Interventions to Reduce Fear of Dentistry in Individuals with Cleft Lip and Palate

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ABSTRACT

Objectives: There is no available clinical evidence to support the use of non-pharmacological intervention to control dental fear or anxiety in a general population. Controlling phobic reactions to dentistry is particularly important in individuals with the cleft lip and palate (CLP) condition, as they require comprehensive healthcare. In order to address these questions, a systematic review was undertaken to assess the effectiveness of non-pharmacological (or psychological) interventions used to decrease levels of dental anxiety in individuals between the ages of 5 and 18 years of age in relation to non-pharmacological or other non-pharmacological interventions. A survey was conducted to assess the level of dental fear among children with CLP, in comparison to non-cleft participants attending for dental treatment. In addition, a randomised controlled trial was employed to determine the impact of two non-pharmacological interventions on self-reported dental fear and behaviour in the dental setting amongst children aged 8-12 year-old with CLP condition.

Materials and Methods: The first part of this project consisted of a systematic review, considered all randomised and controlled clinical trials, which reported the quantitative data evaluating the effectiveness of psychological interventions aimed at reducing anxiety of dental treatment. Three review authors, following the eligibility criteria, independently screened titles and abstracts of studies. Data was summarised with a point estimator and its respective 95 per cent confidence interval. Event data was also quantified using odds rations, relative risks, relative or absolute risk reduction, or number needed to treat as appropriate. Continuous data was reviewed with the standardised mean difference.

The second part of the project was a survey in which a cross-sectional self-report questionnaire survey was undertaken. The questionnaires used were the Facial Image Scale (FIS) (Buchanan and Niven, 2002) and the Modified Child Dental Anxiety Scale (MCDAS) (Wong et al., 1998), Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) (Scherer and Nakamura, 1968), and the Children's Fear Survey Schedule (CFSS) (Wolpe and Lang, 1964). The participants were recruited from the South Thames Cleft Service Database (STCS) and Guy's and St Thomas' NHS Foundation Trust, London, UK. 178 individuals with the condition of CLP drawn from the STCS were compared to a non-cleft group that consisted of 150 non-cleft participants drawn from the Orthodontic Department, Guy's and St Thomas' NHS Foundation Trust. The participants were identified in three age groups; 5-10, 11-15 and 16-20 years of age.

The third part of the project consisted of a prospective randomised controlled trial of two non-pharmacological interventions. The participants were randomly allocated using

sealed envelopes to one of three experimental groups; no intervention, tell-show-do (TSD) and an environmental intervention in the form of positive images. 60 participants (8-12 year olds) were recruited from STCS, Guy's and St Thomas' NHS Foundation Trust, London, UK.

Results: In the systematic review, a total of 278 articles were identified from the searches. Initial screening of the abstracts and titles by all review authors identified 20 articles, which related to psychological interventions to reduce dental anxiety. The full articles were then retrieved. Of these, 6 trials compared the effectiveness of non-pharmacological interventions and were included for more detailed evaluation (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

In the survey, for all age groups, dental fear scores were higher for individuals with CLP than for the control group. The 5-10 year old group had mean FIS values as follows: CLP = 2.17 (SD = 1.04), non-cleft = 1.39 (SD = 0.53), $P < 0.001$. In the 11-15 year old group, the mean MCDAS values were: CLP = 21.56 (SD = 6.80), non-cleft = 16.40 (SD 4.35) $P < 0.001$. The values for the CFSS-DS were: CLP = 33.32 (13.74), non-cleft = 21.54 (SD = 6.02), $P < 0.001$. In the age group of 16-20 year olds, the mean values for MCDAS were: CLP = 22.08 (SD = 8.68), non-cleft = 13.44 (SD = 2.89), $P < 0.001$ and the means for CFSS-DS were: CLP = 36.78 (2.89), non-cleft = 20.92 (SD = 5.63), $P < 0.001$.

In the randomised controlled trial, the mean pre-treatment scores were 34.75 (SD = 12.03), and the mean post-treatment scores 31.7 (SD = 9.99) in the no intervention group. In the TSD group, the mean pre-treatment scores were 29.45 (SD = 13.59), and the mean post-treatment scores 22.85 (SD = 7.84). In the positive images group, the mean pre-treatment scores were 29.40 (SD = 14.65), and the mean post-treatment scores 18.85 (SD = 6.67). The analysis of variance (ANOVA) showed a statistically significant reduction in the post-treatment anxiety scores of the participants when TSD and positive images techniques were used ($P < 0.001$).

Conclusion: The use of non-pharmacological interventions proves successful in the control of dental anxiety. The survey revealed that individuals with CLP have high levels of dental fear in comparison to their age-matched peers. Interventions should focus on prevention and management of fear in this group of patients. The randomised controlled trial showed that the levels of dental fear were significantly reduced when using TSD and positive images techniques. There was no difference in the dental behaviour among the groups when assessed by visual analogue and Frankl scales.

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LIST OF ABBREVIATIONS

B	Unstandardised Regression Coefficient
B	Standardised Regression Coefficient
CDSR	Cochrane Database Systematic Reviews
CENTRAL	Cochrane Central Register of Controlled Trials
CHSS	Cochrane Highly Sensitive Search Strategy
CFSS	Children's Fear Survey Schedule
CFSS-DS	Children's Fear Survey Schedule-Dental Subscale
CI	Confidence Interval
CL	Cleft Lip
CLP	Cleft Lip and Palate
CMG	Cochrane Methods Groups
CONSORT	Consolidated Standards of Reporting Trials
CP	Cleft Palate
CRG	Cochrane Review Groups
df	Degree of Freedom
ENT	Ear Nose and Throat
F	Observed F Value, Regression Analysis
FIS	Facial Image Scale
GDP	General Dental Practitioner
IV	Independent Variable
MCDAS	Modified Child Dental Anxiety Scale
M-H	Mantel-Haenzel Test
n	Number of Participants
P	Probability Value
Q	Cochran's Q
R	Spearman's rho, Non-parametric Correlation Coefficient
R^2	Regression Coefficient
REV/MAN	Review Manager Software

LIST OF ABBREVIATIONS

RCT	Randomised Controlled Trial
SD	Standard Deviation
SE	Standard Error of Mean
SNB	Sella-Nasion-B Point
t	Observed t Value, t-test
TSD	Tell-Show-Do
U	Observed U Value, Mann-Whitney U Test
VAS	Visual Analogue Scale
X^2	Chi-Square Test
Z	Observed Z Value, Mann-Whitney U Test

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1. INTRODUCTION

Dental anxiety is common, affecting between 2.6 per cent (Agras et al., 1969) to 20.5 per cent (Milgrom et al., 1988) of all adults. The development of dental anxiety and more severe dental phobias is multifactorial (Klasseen et al., 2003). According to Rachman, there are three factors responsible for the development of anxiety; direct conditioning, vicarious or indirect learning, and negative information from culture or society (Rachman, 1977). Other studies have revealed conditioning elements related to previous traumatic dental experiences, parental anxiety, and age to be responsible for the development of dental anxiety in children (Davey, 1989; De Jong et al., 1995; Locker et al., 1999). Other factors which may contribute to the development of dental anxiety, are psychological traits and moods (Moore et al., 1991).

Dentistry may involve invasive surgical and dental interventions with a wide variety of sharp instruments and rotary instruments used. This requires the dentist to manage any resultant phobia within the dental settings. There are pharmacological and psychological techniques available that are utilised in the management of dental anxiety. In order to allay the anxiety of children, the American Academy of Pediatric Dentistry has proposed various techniques, namely; voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint, conscious sedation, nitrous oxide, and general anaesthesia (American Academy of Pediatric Dentistry, 2002).

Children with cleft lip and palate undergo a series of operations and have regular medical and dental consultations throughout their early years (Thom, 1990). Anecdotal evidence from clinicians working in this field suggests that many children develop fear of dental treatment, though there are no empirical studies to support or refute this view.

The research undertaken in this dissertation was to:

a) Conduct a systematic review of the literature in order to identify methods to reduce dental fear.

b) Undertake a survey of the levels of dental fear amongst children with a cleft lip and palate condition attending the specialist cleft lip and palate service.

c) Conduct a randomised controlled trial to test the efficacy of an intervention to reduce dental fear in cleft lip and palate patients.

1.1 CLEFT LIP AND PALATE

Cleft lip and palate is the most common craniofacial anomaly and accounts for 65 per cent of all anomalies that affect the head and neck (Coupland and Coupland, 1988). Insults to the developing foetus around 3 to 5 weeks in utero, which affect the first and second arches of the branchial apparatus can result in the development of cleft lip and palate. The expression of clefting in the head and neck is variable, ranging from an isolated unilateral cleft of the lip to a bilateral complete cleft of the lip and palate.

The impact of this type of abnormality on the quality of life of the individual and their family is significant. It requires numerous interventions from various medical, dental and adjunctive professionals from infancy through to adolescence and sometimes beyond in order to establish acceptable function and aesthetics.

1.1.1 INCIDENCE AND PREVALENCE

In general, the frequency of occurrence of cleft lip and palate anomalies in live births ranges between one per 500 and one per 750 (Coupland and Coupland, 1988). However, the type and clinical presentation of clefting vary. Fogh-Andersen, (1942) found that the occurrence of cleft lip and palate together is far more common when compared to the occurrence of cleft lip or palate alone. Cleft lip and palate occurred in 50 per cent of individuals affected with clefts, while the incidences of isolated cleft lip and isolated cleft palate were both 25 per cent of affected individuals. Moreover, previous studies on cleft anomalies have reported that unilateral cleft anomalies are more likely to occur when compared to bilateral anomalies (Fogh-Andersen, 1942; Jansen et al., 1988; Shaw et al., 1991). In addition, in unilateral cleft anomalies, the left side is usually more affected than the right side (Fogh-Andersen, 1942; Jansen et al., 1988).

Numerous studies have attempted to explore the frequency of clefting among different racial groups (Gilmore and Hofman, 1966; Vanderas, 1987; Shaw et al., 1991). Cleft lip

and palate occurred more commonly in North American Indians (3.74/1000), followed by Japanese (0.82 to 3.36/1000), Chinese (1.45 to 4/1000), Caucasians (1/1000), and lastly Afro-Caribbeans (0.18 to 1.67/1000) (Vanderas, 1987).

According to Coupland and Coupland, (1988) one per 700 live births is affected by clefts in the United Kingdom (Coupland and Coupland, 1988) and 1.8 per 1000 live births in Sweden (Marcusson, 2001). The highest incidence of clefting in Europe is in the former Czechoslovakia (1.81/1000), followed by France (1.75/1000), Finland (1.74/1000), Denmark (1.69/1000), Belgium and the Netherlands (1.47/1000), and Italy (1.33/1000) (Derijcke et al., 1996). In Jordan, it is 1.39 per 1000 live births (Alomari and Alomari, 2004) and 1.8 per 1000 live births among Koreans (Kim et al., 2002), while it affects 2.3 per 1000 live births in Indian and Oriental populations (Gorlin et al., 1971). The incidence of cleft anomalies in South America is one in every 1000 live births (Derijcke et al., 1996).

It has also been shown that the distribution of the different types of clefts varies between males and females. Cleft lip, cleft lip and palate, and submucos cleft occur in males more frequently than females, while the incidence of cleft palate is higher in females (4:1) when compared to males (Robert et al., 1996). In contrast the study by Zhou found the opposite. In Chinese population, overall cleft anomalies occur more in males than females at a ratio of 2.01:1 (Zhou et al., 2006).

1.1.2 AETIOLOGY

The aetiology of cleft lip and/or palate is multifactorial. There are numerous studies that showed genetic backgrounds and environmental elements resulting in orofacial clefts (Ardinger, 1989; van den Boogaard et al., 2000; Murray, 2002).

The MSX1 gene was linked with the formation of cleft lip and/or palate (van den Boogaard et al., 2000). Other genes with a strong link include RARA, MTHRF, GABRB3, D4S192, GABRB3 and PVRL1 (Ardinger, 1989). Nonetheless, there was a

strong association between Transforming Growth Factor alpha (TGFα) and orofacial clefts. In addition, there is a strong genetic inclination to clefts provided by elevated concordance rate of monozygotic twins (36 per cent) compared to dizygotic twins (4.7 per cent) (Prescott et al., 2001).

While genetics is an important factor in the development of clefting, it is not the sole factor. Insults to the environment in which the foetus is developing can result in a cleft. Teratogens including phenytoin and thalidomide, and rare exposure were linked to the development of facial clefts (Warkany et al., 1943). In addition, alcohol and smoking have been linked to cleft lip and/or palate conditions (Wyszynski et al., 1996).

1.1.3 CLASSIFICATION

Numerous attempts have been made to classify the different presentations of cleft lip and palate. Due to the fact that the presentation of clefting can be complex and variable, the ideal form of classification should be simple, usable, understandable and based on a sound embryologic and anatomical background. Historically, the first system of classification began with Davis and Ritchie in 1922, followed by Veau (1931), Kernahan and Stark (1958) and nowadays the descriptive method is commonly used.

a) Davis and Ritchie (1922)

David and Ritchie made the first attempt to classify oral clefts. Clefts were classified as; cleft lip alone, cleft palate, and cleft lip, alveolus, and hard and soft palate. Nevertheless, this classification never included the clefts of primary palate or considered clefts of soft palate alone.

b) Veau (1931)

Clefts were classified as soft palate, soft and hard palate, unilateral cleft lip and palate, and finally bilateral cleft lip and palate. However, the Veau's classification lacks the consideration of important landmarks such as the incisive foramen.

c) Kernahan and Stark (1958):

This was based on embryological backgrounds and related to the incisive foramen.

The clefts were classified as follows:

1- Clefts of primary palate: alveolus up to the incisive foramen.

2- Clefts of secondary palate: soft and hard palate, up to the incisive foramen.

3- Clefts of primary and secondary palate: complete/ incomplete, unilateral/ bilateral.

Despite the initial acceptance of the classification, later in 1971, Kernahan modified the classification by developing the stripped Y-symbolic classification. However, in an attempt to include more detailed description of the cleft representation, Elsahy in 1973 and later Millard in 1976, introduced a modification of the Y-symbolic representation.

d) Descriptive:

This method is based on describing the existing clinical presentation of the cleft anomaly and is currently the most commonly used (Thom, 1990).

1.1.4 CLINICAL PRESENTATION

1.1.4.1 GROWTH POTENTIAL:

Growth potential and the related dentofacial relationship in individuals with cleft lip and palate is a subject of controversy. Some investigators relate the altered dentofacial relationship to the number of surgical procedures that individuals with cleft lip and palate will undergo throughout their life (Gilles and Fry, 1921; Bishara, 1973). Gilles and Fry were the first to relate the effect of early palatal surgery on the antero-posterior skeletal relationship (Gilles and Fry, 1921). In contrast, other investigators believe that the growth pattern is altered in cleft individuals when compared to non-cleft individuals. It is postulated that it is this difference in growth potential that leads to dentofacial

relationships that are far from normal (Mestre et al., 1960; Ortiz-Manasterio et al., 1966).

1.1.4.2 SKELETAL

a) ANTERO-POSTERIOR PLANE

There are general findings in individuals with the cleft lip and palate condition that may be due to growth potential differences or scarring from surgical interventions. Regardless of the aetiology, a skeletal discrepancy in antero-posterior dimension is anticipated (Mars et al., 1992; Sommerlad, 1997). The maxilla in individuals with cleft lip and palate has normal growth potentials (Mars and Houston, 1990). However, maxillary retrusion may occur in a number of individuals (Mars et al., 1992). In a cross sectional study, maxillary retrusion was regarded as severe in five per cent of individuals (Mars et al., 1992). In another study, maxillary retrusion occurred in 10 and 50 per cent of individuals with cleft lip and palate (Sommerlad, 1997). The maxillary retrusion was attributed to the reduced growth as a result of scars occurring following lip repair (Mars and Houston, 1990; Da Silva Filho et al., 1992; Filho et al., 1996). In a study conducted in Sri Lankan individuals, maxillary retrusion occurred following lip repair, which led to a reduction in maxillary length by 6.3 millimetres. The authors also found an association between maxillary retrusion and palatal repair when the surgery was performed early in life. This led to an additional 1 millimetre reduction in maxillary length (Mars and Houston, 1990).

In individuals with cleft lip and palate, the mandibular growth is reduced causing a smaller sized mandible when compared to non-cleft individuals (Bishara et al., 1976). There are some reports of an increased maxillary-mandibular planes angle in these patients (Bishara et al., 1976; Cronin and Hunter, 1980; Bishara et al., 1985). This was shown in a study involving 20 individuals with a cleft lip and alveolus, and cleft lip and palate. In these cases the mandible was retruded and the maxillary-mandibular planes angle was increased (Bishara et al., 1976). Few years later, this was confirmed in

another study that compared cleft to non-cleft individuals (Bishara et al., 1985). Moreover, the dimensions of the ramus, body and the total length of the mandible were reduced in the different cleft types (Da Silva Filho et al., 1993). It was also reported that isolated cleft palate would be associated with an increased vertical growth of the mandible, while in cleft lip and alveolus, the mandible was retruded in relation to the cranial base with a reduced Sella-Nasion-B point (SNB) angle (Da Silva Filho et al., 1993).

b) VERTICAL PLANE

A decreased vertical proportion was reported in individuals with cleft lip and palate (Treutlein et al., 1991; and Bishara et al., 1985). Posterior and anterior facial heights were markedly reduced in individuals with cleft lip and palate when compared with non-cleft individuals (Bishara et al., 1985). This was more pronounced in individuals with unilateral clefts than with bilateral clefts of the lip and palate (Bishara et al., 1985).

c) TRANSVERSE PLANE

Various degrees of asymmetry were observed in individuals with a cleft lip and palate (Harvold, 1954; Aduss and Pruzansky, 1968; Dahl, 1970; Nakamura et al., 1972; Bishara et al., 1976; Smahel and Müllerova, 1986). The nasal septum was deviated to the cleft side while the anterior nasal spine deviated to the non-cleft side in individuals with a unilateral cleft lip and palate (Bishara et al., 1976; Aduss and Pruzansky, 1968).

However, a decrease in the degree of deviation was detected following lip repair (Aduss and Pruzansky, 1968). In addition, asymmetry may occur in the lateral segments of the alveolar process and the premaxilla, which, in addition, was tilted upwards (Harvold, 1954; Mølsted and Dahl, 1990).

1.1.4.3 SOFT TISSUE

The width of the mouth, or the interchelion distance is usually reduced in cleft lip and palate individuals when compared to non-cleft individuals (Larson and Nilsson, 1983;

Duffy et al., 2000). The width of the mouth was found to be narrower in cleft individuals (48 millimetres) than non-cleft counterparts (52 millimetres) (Larsson and Nilsson, 1983).

As the width of the mouth is narrower, the lower lip may protrude outward (Duffy et al., 2000). This will be more accentuated with the presence of a hyperactive mentalis muscle (Haring and McCormack, 1964). This hyperactivity, not only will lead to protrusion, but also to a thicker lower lip (Hagerty and Hill, 1963).

1.1.4.4 DENTAL

In general, individuals with a cleft lip with or without the involvement of the palate are more frequently susceptible to different dental abnormalities when compared to the general population (Ranta, 1986). This may include abnormalities in number of teeth, as well as enamel defects in various degrees (Ranta, 1986).

Many investigators regard the lateral incisor as the most commonly missing tooth in cleft individuals (Böhn, 1963; Olin, 1964). Other investigators reported that the lateral incisor will be divided into two teeth leading to the formation of a supernumerary tooth (Millhon and Stafne, 1941; Nagai et al., 1965). Supernumerary lateral incisor occurrence increases with cleft lip anomaly, while the chances decrease as the cleft extends further to involve the palate (Böhn, 1963).

Fukuhara and Saito, (1963) suggested the occurrence of the following dental anomalies in conjunction with various cleft anomalies, these include developmentally missing central and lateral incisors, rotation of the central and lateral incisors, and crowding of the maxillary labial segment. While, Takahama and Aiyama, demonstrated that maxillary canine impaction might occur in the presence of a cleft anomaly (Takahama and Aiyama, 1982).

Hypodontia, or developmentally missing teeth, is a possible complication that would occur in the presence of a cleft anomaly (Böhn, 1963; Ranta, 1986). Usually,

hypodontia occurs outside the cleft region, and by far the most commonly developmentally missing teeth are the lateral incisors and second premolars (Böhn, 1963).

A number of investigators found that delayed eruption of the permanent teeth is not uncommon in cleft lip and palate individuals (Menius et al., 1966; Ranta and Altonin, 1978). The eruption of the permanent teeth, however, may be delayed for approximately six months (Fishman, 1970).

Abnormalities in the shape and form of the teeth occur usually with cleft anomalies (Ranta, 1986). In a study conducted to investigate this it was found that out of 172 individuals with various cleft anomalies, 6.2 per cent of the teeth were of normal shape and form. In addition, 56 per cent of the central incisors were abnormal in shape (Hellquist et al., 1979). Enamel hypoplasia of the incisors is common with cleft anomaly (Dixon, 1968).

Dixon believed that the surgical repair of the lip might lead to the formation of the enamel defect (Dixon, 1968). Kraus and associates found that the prevalence of enamel hypoplasia might be around 16 and 14 per cent in the deciduous dentition and permanent dentition respectively in individuals with cleft lip. While, the prevalence of enamel hypoplasia was found to be approximately seven per cent in the deciduous dentition and eight per cent in the permanent dentition in individuals with cleft lip and palate anomaly (Kraus, 1966).

In summary, different dental defects and malformations may occur in conjunction with cleft anomaly, this may include; developmentally missing teeth, delayed eruption or impaction of the teeth, and abnormalities in the shape and form of the teeth.

1.1.4.5 OTHER COMPLICATIONS

An individual with any form of cleft may have feeding, speech, and/or psychological problems. Speech is affected adversely when the cleft extends to the soft palate.

Children with clefts will be subjected to emotional and cognitive difficulties (Thom, 1990; Millard and Richman, 2001).

1.1.5 MANANGEMENT

The clinical management of an individual with a cleft lip and palate will involve different disciplines of medicine and dentistry. The team involved in the management process will include; Plastic Surgeon, Oral Surgeon, Paediatrician, Ear Nose and Throat (ENT), Paediatric Dentist, Orthodontist, Restorative Dentist, General Dental Practitioner (GDP), Speech and Language Therapist, and Psychologist (Thom, 1990).

The management of a cleft anomaly will entail a number of clinical procedures and appropriate aspects of care from birth until the age of 20 years or even after. The following table will summarise the various steps of management as follows (Thom, 1990):

Table 1-1: Summary of the management of Cleft Lip and/or Palate Patients (Thom, 1990)

Age	**Management**
0-6 Months	• Counselling and dental advice • Counselling and feeding device and advice
0-3 Months	• Lip repair
6 Months- 3 Years	• Regular dental visits • Fluoride supplements • Diet Control
6-9 Months	• Palate Repair
3-6 Years	• GDP regular care and prevention • Regular cleft-team reviews
16 Years	• Prosthetic and restorative consideration, if necessary • Orthodontic treatment
16+ Years	• GDP care • Orthognathic surgery to correct maxillary and mandibular skeletal discrepancy combined with orthodontic treatment
17+ Years	• GDP care • Nasal and soft tissue surgery, if necessary
Adult	• GDP care

1.2 ANXIETY

1.2.1 DEFINITION AND DEVELOPEMENT

Anxiety has been described as “a vague, unpleasant feeling accompanied by a premonition that something undesirable is about to happen” (Kagan and Havemann, 1976). It is a general feeling of discomfort that is provoked when a negative event is anticipated. Normally, it needs time to dissipate and the patient’s emotional state to return to normal. There are three components used by psychologists to explain anxiety. Firstly, is the physiologic component, which includes breathlessness, palpitation and perspiration indicative of parasympathetic nervous activation. Secondly, is the cognitive component, characterised by negative thought patterns and the expectation of failure, for example a lack of concentration and imagining that a worse incident is likely to happen. Thirdly, is the behavioural component, which is in the form of avoidance and escapism from what triggers the state of anxiety (Kent et al., 1996).

Fear is defined as “a normal reaction to a real or imagined threat” (King et al., 1988; Morris and Kratochwill, 1983). It is a term that is often used by many investigators to describe anxiety. However, distinction between the two terms is mandatory since fear is a state that occurs at the moment of an unpleasant event. Unlike anxiety, fear is a short-term condition (Davey, 1989).

Historically, Sohben and Borland have reported that the development of dental anxiety in children is a result of previous family adverse experience and attitude towards dentistry (Sohben and Borland, 1954). Later in the seventies, Lautch revealed that 80 per cent of anxious children had a previous traumatic experience (Lautch, 1971). Classical conditioning was nominated as the over-riding factor in the development of an anxiety state in a dental setting. Based on this idea, neutral stimuli obtain painful properties and become conditioned stimuli along with unconditioned stimuli inducing anxiety. Stimulus and conditioning would result in a wider range of stimuli, including

feelings, sounds, smells and tastes, all leading to distress (Lautch, 1971). In this respect, Forgione and Clarke have suggested that low pain thresholds and previous traumatic dental experiences were the main responsible for the development of dental anxiety (Forgione and Clarke, 1974). Another factor related to dental anxiety was vicarious learning acquired from family, relatives and friends about dental environment. Negative thoughts and opinion transferred from peers and close relatives to children will manifest in severe distress and anxiety from dentistry (Shoben and Borland, 1954; Moore et al., 1991).

