Freeman, 2007, Wong et al., 1998). It should be noted that Howard and Freeman (Howard and Freeman, 2007) reported a significant decrease in the MCDAS_f scores between the first and second administrations of the scales when investigating the test-retest reliability of the MCDAS_f. This was attributed to a reduction in experimental state anxiety in the children due to their familiarity with the scale.

6.22 Sample selection

6.221 Study group

The study group was taken from a convenience sample and therefore, may not be truly representative of the entire population. Patients who failed to attend their appointments were excluded from the study and this group of children could potentially be more anxious of the hospital environment resulting in avoidance behaviour and non-attendance. In addition to this, children who miss their appointments are likely to have reduced socio-economic status which could bias the sample further (Gustafsson et al., 2010b). However, due to the nature of the children's diagnoses, it was likely that failure rates were minimal although these were not specifically recorded. There were two children in the study group with unknown cardiac diagnoses and therefore, they were excluded from the further analysis of the study group. However, they were included in the comparisons with the control group as both these children met the inclusion criteria.

6.222 Control group

A healthy group of children was required for the control group as one of the inclusion criteria was that the children were classed as ASA I. It was felt that the orthodontic clinic would offer a reasonable control group as most patients attending are unlikely to have significant medical histories but would have had some experience of the dental environment. Previous studies involving paediatric cardiology patients have recruited controls from various samples such as children attending cardiology clinics as new patients who have been subsequently diagnosed with healthy hearts (Tasioula et al., 2008), children from population registers (Stecksen-Blicks et al., 2004) and local schools (Pollard and Curzon, 1992), siblings of children with cardiac defects (Hallett et al., 1992) and children attending dental outpatient clinics (Franco et al., 1996). In this study, it was felt that children attending new patient orthodontic clinics would offer the least bias sample. Other control samples that were considered included children from the traumatology clinics at LDI, children from the orthopaedic outpatient department at LGI and children from local schools. However, children who have experienced dental trauma may have increased dental anxiety due to the nature of their dental injuries and children attending other medical outpatient clinics could have been sensitised to the medical environment and have increased dental anxiety as a result. Recruitment from local schools would have been difficult as involvement of the parents in this study was required.

As with the study group, a potential source of bias was patients who failed to attend their consultation appointments as the reason for these failed attendances could relate to dental anxiety. In addition to this, given that highly anxious children may be poor candidates for orthodontic treatment, these patients may not get referred for an orthodontic opinion. However, the new patient orthodontic clinics at LDI and YH were consultant-led clinics with specific referral criteria and therefore, children attending these clinics were likely to have more complex orthodontic problems. Children with severe orthodontic problems will get referred for an orthodontic opinion regardless of their dental anxiety. In addition to this, most patients should have been aware that their new patient consultation would only involve a dental examination and radiographs where indicated and therefore, it was anticipated that failed appointments due to dental anxiety were low.

Due to difficulties recruiting control patients from LDI, a research site at York Hospital was added to the study. Research & Development approval was granted for York Hospital in March 2012. Control recruitment in York began in April 2012 and ran concurrently to recruitment at LDI until June 2012. Whilst the addition of a research site in York was not ideal due to potential differences in socio-economic background from participants recruited at LDI and LGI, the existing study design had allowed such differences to be identified through the recording of the participants' postcodes and subsequent assessment of deprivation. As the cardiology clinic at LGI was a tertiary referral centre, there was a wider catchment area and therefore, some of the cardiology patients may have resided in York. The addition of a second research site was necessary as it enabled the sample size for the control group to be met. However, it is acknowledged that the treatment needs amongst patients attending the orthodontic clinics at YH and LDI could have varied due to differences in the provision of orthodontic services between the two areas. It has been reported that children who are aware they have a dental problem have higher levels of dental anxiety (Bailey et al., 1973). Therefore, children with more severe malocclusions might have reported higher levels of dental anxiety. However, the orthodontic clinics at LDI and YH were both consultant-led hospital services with identical referral criteria (Index of Orthodontic Treatment Need scores 4 or 5) and therefore, the children recruited into the control group at LDI and YH should have had similar orthodontic treatment need. It was not possible to confirm this as data regarding the participants' dental treatment need was not collected during the study.

6.23 Questionnaires

6.231 Aim of the questionnaires

The aim of the questionnaires was to identify differences in the medical and dental histories of the children in the two groups. Therefore, the questionnaires were designed to capture quantitative data rather than qualitative data in order to simplify data analysis. By only collecting quantitative data, there might have been less opportunity to identify potential causal factors for dental anxiety. The collection of qualitative data, i.e. the children's responses to their previous dental and medical experiences, would have enabled more information regarding the children's tolerance in such situations to be gained. Some children may tolerate multiple experiences well yet others may experience a single traumatic medical or dental experience which could lead to higher levels of anxiety. However, the chance of experiencing a traumatic experience would have increased as the number of medical and/or dental experiences increased and therefore, only quantitative data was collected.

6.232 Completion of the questionnaires

Whilst data collection did not involve structured interviews, the chief investigator was present during the completion of the questionnaires. This was primarily to answer any questions the participants had but also had a beneficial effect on questionnaire completion rate. The questionnaires were checked for incomplete data when they were returned and as a result, there was no missing data on any of the questionnaires analysed. The self-completion of the questionnaires enabled data collection to be less time-consuming which meant that disruption to the clinics was minimal.

6.233 Questionnaire design

The questionnaires were designed to include simple questions that were comprehensible to the participants. Furthermore, closed questions were used as far as possible to increase the speed of completion. The readability of the questionnaires used for the study and control groups was checked prior to the pilot study. They had Flesh Reading Ease scores of 72.9 and 74.1 and Flesch-Kincaid Grade levels of 4.9 and 4.7, respectively. This indicated that the questionnaires should be understood by 13-15 year olds which was acceptable as they were completed by the parents in this study.

6.234 Recall bias

The accuracy of the information provided by the participants' parents could not be guaranteed due to recall bias. In addition, it was not possible to assess test-retest reliability of the questionnaires due to difficulties meeting the sample size. Ideally, 10% percent of participants would have completed the questionnaires again after a time interval of two to three weeks. However, data collection was focused on achieving the sample size. Once this had been met, there was likely to have been changes in the medical and dental histories of the participants due to the time interval that would have elapsed during the first and second completion of the questionnaires.

In an attempt to improve the accuracy of the data, where parents in the study group were unable to recall aspects of their child's medical histories, the patient's medical notes were reviewed. Six parents were unsure of their child's general anaesthetic and/or overnight admission history so these were counted from the medical notes. These children may have experienced general anaesthetics and admissions in other hospitals and therefore, the parents were asked this specifically. This method was felt to be more accurate than complete reliance on parental recall for these families. It was not possible to assess factual validity for all participants due to time and clinic pressures. Only overnight hospital admissions were recorded as it was felt that these would be more significant experiences for the child and it allowed the use of a clear question regarding admissions in the questionnaire ("has your child ever spent a night in hospital?"). This removed any ambiguity regarding parental understanding of the term 'admission'.