The correlation between dental anxiety and dental history is a vital step to understand the onset and development of dental distress. This was investigated by Davey (1989) who assessed the conditioning stimuli in the form of painful stimuli in evoking anxiety. All subjects were classified into four groups according to their levels of dental anxiety; anxious group (a), a group who were anxious then became relaxed (a-r), a group who were relaxed initially then acquired anxiety (r-a), and a relaxed group (r). The outcome revealed that the relaxed group experienced the least painful events in their dental history unlike the anxious group who suffered the most of painful situations in their dental history, while there was no difference in the painful events in the other two groups. Moreover, the (a) and (r-a) groups revealed willingness to avoid future dental appointments. The (r-a) demonstrated the presence of a long period between the first dental appointment and the first painful event. This proves an influence of the latent inhibition theory (Lubow, 1973), which explains the inhibition of distress despite the presence of some negative experiences earlier in life (Davey, 1989). Similarly, De Jong and colleagues, found a long period between the first traumatic dental procedure and the first dental visit in the (a-r) group demonstrating a latent inhibition effect (De Jong et al., 1985). They addressed the relative association of dental history and dental anxiety. As the anxious group had the highest amount of traumatic and dental events and in the contrary the relaxed group had lowest number of negative dental incidents (De Jong et al., 1985).

In summary, the development of dental anxiety is complex and related to conditioning stimuli as in past traumatic dental experience and vicarious learning from family and surrounding environment.

1.2.2 MEASUREMENT OF DENTAL ANXIETY

The measurement of anxiety is a vital step towards the management of the existing anxiety in dental settings. There have been four broad groups of measures utilised to assess the level of anxiety: rating scales, self-report measures, physiological measures, and projective measures (Winer, 1982).

1.2.2.1 RATING SCALES

Rating scales utilise lists of questions or statements, which are answered by the patient and then scored. One example is Frankl scale (Frankl et al., 1962), which contains four categories of behaviour that ranges from definitely positive to definitely negative. It acquires considerable amount of reliability although a great deal of bias is found with this scale. Unfortunately, there is a low correlation between outcomes obtained by Frankl scale and other self-report measures (Klorman et al., 1979).

Another example is Venham scale (Venham et al., 1977), it is comprised of two components, anxiety scale and a behavioural scale. Measurements are made in three occasions during the visit and then a mean of the three outcomes, provides a measurement of the anxiety level in the whole appointment. Venham scale possesses a high degree of reliability and a high correlation with self-report and other behavioural measures (Venham et al., 1979).

1.2.2.2 SELF-REPORT MEASURES

These measures require responses from the child or the parent in evaluating the level of anxiety. They are widely used, quick and easy to employ. However, the validity of some of these measures is questionable (Newton and Buck, 2000).

a) Facial Image Scale

Is a measure that intends to assess the level of dental anxiety in younger children. Buchanan and Niven developed this scale that is not only suitable for employment on young children, but is also useful for those children with limited cognitive and linguistic skills (Buchanan and Niven, 2002). It consists of a row of five faces that ranges from very happy to very unhappy. The children are asked to choose one of the faces that would describe their status with a particular experience (Buchanan and Niven, 2002). The validity of the scale was evaluated in a study comprised of 103 children aged 3 to 18 years-old, attended the Dental Hospital in Newcastle.

The Facial Image Scale and Venham Picture Test were both employed and outcomes collected and were compared. The authors found excellent validity using the Facial Image Scale that was comparable to the validity obtained with the Venham Picture Test $R = 0.7$, $n = 103$, $P < 0.001$ (Buchanan and Niven, 2002).

b) Modified Child Dental Anxiety Scale

This is a modification to the Dental Anxiety Scale (Corah, 1969). Wong and co-workers developed this modified scale, which was designed following a study that consisted of 314 children, aged 8 to 15 years old, and derived from two different schools in Liverpool. The scale consists of eight questions related to different dental procedures and uses a 'five points' scale to assess the level of dental anxiety ranging from 'relaxed/not worried' to 'very worried' (Wong et al., 1998). The sum of the scores ranges from five to 40, where five refers to little or no experienced anxiety, while 40 refers to extremely experienced dental anxiety (Howard and Freeman, 2007). The questions aim to assess the level of dental anxiety experienced with a number of dental procedures including examination, injection, restoration, and extraction (Wong et al., 1998). It is designed for children between 8 and 15 years old (Howard and Freeman, 2007).

However, there are two main disadvantages in the Modified Child Dental Anxiety Scale. Firstly, it is not suitable for very young children. Secondly, the child may fail to express his/her level of anxiety under extremely stressful situation and intimidating environment (Howard and Freeman, 2007). In an attempt to overcome the shortcomings encountered with the numeric version of the scale, a faces version was introduced, which would prove successful when used with young and extremely anxious older children (Howard and Freeman, 2007).

The reliability of the faces version Modified Child Dental Anxiety Scale was measured and showed an acceptable internal consistency, which was, 0.84. This was comparable to the level of internal consistency found in Children's Fear Survey Schedule- Dental Subscale, which ranged between 0.85-0.92 (Howard and Freeman, 2007).

The validity, likewise, was assessed for the faces version Modified Child Dental Anxiety Scale, which demonstrated a high degree of validity. This was equivalent to the validity of Children's Fear Survey Schedule-Dental Subscale, which may have the drawback of a lengthy 15 number of questions when compared to the Modified Child Dental Anxiety Scale (Howard and Freeman, 2007).

c) Children's Fear Survey Schedule

The Children's Fear Survey Schedule was developed originally by Lang and Lazovik, in an attempt to assess changes in fearful behaviour and generalised anxiety (Lang and Lazovik, 1963). This was modified by Geer, who created a second form of the Children's Fear Survey Schedule, which assessed generalised anxiety collected from responses of college population (Geer, 1965).

Later, Wolpe and Lang designed the third form of the Fear Survey Schedule. It included various neurotic stimuli that may provoke anxiety and cause disturbed behaviour (Wolpe and Lang, 1964). The survey used letters to identify the different

sub-classifications of the survey in an attempt to facilitate the use of the survey and the analysis of the outcomes. Letter-A refers to animal, while T for tissue damage, death or associated stimuli, C for other classical phobias, S for social stimuli, N for noises, and M for miscellaneous (Wolpe and Lang, 1964).

The survey is a useful tool to assess the level of anxiety in general and to be used in conjunction with behavioural therapy, particularly systematic desensitisation (Wolpe and Lang, 1964).

d) Children's Fear Survey Schedule–Dental Subscale

This was introduced by Scherer and Nakamura to assess anxiety in children. It has been derived from the Children's Fear Survey Schedule designed for adults, which consisted of 80 items, where each item was rated on a one to five point scale. One equals none while five means very much fear (Scherer and Nakamura, 1968).

Later, this was revised by Ollendick to enhance the possibilities of using the instrument in children younger than the age of 9 years (Ollendick, 1983). It consists of 15 items questions, aimed at assessing the level of anxiety in children in dental environment (Aartman et al., 1998). It has a reasonable level of reliability and an acceptable degree of validity (Cuthbert and Melamed, 1982; Aartman et al., 1998). The scores can range between 15 and 75, where a score of 38 and more would be considered a risky degree of dental anxiety (Aartman et al., 1998). Interestingly, the validity of the scale is satisfactory and correlated highly with children's attitudes in dental settings (Cuthbert and Melamed, 1982).

1.2.2.3. PHYSIOLOGICAL MEASURES

A number of measures have been proposed to assess children's physiologic reactions during dental appointments. Heart rate has been a useful measure in assessing the level of anxiety in dental settings (Howitt, 1965). Other measures include basal skin

response, galvanic skin response, Palmar Sweat Index, muscle tension, skin temperature and respiration (Winer, 1982).

1.2.2.4 PROJECTIVE MEASURES

This measure entails the child drawing a picture. The picture is interpreted based on the size, colour, or shade to explore the child's level of anxiety. However, projective measures impart a low level of reliability (Winer, 1982).

1.2.3 INCIDENCE AND PREVALENCE

The incidence of general anxiety was reported to be three to five per cent of the general population (Moore et al., 1992). In the United Kingdom, a survey conducted on the British population and found that 43 per cent of the respondents had some form of dental anxiety (Todd and Walker, 1980). While, in 1988, Adult Dental Health Survey found that 45 per cent of adults have mild to moderate dental anxiety (Todd and Lader, 1991).

In Denmark, a survey conducted on a random sample of 645, found that 4.2-6 per cent suffers from anxiety. This outcome was irrespective of differences in gender or socio-economic classes (Moore, 1993).

There are numerous reports on the prevalence of dental anxiety in children, ranging from three per cent and 21 per cent (Kent, 1991; Milgrom et al., 1993). In one cohort study of 223 children with a mean age of 12 years old, the prevalence of dental anxiety was nine per cent (Murray et al., 1989). A cross sectional study in Singapore revealed a 13.5 per cent dental anxiety levels among 505 children between the ages 10 and 14 years old (Chellappa et al., 1990). In Sweden, the prevalence of dental anxiety in children between 4 and 11 years old was 6.7 per cent (Klingberg et al., 1994). Raadal and co-workers investigated dental anxiety among low socio-economic environment. In a large cross-sectional study in the United States, the dental anxiety affected 19.5 per cent of the participants with an age range of 5-11 year-old (Raadal et al., 1995). One

study from Norway sought to demonstrate the link between dental anxiety and the resultant avoidance of dental appointments. This study found that the prevalence of dental anxiety was 19 per cent in 12-18 year-old patients, with six per cent of patients being diagnosed with dental avoidance (Skaret et al., 1999). Another study from New Zealand found a 10.9 per cent of participants aged 15-18 years old were dentally anxious (Thomson et al., 1997). While, in North West of England, ten per cent of parents reported that their children were dentally anxious (Milsom et al., 2003). Data from Dutch children aged 4-11 years old revealed a six per cent affected with dental anxiety and eight per cent were at risk of developing phobic reaction to dentistry (ten Berg et al., 2002). In the Middle East, Taani and colleagues, investigated the rate of dental anxiety among 12-15 years old children in Jordan. 43 per cent had low levels of dental anxiety while ten per cent were diagnosed with severe dental phobia (Taani et al., 2005).

In a review conducted on dental anxiety and the association with age, gender and other factors, the prevalence of dentally anxious children ranged between 5.7 per cent and 19.5 per cent (Klingberg and Broberg, 2007). Dental anxiety exhibits a considerable reduction with age; this has been demonstrated in many studies (Klingberg et al., 1994; Raadal et al., 1995; Wogelius et al., 2003), A few authors showed insignificant difference with age (Alvesalo et al., 1993; ten Berg et al., 2002). This was demonstrated in a cross-sectional sample of Dutch children, where the overall prevalence of dental anxiety was six per cent with no difference was found between younger children and their older counterparts (ten Berg et al., 2002). In respect to gender, most studies demonstrated a higher level of dental anxiety in girls when compared to boys, although, some researchers showed that girls may exhibit more tolerance and explanatory behaviour in dental settings when compared to boys (Rousset et al., 1997), and others showed no difference in the level of dental anxiety between the genders (Milgrom et al., 1995).

1.2.4 CONSEQUENCES OF DENTAL ANXIETY

There is a general agreement that the consequences of dental anxiety are dental avoidance and compromised oral health. Dental avoidance and compromised oral health, as consequences of dental anxiety were extensively reviewed in the literature (Klingberg et al., 1994; Skaret et al., 1998; Milsom et al., 2003). Dental avoidance, which is the failure to attend dental clinics, is a major consequence of dental anxiety (Ter Horst and De Wit, 1993). In a study conducted to evaluate the degree of dental avoidance in the Public Dental Services in Sweden, patients between the ages of 12 and 18 years old failed to attend or cancelled twelve per cent of the total number of their dental appointments (Skaret et al., 1998). Another study in Sweden showed that 10.5 per cent of children who had behavioural management problems as a result of anxiety, exhibited a significant dental avoidance and compromised oral health. The latter was manifested with extensive carious teeth and a range of dental restorations (Klingberg et al., 1994). In a survey undertaken in England, highly significant rates of carious teeth and a history of previous extractions were found in 5 year-old anxious patients (Milsom et al., 2003). In Denmark, in a cross sectional study of 1235 children aged 6-8 years old, there was an association between children with dental anxiety and the number of missed appointments, although this correlation was weak (95 per cent CI: 1.63–4.18) (Wogelius and Poulsen, 2005).

1.2.5 MANAGEMENT OF DENTAL ANXIETY

In order to allay the anxiety of children, the American Academy of Pediatric Dentistry has proposed various techniques, namely; voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint, conscious sedation, nitrous oxide, general anaesthesia (American Academy of Pediatric Dentistry, 2002). Others have advocated additional methods to reduce anxiety such as the use of contingent distraction, modelling, and contingent escape (Kuhn and Allen, 1994).

a) Voice control

The voice control approach has been proven to be effective in reducing dental anxiety and disruptive behaviour provided that the voice used is moderate in intensity and deep in nature (Greenbaum et al., 1990).

b) Positive reinforcement

It is described as the use of a reward to increase compliant behaviour. A positive reward improves the child's behaviour when given. For example, a sticker as a gift for the child following a cooperative behaviour (Newton et al., 2003). A negative reward which improves the behaviour of the child upon removal of something has also been used. This maybe in the form of a selectively separating the child from the parents to gain a positive reaction towards the planned procedure. Ideally, a negative reinforcement is indicated in tantrum-type behaviour management when the child is extremely uncooperative (Fayle and Tahmassebi, 2003).

c) Distraction

In children with low levels of anxiety, the use of either the contingent or cognitive distraction approaches have been particularly useful in anxiety reduction. The contingent distraction technique involves the continued display of distracting items and materials as long as the child demonstrates acceptable levels of cooperation, while the cognitive technique involves encouraging the child to have thoughts outside the boundaries of the dental situation (Ingersoll et al., 1984).

d) Non-verbal communication

The non-verbal communication technique has also been shown to reduce the level of dental anxiety (Greenbaum et al., 1990). In this technique the dentist communicates with the child via gentle touch while the child communicates with the dentist by means of gestures. For example, the child may be instructed to raise his/her hand if he/she experiences discomfort.

e) Hand over mouth

Although the hand over mouth approach has been proposed by the American Academy of Pediatric Dentistry to be used with children who were able to communicate but were uncooperative, it is a technique that has fallen out of favour with dentists in North America due to the legal consequences that may occur as a result of its use (Acs et al., 2001). In a survey of all paediatric dentists in the United Kingdom, 60 per cent believed that hand over mouth approach should not be used (Newton et al., 2004).

f) Physical restraint

Restraint is defined as, 'To hold back from action, keep in check or under control, repress; to deprive of liberty; and to limit or hamper the activity…' (Webster's encyclopedic unabridged dictionary, 1996). According to the American Academy of Pediatric Dentistry, physical restraint may possibly be achieved by using a mouth prop with or without placing the child in a papoose board or Pedi-wrap. However, the use of physical restraint in behavioural management remains controversial. It is desirable to restrict this approach to patients with disabilities and learning impairment (Peretz and Gluck, 2002). In the United Kingdom, one study found that only two per cent of the dentists preferred the use of physical restraint when dealing with uncooperative children (Crossley and Joshi, 2002). Whilst, 53 per cent of dentists in the United States favoured physical restraint over sedation in the management of 3 year-old children (Peretz and Gluck, 2002).

g) Tell-Show-Do

Tell-show-do (TSD) is by far the commonest method of anxiety reduction utilised in dental settings. In this technique *tell* refers to an explanatory phase, *show* to a demonstration phase and *do* to the actual performance of the procedure (Newton et al., 2003). Dentists do prefer explanatory approaches as opposed to blundering approaches, this has been shown in a survey conducted in the United Kingdom where

66 per cent of the respondents favoured explanatory approach like TSD when compared to more aggressive approaches (Buchanan and Niven, 2003). Similarly, parents feel more comfortable with TSD employed on their children rather than physical restraint or sedation (Murphy et al., 1984).

The other procedures recommended by the American Academy of Pediatric Dentistry such as conscious sedation, nitrous oxide and general anaesthesia, were effective methods of enhancing patient cooperation, however they have the additional drawbacks of having an associated morbidity and being not widely available for implementation by all general dental practitioners due to their additional cost in terms of time and finances (Shaw et al., 1996).

While there were numerous examples in the literature of approaches and techniques to reduce dental anxiety in children, as yet there has been no evidence to demonstrate which method or methods were more effective in this regard.

Evidence based recommendations were needed in this area in order to improve the delivery of dental care to children particularly those with behavioural issues or those who require extensive dental interventions. The advantage of ascertaining the most effective methods of relieving anxiety in children would be manifold including; fewer failed appointments, improved oral health attitudes, more treatments performed in an out-patient setting and the more effective training of dentists in the techniques of patient management.

2. A SYSTEMATIC REVIEW OF PSYCHOLOGICAL INTERVENTIONS FOR REDUCING DENTAL ANXIETY

Systematic reviews seek to collect all available evidence that fits pre-specified eligibility criteria in order to address a specific research question. It is a piece of research that aims at reducing bias through solid systematic methodology. According to Antman, a systematic review attempts to arrange available evidence that fits pre-set eligibility criteria in an attempt to address a research question. It uses clear systematic methods that are set to reduce bias and provide reliable findings to draw conclusions and make decisions (Antman, 1992). The main components for valid systematic reviews are:

1. Clear objectives with well-defined entry criteria for every study.
2. Sound and repeatable methodologies.
3. Systematic search methods to identify all studies that meet the entry criteria.
4. Assessments on the validity of findings of the included studies.
5. Systematic combinations and presentations of the characteristics and findings of the included studies.

The Cochrane Collaboration (www.cochrane.org) aims to prepare, maintain and promotes systematic reviews to provide evidence for clinical interventions and healthcare decisions. Cochrane reviews are published in the Cochrane Database of Systematic Reviews in The Cochrane Library. The Cochrane Handbook for Systematic Reviews of Interventions contains necessary guidance for the preparation and maintenance of Cochrane reviews (Higgins et al, 2009).

According to Cochrane Collaboration, the values are set in The Cochrane Handbook (Higgins et al., 2009) as outlined in Table: 2.1:

Table 2-1: The values of Cochrane Collaboration (Higgins et al., 2009)

1. Collaboration, by internally and externally fostering good communications, open decision-making and teamwork.
2. Building on the enthusiasm of individuals, by involving and supporting people of different skills and backgrounds.
3. Avoiding duplication by good management and co-ordination to maximize economy of effort.
4. Minimizing bias, through a variety of approaches such as scientific rigour, ensuring broad participation, and avoiding conflicts of interest.
5. Keeping up to date, by a commitment to ensure that Cochrane reviews are maintained through identification and incorporation of new evidence.
6. Striving for relevance, by promoting the assessment of healthcare interventions using outcomes that matter to people making choices in health care.
7. Promoting access, by wide dissemination of the outputs of the Collaboration, taking advantage of strategic alliances, and by promoting appropriate prices, content and media to meet the needs of users worldwide.
8. Ensuring quality, by being open and responsive to criticism, applying advances in methodology, and developing systems for quality improvement.
9. Continuity, by ensuring that responsibility for reviews, editorial processes and key functions is maintained and renewed.
10. Enabling wide participation in the work of the Collaboration by reducing barriers to contributing and by encouraging diversity.

The Cochrane Collaboration consists of 53 Cochrane Review Groups (CRGs), responsible for reviews on a specific branch of healthcare. Cochrane Methods Groups (CMG), centres and fields support the groups in the review process. They are responsible for the preparation of the Cochrane Handbook for Systematic Reviews of Interventions.

Cochrane reviews are published in full online in the Cochrane Database of Systematic Reviews (CDSR) twelve times a year, being the integral part of the Cochrane Library. The Cochrane Library is published by Wiley-Blackwell on the internet (www.thecochranelibrary.com) and available on CD-ROM. The CDSR consists of protocols and full reviews. The Cochrane Central Register of Controlled Trials (CENTRAL) contains general information on registered titles and studies. While, The Cochrane Methodology Register (CMR) includes bibliographic information on studies and textbooks on the topic being reviewed,.

The first step in our project was to explore the availability of evidence to support the use of any psychological intervention in reducing dental anxiety. Conducting a sound systematic review would in our opinion address this question. This is the reason for conducting a systematic review titled as: “Psychological Interventions For Reducing Dental Anxiety In Children”. (Published as a protocol, The Cochrane Library, issue 2, 2009)(Appendices: Section: 7-23; Pages: 169-179).

2.1 OBJECTIVES

To assess the data on the effectiveness of psychological interventions (or referred as: non-pharmacological) aimed to decrease levels of dental anxiety in children between the ages of 5 and 18 years old, in relation to no psychological interventions (usual care, regular intervention, etc.) and other psychological interventions.

2.2 METHODS

2.2.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW:

2.2.1.1 TYPES OF STUDY

Randomised and controlled trials assessing the effectiveness of psychological interventions aimed to decrease levels of dental anxiety in children were considered in this review.

2.2.1.2 TYPES OF PARTICIPANTS

Children between the ages of 5 and 18 years old attending for dental treatment.

2.2.1.3 TYPES OF INTERVENTIONS

Any psychological interventions aimed at reducing levels of dental anxiety. This was defined to include, but not limited to, the list of the American Academy of Pediatric Dentistry; voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint.

All these interventions was compared to the following:

- No intervention
- Another psychological intervention

2.2.1.4 TYPES OF OUTCOME MEASURES

- Anxiety levels as measured by a validated questionnaire, validated physiological measure, or projective test
- Disruptive behaviour in dental surgery as measured by validated tool
- Patients and parents satisfaction
- Re-attendance at follow-up appointments

- Time taken to undertake the intervention
- Complications associated with the intervention

2.2.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES:

2.2.2.1 ELECRTONIC SEARCH

The subject search used a combination of controlled vocabulary and free text terms based on the search strategy developed for MEDLINE. The search was combined with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised controlled trials in MEDLINE: the sensitivity maximising version (2009 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 (updated September 2009) (Higgins, 2009) was used.

2.2.2.2 DATABASES SEARCHED

The following databases were searched:

1. The Cochrane Oral Health Group's Trials Register (to 12th August 2010)
2. The Cochrane Central Register of Controlled Trials (CENTRAL)
3. MEDLINE via OVID (1950 to 12th August 2010)
4. EMBASE via OVID (1980 to 12th of August 2010)
5. PsycINFO via OVID (1980 to 12th of August 2010)
6. CINAHL via OVID (1980 to 12th of August 2010)

Search strategy for searching MEDLINE via OVID:

1. DENTAL ANXIETY/
2. ANXIETY DISORDERS/

3. PHOBIC DISORDERS/

4. PANIC DISORDER/

5. (anxiet$ or anxious$ or apprehensive$ or fear$ or fright$ or phobi$ or panic$ or (disrupt$ adj3 (behavior or behaviour))).mp.

6. (dental$ or dentist$).mp. [mp =title, original title, abstract, name of substance word, subject heading word, unique identifier]

7. exp DENTISTRY/

8. (2 or 3 or 4 or 5) and (6 or 7)

9. 1 or 8

10. exp PSYCHOTHERAPY/

11. COUNSELING/

12. HYPNOSIS, DENTAL/

13. NONVERBAL COMMUNICATION/

14. exp MIND-BODY THERAPIES/

15. (psychotherap$ or counsel$).mp. [mp =title, original title, abstract, name of substance word, subject heading word, unique identifier]

16. (cognitiv$ adj6 (intervention$ or therap$ or treat$ or technique$ or behaviour$ or behavior$)).mp.

17. ((behaviour$ or behavior$) adj6 (intervention$ or therap$ or treat$ or technique$)).mp.

18. (distract$ adj3 (cognitive or contingent)).mp.

19. ("voice control" or "non-verbal communication" or "non verbal communication").mp.

20. exp BEHAVIOR CONTROL/

21. (physical adj3 restraint$).mp.

22. ((desensiti$ and psychol$) or (relax$ adj6 (technique$ or therap$ or hypnotherapy)) or (therap$ adj6 touch$) or massage$ or "breathing exercise$" or (modeling and psychol$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

23. ((auditory and distract$) or (audiovisual$ adj6 distract$) or (("audio visual$" or audio-visual$ or visual$ or music$ or verbal$) adj6 distract$)).mp. [mp =title, original title, abstract, name of substance word, subject heading word, unique identifier]

24. ((color$ or colour$ or music$ or play$ or laughter) adj6 therap$).mp.

25. ((verbal$ adj6 encourag$) or "positive reinforce$" or reward$ or reassur$ or "show tell do" or show-tell-do or “tell show do” or tell-show-do or "hand over mouth" or "hand-over-mouth").mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

26. (hypnosis or hypnotic or imagery or "autogenic train$" or hypnotherap$).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

27. or/10-26

28. exp CHILD/

29. (child$ or infant$ or pediatric$ or paediatric$ or adolescent$).mp.