Recall bias could have also affected the reported dental experiences of the children. A more reliable assessment of the children's dental experiences could have been made following a dental examination of each participant. However, for practical reasons, dental examinations were not performed. Furthermore, it was felt that the reliability of using indices such as the total number of primary and permanent diseased, missing and filled teeth (dmft or DMFT) when investigating dental experience is poor. By using such indices, information regarding the exact nature of the dental intervention, for example whether LA was used for a restoration, is not obtained and therefore, there would still be a reliance on the families' memory. Within the index, the 'decay' component could be indicative of dental avoidance behaviour or may simply reflect variations in dentists' treatment philosophy, especially where

the restoration of primary teeth is concerned. Obtaining dental records for all participants was another potential method for assessing the children's dental history but this method would have been heavily reliant on the quality of the dental records.

6.235 Medical and dental aspects of the questionnaire

Parents were specifically asked about their child's experience of LA, "fillings", dental extractions with LA and extractions under GA. These were chosen as they have been investigated in previous studies and have been shown to be anxiety-provoking stimuli. Significant associations between dental anxiety and dental extractions were found by Nuttall et al (Nuttall et al., 2008) who also reported that children who avoided going to the dentist were significantly more likely to have experienced dental extractions both with and without GA. Such avoidance behaviour can impact negatively upon dental health. In this study, the children in the study group had experienced a significantly greater number of general anaesthetics for dental extractions. This could reflect the profession's more radical treatment planning approach of children with CHD who are at increased risk of infective endocarditis. It could also correspond to the higher level of dental anxiety reported in this study and an inability to tolerate dental extractions with local anaesthetic. Exodontia can be a traumatic experience for both the patient and their parent. Balmer et al (Balmer et al., 2004) reported that anxious children find the experience of GA most distressing. Traumatic dental experiences have been frequently cited in association with dental anxiety. Lutch (Lutch, 1971) reported that all the adults in his study who were classed as dental phobics (n=34) had experienced at least one traumatic dental event, as opposed to ten matched control patients (n=34). However, no definition or description of traumatic dental experiences was provided. The patients' perception of traumatic events is likely to be subjective and therefore, highly variable. It has been shown that dentally anxious patients will report more pain and discomfort during operative procedures than those who are not anxious (Harman et al., 2005, Maggiriias and Locker, 2002). Therefore, care is needed when interpreting studies that have analysed dental anxiety against subjective self-reported variables. In a similar way, it should be noted that one of the limitations of this study was that it did not consider the variability in children's ability to tolerate dental treatment. What is distressing to one child may not be to another. The questionnaire was designed to include questions relating to dental interventions that have been correlated with dental anxiety, such as local anaesthetic and the drill (Kleinknecht et al., 1973, Cuthbert and Melamed, 1982). However, information relating to how well the children had tolerated

any previous dental intervention was not recorded. This study did not attempt to identify any specific traumatic events in the children's medical and dental histories. Alwin et al (Alwin et al., 1991) compared a group of children referred to Newcastle Dental Hospital with anxiety or behavioural management problems (n=65) with a control group of children where the reason for referral related to a specific dental problem such as dental trauma (n=42). Following a number of investigations including the use of a questionnaire, the assessment of child and parental anxiety and a parental assessment of the child's anxiety, the authors reported significant differences in the children's reaction to past medical experiences and the anticipation of medical contacts between the two groups. Sermet (1974) also considered the children's reaction to previous medical experiences. The dentally anxious children had more negative attitudes towards hospitals and doctors and were more often reported to have had experiences highly traumatic medical experiences by their parents. However, in the study by Alwin et al (Alwin et al., 1991), only 1.5% of the parents in the study group attributed their child's dental fear to previous medical experiences. In the same study, 80% of the study group had experience of dental treatment under general anaesthetic, compared to 12% of children in the control group. This could be expected as dentally anxious children may struggle to tolerate dental treatment by any other means. However, it is likely that the distress surrounding a dental GA combined with the minimal opportunity for acclimatisation may contribute to the child's dental anxiety. It has been suggested that inhalation sedation should be more frequently used for children with CHD as learning and conditioning experiences are important mechanisms in dental fear (Kleinknecht et al., 1973). In their study, Kleinknecht et al identified the "needle" and the "drill" as the greatest sources of dental fear and felt that inhalation sedation would help to reduce the negative reactions to these stimuli. Furthermore the efficacy of inhalation sedation to reduce dental anxiety in children has been well documented (Veerkamp et al., 1993, Arch et al., 2001).

6.24 Limitations

A limitation of this study was that the timing of potential traumatic medical and dental events of the children was not analysed. It is accepted that children who have experienced such events at an early age may not be able to recall them and therefore, such events are unlikely to impact upon their level of dental anxiety. Ten Berge et al (Ten Berge M., 2002) examined not only the timing of potentially invasive dental procedures but also the children's reactions to them. The parental version of

the CFSS-DS was used as some of the participants were as young as five years old and, therefore, the use of a self-reported measure was not possible. The authors felt that, based on previous research, parents were able to assess their child's anxiety using the parental version of the CFSS-DS. An assessment of the child's fearful behaviour as rated by the dentists on a five-point Likert scale was also recorded. Following a retrospective analysis of the children's dental records, the authors were unable to draw conclusions regarding the impact of the children's age at their first curative dental treatment upon dental fear. This was because there was no significant difference in the ages of the children at their first dental treatment session between the high and low fear children. The authors did suggest that subjective conditioning experiences may have a more important role than actual dental procedures in the development of dental fear in children. Such findings were supported by Townend et al 2000 who reported that anxious children had experienced a greater number of traumatic visits to the dentist, as assessed by their parents (Townend et al., 2000). In this study, anxious children had experienced their first traumatic dental experience at a younger age.

A clinical record of the children's dental health was not obtained and, therefore, comparisons between the two groups were not possible. It might be expected that children attending the orthodontic clinics had optimal oral hygiene and dental health. However, because the orthodontic clinics were all consultant-led, they included children with the highest orthodontic need and therefore, even children with dental disease may have been referred for an orthodontic opinion. Furthermore, not all patients are referred with a view to receiving a course of orthodontic treatment. Some patients with poor oral health and/or poor motivation can be managed by dental extractions alone but orthodontic advice regarding the extraction pattern may be indicated.

The variables in this study were largely objective. Subjective measures, such as the children's reaction to previous medical and dental interventions, were not recorded. Perhaps their level of generalised fear largely determines children's reactions to medical and dental experiences. It may be that the actual dental and medical procedures the children have experienced are of less importance when compared to their subjective response to them. Majstorovic et al (Majstorovic et al., 2001) investigated factors which could predict a child's dental fear and identified a

significant correlation between the children's dental anxiety and previous medical fear, as measured by Broome's Child Medical Fear Questionnaire. The authors did not appear to record any objective measures of the participants' medical histories. Sermet (Sermet, 1974) aimed to explore both quantitative and qualitative aspects of children's medical histories in relation to dental anxiety and reported a significantly greater experience of highly traumatic medical experiences amongst the dentally anxious children. It may be that such findings relate to poorer coping strategies of dentally anxious children and subsequently higher levels of perceived trauma. Versloot et al (Versloot et al., 2004) concluded that the use and choice of coping strategies amongst the 11 year-olds in their study were determined by their level of dental fear and their pain experience. The more fearful children reported a greater use of coping strategies. The aim of this study, however, was to identify any differences in the level of dental anxiety between the study and control groups taking in to consideration any significant differences in the medical and dental experiences of the children. In order to be able to reliably identify possible reasons behind any differences, more detailed questions relating to the children's reactions to previous experiences and general fearfulness would be required. Bailey et al (Bailey et al., 1973) reported more negative dental behaviours and higher anxiety scores in children who had experienced previous unpleasant medical contacts as rated by the children's mothers. This suggests that questions relating to objective measures of previous medical and dental experiences in the clinical setting should be supplemented with a record of the child's reaction to them.