30. 28 or 29

31. 9 and 27 and 30

2.2.2.3 HAND SEARCHES

The following journals were identified as being important to be hand searched for this review:

1. Acta Odontologica Scandinavica (1939 to August 2010)
2. Journal of Dental Research (1919 to August 2010)
3. International Journal of Paediatric Dentistry (1991 to August 2010)
4. Journal of Dentistry for Children (1980 to August 2010)
5. Journal of Community Dentistry and Oral Epidemiology (1980 to August 2010)

2.2.2.4 PERSONAL CONTACT

The review authors contacted the authors of included studies, in order to receive any further information of additional or unpublished studies that was eligible for inclusion in the review. In addition, those recognised in the British and American Societies were contacted.

2.2.2.5 LANGUAGE

Non-English papers were considered for inclusion after an accurate translation.

2.3 DATA COLLECTION AND ANALYSIS

2.3.1 STUDY SELECTION

The titles and abstracts resulting from the searches were independently screened by three review authors to select potentially relevant studies. These studies were obtained in full text and their inclusion assessed independently in duplicate. Any discrepancies with respect to the inclusion or suitability of the papers were resolved by the remaining review authors. The full data extraction and quality assessment was conducted by three review authors. Every study was assessed by each of the review authors

independently. Any disagreement was resolved by discussion. A further review author was contacted in the event that a consensus could not be reached. Any studies that were excluded at this stage were placed in a detailed excluded studies table along with reasons for their exclusion.

2.3.2 DATA EXTRACTION

A specifically designed data extraction form was constructed using the CONSORT statement checklist of items to include when reporting a randomised trial (Moher, 2001). After piloting these data extraction sheets, the review authors independently extracted the data from the included studies. The data extracted provided information on the following review criteria.

- General study information: published/unpublished, authors, title, year of publication, journal published in, year that search was conducted, ethics and consent, country of origin, funding source, language, and contact address.

- Study characteristics and descriptive data: sample size, RCT criteria, number of participants in each randomised group, number of participants remaining at follow up, randomisation method, allocation concealment, blinding, and study duration.

- Participant characteristics: age, gender and inclusion criteria.

- Intervention characteristics: intervention techniques, alternative intervention group(s), follow-up period, number of sessions, type of interventions: individual or group, financial and time costs of the intervention to the provider and receiver, no additional treatment given to either groups, the intervention provider characteristics (e.g. psychologist, dentist etc.), location intervention given in, and any adverse effects that may occur as a result of the intervention.

- Outcome measure characteristics: what type of measures, the results for each measure, baseline and follow-up results, outcome measures and reported outcome measures.

- Results and conclusion: what do the results show and what conclusions have been made in the study.

Comparisons had to be between a control group and/or at least one alternative intervention group. Comparisons were also between the different outcome measures, the intervention techniques, the length of follow-up times and the subgroups.

After data had been extracted in the paper form, the results were presented in a standardised format, to allow for comparisons, such as is formulated in Review Manager 4.2 (RevMan). The inclusion table was slightly a moderated version of that in RevMan, so to include the relevant data for the review. The exclusion table was formulated in the same way, and held papers excluded due to minimal inclusion criteria discrepancies, and at the quality assessment stage.

2.3.3 QUALITY ASSESSMENT

A component approach was undertaken for the quality assessment, as opposed to a scale approach. This approach was adopted due to the higher usage (92 per cent) of this method in previous Cochrane reviews (Moher, 2001), and its appropriateness to sensitivity analysis.

The quality of each individual study was therefore been assessed by a number of components important to the review.

1. Selection bias

- Concealment of allocation of participants to groups (adequate/inadequate/ unclear)

- The method of randomisation is unpredictable and explicitly stated (adequate/inadequate/unclear)

2. Attrition bias

- Loss of participants at follow up is explained (adequate/inadequate/unclear).

3. Detection bias

- Masking of the intervention conductor (yes/no/not applicable)
- Masking of outcome assessment (yes/no)
- Masking of participants (yes/no)

4. Outcome bias

- The outcome measures suitability and effectiveness in relation to the primary outcome measure (adequate/inadequate/unclear).
- Lengths of follow up/number of sessions (adequate/inadequate/unclear).

5. Statistical methodology (adequate/inadequate/unclear).

6. Sample size (adequate/inadequate/unclear).

The quality assessment was piloted on a selection of papers. Each review author independently assessed the quality for each paper. In the event that no consensus was reached, the procedure as described previously in the section on study selection will be repeated. The study author was contacted to clarify any unclear or inadequate characteristics before a final decision on the inclusion was made.

2.3.4 ASSESSMENT OF THE RISK OF BIAS IN INCLUDED STUDIES

An assessment of the risk of bias was undertaken following the recommendations in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions 5.0.2 (Higgins, 2009).

A specific tool was used for assessing risk of bias in each included study. This consisted of a description and a judgment for each entry in a risk of bias table, where each entry addressed a specific feature of the study:

- Sequence generation

- Blinding
- Incomplete outcome data addressed
- Free of selective outcome reporting
- Free of other bias

The judgment for each entry involved answering a question, with answers 'Yes' indicating low risk of bias, 'No' indicating high risk of bias, and 'Unclear' indicating either lack of information or uncertainty over the potential for bias.

Overall risk of bias: studies were categorised according to the following:

- Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met
- Unclear risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were assessed as unclear
- High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met

2.3.5 DATA SYNTHESIS

The statistical methods presented in the Cochrane Handbook were followed for data synthesis. The data was analysed by the statistician using RevMan 5 and reported according to Cochrane Collaboration criteria. For continuous data the mean difference and 95 per cent confidence intervals was calculated. Risk ratios and their 95 per cent confidence intervals were calculated for all dichotomous data.

Results of clinically and statistically homogeneous trials were pooled to provide estimates of the efficacy of the interventions only if the included studies have similar interventions received by similar participants. For the synthesis and meta-analysis of any quantitative data we used the fixed-effect and random-effect models as

appropriate. If it was established that there was significant statistical heterogeneity between the studies we used the random-effects model with studies grouped by action. We planned to assess clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants, the interventions and the outcomes as specified in the criteria for included studies. Statistical homogeneity was assessed using a chi-squared test and the I^2 index where I^2 values over 50 per cent indicate moderate to high heterogeneity (Higgins, 2003). If sufficient RCTs were identified, an attempt was made to assess publication bias using a funnel plot (Egger, 1997). We also considered conducting subgroup analyses. In the event that there were insufficient clinically homogeneous trials for any specific intervention or insufficient study data that can be pooled, a narrative synthesis was presented. Trials were grouped into categories and subcategories on the basis of theoretical and clinical distinctions. The initial grouping was based on the intervention techniques adopted within the trial. The outcome measures adopted by trials within subcategories defined by intervention techniques and the level of anxiety were explored. In addition, the extent that they were similar data was assessed by combination techniques. When sufficient studies were located within the subcategories defined, subgroup analysis was conducted for a selection of study characteristics in order to identify sources of heterogeneity and their influence on the effect size determined, these included:

- Age of patient
- Gender of patient
- Level of anxiety
- Type of intervention

2.3.6 SENSITIVITY ANALYSIS

If there were sufficient included studies we planned to conduct sensitivity analyses to assess the robustness of our review results by repeating the analysis with the following

adjustments: exclusion of studies with unclear or inadequate allocation concealment, blinding of outcomes assessment and completeness of follow up.

2.4 RESULTS

2.4.1 DESCRIPTION OF STUDIES

A total of 278 articles were identified through the electronic searches. Initial screening of the abstracts and titles by all review authors identified 23 articles which was related to psychological interventions to reduce dental anxiety. The full articles were then retrieved. Six trials compared the effectiveness of non-pharmacological interventions and control conditions in reducing dental anxiety were included (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

Six single centred randomised controlled trials were included in the review. These trials were conducted in the United Kingdom, Israel, Peru and Venezuela, and the United States. A clear power calculation was presented in only one of the studies (Fox and Newton, 2006) however sample size was generally adequate in all studies (See: characteristics of included studies).

Table 2.2: Characteristics of included studies (Filcheck et al., 2004)

Methods	• RCT • 60 children requiring restorative dental treatment in a paediatric clinic of a university hospital were randomised
Participants	• 5-12 year-old (32 male and 28 female)
Interventions	• The experimental intervention: standard dental care and listening music, soundtracks and/or audio stories through headphones while undergoing dental treatment • The control intervention: standard dental care and headphones with no access to any of the distractions
Outcomes	• Binary indicator of whether a child was “uncooperative” being the child having 30 per cent or more disruptive intervals, out of a 15 seconds intervals observed
Notes	• Anxiety not assessed, or adjusted for, at baseline • Measure of disruptive behaviour was validated independently • Ethical approval details given

Table 2.3: Risk of bias (Filcheck et al., 2004)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	No	Was not possible
Blinding	No	Was not possible
Incomplete outcome data addressed	Unclear	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

Table 2.4: Characteristics of included studies (Peretz and Gluck, 2005)

Methods	• RCT • Randomised (No details of randomisation were given) • 70 children identified as manifesting strong-willed behaviour
Participants	• 3-6 year-old (37 male and 33 female)
Interventions	• The experimental intervention: distracting the child by showing a magic trick • The control intervention: TSD
Outcomes	• Time (minutes) from beginning of session to sitting on the dental chair • Success in performing dental examination • Frankl behaviour category
Notes	• Ethical approval details not mentioned

Table 2.5: Risk of bias (Peretz and Gluck, 2005)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	No	Was not possible
Blinding	No	Was not possible
Incomplete outcome data addressed	Unclear	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

Table 2.6: Characteristics of included studies (Fox and Newton, 2006)

Methods	• RCT • Randomised (Details of randomisation were given) • 38 children and young adults identified attending dental clinic in South West England
Participants	• 5-18 year-old (32 male and 6 female)
Interventions	• The experimental intervention: positive images of dentistry • The control intervention: dentally neutral images
Outcomes	• Anxiety assessed by Venham Picture Scale yielding an 8-point Likert scale 0-8
Notes	• Groups were balanced by age and gender • All images were independently validated by 4 paediatric dentists • Ethical approval details given

Table 2.7: Risk of bias (Fox and Newton, 2006)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	Yes	
Blinding	Unclear	Was not possible
Incomplete outcome data addressed	No	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

Table 2.8: Characteristics of included studies (Samra-Quintero et al., 2006)

Methods	• RCT • Randomised (No details of randomisation were given) • 100 children and adolescents who were treated at the Child Comprehensive Care Center, Faculty of Dentistry, University of Zulia, Venezuela
Participants	• 6-9 year-old
Interventions	• The experimental intervention: TSD • The control intervention: Usual care
Outcomes	• Blood Pressure
Notes	• For all patients this was their first dental treatment • Groups were balanced by gender and age • Ethical approval details not mentioned

Table 2.9: Risk of bias (Samra-Quintero et al., 2006)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	No	Was not described
Blinding	No	Was not possible
Incomplete outcome data addressed	Unclear	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

Table 2.10: Characteristics of included studies (Pickrell et al., 2007)

Methods	• RCT • Randomised (No details of randomisation were given) • 48 children recruited from community centres and elementary schools in Western Washington State
Participants	• 6-9 year-old (22 male and 26 female)
Interventions	• The experimental intervention: Usual care with a post-treatment memory re-structuring intervention • The control intervention: Usual care and neutral condition
Outcomes	• 1-5 Likert Facial Image Scale
Notes	• Baseline assessment but not adjusted for participants ranged from fearful to those who had no fear at all • Ethical approval details not mentioned but consents were taken

Table 2.11: Risk of bias (Pickrell et al., 2007)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	No	Was not described
Blinding	No	Was not possible
Incomplete outcome data addressed	Unclear	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

Table 2.12: Characteristics of included studies (Olumide et al., 2009)

Methods	• RCT • Randomised • 50 children attending a paediatric dental practice of a university hospital
Participants	• 8-12 year-old (24 male and 26 female)
Interventions	• The experimental intervention: Child-friendly dental information leaflet • The control intervention: Healthy eating leaflets
Outcomes	• 1-5 Likert Facial Image Scale
Notes	• Groups were balanced by gender and age • Ethical approval details were given

Table 2.13: Risk of bias (Olumide et al., 2009)

Items	**Judgment**	**Description**
Adequate sequence generation	Unclear	
Allocation concealment	No	Was not described
Blinding	No	Was not possible
Incomplete outcome data addressed	Unclear	
Free of selective reporting	Unclear	
Free of other bias	Unclear	

2.4.1.1 CHARACTERISTICS OF PARTICIPANTS

The participants included in these trials were children with an age range of 5-18 years old (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). The children attended the dental clinics for regular care. The number of the children included in the trials was 363 children, where 217 children were assigned to different types of interventions, while 147 children were assigned as control (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

2.4.1.2 CHARACTERISTICS OF INTERVENTIONS

A number of interventions were used in these trials namely; magic trick distraction, tell-show-do, positive images, neutral images, leaflets containing friendly information, positive restructuring memory, sensory adapted environment, and distraction techniques (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Tell-show-do intervention was used in two trials (Peretz and Gluck, 2005; Samra-Quintero et al., 2006). In one trial it was compared to a no intervention control (Samra-Quintero et al., 2006), while in another trial it was compared to a magic trick distraction (Peretz and Gluck, 2005). A standard dental care with a distraction by listening to music through headphones, compared to control with usual dental care and headphones served to attenuate operatory noises (Olumide et al., 2009). The effect of positive images was compared to neutral images in reducing the level of dental anxiety (Fox and Newton, 2006). Recently, positive restructuring memory intervention was compared to usual care in the control group (Pickrell et al., 2007). Lastly, a leaflet containing child friendly information was compared to control consisted of a leaflet containing child friendly information on healthy eating (Olumide et al., 2009).

2.4.1.3 CHARACTERISTICS OF OUTCOMES

All trials provided measurements of dental anxiety using different measures (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Self-report measures were used in four trials (Fox and Newton, 2006; Pickrell et al., 2007; Olumide et al., 2009). While, three trials included behavioural measures in the assessment of dental anxiety (Filcheck et al., 2004; Peretz and Gluck, 2005; Pickrell et al., 2007). However, a physiological measure, namely, the blood pressure of the children was used as a measure of the dental anxiety in one trial (Samra-Quintero et al., 2006).

Examples of the behavioural measures used in these trials were; Frankl scale (Peretz and Gluck, 2005) and behavioural observations (Pickrell et al., 2007; Filcheck et al., 2004). Whereas, the self-report measures used were; Venham Picture Scale (Fox and Newton, 2006), Fear Survey Schedule (Pickrell et al., 2007), and Geer Anxiety Scale (Shapiro et al, 2007) and Facial Image Scale (Olumide et al., 2009). In addition, other variables were considered including; the time taken for the child to sit on the dental chair and the acceptance to take a dental radiograph (Peretz and Gluck, 2005).

2.4.2 RISK OF BIAS IN INCLUDED STUDIES (METHODOLOGICAL QUALITY)

2.4.2.1 DESIGN OF THE STUDY

There was a concern about the validity of a crossover study for this outcome as some reviewers independently judged that there was a likelihood of a carry over effect in an intervention that aims to relax anxiety in children facing dental treatment. As such treatment might be the start of a confidence building process in the given situation. However, the decision was made to exclude these studies (Shapiro et al., 2007; Shapiro et al., 2009)(Table 2.14).

Table 2.14: Characteristics of excluded studies

Study	**Reason for exclusion**
Greenbaum et al., 1993	The age range (3.5-7 year-old) dose not meet the inclusion criteria
Veerkamp et al., 1993	The use of nitrous oxide only as a method of intervention
Fuks et al., 1994	The use of Midazolam only as a method of intervention
Veerkamp et al., 1995	The use of nitrous oxide only as a method of intervention
Aitken et al., 2002	The age range (4-6 year-old) dose not meet the inclusion criteria
Shapiro et al., 2007	Cross over study should not be used due to carry over effect
Shapiro et al., 2009	Cross over study should not be used due to carry over effect

2.4.2.2 RANDOMISATION AND ALLOCATION OF CONCEALMENT

The method of randomisation was generally not reported (Peretz and Gluck, 2005; Samra-Quintero et al., 2006; Pickrell et al., 2007). Except for one of the trials (Fox and Newton, 2006). None of the trials reported a method of allocation concealment described (Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007).

2.4.2.3 BLINDING

Blinding for all trials was not possible for either the clinician undertaking the procedure or the parents (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

2.4.2.4 WITHDRAWALS

In most of the trials the number of withdrawals were less than 20 per cent (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Moreover, in one study, it was clearly shown that the withdrawals were included in the statistical analysis (Fox and Newton, 2006).

2.4.2.5 STATISTICAL ANALYSIS

The statistical methodology was generally sound in all six included studies. A power calculation was presented in only one of the studies (Fox and Newton, 2006). Three of the studies reported adjusting their analysis for whether it was the child's first dental treatment (Samra-Quintero et al., 2006; Pickrell et al., 2007). There was a large variation between the studies with regard to the age range of the children with two studies including adolescents with the age range extending to 16 and 18 years old (Fox and Newton, 2006; Samra-Quintero et al., 2006).

2.4.3 EFFECT OF INTERVENTION

A total of 278 articles were identified through the electronic searches. Initial screening of the abstracts and titles by all review authors identified 23 articles which was related to psychological interventions to reduce dental anxiety. The full articles were then retrieved. Six trials compared the effectiveness of non-pharmacological interventions and control conditions in reducing dental anxiety were included (Filcheck et al., 2004; Peretz and Gluck 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Two comparisons were identified, as follows;

2.4.3.1 NON-PHARMACOLOGICAL INTERVENTION VERSUS NO INTERVENTION/USUAL CARE:

Five trials compared the effectiveness of non-pharmacological interventions and control conditions in reducing dental anxiety (Filcheck et al., 2004; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). The control was intended to be no treatment (usual care, regular environment, and a leaflet on benefits of healthy eating). Filcheck and colleagues compared the choice-based distraction using music, sound tracks and audio stories to a control group on 60 children. However, there was no significant difference between the distraction and control groups, despite revealing less disruptive behaviour at 22 per cent in the distraction group in comparison to 16 per cent in the control group (Filcheck et al., 2004) (Figure: 2.1; Table: 2.15). In the contrary, the distraction group exhibited fewer “less cooperative” behaviour and more “very cooperative” behaviour when compared to control group ($P < .012$) (Filcheck et al., 2004). One trial (Fox and Newton, 2006) demonstrated that showing positive images to children prior to the dental appointment reduced the dental anxiety. Providing data on 38 children, dental anxiety as measured by Venham Picture Scale was reduced significantly using positive images when compared to neutral images (0.21 and 3.31 respectively, $P < 0.001$). Another trial (Samra-Quintero et al., 2006) reported on 100 children and used blood pressure as a

means of measuring dental anxiety in two groups. One group had a tell-show-do intervention and the other group served as a control. This trial showed that there was a significant ($P < 0.05$) reduction in dental anxiety in the tell-show-do group compared to controls (Figure: 2.2; Table: 2.15).

Pickrell and co-workers (Pickrell et al., 2007) assessed the dental anxiety and behaviour of 45 children. They reported that restructuring memory intervention substantially reduced dental anxiety measured as opposed to control condition (30.18 and 33.29 respectively, $P < 0.05$) as well as improved the children behaviour in dental settings.

Recently, (Olumide et al., 2009) evaluated the effectiveness of using leaflets containing child friendly dental information compared to control with child friendly leaflets containing information on benefits of healthy eating. There was a reduction in dental anxiety levels in the experiment (Mean = 0.56, SD = 0.82) and control groups (Mean = 0.24, SD = 0.61). There was no significant difference between the two groups ($U = 299.5$).

A meta-analysis was performed to assess the level of significance for the three trials (Fox and Newton, 2006; Olumide et al., 2009; Pickrell et al., 2007) (Figure: 2.3). The aggregated P-value showed that there is a significant reduction of anxiety for the non-pharmacological intervention in relation to the control group when we combine the information of the studies ($Z = 3.37$, $P = 0.0004$).

The test for the heterogeneity was non-significant (Q (1 df = 1.18); $P = 0.28$), indicating that the two studies were not heterogeneous (Fox and Newton, 2006; Samra-Quintero et al., 2006). This showed no statistical significant difference between the two studies in reducing levels of dental anxiety. In other words, there was no substantial difference in alleviating dental anxiety when using tell-show-do technique when compared to using positive images, however both techniques do reduce dental anxiety in children.

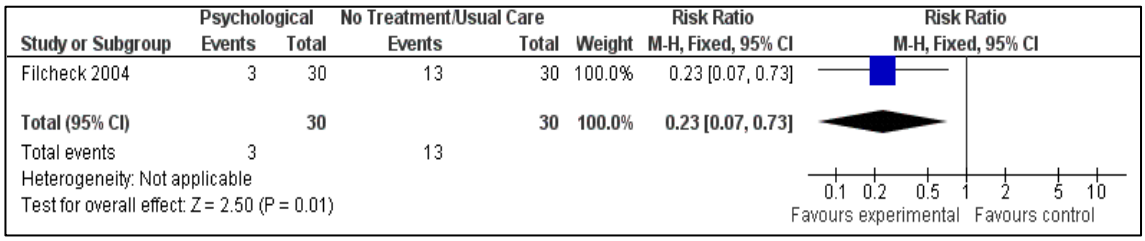

Figure 2.1: Forest plot of comparison: Psychological intervention versus No treatment/Usual care: Number of children with more than 30 per cent disruptive intervals

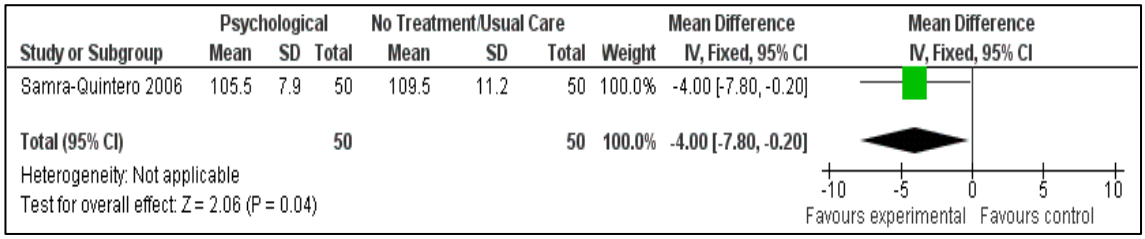

Figure 2.2: Forest plot of comparison: Psychological intervention versus No treatment/Usual care: Systolic blood pressure

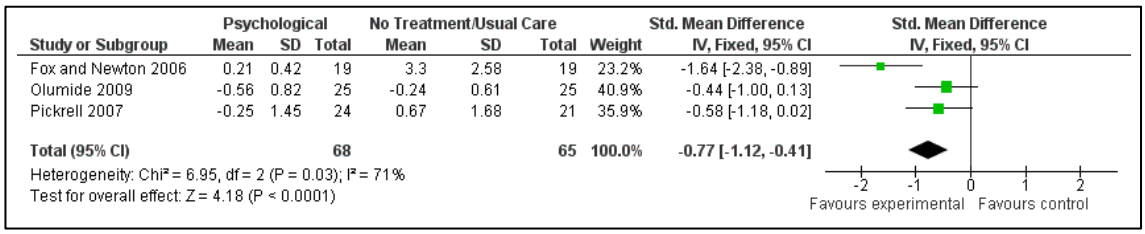

Figure 2.3: Forest plot of comparison: Psychological intervention versus No treatment/Usual care: Magnitude of anxious behaviour

Table 2.15: Psychological intervention versus No treatment/Usual care

Outcome/Subgroups	Studies	Participants	Statistical Method	Effect Estimate
Magnitude of anxious behaviour	3	133	Standard Mean Difference (IV, Fixed, 95 per cent CI)	-0.77 (-1.12, -0.41)
Number of children with more than 30 per cent disruptive intervals	1	60	Risk Ration (M-H, Fixed, 95 per cent CI)	0.23 (0.07, 0.73)
Systolic blood pressure	1	100	Mean Difference (IV, Fixed, 95 per cent CI)	-4 (-7.80, -0.20)

2.4.3.2 IDENTIFYING THE SOURCES OF HETEROGENEITY:

A significant heterogeneity (Q (2 df) = 6.9; P = 0.03) was found between the three studies meta-analysed (Fox and Newton, 2006; Pickrell et al., 2007; Olumide et al., 2009). There were insufficient studies to perform a reliable meta-regression to explore the source of heterogeneity in terms of the study-levels covariates. There was no indication that any of the characteristics relating to study design (baseline adjustment, first-time visit adjustment or maximum age) was a possible source of heterogeneity. In particular, given the tight age range in the studies, age seemed to be an unlikely source of heterogeneity. However, Fox and Newton's results (Fox and Newton, 2006), showing a more marked treatment effect in favour of the psychological intervention, could have resulted from a control in Pickrell's results (Pickrell et al., 2007) that may have restructured the child's memory to a certain extent. A sensitivity analysis was performed excluding Fox and Newton's study and a significant treatment effect in favour of the psychological interventions remained (effect = -0.50; 95 per cent CI. (-0.91, -0.09); P = 0.02).

2.4.3.3 A PSYCOLOGICAL INTERVENTION VERSUS ANOTHER PSYCOLOGICAL INTERVENTION:

One trial (Peretz and Gluck, 2005) provided evidence on dental anxiety derived from 70 children attending the dental clinic that were subjected to either tell-show-do intervention or magic trick distraction intervention. Variables including the time taken for the child to sit on the dental chair, the acceptance to take a dental radiograph, and behavioural observation as assessed by Frankl scale were considered. Results showed that children subjected to the magic trick where faster to sit on the dental chair (141.2 ± 71.5 seconds) when compared to the tell-show-do group (221.7 ± 110.7 seconds). Moreover, radiographs were more acceptable in the magic trick group (91 per cent) when compared to the tell-show-do group (54 per cent). Behavioural observation as assessed by Frankl scale showed more positive behaviour in the magic

trick group (91 per cent) when compared to the tell-show-do group (80 per cent). This study presented summary measures stratified by baseline dental anxiety and whether the first time the child had dental treatment. In both cases, the results were in favour of magic trick intervention Figure: 2.4; Table 2.16).

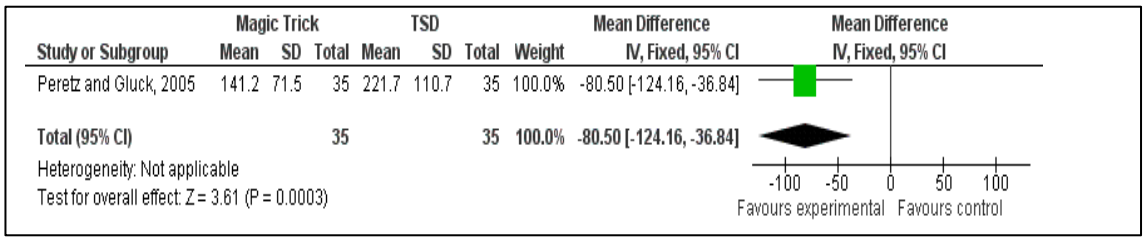

Figure 2.4: Forest plot of comparison: Psychological intervention versus Another psychological Intervention: Time the child takes to sit on the chair

Table 2.16: Psychological intervention versus Another psychological Intervention

Outcome/Subgroups	Studies	Participants	Statistical Method	Effect Estimate
Time the child takes to sit on the chair	1	70	Mean Difference (IV, Fixed, 95 per cent CI)	-80.5 (-124.16, -36.84)

2.5 DISCUSSION

There were a number of interventions advocated in the literature to reduce the levels of dental anxiety. Non-pharmacological interventions were proposed as an effective method to reduce dental anxiety (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

One example is the tell-show-do intervention, which was tested in two trials (Peretz and Gluck, 2005; Samra-Quintero et al., 2006). Dental anxiety was reduced significantly when the tell-show-do intervention was compared to the control condition (Samra-Quintero et al., 2006). However, one of the shortcomings of this study was that the levels of anxiety were assessed by the measurement of the blood pressure of the children. The use of additional measurement techniques in the form of validated questionnaires or behavioural observation techniques would have raised the validity of the outcomes. Another drawback to be taken into account is the sample size (n = 70), as a larger sample and different types of dental procedures would have led to a more power in the overall outcome. In another trial (Peretz and Gluck, 2005), tell-show-do intervention was compared to a magic trick distraction technique. Both interventions showed significant reduction in the level of dental anxiety. This may be attributed to the fact that the children were separated from their parents when the magic trick technique was employed. The selection of only strong willed children is a deficiency in the selection criteria. However, the two trials have provided convincing evidence supporting the use of these two interventions in dental settings particularly the magic trick distraction technique as described by Peretz and Gluck (2005).

Choice based distraction was used to reduce dental anxiety in children undergoing restorative dental care. Music, sound tracks and audio stories distraction technique revealed less disruptive behaviour to headphones without sound distraction. However, this method of distraction failed to provide a significant difference. The use of

distraction techniques in the experimental and control groups justify the lack of significant difference. The implementation of sound distraction should not be abandoned as this method revealed convincing results in “more cooperative” children behaviour (Filcheck et al., 2004).

Pickrell and co-workers demonstrated credible data on the use of memory restructuring intervention in the management of dental anxiety. The intervention is composed of four components. Firstly the visual component, pictures taken previously of the child smiling during the dental procedure were shown back to the child as a visual reminder about the dental experience. Secondly, verbalisation, the child was asked how he/she would explain to the parents how well they handled the dental appointment. Thirdly, concrete example, the child was asked to recall a good example of their improved behaviour. This would lead to the fourth component, the sense of accomplishment. The distinctive feature of this intervention is the fact that it is employed after the dental procedure. This would help particularly, in clinical situations where negative events occurred during the dental appointment (Pickrell et al., 2007).

Despite the small sample size (n = 38) Fox and Newton reported an influential outcome on using positive images as opposed to neutral images in the management of dental anxiety. Positive images of dentistry play a role in social learning and modelling. The authors, however, revealed a methodological problem, the interventionist were aware of the group receiving the intervention and those of the control. However, blinding in clinical trials of psychological interventions is almost impossible. Moreover, children’s behaviour and reaction to the images were recorded at a particular moment in the trial. Different recording moments may have shown different reactions.

Recently, Olumide and associates found no significant difference in alleviating dental anxiety using preparatory dental leaflets when compared to control that had leaflet containing information on benefits of healthy eating. There were numbers of downsides

including; lack of consideration of previous dental history, type of dental treatment to be undertaken, and the type of dental anxiety assessment (Olumide et al., 2009).

The meta-analysis for the three studies (Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007) revealed further convincing evidence supporting the use of non-pharmacological interventions in reducing dental anxiety despite the fact that the five studies used different techniques as well as various measurement methods (Z = 3.37, P = 0.0004).

2.6 CONCLUSION

2.6.1 IMPLICATIONS FOR PRACTICE

The use of non-pharmacological interventions proves successful in the control of dental anxiety. However, there is no evidence to support one particular intervention over another. The trials provided an evidence to support the use of some non-pharmacological interventions. Tell-show-do, magic trick distraction, sensory adaptive environment, restructuring memory and positive image interventions showed promising outcomes in the control of dental anxiety.

2.6.2 IMPLICATIONS FOR RESEARCH

Large, high quality randomised controlled trials, with developmental and behavioural outcomes measured were needed to assess the effectiveness of non-pharmacological interventions. Multi-centre studies will aid in recruiting larger numbers of participants, reducing the heterogeneity of the sample and providing adequate power for the investigation. Different types of interventions should be included and tested for clinical effectiveness.

3. A SURVEY OF LEVELS OF DENTAL FEAR AMONGST INDIVIDUALS WITH CLEFT LIP AND PALATE

3.1 BACKGROUND

Dental anxiety and fear are common and have implications for the quality of life and oral health of the person as a consequence of avoidance of treatment when dental problems arise (Cohen et al., 2000). The term 'fear' is generally used when a stimulus is present to provoke an anxiety response, while 'anxiety' indicates a state of anxiety without a provoking stimulus (Olumide et al., 2009). As previously outlined (Section: 1.2.2; Page: 29), the prevalence of dental anxiety is well documented in numerous reports; one study showed a three to five per cent dental anxiety levels of the general population (Moore et al., 1991). In Denmark, 4.2-6 per cent were found to suffer from anxiety (Moore, 1993). In Sweden, the prevalence of dental anxiety in children between 4 and 11 years old was 6.7 per cent (Klingberg et al., 1994). In England, ten per cent of parents reported that their children were dentally anxious (Milsom et al., 2003). The prevalence of dental fear in cleft lip and palate (CLP) patients is unknown but might be hypothesised to be elevated given the increased likelihood of dental or surgical treatment. At the time of the research, a Medline search did not reveal any previous studies of dental anxiety in CLP. Current theories of the aetiology of fear and anxiety suggest a diathesis-stressor model whereby underlying cognitive vulnerabilities predispose certain individuals to develop fear responses following negative experiences (Mineka and Oehlberg 2008). It is possible that the extensive experience of dental and medical interventions among this group may either predispose them to greater levels of dental anxiety through an increased likelihood of experiencing a negative dental encounter (Mowrer, 1939) or protect the child through the process of latent inhibition (Davey, 1989). What is clear is that given the likelihood and importance of regular dental attendance amongst this group, reducing dental fear, which can be a major barrier to attendance, is critical. These consequences of dental fear demand an

approach to control fear in dental settings. An integral part in this approach is the diagnosis of dental fear. The diagnosis includes mainly the measurement of dental fear. The use of self-reported surveys is common in measuring dental fear. There are a number of surveys available for use for clinical and research purposes. Some surveys have been translated and validated to different languages. The choice to use a particular survey depends on: number of questions, complexity, and validity (Streiner and Norman, 1995). In this study the Facial Image Scale (FIS) was adopted for 5-10 year-old children, and the Modified Child Dental Anxiety (MCDAS), Children's Fear Survey Schedule–Dental Subscale (CFSS-DS), and the Children's Fear Survey Schedule (CFSS) were used for children over 10 years old.

As previously discussed (Section: 1.2.2.2; Page: 27), the Facial Image Scale (FIS) is a measure that intends to assess the level of dental anxiety in younger children. It has been developed to be suitable for younger children with consideration to children with limited cognitive and linguistic skills. It consists of a row of five faces that ranges from very happy to very unhappy. The children were asked to choose one of the faces that would describe their status with a particular experience (Buchanan and Niven, 2002).

The Modified Child Dental Anxiety Scale (MCDAS), whilst the scale uses the term anxiety, fear will be used as a synonym to anxiety in this study. It consists of eight questions related to different dental procedures and uses a 'five points' scale to assess the level of fear ranging from 'relaxed/not worried' to 'very worried'. The sum of the scores ranges from five to 40, where five refers to little or no experienced fear, while 40 refers to extremely experienced fear. Scores of 19 or greater are considered highly dentally fearful. The questions aim to assess the level of dental fear experienced with a number of dental procedures including examination, injection, restoration, and extraction (Wong et al., 1998).

Another dental fear scale is Children's Fear Survey Schedule–Dental Subscale (CFSS-DS). Scherer and Nakamura introduced this scale to assess fear levels in children. It

consists of 15 items, where each item was rated on a one to five point scale. The scores can range between 15 and 75, where a score of 38 and more would be considered a risky degree of dental fear (Aartman et al., 1998).

The correlation between general state anxiety or fear, and dental fear is important in the understanding and possible management of dental fear. One tool to assess the general fear is the Fear Survey Schedule (CFSS). This was developed originally by Lang and Lazovik, in an attempt to assess changes in fearful behaviour and generalised fear (Lang and Lazovik, 1963). Later, Wolpe and Lang designed another form of the FSS. It included various neurotic stimuli that may provoke fear and cause disturbed behaviour (Wolpe and Lang, 1964).

The aim of this study was to assess the level of dental fear among individuals with Cleft Lip and Palate (CLP) when compared to non-cleft individuals.

3.2 PARTICIPANTS AND METHODS

One hundred and seventy eight participants with a CLP anomaly were drawn randomly from the South Thames Cleft Service database and were compared to a control group that consisted of 150 non-cleft individuals attending the Orthodontic Department, Guy's and St Thomas' NHS Foundation Trust. The experimental and control groups were age-matched. The participants were identified at three age groups; 5-10, 11-15, 16-20 years old.

The South Thames Cleft Service database covers those patients living in the South East of the United Kingdom, in a geographical area south of the river Thames with a western border west of Worthing on the South coast of England. This centrally commissioned service was established in 2002 and the database records the details of 3000 individuals.

A postal questionnaire survey was undertaken for the individuals with CLP. 450 potential participants were mailed with the questionnaires. The survey method adopted

followed guidelines on the design of surveys to maximise response rates (Edwards et al., 2002). The non-cleft individuals were invited to participate in the waiting area at the Orthodontic Department, Guy's and St Thomas' NHS Foundation Trust. The questionnaires were posted first class to all potential participants enclosing a covering letter explaining the purpose of the study and a reply-paid envelope (Section: 7-6, Page: 141; Section 7-8, Pages: 143-144). Further similar mailings to non-respondents were undertaken at three weeks and five weeks later respectively (Appendices, Section: 7-7; Page: 142), following the procedure recommended by Dillman (1978). The questionnaires used were the Facial Image Scale (FIS) (Buchanan and Niven, 2002) (Appendices, Sections: 7.9 and 7.10; Pages: 145 and 146), the Modified Child Dental Anxiety Scale (MCDAS) (Wong et al., 1998) (Appendices, Sections: 7.11 and 7.12; Pages: 147 and 148), the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) (Scherer and Nakamura, 1968) (Appendices, Section: 7.13; Page: 149), and the Children's Fear Survey Schedule (CFSS) (Wolpe and Lang, 1964) (Appendices, Section: 7.14; Pages: 150-154). Descriptive statistics were used to describe levels of dental fear between the CLP group and the non-cleft dental patients.

The inclusion criteria for the cleft group included, participants with any form of CLP anomaly within the age range of 5-20 years old. Individuals with other craniofacial syndromes and learning difficulties were excluded. Individuals who decline to participate were excluded as well.

The inclusion criteria for the non-cleft group included participants who are attending the Orthodontic Department at Guy's and St Thomas' NHS Foundation Trust for regular dental care. The age range was 5-20 years old. The exclusion criteria consisted of individuals who decline to participate or those who presented with craniofacial syndromes or learning difficulties.

An ethical approval was granted from the London Surrey Border (Reference: 08/H0806/27) (Appendices, Section: 7.2; Pages: 131-133).

The data was analysed using Statistical Package for Social Sciences (Version 16.0.1), November 2007. The analysis consisted of two stages; demographic characteristics including age, gender, cleft type, previous dental and surgical treatments; and the comparison of the levels of dental fear reported by the participants using ANOVA, with post-Hoc multiple comparison tests (Tukey B).

3.3 RESULTS

3.3.1 SAMPLE CHARACTERISTICS:

The response rate was 55 per cent (*n* = 328 out of 600).

The sample consisted of 54 per cent (*n* = 177) male and 46 per cent (*n* = 151) female participants. 48.78 per cent (*n* = 160) of the sample was 5-10 year-old, 28.65 per cent (*n* = 94) was 11-15 year-old, and 22.56 per cent (*n* = 74) was 16-20 year-old participants.

The sample included different types of cleft anomalies; 41.57 per cent (*n* = 74) of the sample was CLP, 39.88 per cent (*n* = 71) was CP, 15.73 per cent (*n* = 28) was CL, and 2.8 per cent (*n* = 5) with a Submucosal Cleft Palate (Table 3.1).

There was a significant difference in the exposure to dental treatment between the cleft and non-cleft participants in all age groups. Individuals with CLP had more dental appointments than the non-cleft individuals. In contrast, there was no significant difference found in the number of previous surgeries between the cleft and non-cleft participants in older groups, only in the 5-10 year-old group a higher number of surgical interventions were recorded ($P < 0.001$) (Table: 3-1).

Table 3.1: Sample Characteristics

	5-10 Year-Old			11-15 Year-Old			16-20 Year-Old		
	Cleft *n* = 110	Control *n* = 50	Significant	Cleft *n* = 44	Control *n* = 50	Sig	Cleft *n* = 24	Control *n* = 50	Significant
Gender									
M	63	22	$X^2 = 2.43$	19	33	$X^2 = 4.93$	17	12	$X^2 = 0.24$
F	47	28	P = 0.08	25	17	P = 0.02	12	22	P = 0.40
Cleft Type									
CL	16	N/A		8	N/A		2	N/A	
CP	41			23			7		
CLP	49			13			12		
SM	4			0			1		
No of Previous Dental Treatment									
0	6	8	$X^2 = 10.2$	1	8	$X^2 = 8.18$	0	8	$X^2 = 12.6$
1	39	22		10	17		4	14	
2	27	13		11	11		1	10	
3+	38	7	P = 0.017	21	14	P = 0.04	18	18	P = 0.005
Median	2	1		2	1		3+	2	
Mode	1	1		3+	1		3+	3+	
No of Previous Surgeries									
0	46	41	$X^2 = 28.3$	5	6	$X^2 = 7.15$	2	16	$X^2 = 5.53$
1	20	6		0	6		1	4	
2	6	3		6	10		4	7	
3+	38	0	P < 0.001	32	27	P = 0.06	16	23	P= 0.14
Median	1	0		3+	3+		3+	2	
Mode	0	0		3+	3+		3+	3+	

3.3.2 FEAR IN 5-10 YEAR-OLD:

The FIS dental fear scores were higher for participants with CLP than non-cleft participants (P < 0.001) (Table: 3-2).

In order to normalise the anxiety scores used. We increased the FIS scores of group 5-10 year-old by a factor of 8. This allowed numerical direct comparison of all age groups.

Table 3-2: Fear in 5-10 year-old

	Cleft and Control	**Cleft**	**Control**	**Significance**
FIS Overall Scores Mean (SD)	1.93 (0.98)	2.17 (1.04)	1.39 (0.53)	U = 1473.5 P < 0.001
Pro-rated Scores Mean (SD)	15.44 (7.82)	17.39 (8.27)	11.10 (4.26)	U = 1473.5 P < 0.001

3.3.3 FEAR IN 11-15 YEAR-OLD:

The MCDAS dental fear scores were higher for participants with CLP than non-cleft participants (P < 0.001) (Table: 3-3). CFSS-DS scores revealed that CLP participants were more fearful than non-cleft participants (P < 0.001) (Table: 3-3). MCDAS scores above 19 is an indication of elevated fear levels. There were 27 participants (61 per cent) manifested with increased fear of dentistry in the cleft group. In contrast, only 17 participants (34 per cent) of the non-cleft group were diagnosed with increased fear levels (P = 0.007).

The general state anxiety or fear was tested using the CFSS. This showed that participants with CLP are more generally fearful than non-cleft participants although the difference was not significant (P = 0.65) (Table: 3-3).

Table 3-3: Fear in 11-15 year-old

	Cleft and Control	**Cleft**	**Control**	**Significance**
MCDAS Mean (SD)	18.28 (6.17)	21.65 (6.80)	16.40 (4.35)	U = 622.5 P < 0.001
CFSS-DS Mean (SD)	26.79 (11.72)	33.32 (13.74)	21.54 (6.02)	U = 392.5 P < 0.001
CFSS	91.49 (56.95)	95.27 (62.63)	88.21 (52.16)	U = 588 P = 0.65

3.3.4 FEAR IN 16-20 YEAR-OLD:

The MCDAS dental fear scores were higher for participants with CLP than non-cleft participants (P < 0.001) (Table: 3-4). MCDAS scores above 19 is an indication of elevated fear levels. There were 15 participants (65 per cent) manifested with increased fear of dentistry in the cleft group. In contrast, only 3 participants (6 per cent) of the non-cleft group were diagnosed with increased fear levels (P < 0.001). CFSS-DS scores revealed that CLP participants were more fearful than non-cleft participants (P < 0.001) (Table: 3-4).

The general state anxiety or fear was tested using the CFSS. This showed that participants with CLP are more generally fearful than non-cleft participants although the difference was not significant (P = 0.03) (Table: 3-4)

Table 3-4: Fear in 16-20 year-old

	Cleft and Control	**Cleft**	**Control**	**Significance**
MCDAS Mean (SD)	16.16 (6.71)	22.08 (6.86)	13.44 (2.89)	U = 229 P < 0.001
CFSS-DS Mean (SD)	25.92 (12.33)	36.78 (2.89)	20.92 (5.63)	U = 226.5 P < 0.001
CFSS	73.56 (52.16)	97.79 (61.31)	63.33 (44.69)	U = 280 P = 0.03

3.3.5 FEAR IN ALL AGE GROUPS:

For all age groups, dental fear scores were higher for participants with CLP than for the control group. In group 5-10 year-old, means FIS: CLP = 2.17 (SD = 1.04), controls = 1.39 (SD = 0.53), P < 0.001. In group 11-15 year-old, means MCDAS: CLP = 21.56 (SD = 6.80), controls = 16.40 (SD 4.35) P < 0.001. In group 16-20 year-old, means MCDAS: CLP = 22.08 (SD = 8.68), controls = 13.44 (SD = 2.89) P < 0.001. Due to the nature of the categorical data Mann-Whitney (SPSS) test was used to assess the difference in fear scores.

In order to normalise the fear scores used. We increased the FIS scores for group 5-10 year-old by a factor of 8. This allowed numerical direct comparison of all age groups. On the basis of this normalisation, we simply report the values in table 3-5. The results revealed lower levels of dental fear scores in the 5-10 year-old group when compared to the 11-15 year-old and 16-20 year-old groups (Table: 3-5).

Table 3-5: Fear in all age groups

	Mean	**SD**	**Median**	**Mode**
Pro-rated FIS (5-10)	17.3 a	8.2	16	16
MCDAS (11-15)	21.5 b	6.8	20.5	14
MCDAS (16-20)	33.1 b	8.6	20	11

a,b: Subscripts indicate homogenous subsets

3.3.6 CORRELATION OF FEAR MEASURES:

There was a relatively good correlation in all three fear assessment tools (Table: 3-6) ($P < 0.001$). The highest correlation was established between the MCDAS and CFSS-DS (0.71) while the weaker correlation was found between the MCDAS and CFSS (0.41).

Table 3-6: Correlation of fear measures (Spearman's rho, non-parametric)

	11-15 YEAR-OLD			***16-20 YEAR-OLD***		
	CFSS	***MCDAS***	***CFSS-DS***	***CFSS***	***MCDAS***	***CFSS-DS***
CFSS		0.41	0.51		0.61	0.64
MCDAS			0.71			0.63
CFSS-DS						

3.3.7 REGRESSION ANALYSIS:

Regression analysis for all age groups was applied using FIS pro-rated scores for 5-10 year-old and MCDAS for 11-20 year-old. The outcome was the fear score. The predictors were; control versus cleft, age groups, previous dental treatment, and previous surgeries. The method was stepwise. The model $R^2 = 0.204$

Only one variable was significant in the regression model, age group membership (Adjusted $R^2 = 0.044$). This shows that age was the only variable to influence the fear outcome.

Table 3-7: Variables in the model

	Unstandardised		**Standardised**		
	B	*SE*	β	*t*	*Significance*
Constant	21.59	0.68		31.55	P < 0.001
Control vs. Cleft	-6.60	0.76	-0.45	-8.68	P < 0.001
Age	-4.10	0.76	-0.28	-5.41	P < 0.001

3.4 DISCUSSION

This study highlights the levels of dental fear in participants that included children and young adults with CLP. The sample consisted of 328 participants, 178 presented with different types of CLP, while 150 were non-cleft participants. The sample was divided into three groups; 5-10, 11-15, and 16-20 years old groups. This was decided since the CLP patients are reviewed every five years in the centralised services in the United Kingdom. The CLP patients are reviewed at 5, 10, 15, and 20 years old in order to assess the progress and review the past clinical interventions, and plan future necessary interventions.

The sample was randomly invited to participate, however, the sample characteristics revealed a higher number of female compared to male participants in the CLP group. There was no difference found in previous dental treatment between the CLP and non-cleft groups. While, the CLP groups underwent more surgical interventions than the non-cleft participants in the 5-10 year-old group. This was not a surprise particularly as the individuals with CLP undergo surgical procedures such as alveolar bone graft and revised lip or palatal repairs at this period in life.

The dental fear levels among the 5-10 year-old control group were comparable to previously published report on similar cohort of un-affected children (Buchanan and Niven, 2002). When comparing the number of recruited children in both studies who were evaluated using similar assessment tools, it is understandable why comparable results were achieved.

When using higher level of 19 or greater in the MCDAS, the levels of substantial dental fear were significantly higher in the older groups. For the 11-15 year-old group 59 per cent demonstrated elevated dental fear, while the percentage was 61 per cent for the 16-20 year-old group. The levels of dental fear ranged between 8.5-11 per cent in previously published reports (Alvesalo et al., 1993; Klingberg et al., 1994; ten Berg et al., 2002; Klingberg and Boeberg, 2007). Differences in study design, sample size and

characteristics, and the tools used in the various investigations may explain the inconsistency in the fear levels.

The CFSS scores revealed higher levels of general fear amongst CLP participants when compared to non-cleft participants in the 11-15 year-old and 16-20 year-old groups. Although this difference was minimal and not clinically significant, it indicates higher distress amongst cleft participants, which might be attributed to the psychological impacts of the CLP anomaly and the anticipated complex healthcare management required.

The levels of dental fear were higher in the older age groups of the cleft affected participants when compared to non-cleft participants. There was a significant difference in the MCDAS outcomes in the 11-15 year-old and 16-20 year-old cleft groups when compared to the normalised/pro-rated FIS scores for the 5-10 year-old cleft group. These results are in contradiction to previous published data of non-cleft participants but with comparable age (Klingberg et al., 1994; Raadal et al., 1995; Wogelius et al., 2003). One reason for this dissimilarity is the low recruited participants in the current study. Another reason is the method of comparison between the groups, which utilised a mathematical compensation for the number of questions. The current study confirms the findings of a recently conducted study (in press for publication) of 110 children with CLP in Amsterdam (Vogels et al., 2011).