6.25 Data collection

This study had a cross-sectional case-control design involving the use of questionnaires and anxiety scales for data collection. Both the study and control groups were approached in clinical settings. It was important to standardise the data collection as far as practically possible to minimise differences in the surrounding environments during participation. There has been some evidence to suggest that physical environment affects anxiety (Swallow et al., 1975) and it could be argued that children completing the anxiety scales in a dental setting may report higher levels of dental anxiety due to their environment. However, it is likely that the clinical settings of the dental clinics and cardiology clinics had similar effects upon the state anxiety levels of the children and parents who participated. Wogelius et al (Wogelius et al., 2009) did not report a greater prevalence of dental anxiety amongst oncology patients when compared to a group of healthy children. However, the anxiety scale

(CFFS-DS) was completed in different settings in each group and incomplete questionnaires were not excluded from the analysis unless there were more than four missing items. The majority of the study group completed the CFFS-DS at home whilst the control group (including seven children in the study group) completed the scale at school. In theory, children in their home environment might have lower levels of state anxiety which could affect the level of anxiety reflected by the dental anxiety scale. In the current study, one of the reasons for not recruiting controls from a local school related to the differences between the classroom environment and that of a hospital outpatient department.

Participants in both groups were recruited before their consultation with the cardiologist or orthodontist. However, on occasion, participants were taken for their appointment prior to the completion of the anxiety scales and questionnaires. In the vast majority of these cases, due to the short length of the MCDAS_f, the children had already completed the anxiety scale prior to their consultation but the parents required more time to complete the medical and dental questionnaire. In this way, the completion of the MCDAS_f was standardised as far as possible. Furthermore, none of the children received any form of treatment during their consultations and therefore, the timing of the completion of the MCDAS_f was less critical.

6.26 Pilot study

The paperwork used in this study was piloted on a group of 10 families. Following this, minor amendments were made before use in the study. Whilst the questionnaire was not tested for validity or reliability due to time constraints, the pilot study informed its acceptability. Feedback from the pilot study was positive and comments regarding its clarity were received.

6.30 DISCUSSION OF THE RESULTS

6.31 Demographics

The sample size was met. There were 54 participants in the study group and 53 participants in the control group. Unfortunately, it was not possible to match the participants for age, gender and socio-economic status as measured by IMD 2007. However, differences in the age, gender and deprivation between the groups were analysed to exclude possible confounding factors.

6.311 Age

Statistical analysis demonstrated that there was not a significant difference between the mean ages of the participants in the study and control groups. This was important because although there is conflicting evidence concerning the effect of age on dental anxiety, previous research suggests that age could impact upon dental anxiety.

6.312 Gender

With regards to gender, although there were more females in the control group, this difference was not statistically significant according to Chi-square test. If there had been a significant difference in the genders between the two groups, this could have been a potential source of bias as some studies have shown an increased level of dental anxiety amongst females with regards to dentistry in general and also specific aspects of dental care such as seeing and feeling the needle (Kleinknecht et al., 1973). However, this study supported the research which has found no gender predilection for dental anxiety. There was not a significant difference in the mean level of dental anxiety between the boys and the girls.

6.313 Deprivation quintiles

Children seeking orthodontic care have been shown to have more affluent backgrounds (Miguel et al., 2010). This could relate to the fact that patients referred for orthodontic care need to have optimal oral health and caries is associated with low socio-economic status. Whilst this study demonstrated a significant difference in the deprivation quintiles between the two groups, with the study group being significantly more deprived, this was not thought to be a confounding factor following ANCOVA.

The IMD 2007 is the Government's official measure of multiple deprivation at small area level and combines a number of social, economic and housing indicators to produce a single deprivation score for small geographical areas across England. The IMD 2007 offered an efficient method of recording the families' levels of deprivation although data relating to three of the postcodes could not be retrieved. Therefore, these participants were excluded from the analysis of deprivation. Furthermore, whilst the IMD 2007 identifies concentrations of deprivation, there is likely to be variations within each geographical area and therefore, its accuracy cannot always be

guaranteed. Even so, the significant difference between the deprivation quintiles in the groups required further investigation as previous studies have reported a significant relationship between dental anxiety and socio-economic status (Nuttall et al., 2008, Townend et al., 2000). Nuttall et al (2008) reported the findings relating to dental anxiety from the Children's Health survey of 2003. Whilst it should be noted that the measures of dental anxiety were not self-reported but were largely based on the parental assessment of the children's dental anxiety through their behaviour, the authors concluded that extremely anxious children were significantly more likely to come from social class IV or V. The reason for this is difficult to determine. It has been well documented that children from lower socio-economic backgrounds are at higher risk of developing dental caries. This relationship has also been found amongst children with CHD. Urquhart and Blinkhorn examined 134 children with CHD in Scotland and discovered that the majority of dental disease was found in children with lower social class backgrounds (Urquhart and Blinkhorn, 1990). However, when considering the relationship between dental anxiety and dental caries experience, it is difficult to determine whether the higher caries experience leads to increased levels of dental anxiety or whether the dental anxiety results in avoidance behaviour and a subsequent decline in dental health. In order to successfully investigate the cause and effect, a prospective longitudinal cohort study would be required. Nevertheless, it would seem that children from more deprived backgrounds have higher levels of caries and dental anxiety which could pose a significant barrier to the provision of dental care.

The use of the IMD 2007 allowed a comparison of the two groups in terms of socio-economic status so that the potential impact of this could be taken into account. In this study, although there was a significant difference in the deprivation quintiles between the study and control groups, the significant difference between the mean dental anxiety scores in each group remained when the deprivation quintiles were controlled with ANCOVA. The use of one-way ANCOVA enabled the difference in the level of MCDAS_f scores between the study and control group to be explored whilst controlling for the deprivation quintiles which acted as the covariate. As part of ANCOVA, SPSS uses regression procedures to remove the variation in the dependent variable (MCDAS_f) that is due to the covariate. An analysis of variance is then performed on the adjusted scores. In this way, all the variables that were significantly different between the control and study groups were adjusted and the MCDAS_f scores were explored by ANCOVA. This analysis was extremely important

when applied to dental anxiety scores within the context of socio-economic status. It showed that - although there was an overall difference in the socio-economic status of the two groups – this difference did not account for the significant differences demonstrated in the dental anxiety scores between children with and without cardiac disease.

6.32 Child Dental Anxiety

6.321 Comparison of child anxiety between the study and control groups

The results of this study indicated that children with cardiac defects are more dentally anxious than a group of healthy, i.e. ASA I, children. The mean MCDAS_f score was 21.96 (S.D. 5.673) for the study group and 18.48 (S.D. 6.489) for the control group.

The design of this study aimed to identify and eliminate potential confounders where possible. In this way, significant differences in the age, gender and parental dental anxiety levels between the two groups were excluded. Where significant differences in demographics and the past medical and dental histories of the children in the study and control groups were found, ANCOVA was performed to adjust for these differences. The differences in the level of dental anxiety remained significant when deprivation, exodontia experience and GA experience were covariates which indicated that these covariates did not contribute to the difference in the level of dental anxiety between the study and control group. However, the difference in the MCDAS_f scores became just non-significant when overnight admissions was the covariate ($p=0.054$). In this analysis, the overnight admission covariate was not significant ($F(1,104)=2.364$, $p=0.127$) and therefore, did not have a direct effect upon the child dental anxiety. These results would suggest that overnight hospital admissions may have a moderating effect upon the MCDAS_f scores. Sermet (Sermet, 1974) also identified a significantly greater number of hospital admissions amongst dentally anxious children compared to non-anxious children. Furthermore, the anxious children had experienced a significantly greater number of outpatient treatments in hospital which offers support to the theory that a child's previous medical experiences may impact upon their level of dental anxiety.