There was a high correlation of the fear scores between the MCDAS and CFSS-DS (0.71). This consistency validates the present fear scores. One reason for this correlation is the fact that the two fear measures explore similar aspects of the dental environment including; the dental chair, local anaesthetics and restorative procedures.

It is disappointing that only 24 individuals participated in 16-20 cleft group. Clearly other factors played a part in this low recruitment almost certainly including social interactions and activities. It is well recognised that the current study is a cross-

sectional in nature and only based on one centre. A more robust design would have included longitudinal evaluation and multi-centred trials.

Generically dental fear is relatively common feature in the general dental population and is a major factor in the failure to attend at dental clinics (Ter Horst and De Wit, 1993). Clearly, syndromic patients such as cleft are a priority group and we must have a mechanism to support issues of healthcare delivery. In order to identify a strategy to further deliver healthcare for cleft and non-cleft patients we would recommend multi-centred clinical trials to assess the effective methods for alleviating dental fear. Work already exist by the American Academy of Pediatric Dentistry which identifies the following possible interventions for dental fear; voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint, conscious sedation, nitrous oxide, general anaesthesia (American Academy of Pediatric Dentistry, 2002).

3.5 CONCLUSION

Individuals with CLP have high levels of dental fear in comparison to their age-matched peers. Interventions should focus on prevention and management of fear in this group of patients.

4. A RANDOMISED CONTROLLED TRIAL OF PSYCHOLOGICAL INTERVENTIONS TO REDUCE DENTAL FEAR IN INDIVIDUALS WITH CLEFT LIP AND PALATE

4.1 BACKGROUND

The survey results suggest an increased level of dental fear amongst individuals with cleft lip and palate. In this study and drawing on the findings of the systematic review, interventions to alleviate dental fear in this group will be tested. The American Academy of Pediatric Dentistry has proposed various techniques in the management of dental anxiety, namely; voice control, tell-show-do (TSD), positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint, conscious sedation, nitrous oxide, and general anaesthesia (American Academy of Pediatric Dentistry, 2002). Others have advocated additional methods to reduce anxiety such as the use of contingent distraction, modelling, and contingent escape (Kuhn and Allen, 1994). There are few systematic reviews or randomised controlled trials comparing the different techniques either against standard treatment or each other, and a computerised literature search of five databases revealed no trials of non-pharmacological interventions to reduce dental anxiety amongst individuals with cleft lip and palate.

The aim of this study was to determine the impact of two non-pharmacological interventions on self-reported dental fear and behaviour in the dental setting amongst children aged 8-12 years old with cleft lip and palate.

The null hypothesis was that there was no difference observed among the different types of non-pharmacological intervention used in alleviating dental fear.

4.2 PARTICIPANTS AND METHODS

The study was carried out in the dental clinics of the South Thames Cleft Service, Guy's and St Thomas' NHS Foundation Trust, London, the United Kingdom. Ethical approval for the study was obtained from the same Trust (Reference: 09/H0804/6) (Appendices, Section: 7.4; Pages: 136-138). Patient recruitment was undertaken between January 2010 and January 2011.

4.2.1 SAMPLE SIZE

The participants were drawn from the South Thames Cleft Service at Guy's and St Thomas' NHS Foundation Trust. The total number of individuals on the service database is 3000. Inclusion criteria for recruitment to the study was based upon individuals listed on the South Thames Cleft Service database with cleft lip and/or palate anomaly within the age range 8 to 12 years old. Exclusion criteria included individuals who decline to participate, or individuals with other craniofacial syndromes and learning difficulties.

4.2.2 PARTICIPANTS

Sixty participants were drawn from the South Thames Cleft Service; Guy's and St Thomas' NHS Foundation Trust. The study sample size was based on data on the mean and SD of scores from previously published randomised controlled trial in the subject. Estimating that a clinically significant difference among the three groups would be one SD, a sample size of 60 would give 95 per cent power to detect a difference at a significance level of 0.05.

4.2.3 DESIGN

A randomised controlled trial of two non-pharmacological interventions. The participants were randomly allocated to one of three conditions. Allocation was concealed using sealed envelopes. The three groups were; standard treatment, no intervention; tell-show-do (TSD); and an environmental intervention comprising

exposure to positive images of the dental surgery, hereafter referred to as 'positive images' (Fox and Newton, 2006) (Appendices, Section: 7.20; Pages: 162-166).

The participants were approached in the waiting area by one member of the research team, the principal author. The participants were invited to participate, parents and participants were consented (Appendices, Section: 7.16; Pages: 157-158), and the initial anticipatory dental fear levels were assessed using self-reported Children Fear Survey Schedule-Dental Subscale (Scherer and Nakamura, 1968) (Appendices, Section: 7.17; Page: 159). Then, one of the randomly allocated interventions was undertaken as per the allocation schedule. This was followed by the routine dental procedure. The routine dental procedures included a clean and polish, as well as fissure sealants application. Following the dental procedure, the participants' levels of dental fear were again recorded using self-reported Children Fear Survey Schedule-Dental Subscale (Scherer and Nakamura, 1968). Soon after the dental procedure, the paediatric dentist assessed the participant's levels of dental fear using a visual analogue scale (Appendices, Section: 7.18; Page: 160) and Frankl behavioural scale (Frankl, 1962) (Appendices, Section: 7.19; Page: 161). The dental visit was video recorded and two investigators assessed the participant's behaviour using Frankl behavioural scale (Frankl, 1962) for reliability assessment.

4.2.4 THE NON-PHARMACOLOGICAL INTERVENTIONS

The two non-pharmacological interventions used were TSD and positive images. The TSD technique involved an explanatory phase, a demonstration phase and a performance phase (Newton et al., 2003). The positive images consisted of ten photographs of 5 x 7 inches in size. The photographs included two boys aged 8 and 11 years old. The boys in the photographs were smiling and playing with toys in the waiting room. The photographs aimed to familiarise the participants with the dental environment. Four dentists validated these pictures as to representing effective image towards the dental environment. The dentists were required to complete a ten

centimetres visual analogue scale. The scale scores ranged from zero to ten with higher scores indicating a positive attitude to dentistry. The average rating of the four dentists for all ten images was 7.02 (SD = 3.12).

4.2.5 PRIMARY OUTCOME MEASURES

A validated self-reported questionnaire and behavioural scales measured the levels of dental fear. These measures were the Frankl scale (Frankl, 1962), visual analogue scale and the Children's Fear Survey Schedule-Dental Subscale (Scherer and Nakamura, 1968).

4.2.6 ALLOCATION

The paediatric dentist undertaking the intervention was not given the opportunity to choose the type of intervention used. Instead, the name of the interventions were written on a card and sealed in an envelope. On the day, the chief investigator randomly took an envelope and the paediatric dentist performed the intervention written on the card.

4.2.7 BLINDING

The researchers assessing the levels of dental fear were blinded to the type of intervention employed. Participants and their parents were informed about group in which the child was assigned to. Additionally, the member of the research team undertaking the statistical analysis was blinded to group membership by means of a coding system.

4.2.8 WITHDRAWAL

Four withdrawals were counted and included in the trial flow chart (Figure 4-1).

4.2.9 STATISTICAL ANALYSIS

The data was analysed using Statistical Package for Social Sciences (Version 16.0.1), November 2007. The analysis consisted of two stages; demographic characteristics including age, gender, ethnicity, and cleft type; and the comparison of the levels of dental anxiety reported by the participants using ANOVA, with post-Hoc multiple comparison tests (Tukey B).

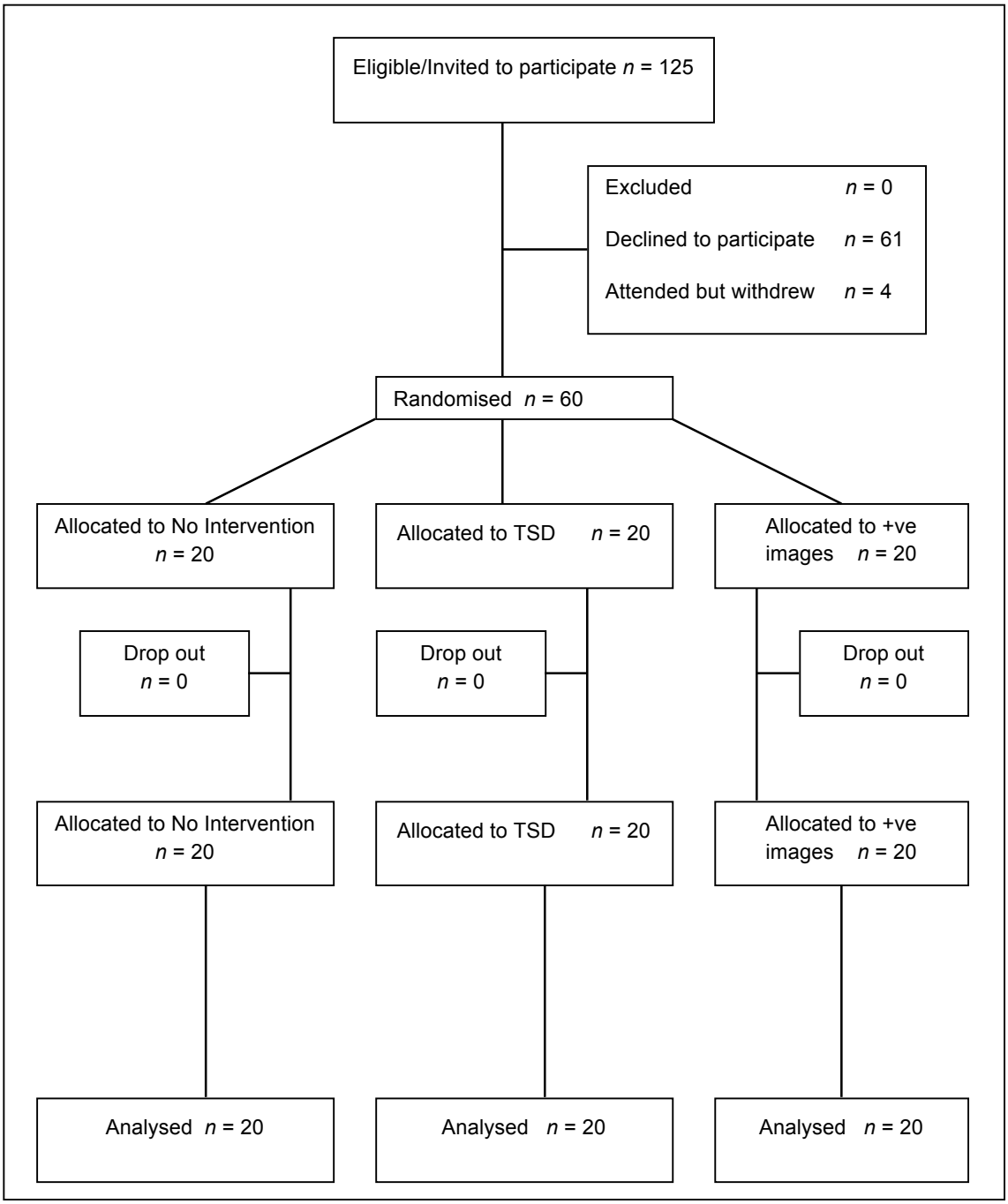

Figure 4-1: The trial flow chart

4.3 RESULTS

4.3.1 SAMPLE CHARACTERISTICS:

The sample consisted of 32 (53.3 per cent) male and 28 (46.7 per cent) female participants. There was no significant difference between genders across the three groups (X^2 = 0.013). There were 12 participants with cleft lip, 19 with cleft palate, 21 with unilateral cleft lip and palate, 7 with bilateral cleft lip and palate, and 1 with a soft palate cleft. There was no significant difference among different cleft types (X^2 = 5.01, P > 0.05) (Table 4-1). Similarly, there was no significant difference in ethnicity among the participants (X^2 = 9.75, P > 0.05) (Table 4-1). However, there was a clear significant difference in the age of the participants (F ratio = 10.44, Significance = 0.001) (Table 4-1). The mean age in the TSD group was 108.6 months (SD = 15.7). While the mean age in the no intervention and positive images groups were significantly higher at 131.2 months (SD = 12.7) and 122.3 months (SD = 18.2) respectively (Table 4-1).

Table 4-1: Characteristics of participants

	No Intervention	**TSD**	**Positive Images**	
Gender (N)				**Significance (Chi Square)**
Male	11	10	11	0.13
Female	9	10	9	
Cleft Type (N)				**Significance (Chi Square)**
CL	5	3	4	5.01
CP	4	7	8	
UCLP	7	7	7	
BCLP	3	3	1	
SPC	1	0	0	
Cleft Type (N)				**Significance (Chi Square)**
White Caucasian	12	14	9	9.75
Asian	2	2	5	
Black	5	0	4	
Mixed	1	4	2	
Age				**ANOVA (Significance)**
	131.2 (12.7)	108.6 (15.7)	122.3 (18.2)	10.44 (0.001)

4.3.2 DENTAL FEAR LEVELS:

The fear levels were measured using self-reported questionnaires and behavioural scales at different intervals during the dental visit. The pre-treatment and post-treatment CFSS-DS scored by the participants revealed different responses among the three groups. In the no intervention group, the mean pre-treatment scores were 34.75 (SD = 12.03), and the mean post-treatment scores 31.7 (SD = 9.99). While, in the TSD group, the mean pre-treatment scores were 29.45 (SD = 13.59), and the mean post-treatment scores 22.85 (SD = 7.84). In the positive images group, the mean pre-treatment scores were 29.40 (SD = 14.65), and the mean post-treatment scores 18.85 (SD = 6.67). The analysis of variance (ANOVA) showed a statistically significant reduction in the post-treatment fear scores of the participants when TSD and positive images techniques were used ($P < 0.001$)(Table 4-2).

The paediatric dentist assessed the behaviour of the participants at the dental chair and during dental examination using a visual analogue scale. In the dental chair, the mean scores were 7.75 (SD = 1.77) for the no intervention group, 8 (SD = 2.22) for the TSD group, and 8.5 (0.82) for the positive images group. There was no significant difference in the participants' behaviour among the groups (0.46). While, during examination, the mean scores were 7.85 (SD = 1.66) for the no intervention group, 8.05 (SD = 2.21) for the TSD group, and 8.5 (0.82) for the positive images group. Similarly, There was no significant difference in the participants' behaviour among the groups (0.73)(Table 4-2).

In addition, the dentist assessed the behavioural levels of the participants throughout the consultation using the Frankl scale. The mean scores were 3.10 (SD = 0.71) for the no intervention group, 3.25 (SD = 0.85) for the TSD group, and 3.25 (0.44) for the positive images group. There was no significant difference in the participants' behaviour among the groups (0.73)(Table 4-2).

Likewise, two investigators assessed the behavioural levels of the participants using the Frankl scale via a five minutes video recording of the dental appointment. The mean scores were 3 (SD = 0.87) for the no intervention, 3.38 (SD = 0.88) for the TSD group, and 3.47 (SD = 0.51) for positive images group. There was no significant difference in the participants' behaviour among the groups (0.22)(Table 4-2).

Table 4-2: Comparisons of fear levels

	No Intervention	**TSD**	**Positive Images**	**F (Significance)**
CFSS Scores *(Mean (SD))*				
Pre-CFSS	34.75 (12.03)	29.45 (13.59)	29.40 (14.65)	1.04 (0.36)
Post-CFSS	31.7 (9.99)*a*	22.85 (7.84)*b*	18.85 (6.67)*b*	13.02 (< 0.001)
VAS				
Dental Chair	7.75 (1.77)	8 (2.22)	8.5 (0.82)	0.99 (0.46)
During Examination	7.85 (1.66)	8.05 (2.21)	8.5 (0.82)	0.31 (0.73)
Frankl Scale				
Dentist	3.10 (0.71)	3.25 (0.85)	3.25 (0.44)	0.31 (0.73)
Video	3 (0.87)	3.38 (0.88)	3.47 (0.51)	1.56 (0.22)

a,b: Subscripts indicate homogenous subsets

4.4 DISCUSSION

This is the first study to assess the effectiveness of non-pharmacological interventions in alleviating dental fear among individuals with cleft lip and palate. Our null hypothesis tested that there is no difference observed among the different types of non-pharmacological intervention used in alleviating dental fear in participants with cleft lip and palate anomaly. This was rejected because our current findings revealed significant success in reducing dental fear when TSD and positive images techniques were employed ($P < 0.001$).

Randomisation is an integral component of the design of any clinical trial. In the current study, randomisation failed to prevent significant differences in sample characteristics. The age of the participants in the TSD group were significantly lower than in the other two experimental groups ($P = 0.001$).

In the current study, the use of TSD and positive images techniques proved successful in reducing dental fear in cleft lip and palate participants. These findings are in agreement with previously published studies (Fox and Newton, 2006; Samra-Quintero et al., 2006). The use of validated positive images and the similar sample size per group between the two studies may explain the match in the overall outcome. Although, the difference between the two studies lies in the fear measurement tools utilised for the assessment of dental fear. Another difference would be that the current study included participants with cleft lip and palate as opposed to non-cleft subjects in Fox and Newton's study. Likewise, Samra-Quintero and colleagues succeeded in alleviating dental fear using TSD technique ($P < 0.001$). The only drawback is the use of blood pressure as the only assessment tool for dental fear. The use of additional measurement tools in the form of self-reported questionnaires or behavioural scales may have revealed different aspects of the outcomes (Samra-Quintero et al., 2006).

On the contrary, Olumide and associates, found no significant difference in fear levels between control and experimental groups (Olumide et al., 2009). The use of child-

friendly dental information leaflets did not alter fear levels considerably in comparison to leaflets containing healthy diet information. The method of assessment and the lack of no intervention group may have an influence on the overall result.

The current results should be viewed with caution. As unlike, in the self-reported questionnaires, there were no differences in the participants' behaviour among the three groups when assessed using visual analogue or Frankl scales. The explanation might be that self-reported questionnaire reveals the participant's personal view about the dental environment, while behavioural scale shows the professional opinion about the participants' behaviour in the dental clinic.

There were no difference in the participants' behaviour scored by the dentist and the two investigators using Frankl scale. This means a validation of the participants' behaviour irrespective of the source of assessment, since the behavioural assessment was made directly by the treating dentist, and indirectly through a video recording of the dental appointment by two investigators.

There were some limitations and confounding elements in this research that we should shed a light on. These include the possibility of bias in sample characteristics, particularly with the lower age range in the TSD group despite the randomisation of allocation. Another possibility is the relatively smaller sample size in each group. A larger sample may possibly have shown different fear reactions towards dental setting. We believe that it is worth conducting controlled trials evaluating fear levels on participants with poor dental behaviour and elevated fear levels.

Further investigations may be required with great emphasis on carefully designed controlled trials, different non-pharmacological techniques, and various fear measurement tools to draw accurate conclusion on the management of dentally fearful patients.

4.5 CONCLUSION

The levels of dental fear were significantly reduced when using TSD and positive images techniques. There was no difference in the dental behaviour among the groups when assessed by visual analogue and Frankl scales.

5. DISCCUSSION AND CONCLUSIONS

At the time of the research, this work was unable to locate any published studies of the incidence and prevalence of dental anxiety or fear amongst individuals with cleft lip and palate. This dissertation has demonstrated that dental fear is potentially prevalent amongst this group of individuals, and explored effective psychological approaches to successfully managing dental anxiety. The project consisted of, firstly, a systematic review that evaluated the clinical evidence available to support the use of any kind of non-pharmacological interventions in controlling dental anxiety. This was important in formulating interventions for inclusion in the randomised controlled trial.

Secondly, a survey was conducted to measure the prevalence of dental fear in cleft lip and palate population. This was significant to draw a base line for the diagnosis of fear of dental environment. It was important to know whether the cleft lip and palate individuals have higher levels of dental fear due to the extensive dental and medical interventions that they have underwent throughout early life, or alternatively, whether the dental fear levels are lower in cleft lip and palate individuals than general population due to their frequent dental and medical appointments. The survey suggests that despite the repeated visits for dental and medical treatment, fear of dental treatment is high amongst this group in comparison to age-matched peers.

Thirdly, a randomised controlled trial was conducted to test the effectiveness of non-pharmacological interventions in reducing dental fear in cleft lip and palate population. No previous study has assessed the use of these techniques in individuals with cleft lip and palate condition. Since these techniques are non-interventional and require minimal cost or training to the dental practitioner and can potentially be very beneficial to the long-term outcomes for the patient, there was a good rationale for evaluating their effectiveness.

5.1 SUMMARY OF FINDINGS

5.1.1 SUMMARY OF THE SYSTEMATIC REVIEW FINDINGS

The systematic review aimed to provide clinical evidence supporting the use of non-pharmacological intervention to reduce fear in dentistry. The review followed the criteria for a Cochrane review which sets strict guidelines for the manner in which studies are selected for inclusion in a systematic review. A total of 278 articles on the topic of non-pharmacological intervention for children were identified through the electronic searches. Initial screening of the abstracts and titles by all review authors identified 23 articles, which related to psychological interventions to reduce dental anxiety. The full articles were then retrieved. Six trials compared the effectiveness of non-pharmacological interventions and control conditions in reducing dental anxiety were included (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Two comparisons were identified, non-pharmacological versus no intervention or control, and two non-pharmacological interventions. In the first comparison, non-pharmacological versus no intervention or control, five trials compared the effectiveness of non-pharmacological interventions and control conditions in reducing dental anxiety (Filcheck et al., 2004: Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). The control was intended to be no treatment in the form of usual care, regular environment, and a leaflet on benefits of healthy eating. Filcheck and colleagues showed no significant difference in disruptive behaviour and distress between the experimental and control groups despite having five times more cooperative children when audio distraction was employed. Audio distraction lead to less disruptive behaviour (22 per cent) in comparison to (16 per cent) without the use of any intervention, yet this difference was not significant (Filcheck et al., 2004). These findings seemed consistent with previous evidence that showed lack of sufficient improvement in distress levels when pleasant audio distractions were utilised (Allen, 2003). Another trial, (Olumide et al., 2009) evaluated

the effectiveness of using leaflets containing child friendly dental information compared to control with child friendly leaflets containing information on benefits of healthy eating. There was a reduction in dental anxiety levels in the experiment (Mean = 0.56, SD = 0.82) and control groups (Mean = 0.24, SD = 0.61). Once again, there was no significant difference between the experimental and control groups (U = 299.5).

In the contrary, there were three studies that revealed a significant difference in favour of non-pharmacological interventions as opposed to control conditions. A meta-analysis was performed to assess the level of significance for the three trials (Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007) (Figure: 2.3; Table: 2.14). The aggregated P-value showed that there is a significant reduction of anxiety for the non-pharmacological intervention in relation to the control group when we combine the information of the studies (Z = 3.37, P = 0.0004). The test for the heterogeneity was non-significant Q (1 degree of freedom = 1.18; P = 0.28), indicating that the two studies were not heterogeneous (Fox and Newton, 2006; Samra-Quintero et al., 2006). This showed no evidence to support the use of tell-show-do technique over positive images in reducing dental anxiety. These studies probably show the importance of the appropriate selection of a given non-pharmacological intervention and the precise application of this technique to deliver the intended outcome in reducing anxiety and improving behaviour in dental settings.

In the second comparison, the two non-pharmacological interventions, only one relevant study was included (Peretz and Gluck, 2005). They provided evidence on the relationship between dental anxiety and the use of two non-pharmacological interventions; tell-show-do intervention or magic trick distraction intervention. Children who were subjected to the magic trick intervention where faster to sit on the dental chair (141.2 ± 71.5 seconds) than the children who were subjected to the tell-show-do (221.7 ± 110.7 seconds). The magic trick intervention facilitated radiographs taking in the magic trick group (91 per cent) when compared to the tell-show-do group (54 per cent). Behavioural observation using Frankl scale showed more positive behaviour in

the magic trick group (91 per cent) when compared to the tell-show-do group (80 per cent). It was clear from the study that magic trick facilitated positive children behaviour in the dental environment. The explanation may be that the magic trick succeeded in diverting the child's attention from the dental procedure they were about to undergo.

In summary, the systematic review revealed that the use of non-pharmacological interventions was significantly useful in controlling dental anxiety. Nevertheless, there is no evidence to support a specific intervention above other available interventions. The trials provided convincing evidence to support the use of some non-pharmacological interventions. These were tell-show-do, magic trick distraction, sensory adaptive environment, restructuring memory and positive image interventions.

5.1.2 SUMMARY OF THE SURVEY FINDINGS

Dental fear amongst individuals with cleft lip and palate may be postulated to be elevated due to the extensive dental and medical care the cleft lip and palate individuals undergo particularly in early life, or may be lowered in comparison to the general population due to latent inhibition as the result of the greater experience of individuals with cleft lip and palate with dental and medical environments. The survey in this dissertation intended to measure the extent and prevalence of dental fear in individuals with CLP condition. The sample comprised participants with CLP and non-cleft participants. The sample was divided into three groups defined by age. The groups were; 5-10 year-old, 11-15 year-old, and 16-20 year-old. This division was planned because individuals with CLP condition normally reviewed at 5, 10, 15, and 20 years of age for assessment and future plans. The findings were interesting; they showed that for all age groups, dental fear scores were higher for individuals with CLP than for the control groups. Group 5-10 year-old, means FIS: CLP = 2.17 (SD = 1.04), controls = 1.39 (SD = 0.53), $P < 0.001$. Group 11-15 year-old, means MCDAS: CLP = 21.56 (SD = 6.80), controls = 16.40 (SD = 4.35), $P < 0.001$. Group 16-20 year-old, means MCDAS: CLP = 22.08 (SD = 8.68), controls = 13.44 (SD = 2.89), $P < 0.001$.