6.322 Child dental anxiety within the study group

Within the study group, the children were classified according to the nature of their cardiac condition i.e. whether it was a structural or conductive defect. Those with structural defects were sub-classified according to the severity of their cardiac diagnosis. Children with more complex cardiac conditions are more likely to have experienced a greater range of medical interventions and to have more frequent exposure to the hospital environment. The questionnaire enabled the past medical experiences of the children, namely overnight hospital admissions and general anaesthetic history, to be analysed. There were no significant differences in the overnight admission histories of between children with structural and conductive cardiac defects, or between the three cardiac diagnosis categories of those with structural defects. Furthermore, there was no difference in the mean number of general anaesthetics experienced by those with structural and conductive defects. However, when the GA history of those with structural defects was analysed further, those with simple defects were shown to have experienced significantly fewer general anaesthetics than those with cardiac defects classified as moderate and great complexity. Despite this, no significant differences were found in the MCDAS_r scores between the cardiac diagnosis categories. This could relate to the limited number of participants with structural defects, or it could be due to the weak correlation between general anaesthetic history and MCDAS_r scores in this study.

6.323 Child dental anxiety and medical experiences

Children who have greater experience of medical contacts theoretically may have increased levels of dental anxiety after being sensitised to the health care environment through their medical experiences. The current investigation found a significantly greater experience of overnight hospital admissions and general anaesthetics amongst the study group. The results of this study indicated that overnight hospital admissions may influence a child's level of dental anxiety. Whilst it is possible that overnight hospital admissions have a greater sensitising effect than the other variables investigated in this study, admission history cannot solely explain the difference in the level of dental anxiety between the two groups. Indeed, Suprabha et al (Suprabha et al., 2011) did not identify any differences in the admission histories of children classed as with high dental fear (CFSS-DS>38) when compared to those with lower CFSS-DS scores. However, when a regression analysis was performed with dental fear as the dependent factor, hospital admission

history appeared to contribute to dental fear. The authors concluded that past medical experiences were likely to influence dental fear but not behaviour. A study of the behaviour of children aged three to six years at a Brazilian University Dental Clinic reported a significant association between previous hospitalisation and negative child behaviour (Colares and Richman, 2002). It is possible that the more negative behaviour reflected a higher level of dental anxiety but this would have been difficult to determine in young children. The child's temperament and lack of ability to cope with experiences such as hospital admissions may be important factors in children whom subsequently manifest dental anxiety. It is likely that other factors that were not identified in this study contribute to the aetiology of dental anxiety amongst paediatric cardiology patients. In order to identify specific predictors, further research into the nature of previous medical experiences in addition to subjective aspects such as the children's response to such experiences is required.

6.324 Child dental anxiety and parental dental anxiety

The present study supported previous research which has suggested a positive correlation between parental and child dental anxiety (Klingberg et al., 1995, Klingberg and Broberg, 2007). Although the correlation was only weak in this study, parental anxiety could be a useful indicator for child dental anxiety. Furthermore, maternal dental anxiety has been shown to be associated with a higher level of untreated caries in their children, even after covariate adjustment (Goettems et al., 2012). This could mean that maternal dental anxiety could have particular significance for paediatric cardiology patients. However, there was no significant difference in the mean level of parental dental anxiety between the control and study groups and therefore, parental dental anxiety could not have contributed greatly to the significant difference in the mean level of child dental anxiety.

6.33 Parental rating of child dental anxiety

There was a medium positive correlation between the parental rating of their child's dental anxiety and the children's self-reported level of dental anxiety. This suggested that parental prediction of their child's dental anxiety may be of clinical use. Whilst previous research has been conflicting, the methodology used in these studies has varied and therefore, conclusions are difficult to draw (Alwin et al., 1991, Klingberg and Broberg, 2007, Rantavuori et al., 2009, Carson and Freeman, 2001). Luoto et al (Luoto, Tolvanen et al. 2010) reported higher specificity than sensitivity values for

parent's ability to recognise dental fear amongst their children although, overall, the parents in their demonstrated poor knowledge of their child's dental fear.

6.34 Access to dental care

In this study, four children did not have regular access to dental care. All of these children were from the study group. An important aspect of the children's dental histories that was not considered was their dental attendance pattern. It has been shown that paediatric cardiology patterns do not always follow regular dental attendance patterns (da Fonseca et al., 2009, Saunders and Roberts, 1997) and therefore, it cannot be guaranteed that the children in this study with access to dental care attended on a regular basis. This could have been a possible confounder as irregular dental attendance has been associated with higher levels of dental anxiety (Bedi et al., 1992a, Milsom et al., 2003).

The results of this study indicate that paediatric cardiology patients have an increased level of dental anxiety. The potential consequences of this are poor dental attendance patterns (Franco et al., 1996) and poorer dental health. Therefore, it is imperative that additional support is offered to children with cardiac defects. One method of providing this that has been recommended by various authors (Urquhart and Blinkhorn, 1990, Franco et al., 1996, Hollis et al., 2012) involves the attendance of dental care professionals at outpatient cardiology clinics. This would not only ensure that paediatric cardiology patients have access to dental care but would also provide an opportunity for oral health promotion. It has been reported that even when children with CHD attend dental appointments regularly, they are not always provided with the appropriate preventive advice (Balmer and Bu'Lock, 2003). Additional dental support at cardiology outpatient clinics would highlight the importance of dental prevention, improve the dental knowledge of the families and permit a referral pathway to specialist paediatric dental services where needed. It has been suggested that paediatric cardiology patients should be seen regularly under specialist care (Grahn et al., 2006). Specialist paediatric dental services have greater experience of managing not only anxious patients but also those with medical conditions. In addition to this, pharmacological adjuncts to dental care, such as inhalation sedation, are more readily available. A study involving web-based questionnaires in Germany aimed to compare the anxiety management techniques employed by general dental practitioners to those of paediatric dentists (Diercke et al., 2012). Although the

response rate was poor, following analysis of the 230 returned questionnaires, the authors concluded that paediatric dentists used a wider range of behaviour techniques, reported an increased use of anxiety questionnaires and reported fewer difficulties associated with the management of dentally anxious children. A significant increase in the use of sedation prior to operative dental treatment in children with CHD has been reported although the authors did not related this finding to an increased level of dental anxiety in this group (Grahm et al., 2006). Furthermore, it has been demonstrated that general dental practitioners not only lack confidence in treating medically compromised children (Parry and Khan, 2000) but also tend to refer anxious children to secondary care (Harris et al., 2008). Whilst there was only one child in the study group who was experiencing toothache, dental attendance during data collection at the cardiac clinic enabled an urgent appointment at LDI to be arranged.

7.00 CONCLUSIONS

- 1) The null hypothesis relating to no difference in the level of dental anxiety between the study and control group was rejected. The study group was significantly more dentally anxious than the control group.
- 2) The null hypothesis stating that there was no difference in the level of dental anxiety with regards to the secondary medical outcome measures (overnight hospital admissions, general anaesthetic history and cardiac complexity category) was accepted. There were no significant differences in the level of dental anxiety between the cardiac diagnosis categories and only weak relationships between child dental anxiety and GA and overnight admission experience.
- 3) The paediatric cardiology patients had a significantly greater experience of exodontia, overnight hospital admissions and general anaesthetics than the control group.
- 4) Although the study group was significantly more deprived, ANCOVA showed that the study group was still more anxious when the difference in the deprivation quintiles between the groups was controlled.
- 4) An ANCOVA using the significantly different variables as covariates suggested that overnight hospital admissions may influence the level of child dental anxiety in this study. Child dental anxiety was not affected by general anaesthetic history or exodontia experience.
- 5) There was a very weak negative correlation between child dental anxiety and increasing age of the children in this study.
- 6) There was a weak positive correlation between the parental and child dental anxiety scores.
- 7) A medium positive correlation was seen in the parent's ability to predict their child's level of dental anxiety.

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APPENDIX I



National Research Ethics Service

NRES Committee Yorkshire & The Humber - Leeds East

Yorkshire and Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 3050108
REVISED LETTER

Dr Amy Hollis
Child Dental Health, Leeds Dental
Institute, Clarendon Way,
Leeds
LS29LU

8th August 2011

Dear Dr Hollis

Study title: An investigation into dental anxiety amongst paediatric
cardiology patients
REC reference: 11/YH/0191

Thank you for your email of 13th July 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

XIV

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	1	28 April 2011
Evidence of insurance or indemnity	1	10 September 2010
GP/Consultant Information Sheets	1	31 October 2010
Investigator CV	1 - Dr A Hollis	17 April 2011
Other: Email from sponsor	1	20 April 2011
Other: Assent Form 8 - 15 year olds	2	31 December 2010
Participant Consent Form: Parents	3	01 June 2011
Participant Consent Form	3	01 June 2011
Participant Information Sheet: Child study group aged 12-16 years	2	31 December 2010
Participant Information Sheet: Parent/Guardian study group	2	31 December 2010
Participant Information Sheet: Child control group aged 12-16 years	2	31 December 2010
Participant Information Sheet: Parent/Guardian control group	2	31 December 2010
Participant Information Sheet: Child study group age 8-11 years old	3	01 June 2011
Participant Information Sheet: Child control group age 8-11 years old	4	01 June 2011
Protocol	4	
Questionnaire: Parental/Guardian Dental Anxiety Scale	2	01 June 2011
Questionnaire: Child Dental Anxiety Scale	2	01 June 2011
Questionnaire: Parent/guardian - Control group	3	01 June 2011
Questionnaire: Parent/guardian - study group	3	01 June 2011
REC application	IRAS 3.0	27 April 2011
Response to Request for Further Information		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/YH/0191	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely



Dr Carol Chu
Chair

Email: jade.thorpe@nhs.net

Copy to: *Rachel de Souza*
Anne Gowing, Leeds Teaching Hospitals NHS Trust

APPENDIX II

The Leeds Teaching Hospitals 
NHS Trust

Ref: Amanda Burd

22/08/2011

Dr Amy Hollis

Leeds Dental Institute
Child Dental Health, Leeds Dental
Institute, Clarendon Way, Leeds
LS2 9LU

Research & Development

Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 2878
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r@d@leedsth.nhs.uk
www.leedsth.nhs.uk

Dear Dr Amy Hollis

**Re: NHS Permission at LTHT for: An investigation into dental anxiety
amongst paediatric cardiology patients
LTHT R&D Number: DT11/9924
REC: 11/YH/0191**

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/sites/research_and_development/.

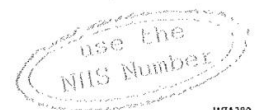
This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

Chairman Mike Collier CBE Chief Executive Maggie Boyle

The Leeds Teaching Hospitals incorporating:
Chapel Allerton Hospital Leeds Dental Institute Seacroft Hospital
St James's University Hospital The General Infirmary at Leeds Wharfedale Hospital



WTA280

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the R&D Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as investigator and the researchers listed on the Site Specific Information form. Should there be any changes to the research team please ensure that you inform the R&D Department and that s/he obtains an appropriate contract, or letter of access, with the Trust if required.

Yours sincerely



Dr D R Norfolk
Associate Director of R&D

Approved documents

The documents reviewed and approved are listed as follows

<i>Document</i>	<i>Version</i>	<i>Date of document</i>
NHS R&D Form	3.0	11/07/2011
SSI Form	3.0	04/07/2011
Directorate Approval		05/07/2011
Protocol	4	December 2010
REC Letter confirming favourable opinion		08/08/2011
Insurance/Indemnity		10/09/2010
GP Letter	1	October 2010
Patient information sheet (REC Approved) Assent Form 8-15yrs	2	June 2011
PIS: Child Study Group (12-16 yrs) (REC Approved)	2	December 2010
PIS: Parent/Guardian Study Group (REC Approved)	2	December 2010
PIS: Child Control Group (12-16yrs) (REC Approved)	2	December 2010
PIS: Parent/Guardian Control Group: (REC Approved)	2	December 2010
PIS: Child Study Group (8-11 yrs) (REC Approved)	3	June 2011
PIS: Child Control Group (8-11 yrs) (REC Approved)	4	June 2011
Questionnaire: Parental/Guardian	2	June 2011
Questionnaire: Dental Anxiety	2	June 2011
Questionnaire: Parent/Guardian Control Group	3	June 2011
Questionnaire: Parent/Guardian Study Group	3	June 2011
Consent form (REC Approved)	3	June 2011

APPENDIX III

York Hospitals 

NHS Foundation Trust

R&D Unit reference: YOR-A02084
EUDRACT number (if applicable):

Dr Amy Hollis
Child Dental health
Leeds Dental Institute
Clarendon
Leeds LS2 9LU

North and East Yorkshire Alliance R&D Unit
Main Office: Learning and Research Centre
York Hospitals NHS Foundation Trust
York
YO31 8HE

Tel: (01904) 726996
Fax: (01904) 731297

15th March 2012

www.northyorksresearch.nhs.uk

Dear Dr Hollis

NHS Management Permission to undertake a research study

Trust: York Teaching Hospital NHS Foundation Trust

Study Title: An investigation into dental anxiety amongst paediatric cardiology patients

Thank you for submitting details of this trial for NHS Management Permission from the above-named Trust, which is a member of the North and East Yorkshire R&D Alliance.

On behalf of the Trust I confirm that Management Permission to conduct the study at this site is granted. The Sponsor should accept this as confirmation that all necessary governance checks have been made. Please note that this NHS Permission is based on the documents included on the attached list. Any subsequent amendments must be notified to the R&D Unit.