We increased the FIS scores of group 5-10 year-old by a factor of 8. This was undertaken to allow age groups comparisons, however the validity of this pro-rating is unknown and may explain differences in the level of fear found in this age group in comparison to the other two groups. MCDAS scores above 19 is an indication of elevated fear levels. In the 11-15 year-old group, there were 27 individuals (61 per cent) who manifested with increased fear of dentistry in the cleft group. In contrast, only 17 individuals (34 per cent) of the non-cleft group were diagnosed with increased fear levels ($P = 0.007$). While, in the 16-20 year-old group, there were 15 individuals (65 per cent) manifested with increased fear of dentistry in the cleft group. In contrast, only 3 individuals (6 per cent) of the non-cleft group were diagnosed with increased fear levels ($P < 0.001$). These percentages were significantly higher in CLP individuals than previously published reports of non-cleft cohorts where the extent of dental fear ranged between 8-11 per cent (Klingberg et al., 1994; Raadal et al., 1995; Alvesalo et al., 1993; ten Berg et al., 2002; Wogelius et al., 2003; Klingberg and Broberg, 2007).

5.1.3 SUMMARY OF THE RANDOMISED CONTROLLED TRIAL FINDINGS

The randomised controlled trial revealed a number of key outcomes. In the no intervention group, the mean post-treatment dental fear score was 31.7 (SD = 9.99). Additionally, in the TSD group, the mean post-treatment score was 22.85 (SD = 7.84). In the positive images group, the mean post-treatment scores were 18.85 (SD = 6.67). The analysis of variance (ANOVA) showed a statistically significant reduction in the post-treatment fear scores of the participants when TSD and positive images techniques were used ($P < 0.001$). There was no significant difference to favour the TSD over the positive images or the vice versa. These findings proved the success of the interventions in reducing dental fear in individuals with different types of CLP. It was in agreement to previous attempt that tested the effectiveness of non-pharmacological interventions in non-cleft individuals (Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrill et al., 2007). In these studies, they used TSD and positive

images as interventions and self-reported questionnaires as methods of assessment. In the current study, we used the Frankl and visual analogue scales by the dentist and two other investigators as additional methods of assessment of the behaviour and reaction of the participants towards dental environment. This validates the outcomes revealing the success in using TSD and positive images to reduce dental fear in individuals with CLP condition.

5.2 LIMITATIONS OF THE STUDIES

5.2.1 LIMITATION OF THE SYSTEMATIC REVIEW

The systematic review provided evidence on the use of non-pharmacological interventions. However, the limitations in the review process were unavoidable. One drawback was the low number of clinical trials in the field of study. Only six trials fulfilled the systematic review criteria for selection and there was a great deal of heterogeneity in the techniques of intervention adopted in each study (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). A larger trial would be useful to draw definite conclusion and explore all aspects on the use of non-pharmacological interventions. For example, only limited numbers of non-pharmacological interventions were tested. These limited numbers of interventions were not even enough to provide evidence to support the use of a particular intervention over another.

None of the trials were multi-centred, only single centred trials were included in the review (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). This is a huge barrier for recruiting larger number of participants, eliminate or at least reduce heterogeneity and increase the power in the trials.

The comparisons in the trials were either between one intervention versus a control or no intervention, or alternatively between two non-pharmacological interventions. It

would have been beneficial to have larger multi-centred trials that included more comparisons, for instance, two or three interventions versus no intervention or control. This approach may highlight evidence in support of an intervention.

The outcomes method of assessment consisted primarily of self-reported questionnaires in the vast majority of the trials. Only one trial used physiological measure in the form of assessing the blood pressure as an indicator of distress. Another trial utilised Frankl scale to evaluate the participants' behaviour in the dental surgery. Ideally, a trial should include assessment using different measurement methodologies to validate the participants' behaviour and fear in the dental environment. Preferably, the parents should be part of the assessment process. Parental self-report questionnaires might be useful. As parents will be helpful in shedding a light on aspects of behaviours and reactions that younger children may not be able to understand or express throughout a trial.

There are important elements in any randomised controlled trials such as; randomisation, allocation of concealment, blinding, and withdrawals. These elements were included in the assessment of the trials in the review. Randomisation is often essential to eliminate bias, facilitate blinding and ensure the validity of any difference in treatment outcomes. The method of randomisation in any given trial is prepared either manually using sealed envelopes or electronically using a computer generated random numbers for all participants. In the six included trials, the method of randomisation was not explained except in one trial (Fox and Newton, 2006). Unfortunately, none of the trials described the method of allocation of concealment (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). Blinding of all participating investigators and participants is not usually possible in clinical trials involving psychological interventions. It is often difficult for the clinician undertaking any given clinical procedures to be blinded. Usually it is only possible to have the member of the research team undertaking the statistical analysis to be blinded. Similarly in this review, in all included trials, blinding was not

possible for either the clinician undertaking the procedure or the parents (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

Withdrawals of invited participants are necessary to be recorded and included in the statistical analysis to avoid bias in the reported outcomes. In most of the trials the number of withdrawals were less than 20 per cent (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009). However, only one trial clearly reported the withdrawals were included in the statistical analysis (Fox and Newton, 2006).

5.2.2 LIMITATION OF THE SURVEY

The recruited sample consisted of 178 individuals with CLP condition and 150 non-cleft participants. There were 50 participants in each of the non-cleft groups. While, the cleft groups consisted of 110 participants in the 5-10 year-old, 44 participants in the 11-15 year-old, and only 24 in the 16-20 year-old. It was not possible to achieve a larger sample size for this survey, although it would have made the results of the study more powerful. Clearly other factors played a part in this low recruitment almost certainly including social interactions and activities. Another factor was the method of recruitment in the cleft groups, where a postal questionnaires method was adopted as opposed to direct recruitment from the waiting area at the Orthodontic Department, Guy's and St Thomas' NHS Foundation Trust that was applied for the non-cleft groups. At the study design stage, it was felt that recruiting cleft participants directly from the waiting area in the South Thames Cleft Service would be complex and time consuming. Accordingly, the survey method adopted followed guidelines on the design of surveys to maximise response rates (Edwards et al., 2002). Other measures to ensure higher response rate were; the questionnaires were posted first class to all potential participants, enclosing a covering letter explaining the purpose of the study, and a reply-paid envelope.

The Facial Image Scale (FIS) was used to assess the dental fear in the 5-10 year-old groups. However, this scale includes only one question with a row of five faces to indicate the distress level. Although this scale is reliable and valid in the assessment of dental fear (Buchanan and Niven, 2002), it lacks any details about the various dental procedures and fear triggering stimuli in the dental environment.

5.2.3 LIMITATION OF THE RANDOMISED CONTROLLED TRIAL

The randomised controlled trial was necessary in this dissertation to evaluate the effectiveness of non-pharmacological interventions in alleviating dental fear in participants with CLP. The trial was cross sectional in nature. Ideally a longitudinal trial would have been essential to reveal more robust outcomes.

The number of recruited participants was relatively low (20 participants pre group). Nevertheless, previous published trials included a sample that ranged between 19-50 per group (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

The trial was single-centred as it took place in the clinics at the South Thames Cleft Service, Guy's and St Thomas' NHS Foundation Trust. A multi-centred methodology would have allowed larger sample and widen the spectrum of recruited participants.

Blinding as discussed earlier is an essential component of any trial. In the current trial, blinding was impossible to be employed on the participants, parents, or clinician. However, the member of the research team undertaking the statistical analysis was blinded to group membership by means of a coding system.

5.3 DISCCUSSION OF FINDINGS IN RELATION TO DENTAL FEAR AND CLP

Dental fear is a very complex phenomenon comprising anxiety, fear and phobia (Berggren et al., 1984). It occurs as a result of normal defensive responses to certain triggering elements such as the dental environment, pain, discomfort, sounds, and

drills. All of these elements act as triggering stimuli to the initiation of dental fear that leads to serious consequences. In severe fearful individuals, avoidance of dental care is a major complication that outlines the effect of negative behaviour towards dental setting. This avoidance may cause marked reduction in the overall health impact of dental treatment (Ter Horst and De Wit, 1993).

The consequences of dental avoidance will be profound particularly in individuals with CLP condition. This is because of the extensive dental and medical care required for this population throughout their entire life. The healthcare delivered ranges from simple dental procedure to extensive surgical interventions including; lip repair, palate repair, alveolar bone graft, and nasal revisions. As discussed previously (Section: 1.1.4.4; Pages: 21-22), there are a number of dental anomalies that are associated with CLP condition. These anomalies may be in the form of supernumerary teeth, missing teeth, or impacted teeth. These anomalies would require various dental interventions including restorative and surgical care, as well as comprehensive orthodontic treatment. As a result, avoidance and poor compliance will lead to serious detrimental oral health complications.

The current dissertation revealed an elevated dental fear in CLP condition compared to non-cleft individuals. Furthermore there was a suggestion that dental fear increased with age, which was in contradiction with previously published studies on non-cleft individuals (Klingberg et al., 1994; Raadal et al., 1995; Wogelius et al., 2003). The systematic review confirmed the success achieved when non-pharmacological interventions were utilised to control fear in dental settings. Clearly, significant reduction in dental fear was attained when interventions like; TSD, positive images, and distractions were used (Filcheck et al., 2004; Peretz and Gluck, 2005; Fox and Newton, 2006; Samra-Quintero et al., 2006; Pickrell et al., 2007; Olumide et al., 2009).

The use of TSD, and environmental interventions in the form of positive images on participants with CLP condition revealed promising outcomes. The outcomes obtained

from self-reported questionnaires indicated significant reduction in post-intervention when compared to pre-intervention scores. The authors successfully showed a control in behaviour and dental fear achieved with the use of TSD and positive images interventions. These interventions hold a number of advantages; they are simple procedures, easy to employ, and not expensive.

In view of these findings we recommend the use of non-pharmacological interventions routinely to alleviate dental fear in individuals we CLP condition and consequently avoid any complications that would jeopardise healthcare delivery.

5.4 RECOMMENDATIONS AND FUTURE IMPLICATIONS

Generally dental fear is a relatively common feature in the general dental population and is a major factor in the failure to attend at dental clinics (Ter Horst and De Wit, 1993). Undoubtedly, syndromic patients such as cleft require comprehensive healthcare. In order to identify a strategy to further deliver healthcare for cleft and non-cleft individuals we would recommend further high quality research studies to assess the effectiveness of methods and strategies for alleviating dental fear and related consequences.

Well-designed randomised controlled trials, with developmental and behavioural outcome measures are required to assess the effectiveness of non-pharmacological interventions. Multi-centred and longitudinal studies will aid in recruiting larger numbers of participants, reducing the heterogeneity of the sample and providing adequate power for the investigation.

5.5 CONCLUSION

The conclusions of the present thesis are as follow:

1. The use of non-pharmacological interventions proves successful in the control of dental fear. However, there is no evidence to support one particular intervention over another.

2. A systematic review revealed trials that provided an evidence to support the use of some non-pharmacological interventions. tell-show-do, magic trick distraction, sensory adaptive environment, restructuring memory and positive image interventions showed promising outcomes in the control of dental anxiety.

3. Individuals with CLP have high levels of dental fear in comparison to their age matched peers. Interventions should focus on prevention and management of fear in this group of patients.

4. There were 61 per cent of 11-15 year-old individuals with CLP manifested with increased fear of dentistry. While, 65 per cent of the 16-20 year-old manifested with increased fear of dentistry.

5. The results revealed lower levels of dental fear levels in the 5-10 year-old group when compared to the 11-15 year-old and 16-20 year-old cleft groups.

6. The randomised controlled trial showed significant reduction in dental fear when using TSD and positive images techniques. There was no difference in the dental behaviour among the groups when assessed by visual analogue and Frankl scales.

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7. APPENDICES

7.1 KING'S COLLEGE SPONSORSHIP LETTER

Professor Robert Lechler
PhD FRCP FRCPath FMedSci
Vice-Principal (Health)
Dean, School of Medicine and
Dental Institute at Guy's, King's College
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Hodgkin Building
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KING'S College LONDON
University of London

TO WHOM IT MAY CONCERN

I write to confirm that King's College London will act as Sponsor to the following study being undertaken by Khalid Al-Mooamar an MPhil/PhD student under the supervision of Professors Tim Newton and Fraser McDonald in the Dental Institute.

Title of Study: Interventions to Reduce Fear of Dentistry in Individuals with Cleft Lip and Palate.

Robert Lechler

14 June 2007

www.kcl.ac.uk

7.2 THE SURVEY'S ETHICAL APPROVAL

NHS

National Research Ethics Service

London - Surrey Borders Research Ethics Committee

St Georges University of London
South London REC Office 1
Corridor 1 - Room 1.13
1st Floor, Jenner Wing
Tooting
London
SW17 0RE

Telephone: 0208 725 0262
Facsimile: 0208 725 1897

30th June 2008

Dr Khalid Al-Moammar
PhD Student
King's College London
Department of Orthodontics
Floor 22, Guy's Tower
Guy's Hospital, London
SE1 9RT

Dear Dr AL-Moammar

Full title of study: **Interventions to reduce fear of dentistry in individuals with cleft lip and palate.**

REC reference number: **08/H0806/27**

Thank you for your letter of 19th May 2008, responding to the Committee's request for further information on the above research and submitting revised documentation, subject to the conditions specified below.

The further information was considered at the meeting of the Sub-Committee of the REC held on the 27th June 2008. A list of the members who were present at the meeting is attached.

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.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed they have no objection.

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.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

08/H0806/27 Page 2

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

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

Document	*Version*	*Date*
Application	5.5	18 March 2008
Investigator CV		18 March 2008
Investigator CV		18 March 2008
Investigator CV		18 March 2008
Protocol	1	18 March 2008
Covering Letter		18 March 2008
Covering Letter		19 May 2008
Letter from Sponsor		14 June 2007
Letter of invitation to participant	2	09 May 2008
Participant Information Sheet	1	09 May 2008
Response to Request for Further Information		19 May 2008
Follow-Up Letter to Participant	1	18 March 2008
Facial Image Scale Questionnaire	1	09 May 2008

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

Now that you have completed the application process please visit the National Research Ethics Website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H0806/27	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

PP gbailey

Dr Hervey Wilcox
Chair

Email: lsbrec@stgeorges.nhs.uk

Enclosures: *List of names and professions of members who were present at the sub-committee meeting and those who submitted written comment*
"After ethical review – guidance for researchers"
Site approval form

Copy to: Mr Keith Brennan
Assistant Head of Administration (Health)
Room 1.8 Hodgkin Building,
Kings College London
Guys Campus
London SE1 1UL

7.3 THE SURVEY'S RESEARCH AND DEVELOPMENT APPROVAL

FW: Study has been registered with R&D 08/H0806/27

Ignatian Karen [Karen.Ignatian@gstt.nhs.uk]

You forwarded this message on 12/08/2008 13:22.

Sent: 31 July 2008 16:52

To: Al-Moammar, Khalid

Dear Khalid

A survey of dental anxiety in individuals with cleft lip and palate; 08/H0806/27: Khalid Al-Moammar

Thank you for submitting your research project to the R&D Department. The project has now been approved by the Trust and has been allocated the Trust R&D registration number RJ1 08/0202 The project has been registered on the Trust's research database.Please quote the R&D registration number in any communications with the R&D Department regarding your project.

Conditions of Approval:

1. The principal investigator must notify R&D of the actual start and end date of the project.
2. The Principal Investigator is responsible for ensuring that Data Protection procedures are observed throughout the course of the project.
3. The agreed protocol must be followed. R&D must be notified of any changes to the protocol prior to implementation.
4. The Principal Investigator and research team must have appropriate substantive or honorary contracts with the Trust. The Principal Investigator is responsible for ensuring that the team is covered.
5. All members of the research team must have completed GCP training - please contact me if training or annual updates are required.
6. Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion (14 April)
7. Trust approval for the research is subject to the research being undertaken in line with the Department of Health's Research Governance Framework, and Trust policies relating to Research Governance. The Research Governance Framework and details of you and your researchers responsibilities within this framework can be found on the Department of Health's website at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

If appropriate it is recommended that you register with the Current Controlled Trials website; http://isrctn.org/

There is a fee per trial registered - if this fee will impose a considerable burden upon your trial resources please contact myself or one of my colleagues in the R&D Department.

In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust's process for the monitoring of projects and the associated guidance is available from the Trust's intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Many thanks for registering your research project

Best regards

Karen

Karen Ignatian BSc Hons
Research Governance Specialist
Guy's & St Thomas' Foundation NHS Trust
3rd Floor Conybeare House
Guy's Hospital
Great Maze Pond
London SE1 9RT
Ext Tel: 02071885736
Int Tel: 85736
Fax: 02071885434
Email: karen.ignatian@GSTT.nhs.uk

7.4 THE RCT'S ETHICAL APPROVAL

NHS

National Research Ethics Service

Guy's Research Ethics Committee
(South London REC Office 3)
Governor's Hall Suite
St Thomas' Hospital
SE1 7EH

Telephone: 020 7188 2260
Facsimile: 020 7188 2258

22 June 2009

Mr Khalid Al-Moammar
PhD Student
King's College London
Floor 22, Orthodontic Department
Guy's Hospital

Dear Mr Al-Moammar

Study Title: **A Randomised controlled trial of interventions to reduce levels of dental anxiety in Cleft lip and palate**
REC reference number: **09/H0804/6**
Protocol number: **1**

Thank you for your letter of 22 June 2009, 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

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).

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.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) 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 the only involvement of the NHS organisation is as a Participant Identification

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

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:

Document	*Version*	*Date*
CVs for Jonathon Timothy Newton & Fraser McDonald		
Questionnaire: Children Fear Survey Schedule		
Covering Letter		19 December 2008
Protocol	1	19 December 2008
Investigator CV	Khalid Al-Moammar	
Application	Parts A & B	19 December 2008
Response to Request for Further Information		22 June 2009
Participant Consent Form: Assent form for Child	2	04 February 2009
Participant Consent Form: Parent/Guardian	2	04 February 2009
Participant Information Sheet	2	04 February 2009
Covering Letter		06 March 2009
Preparatory Leaflet	2	04 February 2009

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

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0804/6	Please quote this number on all correspondence

Yours sincerely

Professor David Bartlett
Chair

Email: stephanie.hill@gstt.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *SL- AR2 for other studies*

Copy to: *Mr Keith Brennan, KCL*

R&D office, GSTFT

7.5 THE RCT'S RESEARCH AND DEVELOPMENT APPROVAL

Guy's and St Thomas' NHS
NHS Foundation Trust

Research & Development
Guy's & St Thomas' Foundation NHS Trust
3rd Floor Conybeare House
Guy's Hospital
St Thomas Street
London SE1 9RT
Tel: 02071885731

Mr. Khalid Al-Moammar
PhD Student
KCL
22nd Floor, Orthodontic Department
Guy`s Hospital
SE1 9RT

24 August 2009

Dear Mr. Al-Moammar

Title: A Randomised Controlled trial of interventions to reduce levels of dental anxiety in cleft lip and palate

In accordance with the Department of Health's Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

- **Ethics number:** 09/H0804/06
- **Sponsor:** KCL
- **End date:** 24/01/2010
- **Protocol:** 1.0 19/12/2008
- **Site:** GSTFT
- **R&D approval Date:** 24/08/2009

R&D have reviewed the documentation submitted for this project and I am pleased to inform you that we are approving the work to proceed within Guy's and St Thomas' NHS Foundation Trust and has been allocated the Trust R&D registration number RJ1 09/N134. Please quote the R&D registration number in any communications with the R&D Department regarding your project.

Conditions of Approval:

- The principal investigator must notify R&D of the actual end date of the project.
- The Principal Investigator is responsible for ensuring that Data Protection procedures are observed throughout the course of the project.
- The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management.
- R&D must be notified of any changes to the protocol prior to implementation.
- Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion (22/06/2010)

If appropriate it is recommended that you register with the Current Controlled Trials website; http://isrctn.org/

Please ensure that you are aware of your responsibilities in relation to The Data Protection Act 1998, NHS Confidentiality Code of Practice, NHS Caldicott Report and Caldicott Guardians, the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

1. The EU Directive on Clinical Trials (Directive 2001/20/EC) and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Regulations 2004;
2. The EU Directive on Principles and Guidelines for Good Clinical Practice (EU Commission Directive 2005/28/EC); and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006;

Amendments
Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

Annual Report
It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

Should you require any further information please do not hesitate to contact us.

In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust's process for the monitoring of projects and the associated guidance is available from the Trust's intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Many thanks for registering your research project

Yours faithfully

Salma Kibaida
R&D Governance Specialist

cc. Chief Investigator
cc. Sponsor

7.6 LETTER TO PARTICIPANT (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT

Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Reference number: 08/H0806/27
Version number: 2
09-05-2008

LETTER TO PARTICIPANT

Name:
Address:
Postcode:
Date:

Dear

RE: A Survey of Levels of Dental Anxiety Amongst Individuals with Cleft Lip and Palate

We are writing to ask for your kind help in completing the enclosed questionnaires. These questionnaires are part of a research project. The project aims to discover how you may feel about visiting the dental clinics.

We would be very grateful if you could take the time to complete these questionnaires and return it in the reply-paid envelope provided.

Your responses will be treated with the utmost confidentiality. They will be processed and stored using a unique identifying code. The results will not be reported in any way which allows individual responses to be identified.

Thank you very much for taking the time to complete this survey.

Yours Sincerely,

Khalid Al-Moammar
Postgraduate Dental Student
Orthodontic Department, KCL Dental Institute
Floor 22, Guy's Hospital
London SE1 9RT

7.7 FOLLOW-UP LETTER TO PARTICIPANT (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT

Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Reference number: 08/H0806/27
Version number: 2
09-05-2008

FOLLOW-UP LETTER TO PARTICIPANT

Name:
Address:
Postcode:
Date:

Dear

RE: A Survey of Levels of Dental Anxiety Amongst Individuals with Cleft Lip and Palate

We are writing to remind you about completing the questionnaires looking at how you may feel about visiting the dental clinics.

As you may be aware, children with cleft lip and palate undergo a series of operations and have regular medical and dental consultations throughout their early years. Your kind help in completing the questionnaires would help us in making the services in our hospital better.

We would like to take this opportunity to remind you that your responses will be treated with the utmost confidentiality. The results will not be reported in any way which allows individual responses to be identified.

Thank you very much for taking the time to complete this survey.

Yours Sincerely,

Khalid Al-Moammar
Postgraduate Dental Student
Orthodontic Department, KCL Dental Institute
Floor 22, Guy's Hospital
London SE1 9RT

7.8 PARTICIPANT'S INFORMATION SHEET (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT

Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Reference number: 08/H0806/27
Version number: 2
19-08-2008

A Survey of Levels of Dental Anxiety Amongst Individuals with Cleft Lip and Palate

Researchers: **Tim Newton**
Fraser McDonald
Khalid Almoammar

You are invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with you friends and relatives if you wish. The project aims to discover how you may feel about visiting the dental clinics.

Thank you for reading this.

1. **What is the purpose of the study?**

   The project aims to discover how you may feel about visiting the dental clinics.

2. **Why I have been chosen?**

   We are interested in finding out whether people who have a cleft lip and palate are more or less frightened about visiting the dentist when compared to people of a similar age who do not have a cleft lip and palate. In order to make this comparison we need a group of people who do not have cleft lip and palate. We are asking children who are attending the dental clinic to take part in this project. You have been asked because you do not have a cleft lip and palate.

3. **Do I have to take part?**

   It is up to you to decide whether or not to take part. If you decide to take part would you take the time to complete these questionnaires. If you decide not to take part this will not affect the treatment you receive.

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NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT

Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

4. What will happen to me if I take part?

If you decide to take part we will ask you take the time to complete the enclosed questionnaires. We will use the information you provide to know how you may feel about visiting the dental clinic.

5. What are the possible risks to take part?

We believe that there are no risks to taking part in this project.

6. What are the possible benefits of taking part?

We believe that there are no benefits to you to taking part in this project.

7. Will my taking part in this study be kept confidential?

All information, which is collected, about you during the course of the project will be kept strictly confidential. At no point will we ask for your name or any detail that might identify you as an individual.

8. What will happen to the results of the study?

The results will be used by Dr Almoammar as part of his PhD project. The research will be published in academic journals.

9. Who has reviewed the study?

This project was reviewed by the London Surrey Border Research Ethics Committee.

10. Contact for further information?

If you would like any further information please do not hesitate to contact Dr Almoammar by phone on 02071884417 or alternatively by e-mail; Khalid.al-moammar@kcl.ac.uk

Thank you for taking the time to read this information.

7.9 FIS FOR CONTROLS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following questions and tick the appropriate number.

Question 1: Are you?

1- Male 2- Female

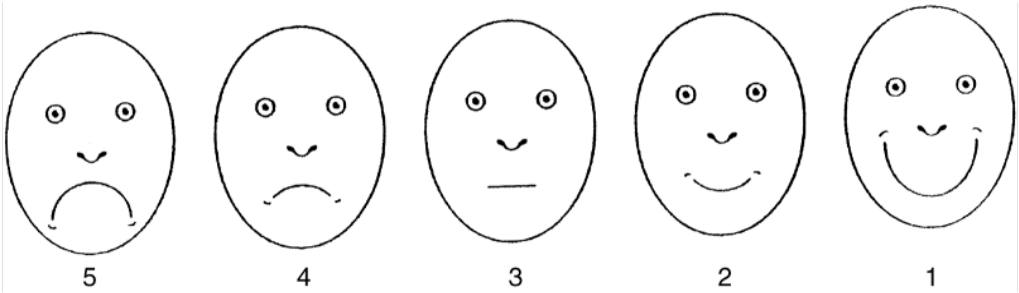
Question 2: How many operations you had?

1- None 2- One 3- Two 4- Three or more

Question 3: Have you had any dental treatment?

1- None 2- Once 3- Twice 4- Three or more

Question 4: How do you feel when visiting the dentist?



7.10 FIS FOR CLP PARTICIPANTS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following questions and tick the appropriate number.

Question 1: Are you?

1- Male 2- Female

Question 2: What type of cleft you have?

1- Cleft Lip 2- Cleft palate only 3- Cleft Lip and Palate

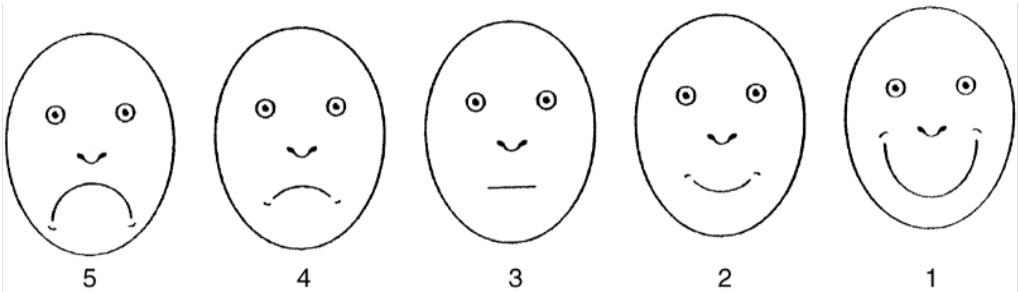
Question 3: How many operations you had?

1- None 2- One 3- Two 4- Three or more

Question 4: Have you had any dental treatment?

1- None 2- Once 3- Twice 4- Three or more

Question 5: How do you feel when visiting the dentist?



7.11 MCDAS FOR CONTROLS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following questions and tick the appropriate number.

Question 1: Are you?

1- Male 2- Female

Question 2: How old are you?

1- 11-15 years old 2- 16-20 years old

Question 3: How many operations you had?

1- None 2- One 3- Two 4- Three or more

Question 4: Have you had any dental treatment?

1- None 2- Once 3- Twice 4- Three or more

Please read the following descriptions. Would you please rate how much anxiety each of them causes you *by circling* the correct description?

1. **If you went to your dentist for treatment tomorrow, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

2. **If you were sitting in the waiting room, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

3. **If you were about to have a tooth drilled, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

4. **If you were about to have your teeth scaled and polished, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

5. **If you were about to have a tooth removed, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

6. **If you were about to have an injection in your gum, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

7. **If you were about to being put to sleep, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

8. **If you were about to have a gas that makes you comfortable but not a sleep, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

7.12 MCDAS FOR CLP PARTICIPANTS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following questions and tick the appropriate number.

Question 1: Are you?

1- Male 2- Female

Question 2: How old are you?

1- 11-15 years old 2- 16-20 years old

Question 3: What type of cleft you have?

1- Cleft Lip 2- Cleft Palate only 3- Cleft Lip and Palate

Question 4: How many operations you had?

1- None 2- One 3- Two 4- Three or more

Question 5: Have you had any dental treatment?

1- None 2- Once 3- Twice 4- Three or more

Please read the following descriptions. Would you please rate how much anxiety each of them causes you *by circling* the correct description?

1. **If you went to your dentist for treatment tomorrow, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

2. **If you were sitting in the waiting room, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

3. **If you were about to have a tooth drilled, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

4. **If you were about to have your teeth scaled and polished, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

5. **If you were about to have a tooth removed, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

6. **If you were about to have an injection in your gum, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

7. **If you were about to being put to sleep, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

8. **If you were about to have a gas that makes you comfortable but not a sleep, how would you feel?**

Not Anxious Slightly Anxious Fairly Anxious Very Anxious Extremely Anxious

7.13 CFSS-DS FOR CONTROLS AND CLP PARTICIPANTS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following descriptions. Would you please rate how much anxiety each of them causes you *by circling* the correct description?

	Not at all	A little	Somewhat	Much	Very Much
1. Making an appointment for dentistry.	1	2	3	4	5
2. Approaching the dentists' surgery.	1	2	3	4	5
3. Sitting in the waiting room.	1	2	3	4	5
4. Being seated in the dental chair.	1	2	3	4	5
5. The smell of the dentist's surgery.	1	2	3	4	5
6. Seeing the dentist walk in	1	2	3	4	5
7. Seeing the anaesthetic needle.	1	2	3	4	5
8. Feeling the needle injected.	1	2	3	4	5
9. Seeing the drill.	1	2	3	4	5
10. Hearing the drill.	1	2	3	4	5
11. Feeling the vibration.	1	2	3	4	5
12. Having your teeth cleaned.	1	2	3	4	5
13. Having x-ray put in my mouth.	1	2	3	4	5
14. Having models or impressions of my mouth.	1	2	3	4	5
15. All things considered, how much scared are you of having dentistry done?	1	2	3	4	5

7.14 CFSS FOR CLP CONTROLS AND CLP PARTICIPANTS (THE SURVEY)

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

Please read the following descriptions. Would you please rate how much anxiety each of them causes you *by circling* the correct description?

	Not at all	A little	Fair amount	Much	Very Much
1. Vacuum cleaners	0	1	2	3	4
2. Open wounds	0	1	2	3	4
3. Being alone	0	1	2	3	4
4. Loud voices	0	1	2	3	4
5. Dead people	0	1	2	3	4
6. Speaking in public	0	1	2	3	4
7. Crossing streets	0	1	2	3	4
8. People who seem insane	0	1	2	3	4
9. Falling	0	1	2	3	4
10. Automobiles	0	1	2	3	4
11. Being teased	0	1	2	3	4
12. Dentists	0	1	2	3	4
13. Thunder	0	1	2	3	4
14. Sirens	0	1	2	3	4
15. Failure	0	1	2	3	4
16. Being teased	0	1	2	3	4
17. Entering people where other people already seated	0	1	2	3	4
18. High places on land	0	1	2	3	4
19. Looking down from high building	0	1	2	3	4

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NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

	Not at all	A little	Fair amount	Much	Very Much
20. Worms	**0**	**1**	**2**	**3**	**4**
21. Imaginary creatures	**0**	**1**	**2**	**3**	**4**
22. Receiving injections	**0**	**1**	**2**	**3**	**4**
23. Strangers	**0**	**1**	**2**	**3**	**4**
24. Bats	**0**	**1**	**2**	**3**	**4**
25. Traveling by train	**0**	**1**	**2**	**3**	**4**
26. Feeling angry	**0**	**1**	**2**	**3**	**4**
27. People in authority	**0**	**1**	**2**	**3**	**4**
28. Flying insects	**0**	**1**	**2**	**3**	**4**
29. Seeing other people injected	**0**	**1**	**2**	**3**	**4**
30. Sudden noises	**0**	**1**	**2**	**3**	**4**
31. Journeys by car	**0**	**1**	**2**	**3**	**4**
32. Dull weather	**0**	**1**	**2**	**3**	**4**
33. Crowds	**0**	**1**	**2**	**3**	**4**
34. Cats	**0**	**1**	**2**	**3**	**4**
35. One person bullying another	**0**	**1**	**2**	**3**	**4**
36. Tough looking people	**0**	**1**	**2**	**3**	**4**
37. Birds	**0**	**1**	**2**	**3**	**4**
38. Sight of deep water	**0**	**1**	**2**	**3**	**4**
39. Being watched working	**0**	**1**	**2**	**3**	**4**
40. Dead animals	**0**	**1**	**2**	**3**	**4**

Guy's and St Thomas' Hospital NHS
NHS Trust

Guy's Hospital
St. Thomas Street
London SE1 9RT
Tel: 020 7188 7188
www.guysandstthomas.nhs.uk

	Not at all	A little	Fair amount	Much	Very Much
41. Weapons	**0**	**1**	**2**	**3**	**4**
42. Dirt	**0**	**1**	**2**	**3**	**4**
43. Journeys by bus	**0**	**1**	**2**	**3**	**4**
44. Crawling insect	**0**	**1**	**2**	**3**	**4**
45. Seeing a flight	**0**	**1**	**2**	**3**	**4**
46. Ugly people	**0**	**1**	**2**	**3**	**4**
47. Fire	**0**	**1**	**2**	**3**	**4**
48. Sick people	**0**	**1**	**2**	**3**	**4**
49. Being criticized	**0**	**1**	**2**	**3**	**4**
50. Strange Shapes	**0**	**1**	**2**	**3**	**4**
51. Being touched by others	**0**	**1**	**2**	**3**	**4**
52. Being in an elevator	**0**	**1**	**2**	**3**	**4**
53. Witnessing a surgical procedure	**0**	**1**	**2**	**3**	**4**
54. Angry people	**0**	**1**	**2**	**3**	**4**
55. Mice or rats	**0**	**1**	**2**	**3**	**4**
56. Human blood	**0**	**1**	**2**	**3**	**4**
57. Animal blood	**0**	**1**	**2**	**3**	**4**
58. Parting from friends	**0**	**1**	**2**	**3**	**4**
59. Enclosed places	**0**	**1**	**2**	**3**	**4**
60. Prospects (Results) of a surgical operation	**0**	**1**	**2**	**3**	**4**

Guy's and St Thomas' Hospital NHS
NHS Trust

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	Not at all	A little	Fair amount	Much	Very Much
61. Feeling rejected by others	0	1	2	3	4
62. Journeys by airplane	0	1	2	3	4
63. Medical odors	0	1	2	3	4
64. Feeling disapproved	0	1	2	3	4
65. Harmless snakes	0	1	2	3	4
66. Cemeteries	0	1	2	3	4
67. Being ignored	0	1	2	3	4
68. Darkness	0	1	2	3	4
69. Premature heart beat (Missing a beat)	0	1	2	3	4
70. Lightening	0	1	2	3	4
71. Doctors	0	1	2	3	4
72. Crippled or deformed people	0	1	2	3	4
73. Making mistakes	0	1	2	3	4
74. Looking foolish	0	1	2	3	4
75. Loosing control of your self	0	1	2	3	4
76. Fainting	0	1	2	3	4
77. Becoming nauseous	0	1	2	3	4
78. Harmless spiders	0	1	2	3	4
79. Being responsible for decisions	0	1	2	3	4

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	Not at all	A little	Fair amount	Much	Very Much
80. Sights of knifes or sharp objects	**0**	**1**	**2**	**3**	**4**
81. Thoughts of being mentally ill	**0**	**1**	**2**	**3**	**4**
82. Taking written tests	**0**	**1**	**2**	**3**	**4**
83. Large open spaces	**0**	**1**	**2**	**3**	**4**
84. Dogs	**0**	**1**	**2**	**3**	**4**
85. Germs	**0**	**1**	**2**	**3**	**4**
86. Taking medicines	**0**	**1**	**2**	**3**	**4**
87. Being punished by God	**0**	**1**	**2**	**3**	**4**
88. Wearing wrong clothes for the occasion	**0**	**1**	**2**	**3**	**4**
89. Ministers or priests	**0**	**1**	**2**	**3**	**4**
90. Hurting the feelings of others	**0**	**1**	**2**	**3**	**4**
91. Undertakers	**0**	**1**	**2**	**3**	**4**
92. Police	**0**	**1**	**2**	**3**	**4**
93. Fish	**0**	**1**	**2**	**3**	**4**
94. Leaving home	**0**	**1**	**2**	**3**	**4**
95. Physical examination	**0**	**1**	**2**	**3**	**4**
96. Insecticides	**0**	**1**	**2**	**3**	**4**
97. Vomiting	**0**	**1**	**2**	**3**	**4**
98. Being in charge	**0**	**1**	**2**	**3**	**4**
99. Hospitals	**0**	**1**	**2**	**3**	**4**

7.15 PARTICIPANT INFORMATION SHEET (THE RCT)

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A RANDOMISED CONTROLLED TRIAL OF INTERVENTIONS TO REDUCE DENTAL ANXIETY IN CLEFT LIP AND PALATE CHILDREN

Reference number: *09/H0804/6*
Version number: *2*
04-02-2009

Researchers: Tim Newton
Fraser McDonald
Khalid Almoammar

You are being invited to take part in a research study at King's College London Dental Institute. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take the time to decide whether or not you wish to take part.

Thank you for reading this.

1. What is the purpose of the study?

A lot of people are worried about going to the dentist. We are studying ways to help young people, particularly children to feel less anxious. This study is looking at two ways to reduce the fear of the dentists during dental appointments. This study is looking at two ways to reduce children's fears of dental procedures.

2. Why have I been chosen?

We are asking children who may have any form of cleft (cleft lip and/or palate) to take part in this project. You have been selected because you are a child with cleft lip and/or palate.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. We will also ask your parent or guardian to sign a form to indicate that they are willing to allow you to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the treatment you receive.

4. What will happen to me if I take part?

We will undertake two simple procedures before the dental treatment. This includes looking at a number of pictures and/or asking you to do the procedure on a plastic model. We will

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then ask you to tell us how anxious you are feeling about your visit by completing a questionnaire. We will ask you to rate your anxiety twice, once before you go into the surgery and once when you are in the dental surgery.

5. What are the possible disadvantages and risks of taking part?

We believe that there are no risks or disadvantages to taking part.

6. What are the possible benefits of taking part?

If the procedures we are studying show a reduction in dental fear, we aim to offer these procedures to dental patients in the future.

7. Will my taking part in this study be kept confidential?

Absolutely. All information which is collected about you during the course of the research will be kept strictly confidential. You will not be asked to put your name on the form we use to assess how anxious you are.

8. What will happen to the results of the research study?

The results will be used by Dr Almoammar as part of his PhD studies. We also hope to publish the research in academic journals.

9. Who has reviewed the study?

This study has been reviewed by the Guy's Hospital Research Ethics Committee (Ref: 07/Q0703/20).

10. Contact for further information

If you would like any further information please feel free to contact Khalid Almoammar either by 'phone on 0207 188 4417 or by e-mail (*khalid.al-moammar@kcl.ac.uk*)

Thank you for taking the time to read this information.

7.16 CONSENT FORMS (THE RCT)

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Reference number: *09/H0804/6*
Version number: *2*
16-04-2009

ASSENT FORM FOR CHILD

Study number: ……
Participant Identifier number for this trial: ……

NB Three copies should be made, for
(1) child, (2) researcher, (3) hospital notes

Title of Project:

A Randomised Controlled Trial of Interventions to Reduce Levels of Dental Anxiety in Cleft Lip and Palate Children

Name of Researcher: Tim Newton, Fraser McDonald and Khalid Al-Moammar

Please initial box

1. I have read the information sheet dated February 2009 (version 2) for this study and have had the opportunity to ask questions. ☐
2. I understand that I only need to take part if I want to and that I can stop being in the study at any time, and this will have no effect on me. ☐
3. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Researcher	Date	Signature

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Version number: *2*
16-04-2009

CONSENT FORM FOR PARENT/GUARDIAN

Centre number: .....
Study number: .....
Participant Identifier number for this trial: .....

NB Three copies should be made, for
(1) child, (2) researcher, (3) hospital notes

Title of Project:

A Randomised Controlled Trial of Interventions to Reduce Levels of Dental Anxiety in Cleft Lip and Palate Children

Name of Researcher: Tim Newton, Fraser McDonald and Khalid Al-Moammar

Please initial box

1. I confirm that I have read and understand the information sheet dated February 2009 (version 2) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to my child's participation in the above study. ☐

Name of Parent/Guardian	Date	Signature
Name of Person taking consent	Date	Signature
Researcher	Date	Signature

7.17 CFSS-DS FOR CLP PARTICIPANT (THE RCT)

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CHILDREN FEAR SURVEY SCHEDULE- DENTAL SUBSCALE

Please read the following descriptions. Would you please rate how much anxiety each of them causes you *by circling* the correct number?

	Not at all	A little	Somewhat	Much	Very Much
1. Making an appointment for dentistry.	1	2	3	4	5
2. Approaching the dentists' surgery.	1	2	3	4	5
3. Sitting in the waiting room.	1	2	3	4	5
4. Being seated in the dental chair.	1	2	3	4	5
5. The smell of the dentist's surgery.	1	2	3	4	5
6. Seeing the dentist walk in	1	2	3	4	5
7. Seeing the anaesthetic needle.	1	2	3	4	5
8. Feeling the needle injected.	1	2	3	4	5
9. Seeing the drill.	1	2	3	4	5
10. Hearing the drill.	1	2	3	4	5
11. Feeling the vibration.	1	2	3	4	5
12. Having your teeth cleaned.	1	2	3	4	5
13. Having x-ray put in my mouth.	1	2	3	4	5
14. Having models or impressions of my mouth.	1	2	3	4	5
15. All things considered, how much scared are you of having dentistry done?	1	2	3	4	5

7.18 VAS FOR THE DENTIST (THE RCT)

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VISUAL ANALOUGE SCALE

A. Would you please rate the child behaviour while he/she on the dental chair?
Where 1 is extremely negative and 10 is extremely positive

1	2	3	4	5	6	7	8	9	10

B. Would you please rate the child behaviour during dental examination?
Where 1 is extremely negative and 10 is extremely positive

1	2	3	4	5	6	7	8	9	10

7.19 FRANKL SCALE FOR THE DENTIST AND INVESTIGATORS (THE RCT)

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FRANKL BEHAVIOUR SCALE

How would you rate the child behaviour and cooperation during the dental visit? Please tick the appropriate number.

1- **Definitely Negative** (Refusal of treatment, crying forcefully and fearful)

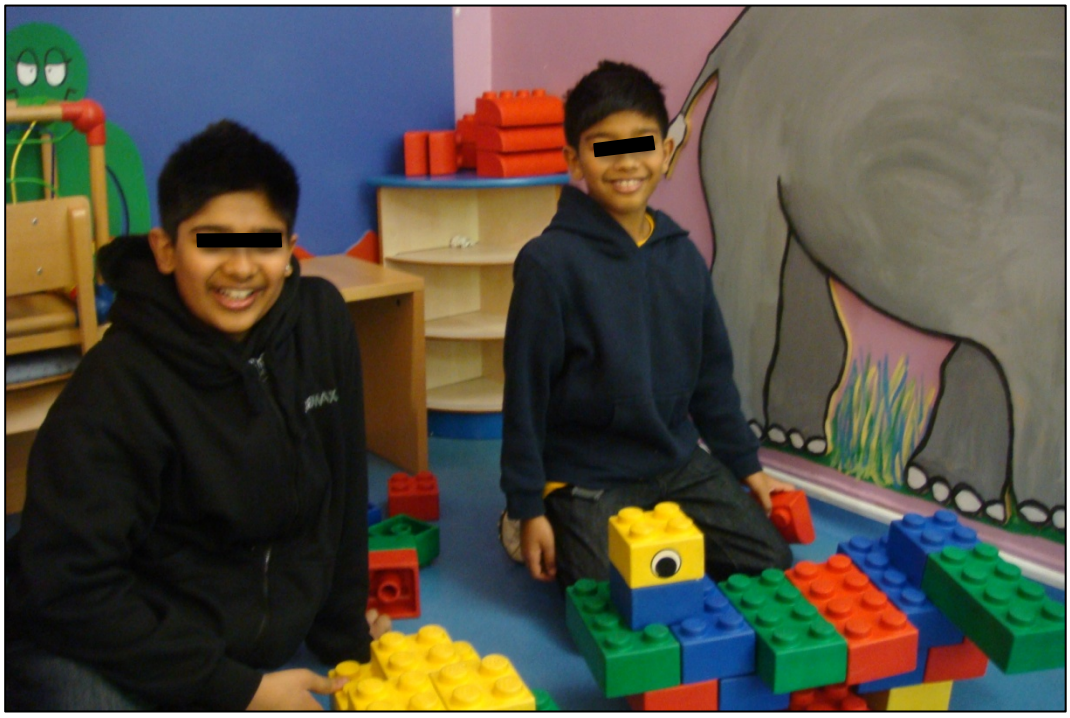
2- **Negative** (Reluctant to accept treatment, uncooperative)

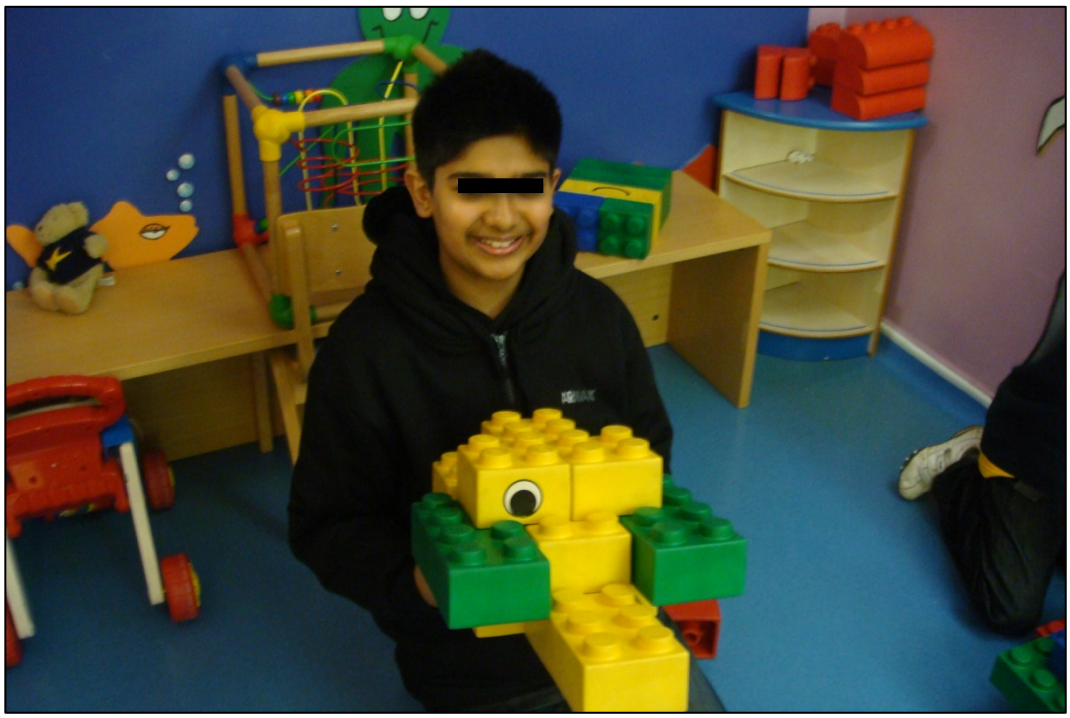
3- **Positive** (Acceptance of treatment; at times cautious but follows directions cooperatively)

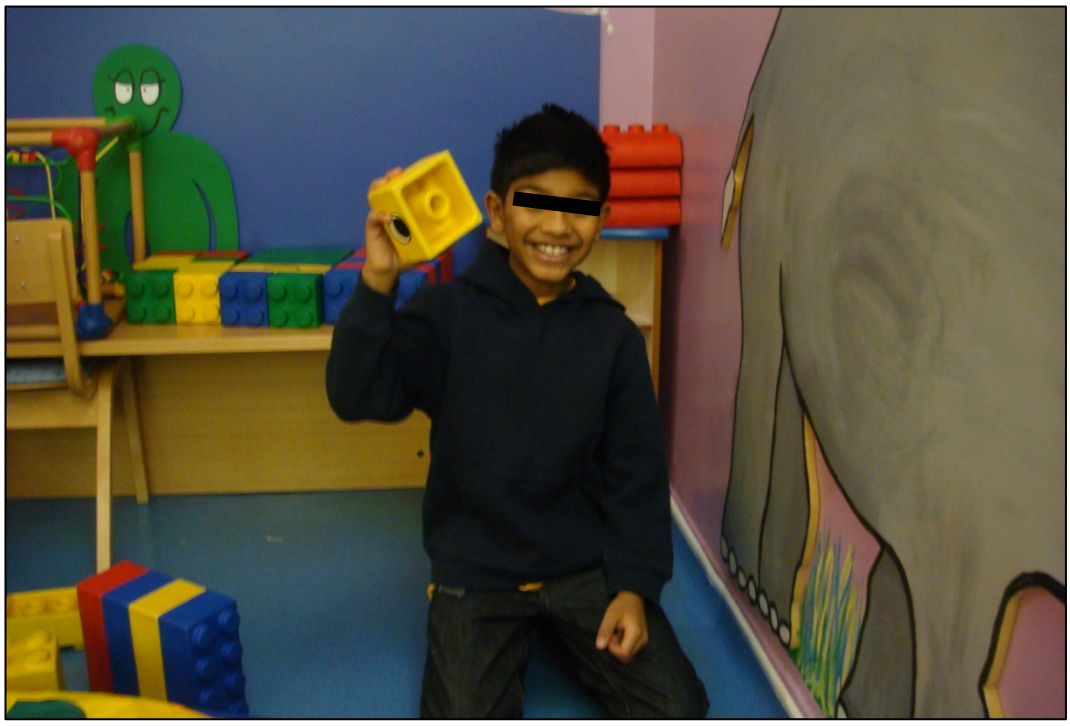
4- **Definitely Positive** (Good rapport and interested in the dental procedure)

7.20 POSITIVE IMAGES INTEFRVENTIONS (THE RCT)

FEBER







AIRMAX

7.21 POSTER PRESENTATION ABSTRACT 2010

Presented at the European Orthodontic Conference, Portorož, Slovenia, June 2010.