Yours sincerely



Caroline Mozley
Head of Research and Development
On behalf of York Teaching Hospital NHS Foundation Trust

cc: R&D Unit Research Monitoring Officer

APPENDIX IV

Diagnosis categories of CHD

Simple congenital heart disease

Native disease

Isolated congenital aortic valve disease

Isolated congenital mitral valve disease

Isolated patent foramen ovale or small atrial septal defect

Isolated small ventricular septal defect

Mild pulmonary stenosis

Repaired conditions

Previously ligated or occluded ductus arteriosus

Repaired atrial septal defect without residua

Repaired ventricular septal defect without residua

Moderate severity

Aorto-left ventricular fistulae

Anomalous pulmonary venous drainage, partial or total

Atrioventricular canal defects (partial or complete)

Coarctation of the aorta

Ebstein's anomaly

Infundibular right ventricular outflow obstruction of significance

Ostium primum atrial septal defect

Patent ductus arteriosus (not closed)

Pulmonary valve regurgitation (moderate to severe)

Pulmonic valve stenosis (moderate to severe)

Sinus of Valsalva fistula/aneurysm

Sinus venosus atrial septal defect

Subvalvar or supra-valvar aortic stenosis (except HOCM)

Tetralogy of Fallot

Ventricular septal defect with

Absent valve or valves

Aortic regurgitation

Coarctation of the aorta

Mitral disease

Right ventricular outflow tract obstruction

Straddling tricuspid/mitral valve

Subaortic stenosis

Great complexity

Conduits, valved or nonvalved

Cyanotic congenital heart (all forms)

Double-outlet ventricle

Eisenmenger syndrome

Fontan procedure

Mitral atresia

Single ventricle (double inlet or outlet, common or primitive)

Pulmonary atresia

Pulmonary vascular obstructive diseases

Transposition of the great arteries

Tricuspid atresia

Truncus arteriosus/hemitruncus

Other abnormalities of atrioventricular or ventriculoarterial connection not included above (i.e., crisscross heart, isomerism, heterotaxy syndromes, ventricular inversion)

APPENDIX V

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry
A Centre for Children with Special Needs

Level 6, Worsley Building
Clarendon Way, Leeds, LS2 9LU
Tel: Direct Line +44 (0)113 343 8369
Tel: Enquiries +44 (0)113 343 6138
Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: A project looking at how some children feel about going to the dentist

Researcher: Amy Hollis

Study information sheet (Child study group age 8-11 years old):

You are being asked to take part in a project looking at how children feel when they go to the dentist. Before you say if you want to take part it is important that you know why the project is being done and what will happen if you take part. Please read this carefully and talk to other people about it if you want. Also, please ask me if there is anything that is not clear or if you would like to know more.

Why is the study being done?

We want to find out how children who go to hospital feel about going to see their dentist.

Why have I been chosen?

You have been chosen because you are visiting the children's heart clinic at the Leeds General Infirmary and are between 8 and 11 years old.

Do I have to take part?

You do not have to take part if you do not want to. Nothing will happen if you don't.

What will happen if I take part?

We would like to ask you some questions about how you feel about going to the dentist and about what happens when you go to the dentist. There are only 8 questions and they are very short. If you change your mind about taking part after starting to answer the questions then you can stop at any time. We would also like to ask your mum or dad some questions about things you have had done at the dentist and at the hospital. We may ask you and your mum or dad to answer the questions a second time later on to check that the answers have not changed.

Will my taking part in the study be kept private?

All the information that we collect will be kept strictly private. Nobody will be able to tell that you have taken part as your name will not appear on the forms.

What happens to the results of the study?

The results will be written and discussed in a special report which will be printed. You will not be identified in the report.

Contact for further information

If you would like to know more you can email us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this. Please keep this and a copy of the consent form for your records.

APPENDIX VI

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry
A Centre for Children with Special Needs

Level 6, Worsley Building
Clarendon Way, Leeds, LS2 9LU
Tel: Direct Line +44 (0)113 343 8369
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Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: A project looking at how some children feel about going to the dentist

Researcher: Amy Hollis

Study information sheet (Child study group age 12-16 years):

You are being asked to take part in a research project looking at how worried children with heart problems are when they go to the dentist. The research is for an educational qualification. Before you decide whether to take part, it is important that you understand why the research is being done and what will happen if you take part. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like further information. Thank you for reading this.

What is the study being done?

Sometimes we find that children who have had a lot of visits to hospital are more worried about going to the dentist. We want to find out if this is true in children who have gone to hospital because they have a problem with their heart. This is the first project to look at this.

Why have I been chosen?

You have been chosen because you are visiting the outpatients cardiology clinic at the Leeds General Infirmary and are between the ages of 8 and 16 years old.

Do I have to take part?

You do not have to take part if you do not want to. Nothing will happen if you don't.

What will happen if I take part?

If you decide to take part you will be asked 8 questions about how you feel when you go to the dentist. Your parent/guardian will be asked similar questions as well as questions about medical or dental treatment you may have had in the past. All responses will be anonymous. We may ask some children and their parents to complete the anxiety questionnaires a second time at their next visit to check that the answers given have not changed.

What are the possible risks of taking part?

There are no risks associated with taking part. If you decide you don't want to take part after starting to answer the questions then you can stop at any time.

Will my taking part in the study be kept confidential?

All the information that we collect will be kept strictly confidential. You will not be able to be identified in any reports or publications.

What happens to the results of the study?

The results will be written and discussed in a research project report and it is likely that they will be published in a scientific journal. However, you will not be identified in any report or publication.

Who has reviewed the study?

The study has been approved by the NHS Research Ethics Service.

Who is organizing and funding the research?

The study is being carried out by a dentist at the Leeds Dental Institute

Contact for further information

If you would like any further information please do contact us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this information sheet. Please keep this and a copy of the consent form for your records.

Leeds Dental Institute

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Tel: Enquiries +44 (0)113 343 6138
Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: Dental Anxiety Amongst Paediatric Cardiology Patients

Researcher: Amy Hollis

Study information sheet (Parent/Guardian of study group):

Dear Parent or Guardian

You and your child are being invited to take part in a research project examining the level of dental anxiety amongst children with heart problems. The research is for an educational qualification. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do not hesitate to ask me if there is anything that is not clear or if you would like further information. Thank you for reading this.

What is the purpose of the study?

Studies have shown the dental health of children with heart problems may be poorer than that of healthy children. It is likely that there are various reasons for this with dental anxiety possibly playing a part. Therefore, the aim of this study is to see how children with heart conditions feel about going to the dentist and to see if this is affected by previous medical interventions. There are currently no other studies examining this.

Why has my child been chosen?

Your child has been chosen because they are visiting the outpatients cardiology clinic at Leeds General Infirmary and are aged between 8 and 16 years old.

Do we have to take part?

Taking part is entirely voluntary and if you decide not to take part, this will not affect you or your child in any way. Furthermore should you take part then decide you want to discontinue participation you can request this at any time

What will happen if we take part?

If you decide to take part you will be asked to complete a short questionnaire about your child's medical and dental histories and a few questions about how you feel when you go to the dentist. Your child will also be asked a few questions about how they feel about going to the dentist. All responses will be anonymous. We may ask some participants to complete the anxiety questionnaires a second time at their next visit to check that the answers given have not changed.

What are the possible risks of taking part?

There are no risks associated with taking part. In the unlikely event that your child becomes upset by the short questionnaire about how they feel at the dentist, the questionnaire can be stopped immediately.

Will our taking part in the study be kept confidential?

All the information that we collect will be kept strictly confidential. You and your child will not be able to be identified in any reports or publications.

What happens to the results of the study?

The results will be reported in a research thesis and it is likely that they will be published in a scientific journal. However, you and your child will not be identified in any report or publication.

Who has reviewed the study?

The study has been approved by the NHS Research Ethics Service.

Who is organizing and funding the research?

The study is being carried out by a dentist at the Leeds Dental Institute

Contact for further information

If you would like any further information please do contact us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this information sheet. Please keep this and a copy of the consent form for your records.