SP 257 *Thursday, June 17 - at 14:30, Touch screen No. 8*

A SURVEY OF LEVELS OF DENTAL ANXIETY AMONGST INDIVIDUALS WITH CLEFT LIP AND PALATE

K Al-Moammar[1], F McDonald[1], P Haers[2], T Newton[1], [1]King's College London Dental Institute and [2]South Thames Cleft Service, London, England

AIM: Dental fear is common in the general population and related to early experience of traumatic dental treatment. The prevalence of dental fear in cleft lip and palate (CLP) subjects is unknown but might be hypothesized to be elevated given the increased likelihood of dental or surgical treatment. The aim of this study was to assess the level of dental and medical setting anxiety among children with CLP.

SUBJECTS AND METHOD: One hundred and eighty two individuals with a CLP drawn from the South Thames Cleft Service Database were compared with a control group of 150 healthy individuals attending the Orthodontic Department, Guy's Hospital. The participants were identified at three ages: 5-10, 11-15 and 16-20 years. A postal questionnaire survey was undertaken for the individuals with CLP, while the questionnaires were completed by the healthy individuals at the orthodontic department. The questionnaires used were the Facial Image Scale (FIS) (Buchanan and Niven, 2002) and the Modified Dental Anxiety Scale (MDAS) (Wong *et al.*, 1998).

RESULTS: For all age groups, dental fear scores were higher for individuals with a CLP than for the control group: 5-10 year-old, mean FIS CLP = 2.17 (SD 1.04), controls = 1.39 (SD=0.53), $P < 0.001$; 11-15 year-old, mean MDAS CLP = 21.56 (SD 6.80), controls = 16.40 (SD 4.35) $P < 0.001$; and 16-20 year-old, mean MDAS CLP = 22.08 (SD 8.68), controls = 13.44 (SD 2.89) $P < 0.001$.

CONCLUSION: Individuals with a CLP have high levels of dental fear in comparison with their age-matched peers. Interventions should focus on prevention and management of fear in this group of patients.

7.22 POSTER PRESENTATION ABSTRACT 2011

Presented at the Annual Conference, the Craniofacial Society of Great Britain and Ireland, York, April 2011.

POSTER 2

Dental Anxiety Amongst Individuals with Cleft Lip and Palate

KHALID AL-MOAMMAR, Fraser McDonald, Alexander Cash, Piet Haers, Tim Newton

King's College London
UK

Background: Dental fear is common in the general population and is related to early experience of traumatic dental treatment. The prevalence of dental fear in cleft lip and palate (CLP) subjects is unknown but it might be hypothesized to be elevated given the increased likelihood of dental or surgical treatment.

Aim: To assess the level of dental and medical setting anxiety among children with CLP.

Methods: 178 individuals with cleft lip and palate drawn from the South Thames Cleft Service Database were compared to a control group that consisted of 150 healthy individuals drawn from the Orthodontic Department, Guy's Hospital. The participants were identified at three age groups; 5-10, 11-15, and 16-20 year-old.

A postal questionnaire survey was undertaken for the individuals with CLP; the questionnaires were completed by the healthy individuals as they attended the Orthodontic Department. The questionnaires used were the Facial Image Scale (FIS) (Buchanan and Niven, 2002), the Modified Dental Anxiety Scale (MDAS) (Wong et al., 1998), and the Children Fear Survey Schedule-Dental Subscale (DCFSS) (Scherer and Nakamura, 1968).

Results: For all age groups, dental fear scores were higher for individuals with CLP than for the control group. The results are as follows: Group 5-10 year-old (means ± SD FIS: CLP= 2.17±1.04, controls= 1.39±0.53, $P<0.001$); Group 11-15 year-old (means ± SD MDAS: CLP= 21.56±6.80, controls= 16.40±4.35 $p<0.001$). Means ± SD DFSS: CLP= 33.32±13.74, controls= 21.54±6.02 $p<0.001$); Group 16-20 year-old (means ± SD MDAS: CLP=22.08±8.68, controls=13.44±2.89 $p<0.001$. Means ± SD DFSS: CLP= 36.78±2.89, controls= 20.92±5.63 $p<0.001$.

Conclusion: Individuals with CLP have high levels of dental fear in comparison to their age matched peers. Interventions should focus on prevention and management of fear in this group of patients.

7.23 COCHRANE REVIEW-PROTOCOL

Psychological interventions for reducing dental anxiety in children (Protocol), The Cochrane Library, Issue 2, 2009.

Psychological interventions for reducing dental anxiety in children (Protocol)

Al-Moammar K, Cash A, Donaldson N, McDonald F, Newton T

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2009, Issue 2

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Psychological interventions for reducing dental anxiety in children (Protocol)
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[Intervention Protocol]

Psychological interventions for reducing dental anxiety in children

Khalid Al-Moammar[1], Alex Cash[2], Nora Donaldson[3], Fraser McDonald[1], Tim Newton[4]

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of psychological interventions aimed to decrease levels of dental anxiety in children between the ages of 5 and 18 years old.

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BACKGROUND

Dental anxiety is relatively common in children and is a major factor that may lead to the failure to attend at dental clinics. This event is termed 'dental avoidance' when anxiety is the over-riding factor in the evasion of dental appointments (ter Horst 1993).

The prevalence of dental anxiety

There are numerous reports of the prevalence of dental anxiety in children, ranging from 16% (Kent 1991) to 3% and 21% (Milgrom 1993). In the North West of England, 10% of parents reported that their children were dentally anxious (Milsom 2003). While, in Sweden, the prevalence of dental anxiety in children between 4 and 11 years old was 6.7% (Klingberg 1994). One study from Norway sought to demonstrate the link between dental anxiety and the resultant avoidance of dental appointments. This study found that the prevalence of dental anxiety was 19% in 12 to 18 years old patients, with 6% of patients being diagnosed with dental avoidance behaviours (Skaret 1999).

In a review conducted on dental anxiety and the association with age, gender and other factors, the prevalence of dentally anxious children ranged between 5.7% and 19.5% (Klingberg 2007). Dental phobia exhibits a considerable reduction with age, this has been demonstrated in many studies, although few others showed insignificant difference with age. This was demonstrated in a cross-sectional sample of Dutch children, where the overall prevalence of dental anxiety was 6% with no difference between younger children and their older counterparts (Ten Berg 2002). In respect to gender, most studies demonstrated a higher level of dental anxiety in girls when compared to boys, although, some researchers showed that girls may exhibit more tolerance and explanatory behaviour in dental settings when compared to boys (Rousset 1997). Other reports showed no difference in the level of dental anxiety between the genders (Milgrom 1995).

The measurement of dental anxiety

The measurement of anxiety is a vital step towards the management of the existing anxiety in dental settings. There have been four measures utilised to assess the level of anxiety, namely: rating scales, self report surveys, physiological measures, and projective measures (Winer 1982).

(1) Rating scales

One example is the Frankl scale (Frankl 1962), which contains four categories of behaviour that ranges from definitely positive to definitely negative. It has a considerable amount of reliability although a great deal of bias is found with the Frankl scale. Unfortunately, there is a low correlation between outcomes obtained by Frankl scale and other measures of self reporting (Klorman 1979).

Another example is the Venham scale (Venham 1977). It comprises of two components, anxiety scale and a behavioural scale. Measurements are made on three occasions during the visits and then a mean is taken of the three outcomes, which provides a measurement of the anxiety level in the whole appointment. The Venham scale has a high degree of reliability with high correlations using self reporting and other behavioural measures (Venham 1979).

(2) Self report measures

These measures require the child or the parent responses in evaluating the level of anxiety. They are widely used, quick and easy to employ. However, the validity of some of these measures is questionable.

One example is the Dental Anxiety Scale (DAS), which includes four questions intended to measure the level of anxiety (Corah 1969). It has acceptable levels of validity and reliability. However, it suffers from complexity. This led Wong and his colleague to modify it into the Modified Dental Anxiety Scale (MDAS). It consists of eight questions related to different dental procedures and uses a 'five points' scale to assess the level of anxiety ranging from relaxed to very worried (Wong 1998).

In Scandinavia, Geer Fear Scale (GFS) has been widely used. It contains 18 items. The sums of the scores range between 18 and 126, where a score of more than 56 is considered extremely anxious in dental settings (Geer 1965). The GFS showed an acceptable validity and reliability in the Scandinavian population (Moore 1991).

Fear Survey Schedule for Children-Revised, is a widely used questionnaire that consists of 80 fear stimuli. Children are requested to identify the triggering elements to the level of anxiety on a three points scale. It is usually used to identify the type of stimuli and events most feared by children (Ollendick 1983).

Another modification is Children's Fear Survey Schedule-Dental Subscale (CFSS-DS). This was introduced by Scherer and Nakamura to assess anxiety in children. It has reasonable reliability although interestingly, the validity of the scale is satisfactory and correlated highly with children's attitudes in dental settings (Cuthbert 1982).

(3) Physiological measures

A number of measures have been proposed to assess children's physiological reactions during dental appointments. Heart rate has been a useful measure in assessing the level of anxiety in dental settings (Howitt 1965). Other measures include basal skin response, galvanic skin response, Palmar Sweat Index, muscle tension, skin temperature and respiration (Winer 1982).

(4) Projective measures

This measure requires the child to draw a picture. The picture is interpreted based on the size, colour, or shade to explore the child's level of anxiety. However, projective measures demonstrate a low level of reliability (Winer 1982).

The consequences of dental anxiety

There is a general agreement on the consequences of dental anxiety. Dental avoidance and compromised oral health, as risks of dental anxiety were extensively reviewed in the literature. Dental

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avoidance, which is the failure to attend dental clinics, is a major consequence to dental anxiety (ter Horst 1993). In a study conducted to evaluate the degree of dental avoidance in the Public Dental Services in Sweden, patients between the ages of 12 and 18 years old failed to attend or cancelled 12% of the total number of their dental appointments (Skaret 1998). Another study in Sweden, showed that 10.5% of children who had behavioural management problems as a result of anxiety, exhibited a significant dental avoidance and compromised oral health. The latter was manifested with extensive carious teeth and a range of dental restorations (Klingberg 1994). In a survey undertaken in England, highly significant rates of carious teeth and a history of previous extractions was found in 5 years old anxious children (Milsom 2003).

The management of dental anxiety

In order to allay the anxiety of children, the American Academy of Pediatric Dentistry has proposed various techniques, namely: voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint, conscious sedation, nitrous oxide, and general anaesthesia (AAPD 2004). Others have advocated additional methods to reduce anxiety such as the use of contingent distraction, modelling, and contingent escape (Kuhn 1994).

- Voice control

The voice control approach has been proven to be effective in reducing dental anxiety and disruptive behaviour provided that the voice used is moderate in intensity and deep in nature (Greenbaum 1990).

- Positive reinforcement

It is described as the use of a reward to increase compliant behaviour. A positive reward improves the child's behaviour when given. For example, a sticker as a gift for the child following a co-operative behaviour (Newton 2004). While, a negative reward which improves the behaviour of the child upon removal of something. This maybe in the form of a selectively separating the child from the parents to gain a positive reaction towards the planned procedure. Ideally, a negative reinforcement is indicated in tantrum-type behaviour management when the child is extremely unco-operative (Fayle 2003).

- Distraction

In children with low levels of anxiety, the use of either the contingent or cognitive distraction approaches have been particularly useful in anxiety reduction. The contingent distraction technique involves the continued display of distracting items and materials as long as the child demonstrates acceptable levels of co-operation, while the cognitive technique involves encouraging the child to have thoughts outside the boundaries of the dental situation (Ingersoll 1984).

- Non-verbal communication

The non-verbal communication technique has also been shown to reduce the level of dental anxiety (Greenbaum 1990). In this technique the dentist communicates with the child via gentle touch while the child communicates with the dentist by means of gestures. For example the child may be instructed to raise his/her hand if he/she experiences discomfort.

- Hand over mouth

Although the hand over mouth approach has been proposed by the American Academy of Pediatric Dentistry to be used with children who are able to communicate but are unco-operative, it is a technique that has fallen out of favour with dentists in North America due to the legal consequences that may occur as a result of its use (Acs 2001). In a survey of all paediatric dentists in the United Kingdom, 60% believed that the hand over mouth approach should not be used (Newton 2004).

- Physical restrain

It is defined as "To hold back from action, keep in check or under control, repress; to deprive of liberty; and to limit or hamper the activity…" (Portland House 1989). According to the American Academy of Pediatric Dentistry, the physical restrain may possibly be achieved by using a mouth prop with or without placing the child in a papoose board or pediwrap. However, the use of physical restrain in behavioural management remains controversial. It is desirable to restrict this approach to patients with disabilities and mental retardations (Peretz 2002). In the United Kingdom, one study found that only 2% of the dentists preferred the use of physical restrain when dealing with unco-operative children (Crossley 2002). Whilst, 53% of dentists in the United States favoured physical restrain over sedation in the management of 3 years old children (Peretz 2002).

- Tell-show-do

Tell-show-do is by far the commonest method of anxiety reduction utilised in dental settings. In this technique tell refers to an explanatory phase, show to a demonstration phase and do to the actual performance of the procedure (Newton 2003). Dentists do prefer explanatory approaches as opposed to blundering approaches, this has been shown in a survey conducted in the United Kingdom where 66% of the respondents favoured an explanatory approach like tell-show-do when compared to more aggressive approaches (Buchanan 2003). Similarly, parents feel more comfortable with tell-show-do to be employed on their children rather than physical restraint or sedation (Murphy 1984).
The other procedures recommended by the American Academy of Pediatric Dentistry such as conscious sedation, nitrous oxide and general anaesthesia, are effective methods of enhancing patient co-operation, however they have the additional drawbacks

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of having an associated morbidity and being not widely available for implementation by all general dental practitioners due to their additional cost in terms of time and finances (Shaw 1996).
While there are numerous examples in the literature of approaches and techniques to reduce dental anxiety in children, as yet there has been no evidence to demonstrate which method or methods are more effective in this regard.
Evidence based recommendations are needed in this area in order to improve the delivery of dental care to children particularly those with behavioural issues or those who require extensive dental interventions. The advantage of ascertaining the most effective methods of relieving anxiety in children would be manifold including fewer failed appointments, improved oral health attitudes, more treatments performed in an out-patient setting and the more effective training of dentists in the techniques of patient management.

OBJECTIVES

To assess the effects of psychological interventions aimed to decrease levels of dental anxiety in children between the ages of 5 and 18 years old.

METHODS

Criteria for considering studies for this review

Types of studies

Only randomised controlled trials (RCTs) assessing the effects of psychological interventions aimed to decrease levels of dental anxiety in children will be considered in this review.

Types of participants

Children between the ages of 5 and 18 years old attending for dental treatment.

Types of interventions

Any psychological intervention aimed at reducing levels of dental anxiety. This to include but not limited to the list of the American Academy of Pediatric Dentistry: voice control, tell-show-do, positive reinforcement, distraction, non-verbal communication, hand over mouth, physical restraint.
All these interventions will be compared to the following:

- No intervention
- Pharmacological interventions including general anaesthesia and sedation.

Types of outcome measures

Primary outcome measures

- Anxiety levels as measured by a validated questionnaire.
- Anxiety levels measured by a validated physiological measure.
- Anxiety levels measured by a validated projective test.
- Disruptive behaviour in dental surgery as measured by validated tool.

Secondary outcome measures

- Patients and parents satisfaction.
- Re-attendance at follow-up appointments.
- Time taken to undertake the intervention.
- Complications associated with the intervention.

Search methods for identification of studies

We will attempt to identify all relevant studies irrespective of language. Non-English papers will be considered for inclusion after an accurate translation.

Electronic searches

To locate and identify studies suitable for the inclusion in the review, a detailed subject search strategy will be devised and revised appropriately for each database searched using a combination of both controlled vocabulary and free text terms.
For the MEDLINE search, the subject search will be run with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* 5.0.1 (updated September 2008) (Higgins 2008) (*see* Appendix 1).
The following databases will be searched from date of inception to the present:

- Cochrane Oral Health Group Trials Register
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue)
- MEDLINE
- EMBASE
- PsycINFO.

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Searching other resources

All eligible studies retrieved from the searches will be checked for relevant references.

The authors of included studies will be personally contacted by the review authors, in order to receive any further information on additional or unpublished studies that may be eligible for inclusion in the review. In addition those recognised in the British and American Societies will also be contacted as well those offering legal expert witness advice.

Data collection and analysis

Study selection

The titles and abstracts resulting from the searches will be independently screened by two review authors to select potentially relevant studies. These studies will be obtained in full text and their inclusion assessed independently and in duplicate. Any discrepancies with respect to the inclusion or suitability of the papers will be resolved by the remaining review authors.

The full data extraction and quality assessment will be conducted by two review authors. Every study will be assessed by each of the review authors independently. Any disagreement will be resolved by discussion. A further review author will be contacted in the event a consensus cannot be reached. Any studies that will be excluded at this stage will be placed in a detailed excluded studies table along with reasons for their exclusion.

Data extraction

A specifically designed data extraction form will be constructed and after piloting these data extraction sheets, two review authors will independently extract the data from the included studies. Any disagreement will be resolved by discussion. A further review author will be contacted in the event a consensus cannot be reached. The data extracted will provide information on the following review criteria.

General study information - published/unpublished, authors, title, year of publication, journal published in, year that search was conducted/ethic's consent, country of origin, funding source, language, and contact address.

Study characteristics and descriptive data - sample size, RCT criteria, number of participants to each randomised group, number of participants remaining at follow up, randomisation method, allocation concealment, blinding, and study duration.

Participant characteristics - age, gender and inclusion criteria.

Intervention characteristics - intervention techniques, alternative intervention group(s), follow-up period, number of sessions, type of interventions: individual or group, financial and time costs of the intervention to the provider and receiver, no additional treatment given to either groups, the intervention provider characteristics (e.g. psychologist, dentist etc.), location intervention given in, and any adverse effects that may occur as a result of the intervention.

Outcome measure characteristics - what type of measures, the results for each measure, baseline and follow-up results, outcome measures and reported outcome measures.

Results and conclusion - what do the results show and what conclusions have been made in the study.

Comparisons must be between a control group and/or at least one alternative intervention group. Comparisons will also be made between the different outcome measures, the intervention techniques, the length of follow-up times and the subgroups.

Assessment of risk of bias in included studies

An assessment of the risk of bias in included studies will be undertaken following the recommendations as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* 5.0.1 (Higgins 2008).

A specific tool for assessing risk of bias in each included study will be adopted. This comprises a description and a judgement for each entry in a risk of bias table, where each entry addresses a specific feature of the study:

- Adequate sequence generation
- Allocation concealment
- Blinding
- Incomplete outcome data addressed
- Free of selective reporting
- Free of other bias.

The judgement for each entry involves answering a questions, with answers 'Yes' indicating low risk of bias, 'No' indicating high risk of bias, and 'Unclear' indicating either lack of information or uncertainty over the potential for bias. An assessment of the overall risk of bias will be summarized involving the consideration of the relative importance of different domains.

Two review authors will independently and in duplicate assess the risk of bias of all included studies. Any disagreement will be discussed and where necessary a third review author will be consulted to achieve consensus. Where uncertainty cannot be resolved, effort will be made to contact authors directly for clarification.

Data synthesis

The statistical methods presented in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.0.1 (Higgins 2008) will be followed for data synthesis. For continuous data the mean difference and 95% confidence intervals will be calculated. Risk ratios and their 95% confidence intervals will be calculated for all dichotomous data.

Results of clinically and statistically homogeneous trials will be pooled to provide estimates of the efficacy of the interventions only if the included studies have similar interventions received by similar participants. For the synthesis and meta-analysis of any

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quantitative data we will use the fixed-effect and random-effects models as appropriate. If it is established that there is significant statistical heterogeneity between the studies we will use the random-effects model with studies grouped by action. We plan to assess clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants, the interventions and the outcomes as specified in the criteria for included studies. Statistical homogeneity will be assessed using a Chi^2 test and the I^2 test where I^2 values over 50% indicate moderate to high heterogeneity (Higgins 2003). If sufficient RCTs are identified, an attempt will be made to assess publication bias using a funnel plot (Egger 1997). We will consider conducting subgroup analyses. In the event that there are insufficient clinically homogeneous trials for any specific intervention or insufficient study data that can be pooled, a narrative synthesis will be presented. Trials will be grouped into categories and subcategories on the basis of theoretical and clinical distinctions. The initial grouping will be based on the intervention techniques adopted within the trial. The outcome measures adopted by trials within subcategories defined by intervention techniques and the level of anxiety will be explored. In addition, the extent that they are similar data will be assessed by combination techniques. Sufficient studies be located within the subcategories defined, subgroup analyses will be conducted for a selection of study characteristics in order to identify sources of heterogeneity and their influence on the effect size determined: These will include:

- Age of patient
- Gender of patient
- Level of anxiety
- Type of intervention.

Sensitivity analysis

If there are sufficient included studies we plan to conduct sensitivity analyses to assess the robustness of our review results by repeating the analysis with the following adjustments: exclusion of studies with unclear or inadequate allocation concealment, unclear or inadequate blinding of outcomes assessment and completeness of follow up.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

(MeSH terms are in UPPERCASE text, free text are in lowercase text.)
1 DENTAL ANXIETY/
2 anxiet$ or anxious$ or apprehensive$ or fear$ or fright$ or phobi$ or panic$
3 ANXIETY DISORDERS/
4 PHOBIC DISORDERS/
5 PANIC DISORDER/
6 dental$ or dentist$
7 ((2 or 3 or 4 or 5) AND 6)
8 1 or 7
9 PSYCHOTHERAPY/
10 HYPNOSIS, DENTAL/
11 AUTOGENIC TRAINING/
12 BEHAVIOR THERAPY/
13 COLOR THERAPY/
14 IMAGERY (PSYCHOTHERAPY)/
15 MUSIC THERAPY/
16 PLAY THERAPY/
17 LAUGHTER THERAPY/
18 MIND-BODY and RELAXATION TECHNIQUES/

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19 RELAXATION TECHNIQUES/
20 BREATHING EXERCISES/
21 (cognitiv$ adj6 (intervention$ or therap$ or treat$ or technique$ or behavior$ or behaviour$))
22 (behavior$ adj6 (intervention$ or therap$ or treat$ or technique$))
23 (behaviour$ adj6 (intervention$ or therap$ or treat$ or technique$))
24 (desensiti$ AND psychol$) or (relax$ adj6 (technique$ or therap$ or hypnotherapy)) or (therap$ adj6 touch$) or massage$ or "breathing exercise*" or (modeling AND psychol$)
25 (auditory AND distract$) or (audiovisual$ adj6 distract$) or (("audio visual*" or visual$ or music$ or verbal$) adj6 distract$)
26 ((color$ or colour$ or music$ or play$) adj6 therap$) or (verbal$ adj6 encourag$) or "positive reinforce$" or reward$ or reassur$ or "tell show do"
27 hypnosis or hypnotic$ or imagery [in ti]
28 hypnosis or hypnotic$ or imagery [in ab]
29 OR/9-28
30 exp CHILD/
31 (child$ or infant$ or pediatric$ or paediatric$ or adolescent$
32 OR/30-31
33 8 AND 29 AND 32

HISTORY

Protocol first published: Issue 2, 2009

CONTRIBUTIONS OF AUTHORS

Conceiving the review and designing the review: Tim Newton (TN), Fraser McDonald (FM), Alex Cash (AC), Nora Donaldson (ND) and Khalid Al-Moammar (KA).

Co-ordinating the review, writing to authors of papers for additional information, obtaining and screening data on unpublished studies, entering data into RevMan and writing the review: KA.

Undertaking searches and data extraction for the review: TN and KA.

Analysis of data and interpretation of data: TN, ND, FM and KA.

DECLARATIONS OF INTEREST

None known.

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