APPENDIX VIII

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry
A Centre for Children with Special Needs
Level 6, Worsley Building
Clarendon Way, Leeds, LS2 9LU
Tel: Direct Line +44 (0)113 343 8369
Tel: Enquiries +44 (0)113 343 6138
Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: A project looking at how some children feel about going to the dentist

Researcher: Amy Hollis

Study information sheet (Child control group age 8-11 years old):

You are being asked to take part in a project looking at how children feel when they go to the dentist. Before you say if you want to take part it is important that you know why the project is being done and what will happen if you take part. Please read this carefully and talk to other people about it if you want. Also, please ask me if there is anything that is not clear or if you would like to know more.

Why is the study being done?

We want to find out how children who go to hospital feel about going to see their dentist.

Why have I been chosen?

You have been chosen because you are healthy, and are between 8 and 11 years old. You will form part of the group that will be compared to the children with heart problems to see if there are any differences in how you feel when you go to the dentist.

Do I have to take part?

You do not have to take part if you do not want to. Nothing will happen if you don't.

What will happen if I take part?

We would like to ask you some questions about how you feel about going to the dentist and about what happens when you go to the dentist. There are only 8 questions and they are very short. If you change your mind about taking part after starting to answer the questions then you can stop at any time. We would also like to ask your mum or dad some questions about things you have had done at the dentist and at the hospital. We may ask you and your mum or dad to answer the questions a second time later on to check that the answers have not changed.

Will my taking part in the study be kept private?

All the information that we collect will be kept strictly private. Nobody will be able to tell that you have taken part as your name will not appear on the forms.

What happens to the results of the study?

The results will be written and discussed in a special report which will be printed. You will not be identified in the report.

Contact for further information

If you would like to know more you can email us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this information sheet. Please keep this and a copy of the consent form for your records.

APPENDIX IX

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry
A Centre for Children with Special Needs
Level 6, Worsley Building
Clarendon Way, Leeds, LS2 9LU
Tel: Direct Line +44 (0)113 343 8369
Tel: Enquiries +44 (0)113 343 6138
Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: A project looking at how some children feel about going to the dentist

Researcher: Amy Hollis

Study information sheet (Child control group age 12-16 years old):

You are being asked to take part in a research project looking at how worried children with heart problems are when they go to the dentist. The research is for an educational qualification. Before you decide whether to take part, it is important that you understand why the research is being done and what will happen if you take part. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like further information. Thank you for reading this.

Why is the study being done?

Sometimes we find that children who have had a lot of visits to hospital are more worried about going to the dentist. We want to find out if this is true in children who have gone to hospital because they have a problem with their heart. This is the first project to look at this.

Why have I been chosen?

You have been chosen because you are medically fit and well, and are between the ages of 8 and 16 years old. You will form part of the group that will be compared to the children with heart problems to see if there are any differences in how children in these groups feel when they go to the dentist.

Do I have to take part?

You do not have to take part if you do not want to. Nothing will happen if you don't.

What will happen if I take part?

If you decide to take part you will be asked 8 questions about how you feel when you go to the dentist. Your parent/guardian will be asked similar questions as well as questions about medical or dental treatment you may have received in the past. All responses will be anonymous. We may ask some children and their parents to complete the anxiety questionnaires a second time at their next visit to check that the answers given have not changed.

What are the possible risks of taking part?

There are no risks associated with taking part. If you decide you don't want to take part after starting to answer the questions then you can stop at any time.

Who will benefit from taking part?

Whilst there are no immediate benefits for you, it is hoped that this work will help to gain a better understanding of the possible reasons behind why children with heart conditions have less healthy mouths than children who do not have heart problems. However if you haven't seen a dentist for a while and would like a check up, this can be arranged at Leeds Dental Institute if you would like.

Will my taking part in the study be kept confidential?

All the information that we collect will be kept strictly confidential. You will not be able to be identified in any reports or publications.

What happens to the results of the study?

The results will be written and discussed in a research project report and it is likely that they will be published in a scientific journal. However, you will not be identified in any report or publication.

Who has reviewed the study?

The study has been approved by the Dental Ethics Research Committee and the NHS Research Ethics Service.

Who is organizing and funding the research?

The study is being carried out by a dentist at the Leeds Dental Institute

Contact for further information

If you would like any further information please do contact us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this information sheet. Please keep this and a copy of the consent form for your records.

APPENDIX X

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry
A Centre for Children with Special Needs
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Clarendon Way, Leeds, LS2 9LU
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Tel: Enquiries +44 (0)113 343 6138
Fax: +44 (0)113 343 6140
Email: den1alh@leeds.ac.uk

Study Title: Dental Anxiety Amongst Paediatric Cardiology Patients**Researcher: Amy Hollis****Study information sheet (Parent/Guardian of control group):**

Dear Parent or Guardian

You and your child are being invited to take part in a research project examining the level of dental anxiety amongst children with heart problems. The research is for an educational qualification. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do not hesitate to ask me if there is anything that is not clear or if you would like further information. Thank you for reading this.

What is the purpose of the study?

Studies have shown the dental health of children with heart problems may be poorer than that of healthy children. It is likely that there are various reasons for this with dental anxiety possibly playing a part. Therefore, the aim of this study is to see if children with heart conditions are more anxious of the dentist and to see if this is affected by previous medical interventions. There are currently no other studies examining this.

Why has my child been chosen?

Your child has been chosen because they are medically fit and well and are aged between 8 and 16 years old. They will form part of the group that will be compared to the children with cardiac problems to see if there are any differences in the levels of dental anxiety between the 2 groups.

Do we have to take part?

Taking part is entirely voluntary and if you decide not to take part, this will not affect you or your child in any way. Furthermore should you take part then decide you want to discontinue participation you can request this at any time.

What will happen if we take part?

If you decide to take part you will be asked to complete a short questionnaire about your child's medical and dental histories and a few questions about how you feel when you go to the dentist. Your child will also be asked a few questions about how they feel about going to the dentist. All responses will be anonymous. We may ask some participants to complete the anxiety questionnaires a second time at their next visit to check that the answers given have not changed.

What are the possible risks of taking part?

There are no risks associated with taking part. In the unlikely event that your child becomes upset by the short questionnaire about how they feel at the dentist, the questionnaire can be stopped immediately.

Who will benefit from taking part?

Whilst there are no immediate benefits for those participating in this project, it is hoped that this work will help to gain a better understanding of the possible reasons behind why children with heart conditions have poorer dental health. However, should your child be having difficulty accessing dental care, an appointment for a dental examination can be arranged at Leeds Dental Institute.

Will our taking part in the study be kept confidential?

All the information that we collect will be kept strictly confidential although your child's dentist will be informed of your involvement. You and your child will not be able to be identified in any reports or publications.

What happens to the results of the study?

The results will be reported in a research thesis and it is likely that they will be published in a scientific journal. However, you and your child will not be identified in any report or publication.

Who has reviewed the study?

The study has been approved by the NHS Research Ethics Service.

Who is organizing and funding the research

The study is being carried out by a dentist at the Leeds Dental Institute

Contact for further information

If you would like any further information please do contact us

Amy Hollis, Specialist Registrar in Paediatric Dentistry den1alh@leeds.ac.uk

Richard Balmer, Consultant in Paediatric Dentistry r.c.balmer@leeds.ac.uk

Thank you for reading this information sheet. Please keep this and a copy of the consent form for your records.

APPENDIX XI

Leeds Dental Institute



UNIVERSITY OF LEEDS

The Centre for Oral Health Sciences

Title: Dental Anxiety amongst Paediatric Cardiology Patients**Researcher: Amy Hollis****Consent form**

Please initial the box on the right hand side of the sheet to indicate that you agree with the statements.

1. I have read and understood the information sheet for the above study (V1:8-10/V2:12-10 delete as appropriate). I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.
2. I understand that participation is voluntary and that I am free to withdraw my child at any time without giving reason and without affecting my child's future care.
3. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the University of Leeds, from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access my child's records.
4. I agree to my child's cardiologist/doctor being informed of our participation in the study.
5. I agree to take part in the study.
6. I have been informed and agree that my child's dentist can be informed of our involvement.

Signature of parent

Signature of researcher

Name (block capitals)

Date

Name (block capitals)

Date

APPENDIX XII

Leeds Dental Institute

The Centre for Oral Health Sciences



Title: A project looking at how some children feel about going to the dentist

Researcher: Amy Hollis

Assent form for 8-15 year olds

(assent means saying that you agree to do something)

A study of dental anxiety in children with heart problems

Has someone else told you about the project?	Yes/No
Do you understand what the project is about?	Yes/No
Have you asked any questions you want?	Yes/No
Have you had your questions answered?	Yes/No
Do you understand that it's OK to stop taking part any time?	Yes/No
Are you happy to take part?	Yes/No

If any of the answers are 'no' or you don't want to take part, don't sign your name.

If you do want to take part please write your name and today's date. If you don't like writing you could draw a smiley face instead.

Your name

Date

The person who explained this project to you needs to sign too.

Name

Date

Signature



Leeds Dental Institute

UNIVERSITY OF LEEDS

The Centre for Oral Health Sciences

Amy Hollis

Specialist Registrar in Paediatric Dentistry

Richard Balmer

Consultant in Paediatric Dentistry

Date:

Dear Sir or Madam

Ref:

Research Project: An investigation into dental anxiety amongst paediatric cardiology patients

I understand the above patient attends your practice for routine dental care. The family have agreed to participate in a research project being carried out at Leeds Dental Institute. The aim of the study is to investigate the level of dental anxiety amongst paediatric cardiology patients and to compare this with a group of children with no relevant medical history. The study involves the participants and their parents completing dental anxiety scales and a short questionnaire relating to their medical and dental histories. This study has been granted ethical and R&D approval (REC ref 11/YH/0191). The above patient has been recruited in the study group. Please do contact me if you have any further queries.

Yours Sincerely

Amy Hollis

Specialist Registrar in Paediatric Dentistry

Department of Paediatric Dentistry
A Centre for Children with Special Needs

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Clarendon Way, Leeds, LS2 9LU

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Email:

dentalh@leeds.ac.uk

r.c.balmer@leeds.ac.uk

APPENDIX XIV

Leeds Dental Institute

The Centre for Oral Health Sciences

Amy Hollis

Specialist Registrar in Paediatric Dentistry

Richard Balmer

Consultant in Paediatric Dentistry

Date:

Dear Sir or Madam

Ref:

Research Project: An investigation into dental anxiety amongst paediatric cardiology patients

I understand the above patient attends your practice for routine dental care. The family have agreed to participate in a research project being carried out at Leeds Dental Institute. The aim of the study is to investigate the level of dental anxiety amongst paediatric cardiology patients and to compare this with a group of children with no relevant medical history. The study involves the participants and their parents completing dental anxiety scales and a short questionnaire relating to their medical and dental histories. This study has been granted ethical and R&D approval (REC ref 11/YH/0191). The above patient has been recruited in the control group. Please do contact me if you have any further queries.

Yours Sincerely

Amy Hollis

Specialist Registrar in Paediatric Dentistry



UNIVERSITY OF LEEDS

Department of Paediatric Dentistry

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APPENDIX XV

Leeds Dental Institute**The Centre for Oral Health Sciences**

Department of Paediatric Dentistry

A Centre for Children with Special Needs

Dental Anxiety Amongst Paediatric Cardiology Patients**Parent/Guardian Questionnaire (study group)**

Date of birth:

Sex: male/female

Please refer to the information sheet before completing the following:-

- 1) What is your postcode?.....

Medical History

- 2) What is your child's heart diagnosis?.....
- 3) How often do they see their cardiologist?.....
- 4) How old were they when their diagnosis was made?.....
- 5) Has your child ever had to spend a night in hospital (*please circle*)?

Yes

No

Unsure

If yes, how many times?.....

How old were they for each admission? i).....

ii).....

iii).....

iv).....

- 6) Has your child ever had a general anaesthetic (been put to sleep)?

Yes

No

Unsure

If no please continue to question 7

Please turn over

APPENDIX XVI

Leeds Dental Institute

The Centre for Oral Health Sciences

DENTAL ANXIETY SCALE FOR PARTICIPANTS

For the 8 questions below I would like you to show me how relaxed or worried you get about the dentist and what happens at the dentist. To show me how relaxed or worried you feel please use the simple scale below. The scale is just like a ruler going from 1 which would show that you are relaxed, to 5 which would show that you are very worried.

- 1 would mean: relaxed / not worried
- 2 would mean: very slightly worried
- 3 would mean: fairly worried
- 4 would mean: worried a lot
- 5 would mean: very worried

How do you feel about...



...going to the dentist generally?	1	2	3	4	5
...having your teeth looked at?	1	2	3	4	5
...having your teeth scraped and polished?	1	2	3	4	5
...having an injection in the gum?	1	2	3	4	5
...having a filling?	1	2	3	4	5
...having a tooth taken out?	1	2	3	4	5
...being put to sleep to have treatment?	1	2	3	4	5
...having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	1	2	3	4	5

Thank you for your time

APPENDIX XVII

Leeds Dental Institute

The Centre for Oral Health Sciences

PARENTAL/GUARDIAN DENTAL ANXIETY SCALE

- 1) If you went to your dentist for TREATMENT TOMORROW, how would you feel?

Not anxious = [1]
Slightly anxious = [2]
Fairly anxious = [3]
Very anxious = [4]
Extremely anxious = [5]

- 2) If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?

Not anxious = [1]
Slightly anxious = [2]
Fairly anxious = [3]
Very anxious = [4]
Extremely anxious = [5]

- 3) If you were about to have your TEETH DRILLED, how would you feel?

Not anxious = [1]
Slightly anxious = [2]
Fairly anxious = [3]
Very anxious = [4]
Extremely anxious = [5]

- 4) If you were about to have your TEETH SCALED AND POLISHED, how would you feel?

Not anxious = [1]
Slightly anxious = [2]
Fairly anxious = [3]
Very anxious = [4]
Extremely anxious = [5]

- 5) If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel?

Not anxious = [1]
Slightly anxious = [2]
Fairly anxious = [3]
Very anxious = [4]
Extremely anxious = [5]

Thank you for your time

APPENDIX XVIII

Leeds Dental Institute

The Centre for Oral Health Sciences

Department of Paediatric Dentistry

A Centre for Children with Special Needs

Dental Anxiety Amongst Paediatric Cardiology Patients

Parent/Guardian Questionnaire (control group)

Date of birth:

Sex: male/female

Please refer to the information sheet before completing the following:-

1) What is your postcode?.....

Medical History

2) Has your child ever had to spend a night in hospital?

 Yes No Unsure

If yes, how many times?.....

How old were they for each admission? i).....

 ii).....

 iii).....

 iv).....

3) Has you child ever had a general anaesthetic (been put to sleep)?

 Yes No Unsure

If no please continue to question 4

Please turn over

